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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

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| Proceeding | 92050171 |
| Party | Plaintiff<br>DePuy, Inc. |
| Correspondence Address | JOE D. LEWIS<br>BARNES & THORNBURG LLP<br>750 17TH ST NW STE 900<br>WASHINGTON, DC 20006<br>UNITED STATES<br>xlewis@btlaw.com |
| Submission | Other Motions/Papers |
| Filer's Name | Joseph D. Lewis |
| Filer's e-mail | xlewis@btlaw.com |
| Signature | /JDL/ |
| Date | 01/05/2011 |
| Attachments | Notice of Filing Deposition of John R. Tighe.pdf ( 229 pages )(10239670 bytes ) |

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

| | | |
|---|---|---|
| DePuy, Inc.,<br><br>Petitioner,<br><br>vs.<br><br>Peak Surgical, Inc.,<br><br>Respondent | : | Cancellation No. 92050171<br>Reg. No. 2,679,873 |

**NOTICE OF FILING DEPOSITION OF JOHN R. TIGHE**

In support of Petitioner's Motion for Sanctions, Petitioner hereby submits the non-confidential portions of the transcript of the Deposition of Mr. John R. Tighe.

Respectfully submitted,

**DePuy, Inc.**

By: _____

Joseph D. Lewis
Attorney for Petitioner
Barnes & Thornburg LLP
750 17th Street, N.W.
Washington, D.C. 20006
(202) 289-1313

**CERTIFICATE OF SERVICE**

The undersigned certifies that a true copy of the foregoing NOTICE OF FILING DEPOSITION OF JOHN R. TIGHE was deposited with the U.S. Postal Service as first class mail, postage prepaid, addressed to Respondent's counsel, Jennifer Lee Taylor, Esq., Morrison & Foerster LLP, 425 Market Street, San Francisco, CA 94105, on the 5th day of January, 2011.

_____
Joseph D. Lewis

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

| | | |
|---|---|---|
| DePuy, Inc., | ) | |
| | ) | Case No. |
| Petitioner, | ) | |
| vs. | ) | 92050171 |
| | ) | |
| PEAK Surgical, Inc., | ) | VOLUME I |
| | ) | |
| Respondent. | ) | Pages 1 - 122 |
| | ) | |

30(b)(6) DEPOSITION OF PEAK SURGICAL, INC.

(JOHN R. TIGHE)

DEPOSITION OF JOHN R. TIGHE

November 3, 2010

Reported by:

CLARE MACY, RPR, CSR #5256

COPY

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# I N D E X


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| Reporter's Certificate | 122 |


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| 2 | 30(b)(6) Notice of Deposition of Peak Surgical, Inc. sent October 22, 2010, with attached Schedule A | 40 |
| 3 | Four-page set of documents regarding a trademark assignment conveyed by Carl Zeiss AG; labeled TRADEMARK REEL: 003552 FRAME 0597 - 600 | 47 |
| 4 | Five-page article entitled "Effects of the Pulsed Electron Avalanche Knife on Retinal Tissue" | 68 |
| 5 | 14-page document containing a brochure entitled "PEAK Surgical, The Pulse of Precision"; a summary of a clinical study; a summary of preclinical results from various tests; Bates Nos. PEAK001 - 14 | 70 |
| 6 | 510(k) Summary of Safety and Effectiveness dated September 14, 1998 for the Motech PEAK Fixation System | 84 |
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| 9 | Paper entitled "PEAK Surgical Receives 510(k) Clearance to Market PEAK Surgery System for Use in General Surgery"; Bates Nos. PEAK0899 - 900 | 94 |
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QUESTIONS INSTRUCTED NOT TO ANSWER

| | LINE/PAGE |
|---|---|
| Do you know if Ms. Taylor had -- if Ms. Carlson communicated with Ms. Taylor in this process of obtaining the Zeiss assignment? | 12/52 |
| Did you ask your counsel if they had any communications between -- any documents reflecting communications between Zeiss and PEAK Surgical? | 2/62 |
| But you have not asked those individuals as you sit here today; is that correct? | 17/62 |

BE IT REMEMBERED that, pursuant to Notice of Deposition, and on Wednesday, November 3, 2010, commencing at the hour of 9:51 a.m., in the offices of Morgan, Lewis & Bockius LLP, 2 Palo Alto Square, 3000 El Camino Real, Suite 700, Palo Alto, California, before me, Clare Macy, a certified shorthand reporter in the State of California, there personally appeared

JOHN R. TIGHE,

called as a witness by the Petitioner, who being by me first duly sworn, was thereupon examined and interrogated as is hereinafter set forth.

--oOo--

JOSEPH D. LEWIS, Attorney at Law, of Barnes & Thornburg LLP, 750 17th Street, N.W., Washington, D.C., 20006, appeared telephonically as counsel on behalf of the petitioner, DePuy, Inc.
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JENNIFER LEE TAYLOR, Attorney at Law, of Morrison & Foerster LLP, 425 Market Street, San Francisco, California 94105-2482, appeared as counsel on behalf of the respondent, PEAK Surgical, Inc.
Tel: (415)268-6538 Fax: (415)268-7522
Email: jleetaylor@mofo.com

--oOo--

NOVEMBER 3, 2010 - WEDNESDAY 9:51 A.M.

VOLUME I

P R O C E E D I N G S

(Whereupon the witness was sworn.)

EXAMINATION BY MS. CASTO:

Q. Good morning. Would you please state your full name for the record.

**A. John Robert Tighe.**

Q. And would you spell your name, please.

**A. John is J-O-H-N; Robert, R-O-B-E-R-T; Tighe, T-I-G-H-E.**

Q. Thank you. And what is your address, Mr. Tighe?

**A. 15961 Cerro Vista Court, Los Gatos, California.**

Q. And do you understand today that your testimony is under oath under penalty of perjury as if you were testifying in a court of law?

**A. Yes.**

Q. Is there any reason that you feel you're not able to testify accurately and truthfully today?

**A. No.**

Q. Have you taken any medication within the last 48 hours which would affect your ability to recall details?

**A. No.**

Q. Have you had your deposition taken before?

**A. Yes.**

Q. And when have you had your deposition taken before?

**A. I've had four depositions taken over the last 15 years.**

Q. Okay. And when was the first deposition that you gave?

**A. The first was when I was with my previous company, ArthroCare, so it would have been about 1996.**

Q. Can you spell the name of that company.

**A. ArthroCare, A-R-T-H-R-O-C-A-R-E. One word.**

Q. And you said 1996, approximately?

**A. Approximately.**

Q. What was the subject of that deposition?

**A. It was an intellectual property dispute.**

Q. What kind of a dispute, intellectual property dispute?

**A. It was a patent infringement case.**

Q. Why were you being deposed in that patent infringement case?

**A. I was the director of sales at the time.**

Q. So were you testifying on behalf of the corporation?

**A. Yes.**

Q. Did you testify in your personal capacity in that case, as to your personal knowledge?

**A. It was to my experience with the company.**

Q. Okay. So you were testifying on behalf of the company and then as an individual based on your personal knowledge in that case?

MS. TAYLOR: Objection. One, that's compound. And two, it mischaracterizes what he said. And three, it calls for legal conclusions. And I don't know if he can answer.

MS. CASTO: Q. Do your best.

**A. I'm not sure. I was called as a -- you know, as an employee of the company. They asked me to be deposed. They deposed many people in the company. I was one of them.**

Q. Did ArthroCare file this patent infringement action?

**A. They did.**

Q. Where?

**A. Where? I'm not sure what jurisdiction. The company at the time was headquartered in Sunnyvale, California.**

Q. ArthroCare was headquartered in Sunnyvale, California?

**A. Yes.**

Q. Where was your deposition taken?

**A. That one, I believe, was here locally.**

Q. And who was the company on the other side of that case?

**A. The other was a company called Mitek Corporation.**

Q. Can you spell that company's name.

**A. M-I-T-E-K.**

Q. And where are they located?

**A. They're in Boston.**

Q. Do you know how that case concluded?

**A. The two parties settled.**

Q. Okay. That was your first deposition. How about your second deposition?

**A. It was right around the year 2000.**

Q. Okay.

**A. It was a contract dispute, a distribution agreement.**

Q. Who brought that suit?

**A. That was brought by Arthrex Corporation.**

Q. Can you spell that company's name.

**A. A-R-T-H-R-E-X.**

Q. Arthrex Corporation; is that what you said?

**A. It might be Arthrex, Inc., but yes.**

Q. Against whom did Arthrex file that suit?

**A. Against ArthroCare.**

Q. Were you testifying on behalf of ArthroCare --

**A. Yes.**

Q. -- in that case?

And that again was in 2000?

**A. Yes.**

Q. Where was that case filed; do you know?

**A. I do not know.**

Q. How did that case resolve; do you know?

**A. It resolved in a settlement.**

Q. And what was the nature of your testimony in that case?

MS. TAYLOR: I'm going to object. It's vague as to the nature of the testimony.

You can answer.

THE WITNESS: I testified to the facts of my knowledge of the -- you know, the case. It was a distribution arrangement that there was a dispute regarding. Again, many people were deposed from ArthroCare. I was one of those.

MS. CASTO: Q. Okay. And your third deposition that you gave, where was that deposition?

**A. Third was -- This was a product liability case.**

Q. Who filed that case?

**A. It was a physician named -- last name is Herzog.**

Q. Can you spell that, please.

**A. H-E-R-Z-O-G.**

Q. All right.

**A. I believe.**

Q. Against whom did Dr. Herzog --

**A. Against ArthroCare.**

Q. ArthroCare?

**A. Yes.**

Q. Do you remember the approximate date that case was filed?

**A. Early 2000s, 2001, 2002.**

Q. And when did you give the deposition in that case?

**A. In that time period.**

Q. In the time period 2001 or 2002; you're not sure which?

**A. Yes, yes.**

Q. And once again, you testified on behalf of ArthroCare; is that correct?

**A. That's correct.**

Q. Okay. What was the nature of your testimony in that product liability case?

MS. TAYLOR: Objection, vague as to "nature."

THE WITNESS: I was called to answer questions about the -- my knowledge of the facts of the case or about the case, again.

MS. CASTO: Q. So your knowledge as to products that were --

**A. Products that were being marketed by ArthroCare.**

Q. Okay. Technical attributes of those products?

**A. More marketing attributes.**

Q. Okay. And your fourth deposition, when did that occur?

**A. That occurred 2003 or '-4 time frame.**

Q. What was the nature of that case?

**A. That was a patent infringement case.**

Q. Who brought that case?

**A. ArthroCare brought that.**

Q. Against whom?

**A. Smith & Nephew Corporation.**

Q. Do you know where that case was filed?

**A. I do not.**

Q. Backing up to the product liability case, do you know where that case filed by Dr. Herzog was filed?

**A. He was based in Portland, Maine, and that's where there was a trial that actually took place.**

Q. Do you know if that was in state or in federal court in Maine?

**A. I do not, no.**

Q. And that case that Dr. Herzog brought went to trial, you said; is that correct?

**A. Yes.**

Q. What was the resolution of that trial?

**A. ArthroCare was found -- you know, there was no liability at ArthroCare.**

Q. And the patent infringement case that ArthroCare filed against Smith & Nephew in around the 2003-2004 time frame -- do I have those facts correct?

**A. Yes.**

Q. How did that case resolve?

**A. That was a settlement between the two companies.**

Q. And once again, what was the nature of your testimony in that patent infringement case?

MS. TAYLOR: Objection, it's vague.

THE WITNESS: Again, to my knowledge of the markets and business dealings of ArthroCare.

MS. CASTO: Q. Okay. So the marketing attributes of the products at issue in that patent infringement action; would that be fair to say?

MS. TAYLOR: Objection, mischaracterizes the

testimony.

THE WITNESS: You know, I don't remember all the questions that were asked.

MS. CASTO: Q. Sure.

**A. It was a long time ago.**

Q. Okay. I'm just asking for your general recollection of what you remember was the nature of your testimony in that case. So if I've misstated your testimony, feel free to clarify it.

**A. No. It was about the business operations of ArthroCare.**

Q. Okay. As they relate to the products at issue in that case?

**A. Yes.**

Q. Okay. Thank you.

And we talked about your four depositions. It sounds like three of these cases went to settlement before there was any sort of a trial. Did you testify in any legal proceedings in any of the four cases you've just described?

MS. TAYLOR: Objection, that's vague.

THE WITNESS: I was a witness at the trial of the Herzog.

MS. CASTO: Q. Okay. Any other instances at all, even beyond these four cases we've just discussed,

where you testified at a legal proceeding, for instance, in a court of law?

**A. No.**

Q. Okay. Thank you.

So I know you've been through deposition before. I won't spend a long time giving you instructions, but we'll just cover some ground rules.

So I'm going to ask you questions. If you don't understand what I ask you, please let me know, and I'll try to rephrase it, explain it. Other than that, I'm going to assume that you understood the question I put to you. Do you understand that?

**A. Okay.**

Q. Okay. Good.

And if you need to take a break, let me know, and we can take a break. The only thing I ask is that if I have a question pending that you answer that question before we take a break.

**A. Okay.**

Q. Do you understand that? Good.

And you might hear Ms. Taylor object to some of my questions. You still need to answer those questions unless she instructs you not to answer. Do you understand that?

**A. Yes.**

Q. Thank you.

And the most important, because I think I've already violated it a couple of times, is that the court reporter is taking down everything we say. So it's important not only that we speak slowly and clearly so that the court reporter can understand us, but rather than responding with "uh-huh's," respond with "yes" or "no."

And then most importantly, that we not talk over each other so that the court reporter can take down our testimony.

Do you understand that?

**A. Yes.**

Q. Thank you.

And your last name is pronounced "Mr. TIE"; is that correct?

**A. "TIE," yes.**

Q. "TIE"?

**A. That's correct.**

Q. Mr. Tighe, would you describe your education for me after high school. So where did you go to college?

**A. I have a BS degree in engineering from the University of Maryland, 1982.**

Q. What field of engineering?

**A. Civil, structural engineering.**

Q. After graduating with this degree in 1982, did you go on to do any other graduate studies?

**A. I did not.**

Q. And I'd like to go over your employment history. So after graduating from college, can you tell me, who was your employer?

**A. First employer was Sweeney Company.**

Q. Can you spell that, please.

**A. S-W-E-E-N-E-Y.**

Q. All right. And when did you start working for Sweeney Company?

**A. 1982.**

Q. When did you stop working for Sweeney Company?

**A. Three or four years later.**

Q. So around 1985; is that fair to say?

**A. Yes.**

Q. What was your position at Sweeney Company?

**A. Project engineer.**

Q. And what were your duties?

**A. To work on the bids for projects.**

Q. Does Sweeney Company make any products -- or did it at the time, I should say, when you were employed by Sweeney?

**A. It was a construction engineering firm.**

Q. And after Sweeney, who did you work for?

**A. A company called Patco Distributors, P-A-T-C-O.**

Q. And you started working for them when?

**A. Right after Sweeney. I worked there for four years.**

Q. Okay. So around 1985 to 1989; is that fair to say?

**A. Yes.**

Q. And what was your position there?

**A. I was a sales representative.**

Q. Is Patco a distributor?

**A. They are a distributor.**

Q. And at the time you were employed as a sales representative, what did Patco distribute?

**A. They were distributing commercial transportation services.**

Q. And what were your duties as a sales rep?

**A. I sold their products that they represented, their buses and other services in the transportation field.**

Q. And after Patco, where did you work next?

**A. A company called Acufex Microsurgical.**

Q. Can you spell that, please.

**A. A-C-U-F-E-X, Microsurgical.**

Q. When did you work for Acufex Microsurgical?

**A. Right after Patco until -- and I worked there about eight years.**

Q. So from around 1989, would you say, until 1997; is that a fair estimate?

**A. Yeah. I think it was '88 to '96, but yes.**

Q. All right. What was your position at Acufex?

**A. I had several positions there.**

Q. Okay. Why don't we start with your first.

**A. Sales representative.**

Q. Okay. What were your duties as sales rep?

**A. To sell the products that Acufex produced.**

Q. And what were the products Acufex produced?

**A. They were medical devices in the orthopedic field.**

Q. Can you describe those medical devices for me.

**A. They were different instruments for arthroscopic surgery and for ACL reconstruction and for shoulder surgery.**

Q. So were these instruments that actually aid the surgeons in performing the surgery?

**A. Yes.**

Q. Is that what these products were?

**A. Yes.**

Q. Were these instruments items that were

actually placed in the body of a patient and stayed there after surgery?

**A. Some were.**

Q. And when did you hold this position of sales rep for Acufex?

**A. I was a rep for about three years.**

Q. What was your next position at Acufex?

**A. Regional manager.**

Q. What were your duties as regional manager?

**A. To manage a group of sales representatives across the mid-Atlantic area.**

Q. And to be clear, what is the mid-Atlantic area? Can you describe that geographic region.

**A. Geographic. My area included Pennsylvania, Maryland, Delaware, Washington DC, Virginia, West Virginia, part of Ohio.**

Q. And in managing this group of sales reps, was this managing sales reps who were selling the same types of products we just discussed that you were selling as a sales rep, these instruments for the orthopedic field?

**A. Yes.**

Q. So the instruments for arthroscopic surgery, ACL reconstruction and shoulder reconstruction; is that correct?

**A. Yes.**

Q. Anything else?

**A. Those were the primary products.**

Q. And how long did you hold this position as regional manager?

**A. About three years.**

Q. And what was your next position at Acufex?

**A. The national sales manager.**

Q. What were your duties as national sales manager?

**A. To manage the group of regional managers and sales representatives across the U.S.**

Q. How many regional managers did you manage in that role?

**A. There were about five to seven.**

Q. Does that mean there were about five to seven regions?

**A. Yes.**

Q. And the product that Acufex was selling at the time was the same ortho field products: Reconstruction of ACL, shoulder reconstruction and, I think you said, arthrosurgery in general; is that correct?

**A. Arthroscopic surgery.**

Q. Arthroscopic surgery?

**A. Yes.**

Q. Thank you.

And once again, these are the primary products of Acufex. And were there any other products that Acufex sold at the time you were there?

**A. There were.**

Q. Okay. What were they?

**A. They were -- There was different video equipment that was used for arthroscopic surgery.**

Q. Anything else?

**A. There were different devices used in the operating room: Leg holders, shoulder holders, all related to the orthopedic field.**

Q. Anything else?

**A. No.**

Q. Okay. Thank you.

When did you hold this position as national sales manager?

**A. It was my last year and a half with the company.**

Q. Okay. I think you testified earlier you believe you left Acufex around 1996; is that correct?

**A. Yes. So it would have been around the '95-'96 time frame, yes.**

Q. Okay. So '95-'96.

What was your next position?

**A. I went to ArthroCare Corporation.**

Q. What position did you hold at ArthroCare?

**A. Director of sales.**

Q. What were your duties?

**A. To manage the sales force in the United States.**

Q. Can you estimate how big the sales force was at the time?

**A. It was a start-up. When I started, it was zero.**

Q. It sounds like an easy management job.

**A. Yeah. I was there 11 years.**

Q. All right. So that sounds like from 1995 to about 2006?

**A. Yes.**

Q. Does that sound right? Okay.

So you managed the sales force. It sounds like you maybe grew the sales force; would that be fair to say?

**A. Yes.**

Q. At the time you left, how big was your sales force?

**A. When I left, I was the senior VP/general manager of all the business units.**

Q. All right. So at the time you concluded your position as director of sales, how big was the sales

force, approximately?

**A. We had 100 indirect employees, independent representatives, that we contracted with in the U.S. We had about a dozen direct employees.**

Q. And what were you selling for ArthroCare? What products did ArthroCare make at that time?

**A. They made electrosurgical products for the orthopedic field and the ENT field and spine.**

Q. And so ENT is ear-nose-throat; is that correct?

**A. That's correct.**

Q. Any other electrical surgical -- electrosurgical products then for the ortho, ENT and spine fields, any other fields?

**A. That was the technology that was developed. We made several products that were used in those fields.**

Q. Okay. But no other fields; is that correct?

**A. Not marketing directly, no.**

Q. What do you mean by that?

**A. ArthroCare had some license arrangements with other companies.**

Q. And what were those license arrangements?

**A. They licensed the technology to Olympus for urology. They licensed the products to Mitek for orthopedics. They licensed the products to Stryker**

**Corporation for the orthopedic field. There may have been others.**

Q. Do you recall any of those others as you sit here today?

**A. I do not.**

Q. When did you hold the position of director of sales?

**A. My first few years there, my first -- until 1999.**

Q. So around '95 to '99; is that correct?

**A. Yes.**

Q. And what was your next position at ArthroCare?

**A. I was the vice president of sales and marketing.**

Q. When did you hold that position?

**A. '99 until about 2004.**

Q. And what were your duties?

**A. I had worldwide responsibility for the sales and marketing of Arthrocare's products.**

Q. And once again, these products were the electrosurgical products for ortho, ENT and spine; is that correct?

**A. Yes. At that time there were additional products.**

Q. What were those products?

**A. We had done several acquisitions, so we acquired other companies' products.**

Q. What were those acquisitions?

**A. There was a company called Atlantech.**

Q. Atlantech?

**A. Yes.**

Q. Can you spell that.

**A. A-T-L-A-N-T-E-C-H.**

Q. Okay. And what were those products?

**A. They were orthopedic products for arthroscopic surgery, ACL reconstruction.**

Q. The other acquisitions?

**A. A company called Opus Medical.**

Q. Spell that, please.

**A. O-P-U-S, Medical.**

Q. And their products?

**A. Their products were for a sutureless rotator cuff anchor system.**

Q. Any other acquisitions?

**A. A company called Parallax.**

Q. And their products?

**A. Products for vertebroplasty.**

Q. What's vertebroplasty?

**A. It's where you put for a -- you put bone cement in the spine to alleviate pain for patients with**

**kyphosis or curved spine.**

Q. Kyphosis means curved spine?

**A. Yeah. It's curved, yes.**

Q. Any other acquisitions?

**A. There was a company, I forget the name, but the products were Rapid Rhino products. They made products for epistaxis.**

Q. Rapid Rhino products, that sounds like it has to do with the nose.

**A. Correct. It's for the ENT space. They had products for ENT.**

Q. What was the other one? I didn't quite catch that.

**A. That was it.**

Q. You said Rapid Rhino, and then you said something else.

**A. They made a product for epistaxis, which is bloody nose basically in trauma indications.**

**And there may have been others, but I think those are the main acquisitions.**

Q. Those are the ones you can remember?

**A. Yes.**

Q. All right. And that was during your tenure as VP of sales and marketing somewhere between '99 and 2004; is that correct?

**A. Between then and the time I left, yes.**

Q. So what was your next position after VP of sales and marketing?

**A. I was a senior VP and general manager.**

Q. What were your duties?

**A. I managed the business units of sports medicine, ENT and spine and, also, all the international business unit.**

Q. When you say you managed the business units of these areas, what does that mean?

**A. The business unit encompassed sales, marketing, research and development for each of those areas.**

Q. And you managed each of those areas' sales, marketing, research and development for these business units: Sports medicine, ENT and spine; is that correct?

**A. And international.**

Q. And international?

**A. Yes.**

Q. What do you mean by that?

**A. There was a separate business unit based in Europe that encompassed all those products as well. It was different personnel, and we treated it as a separate business unit.**

Q. I see, okay.

And you held that position from 2004 until you left; is that correct?

**A. Yes.**

Q. And you left somewhere around 2006; is that correct?

**A. Yes.**

Q. And what was your next position after you left ArthroCare?

**A. I became the CEO of PEAK in June of 2006.**

Q. And that's PEAK Surgical, the respondent in this proceeding; is that correct?

**A. Yes.**

Q. When you joined PEAK Surgical as CEO in June 2006, had the company already been in existence prior to that time?

**A. Yes.**

Q. What sort of products did PEAK Surgical -- Did PEAK Surgical make products in June of 2006 when you joined?

**A. In the process of developing products.**

Q. In the process of developing products, okay.

What products?

**A. Developing the PEAK technology and the PlasmaBlade products for various medical markets.**

Q. What were the medical markets that they were

in the process of developing when you joined in June 2006?

**A. I was the first employee, so the founders started the company in July 2005.**

Q. The founders started the company in July 2005; is that correct?

**A. Yes.**

Q. And what were the various medical products they were developing in June 2006? You said they were developing PlasmaBlade products in various medical fields. Did I get that right?

**A. Yes.**

Q. What were those medical fields at that time?

**A. It included just about every medical field, and it was my job to determine which ones to bring it to market.**

**(Reporter interrupts.)**

THE WITNESS: To bring the PEAK technology to market.

MS. CASTO: Q. So I'm just trying to get an understanding of, when you joined in June 2006, there were no plans to bring it to any specific market; it was your job to figure out which markets to bring the product to market in; is that correct?

**A. Well, again, it was a start-up.**

Q. Uh-huh.

**A. So it is a platform technology that can be used in many medical fields.**

Q. Okay.

**A. And the founders hired me because of my experience to determine which fields to bring it to first.**

Q. Okay. So you were the first employee. I assume you hired employees; is that correct?

**A. That's correct.**

Q. Okay. And so how many employees are there currently at PEAK Surgical?

**A. Currently, there are 60.**

Q. Can you describe the general categories in which these employees all fit? Do you have 50 engineers and one sales rep, or how does that -- Can you give that breakdown.

**A. There are 14 people in sales, in sales management.**

Q. Okay.

**A. There are four or five people in the marketing and clinical department. There are ten people in research and development. There are four in the finance and accounting area. There are three in the quality and regulatory space. And the balance is all in**

**manufacturing and operations, which includes assemblers and managers of the manufacturing process.**

Q. So that looks like approximately 20 employees --

**A. That's about right.**

Q. -- in manufacturing and operations?

**A. Yes.**

Q. What are your current responsibilities as CEO? I assume -- Actually, I shouldn't assume. Are you still CEO of PEAK Surgical?

**A. Yes, I am.**

Q. So do you hold any other titles at PEAK Surgical?

**A. I am a board member, a director.**

Q. Okay. Any other titles?

**A. No.**

Q. What are your current duties as CEO of PEAK Surgical?

**A. To grow our business and to bring value to our shareholders.**

Q. As part of your responsibilities, do you manage any of the 60 employees for PEAK Surgical?

**A. I have seven reports directly, that report directly to me.**

Q. Okay. And who are your seven direct reports?

**A. Andre Bessette, Jeremy Adinger.**

Q. Let me just stop you there. Maybe if you can give me their names and perhaps spell their names and provide their titles for me, that would be helpful.

Andre Bessette?

**A. Andre Bessette is the vice president of marketing and clinical. Jeremy Adinger, A-D-I-N-G-E-R, is the director of operations.**

Q. Okay.

**A. An Nguyen, N- -- How do you spell "Nguyen"?**

MS. TAYLOR: It's N-G-U-Y-E-N.

THE WITNESS: That's it.

MS. CASTO: That is typically how "Nguyen" is spelled.

THE WITNESS: That's how it is spelled.

He is our director of quality and regulatory.

MS. CASTO: Q. An's first name is spelled?

**A. A-N.**

Q. Okay.

**A. Paul Davison, D-A-V-I-S-O-N, is our vice president of R&D.**

**Lori Munoz, M-U-N-O-Z, vice president/CFO.**

**Gwen Drain, D-R-A-I-N, is our director of human resources.**

**James Romero, R-O-M-E-R-O, is our director of**

**sales.**

Q. And for each of these seven direct reports, how long have you managed each of them?

MS. TAYLOR: Objection. It's a compound question.

MS. CASTO: Q. We can take them as a list if you like.

How about Andre Bessette, how long have you managed Andre?

**A. Since he -- Since 2006.**

Q. When did Andre join the company?

**A. Fall of 2006.**

Q. So you've managed Andre since he joined in fall 2006; is that correct?

**A. Yes.**

Q. How about Jeremy Adinger?

**A. Jeremy Adinger, I've managed directly for a year and a half. He joined the company two years ago.**

Q. So Mr. Adinger joined the company in 2008; is that correct?

**A. Yes.**

Q. How about An Nguyen?

MS. TAYLOR: I'm going to object. "How about An Nguyen" isn't a question.

MS. CASTO: I think if we go back to the

questions, we know that I was asking --

MS. TAYLOR: Is it when he joined the company or when he started?

MS. CASTO: How long he has managed him.

MS. TAYLOR: Managing him, okay. I just want to be sure.

THE WITNESS: I've managed An Nguyen since 2008 directly.

MS. CASTO: Q. And when did Mr. Nguyen join PEAK Surgical?

**A. I believe he joined in 2007.**

Q. Who managed him before you did?

**A. A woman named Grace Carlson.**

Q. Is Grace Carlson still with PEAK Surgical?

**A. She is not.**

Q. What was her position at the time that she managed Mr. Nguyen in 2007?

**A. She was the vice president of regulatory and clinical affairs.**

Q. How about Paul Davison, how long have you managed him?

**A. Since 2006.**

Q. And when did Mr. Davison join PEAK Surgical?

**A. He joined in the summer of 2006.**

Q. So he joined right after you; is that correct?

**A. Yes.**

Q. And how about Lori Munoz, how long have you managed her?

**A. Since 2007.**

Q. And when did she join PEAK Surgical?

**A. 2007.**

Q. And Gwen Drain, how long have you managed her?

**A. Since 2006.**

Q. And when did she join PEAK Surgical?

**A. 2006.**

Q. And James Romero, how long have you managed him?

**A. Since early 2009.**

Q. And when did he join PEAK Surgical?

**A. 2008.**

Q. And who managed him before you started?

**A. John Cifarelli.**

Q. Can you spell John's last name?

**A. C-I-F-A-R-E-L-L-I.**

Q. Is Mr. Cifarelli still with PEAK Surgical?

**A. No.**

Q. What position did he hold when he managed Mr. Romero?

**A. He was the vice president of sales.**

Q. Where is your office located?

**A. Palo Alto, California.**

Q. A couple of follow-up questions about your direct reports.

Are you doing okay? Do you need a break?

**A. No. I'm fine.**

Q. So as vice president of marketing and clinical, what are Mr. Bessette's duties?

**A. To manage the marketing of PEAK products worldwide. He also manages our OUS, our international distribution network.**

Q. What does "OUS" stand for?

**A. Outside the U.S.**

Q. Okay.

**A. And he also manages our clinical affairs.**

Q. What do you mean when you say he manages your clinical affairs?

**A. He manages a group of people that perform -- that work with to perform preclinical and clinical studies using PEAK technology.**

Q. And what are preclinical studies?

**A. Animal studies, generally.**

Q. Are there any other types of preclinical studies?

**A. You can have human cadaver tissue as a preclinical study. There can be other benchtop**

**experiments that are considered preclinical.**

Q. What is a benchtop experiment?

**A. Any type of scientific measurement that you are doing in a lab that you're documenting.**

Q. So lab experiments are sometimes referred to as preclinical --

**A. Yes.**

Q. -- studies, okay.

What are clinical studies?

**A. Generally referred when you have human clinical use, so human use.**

Q. That's living human use as opposed to human cadavers; is that right?

**A. Yes.**

Q. Is it ever done in labs?

**A. It depends on the products, I guess.**

Q. Okay. So lab experiments can be preclinical studies, but lab experiments can also be clinical studies?

**A. Is this in general or --**

Q. Yeah, in general. I'm just trying to get an understanding of the difference between a preclinical study and a clinical study.

**A. I guess you could have a clinical study in a lab if you were doing a study on a knee brace. You**

**would be in a lab. You've got a patient. Yes. So it could be done.**

Q. Okay. How about at PEAK Surgical with its products, does it do any lab clinical studies?

**A. No.**

MS. CASTO: I will introduce the first deposition exhibit. We'll be marking these DePuy 1 and 2. The first is the Notice of Deposition to Mr. John R. Tighe. I'm going to have the reporter mark these exhibits and then hand them to you. You probably are used to this process.

(Whereupon, Notice of Deposition of Mr. John R. Tighe sent October 22, 2010 was marked for identification and attached to the deposition as Exhibit 1.)

MS. CASTO: Counsel.

And DePuy Exhibit 2 is the 30(b)(6) Notice of Deposition to PEAK Surgical.

(Whereupon, 30(b)(6) Notice of Deposition of Peak Surgical, Inc. sent October 22, 2010, with attached Schedule A, was marked for identification and attached to the deposition as Exhibit 2.)

MS. CASTO: Q. I'm going to ask you to look at Exhibits 1 and 2, Mr. Tighe, and we'll start with

Exhibit 1 when you're ready. So just tell me when you're ready.

MS. TAYLOR: And "ready" means when he's done looking at it? Is that what you're asking him to tell you?

MS. CASTO: That's correct.

Q. When you're done reviewing it, tell me when you're ready.

MS. TAYLOR: Okay.

THE WITNESS: Yes, I'm ready.

MS. CASTO: Q. Okay. So looking at Exhibit 1, have you seen this document before?

**A. No, not until you just gave it to me.**

Q. Okay. And then looking at Exhibit 2, have you seen this document before?

**A. No.**

Q. Okay.

**A. I saw this list before the deposition started that you guys went through.**

Q. Okay. When did you first see the list that is appended as Schedule A to Exhibit 2?

**A. Right before we started here.**

Q. As we sat here in the deposition room this morning was the first time you saw that?

**A. Yes.**

Q. So we're going to go through the Schedule A to Exhibit 2. So if I can have you turn back to that page on Exhibit 2 --

**A. Deposition to begin at 2:30? Does that matter?**

Q. No. I think counsel have been negotiating as to who was going to be appearing for that deposition, and it turns out that apparently you're going to be. I just want to get that on the record, if I might.

So before we started the deposition, we walked through the topics listed on this Schedule A. And I just want to walk through them again to confirm which topics you have been designated to testify to on behalf of PEAK Surgical. Okay?

**A. Okay.**

Q. So looking at Schedule A, my understanding is that you have been designated to speak on behalf of PEAK Surgical on topics 3, 8 --

MS. TAYLOR: With respect to 8, to clarify, there have been no business dealings; therefore, PEAK Surgical has not designated anyone to discuss -- to testify as to business dealings. Mr. Tighe is being designated to testify as to communications only.

MS. CASTO: Q. But Mr. Tighe could also testify to the lack of business dealings on behalf of

PEAK Surgical?

MS. TAYLOR: He certainly is capable of --

MS. CASTO: Of answering that question?

MS. TAYLOR: -- of answering the question that there have been none, yes.

MS. CASTO: Q. Okay. So once again, I'll just walk through the topic numbers so we know what you have been designated to testify on behalf of PEAK Surgical.

3, 8 --

**A. Can I borrow your pen?**

MS. TAYLOR: Oh, you don't want to mark on that.

THE WITNESS: Sorry. That's all right.

MS. TAYLOR: I don't think it matters.

MS. CASTO: Q. You know what? You can. If you want to mark on it, that's fine. You can mark on it.

3, 8, 9, 13 -- 13 is actually on that first page.

**A. Yeah, I see it.**

Q. 19, 20.

MS. TAYLOR: On 20, I want to clarify, again, that we informed you there are no license agreements, so Mr. Tighe's designation is only to the extent he can

testify that there are none. He cannot testify as to what they are. I just want to be clear on that.

MS. CASTO: He can testify that there are none?

MS. TAYLOR: Exactly.

So go ahead and mark 20.

THE WITNESS: I got it.

MS. CASTO: Q. 22.

**A. Okay.**

Q. And 29.

So these are the topics that you have been designated to testify on behalf of PEAK Surgical; is that correct?

**A. Yes.**

Q. Did you do anything to investigate these topics?

MS. TAYLOR: Objection, that's vague.

THE WITNESS: I spoke with counsel yesterday.

MS. CASTO: Q. Other than speaking with counsel yesterday, did you do anything to investigate any of these topics?

**A. No.**

Q. In preparing for your deposition today, did you look at any documents?

**A. I did not.**

Q. Other than speaking with counsel, did you speak with anybody in preparation for your deposition today?

**A. No.**

Q. Did you make any notes in preparing for your deposition today?

**A. No.**

Q. Were you involved in the selection of the PEAK mark?

MS. TAYLOR: I'm going to object that it's vague.

THE WITNESS: I'm not sure what you mean by the selection. PEAK was a --

MS. CASTO: Q. Let me see if I can clarify. Were you involved in the adoption of the PEAK mark by PEAK Surgical?

MS. TAYLOR: Again, it's vague.

THE WITNESS: PEAK was the name of the company when I joined.

MS. CASTO: Q. Okay. So did you have any involvement in selecting the PEAK trademark for PEAK Surgical's products?

MS. TAYLOR: Again, it's vague.

THE WITNESS: I don't know about selecting the mark. We -- Grace Carlson managed the process of

applying for various trademarks for the company.

MS. CASTO: Q. Okay. By the way, did you speak with Andre Bessette in preparing for your deposition today?

**A. I did not.**

Q. Did you speak with him in preparation for his deposition?

**A. I did not.**

Q. Okay. And Grace Carlson was the vice president of regulatory and clinical affairs; is that correct?

**A. Yes.**

MS. CASTO: Court Reporter, can you read back Mr. Tighe's answer to my previous question where he said that Grace Carlson was involved or Grace Carlson played a role in the trademark. I didn't quite catch that.

(Record read by the reporter as follows:
I don't know about selecting the mark.
We -- Grace Carlson managed the
process of applying for various
trademarks for the company.)

MS. CASTO: Q. So did Grace Carlson then apply for the PEAK mark in the U.S.; is that what you're saying?

**A. That's possible. I'm not sure who actually**

**applied.**

Q. Okay. If you wanted to confirm, what would you do?

**A. I'd look up the -- I'd call my counsel and ask who was working with them at the time we applied.**

Q. Is that because your counsel has actually managed the trademark applications for PEAK Surgical?

**A. Yes.**

Q. And that would be Ms. Taylor?

**A. Yes.**

Q. And has Ms. Taylor managed the trademark prosecution for all of PEAK Surgical's trademarks?

**A. Yes.**

Q. U.S. and worldwide?

**A. Yes.**

MS. CASTO: Let me introduce the next exhibit, three.

(Whereupon, a four-page set of documents regarding a trademark assignment conveyed by Carl Zeiss AG was marked for identification and attached to the deposition as Exhibit 3.)

MS. CASTO: Q. This is the -- I'll let you take a look at that.

It's a three-page exhibit, and it bears Reel and Frame Nos. 003552 -- Reel number, Frame No. 0597

through 0600.

Mr. Tighe, do you recognize what this document is?

**A. I believe so.**

Q. What is it?

**A. I believe it's a record of Carl Zeiss assigning the PEAK trademarks to PEAK.**

Q. And were you involved in the assignment from Carl Zeiss to PEAK Surgical of this trademark?

MS. TAYLOR: Objection, it's vague.

THE WITNESS: I was involved to the extent that Grace Carlson reported to me, and she managed that process.

MS. CASTO: Q. And looking at page 3 of this exhibit, this bears what appears to be Grace Carlson's signature; is that correct?

**A. Yes.**

Q. There's an "M.D." at the end of Grace's name. Does that refer to the fact that she's a medical doctor?

**A. Yes, she is.**

Q. Okay. So Grace managed the process of obtaining the assignment from Carl Zeiss; is that correct?

**A. Yes.**

Q. And you supervised Ms. Carlson in that

process; is that correct?

**A. I supervised Grace Carlson. I didn't supervise all of her -- every detail of what she did.**

Q. Okay. Did you play any role in this assignment?

MS. TAYLOR: Objection, it's vague.

THE WITNESS: I played a role that -- in fact, that this was a -- kind of a follow-up to getting the assignment from Carl Zeiss.

MS. CASTO: Q. What do you mean a follow-up to it?

**A. Carl Zeiss had originally licensed the PEAK technology from Stanford.**

Q. Licensed the PEAK technology from Stanford?

**A. Yes.**

Q. Okay. So it was a license out from Stanford, a license in to Carl Zeiss; is that correct?

**A. It was a license to -- yeah, to Carl Zeiss. That's my understanding.**

Q. And you're referring to this as the PEAK technology from Stanford; is that correct?

**A. Correct.**

Q. And what is the PEAK technology you're referring to?

**A. PEAK technology is the technology that we've**

**developed, the unique wave forms and insulation design that encompasses the IP.**

Q. Did you say "unique wave forms and insulation"?

**A. Well, the PEAK technology refers to eight issued patents that we've licensed from Stanford.**

Q. You've licensed eight patents in from Stanford; is that correct?

**A. Yes.**

Q. And I was just wanting to clarify, was that term "insulation" or "installation"?

**A. Insulation.**

Q. Insulation, okay.

MS. TAYLOR: When it works for you, can we take a short break?

MS. CASTO: Let's take a break.

MS. TAYLOR: Okay.

(Recess taken from 10:55 to 11:07 a.m.)

MS. CASTO: Q. So Mr. Tighe, you testified earlier that Grace Carlson was involved in managing the process for obtaining PEAK Surgical's trademarks; is that correct?

**A. Yes.**

Q. So what exactly did Ms. Carlson do in managing that process?

MS. TAYLOR: Lacks foundation, perhaps calls for speculation.

MS. CASTO: Q. Do you know?

**A. She managed the process if we had names that we wanted to get to file for trademarks. She communicated with Zeiss to get the assignment of previous trademarks. She managed that process, you know, with our attorneys.**

Q. Did she conduct clearance searches for marks PEAK Surgical was interested in using?

MS. TAYLOR: Lacks foundation.

MS. CASTO: Q. Do you know?

**A. I don't know.**

Q. So just so I'm clear that I understand your knowledge as to what Ms. Carlson did in managing the process of acquiring trademarks for PEAK Surgical, she spoke with your counsel, and that would be Ms. Taylor; is that correct?

**A. That's correct.**

Q. And then what else are you aware that she did in managing that process?

**A. I know that she -- the document showed she communicated with Zeiss to get the assignment of PEAK.**

Q. Do you know if she initiated that communication with Zeiss to get the assignment?

**A. I'm not sure who called whom.**

Q. So you're not sure if she contacted Zeiss directly?

**A. At some point I know they communicated. I don't know who called who first.**

Q. Okay. Do you know how they communicated? Was it over the phone?

**A. I'm not sure.**

Q. You don't know whether or not there were any written communications?

**A. I'm not sure.**

Q. Do you know if Ms. Taylor had -- if Ms. Carlson communicated with Ms. Taylor in this process of obtaining the Zeiss assignment?

MS. TAYLOR: I'm going to object and instruct not to answer because that would be attorney-client privileged communication.

MS. CASTO: Q. Do you know if Ms. Taylor communicated with Zeiss?

MS. TAYLOR: I'm going to object and instruct the witness not to answer to the extent that the witness' knowledge comes from communications with counsel. If he has independent knowledge, then he may respond with respect to knowledge that you obtained from someone other than counsel.

THE WITNESS: What was the question again?
MS. CASTO: Can you read back the question.
(Whereupon, the reporter read the last question.)
THE WITNESS: I don't know.
MS. CASTO: Q. Who at the company would know?
MS. TAYLOR: I think that assumes facts and lacks -- It assumes facts, and it's the same issue, potentially attorney-client privilege.
THE WITNESS: Grace Carlson may know.
MS. CASTO: Q. Is she still with the company?
**A. No.**
Q. Where is Grace Carlson?
**A. She is in Chicago finishing her residency.**
Q. Do you know where she's doing her residency?
**A. I believe it's Northwestern Hospital.**
Q. Do you know what her residency is in? Is she in a particular department at Northwestern?
**A. She is a general practitioner, or will be.**
Q. Internal medicine then; do you know?
**A. I don't know.**
Q. Do you know when she began her residency at Northwestern?
**A. She began in 2008.**
Q. Is that when she left PEAK Surgical?

**A. Yes.**

Q. You earlier mentioned that -- I believe, that Zeiss had originally licensed the PEAK technology from Stanford; is that correct?

**A. Yes, that's my understanding.**

Q. And what did Zeiss do under that license; do you know?

**A. I do not know.**

Q. If you wanted to find out, what would you do?

**A. I guess I would contact Carl Zeiss.**

Q. Is there anyone at the company at PEAK Surgical you could ask to find out what Zeiss did under that license?

**A. No.**

Q. Anyone outside the company other than Carl Zeiss? Would, for instance, Grace Carlson know?

**A. No.**

Q. She wouldn't know?

**A. Again, no -- If I could rephrase the question. Know what about Carl Zeiss?**

Q. What Zeiss did under the license it acquired from Stanford to the PEAK technology.

**A. What he did. I'm sure they had a host of activities. I'm not sure who -- No one within PEAK, including ex-employees, would know the whole extent of**

**Zeiss's activities using the PEAK technology.**

Q. Okay.

**A. We would have no way of knowing that.**

Q. So how did it come about that PEAK Surgical acquired the assignment from Carl Zeiss; do you know?

**A. PEAK Surgical, the founders, which included Mark Blumenkranz, who is the chair of ophthalmology --**

Q. Can you spell that last name, please.

**A. B-L-U-M-E-N-K-R-A-N-Z.**

Q. Chair of ophthalmology where?

**A. Stanford.**

Q. And he is one of the founders --

**A. Yes.**

Q. -- of PEAK Surgical; is that correct?

**A. Yes, that's correct.**

Q. Okay. You were explaining his role.

**A. He was aware of the technology because it was developed at Stanford.**

Q. Okay.

**A. He worked with three founders to form the company PEAK Surgical in -- The company was incorporated in the State of Delaware in July 2005.**

Q. Okay. And so Dr. Blumenkranz was aware of the PEAK technology at Stanford because he was chair of ophthalmology there, and he approached Zeiss? I'm

trying to figure out how it came about that PEAK Surgical acquired this assignment from Zeiss.

**A. Once PEAK Surgical was formed, PEAK Surgical, the founders, negotiated a license agreement with Stanford --**

Q. Okay.

**A. -- the Office of Technology and Licensing --**

Q. Okay.

**A. -- to license the patents that incorporated the PEAK technology. That's how we obtained the PEAK technology.**

Q. Did Stanford have any trademark rights to the mark PEAK at that time?

**A. I don't know.**

Q. So PEAK Surgical negotiated with Stanford for a license to the patents to the PEAK technology?

**A. Correct.**

Q. And what did PEAK Surgical do in order to acquire the assignment? What did they do, if anything, in order to acquire the trademark assignment from Zeiss?

**A. We knew that previous to PEAK having the license to the technology, that Zeiss had some type of license with Stanford. And I don't know what happened to that license, but the license became available. We licensed the technology from Stanford and, as follow-up,**

**obtained the assignment of the PEAK trademark from Zeiss.**

Q. Okay. So PEAK Surgical then to your knowledge reached out to Zeiss to acquire the trademark assignment; is that correct?

**A. Grace Carlson did, or Zeiss communicated with Grace Carlson, exactly. As I mentioned before, I don't know how they communicated.**

Q. So the license that PEAK Surgical obtained from Stanford to the PEAK technology, is that an exclusive license?

**A. Yes. It's an exclusive license for all medical applications for this technology.**

Q. And to your knowledge, Zeiss previously had an exclusive license in that same space; is that correct?

**A. I don't know. I do not know the extent of the license that they had with Stanford.**

Q. Okay.

**A. We do not have visibility to that license.**

Q. Okay. But you know that PEAK Surgical has the exclusive license to the PEAK technology in the medical space?

**A. For all medical applications worldwide.**

Q. Okay. Do you know if Jennifer Taylor represented PEAK Surgical in obtaining the assignment

from Zeiss?

MS. TAYLOR: I'm going to caution the witness not to answer to the extent the witness' only knowledge is through communications with counsel.

THE WITNESS: May have helped with the legal work to obtain this assignment.

MS. CASTO: Q. You were looking at the assignment record. Is there something on that record that indicates that to be the case?

**A. Well, somebody had to draft this assignment letter. So I don't know if somebody from Zeiss did this, attorneys, or if our attorneys did. If it was our attorneys, it would have been Morrison & Foerster.**

Q. Looking at the first page of Exhibit 3, about three-fourths of the way down on that first page, do you see the Correspondent Name field and the name Jennifer Lee Taylor?

**A. There you go, yes.**

Q. And that is PEAK Surgical's counsel?

**A. Yes.**

Q. Are you aware of any PEAK Surgical business records which reflect communications between PEAK Surgical, and that would include PEAK Surgical's counsel, and Zeiss regarding this assignment?

**A. I'm not aware of any documents.**

Q. Does PEAK Surgical maintain any sort of file regarding the Zeiss assignment?

**A. It's possible.**

Q. In preparing for your deposition today and specifically to speak with regard to deposition topic 8 for business dealings or communications between PEAK Surgical and Carl Zeiss, what investigation did you conduct with regard to that topic?

**A. We haven't had any business dealings. The only communication I'm aware of is the communication between Grace Carlson to obtain this assignment.**

Q. Did you look for any business records of communications between PEAK Surgical and Zeiss with regard to this assignment?

**A. Today? I have not.**

Q. Did you ask anyone at PEAK Surgical to look for any such records?

**A. I have not.**

Q. If you were to look for such records, where would you look?

MS. TAYLOR: Calls for speculation.

THE WITNESS: Again, I know there were no business dealings with Zeiss, so I'm not sure. If I had to double-check, I would check some files.

MS. CASTO: Q. You know that there were

communications with Zeiss?

**A. Only to the extent that the assignment was completed.**

Q. Where would you look for any communications between PEAK Surgical and Zeiss in PEAK Surgical's records?

**A. Under Z. I don't know. I'm not sure what you mean. I guess --**

Q. Does PEAK Surgical maintain any files of any of the assignments it acquires?

**A. This is the only assignment that we've acquired, so it's not like there's a big file of assignments.**

Q. Does PEAK Surgical maintain files of any agreements it enters with other parties?

**A. Yes.**

Q. And where are those files maintained?

**A. Various departments within the company.**

Q. What departments?

**A. Each of the seven reports that I mentioned to you maintains files of agreements that they may have.**

Q. So this would be in the operations, is one department; is that correct?

**A. Right.**

Q. Quality and regulatory affairs, is that --

**A. Regulatory affairs, yeah. Human resources.**

Q. Research and development?

**A. Research and development.**

Q. Human resources, sales.

So for instance, how about this license in from Stanford to the PEAK technology, who maintains that file?

**A. That file is either with our CFO or the human resources individual.**

Q. Did PEAK Surgical produce a copy of this -- the Zeiss assignment in this action?

**A. I'm not sure what documents were produced. I did not review them all.**

Q. Do you know where this assignment, as in Exhibit 3, where this is maintained at PEAK Surgical?

**A. If we have a copy at PEAK Surgical, it's probably with either Mr. Bessette, Ms. Drain or Ms. Munoz and, I assume, also with our counsel.**

Q. So if you were to look for communications related to this assignment, who would you ask?

**A. I would ask Andre Bessette, Gwen Drain or Lori Munoz.**

Q. Who at PEAK Surgical is maintaining trademark files?

**A. Gwen Drain and Andre Bessette, along with our**

**counsel.**

Q. Did you ask your counsel if they had any communications between -- any documents reflecting communications between Zeiss and PEAK Surgical?

MS. TAYLOR: I'm going to instruct the witness not to answer. That would be an attorney-client communication. I'm instructing him not to answer.

MS. CASTO: Q. Would counsel be someone else you would look to to find copies of records of communications between Zeiss and PEAK Surgical?

**A. As I mentioned, any communication -- anything regarding trademarks, I would -- if I needed to look for documents, I would look at -- I would ask Andre Bessette, Gwen Drain and our counsel. Between those three, we should have any documents that we need for -- that relate to these subjects.**

Q. But you have not asked those individuals as you sit here today; is that correct?

MS. TAYLOR: I have to instruct him not to answer because part of that would be a communication with an attorney. So he can't answer yes or no. If you want to break it out to the individual people, he can answer as to the others.

MS. CASTO: Q. Mr. Bessette: Did you ask Mr. Bessette for any communications between Zeiss and

PEAK Surgical?

MS. TAYLOR: And do you mean written communications?

MS. CASTO: Q. Any communications.

**A. I have not asked Mr. Bessette.**

Q. How about Ms. Drain?

**A. I have not.**

Q. And Ms. Munoz?

**A. No.**

Q. So you don't know who PEAK Surgical communicated with at Zeiss in negotiating this assignment; is that correct?

**A. As I mentioned, Grace Carlson communicated with Zeiss.**

Q. And who did Grace Carlson communicate with at Zeiss?

**A. I do not know. Let me see who signed it here. I don't know.**

Q. And you didn't look for any records to determine these facts as to who Grace Carlson communicated with at Zeiss; is that correct?

**A. I have not.**

Q. Did PEAK Surgical provide any consideration for the assignment it acquired from Zeiss?

MS. TAYLOR: Objection. That calls for a

legal conclusion as to what consideration is.

MS. CASTO: Q. Do you know what consideration is, Mr. Tighe?

**A. Money.**

Q. That's a good start.

Did Zeiss obtain any money payments from PEAK Surgical --

**A. I'm not aware of any.**

Q. -- as part of this assignment?

Are you aware of anything else Zeiss obtained by assigning this trademark to PEAK Surgical?

**A. I'm not aware of anything else.**

Q. Are you aware of any other business deals between PEAK Surgical and Zeiss?

**A. I am not aware of any.**

Q. Have you investigated within PEAK Surgical to determine if anyone else is aware of any other business deals between PEAK Surgical and Zeiss?

**A. I have not investigated. There would be no reason to have any business dealings between PEAK and Zeiss.**

Q. If you were to investigate whether there were any business dealings between Zeiss and PEAK Surgical, where would you look?

MS. TAYLOR: Calls for speculation.

THE WITNESS: I would ask the three individuals I mentioned previously.

MS. CASTO: Q. Is that Mr. Bessette, Ms. Drain and Ms. Munoz?

**A. Yes.**

Q. Okay. Anything else?

**A. Other than, again, Grace Carlson.**

Q. Are you aware of any use of the PEAK mark by Zeiss in 2006?

**A. Zeiss published some papers in and around that time frame that mentioned the use of the PEAK technology.**

Q. So Zeiss was selling a product in 2006 that used the PEAK technology?

MS. TAYLOR: Mischaracterizes the testimony.

THE WITNESS: You asked if they used the name. I know they used the name PEAK. I am not aware -- I don't know if they were selling or not. I wouldn't have knowledge of their revenue or sales.

MS. CASTO: Q. So they referenced the name PEAK in some published materials in 2006; is that your testimony?

**A. Yes.**

Q. And what are those materials?

**A. There are a couple of medical publications**

**that reference the PEAK technology.**

Q. And they're dated 2006?

**A. I don't know the exact dates, but some are '05, '06, might be '07.**

Q. Where did you see these publications?

**A. Medical journals.**

Q. Do you have these publications currently in your possession?

**A. Yes.**

Q. Do you know if they've been produced by PEAK Surgical in this matter?

**A. I don't know.**

Q. So your testimony is that in the 2005-2006-2007 time frame, Zeiss published medical journal articles in which it referred to the PEAK mark. Did Zeiss have a license to the PEAK technology at Stanford during that time?

**A. Let's back up. First of all, Zeiss doesn't publish. The medical journal publishes an article. These are peer-reviewed publications that used and mentioned the PEAK name.**

Q. They were not written by Zeiss?

**A. No. They're written by the authors.**

Q. Okay. So let's back up because my question was, are you aware of Zeiss's use of the PEAK mark in

2006? That was my specific question. And you referred to these articles. So if we need to clarify, let's do that.

**A. Yeah. Let's clarify.**

**So Zeiss was mentioned as an underwriter, supporter, of these papers in the disclaimer at the bottom. There were various medical personnel, physicians, who were authors of the paper, and they mentioned PEAK technology. These are published papers. PEAK Surgical had nothing to do with these papers.**

Q. Okay. But these articles were not Zeiss using the PEAK mark; is that correct? These are journal articles written by another party?

MS. TAYLOR: First, it's compound. Second, it's calling for a legal conclusion.

THE WITNESS: Yeah. I don't know. It's -- These were -- Again, these were medical journals that were published, articles that referenced the PEAK name and also mentioned Zeiss.

MS. CASTO: Q. But these articles were not written by Zeiss; is that correct?

**A. I assume they were written by the authors who are listed at the top of the page. And these are physicians primarily.**

**Zeiss may have supported these studies. In**

**fact, I think that's what the disclaimer references. So who actually wrote them, I don't know.**

Q. In 2006, are you aware, was Zeiss selling any products under the PEAK mark?

MS. TAYLOR: Objection, asked and answered.

THE WITNESS: I don't know. I do not know.

MS. CASTO: Q. How about in 2005, are you aware of any products sold by Zeiss under the PEAK mark?

**A. I'm not aware.**

Q. How about 2004?

**A. I don't know.**

Q. And 2003?

**A. I don't know. I'm not sure when they obtained their license from Stanford.**

MS. CASTO: I'm going to introduce -- I think we're at Exhibit 4.

(Whereupon, a five-page article entitled "Effects of the Pulsed Electron Avalanche Knife on Retinal Tissue" was marked for identification and attached to the deposition as Exhibit 4.)

MS. CASTO: Q. And this is a 2002 article entitled "Effects of the Pulsed Electron Avalanche Knife on Retinal Tissue." It appears to be published in the AMA journal, ARCH OPHTHALMOL. Did I pronounce that

correctly, Mr. Tighe?

**A. I guess so.**

Q. Are you aware of this?

**A. I don't read that one regularly.**

Q. You don't read that one regularly.

Do you know what the phrase "pulsed electron avalanche knife" is that you see there referred in the title?

**A. I don't know exactly, but it looks like it references the PEAK technology.**

Q. Do you know what that phrase means, "pulsed electron avalanche knife"?

**A. Again, I believe it's an acronym for the -- or trying to be a description of the technology.**

Q. So "PEAK" was used as an acronym for the phrase "pulsed electron avalanche knife"; is that correct?

MS. TAYLOR: Objection, vague as to time and who was doing it.

THE WITNESS: Yeah. I'm not sure.

MS. CASTO: Q. At least as of this time and this article in 2002.

**A. It appears, yes.**

MS. CASTO: Introducing Exhibit 5, this is a document that bears Bates Nos. PEAK001 through 014.

(Whereupon, a 14-page document containing a brochure entitled "PEAK Surgical, The Pulse of Precision"; a summary of a clinical study; a summary of preclinical results from various tests; Bates Nos. PEAK001 - 14a copy of a booklet entitled "PEAK Surgical, The Pulse of Precision" was marked for identification and attached to the deposition as Exhibit 5.)

MS. CASTO: Q. Mr. Tighe, I'll ask you to take a look at this document.

Are you familiar with this document?

**A. Yes.**

Q. What is it?

**A. It's really three documents.**

Q. All right.

**A. It looks like the first few pages are a brochure that we have produced. Starting with 005, it's a summary of a clinical study that we used the PEAK technology. Starting with 007 is a summary of preclinical results from various tests that were performed.**

Q. Okay. So if you look at page 13, and second from the bottom is a publication entitled "Effects of the Pulsed Electron Avalanche Knife on Retinal Tissue"

dated in 2002 and identifies the authors.

**A. Yes.**

Q. Is this the same publication that we've marked as Exhibit 4?

MS. TAYLOR: Lacks foundation.

MS. CASTO: Q. Do you know?

**A. It appears to be.**

Q. You see there it contains the date 2002, and it looks like, I guess, a volume No. 120 and then pages 636 to 640. And if you look at Exhibit 4, that same date appears; Volume 120; pages 636 to 640. Is that your basis for saying you believe that's the same article or publication in Exhibit 4?

**A. Yes, that's correct.**

Q. So do you know what the pulsed electron avalanche knife does?

**A. Yes.**

Q. What does it do?

**A. It cuts tissue precisely with minimal thermal damage.**

Q. Do you know what entities have participated in manufacturing the products marketed in connection with the mark PEAK?

MS. TAYLOR: Could you repeat that question again.

(Whereupon, the reporter read the last question.)

MS. TAYLOR: You mean PEAK Surgical's products? Is that what you're asking?

MS. CASTO: Q. We can ask about PEAK Surgical. We'll start with PEAK Surgical.

**A. I'm familiar with PEAK Surgical products that we manufacture, yes.**

Q. And PEAK Surgical manufactures them in-house?

**A. We manufacture certain components in-house, and we use a contract manufacturer for other components.**

Q. And who is that contract manufacturer for these other components?

**A. For the generator, we use a manufacturer, contract manufacturer, called California MedTech.**

Q. And the generator is a component?

**A. It's a component of the system.**

Q. Any other contract manufacturers?

**A. No.**

Q. Other than PEAK Surgical's products, do you know of any entities that have participated in manufacturing products marketed in connection with the PEAK mark?

**A. Only to the extent that I've read these papers, several clinical papers or preclinical papers in**

**some cases, that describe the technology during the time that Zeiss had the license.**

Q. What papers?

**A. I mentioned there were -- Before we produced this exhibit, there were -- there are at least two or three journal papers that are published that describe the use of PEAK technology.**

Q. By whom?

**A. Again, there's a list of medical authors. I can't recite each one. And you know, they are published by different medical journals.**

Q. So these journal articles identified entities who have manufactured products in connection with the PEAK mark?

MS. TAYLOR: That mischaracterizes his testimony.

THE WITNESS: They describe the use of the technology. To what extent manufacturing was accomplished, completed and by whom, I don't know.

MS. CASTO: Q. So that information wouldn't be in these articles; is that correct?

MS. TAYLOR: It calls for speculation.

THE WITNESS: It may.

MS. CASTO: Q. But as you sit here today, you're not aware of any information in these articles

you've been telling me about that identify entities who manufacture products in connection with the PEAK mark?

**A. The articles mention in some cases Carl Zeiss.**

Q. Carl Zeiss manufacturing these products?

MS. TAYLOR: Mischaracterizes the testimony.

THE WITNESS: They mention Carl Zeiss. Again, to what extent Carl Zeiss is involved -- I'm aware that they had a license on the technology. To what extent they commercialized products, I don't know.

MS. CASTO: Q. Again, you're not aware of any use by Carl Zeiss of the PEAK mark in selling any products; is that correct?

MS. TAYLOR: Mischaracterizes the testimony and calls for a legal conclusion.

THE WITNESS: Again, I'm aware that Carl Zeiss was involved with preclinical and clinical studies using the technology to the extent that they sponsored some of these articles or helped underwrite or used consultants of theirs to author the articles.

MS. CASTO: Q. So I just want to understand and be clear about what you know about Carl Zeiss's use of the PEAK mark to sell any products.

**A. Okay.**

Q. You testified earlier you weren't aware of anything in 2006, in 2005, in 2004, in 2003. I just

want to be clear that's your testimony.

**A. Okay.**

MS. TAYLOR: That mischaracterizes his testimony, and I need to object.

THE WITNESS: I'm clear -- Well, again, if you could rephrase the question.

MS. CASTO: Q. Are you aware of any -- I think we covered this before.

**A. Okay.**

Q. And I just want to be sure I understand your testimony, especially in light of Counsel's objections. And I don't think she's right about this. But I asked you before, I think quite clearly, are you aware of any use by Zeiss of the PEAK mark to sell any products?

**A. And I believe I mentioned and I referenced these articles are my only knowledge of Zeiss's use in connection with the PEAK mark.**

Q. Okay. These articles are your only knowledge of any use by Zeiss of the PEAK mark, but these articles don't identify any products sold by Zeiss under the PEAK mark; is that correct?

MS. TAYLOR: Wait.

THE WITNESS: Well, there's two questions there.

MS. TAYLOR: Yeah. There's two questions.

It's a compound question, and it's vague, and it's ambiguous.

MS. CASTO: Q. Answer to the best of your ability.

MS. TAYLOR: Or if you can't answer, ask her to rephrase the question.

THE WITNESS: The only knowledge I have of Zeiss's activities are through these articles. These articles describe products. They describe products used in preclinical and clinical settings.

MS. CASTO: Q. So no product sales?

**A. I don't know.**

Q. Are preclinical settings -- Do you sell products in a preclinical setting?

**A. We do not.**

Q. Do you sell them in a clinical setting?

**A. Yes.**

Q. Are you aware of any clinical studies by Zeiss during 2003 to 2006?

**A. Yes.**

Q. What are those?

**A. Again, I don't have the title. We can probably look it up. There are published articles that describe some human case studies in Germany. It might have been Austria. It was in Europe.**

Q. What time frame?

**A. I don't know the publication, but it is within that 2002 to 2007 time frame.**

Q. Where would you look to find that?

**A. I would look in medical journal files. It may be referenced right here, actually.**

Q. When you say "right here," you're talking about in Exhibit 5?

**A. Yes, in the bibliography section there.**

Q. Can you point out any?

**A. I cannot, without looking at the actual article itself.**

**Here it is. I take that back. Right above. "Publications describing clinical use of the PEAK technology." So here, this Priglinger, "new technology for cataract surgery," 2007, I believe that was a clinical use.**

Q. What is your basis for saying you believe that was a clinical use?

**A. Because it says "publications describing clinical use."**

Q. This first reference by Priglinger?

**A. Yeah. I believe all four of those references reference a clinical use of the technology.**

Q. By Zeiss?

**A. Again, no. It's by the JOURNAL OF OPHTHALMOLOGY, the JOURNAL OF CATARACT REFRACTIVE SURGERY, RETINA journal, ARCHIVE OF OPHTHALMOLOGY. That's who the publications are by, and the authors are listed here.**

Q. So we can't tell as we look at this list of four publications who the clinical study -- who conducted the clinical study?

**A. As far as the physician, the author conducted the study. They are writing the paper. As far as, you know, what roles Zeiss had, I can't tell by looking at this without pulling the article. And even then, they may mention Zeiss, but I still don't know the role, the complete role that Zeiss played in supporting those studies.**

Q. Do you have these publications in your possession at PEAK Surgical, these four publications that you reference here?

**A. I'm sure we do.**

Q. But you don't know if you've produced these publications?

**A. I don't know.**

Q. Okay. These publications are dated -- two in 2005. Does that mean those studies were conducted in 2005?

**A. Not necessarily. It means when they are published. They could have been done a year to three years before. Each publication has a various path before it gets published.**

Q. The same is true for the 2006 publication?

**A. Correct.**

Q. And for the 2007 publication, the same is true?

**A. Correct.**

Q. So what was Zeiss's role, if any, in the development of the technology that PEAK Surgical is marketing today?

MS. TAYLOR: Calls for speculation.

THE WITNESS: They had a license to the technology from Stanford. We obtained a license for the technology, the same technology. December 2005 was the date of our license.

MS. CASTO: Q. So my question was about the development of the technology that PEAK Surgical is marketing today. What role did Zeiss play --

**A. Your question was about Zeiss. So --**

Q. Right. What role did Zeiss play in the development of the technology that PEAK Surgical is selling today?

**A. I don't --**

MS. TAYLOR: It's ambiguous; it's vague; it calls for speculation; and it's been asked and answered.

THE WITNESS: I don't know the role. I don't know what Zeiss developed other than what is written in these articles. I know that we licensed the technology, you know, in December 2005 from Stanford.

MS. CASTO: Q. And you know that Zeiss prior to that time had licensed the technology out of Stanford; right?

**A. Yes.**

Q. Okay. You don't know if Zeiss actually participated in developing any technology that you acquired from Stanford by license; is that correct?

**A. We acquired the license to the technology. We obtained a paper license. We didn't acquire any devices or any --**

Q. Or know-how?

**A. No.**

Q. You just obtained a license, and then PEAK Surgical developed its own technology in-house; is that correct?

**A. Well, the technology is based on the PEAK technology from Stanford, the IP that we licensed. But yes, we developed the products ourselves.**

Q. Did Zeiss participate in that with PEAK

Surgical?

**A. No.**

Q. Turning back to Exhibit 5, when was the product identified in this exhibit first produced?

MS. TAYLOR: I'm going to object that it's compound. He said it's three different documents.

MS. CASTO: This is how PEAK Surgical produced it to us.

MS. TAYLOR: I don't know who stapled them together.

THE WITNESS: We first -- When we produced the technology? I'm sorry. If you can rephrase. When we first --

MS. CASTO: Q. Yes. When was the product produced?

**A. We received FDA clearance for the technology in July 2008. We developed the technology from the very beginning when we first obtained the license. That's when development began.**

Q. And that development began when you obtained that license which was in December 2005?

**A. Correct.**

Q. And how is the product identified in this exhibit used?

**A. It is used to cut soft tissue and stop**

**bleeding at the same time with little thermal damage in a variety of medical procedures.**

Q. Do you know what products are currently sold by PEAK Surgical under the PEAK mark?

**A. Yes, I'm aware of the products that we sell.**

Q. And what are those products?

**A. They consist of the PEAK generator, and there are a variety of different disposable blades that are used to plug into the generator.**

Q. Looking at Exhibit 5, if you would turn to the second page, is this a picture of the -- I think you called it the PEAK generator?

**A. Yes.**

Q. So this is essentially the base unit sold by PEAK Surgical?

**A. Correct.**

Q. And then you said there are a variety of disposable blades that get plugged into this generator; is that correct?

**A. Yes.**

Q. Is one of those blades sitting on top of that picture?

**A. Yes, it is.**

Q. And if you turn to page 4 of Exhibit 5, are there other examples of the variety of disposable

blades?

**A. There are pictures of three of them on page 4, yes.**

Q. Are you aware of any use by any other parties of the PEAK mark for goods and services in the medical field?

**A. I am not aware.**

Q. At the time PEAK Surgical was considering whether to adopt the PEAK mark, did it conduct any trademark clearance investigations to determine if others in the medical field were using the mark?

**A. I'm not sure what research was performed. We obtained the license for the PEAK technology from Stanford and then followed up with Zeiss to get the assignment of the PEAK mark.**

Q. Other than that, you're not aware of any sort of clearance work for the trademark?

**A. If we did any research work, it would have been through our counsel.**

Q. So counsel would have performed the searches; is that your testimony?

**A. Or it's possible that Grace Carlson or some other consultants performed some research, but I'm not aware of any specific research.**

Q. Are you aware that DePuy had been using the

PEAK mark?

**A. Not until we were contacted by DePuy.**

MS. CASTO: All right. I'm going to introduce three more exhibits. 6, 7 and 8.

(Whereupon, a 510(k) Summary of Safety and Effectiveness dated September 14, 1998 for the Motech PEAK Fixation System was marked for identification and attached to the deposition as Exhibit 6.)

(Whereupon, a 501(k) Summary dated January 4, 2007 for the Peak FX Hip Plate was marked for identification and attached to the deposition as Exhibit 7.)

(Whereupon, a package insert for DePuy's PEAK fixation system was marked for identification and attached to the deposition as Exhibit 8.)

MS. CASTO: Exhibit 6, 7 and 8.

For the record, Exhibit 6 is a 510(k) Summary of Safety and Effectiveness. It bears a date of September 14, 1998, and this is for the DePuy Motech PEAK Fixation System.

Exhibit 7 is a 510(k) Summary which bears a date of January 4th, 2007. The name of the sponsor, again, is DePuy Orthopedics, Inc., and the product is Peak FX Hip Plate.

Then the last exhibit is a package insert for DePuy's PEAK fixation system.

Q. Were you aware that DePuy had these products which bear the PEAK mark in '98 and 2007?

MS. TAYLOR: Objection. It's compound and also mischaracterizes the documents. They speak for themselves.

THE WITNESS: I was not aware that DePuy was using the PEAK mark in some way until we were contacted by DePuy.

MS. CASTO: Q. And I believe you testified before that you weren't aware of any other entities using the PEAK --

**A. I'm not aware of any.**

Q. -- mark at any time; is that correct?

**A. That's correct, for any medical goods.**

MS. CASTO: I think we are at a point where we can take a short lunch break.

We can go off the record.

(Lunch recess taken from 12:08 to 12:47 p.m.)

MS. CASTO: Q. I want to go back to the topic of communications between Zeiss and PEAK Surgical.

**A. Okay.**

Q. What was the first communication between Zeiss and PEAK Surgical?

MS. TAYLOR: Lacks foundation.

MS. CASTO: Q. Do you know?

**A. I don't know. I -- It would have been between Grace and Zeiss reaching out to arrange this transfer of the trademark.**

Q. But you don't know what that first communication was?

**A. I do not.**

Q. So you don't know the date of that first communication?

**A. Sometime in the 2006 -- when was it -- 2006 time frame when Grace Carlson joined the company.**

Q. What is your basis for saying it was in 2006?

**A. It could have been early 2007. The date of the assignment, I guess, was early 2007. So sometime between the time Grace was hired -- she was hired in July 2006 -- until this assignment was dated February 2007. So sometime in that time frame is when the communication would have occurred.**

Q. So your basis for saying that is you know that the communication occurred between -- the first communication occurred between Grace Carlson and Zeiss; is that correct?

**A. Yes.**

Q. How do you know that?

**A. There was nobody else at the company. We had in that time period, 2006 -- I was an employee, Grace. We had maybe three employees. There was no reason to communicate to Zeiss for any reason.**

Q. So as of July 2006, there were three employees at PEAK Surgical; is that correct?

**A. Yes.**

Q. And that was you and Grace Carlson and who else?

**A. Paul Davison.**

Q. And so your basis for saying that Grace Carlson had the first communication with Zeiss is because you know you didn't have the first communication with Zeiss; is that correct?

MS. TAYLOR: Mischaracterizes the testimony.

THE WITNESS: Her job was to, as I mentioned -- among her regulatory and clinical affairs was also in applying for trademarks and managing our trademark process. This transfer was part of that process. So she would have been the one responsible for managing that process. It would not have been myself. It would not have been Paul Davison.

MS. CASTO: Q. So you know for a fact, though, that you did not have the first communication with Zeiss?

**A. I have not had any communication with Zeiss.**

Q. And how do you know Paul Davison didn't have any communication with Zeiss?

**A. I don't know of any reason why he would.**

Q. And how do you know Grace had this communication? How do you know? What is your knowledge based on?

**A. Based on verbal communications that she was getting this transfer in the process, getting this transfer from Zeiss --**

Q. So Grace told you --

**A. -- and the fact that it occurred then.**

Q. So Grace told you about this process of getting this assignment transferred from Zeiss?

**A. Yes. She updated periodically, yeah, sure.**

Q. What did she tell you?

**A. That she had contacted someone from Zeiss and that we were getting the trademark assigned to PEAK.**

Q. Do you know when she told you this?

**A. I do not.**

Q. What about after that first communication, do you know when the second communication occurred?

**A. I do not.**

Q. Do you know who that communication occurred between, that second communication after the first?

MS. TAYLOR: It assumes facts.

THE WITNESS: Yeah. I don't know. And I don't know the number of times, whether it was one, two or three, there was communication. I know that Grace was in charge of the -- managing that process, and then it came to fruition apparently when the document was signed.

MS. CASTO: Q. Do you know if there were drafts exchanged of this assignment between --

**A. I do not.**

Q. -- between Zeiss and PEAK?

**A. I do not.**

Q. You don't know?

**A. I don't know.**

Q. Do you know if there were any letters exchanged between Zeiss and PEAK Surgical?

**A. I'm not aware of any.**

Q. So as you sit here today testifying on behalf of the corporation, it's your testimony that you are not aware of any communications between Zeiss and PEAK Surgical?

MS. TAYLOR: That mischaracterizes his testimony.

THE WITNESS: I'm aware that Grace and someone at Zeiss had communicated in some way. I do not know if

it was phone, email, text message, whatever. They obviously communicated because the assignment was then completed. I don't know the form of the communication or the frequency.

MS. CASTO: Q. And who negotiated the terms of the assignment?

**A. Grace Carlson, along with our attorneys.**

Q. And on Zeiss's side, who negotiated the terms?

**A. I don't know.**

Q. Do you know who communicated on behalf of Zeiss?

**A. I do not.**

Q. You testified earlier that Zeiss did not receive any money in exchange for this assignment; is that correct?

MS. TAYLOR: That mischaracterizes his testimony.

MS. CASTO: I asked him if that's correct.

MS. TAYLOR: You summarized the testimony incorrectly, so I'm making an objection that it mischaracterizes his testimony.

THE WITNESS: I do not believe that Zeiss received any compensation for this. I'm not aware of any.

MS. CASTO: Q. Do you know, why did Zeiss

give PEAK Surgical the rights to this trademark for free?

MS. TAYLOR: That assumes facts.

THE WITNESS: I don't know.

MS. CASTO: Q. You testified earlier that Zeiss may have been doing a clinical study in 2007. Have I summarized your testimony accurately?

MS. TAYLOR: I'm going to object that it mischaracterizes the testimony.

THE WITNESS: I'm aware that Zeiss is referenced in clinical publications that published in 2007 and earlier.

MS. CASTO: Q. So if Zeiss were conducting a clinical study in 2007, wouldn't that cause problems with the exclusive license PEAK Surgical obtained from Stanford in December of 2005?

**A. If they were conducting them during that period, yes. If they were publishing papers, many times these papers are published a year or two afterwards. So when these publications occurred in 2007, at least one did, when the studies were performed, the dates the patients were treated, I would not have knowledge of that.**

Q. But if there were clinical studies in 2007, that would be a problem with PEAK Surgical's exclusive

rights to that PEAK technology?

MS. TAYLOR: Wait --

THE WITNESS: If they were --

MS. TAYLOR: -- wait, wait. I'm going to object. Calls for speculation. It calls for a legal conclusion. And it's vague, and it's ambiguous.

THE WITNESS: I'm not sure what the problem would be, but I'm not aware of any conflicts during the time after we licensed the technology from Stanford that Zeiss was commercializing the product in any way.

MS. CASTO: Q. So you're not aware that Zeiss was commercializing the product in any way after you acquired the license in December of 2005; is that correct?

**A. Correct, other than the studies that they were publishing.**

Q. But you don't know when those studies occurred?

**A. No, I do not. I can only go by the date that is written on the document when they were published.**

Q. But you're talking about the date on Exhibit 5 of these four --

**A. The date on Exhibit 4. It looks like this one was published in May of 2002.**

Q. So that was before you acquired rights in

2005?

**A. We also in Exhibit 5 referenced several clinical studies that each had different dates. I'm trying to find that page.**

**Page 13 looks like there was a clinical study published in 2007, there was one in 2006, one in 2005, and another one in 2005.**

Q. Those aren't the dates of the clinical studies, though?

**A. Those are dates they are published.**

Q. But we don't know, as we sit here -- We can't tell from this list when those clinical studies were done?

**A. Correct. That's correct.**

Q. If they were done after you acquired your license in December of 2005, would that run afoul of the exclusive license you acquired in December 2005?

MS. CASTO: Calls for speculation, it's vague and ambiguous, and it potentially calls for a legal conclusion.

THE WITNESS: Potentially.

MS. CASTO: Q. Are you aware of any instances of confusion between anyone else's products that might bear the PEAK mark and PEAK Surgical's products?

**A. I'm not aware of any.**

Q. Turning back to Exhibit 6, 7 and 8, are you aware of any instances of confusion between DePuy's products identified in these exhibits and PEAK Surgical's products?

**A. I'm not aware of any confusion, no.**

Q. We had talked earlier today about some FDA clearances. I'd like to go over some of that material.

**A. Okay.**

Q. I'm going to introduce a few exhibits to help us along.

Exhibit No. 9 bears Bates No. PEAK899 to 900.

(Whereupon, a paper entitled "PEAK Surgical Receives 510(k) Clearance to Market PEAK Surgery System for Use in General Surgery" was marked for identification and attached to the deposition as Exhibit 9.)

MS. CASTO: Then Exhibit 10 bears Bates No. PEAK0977 through 979.

(Whereupon, a letter dated July 22, 2008 from Mark N. Melkerson to Grace A. Carlson, M.D., with enclosure, was marked for identification and attached to the deposition as Exhibit 10.)

MS. CASTO: And Exhibit 11 is PEAK0980 to 982.

(Whereupon, a Certificate for Full Quality Assurance dated January 16, 2009 was marked

for identification and attached to the deposition as Exhibit 11.)

MS. CASTO: And 12 is PEAK0974 through 976.

(Whereupon, a letter dated December 3, 2008 from Mark N. Melkerson to Grace A. Carlson, M.D. was marked for identification and attached to the deposition as Exhibit 12.)

MS. CASTO: Q. I'll ask you to take a look at those. Let me know when you've had a chance to look them over.

**A. Okay.**

Q. Are you familiar with these documents?

**A. Yes.**

Q. Tell me, what is a 510(k) clearance?

**A. It is a designation by the FDA for Class II devices that describes a process for obtaining approval for use in patients in the United States.**

Q. What is a class 2 device?

**A. There are four classes of devices. Class 2 is the designation, the bucket, if you will, that electrosurgery devices such as PEAK are classified by the FDA. Other higher risk devices, pacemakers and other things, are class 3 and 4. Lower risk devices are class 1.**

Q. So before you can use these devices with

patients, you have to obtain a 510(k) clearance from the FDA; is that correct?

**A. That's correct.**

MS. TAYLOR: That mischaracterizes the testimony. And I think it calls for a legal conclusion.

THE WITNESS: That's basically correct, yes. You must have a 510(k) in the United State for a class 2 device if you are going to use the device on patients.

MS. CASTO: Q. And what is the process for obtaining a 510(k) clearance?

**A. There's entire guidelines that the FDA has outlined for submitting products and designs and data that you submit to the agency.**

Q. And can you walk me through that process, please.

**A. It's a very detailed process. It involves drawings and marketing specifications and some preclinical data and other safety and data that -- Also, you point to a predicate device that is also on the market, and you compare your new device to this predicate device. That is the basis of the 510(k) process.**

Q. So there's an existing product on the market that's fairly similar to the one you're trying to get cleared; is that correct?

**A. It's similar in regards to safety and efficacy. It may not be the same in performance. And companies will then designate that predicate device and do their testing relative to the predicate device.**

**And the FDA uses that information to form the basis of their 510(k) approval.**

Q. So before the product can be made commercially available, it must obtain a 510(k) clearance; is that correct?

**A. Before it can be used on patients, it must obtain 510(k) clearance. Commercially available, you can show it at trade shows as long as you have a disclaimer that it hasn't been approved yet. If it is clearly marked, you can do labs, preclinical studies without 510(k) clearance.**

Q. But no clinical studies until you obtain 510(k) clearance?

**A. That's correct.**

MS. CASTO: I will introduce another exhibit, 13, PEAK0896 through 898.

(Whereupon, a PEAK Surgical press release entitled "PEAK Surgical Names John Cifarelli Vice President, Sales was marked for identification and attached to the deposition as Exhibit 13.)

MS. CASTO: Q. Let me know once you've had a chance to look at that exhibit.

**A. Okay.**

Q. And are you familiar with this document?

**A. Yes.**

Q. What is it?

**A. It's a press release that describes the hiring of our VP of sales, John Cifarelli.**

Q. So this release -- And I'll ask you to look at the bottom of the first paragraph, where it -- I think it's the last two lines, where it says, "Cifarelli and his team will sell the company's PEAK Surgery System once the pre-market notification (510k) has been cleared by the U.S. Food and Drug Administration."

So again, that means that this 510(k) clearance is required before you can sell this product?

**A. That's correct.**

Q. But you can, I think you said, show it at trade shows with a disclaimer --

**A. Yes.**

Q. -- before that time?

And what is the date that PEAK Surgical obtained 510(k) clearance for its PEAK Surgical System?

**A. It was July 2008.**

Q. And do we see that on Exhibit 10? This date,

July 2008?

**A. Yes, that's correct.**

Q. Did PEAK Surgical request that Zeiss abandon any of the trademarks that were assigned in the assignment document?

MS. TAYLOR: Calls for speculation.

THE WITNESS: I'm not aware of any request.

MS. CASTO: Q. If you wanted to find out, what would you do?

MS. TAYLOR: Calls for speculation.

THE WITNESS: Contact Grace Carlson.

MS. CASTO: Q. Anything else?

**A. No. She's the only person that had communication with Zeiss.**

Q. Did counsel have communication with Zeiss?

MS. TAYLOR: I'm going to instruct the witness not to answer to the extent that his only knowledge regarding a response to that question is a communication with counsel.

MS. CASTO: Communications between Zeiss and PEAK Surgical are not confidential and privileged. I'm asking him if he knows if counsel acting for PEAK Surgical had communications with Zeiss. That's a legitimate question about nonprivileged material.

MS. TAYLOR: It is not legitimate if he

answers based upon information he learned about only from counsel.

MS. CASTO: But that information wouldn't be confidential to PEAK Surgical. That would be information of communications between PEAK Surgical and Zeiss, another party. That's not a privileged --

MS. TAYLOR: If I told him I had a discussion with someone, my discussion with him is privileged. There's no question about that. So he may answer the question to the extent he has knowledge apart from what he has been told by his attorney.

MS. CASTO: I will disagree with --

MS. TAYLOR: That's fine.

MS. CASTO: -- your interpretation of the privilege laws, and we can take it up with the board if we need to.

MS. TAYLOR: That's fine.

THE WITNESS: I'm not aware of any communication between our counsel and Zeiss directly.

MS. CASTO: We may need to take a break in a little while so I can see where we are. But I did want to come back to this topic that you've been designated as the corporate witness to testify about communications between Zeiss and PEAK Surgical.

I understand from the testimony that you have

not investigated whether or not there are any files at the corporation or any persons with knowledge like Mr. Bessette or Ms. Drain or Ms. Munoz, who may have information as to whether there were communications or would have information as to the communications between Zeiss and PEAK Surgical.

I believe that PEAK Surgical had the duty to investigate that topic, and my proposal would be that you would investigate that and come back and provide me with the results of that investigation.

MS. TAYLOR: I will respond that Mr. Tighe is properly prepared for his deposition. We will not bring him back to testify on those topics.

He has testified that Grace Carlson had the communications. Grace Carlson is no longer employed by the company. She is the one who is knowledgeable about it. He is not obligated to go out and track down former employees to question them about discussions they had with another company three years ago.

With respect to the documents that have been produced in the case, all documents that were responsive to the document request have, in fact, been produced in this case. We're not aware of any that were withheld. We're not aware of any written communications. If there were written communications, you would have received

them.

So you are trying to suggest he was not properly prepared. In fact, Grace Carlson is the person who is knowledgeable. He has testified that he knows that Grace Carlson had the communications. He has testified that he knows that an assignment was signed.

That's all we have. We have been telling you guys for two years we don't know what went on at Carl Zeiss. All we can do is tell you what we currently know, and he has testified as to that. If you had wanted to take Grace Carlson's deposition, her name is on that assignment document. It was a document that was produced ages ago. It's a document that was recorded in the trademark office. It's a document that you printed out from the trademark office and introduced as an exhibit. You could have worked on that a long time ago. It's a little too late now.

MS. CASTO: Mr. Tighe has testified that he has not done any investigation to prepare for his deposition today.

MS. TAYLOR: He's not required to.

MS. CASTO: He has not -- He is required to testify based on an investigation that PEAK Surgical has conducted. He has not talked to anybody like Mr. Bessette, Ms. Munoz, Ms. Drain about what they may

know about these communications. And Mr. Tighe testified that they may have information about this.

MS. TAYLOR: He has not testified that they may have information. He has said if he was going on a hypothetical hunt for documents that you believe exist but that do not exist because they were not produced in this case, those are the people he would have looked to for their files. That's what he's testified to.

We did a thorough document production. You got the documents. You have everything. The issue is that Grace Carlson is the one who directly communicated with Carl Zeiss. And she's no longer employed by PEAK Surgical.

MR. LEWIS: We did not receive any documents.

MS. TAYLOR: Joe, hold on.

Mr. Tighe is the person most knowledgeable about the company because he was Grace Carlson's supervisor. He testified that she reported to him about her communications with Carl Zeiss. He doesn't remember those communications because they were three years ago.

He doesn't have to do anything more than that. He is the most knowledgeable person at the company. There are no documents. That's the problem here.

THE WITNESS: In regards to discovery, Andre Bessette with the company coordinated discovery whenever

the discovery list was produced to us. So I did not personally go to Gwen, Lori, et cetera, so Andre is the one who put all this stuff together and provided it to counsel.

MS. TAYLOR: And that was 15 months ago.

MS. CASTO: Let's give Mr. Lewis a chance to say what he was trying to say.

MR. LEWIS: Right. I was going to say, we did not receive even so much as a cover letter related to this assignment document, nor any transmittal letters or letters about the terms or drafting of the agreement between Zeiss and PEAK Surgical.

MS. TAYLOR: My understanding is there were no such documents to be produced. We looked for them. We did not neglect our duty. We looked.

MS. CASTO: Joe, if you want, we can go off the record for a while, but I was going to introduce my next two exhibits.

MR. LEWIS: I guess -- Go ahead.

MS. CASTO: All right. This will be Exhibit 14. And Exhibit 14 is a letter dated October 17th, 2006. It's an unsigned letter from V.T. Giordano to Jennifer Taylor.

(Whereupon, a letter dated October 17, 2006 from V.T. Giordano to Jennifer Lee Taylor was

marked for identification and attached to the deposition as Exhibit 14.)

MS. CASTO: And Exhibit 15 is a letter dated December 1, 2006 from V.T. Giordano to Jennifer Taylor.

(Whereupon, a letter dated December 1, 2006 from V.T. Giordano to Jennifer Lee Taylor was marked for identification and attached to the deposition as Exhibit 15.)

MS. CASTO: Q. Let me know when you've had a chance to review those exhibits, Mr. Tighe.

**A. Yes.**

Q. Have you seen these letters before?

**A. I have not.**

Q. Were you aware that Ms. Taylor sent these letters on PEAK Surgical's behalf?

**A. I was not aware of it. As I mentioned, Grace Carlson, along with the attorneys, were handling the assignment. This appears to be part of that process.**

Q. Do you know why PEAK Surgical didn't identify and produce these documents in searching for documents in its possession, custody and control that relate to communications regarding the Zeiss assignment?

**A. I don't know why. It's possible because the document was between Morrison & Foerster and Zeiss.**

Q. Do you understand that PEAK Surgical would

have an obligation to produce these documents in response to the requests that DePuy has made in this proceeding?

MS. TAYLOR: I'm going to object to the extent it calls for a legal conclusion.

THE WITNESS: As I mentioned, I have not seen these letters.

MS. CASTO: Q. And you're testifying on behalf of the company with regard to communications between Zeiss and PEAK Surgical; correct?

**A. Yes.**

MS. CASTO: Can we take a five-minute break?

MS. TAYLOR: Are we almost done?

MS. CASTO: We are almost done for today.

MS. TAYLOR: With Mr. Tighe and then -- Are you almost done with Mr. Tighe?

MS. CASTO: We can go off the record.

(Discussion off the record)

MS. CASTO: I have no further questions for today. I do hold this deposition open and ask that PEAK Surgical produce all of the communications between PEAK Surgical and Zeiss regarding the assignments. And once we've received all of those communications, then we will want to reconvene the deposition to ask questions regarding them.

I note that these communications were requested well over a year ago in Request for Production 6 and 13 and have not been turned over, and they should have been at that time.

MS. TAYLOR: Okay. Our response is, what were the objections to Requests for Production 6 and 13?

MS. CASTO: You tell me.

MS. TAYLOR: I'm asking you. You're the one who has been looking at it, obviously. Did we meet and confer? Has a motion to compel been filed? What were the objections?

MS. CASTO: My understanding is the objections were "We don't have any," which is exactly --

MS. TAYLOR: We made no objection to 6 and 13?

MS. CASTO: My understanding is that PEAK Surgical's response is "We have no such documents."

MS. TAYLOR: But what were the requests?

MS. CASTO: They were requests for communications regarding the assignment.

MS. TAYLOR: Okay. Our response is that Mr. Tighe has testified today that he is aware that Ms. Carlson reached out to Carl Zeiss or worked with Carl Zeiss in order to get an assignment.

You have obviously contacted somebody to get communications from another attorney regarding the

assignment. Did you get additional communications from the other attorney?

MS. CASTO: Well, these were actually communications between another attorney and you.

MS. TAYLOR: I know, and my question to you is, how did you get those documents?

MS. CASTO: By subpoena.

MS. TAYLOR: We were not served with a notice of subpoena in this case.

MS. CASTO: You were.

MS. TAYLOR: When were we served with a notice of subpoena?

MS. CASTO: Joe, did you want to interject?

MR. LEWIS: I can look it up. Hold on.

MS. CASTO: I think I have it as well.

September 4th, 2009.

MS. TAYLOR: And what was produced in response to the subpoena? Those two documents?

MS. CASTO: There were two responses.

MS. TAYLOR: What was produced?

MS. CASTO: These two.

MR. LEWIS: These documents were among those produced.

MS. CASTO: They were among --

MS. TAYLOR: Were there additional documents

produced?

MR. LEWIS: Yes.

MS. TAYLOR: Could you show those documents to me? I've never seen them.

MR. LEWIS: We can discuss this outside of the deposition of this witness.

MS. TAYLOR: I think we should talk about it right now on the record because you got documents over a year ago that you've never disclosed to me. And now you're attempting to hold open a deposition because you believe there are additional documents. What were the additional documents that you received in response to your subpoena?

MR. LEWIS: I can review my file and see about sending them to you.

MS. TAYLOR: Did you receive any other documents that enclosed -- you were complaining a moment ago you never received an enclosure letter. Did you receive an enclosure letter for the assignment agreement?

MR. LEWIS: I'm not going to go through every document that we received because, regardless of whether we received it or not through another source, PEAK Surgical is obligated to produce it.

MS. TAYLOR: That's avoiding my question. My

question is, did you receive the assignment enclosure letter in response to your subpoena?

MR. LEWIS: I don't know what you mean by "assignment enclosure letter."

MS. TAYLOR: You said earlier that you never even received an enclosure letter. Did you receive an enclosure letter?

MS. CASTO: Let's go off the record.

MS. TAYLOR: Actually, no. I prefer to stay on.

MS. CASTO: This is my deposition. I want the court reporter to go off the record, please.

(Discussion off the record)

MS. CASTO: We can go back on the record.

MS. TAYLOR: So for the record, what we're going to do is I'm going to walk over to my office and see if they can fax down to me from San Francisco any communications with Mr. Giordano or Carl Zeiss. We will come back, and we will resume the deposition of Mr. Tighe at that point in time. I am hoping we can do it within an hour.

Thank you.

(Recess taken from 1:33 to 3:12 p.m.)

(Whereupon, a letter dated September 18, 2006 from Jennifer Lee Taylor to Vito T. Giordano

was marked for identification and attached to the deposition as Exhibit 16.)

(Whereupon, a letter dated October 17, 2006 from V.T. Giordano to Jennifer Lee Taylor was marked for identification and attached to the deposition as Exhibit 17.)

(Whereupon, a letter dated October 19, 2006 from Jennifer Lee Taylor to Vito T. Giordano was marked for identification and attached to the deposition as Exhibit 18.)

(Whereupon, a letter dated December 1, 2006 from V.T. Giordano to Jennifer Lee Taylor, with enclosure, was marked for identification and attached to the deposition as Exhibit 19.)

(Whereupon, a letter dated December 21, 2006 from Jennifer Lee Taylor to V.T. Giordano, with enclosure, was marked for identification and attached to the deposition as Exhibit 20.)

(Whereupon, a letter dated 23.1.2007 from Claudia Bolsinger to Jennifer Lee Taylor was marked for identification and attached to the deposition as Exhibit 21.)

(Whereupon, a letter dated January 30, 2007 from Jennifer Lee Taylor to Claudia Bolsinger was marked for identification and attached to

the deposition as Exhibit 22.)

MS. CASTO: Q. Mr. Tighe, we took a break for about the last hour and a half or so. And I understand that you walked over with your counsel to Counsel's office to look through files to find nonprivileged communications to be produced and that you have provided these to me through your counsel, and I've marked them as exhibits; is that correct?

**A. Yes.**

Q. Okay. And for the record, we've marked a letter dated September 18, 2006 from Jennifer Taylor to Vito Giordano as Exhibit 16.

As Exhibit 17, we've marked a letter dated October 17, 2006 from Vito Giordano to Jennifer Taylor.

As Exhibit 18, we've marked a letter dated October 19th, 2006 from Jennifer Taylor to Vito Giordano.

As Exhibit 19, we've marked a letter dated December 1, 2006 from Vito Giordano to Jennifer Taylor.

As Exhibit 20, we've marked a letter dated December 21st from Jennifer Taylor to Vito Giordano. And it encloses two pages, including a partially executed assignment signed by Grace Carlson of PEAK Surgical and an Exhibit A to that assignment.

As Exhibit 21, we've marked a letter dated

January 23rd, 2007 from Claudia Bolsinger, spelled B-O-L-S-I-N-G-E-R, Corporate Legal Affairs for Carl Zeiss, to Ms. Taylor at Morrison Foerster.

And as Exhibit 22, we've marked a letter dated January 30th, 2007 from Jennifer Taylor to Claudia Bolsinger of Carl Zeiss.

Have you had a chance to review those --

**A. Yes.**

Q. -- exhibits? Thank you.

Mr. Tighe, I note in Exhibit 16 and in all of these exhibits, 16 through 22, were produced to PEAK -- pardon me. Strike that.

-- produced to DePuy, Inc. in the middle of your deposition.

This first, Exhibit 16, refers to two licenses. One license purports to be between PEAK Surgical and Stanford University, and another license which appears to be with Carl Zeiss. And neither of these licenses have been produced in this proceeding despite numerous document requests over a year ago, including Requests for Production 8, 18, 28 and 32.

MS. TAYLOR: Can you tell us what 8, 18, 28 and 32 are, please.

MS. CASTO: Q. They ask for licenses that deal with these trademark rights. And from the text of

this letter, Exhibit 16, it says that PEAK Surgical currently holds a license from Stanford University, under which PEAK Surgical is permitted to use a particular patented technology as well as to use and to file applications to register the PEAK trademark in connection with a medical device.

And then there is a license identified in the second paragraph that Carl Zeiss apparently held. Apparently, the term of that license from the letter is December 15th, '99 to August 17, 2004. And according to this letter, as part of that license, Zeiss was permitted to use the PEAK trademark.

DePuy, Inc. has asked for these license agreements in this proceeding and has not received them. And I cannot examine you on these records without receiving these licenses.

MS. TAYLOR: I'll respond to that. First of all, these are not trademark licenses, these are technology licenses. And I don't think that you had any request for technology licenses.

MS. CASTO: This license says --

MS. TAYLOR: The letter says?

MS. CASTO: The letter says that the license is to use and to file applications to register PEAK trademark.

MS. TAYLOR: Ask Mr. Tighe what the license is for. He will tell you.

MS. CASTO: Q. Mr. Tighe, is it correct, as it's identified here in Exhibit 16, that the license between PEAK Surgical and Stanford includes a license to use and file applications to register the PEAK trademark?

**A. The license covers only the patents in technology. It doesn't not include trademarks.**

Q. Do you know why this letter from PEAK Surgical's representative to Zeiss's attorney says that it does cover trademarks?

**A. I do not know.**

Q. If you wanted to find out, what would you do?

MS. TAYLOR: Calls for speculation.

THE WITNESS: I would have an attorney review the Stanford license, I guess.

MS. CASTO: Q. Is that license in PEAK Surgical's possession, custody or control? Do you have a copy of that license in your files?

**A. Yes. We have a copy of the Stanford license.**

Q. Do you have a copy of the license between Zeiss and Stanford in your files?

**A. We do not.**

Q. Do you know if that license is in the files of

your attorney?

**A. I do not know.**

Q. Well, beyond this -- we have received these letters. We are in the course of studying them and to see if there are other documents that we need to request. But we would maintain that we need to look at those licenses. This letter says, clearly, that trademarks are covered in this license, and we would demand the immediate production of it so we can ask questions about that license.

MS. TAYLOR: You can ask Mr. Tighe all the questions you want about the license agreement. He's familiar with the license agreement. He has testified it does not go to the trademarks.

MS. CASTO: Without seeing that license agreement and with this contradictory statement in this letter, I believe we're entitled to look at that license agreement.

MS. TAYLOR: You can serve a discovery request for it.

MR. LEWIS: It's already been served.

MS. TAYLOR: Which one?

MR. LEWIS: No. 18.

MS. TAYLOR: Please read to me what --

MR. LEWIS: "All license agreements relating

to Respondent's marks."

MS. TAYLOR: It doesn't relate to the mark. It was not responsive. If you want to serve a document request -- discovery does not close until Friday -- you may serve a document request for the license agreement for the technology between Stanford University and PEAK Surgical. We will respond to that.

MS. CASTO: And beyond that, we will ask for a privilege log of the communications withheld on grounds of privilege from the files that were searched this afternoon.

MS. TAYLOR: That's fine.

MS. CASTO: I have no further questions at this time. We'll continue to review these documents, and we reserve the right to hold this deposition open.

MS. TAYLOR: We disagree.

If you have questions on these documents, you need to ask Mr. Tighe today. I note that you received or Mr. Lewis received on September 10th, 2009 the letter from Mr. Giordano to me and a second one -- yes, two letters from Mr. Giordano to me, and you waited 14 months to raise any issue with our document production regarding the correspondence with Carl Zeiss. We've produced it to you. If you have any questions regarding the correspondence with Carl Zeiss, those need to be

asked today because those are these documents.

We can separately deal with a document request that seeks the technology license between PEAK Surgical and Stanford University. That has not been served, and discovery closes on Friday.

So if you have questions on these documents that you marked as Exhibit 16 through 22, they need to be asked today.

MS. CASTO: We have no further questions at this time. We do reserve the right to hold this deposition open, and we're done unless you have some questions you want.

MS. TAYLOR: Do you have any questions on Exhibits 16 through 22?

MS. CASTO: I do not know. I have not had a chance to thoroughly review them.

MS. TAYLOR: Then let us sit here while you review them. Mr. Tighe is not going to come back so you can ask him questions about documents that we produced.

MS. CASTO: Well, beyond this, we're entitled to a privilege log which we have not obtained yet. And we need to get that so we can see what else has been withheld on grounds of privilege.

MS. TAYLOR: When did you request the privilege log first?

MR. LEWIS: It is in the original document request.

MS. TAYLOR: And when did you ask us about it? Have you ever pointed out to us that you thought we needed to produce a privilege log?

MR. LEWIS: I believe there is correspondence afterwards. As you know, the case has been suspended for --

MS. TAYLOR: Yes. And frankly --

MR. LEWIS: -- for a while, so during that period it was not --

MS. CASTO: If I may jump in --

MS. TAYLOR: Does anything in that correspondence go to a privilege log because I don't recall being asked for a privilege log. I don't recall withholding documents. I don't recall being asked for a privilege log. I don't recall hearing from you that you thought our document production was incomplete vis-a-vis Carl Zeiss. And now, once again, we're trying to delay things. I'm a little bit concerned about the pattern here.

MS. CASTO: Well, let me just jump in that I believe that PEAK Surgical had a duty to prepare a privilege log, which was requested over a year ago, and that the failure to do so timely waives privilege as to

those withheld documents.

MS. TAYLOR: That's incorrect. That's incorrect. No documents were withheld as a result of our production of the documents a year ago. None was withheld.

As you know, today we went back and looked in our files at your request because you found out 14 months ago that there was correspondence with a third-party law firm. We did not -- I personally was not involved in the production of documents in this case. I was not aware that all of the communications were not produced. Nobody raised that issue with us. I just walked across the street, I pulled out these communications, I've given them to you.

If there are privileged documents that are responsive in our firm files, we will give you a privilege log. However, no privilege has been waived. We didn't even look in those files until today when you raised for the first time the issue that it seems the production had not been complete. So we will take a look at that issue, but we did not waive any privileges.

But my understanding is you have no questions on Exhibit 16 through 22, that you will attempt to hold the deposition open. Our view is it's concluded, and we will not be producing Mr. Tighe again. But if you want

to send a document request for the technology license, we will respond to that one. We will certainly respond to that.

MS. CASTO: And we're off the record.

THE REPORTER: Ms. Taylor, do you want a copy of the transcript?

MS. TAYLOR: Sure.

(Whereupon, the deposition was concluded at 3:25 p.m.)

_____

JOHN R. TIGHE

STATE OF CALIFORNIA ) SS.

I do hereby certify that the witness in the foregoing deposition was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth in the within-entitled cause; that said deposition was taken at the time and place therein stated; that the testimony of the said witness was reported by me, a certified shorthand reporter and disinterested person, and was under my supervision thereafter transcribed into typewriting, and when so transcribed was carefully read to or by the said witness, and, being in every desire, was thereafter by the said witness duly subscribed; that if unsigned by the witness, signature has been waived in accordance with stipulation between counsel for the respective parties.

And I further certify that I am not of counsel or attorney for either or any of the parties to said deposition nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand this 15th day of November, 2010.

Clare Macy

CLARE MACY, Certified Shorthand Reporter

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

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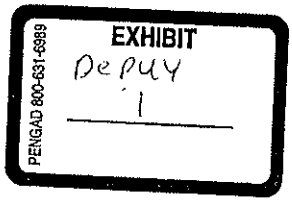
|---|---|---|
| DePuy, Inc., | : | |
| Petitioner, | : | |
| vs. | : | Cancellation No. 92050171 |
| Peak Surgical, Inc., | : | |
| Respondent | : | |

## NOTICE OF DEPOSITION

TO: Peak Surgical, Inc.,

Pursuant to Fed. R. Civ. Pro. Rule 30, Petitioner, DePuy, Inc. ("Petitioner" or "DePuy"), will take the deposition of Mr. John R. Tighe by oral examination on November 3, 2010. The deposition will be conducted at the law offices of Morgan, Lewis & Bockius LLP, 2 Palo Alto Square, 3000 El Camino Real, Suite 700, Palo Alto, CA 94306, before a notary public or another officer authorized to administer oaths under law, and will be transcribed stenographically. The deposition will begin at 9:30 A.M., and will continue until completed.



You are invited to attend and participate in the manner provided by the Federal Rules of Civil Procedure.

Respectfully submitted,

**DePuy, Inc.**

By: _____

Joseph D. Lewis
Attorney for Petitioner
Barnes & Thornburg LLP
750 17th Street, N.W.
Washington, D.C. 20006
(202) 289-1313

**CERTIFICATE OF SERVICE**

The undersigned certifies that a true copy of the foregoing Notice of Deposition was deposited with the U.S. Postal Service as first class mail, postage prepaid, addressed to Respondent's counsel, Jennifer Lee Taylor, Esq., Morrison & Foerster LLP, 425 Market Street, San Francisco, CA 94105, by first class mail, postage prepaid, on the 22nd day of October 2010, with a copy sent by facsimile.

_____
Joseph D. Lewis

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

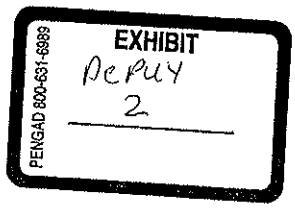
| | | |
|---|---|---|
| DePuy, Inc., | : | |
| | : | |
| Petitioner, | : | |
| | : | |
| vs. | : | Cancellation No. 92050171 |
| | : | |
| Peak Surgical, Inc., | : | |
| | : | |
| Respondent | : | |

## NOTICE OF DEPOSITION

TO: Peak Surgical, Inc.,

Pursuant to Fed. R. Civ. Pro. Rule 30(b)(6), Petitioner, DePuy, Inc. ("Petitioner" or "DePuy"), will take the deposition of Peak Surgical, Inc., by oral examination on November 3, 2010. The deposition will be conducted at the law offices of Morgan, Lewis & Bockius LLP, 2 Palo Alto Square, 3000 El Camino Real, Suite 700, Palo Alto, CA 94306, before a notary public or some other officer authorized to administer oaths under law, and will be transcribed stenographically. The deposition will begin at 2:30 P.M., and will continue day to day until completed.

Respondent is directed pursuant to Rule 30(b)(6) to designate one or more officers, directors, managing agents or other persons, with the most knowledge of, and who consent to testify on its behalf with respect to the matters identified in Schedule A, which is attached hereto.



You are invited to attend and participate in the manner provided by the Federal Rules of Civil Procedure.

Respectfully submitted,

**DePuy, Inc.**

By: _____

Joseph D. Lewis
Attorney for Petitioner
Barnes & Thornburg LLP
750 17th Street, N.W.
Washington, D.C. 20006
(202) 289-1313

## CERTIFICATE OF SERVICE

The undersigned certifies that a true copy of the foregoing Notice of Deposition was deposited with the U.S. Postal Service as first class mail, postage prepaid, addressed to Respondent's counsel, Jennifer Lee Taylor, Esq., Morrison & Foerster LLP, 425 Market Street, San Francisco, CA 94105, by first class mail, postage prepaid, on the 22nd day of October 2010, with a copy sent by fax transmission.

_____
Joseph D. Lewis

DCDS01 JYL 136927v2

## SCHEDULE A

1. The documents produced in response to the discovery requests in this proceeding

2. The adoption, creation, selection and selection of the mark PEAK.

3. The phrase "Pulsed Electron Avalanche Knife".

4. Each product which has been offered by Respondent or any person authorized by Respondent under or by reference to the mark PEAK.

5. The channels of trade for Respondent's products sold under the mark PEAK.

6. The packaging, labels, instructional manuals, package inserts on which the mark PEAK has appeared.

7. The advertisements, sales catalogs, brochures, Internet web pages or other items of promotional material which Respondent has created and/or distributed in connection with the mark PEAK.

8. Business dealings or communications between Peak Surgical, Inc. and Carl Zeiss AG.

9. Any trademark assignment to Peak Surgical, Inc. from Carl Zeiss AG, and the circumstances surrounding the assignment and all correspondence, relating or referring thereto.

10. outlets for sale of each product and service which has been offered by Respondent under or by reference to the mark PEAK.

11. Distributors and/or licensees offering products or services under or by reference to the mark PEAK

12. All documents relating to any efforts by Respondent to assert or enforce its rights in the mark PEAK against third parties.

13. Use by persons other than Respondent of any trademark incorporating PEAK for goods and services in the medical field.

14. Promotional activities of Respondent.

15. Trade shows at which Respondent has been an exhibitor or sponsor.

16. Any instances wherein a person has been confused, mistaken or deceived as to the source of products and/or services offered under or by reference to the mark PEAK.

17. Market research or competitive research done by or for Respondent in relation to products sold or intended to be sold under the mark PEAK.

18. Sales agents that have promoted the sale the Respondent's products under the mark PEAK.

19. Persons, firms, or other entities that have manufactured, designed, or developed the products marketed or intended to be marketed in connection with the mark PEAK.

20. License agreements relating to Respondent's Marks.

21. Rules or guidelines for use of Respondent's Marks.

22. Use of the mark PEAK by Carl Zeiss AG or any predecessor in interest of Respondent.

23. Any survey, poll or similar investigation conducted by or on behalf of Respondent relating to recognition of the Respondent's Marks or of Respondent by the public or the trade.

24. Applications to register any trademark comprising PEAK.

25. Any unsolicited publicity or recognition obtained or received by Respondent in relation to products offered or intended to be offered in connection with the mark PEAK.

26. The prices for each product of Respondent sold under the mark PEAK.

27. Media outlets used by Respondent to advertise products offered under the mark PEAK.

28. Respondent's knowledge of Petitioner or any trademark of Petitioner.

29. The nature of electrosurgical or electrocautery procedures for tissue cutting, tissue resectioning, hemostasis, and coagulation of blood vessels

30. Clinical studies and clinical trials relating to surgical knives sold under the mark PEAK.

# TRADEMARK ASSIGNMENT

Electronic Version v1.1
Stylesheet Version v1.1

| | |
|---|---|
| SUBMISSION TYPE: | NEW ASSIGNMENT |
| NATURE OF CONVEYANCE: | ASSIGNS THE ENTIRE INTEREST AND THE GOODWILL |

CONVEYING PARTY DATA

| Name | Formerly | Execution Date | Entity Type |
|---|---|---|---|
| Carl Zeiss AG | | 02/06/2007 | CORPORATION: GERMANY |

RECEIVING PARTY DATA

| | |
|---|---|
| Name: | PEAK Surgical, Inc. |
| Street Address: | 2464 Embarcadero Way |
| City: | Palo Alto |
| State/Country: | CALIFORNIA |
| Postal Code: | 94303 |
| Entity Type: | CORPORATION: DELAWARE |

PROPERTY NUMBERS Total: 1

| Property Type | Number | Word Mark |
|---|---|---|
| Registration Number: | 2679873 | PEAK |

CH $40.00 2679873

CORRESPONDENCE DATA

Fax Number: (415)268-7522
*Correspondence will be sent via US Mail when the fax attempt is unsuccessful.*
Phone: 415 268 6538
Email: rlal@mofo.com
Correspondent Name: Jennifer Lee Taylor
Address Line 1: Morrison & Foerster LLP, 425 Market St.
Address Line 4: San Francisco, CALIFORNIA 94105-2482

| | |
|---|---|
| ATTORNEY DOCKET NUMBER: | 59599-6001.001 |
| NAME OF SUBMITTER: | Jennifer Lee Taylor |
| Signature: | /Jennifer Lee Taylor/ |
| Date: | 05/31/2007 |



EXHIBIT
DePuy
3
PENGAD 800-631-6989

Total Attachments: 2
source=59599-6001.001 - assignment from carl zeiss to peak#page1.tif
source=59599-6001.001 - assignment from carl zeiss to peak#page2.tif

## ASSIGNMENT

WHEREAS, Carl Zeiss AG, a German corporation with its principal place of business located at 73447 Oberkochen, Germany ("**Assignor**"), is the sole owner of all rights, title and interest in and to the trademarks listed in the attached **Exhibit A** (the "**Trademarks**"); and

WHEREAS, Assignor wishes to assign all rights, title and interest in and to the Trademarks to PEAK Surgical, Inc., a Delaware corporation with its principal place of business located at 2464 Embarcadero Way, Palo Alto, CA 94303 ("**Assignee**"), and Assignee wishes to accept such assignment;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Assignor hereby assigns, grants, transfers and conveys (and agrees to assign, grant, transfer and convey) to Assignee, its successors and assigns all right, title and interest throughout the world in and to the Trademarks, together with all national, foreign, state and common law registrations, applications for registration and renewals and extensions thereof; all goodwill associated therewith; and all benefits, privileges, causes of action and remedies relating to any of the foregoing, whether before or hereafter accrued (including, without limitation, the exclusive rights to apply for and maintain all such registrations, renewals and/or extensions; to sue for all past, present or future infringements or other violations of any rights in the Trademarks; and to settle and retain proceeds from any such actions).

Assignor also agrees to execute such written instruments, extend such other cooperation and perform such other acts as may be necessary, in the opinion of Assignee, to register a trademark or otherwise enforce Assignee's rights in the Trademarks; and Assignor hereby irrevocably appoints Assignee and any of its officers as Assignor's attorney in fact to undertake such acts in Assignor's name.

This assignment agreement constitutes the entire agreement between Assignor and Assignee concerning the subject matter hereof and supersedes all prior or contemporaneous discussions, communications and agreements, whether oral or written, between Assignor and Assignee relating to the subject matter hereof.

IN WITNESS THEREOF, the Assignor has executed this document by the name of its duly authorized officer, as of February 6, 2007.

**CARL ZEISS AG**

By: _____

Name: ppa. Hoffmann ppa. Bolsinger

Title: managing clerk managing clerk

**PEAK SURGICAL, INC.**

By: Grace A Carlson MD

Name: Grace A. Carlson

Title: VP Regulatory + Clinical Affairs



sf-2237369 v1

TRADEMARK
REEL: 003552 FRAME: 0599

## EXHIBIT A

### TRADEMARKS

| Mark | Country | Application No. | Reg. No. | Issue Date |
|---|---|---|---|---|
| PEAK | Germany | | 30087001 | 30.11.2010 |
| PEAK | International (Austria, Benelux, Spain, Italy, Portugal, Switzerland, Denmark, Finland, Greece, Great Britain, Sweden) | | 762103 | 19.06.2011 |
| PEAK | Argentina | | 1886102 | 19.09.2012 |
| PEAK | Australia | | 866873 | 20.02.2011 |
| PEAK | Brazil | 823700895 | | |
| PEAK | Canada | | TMA606803 | 01.04.2019 |
| PEAK | Ireland | | 223368 | 19.02.2011 |
| PEAK | Mexico | | 815515 | 03.04.2011 |
| PEAK | USA | | 2679873 | 28.01.2013 |



RECORDED: 05/31/2007

TRADEMARK
REEL: 003552 FRAME: 0600

NEW INSTRUMENT

# Effects of the Pulsed Electron Avalanche Knife on Retinal Tissue

*Daniel. V. Palanker, PhD; Michael F. Marmor, MD; Andre Branco, MD; Philip Huie, MSc; Jason M. Miller, MSc; Steven R. Sanislo, MD; Alexander Vankov, PhD; Mark S. Blumenkranz, MD*

**Objectives:** To evaluate the precision of retinal tissue dissection by the pulsed electron avalanche knife (PEAK) and to assess possible toxic effects from this device.

**Methods:** To demonstrate precision of cutting, bovine retina (in vitro) and rabbit retina (in vivo) were incised with the PEAK. Samples were examined by scanning electron microscopy and histologic examination (light microscopy). To evaluate possible toxic effects in rabbit eyes, 30000 pulses were delivered into the vitreous 1 cm above the retina. Histologic examinations and electroretinography were performed at intervals up to 1 month after exposure.

**Results:** Cuts in postmortem bovine retina showed extremely sharp edges with no signs of thermal damage. Full-thickness cuts in living attached rabbit retina were similarly sharp and were typically less than 100 µm wide. No signs of retinal toxic effects were detected by histologic examination or electroretinography.

**Conclusions:** The PEAK is capable of precise cutting through retinal tissue, and there are no demonstrable retinal toxic effects from its use. The precision and tractionless nature of PEAK cutting offers advantages over mechanical tools and laser-based instrumentation. We believe this new device will prove useful in a variety of vitreoretinal surgical applications.

*Arch Ophthalmol. 2002;120:636-640*

*From the Department of Ophthalmology, School of Medicine (Drs Palanker, Marmor, Branco, Sanislo, and Blumenkranz and Messrs Huie and Miller) and W. W. Hansen Experimental Physics Laboratory (Drs Palanker and Vankov), Stanford University, Stanford, Calif. Stanford University is the owner of a patent covering the use of the electric plasma-mediated cutter. Should the Stanford University receive royalties or other financial remuneration in the future related to the patent, Dr Palanker may receive a share in accordance with the Stanford University Institutional Patent Policy and Procedures, which include royalty-sharing provisions. Drs Palanker and Blumenkrantz are consultants to Carl Zeiss, Inc, Jena, Germany.*

RECENTLY, OUR group developed a new type of surgical instrument for precise microdissection of tissue in liquid media. This device, called the pulsed electron avalanche knife (PEAK), uses electrical pulses rather than laser light for the generation of plasma microstreamers in physiological medium or in tissue.[1] Nanosecond pulses of high voltage (2-7 kV) applied to an intraocular microelectrode produce plasma in a conductive fluid, which is confined to the immediate vicinity (several tens of micrometers) of the instrument's tip (**Figure 1**). High temperatures associated with this process cause explosive evaporation of the surrounding liquid that results in ablation or dissection of the adjacent tissue. Because of the short duration of the pulse, dissection takes place with no thermal damage to the surrounding tissue; the cuts are purely mechanical and can be very well controlled.

Lasers that generate plasma have been used within the eye for a number of years without evidence of toxic effects beyond the mechanical effects, and neither glass nor tungsten (which form the PEAK microelectrode) is known to have a toxic effect on ocular tissue.[2] Nevertheless, free radicals produced by plasma in liquid,[3] UV light emitted by plasma,[4] and metal etched from the electrode tip could, in theory, have a toxic effect on tissue.

In this work, we demonstrate the precision of the PEAK in cutting of retinal tissue, both in vitro and in vivo, and evaluate whether there are any toxic effects from free radicals, UV light, or etched metal associated with application of the PEAK.

## RESULTS

### PRECISION OF CUTTING WITH THE PEAK

Cuts were made in bovine retina while the probe was held by hand and moved with a velocity of approximately 1 mm/s. Scanning electron microscopy (**Figure 2**) showed crisp cuts of about 50 µm in width. Some perforations from single PEAK pulses were seen at the edge of the cut. A histologic section of a similar cut (**Figure 3**) showed that the edges of the cut were remarkably abrupt and there were no signs of coagulation or cellular disruption beyond the edge.



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EXHIBIT
DePuy
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## MATERIALS AND METHODS

Ten bovine eyes were obtained from a local slaughterhouse 3 hours after death and packed on ice during delivery. Retinal dissection with the PEAK was performed through the vitreous after removal of cornea, lens, and iris with the use of 100-nanosecond pulses at 50 μJ with a repetition rate of 20 Hz. This energy level is near the minimum required to produce a full-thickness retinal cut.

Fifteen albino rabbits weighing 3.0 to 3.5 kg were used in accordance with the Association for Research in Vision and Ophthalmology Statement Regarding the Use of Animals in Ophthalmic and Vision Research. Before retinal cutting, a partial vitrectomy was performed via a 1-mm sclerotomy made 3 mm behind the limbus. The PEAK probe (shown diagrammatically in Figure 1) was inserted through the same sclerotomy, and 2 linear cuts of about 4 mm in length were made parallel to the medullary ray with the use of 100-nanosecond pulses of 17 μJ with a repetition rate of 10 Hz. This energy level was just sufficient to cut the full thickness of the retina without producing hemorrhage. The eyes were enucleated immediately thereafter and fixed in glutaraldehyde-paraformaldehyde fixative, postfixed in osmium tetroxide, and embedded in epoxy resin (Epon 812; Electron Microscopy Sciences, Fort Washington, Pa). One-micrometer sections were cut on an ultramicrotome and stained with toluidine blue for light microscopy.

For scanning electron microscopy, retina was fixed in glutaraldehyde-paraformaldehyde fixative (1.25%/1% in 0.2M sodium cacodylate buffer) at room temperature for 30 minutes. The tissue was then fixed for an additional 18 hours at 4°C, rinsed in buffer, and postfixed in osmium tetroxide. The tissue was washed with distilled water, dehydrated in a series of ethanols, transferred to absolute acetone, and critical point dried. The dried tissues were then mounted on stubs and plasma coated with gold.

To test for possible toxic effects from the PEAK probe, we applied the discharges into the vitreous of 10 rabbit eyes. To maximize concentration of the substances released during the procedure, no infusion and no irrigation were attached to the eye. Electroretinography (ERG) was performed on 5 rabbits before, and at intervals after, the procedure. For ERG recordings, the pupils were dilated and the eyes dark adapted for 20 minutes. A jet contact lens electrode was positioned on the cornea with a reference wire placed under the eyelid and a ground attached to the ear. The stimulus flashes at setting 1 were applied with a flash lamp (PS22; Grass Instruments Co, West Warwick, RI). The signal was amplified with a preamplifier (SR530; Stanford Research Systems Inc, Mountain View, Calif) and recorded on an oscilloscope (TDS 620B; Tektronix Inc, Irvine, Calif). In 5 other rabbits, we applied the same PEAK treatment and enucleated the eyes 4 and 14 days after surgery for histologic evaluation with light microscopy.

Light emission from the PEAK was measured with a large-area silicon photoreceiver (model 2031; New Focus Inc, San Jose, Calif).

To compare the rates of metal erosion from the PEAK with that of conventional diathermy, we applied the Wet-Field Hemostatic Eraser (Mentor Ophthalmic Inc, a division of Goldman and Shurtleff Inc, Randolf, Mass) powered by a Wet-Field Coagulator (Mentor Ophthalmic Inc) at settings typical for retinal applications (25/70 on the instrument's scale).

In all the surgical applications of the PEAK in this study, pulses of 100-nanosecond duration and negative polarity were applied to the central wire of the PEAK probe, while the coaxial needle served as a return electrode (see Figure 1).

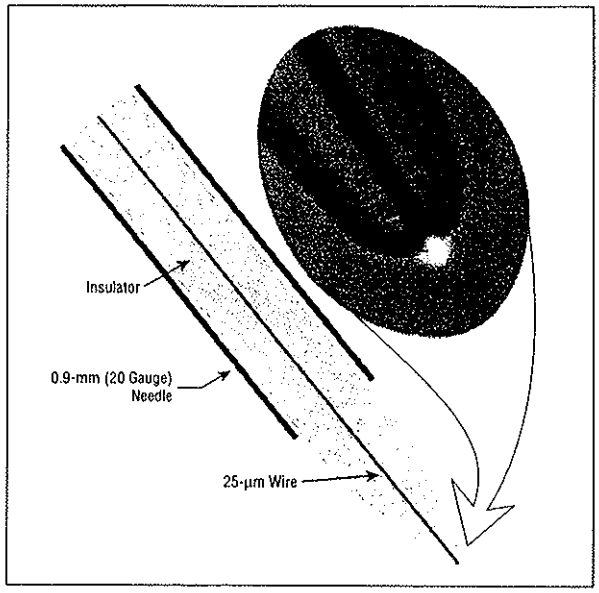


**Figure 1.** Diagram of the intraocular pulsed electron avalanche knife probe. Inset is a photograph of the plasma formed in saline in front of the probe.

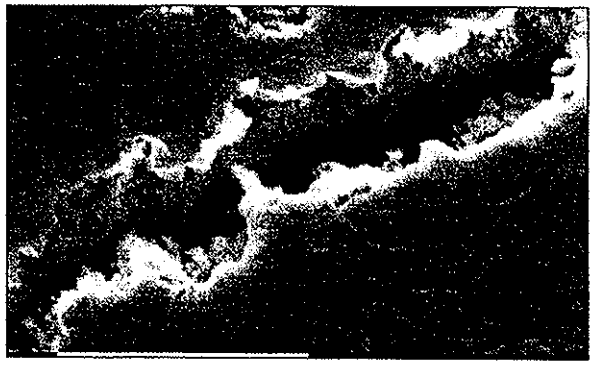

**Figure 2.** Scanning electron micrograph of the cut in bovine retina produced by pulses of 50 μJ at 20-Hz repetition rate. Bar (black as well as white lines) indicates 0.1 mm (original magnification ×503).

In living rabbit eyes, a single PEAK pulse produced a small crater from which tissue was removed to about half retinal thickness (**Figure 4**). By applying pulses at a repetition rate of 10 Hz and scanning across the retina at a rate of 0.5 to 1.0 mm/s, we made full-thickness cuts through retina without choroidal damage. There was no bleeding from cuts through avascular rabbit retina, but the major retinal vessels bled if cut, since the device does not coagulate tissue. Typical cuts, as shown in **Figure 5**, were remarkably clean and sharp. The width of the dissected zone was generally less than 100 μm, and neither retinal detachment nor signs of thermal damage were observed near the cut. If multiple pulses were delivered to one location, there



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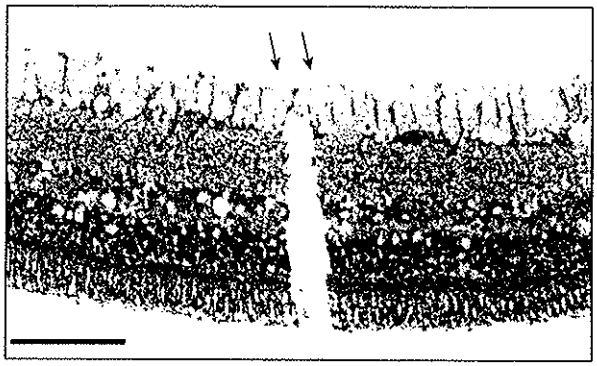

**Figure 3.** A full-depth cut in bovine retina resulting from application of 50-μJ pulses at 20 Hz and 1 mm/s scanning rate. The walls of the cut are remarkably sharp, and no signs of coagulation or other thermal damage are observed at the edges (arrows). Bar indicates 0.1 mm.

**Figure 4.** Center of the crater produced in the rabbit retina by a single shot of 17 μJ. The retina was detached from the retinal pigment epithelium and choroid during the sample preparation. Arrows show the edges of the cut; bar indicates 0.1 mm; photograph was taken with ×20 objective.

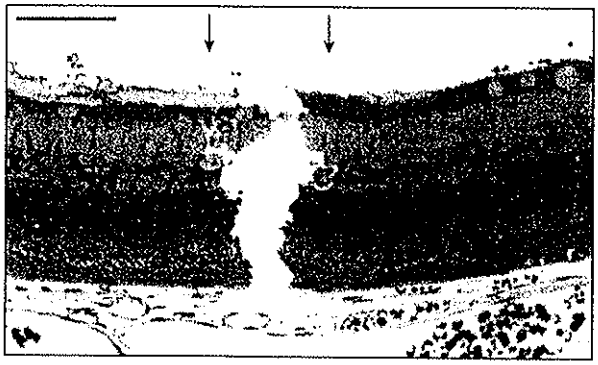

**Figure 5.** Histologic section of the full-thickness cut in rabbit retina produced at discharge energy of 17 μJ per pulse, repetition rate of 10 Hz, and scanning rate of about 1 mm/s. Arrows show the edges of the cut; bar indicates 0.1 mm; photograph was taken with ×20 objective.

was deeper penetration into the choroid, resulting in hemorrhage (**Figure 6**). Although PEAK effects at these settings were readily apparent histologically, they were nearly invisible to a surgeon using an operating microscope; the surgeon saw only very faint whitening of the retina along the line of scanning with the probe. In contrast, the cuts in detached retina and epiretinal membranes were readily observable, since these tissues are more opaque, and the gap was easily seen as they split apart during dissection.

## TOXIC EFFECTS FROM PEAK APPLICATIONS

To measure the erosion rate of the tungsten wire in a PEAK probe, we took micrographs of the electrode after progressively larger numbers of discharges (**Figure 7**). At pulse energy of 150 μJ, the erosion rate was on the order of 0.065 $\mu m^3$ per pulse. During "maximal" surgery, which we estimate might involve 10 minutes of cutting time and $3 \times 10^4$ pulses, the total eroded volume would be on the order of $2 \times 10^3$ $\mu m^3$ (equivalent to 0.04 μg or 0.2 nmol).

**Figure 6.** Histologic section of the same cut at the site of choroidal bleeding. Note the sharp edges of the cut (arrows) and lack of retinal detachment and of thermal damage at the edges. Bar indicates 0.1 mm; photograph was taken with ×20 objective.

For comparison, we measured the amount of metal released by a standard wet-field diathermy probe in typical operational conditions. As can be seen in **Figure 8**, about $3 \times 10^5$ $\mu m^3$ of iron was removed during 100 seconds of application. The total duration of coagulation treatment in typical vitreoretinal surgery is less than 20 seconds (with pulses of 1-3 seconds in duration), which would correspond to $6 \times 10^4$ $\mu m^3$ (0.5 μg, 8 nmol) of iron released into vitreous during a coagulation-intensive operation.

To directly evaluate possible toxic effects of the PEAK probe to retina, we applied $3 \times 10^4$ pulses of 180 μJ in 5 rabbit eyes. The energy was delivered into vitreous toward the posterior pole about 1 cm from the retina, and the eyes were not perfused to maximize possible toxic effects. Preoperatively and at 7, 11, and 30 days after the operation, ERG was performed. The results from all 5 animals were essentially identical and showed no influence of the procedure on the ERG (**Figure 9**).

Five additional animals were exposed to the same procedure and were killed 4 and 14 days after the treatment. Light microscopy of histologic sections showed no retinal changes in the eye exposed to the PEAK compared with the control eye.

## COMMENT

The PEAK makes cuts through bovine and rabbit retina that are remarkably sharp, with no evidence of cellular



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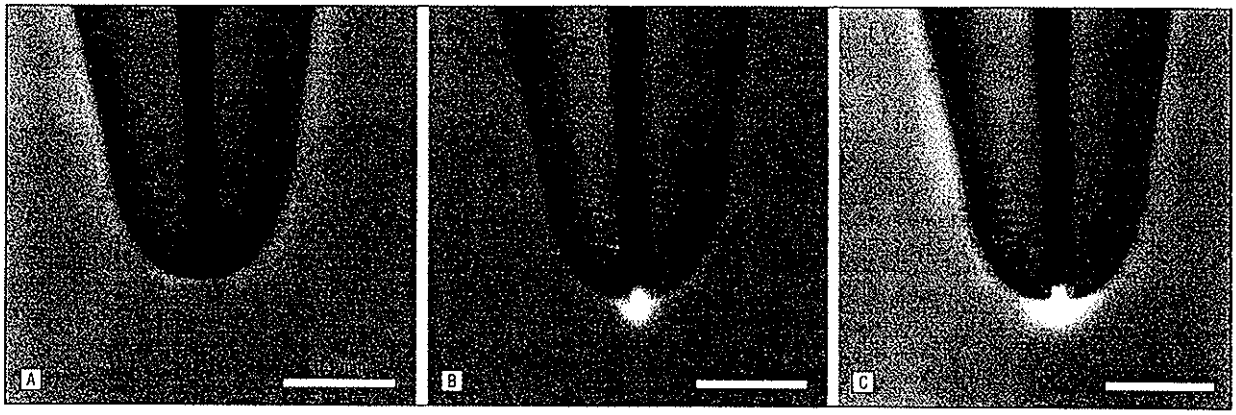


**Figure 7.** Pulsed electron avalanche knife probe photographed on inverted microscope via ×20 objective during the treatment. A, Probe before the irradiation. B, Erosion after 50000 pulses at 150 µJ per pulse. Bright plasma streamer is seen in front of the tip. C, Erosion after 106000 pulses. Plasma originates at the surface of metal deeper inside the probe; 13 µm of 25-µm-thick tungsten wire was etched.

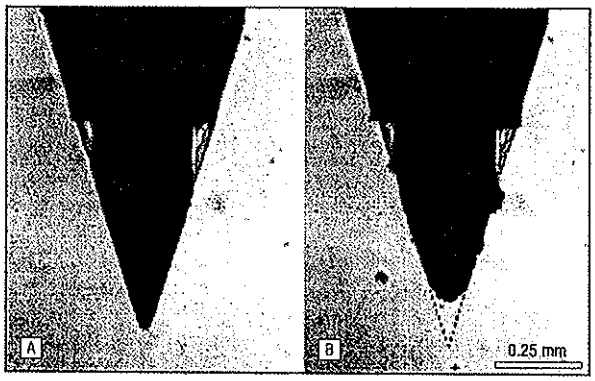


**Figure 8.** Diathermy probe after 20 seconds (A) and 100 seconds (B) of treatment in isotonic sodium chloride solution. Photograph was taken with ×10 objective; dashed lines schematically indicate the initial shape of the tip.

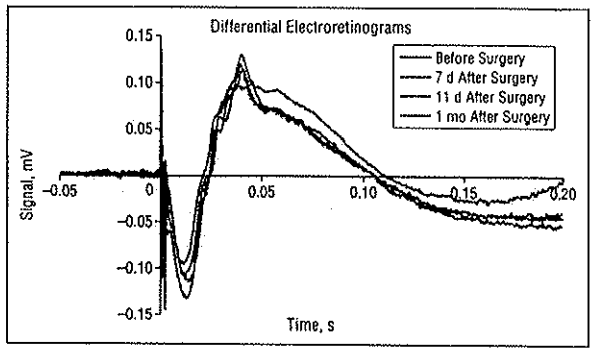


**Figure 9.** Electroretinographic measurements before and after (7, 11, and 30 days) treatment of the rabbit eye with 30000 pulses of 180 µJ. The results from the other 4 animals were essentially identical.

damage at distances beyond the first layer of cells adjacent to the edge. Such cutting resembles cracking rather than ablation of tissue, since very little material seems to be ejected from the application site. The cuts are so clean, in fact, that in attached retina they are nearly invisible to a surgeon using an operating microscope. For this reason it will be important to perform further studies to define the proper and safe pulse energies for different applications on the retina. Visibility of cuts is less of a problem with detached retina and epiretinal membranes, since the cuts are readily observable in these more opaque tissues, and because these tissues tend to spread apart during dissection (leaving a gap that is easily observed on a dark background). Longer-term studies are needed to assess whether there is any injury to cells at the margins of the PEAK cuts that was not visible in tissue enucleated immediately after surgery. Our present experiments, which were designed to show only the precision of cutting, did not look beyond the immediate effects of the surgery.

Since histologic examination of the cut retina shows no signs of coagulation effects, the faint whitening of the retinal surface that we observed during cutting of the attached retina may be a result of axoplasmic flow abnormalities from damage to nerve fiber layer in the cut area. It should be emphasized that, since energy deposition is localized at the end of the probe, the instrument cuts most efficiently if it is held close to the tissue (within 100 µm). Cutting width and depth are highly reproducible with a fixed position of the probe. However, reproducibility of cutting in vivo, especially on attached retina, will be influenced by hand control and the fact that natural tremor of a human hand itself is on the order of 100 µm (or more). Pushing the probe into attached retina would eliminate this problem, but it must be avoided to prevent mechanical damage. On the other hand, on detached retina and epiretinal membranes, higher energy can be applied and the probe can safely touch the tissue to ensure a close contact. As a result, clinical cutting of detached retina and epiretinal membranes is more reproducible than cutting of attached retina.

Advantage of the PEAK as compared with scissors or blades is mainly in the tractionless nature of its cutting. Erbium:YAG[5,6] and argon fluoride excimer lasers[7,8] have also been applied for tractionless vitreoretinal cutting, but these devices did not gain widespread acceptance in practice mostly because of the high cost, large size, and somewhat rigid fibers. The PEAK is a much smaller and less expensive device, with a light handpiece and very flexible cable. In addition, PEAK probes can be bent at any angle without losing cutting efficiency.

The availability of a precise microsurgical tool capable of producing microscopic cuts of controlled width



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and depth without traction should facilitate many aspects of vitreoretinal surgery. The PEAK will be useful in the performance of the circumferential and radial retinotomies and in the dissection of complex epiretinal and fibrovascular membranes. Its value will be particularly evident in eyes where excessive traction or pressure could cause collateral damage, such as those with atrophic underlying retina susceptible to tractional tears, and with membranes adjacent to blood vessels or overlying detached retina. In addition, this tool may be applied to posterior and anterior capsulotomy and other ocular surgical procedures.

The generation of plasma in liquids could, in theory, be toxic to tissue on the basis of the formation of free radicals, the generation of UV light, and the erosion of a metal electrode. To calculate the maximal exposure that is likely to occur, typical applications of PEAK require discharge energies between 50 and 150 μJ, at a pulse repetition rate of about 30 Hz, and the total number of pulses does not exceed 5000. An exceedingly large exposure, which we shall use for the sake of discussion, would be 10 minutes of total application time at 100 μJ and 50 Hz ($3 \times 10^4$ pulses). With this exposure, the total deposited energy is 3 J, and the average cumulative energy density in the posterior pole of a human eye would be about 0.75 J/mL.

Free radicals (·H and·OH) can be produced directly by plasma-mediated discharge, but their lifetime in water is only about 70 nanoseconds, during which they can only diffuse about 20 nm[3]. Thus, free radicals will have no effect beyond the zone of mechanical damage (which may vary between a few and a few hundred micrometers). The recombination of 2 OH radicals can produce hydrogen peroxide ($H_2O_2$), which is a strong and long-living oxidizer. However, it has been shown[3] that the threshold energy density to produce detectable $H_2O_2$ toxicity is about 500 J/mL, which is 3 orders of magnitude greater than would occur with the PEAK.

Our measurements of light emission by plasma indicate that UV toxicity is also unlikely to occur during PEAK surgery, since the total dose of photic irradiation during a PEAK-intensive operation (involving $3 \times 10^4$ pulses) would be 6 orders of magnitude lower than the established danger levels for retinal exposure to UV light (5 J/cm²).[9] One possible source of PEAK toxicity involves deposition of eroded metal from the microelectrode. We compared the amount of metal etched from the PEAK probe in typical operational conditions with that released by a standard wet-field diathermy probe. Diathermy electrodes are made of steel and erode during electrosurgery, producing iron ions in various oxidation states. Iron metal and iron compounds have important toxic actions on the eye. These have been studied for more than a century and have been the subject of an extensive body of literature.[10,11] According to our measurements, 0.5 μg (or 8 nmol) of steel is eroded during 20 seconds of application of diathermy at typical vitreoretinal settings, which is about 25% of the threshold amount of iron shown to be toxic if injected into the vitreous.[11] However, eyes are perfused during retinal surgery, which should reduce the toxic load by a considerable margin (a factor of 2 to 10 on the basis of typical perfusion rates and duration). To our knowledge, no observations of retinal (or other) toxic effects from diathermy probes have been reported so far, even though some operations may have involved even longer exposures.

The central electrode in the PEAK probe is made of tungsten. No toxic effect from tungsten metal has been found in experiments with intravitreal implants in rabbit eyes.[10,12] During typical surgery involving $3 \times 10^4$ pulses, 0.04 μg (or 0.2 nmol) of tungsten will be eroded. This amount is only 2.5% of the number of moles of iron left in the eye after application of diathermy for 20 seconds. Since 8 nmol of rather toxic metallic iron released by diathermy does not seem to have any adverse effects on ocular tissues during surgery, the much smaller amount (0.2 nmol) of nontoxic tungsten is probably safe. These estimations have also been supported by the lack of adverse effects of PEAK treatments on the ERG and on retinal histologic findings in our experiments.

We conclude that the PEAK is capable of precise cutting through retinal tissue, and that there are no demonstrable retinal toxic effects from the use of this device. The precision and tractionless nature of PEAK cutting offers potential advantages over mechanical tools, as well as over laser-based cutting instrumentation. We believe this new device could be useful in a variety of vitreoretinal surgical applications.

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*This study was supported by grant 1 R01 EY12888-01A1 from the National Eye Institute, Bethesda, Md, and by Carl Zeiss Inc, Jena, Germany.*

*We thank Rupa Dalal for her help with sample preparations.*

*Corresponding author and reprints: Daniel V. Palanker, PhD, W. W. Hansen Experimental Physics Laboratory, Stanford University, Stanford, CA 94305-4085 (e-mail: palanker@stanford.edu).*

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PEAK™
surgical

# THE PULSE OF PRECISION.

THE PRECISION OF A SCALPEL AND THE BLEEDING CONTROL OF TRADITIONAL ELECTROSURGERY WITHOUT THE EXTENSIVE COLLATERAL TISSUE DAMAGE.

EXHIBIT
Dc PU4
5

PENGAD 800-631-6989

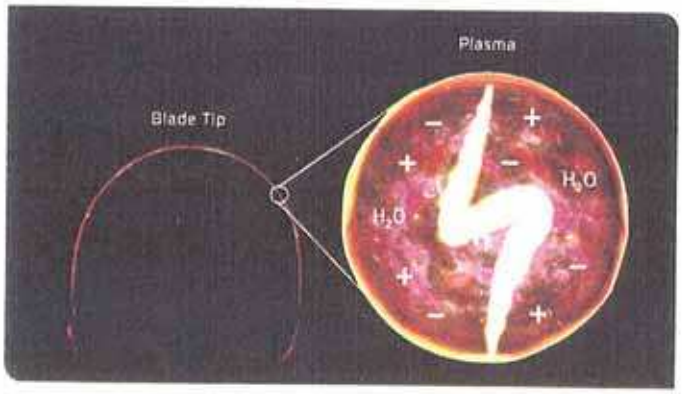
The company's flagship product, the PEAK® Surgery System, balances a unique radiofrequency power source—the PULSAR® Generator—with a series of disposable devices—the PEAK PlasmaBlades™—to address a broad range of surgical applications.

The PEAK Surgery System consists of the PULSAR Generator, optional PULSAR Wireless Footswitch, PULSAR Cart, and PEAK PlasmaBlades

## PEAK Technology Overview

The PEAK Surgery System strikes a unique balance between precision cutting and bleeding control. The System is composed of a novel **Pulsed Plasma Technology** along with a proprietary **TPS (Thermal Protection Shield) Insulation Technology** which comes together to enable a surgeon to:

- Cut precisely through any type of tissue—from skin to fat to muscle
- Significantly reduce collateral thermal damage—leaving healthy tissue to heal quickly
- Fine tune the amount of bleeding control to the target tissue—effectively minimizing excess thermal damage
- Utilizes about ½ the amount of energy (watts) than traditional electrosurgery technologies
- Operate at 50% lower temperatures than traditional electrosurgery technologies
- Maintain superior performance in both a wet and dry field

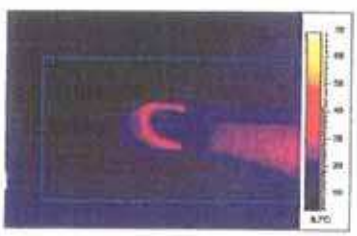



Plasma discharge along the exposed active electrode edge. Device tip is 99.5% insulated

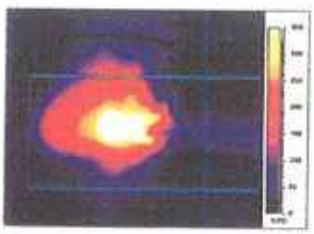
Plasma acts as a conductive medium to allow energy to interact with the target tissue at much lower power levels

## What is plasma?

Plasma is an electrically conductive cloud created when the RF energy contacts tissue. It is comprised of water vapor and charged particles called ions (positive and negative charges) from the breakdown of the tissue. This conductive cloud or "plasma" allows the energy to cross at much lower levels. This use of lower energy via plasma leads to lower operating temperatures and less thermal damage.



PEAK Avg temp 40 - 50 C



Electrosurgery Avg temp 250 - 350 C

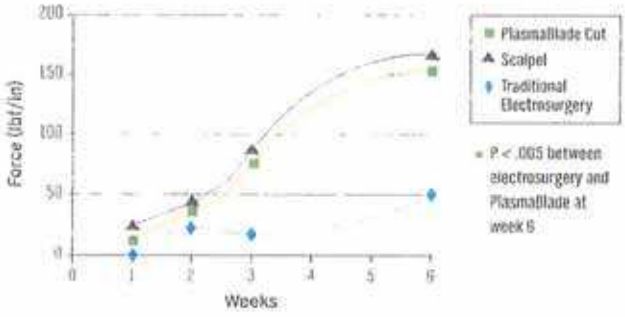
## PlasmaBlade Demonstrates Faster, Stronger Healing in Preclinical Studies

In preclinical study data presented at the **American College of Surgeons Annual Clinical Meeting** in October, 2007,[1] the PlasmaBlade showed:

- 60% less bleeding than a scalpel, with no increase in collateral damage
- 75% less thermal damage than traditional electrosurgery
- Positive wound healing profile similar to the cold scalpel
- Stronger surgical incision wound healing
- Reduced inflammatory reaction
- Reduced scarring
- 66% less force needed to cut tissue
- Increased cutting speed and precision
- Little to no surgical smoke in the Cut mode

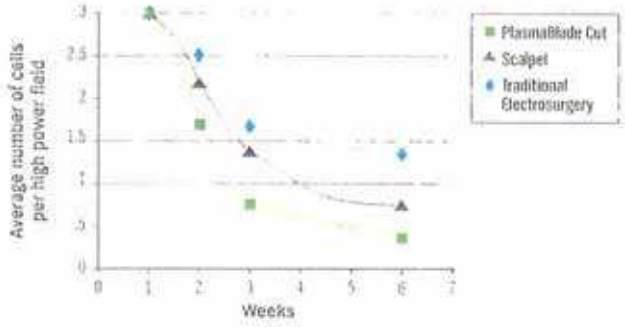
### Skin Healing Study

Wound Pull Strength



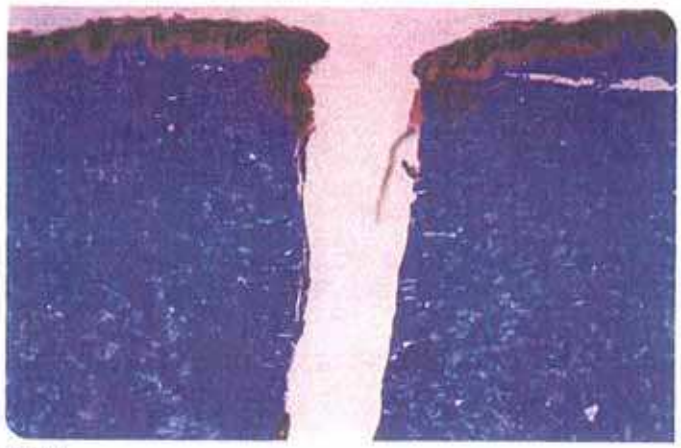

### Skin Healing Study

Inflammatory Response

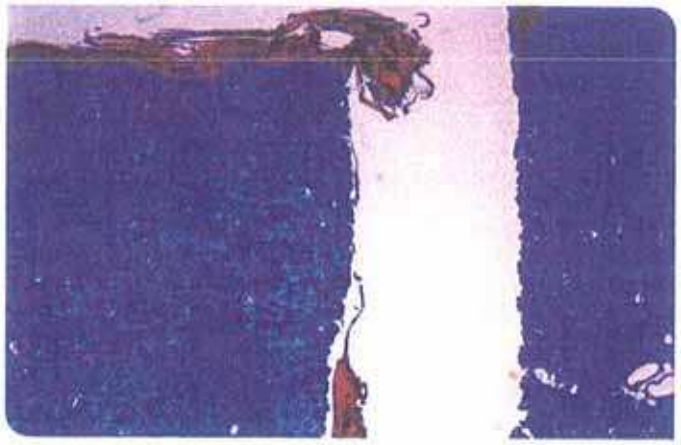



## The Fascia Healing Study[2] showed the PlasmaBlade to have:

- Similar incision healing to the scalpel
- Significantly stronger incision healing than traditional electrosurgery at week 1
- Reduced inflammation compared to traditional electrosurgery



Scalpel



PlasmaBlade

Traditional Electrosurgery

## The PEAK PlasmaBlade...

# Precision. Bleeding control. Minimal thermal damage.

[1] SA Loh, GA Carlson, E Hoang, KL Duncan, GC Gurtner. Comparative healing of surgical incisions created by standard electrosurgery, PEAK PlasmaBlade, and standard scalpel blade. J Am Coll Surg 2007 (Suppl);207:S54.
[2] Data on file at PEAK Surgical, Inc.

PEAK003

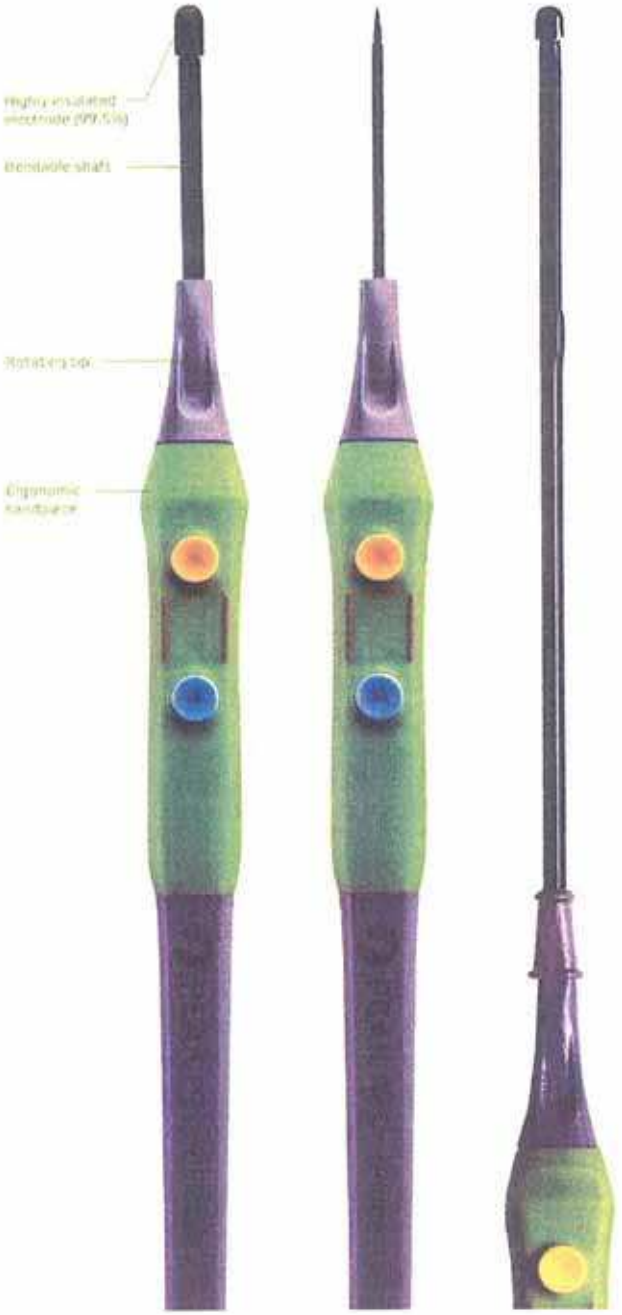
## The PULSAR Generator features:

- "Plug-n-play" user-friendly interface
- Simple 1 to 10 numeric set points
- Dual output control – Power & Voltage
- 460 KHz to 4 MHz operating frequency
- 350 to 4500 Volts
- 0.5 to 50 Watts
- Tissue impedance feedback and auto-adjust
- Patient Return Electrode (pad) connection sensing

| CUT | SET POINT | COAG |
|---|---|---|
| · 60% less bleeding than scalpel<br>· Equivalent residual tissue damage to the scalpel's mechanical crush zone<br>· 75 to 90% less thermal damage than traditional electrosurgery | 1<br>2<br>3<br>4<br>5 | · Equivalent hemostasis to traditional electrosurgery<br>· 50% less thermal damage compared to traditional electrosurgery |
| · Equivalent simultaneous hemostasis to traditional electrosurgery<br>· 50% less thermal damage | 6<br>7<br>8<br>9<br>10 | |

| PRODUCT | CATALOGUE NUMBER | DESCRIPTION |
|---|---|---|
| PEAK PlasmaBlade 4.0 | PS200-040 | 4.0mm wide spatula tip |
| PEAK PlasmaBlade Needle | PS200-001 | Ultra-fine needle point tip |
| PEAK PlasmaBlade EXT | PS215-040 | 15cm extended shaft, 4.0mm spatula tip |
| PULSAR Generator | PS100-100 | |
| PULSAR Wireless Footswitch | PS100-200 | |
| PULSAR Cart | PS100-300 | |

## The PEAK PlasmaBlade Family




PlasmaBlade 4.0 | PlasmaBlade Needle | PlasmaBlade EXT

For more information or to schedule a demonstration, please contact
PEAK Surgical Customer Service at 888-792-PEAK or visit www.peaksurgical.com

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LBL-00012 Rev. D

PEAK004

# PRECISE Clinical Outcomes Study

Howard Rosenberg, MD[1]; Joshua G. Vose MD[2]; Geoffrey Gurtner, MD[3]
*[1]Accent on Aesthetics Plastic Surgery, Mountain View CA; [2]PEAK Surgical, Inc. Palo Alto CA; [3]Department of Plastic & Reconstructive Surgery, Stanford University School of Medicine*

**Introduction:** Building on preclinical results presented at the 2007 American College of Surgeons meeting (New Orleans, LA) demonstrating that incisions made with the PEAK PlasmaBlade™ result in stronger healed wound strength, and decreased inflammation compared to traditional electrosurgery (Bovie) with equivalent skin scarring to scalpel, PEAK Surgical launched the PRECISE clinical study series examining patient outcomes compared to the standard of care.

**Thermal Injury Profile**

**Scalpel**

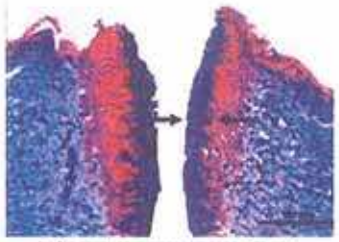
**Study Design:** Prospective, randomized, single-blind controlled study of 20 patients undergoing abdominoplasty with the PlasmaBlade or the standard of care, scalpel and traditional electrosurgery.

Patients submitted to three sets of comparison incisions with scalpel, PlasmaBlade and ES prior to abdominoplasty. Sets were placed at 6 and 3 weeks prior to surgery and again on the day of abdominoplasty.

**PlasmaBlade Cut**

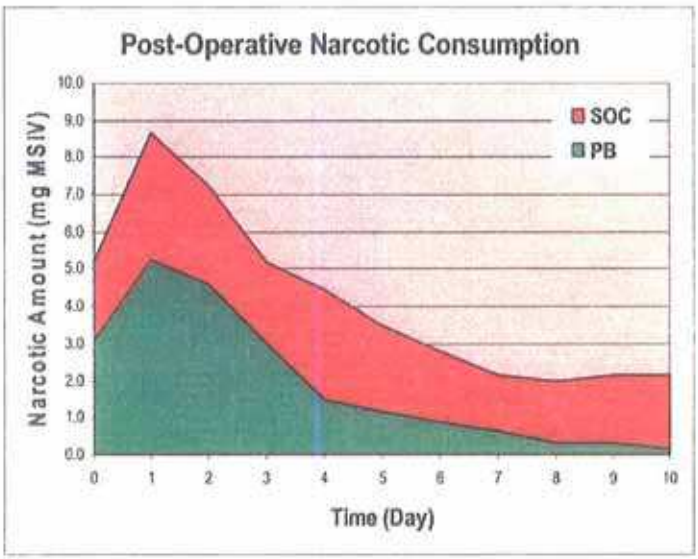
**Primary Endpoints:**

- Wound histology & healed strength
- Narcotic consumption
- Drain output
- Operative time
- Drop in Hemoglobin
- Return to activity level and diet volume



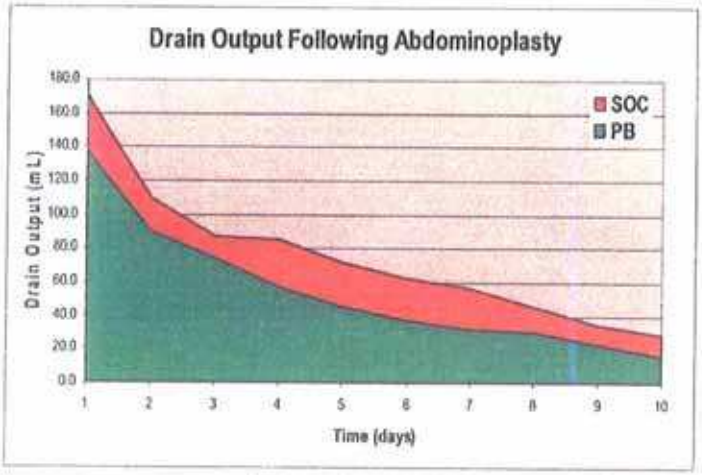
**Electrosurgery Cut**

**Narcotic Consumption:**

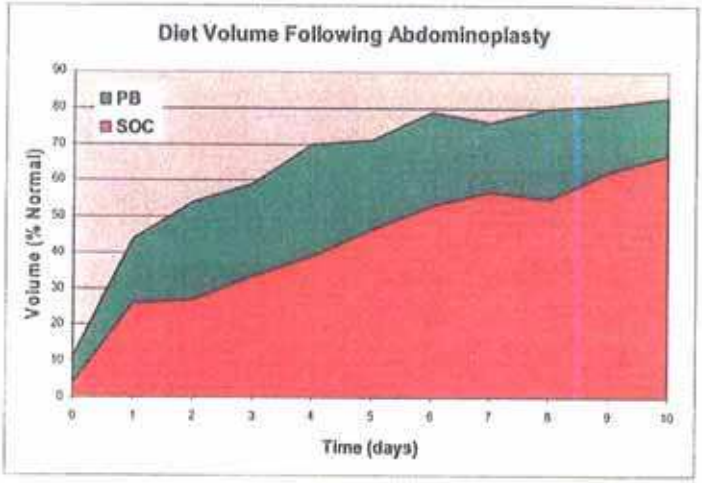


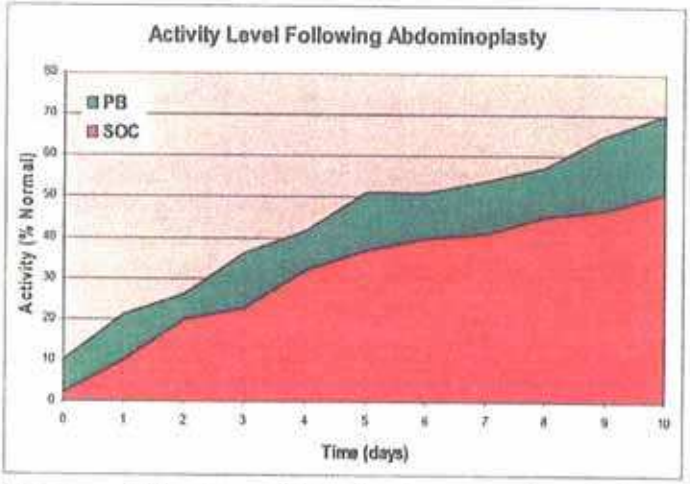

- PlasmaBlade (PB) patients required 37% less narcotics through discharge compared to standard of care (SOC) patients ($p < 0.005$)
- PlasmaBlade patients consumed 49% less narcotics through the 10 day post-operative period ($p < 0.05$)

# PRECISE Clinical Outcomes Study




- PlasmaBlade patients produced 31% less drain output compared to the standard of care (SOC) group ($p < 0.05$)
- Two seromas required drainage in the standard of care study group
- No seromas detected in the PlasmaBlade study group




## Compared to the Standard of Care…PlasmaBlade patients demonstrated:

- 34% improved reported diet volume over 10 post-operative days ($p < 0.05$)
- 26% improved reported activity level over 10 post-operative days ($p = 0.09$)
- 57% less drop in Hemoglobin ($1.6 \pm 0.7$g vs. $0.7 \pm 0.2$g, $p = 0.07$)
- Equivalent skin scarring compared to scalpel ($p < 0.05$)
- Equivalent operative time ($p < 0.05$)
- 75% less thermal injury depth in adjacent tissue ($p < 0.005$)
- 65% and 42% stronger healed wound strength at 3 and 6 weeks ($p < 0.005$)

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Data on file at PEAK Surgical, Inc., and submitted to American College of Surgeons 2009 Annual Meeting

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LBL-00056 Rev. C

# PEAK PlasmaBlade and Pulsed Plasma Technology: A Summary of Preclinical Results

*Jonathan S. Berek, MD, MMS; Paul D. Blumenthal, MD; Edward I. Chang, MD; Mark S. DeFrancesco, MD, MBA; Geoffrey C. Gurtner, MD; Eric Huang, MD, PhD; Kai Ihnken, MD; Mary T. Jacobson, MD; Gregory S. Keller, MD; Teresa Knight, MD; Shang A. Loh, MD; Charlene E. Reimnitz, MD; Robert C. Robbins, MD; Howard L. Rosenberg, MD; Steven M Schwartz, MD; Lawrence M. Shuer, MD; Bryant A. Toth, MD; Thomas M. Krummel, MD*

| TITLE | MODEL | SUMMARY | PRESENTED |
|---|---|---|---|
| Comparative healing of surgical incisions created by standard electrosurgery, PEAK PlasmaBlade, and standard scalpel blade | *In vivo* porcine skin | PlasmaBlade showed:<br>· 75% less thermal damage vs. ES<br>· 66% less scarring vs. ES<br>· 63% greater wound strength vs. ES<br>· 60% less bleeding vs. scalpel<br>· Less inflammation vs. ES | Podium, The American College of Surgeons Annual Meeting (2007) New Orleans, LA |
| Evaluation of PEAK PlasmaBlade for obstetric and gynecologic surgery vs. traditional electrosurgery | *Ex vivo* human abdominal skin and *in vivo* porcine skin | PlasmaBlade caused significantly less thermal damage vs.:<br>· Uncoated electrosurgery tip<br>· PFTE (Teflon) coated electrosurgery tip<br>· Epitome® Scalpel (fine wire, ceramic) | Poster, The American College of Obstetrics and Gynecology Annual Meeting (2008) New Orleans, LA |
| Preservation of tissue integrity and decreased tissue damage with PEAK PlasmaBlade | *In vivo* porcine skin | Histological scoring for injury showed no difference between PlasmaBlade and scalpel; both were significantly less than the ES group. Scar formation was similar between scalpel and PlasmaBlade, but significantly less than ES. | Podium, The Plastic Surgery Research Council Annual Meeting (2008) Springfield, IL |
| Evaluation of the PEAK PlasmaBlade in Neurosurgery Applications Compared to Standard Electrosurgical Tools and Standard Scalpel Blade | *In vivo* bovine brain | Histological evaluation of the brain tissue showed that PlasmaBlade cuts and spot coagulation produced little collateral damage compared to cuts made with an electrosurgical needle, or coagulation from bipolar cautery. | Poster, Congress of Neurological Surgeons Annual Meeting (2007) San Diego, CA |
| Evaluation of PEAK PlasmaBlade Needle for Plastic and Reconstructive Surgery Compared to Standard Electrosurgery | *In vivo* porcine skin, bovine cartilage, and *ex vivo* human abdominal skin | Histological evaluation of human skin, porcine skin, and cartilage samples showed that the PlasmaBlade Needle cuts produced minimal collateral damage (about 50% of the thermal damage demonstrated by the Colorado Needle). In the porcine skin cuts, bleeding was significantly reduced in the PlasmaBlade Needle versus scalpel wounds while bleeding was similar to cuts produced with the Colorado Needle. | Poster, American Academy of Facial Plastic and Reconstructive Surgery Annual Meeting (2008) Chicago, IL |

## INTRODUCTION

The PEAK PlasmaBlade™ tissue dissection devices are a family of new surgical instruments that use PEAK Surgical's proprietary Pulsed Plasma Technology™ for soft-tissue cutting and coagulation with minimal thermal injury. These PlasmaBlades work in conjunction with the PULSAR™ Generator to create the PEAK Surgery System (Fig 1).

Working with a number of surgeon investigators, PEAK Surgical has conducted preclinical studies of the PEAK Surgery System in a variety of *in vivo* and *ex vivo* animal models. Overall, these studies have demonstrated that the PEAK Surgery System has a wide range of capabilities. The system can cut with the same precision as a scalpel with minimal to no thermal damage at the low settings, but also can be dialed up to deliver hemostasis capability equivalent to conventional electrosurgical technology. This paper presents a summary of the experimental approaches, results and conclusions from the preclinical studies performed using the PEAK Surgery System. The key features and benefits determined from these studies are summarized in Table 1.

*Figure 1.*

| CUT | SET POINT | COAG |
|---|---|---|
| · 60% less bleeding than a scalpel<br>· Equivalent residual tissue damage to the scalpel's mechanical crush zone<br>· 75 to 90% less thermal damage than traditional electrosurgery | 1<br>2<br>3<br>4<br>5 | · Equivalent hemostasis to traditional electrosurgery<br>· 50% less thermal damage compared to traditional electrosurgery |
| · Equivalent simultaneous hemostasis to traditional electrosurgery<br>· 50% less thermal damage | 6<br>7<br>8<br>9<br>10 | |

*TABLE 1: Setting-dependent properties of the PEAK Surgery System*

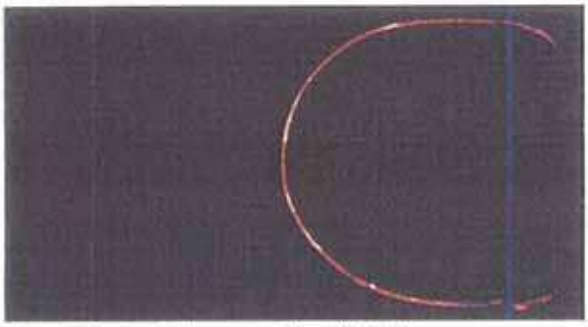
## RESULTS

A wide range of outcomes were evaluated in a variety of studies and included system operating temperature, thermal effect, bleeding control, cutting ease and smoke generation during acute use. Chronic studies evaluated outcomes such as wound scarring, wound strength and inflammatory response. Studies were performed on a variety of tissues including skin, fat, fascia, and muscle. Highlights of the results from these various studies are discussed in more detail below.

### Operating Temperature and Corresponding Thermal Effect:

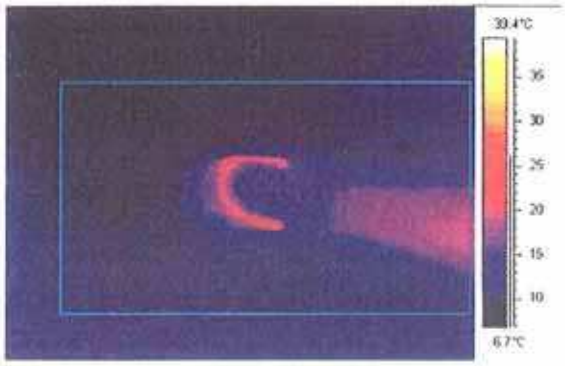
Results of preclinical research have shown that, due to the highly insulated electrode configuration (Fig. 2) and the use of pulsed electrical waveforms, the PEAK Surgery System uses about one-half the amount of energy (watts) used by traditional electrosurgical technology to achieve similar cutting and coagulation results.

This reduction in energy used has been found to translate into operating temperatures that are about one-half those of traditional electrosurgical technologies (Fig. 3), with a corresponding reduction in heat transfer and an approximately 50 to 90 percent reduction in the depth of thermal damage in adjacent tissues (Fig. 4).

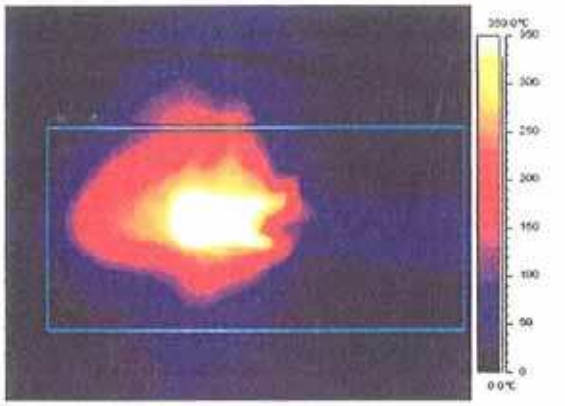


*Plasma discharge along the exposed edge of the blade*

*Figure 2.*



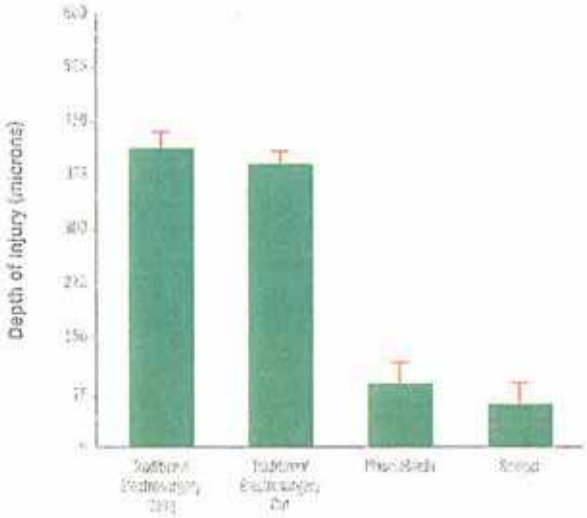

*PEAK Avg temp 40 - 50 C*




*Electrosurgery Avg temp 250 - 350 C*

*Figure 3.*

### Acute Tissue Injury




- PlasmaBlade versus scalpel showed no significant difference in damage.

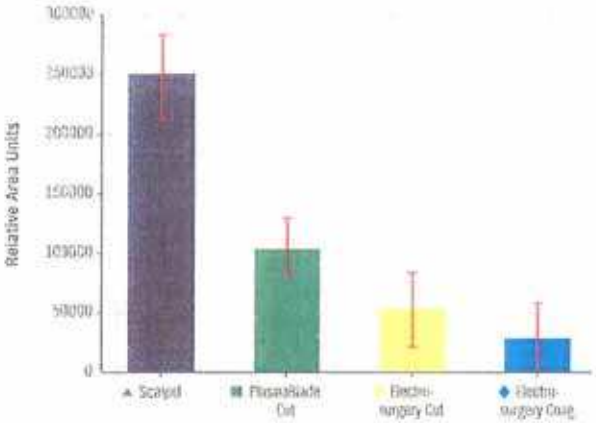
*Figure 4.*

## Bleeding Control:

Even though the PEAK Surgery System causes significantly reduced levels of thermal damage compared to traditional electrosurgery, significant bleeding control is still built into the technology. Preclinical work has shown that incisions created while on the "low cut" settings bled 60 percent less than with a scalpel, while on the higher cut settings and in coagulation mode, the PEAK Surgery System achieved hemostasis equivalent to traditional electrosurgery but with half the amount of thermal injury (Fig. 5).

### Bleeding Evaluation

Bleeding Following Incision for 60 Seconds




* A 60% reduction in bleeding was observed with PlasmaBlade versus scalpel (p=0.001)

*Figure 5.*

### Acute Thermal Damage Histology

*porcine skin*

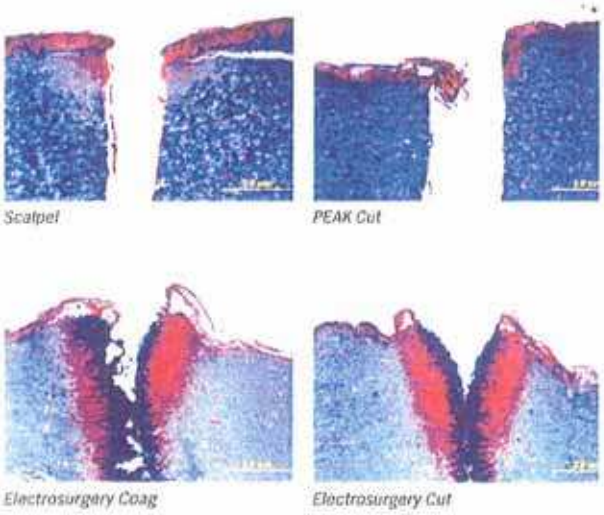
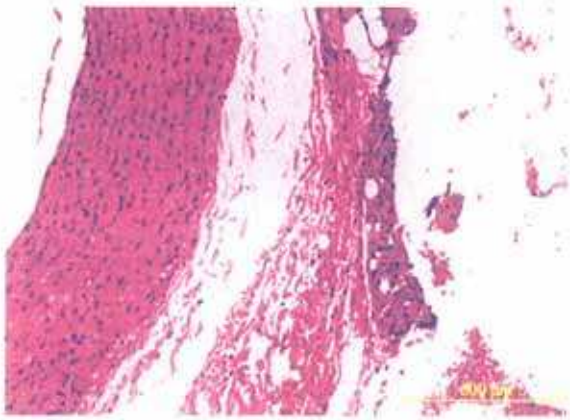



*Figure 6.*

### Histological Evaluation

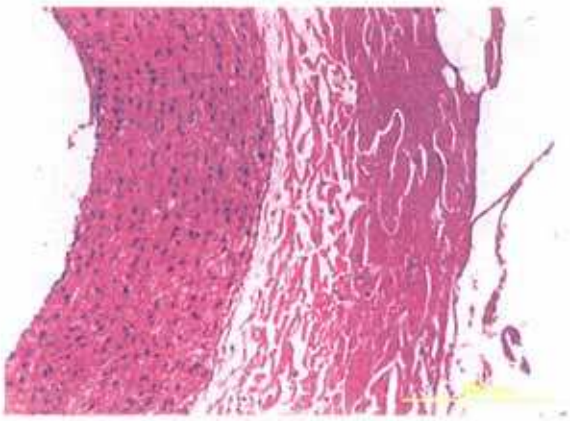
*porcine thoracic artery*

**PEAK PlasmaBlade 10X**



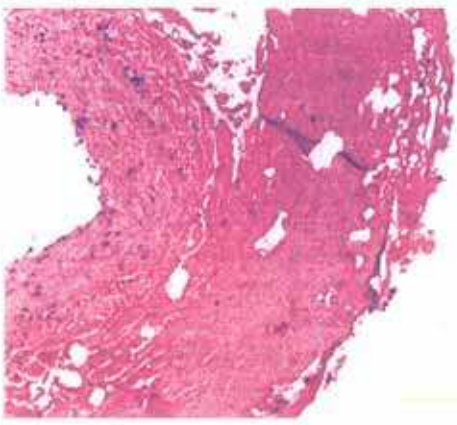
*Edge of PlasmaBlade cut is clean, thermal damage 50-125 um*

**Harmonic Scalpel® 10X**



*Zone of damage 100-300 um*

**Electrosurgery 10X**



*Zone of thermal necrosis 250-500 um*

*Figure 7.*

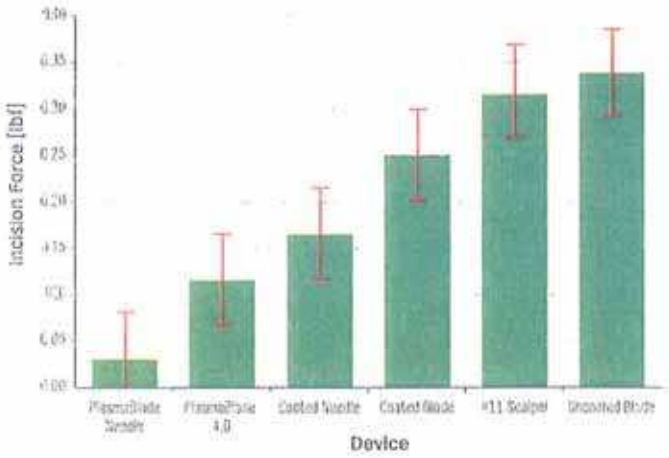
## Ease of Cutting:

The PEAK Surgery System has been shown to cut easily and smoothly, requiring just one-quarter of the force needed for cutting tissue with a scalpel and one-half that needed for cutting with traditional electrosurgical technologies used in "cut" mode (Fig. 8). The PlasmaBlade has also been shown to operate in both wet and dry fields, allowing a surgeon to maintain superior cutting performance even through a bloody surgical field (data on file at PEAK Surgical).

## Smoke Generation:

Another important preclinical finding is that the PEAK Surgery System generates significantly less surgical smoke than traditional electrosurgery when used in cut mode (settings 1 through 8, data on file at PEAK Surgical). As discussed in the literature, surgical smoke is a potential hazard to the health of both surgical staff and patients, and numerous agencies have called for measures to reduce surgical smoke exposure in the operating room (Occupational Safety and Health Administration, 2008; Barrett, 2003; Alp, 2006; Bigony, 2007).

### Incision Forces: Energized Devices in Cut Mode Vs. Scalpel




* Note: The PlasmaBlades utilized PULSAR set point Cut 4. The electrosurgery electrodes used Cut 25 watts.

*Figure 8.*

## Wound Healing:

Two chronic studies were performed to evaluate wound healing up to six weeks. One study was performed in a porcine skin model, and one in a rat fascia model. Both studies showed that wounds created by the PEAK Surgery System healed virtually identically to scalpel wounds, and that reduced thermal injury from the PEAK Surgery System resulted in a reduction in inflammatory response and an increase in wound strength.

The porcine skin study found that the PlasmaBlade was comparable to a scalpel in wound healing profile, with a 75 percent reduction in acute thermal damage and significantly reduced inflammatory response (as measured by inflammatory cell infiltration). Meanwhile, the burst strength of wounds created by the PEAK Surgery System was essentially identical to those created by a scalpel and were three times as strong as the electrosurgery wounds at six weeks ($p<0.005$) (Figs. 9,10).

In the fascia study, burst strength at one week in wounds created by the PEAK Surgery System was essentially equivalent to scalpel wounds, and was significantly better than traditional electrosurgery. Inflammation was also reduced with the PlasmaBlade relative to traditional electrosurgery (Figs. 11,12).

### Skin Healing Study

Wound Pull Strength

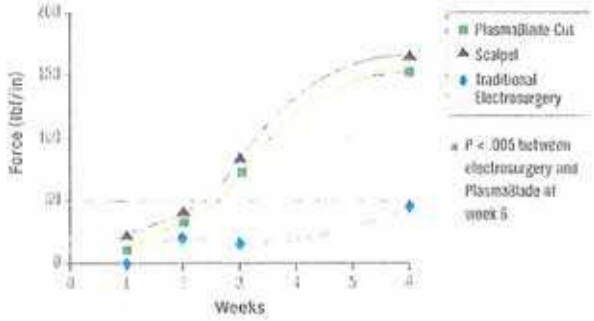



*Figure 9.*

### Fascia Healing Study

Wound Pull Strength

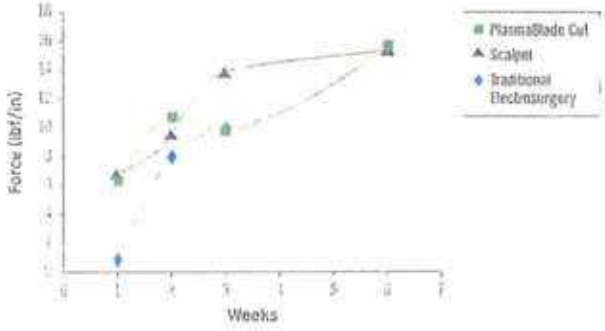
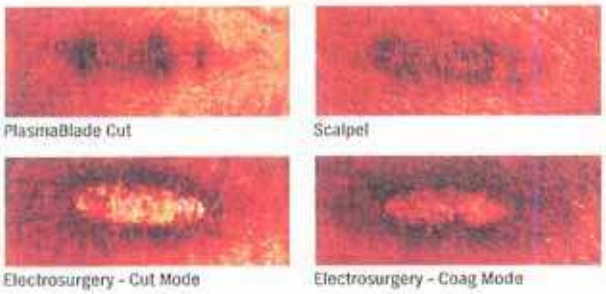



*Figure 11.*

## Scarring:

Results of the chronic skin healing study also demonstrated that wounds created with the PlasmaBlade heal well, and the scar looks virtually identical to that of a wound created by a scalpel. When compared to traditional electrosurgery, the PlasmaBlade had 66 percent less scarring (Fig. 13).




*Note: Scar formation at six weeks post-incision was comparable between PlasmaBlade and scalpel incisions, but significantly less that in the incision made by traditional electrosurgery (p=0.02 and 0.03, respectively)*

*Figure 13.*

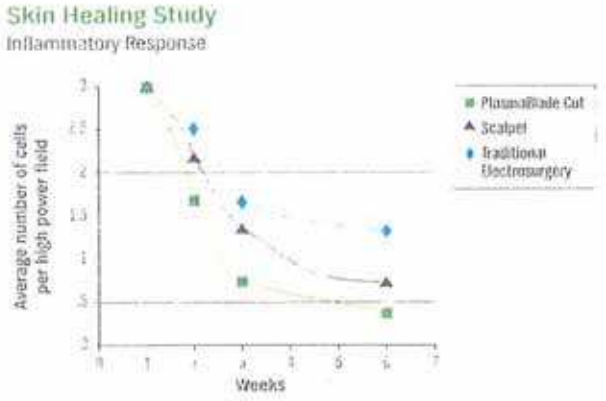



*Figure 10.*

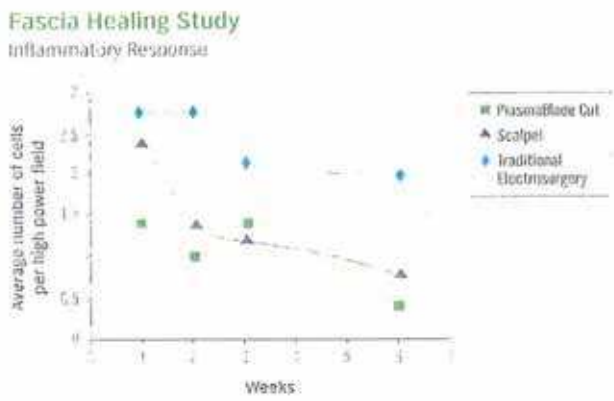



*Figure 12.*

## Independent Research Studies Support PEAK Surgical's Findings:

Also of note, a group of investigators at Stanford University has independently published work investigating the use of an earlier version of the PEAK Pulsed Plasma Technology in human *ex vivo* and *in vivo* models for ophthalmological applications (please see studies in Appendix A at the end of this paper). The technology was successfully evaluated in humans for vitreoretinal and cataract surgeries providing further demonstration of the extreme precision of which the technology is capable.

# DISCUSSION

The many preclinical studies conducted using the PlasmaBlade and the PEAK Surgery System have demonstrated the PlasmaBlade's ability to cut a variety of tissues with scalpel-like precision and control bleeding as well as traditional electrosurgery, but without all the thermal injury. These findings suggest that use of the PlasmaBlade may be beneficial in a number of ways:

### 1. Potential for reduction in incidence of collateral tissue injury

As described previously, the PlasmaBlade has the potential to reduce the incidence of unintentional tissue injury because the pulsed electrical waveforms and highly insulated cutting electrode are specifically engineered to minimize collateral thermal damage. Preclinical studies have shown that the PlasmaBlade's cutting is more comparable to the incision made by a traditional scalpel than to conventional electrosurgery, and the thermal damage zone has typically been reduced in depth by a factor of two to ten, depending on the tissue tested and the instrument settings.

Additionally, cuts made with the PlasmaBlade were achieved with much less force and with significantly less tissue sticking than a traditional scalpel or electrosurgical tool during preclinical experiments. The tissue did not have to be put under tension during cutting, suggesting that the PlasmaBlade may allow greater control over the depth of cutting and reduce the chances of slippage, tearing, unintentional extension of incisions and accidental cutting of adjacent tissues or organs.

### 2. Potential for reduced bleeding, improved wound healing and reduced scarring

Surgeries that require a scalpel's precision must nevertheless have a method for controlling bleeding during surgery, both for the sake of minimizing blood loss and for maintaining adequate visualization of the field. While pre-clinical data suggest that the PlasmaBlade possesses many of the positive cutting qualities of a traditional scalpel, its observed ability to control bleeding makes it an appropriate device for use on numerous soft tissues. Unlike a scalpel, the PlasmaBlade has the coagulation capabilities of conventional electrosurgery, so that bleeding can be controlled without switching instruments.

Furthermore, the results of skin and fascia healing studies suggest that surgeries with the PlasmaBlade may have a very desirable wound healing profile. The PlasmaBlade incisions healed virtually identically to the scalpel wounds and the reduced thermal injury from the PEAK Surgery System resulted in a reduction in inflammatory response and an increase in wound strength. With fascia tissue, early return of wound strength is important to avoid wound herniation.

These findings corroborate work previously published in the scientific literature that shows an association between thermal injury to the tissue and compromised surgical incision wound healing (Gelman et al.,1994).

### 3. Potential to increase operating room efficiency and/or staff safety

A number of mechanisms can be postulated by which the PlasmaBlade may also enable greater surgical efficiency and enhanced safety for the OR staff. Fast, smooth cutting with integrated bleeding control could potentially shorten the amount of time needed for a given procedure, as could the ease with which the PlasmaBlade can be wiped clean with a simple piece of gauze (a scratch pad is not required).

During preclinical studies, tissue could be cut with precision, coagulated, and directly manipulated with the PlasmaBlade, without concern of a loss of performance when the surgical field filled with blood, liquefied fat or other fluids. With all of these capabilities in one instrument, the PlasmaBlade could be used without repeatedly switching tools during surgery, improving workflow efficiency and potentially reducing the chance for sharps injuries or burns encountered when switching between a scalpel blade and an electrosurgery device.

And, because the PlasmaBlade cuts tissue via a plasma-mediated mechanism, the system produced little to no surgical smoke during preclinical studies when used in "cut" mode (data on file at PEAK Surgical). It is currently estimated that more than 500,000 surgeons, nurses and other OR staff are exposed to surgical smoke every year, with potentially serious long term health consequences. This gaseous byproduct of thermal electrosurgery contains a complex mixture of intoxicants, toxins, carcinogens and irritants such as carbon monoxide, acrylonitrile, hydrogen cyanide and benzene and has been estimated to have the mutagenicity of cigarette smoke. Surgical smoke also contains aerosolized viable and non-viable cellular material, which have been demonstrated to carry intact, infectious virions and could represent a vehicle for transmission of human papillomavirus (HPV), human immunodeficiency virus (HIV) and other dangerous viruses. The U.S. Occupational Safety and Health Administration, the Association of periOperative Registered Nurses and others have issued warnings regarding the potential health risks to those exposed to surgical smoke, and have published guidelines that recommend the purchase of equipment to mitigate exposure (Occupational Safety and Health Administration 2008; Barrett, 2003; Alp, 2006; Bigony, 2007).

### 4. Potential economic benefits

Although the disposable PlasmaBlades are more expensive per unit than conventional electrosurgical pencils or electrodes, they are similarly priced to ultrasonic and other advanced energy devices, and the PEAK Surgical System is significantly less expensive than laser based surgical systems. Furthermore, it is possible that the potential efficiency and safety enhancements discussed above could translate to long term economic savings that would more than offset the initial investment in equipment.

## CONCLUSION

Taken all together, these results have demonstrated the system's utility in a wide number of soft tissue types and in delicate applications where the PlasmaBlade may provide a marked improvement over conventional electrosurgical technologies, including:

- Surgical incision of skin with minimal bleeding, tissue injury and scarring and improved surgical incision wound healing *(in vivo* porcine and *ex vivo* human skin models)
- Nerve- and vasculature-sparing dissection (porcine internal mammary artery, rabbit and human retinas)
- Dissection of tissues that would be encountered as successive layers during surgery, e.g. skin, fat, muscle, fascia, etc.
- Extremely delicate tissue dissection (bovine lenses and capsules, porcine corneas; human cataracts and retinas *in vivo* as studied by an independent group at Stanford University)

Additional research studies are ongoing, but the preclinical results to date suggest that the PlasmaBlade may be useful in a wide range of procedures in which the minimization of thermal damage is highly desirable.

## LIST OF CITATIONS


Alp, E. B. (2006). Surgical smoke and infection control. *J Hosp Infection*, 62, 1-5.

Barrett, W. a. (2003). Surgical smoke – a review of the literature. *Surg Endosc*, 17, 979-987.

Bigony, L. (2007). Risks associated with exposure to surgical smoke plume: a review of the literature. *AORN Journal*, 86, 1013.

Gelman, C. L., Barroso, E. G., Britton, C. T., Haklin, M. F., & Staren, E. D. (1994). The Effect of Lasers, Electrocautery, and Sharp Dissection on Cutaneous Flaps. *Plast Reconstr Surg*, 94, 829.

*Occupational Safety and Health Administration.* (2008). Retrieved from www.osha.gov

## APPENDIX A: Bibliography

### Presentations

- "Comparative Healing of Surgical Incisions Created by a Standard Electrosurgery, PEAK Electrosurgical Cutting Tool, and Standard Scalpel Blade." SA Loh, GA Carlson, EI Chang, EJ Huang, and GC Gurtner. Podium presentation at the American College of Surgeons Annual Meeting, October 9, 2007, New Orleans, LA.
- "Comparative Healing of Surgical Incisions Created by a Standard Electrosurgery, PEAK Electrosurgical Cutting Tool, and Standard Scalpel Blade." EI Chang, SA Loh, GA Carlson, E Huang, GC Gurtner. Podium Presentation at the Plastic Surgery Research Council 2008 Annual Meeting, May 28-31, 2008, Springfield, IL.

### Posters

- "Evaluation of PEAK PlasmaBlade Needle For Plastic and Reconstructive Surgery Compared To Standard Electrosurgery." GS Keller, HL Rosenberg, E Huang, and GA Carlson. American Academy of Facial Plastic and Reconstructive Surgery Annual Meeting, September 18-21, 2008, Chicago, IL.
- "Evaluation of PEAK PlasmaBlade for Obstetric and Gynecologic Surgery vs. Traditional Electrosurgery." P Blumenthal, MT Jacobson, E Huang, GA Carlson, and JS Berek. American College of Obstetrics and Gynecology 2008 Annual Meeting, May 3-7, 2008, New Orleans, LA.
- "Evaluation of the PEAK Electrosurgical Tool in Neurosurgery Applications Compared to Standard Electrosurgical Tools and Standard Scalpel Blade." LM Shuer, GA Carlson, and S Taylor. Congress of Neurological Surgeons Annual Meeting, September 15-20, 2007, San Diego, CA.

### Publications describing clinical use of the PEAK technology

- Priglinger SG, Haritoglou C, Palanker DV, et al. "Pulsed electron avalanche knife: new technology for cataract surgery." Br J Ophthalmol. 2007; 91:949-54.
- Priglinger SG, Haritoglou C, Palanker D, et al. "Pulsed electron avalanche knife for capsulotomy in congenital and mature cataract." J Cataract Refract Surg. 2006; 32:1085-88.
- Priglinger SG, Haritoglou C, Mueller A, et al. "Pulsed Electron Avalanche Knife in Vitreoretinal Surgery." Retina. 2005; 25:889-96.
- "Pulsed Electron Avalanche Knife (PEAK-fc) for Dissection of Retinal Tissue." Arch Ophthalmol. 2005; 123:1412-18.

### Additional publications describing the PEAK technology

- Palanker D, Vankov A, and Huie P. "Electrosurgery with Cellular Precision." IEEE Trans Biomed Eng. 2008; 55:838-41.
- Palanker D, Vankov A, Freyvert Y, and Huie P. "Pulsed Electrical Stimulation for Control of Vasculature: Temporary Vasoconstriction and Permanent Thrombosis." Bioelectromagnetics. 2008; 29:100-7.
- Vankov A and Palanker D. "Nanosecond plasma-mediated electrosurgery with elongated electrodes." J Appl Phys. 2007; 101: 124701.
- Vankov A, Huie P, Blumenkranz M, and Palanker D. "Electro-adhesive forceps for tissue manipulation." Ophthalmic Technologies, SPIE. 2004; 5314:270-4.
- Palanker D, Vankov A, Bilbao K, et al. "Optimization of the Pulsed Electron Avalanche Knife for Anterior Segment Surgery." Ophthalmic Technologies, SPIE. 2003; 4951:56-61.
- Miller JM, Palanker DV, Vankov A, et al. "Precision and Safety of the Pulsed Electron Avalanche Knife in Vitreoretinal Surgery." Arch Ophthalmol. 2003; 121:871-7.
- Palanker DV, Marmor MF, Branco A, et al. "Effects of the Pulsed Electron Avalanche Knife on Retinal Tissue." Arch Ophthalmol. 2002; 120:636-40.
- Palanker DV, Miller JM, Marmor MF, et al. "Pulsed Electron Avalanche Knife (PEAK) for Intraocular Surgery." Invest Ophthalmol Vis Sci. 2001; 42:2673-78.

**PEAK Surgical, Inc.**
2464 Embarcadero Way
Palo Alto, CA 94303

Tel 888 792 PEAK
Tel 650 331 3020
Fax 650-331-3293

www.peaksurgical.com

PEAK,® PEAK PlasmaBlade,™ Pulsed Plasma Technology™ and PULSAR™ are registered and/or trademarks of PEAK Surgical, Inc.

Epitome® is a registered trademark of Utah Medical Products, Inc.

Harmonic Scalpel® is a registered trademark of Ethicon Endo-Surgical, Inc.

LBL-00023 Rev A

SEP 14 1998

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K982483

**NAME OF FIRM:**
DePuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

**510(K) CONTACT:**
Arlene C. Saull, RAC
Sr. Submissions Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988

**TRADE NAME:**
Motech PEAK™ Fixation System

**COMMON NAME:**
Bone Fixation Appliance

**CLASSIFICATION:**
Class II, per 21 CFR, 888.3030: Single/multiple component metallic bone fixation appliances and accessories.

**DEVICE PRODUCT CODE:**
87 HRS Plate, Fixation, Bone

**SUBSTANTIALLY EQUIVALENT DEVICES:**
DePuy Motech PEAK™ 3mm Rod Fixation System
ACE Universal Reconstruction Plates

**INTENDED USE AND DEVICE DESCRIPTION:** (The subject devices are part of the DePuy Motech PEAK 3mm Rod Fixation System.)

The DePuy Motech PEAK 3mm Rod Fixation System is intended for use in treating fractures of the pelvis, acetabulum, clavicle, scapula, and distal humerus. The predicate system consists of 3mm rods in various lengths, rod connectors, pin nut, and bone screws. The subject devices consist of a Transverse Connector Hook used to connect the 3mm rods at right angles or transversely across the fracture; an Inner Screw used to hold the rods and hook connectors together; and the Transverse Connector Assembly that consists of the subject Transverse Hook Connector, subject Inner Set Screw, and the predicate 3mm Fixation Rod (K980368).

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The subject devices are made from similar material as the predicate DePuy Motech PEAK 3mm Rod Fixation System, and the predicate ACE Universal Reconstruction Plates. Both predicate systems and the subject devices are intended to treat fractures of the pelvis, acetabulum, clavicle, scapula, and distal humerus, using rigid fixation to secure the fracture. Mechanical testing provided with the premarket notification for the DePuy Motech PEAK 3mm Fixation Rod System exceeds that of the ACE 3.5mm Reconstruction Plate System.

END OF 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FORM



EXHIBIT
DePuy
6
PENGAD 800-631-6989

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1998

Arlene C. Saull, RAC
Senior Submissions Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K982483
Trade Name: DePuy Motech™ PEAK™ Transverse Connector
Regulatory Class: II
Product Code: HRS
Dated: July 15, 1998
Received: July 17, 1998

Dear Ms. Saull:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS

510(k) Number (if known) _____

Device Name PEAK™ Fixation System 3.0mm

*The subject devices (inner screw, transverse connector hook and transverse rod connector assembly) are being added to the 3.0mm PEAK Fixation System.*

Indications for Use:

The DePuy Motech PEAK 3mm Fixation Rod System is intended for use in treating fractures of the pelvis, acetabulum, clavicle, scapula, and distal humerus.

---

Concurrence of CDRH, Office of Device Evaluation:

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982483

Prescription Use X OR Over-The Counter Use ____(Per 21 CFR 801.109)

K063509

JAN - 4 2007

# 510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

| | |
|---|---|
| **NAME OF SPONSOR:** | DePuy Orthopaedics, Inc.<br>700 Orthopaedic Drive<br>Warsaw, Indiana 46582<br>Establishment Registration Number: 1818910 |
| **510(K) CONTACT:** | Rhonda Myer<br>Regulatory Affairs<br>Telephone: (574) 371-4927<br>Facsimile: (574) 371-4987<br>Electronic Mail: Rmyer7@dpyus.jnj.com |
| **DATE PREPARED:** | November 6, 2006 |
| **PROPRIETARY NAME:** | Peak Fx Hip Plate |
| **COMMON NAME:** | Bone Screw and Plate for Internal Fixation |
| **CLASSIFICATION:** | Class II device per 21 CFR 888.3030:<br>Single/Multiple component metallic bone fixation appliances and accessories |
| **DEVICE PRODUCT CODE:** | 87 KTT |
| **SUBSTANTIALLY EQUIVALENT DEVICES:** | **DePuy Captured Hip Screw System (CHS),** K813554, cleared on January 12, 1982 |

**DEVICE DESCRIPTION:**

The DePuy Peak Fx Hip Plate System is comprised of plates in various lengths with two to twelve holes, barrel/ lag screw assemblies in various lengths with angles from 125° to 140°, a key and key screw, and a limited collapse cap.

**INTENDED USE AND INDICATIONS:**

**Intended Use:**

The DePuy Peak Fx Hip Plate is intended for internal fixation of hip fractures.

**Indications for Use:**

The Peak Fx Hip Plate is indicated for the following fractures of the proximal femur:

- Basilar neck fractures
- Intertrochanteric fractures
- Subtrochanteric fractures

The Peak Fx Hip Plate is indicated for stable and unstable fractures in which a stable medial buttress can be reconstructed.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The substantial equivalence of the DePuy Peak Fx Hip Plate is shown by its similarity in intended use, indications for use, materials and design to the existing DePuy Captured Hip Screw System (CHS), K813554, cleared on January 12, 1982.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Regulatory Associate, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

JAN 04 2007

Re: K063509
Trade/Device Name: Peak Fx Hip Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, HRS
Dated: November 17, 2006
Received: November 20, 2006

Dear Ms. Myer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use Statement

510 (k) Number (if known): K063509

Device Name: _____

**Indications for Use:**

The Peak Fx Hip Plate is indicated for the following fractures of the proximal femur:

- Basilar neck fractures
- Intertrochanteric fractures
- Subtrochanteric fractures

The Peak Fx Hip Plate is indicated for stable and unstable fractures in which a stable medial buttress can be reconstructed.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K063509

0902-90-016 Rev. G

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# PEAK Anterior Compression Plate System

# PEAK Polyaxial Anterior Cervical Plate System

# DOC Ventral Cervical Stabilization System

# SLIM-LOC™ Anterior Cervical Plate System

# EAGLE™ Anterior Cervical Plate System

# SWIFT™ Anterior Cervical Plate System

# UNIPLATE™ Anterior Cervical Plate System

# SKYLINE™ Anterior Cervical Plate System

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## IMPORTANT NOTE TO OPERATING SURGEON

Anterior Cervical Stabilization System implants, like other internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking the implant components. It is essential to instruct patients about restrictions on their activities in the postoperative period and to examine the patient postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used or if a pseudarthrosis develops.

The surgeon may determine to remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

## DESCRIPTION

The PEAK Anterior Compression Plate System consists of an assortment of titanium alloy plates and screws. The plates are available in lengths ranging from 25-94mm to accommodate one to four segments of fixation. The system also includes 3.5mm cortical and 4.0mm cancellous titanium alloy screws which are available in lengths ranging from 8mm-30mm.

The PEAK Polyaxial Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The anterior cervical plates range in size from 24mm to 110mm in length to accommodate one to four segments of fixation. The cancellous screws are available in 4.0mm and 4.35mm diameters. They are fully threaded and have lengths ranging from 10 to 26mm.

The DOC Ventral Cervical Stabilization System is a titanium alloy platform, plate, rod and screw system used to assist spinal surgeons in correction of cervical spine defects and stabilization. The DOC Ventral Cervical Stabilization System, in its fully assembled form, consists of a plate or two laterally placed rods joined by platforms which lie on the anterior vertebral surface. The system is anchored to the vertebrae with screws. The implant provides supplemental stability to the cervical spine following anterior cervical fusion. Depending on the implant configuration, it may serve as either a rigid (load-bearing) or dynamic (load-sharing) construct.

The following types of components are available in the system: Rods, Plates, Platforms, Inner and Outer Bone Screws, Graft Screws and Cross Connectors. All components are manufactured from implant grade titanium alloy which conforms to ASTM F-136 specifications. Assemblies are also available for convenience of the surgeon. These are pre-assembled partial constructs consisting of one platform, one cross connector, two rods and two locking screws.

**Platform:** Platforms are designed to connect the rods and anchor to the vertebral bodies with bone screws. All platforms may be used with either solid bone screws (for bicortical fixation) or the combination of outer and inner bone screws (a hollow outer bone screw used with a solid inner locking screw designed for unicortical fixation). Screw selection is determined by physician preference. All platforms are designed to be used with two rods in forming the construct.

Platforms are available in lockable and non-locking designs. Lockable platforms have extensions which accept platform/cross connector locking screws for securing the platform to the rods. Lockable platforms are required for use at the end of the construct opposite the rod heads.

If a rigid configuration is preferred to a dynamic (i.e., load sharing) configuration, a lockable platform must also be utilized adjacent to the rod heads. If a load-sharing configuration is desired, the platform adjacent to the rod heads is not locked to the rods.

Various platforms are designed for angled insertion of the screw into the vertebral body. They are available in both lockable and non-locking designs. These platforms have a fin feature on one side which engages the vertebra from within the disc space for optimal positioning and fixation.

Various platforms are designed for straight (perpendicular) insertion of the screw into the vertebral body. They are available in both lockable and non-locking designs.

One platform design is available for fixation of the construct to an intervertebral graft. This platform features a horizontal slot and spherical nest to accommodate variation in screw entry site and in trajectory into the graft.

Platform selection is based on physician preference and patient anatomy.

The SLIM-LOC™ Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The plates are available in lengths ranging from 22-111mm in configurations with 2, 3, 4, 5 or 6 pairs of screw holes. The SLIM-LOC screws are available in 4.5mm in diameter and are available as self-drilling in even length sizes ranging from 10-18mm or self-tapping in even length sizes ranging from 10-26mm. Larger diameter screws (4.8mm) are available in 12, 14, and 16mm lengths.

The EAGLE™ Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The plates are available with two to six screw hole pairs in various lengths. The screws are available in various sizes and screw-tip geometries.

The SWIFT™ Anterior Cervical Plate System is manufactured from titanium alloy and consists of segmented plates that allow up to 2mm of controlled graft settling between each of the segments. The plates are available with two to six screw hole pairs, in various lengths and two configurations, discectomy and corpectomy. The screws are available in various sizes and screw-tip geometries. A graft screw is available for use in the corpectomy plates.

The UNIPLATE™ Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The anterior cervical plates are available in various lengths to accommodate one to two segments of fixation. The screws are available in various sizes and tip geometries.

The SKYLINE™ Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The plates have two to six screw hole pairs in various lengths. The screws are available in various sizes and screw-tip geometries. Both constrained and variable screws are available to create a constrained, variable or hybrid configuration.

## CLEANING AND STERILIZATION

Implants of the Cervical Plating Stabilization Systems are supplied either sterile, or clean and not sterile. For components provided sterile, ensure that the package is not damaged prior to use.

For non-sterile devices, ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Testing was conducted to develop the following RECOMMENDATIONS FOR STEAM STERILIZATION:

| | |
|---|---|
| Cycle | Pre-Vacuum |
| Temperature | 270°F<br>132°C |
| Exposure time | 6 min. |

## USAGE

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

DePuy Spine spinal system components should not be used with components of other manufacturers.

**In order to obtain controlled vertical translation (load-sharing), correct placement of selected components is critical.**

**Please refer to surgical technique manual for specific instructions.**

## INDICATIONS

CAUTION: U.S.A. Law restricts this device to sale by or on the order of a physician.

The SLIM-LOC Anterior Cervical Plate System and SKYLINE™ Anterior Cervical Plate System are indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disk disease, spinal canal stenosis and cervical myelopathy.

The PEAK Anterior Compression Plate System, PEAK Polyaxial Anterior Cervical Plate System, DOC Ventral Cervical Stabilization System, EAGLE Anterior Cervical Plate System, SWIFT Anterior Cervical Plate System, and UNIPLATE Anterior Cervical Plate System are intended for anterior cervical intervertebral body fixation. These systems are indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

The UNIPLATE Anterior Cervical Plate System is also indicated for treatment of spinal stenosis.

**WARNING:** These devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

## POSTOPERATIVE MOBILIZATION

Until maturation of the fusion is confirmed by radiographic examination, external immobilization (such as bracing) may be recommended, based on physician judgment.

Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

## CONTRAINDICATIONS

- Active systemic infection or an infection localized to the site of the proposed implantation.



- Severe osteoporosis may prevent adequate fixation of screws and thus preclude the use of this or any other spinal instrumentation system.
- Patients who have been shown to be safely and predictably treated without internal fixation.
- Open wounds.

## RELATIVE CONTRAINDICATIONS:

Relative contraindications include any entity or condition that totally precludes the possibility of fusion (e.g., cancer, kidney dialysis or osteopenia), obesity, certain degenerative diseases, and foreign body sensitivity.

## WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES.

### WARNINGS

The following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient before surgery.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury.

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
3. **MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.
4. **PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be extremely important to the eventual success of the procedure:

   A. **The patient's occupation or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

   B. **A condition of senility, mental illness, alcoholism, or drug abuse.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

   C. **Certain degenerative diseases.** In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.

   D. **Foreign body sensitivity.** The surgeon is advised that no pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

   E. **Smoking.** Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

**WARNING:** If bony fusion does not occur within an expected period of time, the screws may break due to the high and sustained loading of these devices. This has been noted in patients with delayed, psuedoarthrosis or non-union and can result in the need to revise the device(s).

## PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metal implants should be done only with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage of the implant. Do not use implant if damage is suspected.

   Excessive torque applied to the screws when seating the plate may cause failure of the bone resulting in stripped threads and/or compromised screw purchase.
3. **BENDING THE CONSTRUCT.** Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured it is recommended that a new construct is contoured correctly rather than reverse bending the over-contoured construct.
4. **REMOVAL OF THE IMPLANT AFTER HEALING.** If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved in a second surgery.
5. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and participating in any type of sports. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

## POSSIBLE ADVERSE EFFECTS

1. Nonunion, delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
9. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
10. Bursitis.
11. Paralysis.
12. Esophageal perforation, erosion or irritation.
13. Screw back-out, possibly leading to esophageal erosion, implant loosening, and/or reoperation for device removal.
14. Damage to lymphatic vessels and/or lymphatic fluid exudation.
15. Spinal cord impingement or damage.
16. Fracture of bony structures.
17. Degenerative changes or instability in segments adjacent to fused vertebral levels.
18. Death.

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**SYMBOL TRANSLATION**

| | | | |
|---|---|---|---|
| LOT — LOT NUMBER | SINGLE USE | NONSTERILE — NONSTERILE | MANUFACTURER |
| REF — CATALOG NUMBER | XXXX-XX — USE BY | STERILE R — STERILIZATION BY IRRADIATION | EC REP — AUTHORIZED EUROPEAN REPRESENTATIVE |
| QTY — QUANTITY | SEE INSTRUCTIONS FOR USE | STERILE EO — STERILIZATION BY ETHYLENE OXIDE | DIST — DISTRIBUTED BY |
| Rx Only — Federal (USA) law restricts this device to sale by or on the order of a physician | STERILE — STERILE | MADE IN — MADE IN | SZ — SIZE |

**MATERIAL** MATL

| | | |
|---|---|---|
| A/T ACROFLEX™/Ti — ACROFLEX™/Titanium | PY — Polyester | SS/RADEL™/ SRTA Ti Al Nitride — Stainless Steel/RADEL™/ Titanium Aluminum Nitride |
| A Al — Aluminum | P POLYMER — Polymer | STA SS/Ti Al Nitride — Stainless Steel/ Titanium Aluminum Nitride |
| A/P Al/PL — Aluminum/Plastic | P/CM PE/CoCrMo — Polyethylene/Cobalt Chromium Molybdenum | S/U SS/ULTEM — Stainless Steel/Ultem |
| B/R Ba/RADEL™ — Barium/RADEL™ | P/C POLYMER/CARBON FIBER COMPOSITE — Polymer/ Carbon Fiber Composite | T Ti — Titanium and its alloys |
| CaP CALCIUM PHOSPHATE — Calcium Phosphate | S SS — Stainless Steel | S/R SS/RADEL™ — Stainless Steel/RADEL |
| CM CoCrMo — Cobalt Chromium Molybdenum | S/A SS/Al — Stainless Steel/Aluminum | R/T POLYOLEFIN RUBBER/Ti — Polyolefin Rubber/Titanium |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE — Cobalt Chromium Molybdenum/ Titanium/Calcium Phosphate | S/BR SS/Ba/RADEL™ — Stainless Steel/ Barium/RADEL | T/A Ti/Al — Titanium/Aluminum |
| F FOAM — Foam | S/P SS/PHENOLIC — Stainless Steel/Phenolic | Ti/UHMWPE/HA — Titanium/Ultra-High Molecular Weight Polyethylene/ Hydroxyapatite |
| HA — Hydroxyapatite | S/PL SS/PL — Stainless Steel/Plastic | SS/Ti — Stainless Steel/Titanium |
| NiTi Ni/Ti — Nickel/Titanium | SRSI SS/RADEL™/ SILICONE — Stainless Steel/ RADEL™/Silicone | SS/Al/SILICONE — Stainless Steel/ Aluminum/Silicone |
| PL — Plastic | SRSN SS/RADEL™/ SILICONE/Ti Al Nitride — Stainless Steel/ RADEL™/Silicone/ Titanium Aluminum Nitride | S/SI SS/SILICONE — Stainless Steel/Silicone |
| P/F PL/FOAM — Plastic/Foam | | |

CZ

# PŘEDNÍ KOMPRESNÍ DLAHOVÝ SYSTÉM PEAK

# POLYAXIÁLNÍ PŘEDNÍ KRČNÍ DLAHOVÝ SYSTÉM PEAK

# VENTRÁLNÍ SYSTÉM KRČNÍ STABILIZACE DOC

# PŘEDNÍ KRČNÍ DLAHOVÝ SYSTÉM SLIM-LOC™

# PŘEDNÍ KRČNÍ DLAHOVÝ SYSTÉM EAGLE™

# PŘEDNÍ KRČNÍ DLAHOVÝ SYSTÉM SWIFT™

# PŘEDNÍ KRČNÍ DLAHOVÝ SYSTÉM UNIPLATE™

# PŘEDNÍ KRČNÍ DLAHOVÝ SYSTÉM SKYLINE™

## DŮLEŽITÁ POZNÁMKA PRO OPERATÉRA

Implantáty systému přední krční stabilizace mají omezenou životnost stejně jako jiná zařízení pro interní fixaci. Významný vliv na tuto životnost má úroveň aktivity pacienta. Pacient musí být informován, že jakákoli aktivita zvyšuje riziko uvolnění, ohnutí nebo prasknutí součástí implantátu. Je nutné uvědomit pacienty o omezení aktivity v pooperačním období a provést pooperační vyšetření pacienta za účelem kontroly vývoje svalku a stavu součástí implantátu. Součásti implantátu se mohou ohnout, zlomit nebo uvolnit, i když již došlo k vytvoření pevného kostního svalku. Proto musí být pacient upozorněn na to, že se součásti implantátu mohou ohnout, zlomit nebo uvolnit, i když jsou omezení aktivity dodržována.

Omezení způsobená anatomickými faktory a moderními operačními materiály jsou příčinou, proč kovové implantáty nemohou vydržet věčně. Jejich účelem je poskytnout dočasnou vnitřní oporu, zatímco dochází ke konsolidaci svalku. Tyto typy implantátů nejčastěji selhávají, není-li použit kostní štěp nebo vyvíjí-li se pseudoartróza.

Po vytvoření kostního svalku může operatér rozhodnout o vyjmutí těchto implantátů. Možnost druhé operační procedury musí být projednána s pacientem a je nutné zabývat se i riziky spojenými s druhou operační procedurou. Pokud se implantáty zlomí, musí lékař rozhodnout, zda mají být vyjmuty. Musí při tom zvážit stav pacienta a rizika spojená s přítomností zlomeného implantátu.

## POPIS

Přední kompresní dlahový systém PEAK se skládá z kolekce dlažek a šroubů ze slitiny titanu. Dlažky se dodávají v délce od 26 do 94 mm, aby pojaly jeden až čtyři fixační segmenty. Součástí systému jsou i 3,5 mm kortikální šrouby a 4,0 mm spongiózní šrouby ze slitiny titanu dodávané v délce od 8 mm do 30 mm.

Polyaxiální přední krční dlahový systém PEAK se skládá z kolekce dlažek a šroubů ze slitiny titanu. Délka předních krčních dlažek se pohybuje od 24 mm do 110 mm, aby pojaly jeden až čtyři fixační segmenty. Spongiózní šrouby se dodávají s průměrem 4,0 mm a 4,35 mm. Mají závity po celé délce a jejich délka je v rozsahu od 10 do 26 mm.

Ventrální systém krční stabilizace DOC se skládá z platforem, dlažek, šroubů a tyčinek ze slitiny titanu, které pomáhají operatérovi při nápravě defektů a stabilizaci krční páteře. Úplná sestava ventrálního systému krční stabilizace DOC se skládá z dlažky nebo dvou postranních tyčinek spojených platformami uloženými na přední ploše obratle. Systém je šroubky ukotven k obratlům. Implantát poskytuje dodatečnou stabilitu krční páteři po přední krční fúzi. V závislosti na konfiguraci může implantát sloužit buď jako rigidní konstrukce (nosná), nebo jako dynamická konstrukce (sdílející zatížení).

V systému jsou k dispozici tyto typy součástí: tyčinky, dlažky, platformy, vnitřní a vnější kostní šrouby, šrouby do štěpů a příčné konektory. Všechny součásti jsou vyrobeny ze slitiny titanu pro implantáty, která je určena pro implantáty a vyhovuje specifikacím ASTM F-136. Pro pohodlí operatéra se některé součásti dodávají předem sestavené. Jedná se o částečné sestavy, které se skládají z jedné platformy, jednoho příčného konektoru, dvou tyčinek a dvou zajišťovacích šroubů.

Platforma: Platformy spojují tyčinky a jsou ukotveny k obratlům kostními šrouby. Všechny platformy se mohou používat buď s pevnými kostními šrouby (pro bikortikální fixaci), nebo v kombinaci s vnějšími či vnitřními kostními šrouby (dutý vnější kostní šroub použitý s pevným vnitřním zajišťovacím šroubem určeným pro unikortikální fixaci). Šrouby vybírá lékař. Všechny platformy se při vytváření sestavy používají se dvěma tyčinkami.

Platformy se dodávají v uzamykatelném a neuzamykatelném provedení. Uzamykatelné platformy mají rozšířenou část, do níž se vejdou zajišťovací šrouby platformových nebo příčných konektorů pro upevnění platformy k tyčinkám. Uzamykatelné platformy se v sestavě musí používat na konci, který je naproti hlavám tyčinek.

Dáte-li přednost rigidní konfiguraci před dynamickou (tj. sdílející zatížení), musí být uzamykatelná platforma použita také vedle hlav tyčinek. Pokud je požadována konfigurace přebírající zatížení, není platforma vedle hlav tyčinek k tyčinkám připevněna.



Některé platformy jsou navrženy pro zavádění šroubů do těl obratlů pod úhlem. Dodávají se v uzamykatelném a neuzamykatelném provedení. Tyto platformy mají na jedné straně křidélko, které upevňuje obratel z oblasti ploténky pro dosažení optimální polohy a fixace.

Některé platformy jsou navrženy pro přímé (kolmé) zavádění šroubů do těl obratlů. Dodávají se v uzamykatelném a neuzamykatelném provedení.

Jeden model platformy se dodává pro upevnění sestavy k meziobratlovému štěpu. Tato platforma slouží jako vodorovná štěrbina a sférické lůžko, které pojme řadu různých míst a drah zavádění šroubů do štěpu.

Platformu vybírá lékař podle anatomie pacienta a svých zkušeností.

Přední krční dlahový systém SLIM-LOC™ se skládá z kolekce dlažek a šroubů ze slitiny titanu. Dlažky se dodávají v délkách od 22 do 111 mm a v konfiguracích s 2, 3, 4, 5 a 6 páry otvorů pro šrouby. Šrouby SLIM-LOC se dodávají s průměrem 4,5 mm v samořezném provedení ve stejných délkách od 10 až 18 mm nebo v samořezném provedení ve stejných délkách v rozsahu od 10 do 26 mm. Šrouby s větším průměrem (4,8 mm) se dodávají v délce 12, 14 a 16 mm.

Přední krční dlahový systém EAGLE™ se skládá z kolekce dlažek a šroubů ze slitiny titanu. Dlažky se dodávají se dvěma až šesti páry otvorů pro šrouby v různých délkách. Šrouby se dodávají v různých velikostech a s různými geometriemi hrotu šroubu.

Přední krční dlahový systém SWIFT™ je vyroben z titanové slitiny a skládá se ze segmentovaných dlažek, které umožňují až 2 mm kontrolované usazení štěpu mezi každým segmentem. Dlažky se dodávají se dvěma až šesti páry otvorů pro šrouby v různých délkách a dvou konfiguracích - diskektomie a korporektomie. Šrouby se dodávají v různých velikostech a s různými geometriemi hrotu šroubu. Šroub pro štěp se dodává pro použití u dlažek pro korporektomii.

Přední krční dlahový systém UNIPLATE™ se skládá z kolekce dlažek a šroubů ze slitiny titanu. Přední krční dlažky se dodávají v různých délkách, aby pojaly jeden až dva fixační segmenty. Šrouby se dodávají v různých velikostech a s různými geometriemi hrotu.

Přední krční dlahový systém SKYLINE™ se skládá z kolekce dlažek a šroubů ze slitiny titanu. Dlažky mají dva až šest párů otvorů pro šrouby v různých délkách. Šrouby se dodávají v různých velikostech a s různými geometriemi hrotu šroubu. Omezené a nastavitelné šrouby se dodávají pro vytvoření omezené, nastavitelné nebo hybridní konfigurace.

## ČIŠTĚNÍ A STERILIZACE

Implantáty systémů krční dlahové stabilizace se dodávají buď sterilní, nebo čisté a nesterilní. U součástí, které jsou dodávány sterilní před použitím zkontrolujte, zda není obal poškozen.

Všechny nesterilní součásti by měly být sterilizovány podle doporučených metod standardů ISO 8828 a směrnic asociace sálových sester AORN pro sterilizace v nemocnicích.

Na základě testů vznikla následující DOPORUČENÍ PRO PARNÍ STERILIZACI:

| | |
|---|---|
| Cyklus: | Podtlak |
| Teplota: | 270 °F<br>132 °C |
| Čas expozice: | 6 minut |

## POUŽITÍ

Operatér musí být podrobně seznámen nejen s lékařskými a chirurgickými aspekty implantátu, ale musí znát také mechanická a metalurgická omezení kovových chirurgických implantátů. Velmi důležitá je pooperační péče. Před zhojením kosti musí být pacient informován o omezeních kovového implantátu a upozorněn na omezení při zatěžování implantátu a tělesné námaze. Pacient by měl být upozorněn, že nedodržení pooperačních pokynů by mohlo vést k selhání implantátu a k nutnosti další operace za účelem vyjmutí zařízení.

Součásti systému pro operaci páteře od společnosti DePuy Spine by se neměly používat se součástmi od jiných výrobců.

Má-li být dosaženo řízeného vertikálního přenesení zátěže (sdílení zatížení), je nezbytné, aby byly vybrané součásti umístěny správně.

Konkrétní pokyny najdete v příručce operační techniky.

## INDIKACE

UPOZORNĚNÍ: Zákony USA omezují prodej tohoto zařízení na prodej lékařem nebo na lékařský předpis.

Přední krční dlahové systémy SLIM-LOC a SKYLINE™ jsou určeny pro stabilizaci krční páteře v oblasti od C2 po C7 pomocí unikortikální fixace šrouby na přední straně těl obratlů. Mezi klinické indikace pro použití předních dlažek patří: nestabilita způsobená traumatem, nestabilita spojená s korekcí deformity krční lordózy a kyfózy, nestabilita spojená s pseudoartrózou v důsledku předchozí nezdařené operace krční páteře, nestabilita spojená s větší rekonstrukční operací primárních tumorů nebo metastatických zhoubných tumorů krční páteře, nestabilita spojená s jednostupňovou nebo vícestupňovou korpetomií při pokročilém degenerativním onemocnění plotének, stenóza páteřního kanálu a krční myleopatie.

Přední kompresní dlahový systém PEAK, polyaxiální přední krční dlahový systém PEAK, ventrální systém krční stabilizace DOC, přední krční dlahový systém EAGLE, přední krční dlahový systém SWIFT a přední krční dlahový systém UNIPLATE jsou určeny pro přední intervertebrální fixaci obratlů krční páteře. Tyto systémy jsou určeny pro pacienty, u nichž je požadována stabilita po přední cervikální fúzi pro níže uvedené indikace. Zamýšlená oblast léčby je v rozmezí C2 až T1.

Mezi indikace patří symptomatická spondylóza krční páteře, trauma, fraktura, poúrazová kyfóza nebo lordóza, tumor, degenerativní onemocnění meziobratlových plotének (definované jako diskogenní bolest s degenerací ploténky potvrzená anamnézou a rentgenovými snímky), opakovaná operace z důvodu neúspěšné fúze nebo nestability po operaci pro výše uvedené indikace.

Přední krční dlahový systém UNIPLATE je také určen k léčbě stenózy páteře.

UPOZORNĚNÍ: Tato zařízení nejsou schválena k přišroubování ani k fixaci k zadním pediklům krční, hrudní nebo bederní páteře.

## POOPERAČNÍ MOBILIZACE

Než je rentgenem potvrzena zralost svalku, může být podle uvážení lékaře doporučeno vnější znehybnění (např. korzetem).

Stejně důležitou součástí pokusu o zabránění výskytu klinických problémů, které mohou doprovázet selhání fixace, je poučení pacienta, aby snížil zatěžování implantátů.

## KONTRAINDIKACE

- aktivní systémová infekce nebo infekce v místě zamýšleného vložení implantátu
- těžká osteoporóza může zamezit dostatečnému upevnění šroubů a znemožnit použití tohoto nebo jakéhokoliv jiného systému nástrojů pro operaci páteře
- pacienti, kteří byli spolehlivě a předvídatelně ošetřeni bez interní fixace
- otevřená poranění

## RELATIVNÍ KONTRAINDIKACE:

Mezi relativní kontraindikace patří jakákoliv věc nebo podmínky, které zcela znemožňují fúzi (např. rakovina, dialýza ledvin nebo osteopenie), obezita, určitá degenerativní onemocnění a přecitlivělost na cizí tělesa.

## UPOZORNĚNÍ, PREVENTIVNÍ OPATŘENÍ A NEŽÁDOUCÍ ÚČINKY PŘI POUŽITÍ KOVOVÝCH ZAŘÍZENÍ PRO DOČASNOU INTERNÍ FIXACI

### UPOZORNĚNÍ

Operatér by měl znát a vysvětlit pacientovi následující specifická upozornění, preventivní opatření a nežádoucí účinky. Tato upozornění nezahrnují všechny nežádoucí účinky, ke kterým může obecně při operaci dojít, ale jsou závažným činitelem, který je nutné vzít v úvahu při použití takových zařízení, jako jsou kovová interní fixační zařízení. Pacient by měl být před operací seznámen s obecnými riziky operace.

Mezi potenciální rizika spojená s použitím tohoto systému, která mohou vyžadovat další operaci, patří: zlomení součásti zařízení, ztráta fixace, pakloub, fraktura obratle, neurologické poranění a vaskulární nebo viscerální poranění.

1. **SPRÁVNÁ VOLBA IMPLANTÁTU JE VELMI DŮLEŽITÁ.** Možnost úspěšné fixace se zvyšuje volbou správné velikosti, tvaru a konstrukce implantátu. I když správný výběr může minimalizovat rizika, velikost a tvar lidských kostí představuje omezení velikosti, tvaru a síly implantátu. Kovová zařízení pro interní fixaci nemohou snášet takové aktivity jako zdravá kost. Od žádného implantátu nelze očekávat, že odolá úplnému zatížení bez podpory.
2. **IMPLANTÁTY SE MOHOU ZLOMIT, JSOU-LI VYSTAVENY ZVÝŠENÉMU ZATÍŽENÍ SPOJENÉMU S PRODLOUŽENÝM HOJENÍM NEBO PAKLOUBEM (PSEUDOARTRÓZA).** Nástroje pro interní fixaci sdílejí zatížení a používají se pro dosažení správné polohy, než dojde k normálnímu zhojení. Pokud trvá hojení déle nebo k němu vůbec nedojde, může se implantát v důsledku únavy kovového materiálu nakonec zlomit. Největší vliv na životnost implantátu mají kromě ostatních podmínek stupeň spojení a jeho úspěšnost, námaha způsobená zatěžováním a úroveň aktivity. Zářezy, škrábance a ohýbání implantátu během operace mohou také přispět k brzkému selhání. Pacienti by měli být plně informováni o rizicích selhání implantátu.
3. **KOMBINOVÁNÍ KOVŮ MŮŽE ZPŮSOBIT KOROZI.** Poškození korozí má mnoho forem a některé z nich se vyskytují u kovů chirurgicky implantovaných pacientům. Plošná nebo rovnoměrná koroze je přítomna ve všech implantovaných kovech a slitinách. Rychlost koroze kovových implantátů je většinou velmi nízká vzhledem k přítomnosti pasivních vrstev na povrchu. Kontakt rozdílných kovů, například titanu a nerezavějící oceli, urychluje proces koroze nerezavějící oceli a dochází k prudšímu napadení. Koroze často urychluje únavu materiálu implantátů a jejich zlomení. Zvýší se také podíl kovových složek uvolňovaných do tělního systému. Zařízení pro interní fixaci, například tyčinky, háčky, dráty atd., která se dotýkají jiných kovových předmětů, musí být vyrobena ze stejných nebo kompatibilních materiálů.
4. **VÝBĚR PACIENTŮ.** Při výběru pacientů, u nichž má být použito zařízení pro interní fixaci, mohou být pro úspěch procedury velmi důležité tyto faktory:

   A. **Zaměstnání a aktivity pacienta:** Pokud pacient v zaměstnání nebo v rámci jiné činnosti zvedá těžké předměty, zatěžuje svaly, otáčí se, opakovaně se ohýbá, shýbá, běhá, hodně chodí nebo se věnuje manuální práci, nesmí tyto činnosti provádět, dokud kost není úplně zhojena. Pacient nemusí být schopen vrátit se k těmto činnostem bez omezení, i když došlo k úplnému zahojení.

   B. **Senilita, duševní nemoci, alkoholismus a užívání drog:** Tyto a další stavy by mohly zapříčinit, že pacient bude ignorovat určitá nezbytná omezení a opatření důležitá pro použití zařízení, což by mělo za následek neúspěšné použití implantátu nebo jiné komplikace.

   C. **Určitá degenerativní onemocnění.** V některých případech může být v době implantace průběh degenerativních onemocnění tak pokročilý, že by to mohlo podstatně snížit očekávanou životnost nástroje. V takových případech mohou být ortopedické pomůcky považovány jen za oddalovací techniku nebo dočasné opatření.



   D. **Přecitlivělost na cizí tělesa.** Operatér by si měl být vědom, že žádný předoperační test nemůže úplně vyloučit možnost zvýšené senzitivity nebo alergické reakce. Jsou-li implantáty v těle po určitou dobu, může se vyvinout u pacientů vyvinout přecitlivělost nebo alergie.

   E. **Kouření.** U pacientů, kteří kouří, byl po operačních procedurách s použitím kostního štěpu pozorován častější výskyt pseudoartrózy. Kouření dále způsobuje difúzní degeneraci meziobratlových plotének. Pokročilá degenerace přilehlých segmentů způsobená kouřením může vést k pozdějšímu klinickému selhání (návrat bolesti), dokonce i po úspěšné fúzi a počátečním klinickém zlepšení.

UPOZORNĚNÍ: Pokud v očekávané době nedojde ke kostní fúzi, šrouby mohou v důsledku vysokého a trvalého zatížení tohoto zařízení prasknout. K tomu došlo u pacientů s prodlouženým hojením, pseudoartrózou nebo nezhojením. Důsledkem takové situace může být nutnost revize zařízení.

### BEZPEČNOSTNÍ OPATŘENÍ

1. **CHIRURGICKÉ IMPLANTÁTY NESMĚJÍ BÝT NIKDY OPAKOVANĚ POUŽITY.** Explantovaný implantát by nikdy neměl být implantován opakovaně. Přestože zařízení vypadá nepoškozené, může obsahovat drobné vady a známky vnitřního tlaku, které mohou vést k brzkému zlomení.
2. **VELMI DŮLEŽITÉ JE SPRÁVNÉ ZACHÁZENÍ S IMPLANTÁTEM.** Tvarování kovových implantátů provádějte jen s řádným vybavením. Operatér by se měl při tvarování vyvarovat jakéhokoliv škrábání, řezání do implantátu a jeho ohýbání na opačnou stranu. Změny způsobí defekty v provedení povrchu a vnitřní tlak, které by se mohly stát hlavní příčinou možného prasknutí implantátu. Implantát nepoužívejte, máte-li podezření, že je poškozen.

   Nadměrné utažení šroubů při usazování dlažky může způsobit poškození kosti a vyústit ve stržení závitů nebo omezení pevnosti přichycení šroubu.
3. **OHÝBÁNÍ KONSTRUKCE.** Součásti ze slitiny titanu se nesmějí ohýbat ostře ani na opačnou stranu. Pokud došlo k nevhodnému vytvarování konstrukce, doporučuje se vytvarovat novou, nikoli ohýbat nevhodně vytvarovanou konstrukci na opačnou stranu.
4. **VYJMUTÍ IMPLANTÁTU PO ZAHOJENÍ.** Není-li zařízení po ukončení zamýšleného použití vyjmuto, může nastat některá z následujících komplikací: (1) koroze a následná reakce okolní tkáně nebo bolest, (2) migrace implantátu a následné poranění, (3) riziko dalšího poranění způsobené pooperačním traumatem, (4) ohnutí, uvolnění anebo prasknutí, které by mohlo znemožnit nebo ztížit vyjmutí, (5) bolest, nepohodlí nebo abnormální pocity způsobené přítomností zařízení, (6) možné zvýšení rizika infekce a (7) ztráta kosti z důvodu ochrany před zátěží. Operatér by měl při rozhodování o vyjmutí implantátu důkladně zvážit rizika a výhody. Po vyjmutí implantátu by měla následovat přiměřená pooperační léčba, aby nedošlo k opakované zlomenině nebo deformitě. Je-li pacient starší a má-li nízkou úroveň aktivity, může se operatér rozhodnout implantát ponechat a vyhnout se tak riziku spojenému s druhou operací.
5. **PACIENTA DOSTATEČNĚ INFORMUJTE.** Mezi nejdůležitější aspekty úspěšného zahojení kosti patří pooperační péče a pacientova schopnost a ochota dodržovat pokyny. Pacient musí být seznámen s omezeními implantátu a poučen o tom, že má omezit a snížit fyzické aktivity, zejména zvedání a otáčivé pohyby a účast na jakémkoliv typu sportu. Pacient by měl vědět, že kovový implantát není tak pevný, jako normální zdravá kost a při nadměrné zátěži by se mohl uvolnit, ohnout nebo zlomit, zvlášť pokud nedošlo k úplnému zhojení kosti. U implantátů, které byly dislokovány nebo poškozeny nevhodnou činností, může dojít k migraci a poškození nervů nebo krevních cév. Při pooperační rehabilitaci jsou ohrožení především aktivní, oslabení nebo dementní pacienti, kteří neumějí správně používat podpěrná zařízení.

### MOŽNÉ NEŽÁDOUCÍ ÚČINKY

1. pakloub, prodloužené hojení
2. ohnutí nebo zlomení implantátu, uvolnění implantátu
3. přecitlivělost na kov nebo alergická reakce na cizí těleso
4. infekce, časná nebo pozdní
5. úbytek hustoty kosti z důvodu ochrany před zatížením
6. bolest, nepohodlí nebo abnormální pocity z důvodu přítomnosti zařízení
7. poškození nervu v důsledku operačního traumatu nebo přítomnosti zařízení neurologické potíže včetně radikulární bolesti, přiškrcení nervů v jizevnaté tkáni, svalová slabost a parestézie
8. vaskulární poškození by mohlo vést ke katastrofálnímu nebo smrtelnému krvácení špatně umístěné implantáty přilehlé k velkým tepnám nebo žilám by mohly erodovat tyto cévy a způsobit katastrofální krvácení v pozdním pooperačním období
9. trhliny v tvrdé pleně mozkové vzniklé při operaci si mohou vyžádat další operaci za účelem rekonstrukce tvrdé pleny mozkové nebo způsobit chronický únik mozkomíšního moku nebo píštěl a možný zánět mozkových blan
10. burzilida
11. paralýza
12. perforace, eroze nebo podráždění jícnu
13. vytažení šroubu, které může vést k erozi jícnu, uvolnění implantátu anebo reoperaci z důvodu vyjmutí zařízení
14. poškození lymfatických cév anebo vylučování lymfatické tekutiny
15. utlačení nebo poškození míchy
16. zlomenina kostních struktur
17. degenerativní změny nebo nestabilita segmentů přilehlých ke spojeným úrovním obratlů
18. smrt

OMEZENÁ ZÁRUKA A ODMÍTNUTÍ ODPOVĚDNOSTI: PRODUKTY SPOLEČNOSTI DEPUY SPINE JSOU PŮVODNÍMU KUPUJÍCÍMU PRODÁVÁNY S OMEZENOU ZÁRUKOU NA VÝROBNÍ A MATERIÁLOVÉ VADY. VŠECHNY OSTATNÍ ZÁRUKY, VÝSLOVNĚ UVEDENÉ NEBO PŘEDPOKLÁDANÉ, VČETNĚ ZÁRUK OBCHODOVATELNOSTI A VHODNOSTI PRO DANÝ ÚČEL, JSOU TÍMTO ODMÍTNUTY.

POKUD MEZI DATEM VYDÁNÍ/REVIZE A DATEM KONZULTACE UPLYNULY VÍCE NEŽ DVA ROKY, OBRAŤTE SE NA ZÁSTUPCE SPOLEČNOSTI DEPUY SPINE™ A POŽÁDEJTE HO O AKTUÁLNÍ INFORMACE na telefonním čísle 800-365-6633 nebo +1-508-880-8100.

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DATUM POSLEDNÍ REVIZE:
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**VYSVĚTLENÍ SYMBOLŮ**

| | | | |
|---|---|---|---|
| LOT ČÍSLO ŠARŽE | NA JEDNO POUŽITÍ | NONSTERILE NESTERILNÍ | VÝROBCE |
| REF KATALOGOVÉ ČÍSLO | XXXX-XX DATUM POUŽITÍ | STERILE R STERILIZOVÁNO OZÁŘENÍM | EC REP AUTORIZOVANÝ ZÁSTUPCE PRO EVROPU |
| QTY MNOŽSTVÍ | VIZ NÁVOD K POUŽITÍ | STERILE EO STERILIZOVÁNO ETYLENOXIDEM | DIST DISTRIBUCE |
| Rx Only Federální zákony USA omezují prodej tohoto zařízení na prodej lékařem nebo na lékařský předpis. | STERILE STERILIZOVÁNO | MADE IN VYROBENO | SZ VELIKOST |

**MATERIÁL MATL**

| | | |
|---|---|---|
| A/T ACROFLEX™/Ti ACROFLEX™/Titan | PY Polyester | SS/RADEL™/ SRTA Ti Al Nitride Nerezavějící ocel/RADEL™/ Titan-aluminium-nitrid |
| A Al Aluminium | P POLYMER Polymer | STA SS/Ti Al Nitride Nerezavějící ocel/ Titan-aluminium-nitrid |
| A/P Al/PL Aluminium/Umělá hmota | P/CM PE/CoCrMo Polyetylén/Slitina kobalt, chrom, molybden | S/U SS/ULTEM Nerezavějící ocel/Ultem |
| S/R Ba/RADEL™ Baryum/RADEL™ | POLYMER/CARBON P/C FIBER COMPOSITE Kombinace polymeru s uhlíkovým vláknem | T Ti Titan a jeho slitiny |
| CaP CALCIUM PHOSPHATE Kalciumfosfát | S SS Nerezavějící ocel | S/R SS/RADEL Nerezavějící ocel/RADEL™ |
| CM CoCrMo Slitina kobalt, chrom, molybden | S/A SS/Al Nerezavějící ocel/Aluminium | R/T POLYOLEFIN RUBBER/Ti Polyolefinová guma/Titan |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Slitina kobalt, chrom molybden/Titan/Kalciumfosfát | SBR SS/Ba/RADEL™ Nerezavějící ocel/ Baryum/RADEL™ | T/A Ti/Al Titan/Aluminium |
| F FOAM Pěna | S/P SS/PHENOLIC Nerezavějící ocel/Fenoplast | Ti/UHMWPE/HA Titan/Vysokomolekulární polyethylen/Hydroxylapatit |
| HA Hydroxylapatit | S/PL SS/PL Nerezavějící ocel/Umělá hmota | SS/Ti Nerezavějící ocel/Titan |
| NiTi Ni/Ti Nikl/Titan | SS/RADEL™/ SRSI SILICONE Nerezavějící ocel/ RADEL™/Silikon | SS/Al/SILICONE Nerezavějící ocel/ Aluminium/Silikon |
| PL Umělá hmota | SS/RADEL™/ SRSN SILICONE/Ti Al Nitride Nerezavějící ocel/RADEL™/ Silikon/Titan-aluminium-nitrid | S/SI SS/SILICONE Nerezavějící ocel/Silikon |
| P/F PL/FOAM Umělá hmota/Pěna | | |



da

# PEAK ANTERIORT KOMPRESSIONSSKINNESYSTEM

# PEAK POLYAKSIALT ANTERIORT CERVIKALSKINNESYSTEM

# DOC VENTRALT CERVIKALT STABILISERINGSSYSTEM

# SLIM-LOC™ ANTERIORT CERVIKALSKINNESYSTEM

# EAGLE™ ANTERIORT CERVIKALSKINNESYSTEM

# SWIFT™ ANTERIORT CERVIKALSKINNESYSTEM

# UNIPLATE™ ANTERIORT CERVIKALSKINNESYSTEM

# SKYLINE™ ANTERIORT CERVIKALSKINNESYSTEM

## VIGTIG OPLYSNING TIL DEN ANSVARLIGE KIRURG

Anteriore cervikale stabiliseringssystemimplantater har en begrænset levetid ligesom alle andre interne fikseringsimplantater. Patientens aktivitetsniveau har en betydelig indvirkning på denne levetid. Patienten skal informeres om, at enhver aktivitet forøger risikoen for løsning, bøjning eller brud på implantatkomponenterne. Det er af afgørende betydning at instruere patienter i at begrænse deres aktiviteter i den postoperative periode og at undersøge patienter postoperativt for at vurdere fusionsmassens udvikling og implantatkomponenternes status. Selv om der forekommer massiv knoglefusion, kan implantatkomponenter ikke desto mindre bøje, frakturere eller løsne sig. Derfor skal patienten informeres om, at implantatkomponenter kan bøje, frakturere eller løsne sig, selv om aktivitetsbegrænsningerne følges.

På grund af begrænsningerne, der skyldes anatomiske faktorer og moderne operationsmaterialer, vil metalimplantater ikke have en ubegrænset levetid. Deres formål er at yde midlertidig, intern støtte, mens fusionsmassen konsolideres. Der er større risiko for, at disse implantattyper svigter, hvis der ikke anvendes knogletransplantater, eller hvis der udvikler sig en pseudoartrose. Kirurgen kan beslutte at fjerne disse implantater, når der er indtruffet knoglefusion. Muligheden for endnu et operativt indgreb samt de risici, der er forbundet hermed, skal diskuteres med patienten. Hvis implantaterne frakturerer, skal beslutningen om, hvorvidt de skal fjernes, træffes af lægen, som skal bedømme patientens tilstand og de risici, der er forbundet med tilstedeværelsen af det frakturerede implantat.

## BESKRIVELSE

PEAK anteriort kompressionsskinnesystem består af en række skinner og skruer af titaniumlegering. Skinnerne fås i længder fra 26-94 mm, der passer til en til fire fikseringssegmenter. Systemet omfatter også 3,5 mm kortikalskruer og 4,0 mm spongiosaskruer af titaniumlegering, der fås i længder fra 8 mm til 30 mm.

PEAK polyaksialt anteriort cervikalskinnesystem består af en række skinner og skruer af titaniumlegering. De anteriore cervikalskinner findes i størrelser fra 24 mm til 110 mm, så de passer til en til fire fikseringssegmenter. Spongiosaskruerne fås i diametre på 4,0 mm og 4,35 mm. De har fuldt gevind og findes i længder fra 10 til 26 mm.

DOC ventralt cervikalt stabiliseringssystem er et platform-, skinne-, stav- og skruesystem af titaniumlegering, der anvendes til at hjælpe spinalkirurger ved korrektion af cervikale rygsøjledefekter og -stabilisering. DOC ventralt cervikalt stabiliseringssystem består i sin fuldt samlede form af en skinne eller to lateralt anbragte stave, der er forbundet ved hjælp af platforme, der ligger på den anteriore hvirveloverflade. Systemet er forankret til hvirvlen med skruer. Implantatet giver supplerende stabilitet til den cervikale rygsøjle efter anterior cervikal fusion. Afhængigt af implantatetkonfigurationen kan den bruges som enten en stiv (belastningsunderstøttende) eller dynamisk (belastningspredende) konstruktion.

Der findes følgende komponenttyper i systemet: Stave, skinner, platforme, indre og ydre knogleskruer, implantatskruer og tværsamlestykker. Alle komponenter er fremstillet af en titaniumlegering af implantatkvalitet, der er i overensstemmelse med specifikationerne ASTM F-136. Der er også samlinger til rådighed for at gøre det lettere for kirurgen. Disse er præsamlede, delvise konstruktioner, der består af en platform, et tværsamlestykke, to stave og to blokeringsskruer.

**Platform:** Platforme er designede til at forbinde stavene og ankeret til hvirvellegemerne med knogleskruer. Alle platforme kan anvendes med enten massive knogleskruer (til bikortikal fiksering) eller kombinationen af ydre og indre knogleskruer (en hul ydre knogleskrue anvendt sammen med en massiv indre blokeringsskrue, der er designet til unikortikal fiksering). Skruevalget træffes af lægen. Alle platforme er designede til at blive anvendt sammen med to stave ved dannelsen af konstruktionen.

Platforme leveres i låselige og ikke-låselige design. Låselige platforme er udstyret med forlængere, der accepterer blokeringsskruer til platforme/tværsamlestykker til at sikre platformen til stavene. Låselige platforme er påkrævet til brug for enden af konstruktionen modsat stavhovederne.

Hvis der foretrækkes en stiv konfiguration frem for en dynamisk (dvs. belastningsspredende) konfiguration, skal der også anvendes en låselig platform ved siden af stavhovederne. Hvis der ønskes en belastningsspredende konfiguration, er platformen ved siden af stavhovederne ikke låst til stavene.

Der er designet mange forskellige platforme til vinkelformet insertion af skruen i hvirvellegemet. De leveres i både låselige og ikke-låselige design. Disse platforme har en finneanordning på den ene side, som griber ind i hvirvlen indefra discusrummet for at opnå optimal anbringelse og fiksering.

Der er designet mange forskellige platforme til lige (vinkelret) insertion af skruen i hvirvellegemet. De leveres i både låselige og ikke-låselige design.

Der findes et platformdesign til fiksering af konstruktionen til et intervertebralt implantat. Denne platform indeholder en vandret spalteåbning og en kuglefordybning til at skaffe variation i skrueindgangssted og i banen til implantatet.

Valg af platform baseres på lægens vurdering og patientens anatomi.

SLIM-LOC™ anteriort cervikalskinnesystem består af en række skinner og skruer af titaniumlegering. Skinnerne fås i længder fra 22 til 111 mm i konfigurationer med 2, 3, 4, 5 eller 6 par skruehuller. SLIM-LOC skruerne fås med en diameter på 4,5 mm og leveres som selvborende i lige længder fra 10-18 mm eller selv-skærende i lige længder fra 10-26 mm. Skruer med større diameter (4,8 mm) fås i længder på 12, 14 og 16 mm.

EAGLE™ anteriort cervikalskinnesystem består af en række skinner og skruer af titaniumlegering. Skinnerne fås med 2-6 par skruehuller i diverse længder. Skruerne fås i diverse størrelser og med diverse spidsformer.

SWIFT™ anteriort cervikalskinnesystem er fremstillet af titaniumlegering og består af segmenterede skinner, hvor der er plads til op til 2 mm kontrolleret implantatplacering mellem hvert segment. Skinnerne fås med 2-6 par skruehuller, i diverse længder og i to konfigurationer, til diskektomi og korpektomi. Skruerne fås i diverse størrelser og med diverse spidsformer. Der fås en implantatskrue til korpektomiskinner.

UNIPLATE™ anteriort cervikalskinnesystem består af en række skinner og skruer af titaniumlegering. Skinnerne fås i diverse længder for at kunne tilpasses fiksering af et til to segmenter. Skruerne fås i diverse størrelser og med diverse spidsformer.

SKYLINE™ anteriort cervikalskinnesystem består af en række skinner og skruer af titaniumlegering. Skinnerne har to til seks par skruehuller i diverse længder. Skruerne fås i diverse størrelser og med diverse skruespidsformer. Der findes både faste og variable skruer til dannelse af en fast, variabel eller hybrid konfiguration.

## RENGØRING OG STERILISERING

Implantaterne i cervikalskinne-stabiliseringssystemerne leveres enten sterile eller rene og usterile. Ved komponenter, der leveres sterile, skal det sikres, at pakningen ikke er beskadiget inden brug.

Ved usterile produkter bør ISO 8828 eller AORN's anbefalede praksis for hospitalssterilisering følges for alle komponenter.

Der er foretaget afprøvninger for at udvikle følgende ANBEFALINGER FOR DAMPSTERILISERING:

| | |
|---|---|
| Cyklus | Prævakuum |
| Temperatur | 270 °F<br>132 °C |
| Eksponeringstid | 6 min. |

## ANVENDELSE

Kirurgen skal have grundigt kendskab til ikke blot de medicinske og kirurgiske aspekter af implantatet, men skal også være klar over de mekaniske og metallurgiske begrænsninger ved kirurgiske metalimplantater. Efterbehandling er yderst vigtig. Patienten skal informeres om metalimplantatets begrænsninger og advares vedrørende vægtbelastning og kropsbelastninger af implantatet inden fuld knogleheling. Patienten skal informeres om, at manglende overholdelse af postoperative anvisninger kan føre til implantatsvigt og herefter muligt behov for yderligere indgreb til fjernelse af implantatet.

DePuy Spine spinalsystem-komponenter må ikke bruges med komponenter fra andre producenter.

**For at opnå kontrolleret vertikal overføring (belastningsspredende), er korrekt placering af valgte komponenter af afgørende betydning.**

**Der henvises til operationsteknikmanualen for specifikke anvisninger.**

## INDIKATIONER

FORSIGTIG: I henhold til gældende lov (USA) må disse anordninger kun forhandles til eller ordineres af en læge.

SLIM-LOC anteriort cervikalskinnesystem og SKYLINE™ anteriort cervikalskinnesystem er beregnet til stabilisering af cervikalrygsøjlen fra C2 til C7 ved hjælp af unikortikal skruefiksering ved den anteriore flade af vertebrae. De specifikke kliniske indikationer for anterior skinnefiksering omfatter: ustabilitet forårsaget af traume, ustabilitet associeret med korrektion af cervikal lordose- og kyfosedeformitet, ustabilitet associeret med pseudoarthose som et resultat af tidligere mislykket spinalkirurgi, ustabilitet associeret med større rekonstruktiv kirurgi for primærtumorer eller metastatiske maligne tumorer i cervikalsøjlen, ustabilitet associeret med korpektomi på enkelt eller multipelt niveau ved fremskreden, degenerativ discussygdom, spinalkanalstenose og cervikal myelopati.

PEAK anteriort kompressionsskinnesystem, PEAK polyaksialt anteriort cervikalskinnesystem, DOC ventralt cervikalt stabiliseringssystem, EAGLE anteriort cervikalskinnesystem, SWIFT anteriort cervikalskinnesystem og UNIPLATE anteriort cervikalskinnesystem er beregnet til cervikal fiksering af intervertebrallegemet. Disse systemer indiceres til patienter, hvor der ønskes stabilitet efter anterior cervikal fusion på grund af de indikationer, der er opført herunder. De påtænkte behandlingsniveauer går fra C2 til T1.



Indikationer omfatter symptomatisk cervikal spondylose, traume, fraktur, posttraumatisk kyfose eller lordose, tumor, degenerativ discussygdom (defineret som discogen rygsmerte med degeneration af discus bekræftet af forløb og røntgenundersøgelser), reoperation på grund af mislykket fusion eller ustabilitet efter operation, der er foretaget efter ovenstående indikationer.

UNIPLATE anteriort cervikalskinnesystemet er også indiceret til behandling af spinalstenose.

ADVARSEL: Disse implantater er ikke godkendt til skruefastgøring eller -fiksering til de posteriore elementer (pedikler) i den cervikale, thorakale eller lumbale rygsøjle.

## POSTOPERATIV MOBILISERING

Ekstern immobilisering (såsom skinne) kan anbefales efter lægens vurdering, indtil røntgenundersøgelse bekræfter modning af fusionen.

Patientanvisninger på at mindske belastning af implantaterne er en lige så vigtig del af forsøget på at undgå forekomsten af kliniske problemer, der kan være en følgevirkning af fikseringssvigt.

## KONTRAINDIKATIONER

- Aktiv systemisk infektion eller en infektion, der er lokaliseret til det foreslåede implantationssted.
- Svær osteoporose kan hindre tilstrækkelig fiksering af skruer og således udelukke anvendelsen af dette eller ethvert andet spinalinstrumenteringssystem.
- Patienter, som har vist sig at være sikkert og forudsigeligt behandlet uden intern fiksering.
- Åbne sår.

## RELATIVE KONTRAINDIKATIONER:

Relative kontraindikationer omfatter enhver eksistens eller tilstand, der fuldstændigt udelukker muligheden for fusion (dvs. cancer, nyredialyse, eller osteopeni), fedme, visse degenerative sygdomme og overfølsomhed over for fremmedlegemer.

## ADVARSLER, FORHOLDSREGLER OG BIVIRKNINGER VEDRØRENDE MIDLERTIDIGE INTERNE METAL-FIKSERINGSIMPLANTATER

### ADVARSLER

Følgende er særlige advarsler, forholdsregler og bivirkninger, som kirurgen skal forstå og forklare patienten. Disse advarsler omfatter ikke alle bivirkninger, som kan opstå ved kirurgi i almindelighed, men er vigtige betragtninger især for interne metalfikseringsimplantater. Generelle operationsrisici skal forklares for patienten inden operation.

Mulige risici, der identificeres med anvendelsen af dette implantatsystem, og som kan kræve yderligere operation, omfatter: Fraktur af implantatkomponent, manglende fiksering, manglende heling, fraktur af hvirvlen, neurologisk læsion og vaskulær læsion eller læsion af indre organer.

1. **KORREKT IMPLANTATVALG ER YDERST VIGTIGT.** Muligheden for tilfredsstillende fiksering øges ved korrekt valg af størrelse, form og implantatdesign. Mens korrekt valg kan være med til at mindske risici, giver størrelsen og formen på menneskelige knogler begrænsninger af størrelsen, formen og styrken på implantater. Interne metalfikseringsimplantater kan ikke modstå samme aktivitetsniveauer som de niveauer, der belaster normal sund knogle. Intet implantat kan forventes i det uendelige at modstå understøttet fuld vægtbelastning.
2. **IMPLANTATER KAN FRAKTURERE, NÅR DE UDSÆTTES FOR ØGET BELASTNING FORBUNDET MED FORSINKET ELLER MANGLENDE HELING.** Interne fikseringsimplantater er belastningsspredende anordninger, som bruges til at opnå opretning, indtil der indtræffer normal heling. Hvis heling er forsinket eller ikke forekommer, kan implantatet med tiden frakturere på grund af metaltræthed. Implantatets levetid vil bl.a. dikteres af helingsgraden, belastninger forårsaget af vægtbelastning og aktivitetsniveauer. Skrammer, ridser eller bøjning af implantatet under operationsforløbet kan også bidrage til tidligt svigt. Patienter bør modtage fuld information om risici for implantatsvigt.
3. **METALSAMMENSÆTNINGER KAN FORÅRSAGE KORROSION.** Der er mange former for korrosionskader, og flere af disse forekommer på metaller, der implanteres i mennesker. Der forekommer generel eller ensartet korrosion på alle implanterede metaller og legeringer. Hyppigheden af tærende angreb på metalimplantater er sædvanligvis meget lav på grund af belægninger med passiv overfladefilm. Forskellige metaller, der kommer i kontakt med hinanden, såsom titanium og rustfrit stål, øger hastigheden på korrosionsprocessen for rustfrit stål, og flere angreb opstår hurtigt. Forekomsten af korrosion fremskynder ofte træthedsfraktur på implantater. Mængden af frigjorte metalforbindelser i kroppen øges også. Interne fikseringsimplantater, såsom stave, kroge, tråde osv., som kommer i kontakt med andre metalgenstande, skal være fremstillet af de samme eller kompatible materialer.
4. **PATIENTVALG.** Når patienter skal godkendes til implantation af interne fikseringsanordninger, kan følgende faktorer være yderst vigtige for det endelige resultat af indgrebet:

   A. **Patientens beskæftigelse eller aktivitet.** Hvis patientens beskæftigelse eller andre aktiviteter medfører løftning af tunge genstande, muskelbelastninger. drejninger, gentagne bøjninger, forøverbøjet gang, løb. gang i stor udstrækning eller manuelt arbejde, skal han/hun ikke genoptage disse aktiviteter, før knoglen er fuldt helet. Selv efter fuld heling vil patienten måske ikke være i stand til at genoptage disse aktiviteter med et vellykket resultat.

B. **Tilstande, der indebærer senilitet, sindssygdom, alkoholisme eller medikamentmisbrug.** Disse tilstande kan bl.a. forårsage, at patienten ignorerer visse nødvendige begrænsninger og forholdsregler ved anvendelsen af implantatet, som resulterer i implantatsvigt eller andre komplikationer.

C. **Visse degenerative sygdomme.** I nogle tilfælde kan udviklingen af degenerativ sygdom være så fremskreden på implantationstidspunktet, at den i væsentlig grad kan mindske implantatets forventede levetid. I sådanne tilfælde kan ortopædiske implantater kun betragtes som en forsinkende teknik eller en midlertidig komponent.

D. **Overfølsomhed over for fremmedlegemer.** Kirurgen er klar over, at en præoperativ test ikke fuldstændig kan udelukke muligheden for overfølsomhed eller allergisk reaktion. Patienter kan udvikle overfølsomhed eller allergi, når implantater har været i kroppen i et stykke tid.

E. **Rygning.** Det har vist sig, at patienter, der ryger, hyppigere udvikler pseudoartrose efter kirurgiske indgreb, hvor der er anvendt knogleimplantat. Desuden har rygning vist sig at forårsage diffus degeneration af disci mellem hvirvellegemerne. Tiltagende degeneration af nærliggende segmenter, der er forårsaget af rygning, kan føre til sent klinisk svigt (tilbagevendende smerte) selv efter vellykket fusion og begyndende kliniske fremskridt.

**ADVARSEL:** Hvis knoglefusion ikke sker inden for et forventet tidsrum, kan skruerne gå i stykker på grund af disse implantaters høje og vedvarende belastning. Dette er bemærket hos patienter med sen pseudoarthrose eller manglende heling og kan medføre revision af implantatet (implantaterne).

## FORHOLDSREGLER

1. **KIRURGISKE IMPLANTATER MÅ ALDRIG GENBRUGES.** Et eksplanteret metalimplantat må aldrig genbruges. Selv om implantatet forekommer ubeskadiget, kan det have små defekter og interne belastningsmønstre, som kan føre til tidlig fraktur.
2. **KORREKT BEHANDLING AF IMPLANTATET ER YDERST VIGTIG.** Konturering af metalimplantater bør kun foretages med korrekt udstyr. Den ansvarlige kirurg bør undgå at skramme, ridse eller bøje implantaterne i modsat retning ved konturering. Ændringer vil resultere i defekter i overfladebelægningen og interne belastninger, som kan blive fokus for eventuelt implantatbrud. Implantatet må ikke anvendes, hvis der er mistanke om beskadigelse.

   Overdreven drejning af skruerne ved fastgørelse af skinnen kan forårsage knoglesvigt med ødelagte gevind og/eller kompromitteret skruefæste som følge.
3. **BØJNING AF KONSTRUKTIONEN.** Komponenter af titaniumlegering må aldrig bøjes skarpt eller i modsat retning. Hvis en konstruktion er overkontureret, anbefales det, at en ny konstruktion kontureres korrekt i stedet for at bøje den overkonturerede konstruktion i modsat retning.
4. **FJERNELSE AF IMPLANTATET EFTER HELING.** Hvis implantatet ikke fjernes, når den påtænkte anvendelse er fuldført, kan enhver af følgende komplikationer forekomme: (1) Korrosion, med lokaliseret vævsreaktion eller smerte. (2) Migration af implantatplacering resulterende i læsion. (3) Risiko for yderligere læsion fra postoperativ traume. (4) Bøjning, løsning og/eller brud, som kan umulig- eller vanskeliggøre fjernelse. (5) Smerte, ubehag eller unormale følelser på grund af implantatets tilstedeværelse. (6) Mulig øget infektionsrisiko, og (7) knogletab på grund af belastningsbeskyttelse. Kirurgen bør omhyggeligt veje risici mod fordele, når det skal besluttes, hvorvidt implantatet skal fjernes. Fjernelse af implantat skal efterfølges af efterbehandling for at undgå en ny fraktur eller deformation. Hvis patienten er ældre og har et lavt aktivitetsniveau, kan kirurgen vælge ikke at fjerne implantatet og således undgå de risici, som endnu et operativt indgreb indebærer.
5. **TILSTRÆKKELIG PATIENTANVISNING.** Efterbehandling og patientens evne og villighed til at følge anvisninger er blandt de vigtigste aspekter ved vellykket knogleheling. Patienten skal gøres klar over implantatets begrænsninger og instrueres i at begrænse og indskrænke fysiske aktiviteter, i særlig grad løftende og drejende bevægelser og enhver form for sportsudøvelse. Patienten skal forstå, at et metalimplantat ikke er så stærkt som en normal sund knogle, og at det kan løsne sig, bøje og/eller frakturere, hvis der kræves for meget af det, særlig når der ikke er forekommet fuldkommen knogleheling. Implantater, der er anbragt forkert eller er beskadigede, kan vandre og beskadige nerver eller blodkar. En aktiv, debil eller dement patient, som ikke kan anvende anordninger til vægtstøtte korrekt, er særlig udsat under postoperativ revalidering.

## MULIGE BIVIRKNINGER

1. Manglende og sen heling.
2. Bøjning eller brud på implantat. Løsning af implantat.
3. Metaloverfølsomhed eller allergisk reaktion over for fremmedlegeme.
4. Infektion, tidlig eller sen.
5. Aftagende knogletæthed på grund af belastningsbeskyttelse.
6. Smerte, ubehag eller unormale følelser forårsaget af implantatets tilstedeværelse.
7. Nervelæsion på grund af operationstraume eller implantatets tilstedeværelse. Neurologiske vanskeligheder omfatter radikulær smerte, nervefiksering i arvæv, muskelsvaghed og paræsthesia.
8. Vaskulær læsion kan resultere i katastrofal eller dødelig blødning. Forkert placerede implantater, der ligger tæt på store arterier eller vener, kan arrodere disse kar og forårsage katastrofal blødning i den sene efterbehandlingsperiode.
9. Ruptur af dura, opdaget under operation, kan resultere i behov for yderligere operation for at opnå heling af dura, en kronisk CSF lækage eller fistel og mulig meningitis.
10. Bursitis.



11. Paralyse.
12. Perforering, erosion eller irritation af spiserøret.
13. Skruetilbagetrækning, der muligvis fører til erosion af spiserøret, implantatløsning og/eller reoperation for at fjerne implantat.
14. Læsion af lymfekar og/eller ekssudation af lymfevæske.
15. Stød mod eller beskadigelse af rygmarven.
16. Fraktur af knoglestrukturer.
17. Degenerative ændringer eller ustabilitet i segmenter, der ligger tæt på sammenloddede hvirvelniveauer.
18. Død.

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**SYMBOLOVERSÆTTELSE**

| | | | |
|---|---|---|---|
| LOT PARTINUMMER | ENGANGSBRUG | NONSTERILE IKKE STERIL | PRODUCENT |
| REF KATALOGNUMMER | XXXX-XX ANVENDES FØR | STERILE R STERILISATION VED BESTRÅLING | EC REP AUTORISERET EU-REPRÆSENTANT |
| QTY MÆNGDE | SE BRUGSVEJLEDNING | STERILE EO STERILISATION MED ETYLENOXID | DIST DISTRIBUERET AF |
| Rx Only Amerikansk lov begrænser denne anordning til salg af eller på bestilling af en læge. | STERILE STERIL | MADE IN FREMSTILLET I | SZ STØRRELSE |

**MATERIALE** MATL

| | | |
|---|---|---|
| A/T ACROFLEX™/Ti ACROFLEX™/Titanium | PY Polyester | SS/RADEL™/ SRTA Ti Al Nitride Rustfrit stål/RADEL™/ Titan-aluminium-nitrid |
| A Al Aluminium | P POLYMER Polymer | STA SS/Ti Al Nitride Rustfrit stål/ Titan-aluminium-nitrid |
| A/P Al/PL Aluminium/Plast | P/CM PE/CoCrMo Polyethylen/ Kobolt-krommolybdæn | S/U SS/ULTEM Rustfrit stål/Ultem |
| B/R Ba/RADEL™ Barium/RADEL™ | P/C POLYMER/CARBON FIBER COMPOSITE Polymer/Kulfiberkomposit | T Ti Titanium og dets legeringer |
| CaP CALCIUM PHOSPHATE Calciumphosphat | S SS Rustfrit stål | S/R SS/RADEL™ Rustfrit stål/RADEL™ |
| CM CoCrMo Kobolt-krommolybdæn | S/A SS/Al Rustfrit stål/Aluminium | R/T POLYOLEFIN RUBBER/Ti Polyolefingummi/Titanium |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Kobolt-krommolybdæn/ Titanium/Calciumphosphat | SBR SS/Ba/RADEL™ Rustfrit stål/Barium/RADEL™ | T/A Ti/Al Titanium/Aluminium |
| F FOAM Skum | S/P SS/PHENOLIC Rustfrit stål/Fenol | Ti/UHMWPE/HA Titanium/Polyethylen med ultrahøj molekylvægt/ Hydroxyapatit |
| HA Hydroxyapatit | S/PL SS/PL Rustfrit stål/Plast | SS/Ti Rustfrit stål/Titanium |
| NiTi Ni/Ti Nikkel/Titanium | SRSI SS/RADEL™/ SILICONE Rustfrit stål/RADEL™/Silikone | SS/Al/SILICONE Rustfrit stål/Aluminium/Silikone |
| PL Plast | SRSN SS/RADEL / SILICONE/Ti Al Nitride Rustfrit stål/RADEL™/Silikone/ Titan-aluminium-nitrid | S/SI SS/SILICONE Rustfrit stål/Silikone |
| P/F PL/FOAM Plast/Skum | | |

nl

# PEAK ANTERIEUR COMPRESSIEPLAATSYSTEEM

# PEAK POLYAXIAAL ANTERIEUR CERVIXPLAATSYSTEEM

# DOC VENTRAAL CERVICAAL STABILISATIESYSTEEM

# SLIM-LOC™ ANTERIEUR CERVIXPLAATSYSTEEM

# EAGLE™ ANTERIEUR CERVIXPLAATSYSTEEM

# SWIFT™ ANTERIEUR CERVIXPLAATSYSTEEM

# UNIPLATE™ ANTERIEUR CERVIXPLAATSYSTEEM

# SKYLINE™ ANTERIEUR CERVIXPLAATSYSTEEM

## BELANGRIJKE OPMERKING VOOR DE BEHANDELEND CHIRURG

Anterieure cervicale stabilisatiesysteemimplantaten hebben, zoals andere interne fixeringshulpmiddelen, een beperkte gebruiksduur. Het activiteitenniveau van de patiënt heeft een aanzienlijk effect op deze gebruiksduur. Uw patiënt dient erop gewezen te worden dat lichamelijke activiteiten het risico van losraken, verbuigen of breken van de implantaten verhogen. Het is belangrijk uw patiënten op de hoogte te stellen over beperkingen in hun activiteiten in de postoperatieve periode en uw patiënt na de operatie te onderzoeken om de ontwikkeling van de fusiemassa en de status van de implantaatonderdelen te evalueren. Zelfs als goede botfusie plaatsvindt, is het mogelijk dat implantaatonderdelen verbuigen, breken of losraken. De patiënt dient er op gewezen te worden dat de implantaatonderdelen kunnen verbuigen, breken of losraken, zelfs al heeft hij of zij de activiteiten beperkt.

Vanwege de beperkingen die inherent zijn aan zowel anatomische overwegingen als aan moderne chirurgisch materialen is het onmogelijk metalen implantaten te maken met een onbeperkte levensduur. Het doel van de implantaten is om tijdelijk interne steun te verschaffen terwijl de botfusie consolideert. De kans op falen van dit type implantaat wordt groter als er geen bottransplantaat wordt gebruikt of als er pseudoartrose ontstaat.

De chirurg kan beslissen om deze implantaten te verwijderen nadat de botfusie geheel doorbouwd is. De mogelijkheid van een tweede operatie alsmede de risico's die zijn verbonden aan deze tweede operatie dienen met de patiënt te worden besproken. Als de implantaten breken, dient de beslissing om ze te verwijderen te worden genomen door de arts, die daarbij de lichaamsgesteldheid van de patiënt en de risico's verbonden aan de aanwezigheid van het gebroken implantaat in overweging dient te nemen.

## BESCHRIJVING

Het PEAK anterieure compressieplaatsysteem bestaat uit een assortiment platen en schroeven van een titaniumlegering. De platen zijn verkrijgbaar in lengtematen van 26 mm tot 94 mm, geschikt voor een tot vier fixatiesegmenten. Het systeem omvat tevens corticale schroeven van 3,5 mm en spongieuze schroeven van 4,0 mm van een titaniumlegering, in lengtematen van 8 mm tot 30 mm.

Het PEAK polyaxiale anterieure cervixplaatsysteem bestaat uit een assortiment platen en schroeven van een titaniumlegering. De platen zijn verkrijgbaar in lengtematen van 24 mm tot 110 mm, geschikt voor een tot vier fixatiesegmenten. De spongieuze schroeven zijn verkrijgbaar met een diameter van 4,0 mm en 4,35 mm. Ze hebben een schroefdraad over de gehele lengte en lengtematen van 10 mm tot 26 mm.

Het DOC ventraal cervicaal stabilisatiesysteem is een systeem met platforms, platen, staven en schroeven, vervaardigd van een titaniumlegering, dat wordt gebruikt bij de behandeling van afwijkingen aan, en voor stabilisatie van, de halswervels. Het DOC ventraal cervicaal stabilisatiesysteem in geheel geassembleerde vorm bestaat uit een plaat of twee lateraal geplaatste staven die verbonden zijn met platforms die op het anterieure werveloppervlak rusten. Het systeem wordt met behulp van schroeven op de wervels verankerd. Het implantaat verschaft additionele stabiliteit van de halswervelkolom na anterieure cervicale fusie. Afhankelijk van de configuratie van het implantaat kan het als rigide (lastdragend) element of als dynamisch (lastverdelend) element fungeren.

Het systeem omvat de volgende onderdelen: staven, plaatjes, platforms, binnen- en buitenbotschroeven, transplantaatschroeven en dwarsconnectors. Alle onderdelen zijn vervaardigd van een titaniumlegering voor implantaten die voldoet aan de specificaties van norm ASTM F-136. Om het gebruiksgemak voor de chirurg te verhogen zijn er ook reeds voorgeassembleerde onderdelen beschikbaar. Dit zijn reeds gedeeltelijk geassembleerde constructies die bestaan uit een platform, een dwarsconnector, twee staven en twee borgschroeven.

Platform: De platforms worden verbonden met de staven en op de wervellichamen verankerd door middel van de botschroeven Alle platforms kunnen gebruikt worden met massieve botschroeven (voor bicorticale fixatie) of met een combinatie van buiten- en binnenbotschroeven (een holle buitenbotschroef met een massieve interne bevestigingsschroef voor unicorticale fixatie). De keuze van de schroeven is gebaseerd op de voorkeur van de arts. Alle platforms zijn bestemd voor gebruik met twee staven, en vormen daarmee de constructie.



De platforms zijn beschikbaar in vergrendelbare en niet-vergrendelbare uitvoering. De vergrendelbare platforms hebben verlengstukken voor bevestiging van platform/dwarsconnectorborgschroeven om het platform stevig met de staven te verbinden. De vergrendelbare platforms dienen gebruikt te worden aan het uiteinde van de constructie, tegenover de staafkoppen.

Als de voorkeur wordt gegeven aan een rigide configuratie boven een dynamische (d.w.z. lastverdelende) configuratie, dient ook aan de kant van de staafkoppen een vergrendelbaar platform gebruikt te worden. Als een lastverdelende configuratie gewenst is, wordt het platform aan de kant van de staafkoppen niet op de staven vergrendeld.

Er zijn verscheidene platforms waarbij de botschroef onder een hoek in het wervellichaam geplaatst kan worden. Deze platforms zijn zowel in vergendelbare als in niet-vergrendelbare uitvoering beschikbaar. De platforms hebben aan één kant een vin die de wervel vanuit de discusruimte vastgrijpt voor optimale plaatsing en fixatie.

Verscheidene platforms zijn bestemd voor het onder een rechte hoek (haaks) inbrengen van de schroef in het wervellichaam. Ze zijn zowel in vergrendelbare als in niet-vergrendelbare uitvoering beschikbaar.

Er is een platformuitvoering die het mogelijk maakt om de constructie op het intercorporele transplantaat te verbinden. Dit platform heeft een horizontale gleuf met een sterische uitsparing waardoor variaties in het beginpunt en de baan van de transplantaatschroef in het transplantaat mogelijk zijn.

Keuze van het type platform is gebaseerd op de voorkeur van de arts en op de anatomie van de patiënt.

Het SLIM-LOC™ anterieur cervixplaatsysteem bestaat uit een assortiment platen en schroeven van een titaniumlegering. De platen zijn verkrijgbaar in lengtematen van 22 mm tot 111 mm en met 2, 3, 4, 5 of 6 paar schroefopeningen. De SLIM-LOC schroeven zijn verkrijgbaar met een diameter van 4,5 mm en zijn verkrijgbaar in zelfborende even lengtematen van 10 mm tot 18 mm of in zelftappende even lengtematen van 10 mm tot 26 mm. Schroeven met een grotere diameter (4,8 mm) zijn verkrijgbaar met een lengte van 12, 14 of 16 mm.

Het EAGLE™ anterieur cervixplaatsysteem bestaat uit een assortiment platen en schroeven van een titaniumlegering. De platen zijn verkrijgbaar met van twee tot zes schroefgatparen in diverse lengtematen en twee configuraties. De schroeven zijn verkrijgbaar in diverse maten met diverse typen schroeftipgeometrie.

Het SWIFT™ anterieur cervixplaatsysteem is vervaardigd van een titaanlegering en bestaat uit gesegmenteerde platen die maximaal 2 mm gecontroleerde inzakking van het transplantaat tussen de afzonderlijke segmenten toelaten. De platen zijn verkrijgbaar met van twee tot zes schroefgatparen, in diverse lengtematen en twee configuraties, voor discectomie en voor corpectomie. De schroeven zijn verkrijgbaar in diverse maten met diverse typen schroeftipgeometrie. Er is een transplantaatschroef verkrijgbaar voor gebruik in de corpectomieplaten.

Het UNIPLATE™ anterieur cervixplaatsysteem bestaat uit een assortiment platen en schroeven van een titaniumlegering. De anterieure cervixplaten zijn verkrijgbaar in diverse lengtematen, geschikt voor één of twee fixatiesegmenten. De schroeven zijn verkrijgbaar in diverse maten met diverse typen tipgeometrie.

Het SKYLINE™ anterieur cervixplaatsysteem bestaat uit een assortiment platen en schroeven van een titaniumlegering. De platen zijn verkrijgbaar met van twee tot zes schroefgatparen in diverse lengtematen. De schroeven zijn verkrijgbaar in diverse maten met diverse typen schroeftipgeometrie. Zowel bewegingsbeperkte als variabele schroeven zijn verkrijgbaar om zo een bewegingsbeperkte, variabele of hybride configuratie mogelijk te maken.

## REINIGING EN STERILISATIE

De implantaten van het stabilisatiesysteem met cervixplaten worden steriel of schoon en niet-steriel geleverd. Van onderdelen die steriel geleverd worden dient u de verpakking vóór gebruik te inspecteren op eventuele beschadigingen.

Voor niet-steriele onderdelen dient het protocol volgens ISO 8828 of AORN voor sterilisatie in het ziekenhuis gevolgd te worden.

Er zijn tests uitgevoerd voor het ontwikkelen van de volgende AANBEVELINGEN VOOR STOOMSTERILISATIE:

| | |
|---|---|
| Cyclus | voorvacuüm |
| Temperatuur | 270 °F<br>132 °C |
| Blootstellingstijd | 6 min |

## GEBRUIK

De chirurg dient niet alleen grondig vertrouwd te zijn met de medische en chirurgische aspecten van het implantaat, maar dient tevens de mechanische en metallurgische beperkingen van metalen chirurgische implantaten te kennen. Postoperatieve zorg is uitermate belangrijk. De patiënt dient gewezen te worden op de beperkingen van het metalen implantaat en dient gewaarschuwd te worden in verband met gewichts- en bewegingsbelasting van het implantaat voordat genezing van het bot heeft plaatsgevonden. De patiënt dient erop gewezen te worden dat niet navolgen van de postoperatieve instructies ertoe kan leiden dat het implantaat faalt en dat het noodzakelijk kan zijn het implantaat naderhand operatief te verwijderen.

De onderdelen van het DePuy Spine spinaalsysteem mogen niet worden gebruikt met onderdelen van spinaalsystemen van andere merken.

**Voor het verkrijgen van een gecontroleerde verticale translatie (lastverdeling) is juiste plaatsing van de geselecteerde onderdelen van doorslaggevend belang.**

**Zie de chirurgische handleiding voor specifieke aanwijzingen.**

## INDICATIES

**LET OP:** Krachtens de Amerikaanse wetgeving is de verkoop van deze hulpmiddelen alleen toegestaan aan, of op voorschrift van, een arts.

Het SLIM-LOC anterieur cervixplaatsysteem en het SKYLINE™ anterieur cervixplaatsysteem zijn bestemd voor stabilisatie van de halswervelkolom van C2 tot C7 met behulp van unicorticale schroeffixatie op het anterieure oppervlak van de wervellichamen. Specifieke klinische indicaties voor anterieur gebruik van platen omvatten: instabiliteit door trauma; instabiliteit i.v.m. correctie van cervicale lordose en kyfose deformitas; instabiliteit i.v.m. pseudoartrose als resultaat van eerdere mislukte halswerveloperaties; instabiliteit i.v.m. ingrijpende reconstructieve operaties voor primaire tumoren van de halswervels of metastatische maligne tumoren van de halswervelkolom; instabiliteit i.v.m. corpectomie van een of meer niveaus bij gevorderde degeneratieve discusaandoening, stenose van het wervelkanaal of cervicale myelopathie.

Het PEAK anterieur compressieplaatsysteem, het PEAK polyaxiaal anterieur cervixplaatsysteem, het DOC ventraal cervicaal stabilisatiesysteem, het EAGLE anterieur cervixplaatsysteem, het SWIFT anterieur cervixplaatsysteem en het UNIPLATE anterieur cervixplaatsysteem zijn bestemd voor anterieure fixatie van de cervicale tussenwervelschijven. Deze systemen zijn bestemd voor patiënten bij wie stabiliteit gewenst is na anterieure halswervelfusie voor de onderstaande indicaties. De voor behandeling bestemde niveaus zijn de niveaus van C2 tot T1.

Indicaties omvatten symptomatische halswervelspondylose, trauma, breuk, posttraumatische kyfose of lordose, tumoren, discusdegeneratie (gekenmerkt door discogene pijn met degeneratie van de discus bevestigd door anamnese en radiologisch onderzoek), herhaalde operatie i.v.m. mislukte fusie of instabiliteit na eerdere operatie(s) voor de bovenstaande indicaties.

Het UNIPLATE anterieur cervixplaatsysteem is tevens bestemd voor behandeling van stenose van het wervelkanaal.

**WAARSCHUWING:** Deze implantaten zijn niet goedgekeurd voor schroefbevestiging of fixatie op de posterieure elementen (pedikels) van hals-, borst- of lendenwervels.

## POSTOPERATIEVE IMMOBILISATIE

Externe immobilisatie (b.v. korset of kraag) kan worden aanbevolen totdat de genezing van de botfusie is aangetoond met behulp van röntgenonderzoek, volgens inzicht van de arts.

Ook instructies aan de patiënt voor het ontlasten van de implantaten vormen een belangrijk aspect van het streven om klinische problemen als gevolg van het mislukken van de fixatie te voorkomen.

## CONTRA-INDICATIES

- Actieve systemische infectie of een plaatselijke infectie op de voorgenomen plaats van implantatie.
- Ernstige osteoporose kan voldoende fixatie van de schroeven belemmeren en kan zodoende het gebruik van dit of andere spinaalsystemen onmogelijk maken.
- Bewijs dat veilige en voorspelbare wijze behandeling zonder interne fixatie mogelijk is.
- Open wonden.

## RELATIEVE CONTRA-INDICATIES

Relatieve contra-indicaties worden gevormd door alle entiteiten of situaties die fusie geheel onmogelijk maken (zoals kanker, nierdialyse of osteopenie), obesitas, bepaalde degeneratieve aandoeningen en corpus-alienumgevoeligheid.

## WAARSCHUWINGEN, VOORZORGEN EN BIJWERKINGEN IN VERBAND MET METALEN INTERNE FIXERINGSHULP-MIDDELEN

### WAARSCHUWINGEN

Hierna volgen enkele specifieke waarschuwingen, voorzorgen en bijwerkingen die de chirurg dient te weten en die uitgelegd dienen te worden aan de patiënt. Deze waarschuwingen omvatten niet alle bijwerkingen die in het algemeen kunnen optreden bij een operatie, maar zijn belangrijke bevindingen die specifiek gelden voor gebruik van metalen interne fixeringshulpmiddelen. De algemene risico's van een operatie dienen vóór de operatie aan de patiënt te worden uitgelegd.

Het gebruik van dit hulpmiddelsysteem brengt onder andere de volgende risico's met zich mee, die aanvullend operatief ingrijpen kunnen vereisen: breuk van implantaatonderdelen, loslaten van het implantaat, uitblijven van fusie, wervelfractuur, neurologische beschadiging en vasculaire of viscerale beschadiging.

1. **HET IS UITERMATE BELANGRIJK DAT U HET JUISTE IMPLANTAAT KIEST.** De kans op een goede fixatie wordt verhoogd door keuze van een implantaat van de juiste maat en vorm en van het juiste ontwerp. Hoewel een juiste selectie kan helpen bij het verminderen van risico's, worden de afmeting, vorm en sterkte van de implantaten beperkt door de afmeting en vorm van de menselijke beenderen. Metalen interne fixeringshulpmiddelen kunnen niet dezelfde belastingen weerstaan die gezonde beenderen ondergaan. Men kan van geen enkel implantaat verwachten dat het gedurende onbepaalde tijd bestand is tegen de niet-ondersteunde belasting van het volle gewicht.
2. **IMPLANTATEN KUNNEN BREKEN ALS ZE WORDEN BLOOTGESTELD AAN EEN VERHOOGDE BELASTING IN VERBAND MET VERTRAAGDE OF UITBLIJVENDE FUSIE.** Interne fixeringshulpmiddelen zijn lastverdelende implantaten die het bot in de juiste positie houden totdat normale genezing is verkregen. Als de genezing wordt vertraagd of uitblijft, bestaat er een kans dat het implantaat uiteindelijk breekt als gevolg van metaalmoeheid. De levensduur van het implantaat hangt onder andere af van de mate van succes van het fusieproces, de belasting veroorzaakt door het gedragen gewicht en het activiteitenniveau. Ook inkepingen, krassen of buigen van het implantaat gedurende de operatie kunnen leiden tot voortijdig falen. De patiënt dient uitgebreid te worden gewezen op de risico's die het gevolg kunnen zijn van het falen van een implantaat.
3. **HET COMBINEREN VAN VERSCHILLENDE METALEN KAN CORROSIE VEROORZAKEN.** Er bestaan vele vormen van beschadiging door corrosie en verscheidene daarvan doen zich voor bij metalen die operatief geïmplanteerd worden bij mensen. Algemene of uniforme corrosie vindt plaats op alle geïmplanteerde metalen en legeringen. De snelheid van corrosieve aantasting van metalen implantaten is gewoonlijk zeer laag door de aanwezigheid van passieve oppervlaktelagen. Bij het samenbrengen van verschillende metalen, zoals titanium en roestvast staal, wordt het corrosieproces van het roestvast staal versneld en vindt aantasting versneld plaats. De aanwezigheid van corrosie versnelt dikwijls de vermoeiingsbreuk van de implantaten. Ook de hoeveelheid metaalverbindingen die vrijkomt in het lichaam neemt toe. Interne fixeringshulpmiddelen zoals staven, haken, draden en dergelijke die in aanraking komen met andere metalen voorwerpen, dienen te zijn vervaardigd uit hetzelfde of een compatibel metaal.
4. **SELECTIE VAN PATIËNTEN.** Bij het selecteren van patiënten voor interne fixeringshulpmiddelen kunnen de volgende factoren van groot belang zijn voor het uiteindelijke succes van de operatie:

   A. **Het beroep of de activiteit van de patiënt.** Als de patiënt een beroep of activiteit uitoefent bestaande uit het tillen van zware lasten, belasting van de spieren, draaien, herhaaldelijk buigen, bukken, hardlopen, veelvuldig wandelen of handarbeid, mag hij/zij deze activiteiten pas hervatten nadat het bot volledig is genezen. Zelfs bij volledige genezing bestaat er een kans dat de patiënt deze activiteiten niet met succes kan hervatten.

   B. **Seniliteit, psychische aandoeningen, alcoholisme of gebruik van verdovende middelen.** Onder andere deze factoren kunnen ertoe leiden dat de patiënt bepaalde noodzakelijke beperkingen en voorzorgen bij het gebruik van dit instrument negeert, wat kan leiden tot falen van het implantaat of andere complicaties.

   C. **Bepaalde degeneratieve aandoeningen.** In sommige gevallen zal de degeneratieve aandoening zo ver gevorderd zijn ten tijde van implantatie dat dit de verwachte gebruiksduur van het hulpmiddel aanzienlijk vermindert. In dergelijke gevallen dient men orthopedische hulpmiddelen alleen te beschouwen als een vertragende techniek of tijdelijke remedie.

   D. **Corpus-alienumgevoeligheid.** De chirurg wordt erop gewezen dat geen enkele preoperatieve test de mogelijkheid van overgevoeligheid of allergische reacties volledig kan uitsluiten. Een patiënt kan een overgevoeligheid of allergie ontwikkelen nadat de implantaten gedurende een zekere periode in het lichaam aanwezig zijn geweest.

   E. **Roken.** Bij patiënten die roken is een hogere incidentie van pseudoartrose vastgesteld na operaties met gebruik van bottransplantaat. Bovendien is aangetoond dat roken een diffuse degeneratie van de tussenwervelschijven kan veroorzaken. Progressieve degeneratie van aangrenzende segmenten veroorzaakt door roken kan resulteren in een late klinische mislukking (terugkerende pijn), zelfs na succesvolle fusie en aanvankelijke klinische verbetering.

**WAARSCHUWING:** Als botfusie niet plaatsvindt binnen de te verwachten periode, kunnen de schroeven breken als gevolg van de sterke en aanhoudende belasting van deze hulpmiddelen. Dit is geconstateerd bij patiënten met vertraagde fusie, pseudoartrose of uitblijven van fusie en kan revisie van het/de hulpmiddel(en) noodzakelijk maken.

## VOORZORGEN

1. **CHIRURGISCHE IMPLANTATEN MOGEN NOOIT OPNIEUW WORDEN GEBRUIKT.** Een geëxplanteerd metalen implantaat mag nooit opnieuw worden geïmplanteerd. Hoewel het implantaat onbeschadigd kan lijken, kan het kleine defecten en interne stresspatronen hebben die kunnen leiden tot voortijdige breuk.
2. **CORRECT GEBRUIK VAN HET IMPLANTAAT IS UITERMATE BELANGRIJK.** Het bijvormen van metalen implantaten mag alleen worden uitgevoerd met daartoe geëigende instrumenten. De behandelend chirurg dient het inkepen, krassen of terugbuigen van de implantaten bij het vormgeven te voorkomen. Wijzigingen aan het implantaat veroorzaken defecten in de oppervlakteafwerking en interne spanningen, wat uiteindelijk een breuk van het implantaat kan teweegbrengen. Niet implanteren als u beschadiging vermoedt.

   Overmatige torsie van de schroeven bij het aanbrengen van de plaat kan falen van het bot veroorzaken, wat ertoe leidt dat de schroefdraden gestript raken en/of niet goed grijpen.
3. **BUIGEN VAN DE CONSTRUCTIE.** Onderdelen van een titaniumlegering mogen nooit scherp gebogen of teruggebogen worden. Als een constructie te ver is doorgebogen, wordt aanbevolen een nieuwe constructie juist bij te vormen; niet proberen om de te ver doorgebogen constructie weer terug te buigen.
4. **VERWIJDERING VAN HET IMPLANTAAT NA GENEZING.** Als het implantaat niet wordt verwijderd na het bedoelde gebruik, kunnen de volgende complicaties optreden: (1) corrosie, met plaatselijke weefselreactie of pijn; (2) migratie van het implantaat met letsel als gevolg; (3) kans op bijkomstig letsel door postoperatief trauma; (4) buigen, losraken en/of breuk, wat de verwijdering onpraktisch of moeilijk kan maken; (5) pijn, ongemak of abnormale sensaties door de aanwezigheid van het instrument; (6) mogelijk verhoogd risico van infectie; (7) botverlies door stress shielding. De chirurg dient de voor- en nadelen voorzichtig af te wegen bij de beslissing om het implantaat te verwijderen. De verwijdering van het implantaat dient te worden gevolgd door een geschikte

postoperatieve behandeling om herhaalde botbreuk of deformitas te voorkomen. Als het een oudere patiënt betreft met een laag activiteitenniveau, kan de chirurg beslissen om het implantaat niet te verwijderen en zodoende de risico's van een tweede operatie te vermijden.

5. **STEL DE PATIËNT VOLDOENDE OP DE HOOGTE.** Postoperatieve zorg en het vermogen en de bereidheid van de patiënt om de instructies te volgen zijn zeer belangrijke aspecten voor een succesvolle genezing van het bot. De patiënt dient op de hoogte te worden gesteld van de beperkingen van het implantaat en erop te worden gewezen fysieke activiteiten te beperken, vooral til- en draaibewegingen en elke vorm van sport. De patiënt dient te begrijpen dat een metalen implantaat niet zo sterk is als normaal gezond bot en dat het kan losraken, buigen en/of breken als men het overmatig belast, vooral als het bot niet volledig is genezen. Implantaten die door de verkeerde lichaamsbeweging verplaatst of beschadigd raken, kunnen migreren en de zenuwen of bloedvaten beschadigen. Met name een actieve, zwakzinnige of demente patiënt die gewichtondersteunende hulpmiddelen niet op de juiste manier kan gebruiken loopt gevaar gedurende postoperatieve rehabilitatie.

## MOGELIJKE BIJWERKINGEN

1. Uitblijven van de fusie, vertraagde fusie.
2. Buigen of breken van het implantaat. Losraken van het implantaat.
3. Overgevoeligheid voor metaal of allergische reactie op een corpus alienum.
4. Infectie, vroeg of laat.
5. Verminderde botdichtheid door stress shielding.
6. Pijn, ongemak of abnormale sensaties door de aanwezigheid van het implantaat.
7. Zenuwletsel door chirurgisch trauma of de aanwezigheid van het implantaat. Neurologische problemen, waaronder radiculaire pijn, verstrikt raken van zenuwen in littekenweefsel, spierzwakte en paresthesie.
8. Beschadiging van de bloedvaten kan resulteren in noodlottige of fatale bloedingen. Niet goed geplaatste implantaten in de nabijheid van grote slagaders of aders kunnen deze bloedvaten doen eroderen met als gevolg een noodlottige bloeding laat in de postoperatieve periode.
9. Scheurtjes in de duraschede die ontstaan tijdens de operatie kunnen leiden tot een tweede operatie om de duraschede te repareren, tot chronische lekkage van cerebrospinale vloeistof, een fistel en mogelijk meningitis.
10. Bursitis.
11. Verlamming.
12. Perforatie, erosie of irritatie van de slokdarm.
13. Spontaan losdraaien van een schroef, wat kan leiden tot oesofaguserosie, losraken van het implantaat en/of de noodzaak tot operatie ter verwijdering van het implantaat.
14. Beschadiging van lymfatische bloedvaten en/of exsudatie van lymfatisch vocht.
15. Afklemming of beschadiging van het ruggenmerg.
16. Breuk van botstructuren.
17. Degeneratieve veranderingen of instabiliteit van segmenten naast de gefuseerde wervels.
18. Dood.

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**VERTALING VAN SYMBOLEN**

| | | | |
|---|---|---|---|
| LOT PARTIJNUMMER | VOOR EENMALIG GEBRUIK | NONSTERILE NIET-STERIEL | FABRIKANT |
| REF CATALOGUS-NUMMER | XXXX-XX TE GEBRUIKEN VOOR | STERILE R STERILISATIE DOOR BESTRALING | EC REP GEVOLMACHTIGDE IN DE EUROPESE UNIE |
| QTY HOEVEELHEID | ZIE GEBRUIK-SAANWIJZING | STERILE EO STERILISATIE DOOR ETHYLEENOXIDE | DIST VERHANDELD DOOR |
| Rx Only Krachtens de federale wetgeving (in de VS) mag dit hulpmiddel uitsluitend door of in opdracht van een arts worden verkocht. | STERILE STERIEL | MADE IN VERVAARDIGD IN | SZ MAAT |

**MATERIAAL MATL**

| | | |
|---|---|---|
| A/T ACROFLEX®/Ti ACROFLEX®/titanium | PY Polyester | SS/RADEL®/ Ti Al Nitride SRTA Roestvrij staal/RADEL®/ titanium-aluminiumnitride |
| A Al Aluminium | P POLYMER Polymeer | STA SS/Ti Al Nitride Roestvrij staal/ titanium-aluminiumnitride |
| A/P Al/PL Aluminium/plastic | P/CM PE/CoCrMo Polyethyleen/ kobalt-chroom-molybdeen | S/U SS/ULTEM Roestvrij staal/Ultem |
| B/R Ba/RADEL® Barium/RADEL® | P/C POLYMER/CARBON FIBER COMPOSITE Polymeer/ koolstofvezelcomposiet | T Ti Titanium en zijn legeringen |
| CaP CALCIUM PHOSPHATE Calciumfosfaat | S SS Roestvrij staal | S/R SS/RADEL Roestvrij staal/RADEL® |
| CM CoCrMo Kobalt-chroom-molybdeen | S/A SS/Al Roestvrij staal/aluminium | R/T POLYOLEFIN RUBBER/Ti Polyolefinerubber/titanium |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Kobalt-chroom-molybdeen/ titanium/calciumfosfaat | SBR SS/Ba/RADEL® Roestvrij staal/barium/RADEL® | T/A Ti/Al Titanium/aluminium |
| F FOAM Schuim | S/P SS/PHENOLIC Roestvrij staal/fenolhars | Ti/UHMWPE/HA Titanium/polyethyleen met ultrahoog molecuulgewicht/ hydroxyapatiet |
| HA Hydroxyapatiet | S/PL SS/PL Roestvrij staal/plastic | SS/Ti Roestvrij staal/titanium |
| NiTi Ni/Ti Nikkel/titanium | SRSI SS/RADEL®/ SILICONE Roestvrij staal/RADEL®/silicone | SS/Al/SILICONE Roestvrij staal/ aluminium/silicone |
| PL Plastic | SRSN SS/RADEL®/ SILICONE/Ti Al Nitride Roestvrij staal/RADEL®/silicone/ titanium-aluminiumnitride | S/Si SS/SILICONE Roestvrij staal/silicone |
| P/F PL/FOAM Plastic/schuim | | |

fi

# PEAK- ANTERIORINEN KOMPRESSIOLEVYJÄRJESTELMÄ

# PEAK- ANTERIORINEN POLYAKSIAALINEN SERVIKAALILEVYJÄRJESTELMÄ

# DOC- VENTRAALINEN KAULARANGAN STABILOINTIJÄRJESTELMÄ

# SLIM-LOC™- ANTERIORINEN SERVIKAALILEVYJÄRJESTELMÄ

# EAGLE™- ANTERIORINEN SERVIKAALILEVYJÄRJESTELMÄ

# SWIFT™- ANTERIORINEN SERVIKAALILEVYJÄRJESTELMÄ

# UNIPLATE™- ANTERIORINEN SERVIKAALILEVYJÄRJESTELMÄ

# SKYLINE™- ANTERIORINEN SERVIKAALILEVYJÄRJESTELMÄ

## TÄRKEÄ HUOMAUTUS HOITAVALLE KIRURGILLE

Anteriorisilla kaularangan stabilointi-implantaateilla, kuten millä tahansa sisäisillä fiksaatiolaitteilla, on rajallinen käyttöikä. Potilaan aktiviteettitasolla on merkittävä vaikutus tähän käyttöikään. Potilaalle on kerrottava, että mikä tahansa toiminta lisää implantaatin osien löystymisen, taipumisen tai murtumisen riskiä. On oleellista neuvoa potilasta rajoittamaan leikkauksen jälkeisiä toimiaan sekä tutkia potilas leikkauksen jälkeen fuusiomassan kehityksen ja implantaatin osien tilan arvioimiseksi. Vaikka kiinteä luun yhteenkasvu tapahtuukin, implantaatin osat voivat silti taipua, murtua tai löystyä. Sen vuoksi potilaan täytyy saada tietää, että implantaatin osat voivat taipua, murtua tai löystyä, vaikka hän noudattaakin liikuntarajoituksia.

Anatomisten syiden ja nykyaikaisten kirurgisten materiaalien vuoksi metalli-implantaatteja ei pystytä valmistamaan sellaisiksi, että ne kestäisivät loputtomasti. Niiden tarkoitus on tarjota väliaikaista, sisäistä tukea fuusiomassan lujittuessa. Tämäntyyppiset implantaatit rikkoutuvat todennäköisimmin, jos luusiirrettä ei käytetä lainkaan tai valenivel muodostuu.

Kirurgi voi päättää poistaa nämä implantaatit luutumisen tapahduttua. Potilaan kanssa on keskusteltava mahdollisesta uudesta toimenpiteestä samoin kuin uuteen toimenpiteeseen liittyvistä riskeistä. Mikäli implantaatit murtuvat, poistamispäätöksen tekee lääkäri, jonka täytyy ottaa huomioon potilaan kunto ja rikkoutuneesta implantaatista aiheutuvat riskit.

## KUVAUS

PEAK- anteriorinen kompressiolevyjärjestelmä koostuu titaaniseoksesta valmistetuista levyistä ja ruuveista. Levyjä on saatavana 26-94 mm:n pituisina 1-4 nikamasegmentin fiksaatiota varten. Järjestelmään sisältyy lisäksi titaaniseoksesta valmistettuja 3,5 mm:n kortikaaliluuruuveja ja 4,0 mm:n hohkaluuruuveja, joita on saatavana 8-30 mm:n pituisina.

PEAK- anteriorinen polyaksiaalinen servikaalilevyjärjestelmä koostuu titaaniseoksesta valmistetuista levyistä ja ruuveista. Anteriorisia servikaalilevyjä on saatavana 24-110 mm:n pituisina 1-4 nikamasegmentin fiksaatiota varten. Hohkaluuruuveja on saatavana 4,0 mm:n ja 4,35 mm:n läpimittaisina. Niissä on kierteet koko pituudelta, ja niitä on saatavana 10-26 mm:n pituisina.

DOC- ventraalinen kaularangan stabilointijärjestelmä on titaaniseoksesta valmistetusta alustasta, levystä, sauvasta ja ruuveista muodostuva kokonaisuus, jota selkärankakirurgit käyttävät apuna kaularangan defektien korjaamisessa ja stabiloinnissa. DOC- ventraalinen kaularangan stabilointijärjestelmä koostuu täysin koottuna levystä tai kahdesta lateraalisesti asetetusta sauvasta, joita yhdistävät kaularangan etupintaan asetelut alustat. Järjestelmä ankkuroidaan nikamiin ruuveilla. Implantaatti toimii kaularangan lisätukena kaularangan anteriorisen fuusion jälkeen. Implantaatin kokoonpanon mukaan se voi toimia joko jäykkänä (kantavana) tai dynaamisena (kuormituksen jakavana) rakenteena.

Järjestelmään on saatavana seuraavat komponentit: sauvat, levyt, alustat, sisä- ja ulkoluuruuvit, luusiirreruuvit ja ristisiteet. Kaikki komponentit on valmistettu ASTM F-136 -standardin mukaisesta implantaattiluokan titaaniseoksesta. Kirurgin työn helpottamiseksi on saatavana myös valmiita rakenteita. Nämä ovat esikoottuja osarakennelmia, jotka koostuvat yhdestä alustasta, yhdestä ristisiteestä, kahdesta sauvasta ja kahdesta lukitusruuvista.

**Alusta:** Alustat on tarkoitettu yhdistämään sauvat ja ankkuri nikaman solmuun luuruuveilla. Kaikkia alustoja voidaan käyttää joko umpinaisten luuruuvien (kaksikuorinen fiksaatio) tai ulko- ja sisäluuruuviyhdistelmän kanssa (ontto ulkoluuruuvi, jota käytetään umpinaisen sisälukitusruuvin kanssa yksikuoriseen fiksaatioon). Lääkäri valitsee ruuvit harkintansa perusteella. Kaikki alustat on suunniteltu käytettäväksi kahden sauvan kanssa rakenteen muodostamisessa.

Alustoja on saatavana lukittavina tai lukittumattomina. Lukittavissa alustoissa on jatkeet, joihin voidaan kiinnittää alustan/ristisiteen lukitusruuvit, joilla alusta kiinnitetään sauvoihin. Lukittuvat alustat on kiinnitettävä sauvojen päitä vastapäätä olevaan rakenteen päähän.



Jos valitaan jäykkä rakenne dynaamisen (kuormituksen jakavan) rakenteen asemasta, lukittuvaa alustaa on käytettävä myös sauvojen päiden puoleisessa päässä. Jos halutaan kuormituksen jakava rakenne, sauvojen päänpuoleista alustaa ei lukita sauvoihin.

Saatavana on alustoja, jotka on suunniteltu siten, että ruuvit voidaan viedä sisään nikaman solmuun kulmassa. Niitä on saatavana sekä lukittavina että lukittumattomina. Näiden alustojen toisessa laidassa on ripa, joka kiinnittyy nikamaan välilevytilan sisältä parhaan mahdollisen asennon ja fiksaation saavuttamiseksi.

Monet alustat on suunniteltu siten, että ruuvien sisäänvienti nikamasolmuun voi tapahtua suorassa kulmassa. Niitä on saatavana sekä lukittavina että lukittumattomina.

Saatavana on yksi alustamalli rakenteen kiinnittämiseksi intervertebraaliseen siirteeseen. Tässä alustassa on horisontaalinen aukko ja pyöreä pesä erilaisia ruuvien sijoituskohtia ja siirteeseen vieviä ratoja varten.

Lääkäri valitsee alustat harkintansa perusteella potilaan anatomian huomioon ottaen.

SLIM-LOC™- anteriorinen servikaalilevyjärjestelmä koostuu titaaniseoksesta valmistetuista levyistä ja ruuveista. Levyjä on saatavana 22-111 mm:n pituisina. Niissä voi olla 2, 3, 4, 5 tai 6 ruuvinreikäparia. SLIM-LOC-ruuveja on saatava 4,5 mm:n läpimittaisina itseporautuvina tasapituuksina (10-18 mm) tai itsekierteittävinä tasapituuksina (10-26 mm). Suurempiläpimittaisia (4,8 mm) ruuveja on saatavana 12, 14 ja 16 mm:n pituisina.

EAGLE™- anteriorinen servikaalilevyjärjestelmä koostuu titaaniseoksesta valmistetuista levyistä ja ruuveista. Levyjä on saatavana 2-4 ruuvireikäpareina ja eri pituisina. Ruuveja on saatavana eri kokoisina ja ruuvauskärkimallisina.

SWIFT™- anteriorinen servikaalilevyjärjestelmä on valmistettu titaaniseoksesta ja koostuu osista, jotka mahdollistavat siirteen asettumisen enintään 2 mm verran jokaisen osan välillä. Levyjä on saatavana 2-6 ruuvireikäpareina, eri pituisina ja kahden eri mallisena: diskektomia ja korpektomia. Ruuveja on saatavana eri kokoisina ja ruuvauskärkimallisina. Siirreruuvi on saatavana käytettäväksi korpektomialevyjen kanssa.

UNIPLATE™- anteriorinen servikaalilevyjärjestelmä koostuu titaaniseoksesta valmistetuista levyistä ja ruuveista. Anteriorisia servikaalilevyjä on saatavana eri pituisina yhden tai kahden nikamasegmentin fiksaatiota varten. Ruuveja on saatavana eri kokoisina ja eri mallisilla kärjillä varustettuina.

SKYLINE™- anteriorinen servikaalilevyjärjestelmä koostuu titaaniseoksesta valmistetuista levyistä ja ruuveista. Levyjä on saatavana 2-6 ruuvireikäparina ja eri pituisina. Ruuveja on saatavana eri kokoisina ja ruuvauskärkimallisina. Saatavilla on sekä jäykkiä että joustavia ruuveja, ja niillä voidaan saada aikaan jäykkä, joustava tai sekamuotoinen rakenne.

## PUHDISTUS JA STERILOINTI

Kaularangan stabilointijärjestelmän implantaatit toimitetaan joko steriloituina tai puhtaina ja steriloimattomina. Käytettäessä steriloituja komponentteja on varmistettava, että pakkaus ei ole vaurioitunut.

Steriloimattomien komponenttien steriloinnissa on noudatettava ISO 8828- tai AORN-standardien mukaisia sterilointimenetelmiä.

Testien tuloksena kehitettiin seuraavat HÖYRYSTERILOINTISUOSITUKSET:

| | |
|---|---|
| Ohjelma: | Esityhjiö |
| Lämpötila: | 132 °C (270 °F) |
| Sterilointiaika: | 6 min |

## KÄYTTÖ

Kirurgin on tunnettava niin implantaatin lääketieteelliset kuin kirurgisetkin puolet perusteellisesti, minkä lisäksi hänen on tunnettava metallisten kirurgisten implantaattien mekaaniset ja metallurgiset rajoitukset. Leikkauksen jälkeinen hoito on erittäin tärkeää. Potilaalle on kerrottava metalli-implantaatin rajoituksista ja häntä on varoitettava kuormittamasta ja rasittamasta laitetta ennen kiinteää luun parantumista. Potilasta on varoitettava, että leikkauksen jälkeisten ohjeiden laiminlyönti voi johtaa implantaatin rikkoutumiseen ja mahdolliseen uusintaleikkaukseen laitteen poistamiseksi.

DePuy Spine -selkärankajärjestelmän osia ei saa käyttää muiden valmistajien osien kanssa.

**Valittujen komponenttien sijoittaminen on erittäin tärkeää oikean pystytranslaation (kuormituksen jakamisen) aikaansaamiseksi.**

**Yksityiskohtaiset ohjeet on esitetty toimenpideoppaassa.**

## INDIKAATIOT

VAROITUS: Yhdysvaltain laki rajoittaa tämän tuotteen myynnin lääkärin toimesta tai määräyksestä tapahtuvaksi.

SLIM-LOC- anteriorinen servikaalilevyjärjestelmä ja SKYLINE™- anteriorinen servikaalilevyjärjestelmä on tarkoitettu kaularangan stabilointiin C2-C7-tasoilla käyttämältä unikortikaalista ruuvifiksaatiota nikamien etupinnalle. Spesifisiä kliinisiä käyttöaiheita ovat trauman aiheuttama instabiliteetti, kaularangan lordoosi- ja kyfoosideformiteetin korjaukseen liittyvä instabiliteetti, aikaisempien kaularankaan kohdistuvien kirurgisten toimenpiteiden komplikaationa ilmenevä, valeniveleen liittyvä instabiliteetti, kaularangan primaarituumorin tai etäpesäkkeen vuoksi suoritettuihin laajoihin rekonstruktiivisiin toimenpiteisiin liittyvä instabiliteetti, pitkälle edenneen degeneratiivisen välilevysairauden, spinaalistenoosin tai kaularangan alueen myelopatian vuoksi suoritettuihin yhden tai useamman tason korpektomioihin liittyvä instabiliteetti.

PEAK- anteriorinen kompressiolevyjärjestelmä, PEAK-anteriorinen polyaksiaalinen servikaalilevyjärjestelmä, DOC- ventraalinen kaularangan stabilointijärjestelmä, EAGLE- anteriorinen servikaalilevyjärjestelmä, SWIFT- anteriorinen servikaalilevyjärjestelmä ja UNIPLATE- anteriorinen servikaalilevyjärjestelmä on tarkoitettu niskanikamien anterioriseen intervertebraaliseen fiksaatioon. Nämä järjestelmät on tarkoitettu potilaille, jotka tarvitsevat lisätukea kaularangan anteriorisen fuusion jälkeen alla olevien käyttöaiheiden mukaisesti. Järjestelmät on tarkoitettu käytettäviksi tasoilla C2-T1.

Käyttöaiheita ovat oireita aiheuttava kaularangan spondylcosi, trauma, murtuma, posttraumaattinen kyfoosi tai lordoosi, kasvain, rappeuttava välilevysairaus (diskogeeninen kipu, joka perustuu anamneesiin ja röntgentutkimusten vahvistamaan välilevyn rappeumaan), epäonnistuneen fuusion uusintaleikkaus tai edellä mainittujen käyttöaiheiden vuoksi suoritettua leikkausta seuraava instabiliteetti.

UNIPLATE- anteriorinen servikaalilevyjärjestelmä on tarkoitettu myös spinaalistenoosin hoitoon.

VAROITUS: Näitä järjestelmiä ei ole hyväksytty kiinnitettäviksi ruuveilla kaularangan, rintarangan tai lannerangan posteriorisiin osiin (pedikkeleihin).

## LEIKKAUKSEN JÄLKEINEN LIIKUNTA

Ulkopuolinen immobilisaatio (lastan tai kipsin avulla) on suositeltavaa lääkärin harkinnan mukaan, kunnes röntgenkuva vahvistaa fuusiomassan kehittymisen.

Potilaalle annetut ohjeet implantaattiin kohdistuvan rasituksen vähentämiseksi ovat yhtä tärkeitä myös fuusion epäonnistumiseen liittyvien kliinisten ongelmien välttämisen kannalta.

## VASTA-AIHEET

- Aktiivinen systeeminen tulehdus tai ehdotetussa implantointikohdassa sijaitseva paikallinen tulehdus.
- Vaikea osteoporoosi voi estää ruuvien riittävän fiksaation ja siten estää tämän tai muiden selkärankainstrumenttijärjestelmien käytön.
- Potilaat, joita on hoidettu turvallisesti ja odotetusti ilman sisäistä fiksaatiota.
- Avohaavat.

## SUHTEELLISET VASTA-AIHEET

Suhteellisia vasta-aiheita ovat fuusion kokonaan estävät tekijät tai tilat (kuten syöpä, dialyysihoito tai osteopenia), liikalihavuus, tietyt rappeuttavat sairaudet ja yliherkkyys vierasesineille.

## VÄLIAIKAISIA, SISÄISIÄ METALLIFIKSAATIOLAITTEITA KOSKEVIA VAROITUKSIA, VAROTOIMIA JA HAITTAVAIKUTUKSIA.

### VAROITUKSIA

Seuraavassa esitetään erityisiä varoituksia, varotoimia ja haittavaikutuksia, jotka kirurgin tulisi ymmärtää ja selittää potilaalle. Nämä varoitukset eivät sisällä kaikkia yleisiä leikkaukseen liittyviä haittavaikutuksia, vaan ne ovat huomioita, jotka liittyvät erityisesti sisäisiin metallisiin fiksaatiolaitteisiin. Yleiset leikkaukseen liittyvät riskit tulisi selittää potilaalle ennen leikkausta.

Tämän laitejärjestelmän käyttöön liittyviä mahdollisia riskejä, jotka vaativat uutta leikkausta, ovat laitteen osan murtuminen, fiksaation menetys, luutumattomuus, nikaman murtuminen, hermovaurio ja verisuoniston tai sisäelinten vamma.

1. **IMPLANTAATIN OIKEA VALINTA ON ERITTÄIN TÄRKEÄÄ.** Tyydyttävän fiksaation mahdollisuutta voidaan parantaa valitsemalla asianmukaisen kokoinen, muotoinen ja mallinen implantaatti. Vaikka asianmukainen valinta voi auttaa riskien minimoinnissa, ihmisen luiden koko ja muoto asettavat rajoituksia implantaattien koolle, muodolle ja kestävyydelle. Metalliset sisäiset fiksaatiolaitteet eivät kestä samaa aktiviteettitasoa kuin normaali, terve luu. Minkään implantaatin ei voida olettaa kestävän täyden ruumiinpainon kuormitusta tuetta loputtomiin.
2. **IMPLANTAATIT VOIVAT MURTUA, JOS NE JOUTUVAT ALTTIIKSI VIIVÄSTYNEESTÄ KIINNITTYMISESTÄ TAI KIINNITTYMÄTTÄ JÄÄMISESTÄ JOHTUVALLE, KASVAVALLE KUORMITUKSELLE.** Sisäiset fiksaatiolaitteet ovat kuormitusta tasaavia laitteita, joita käytetään oikaisun aikaansaamiseksi, kunnes normaali parantuminen tapahtuu. Mikäli parantuminen viivästyy tai parantumista ei tapahdu lainkaan, implantaatti saattaa lopulta murtua metallin väsymisen vuoksi. Luutumisen onnistumisaste, ruumiinpainon kantamisesta aiheutuva kuormitus ja aktiviteettitaso muiden muassa määräävät implantaatin kestoajan. Myös uurteet, naarmut tai implantaatin taivuttaminen toimenpiteen yhteydessä voivat aiheuttaa ennenaikaisen rikkoutumisen. Potilaiden tulee olla täysin tietoisia implantaatin rikkoutumisen vaaroista.
3. **METALLIEN SEKOITTAMINEN VOI AIHEUTTAA SYÖPYMISTÄ.** On olemassa monia eri syöpymisvaurioita, ja monet niistä tapahtuvat metalleissa, joita implantoidaan ihmisiin. Yleistä tai yhdenmukaista syöpymistä tapahtuu kaikissa kehoon asennetuissa metalleissa tai metalliseoksissa. Metalli-implantaattien syöpymisaste on tavallisesti hyvin alhainen passiivisten pintakalvojen vuoksi. Toisistaan poikkeavien metallien, kuten titaani ja ruostumaton teräs, joutuminen kosketuksiin keskenään nopeuttaa ruostumattoman teräksen syöpymisprosessia. Syöpyminen nopeuttaa monesti implantaattien väsymismurtumien esiintymistä. Myös kehoon joutuvien metalliyhdisteiden määrä lisääntyy. Sisäisten fiksaatiolaitteiden, kuten sauvat, koukut, langat yms., jotka joutuvat kosketuksiin toisten metalliesineiden kanssa, on oltava samanlaisista tai yhteensopivista metalleista valmistettuja.
4. **POTILAIDEN VALINTA.** Valittaessa potilaita, joille voidaan asentaa sisäinen fiksaatiolaite, seuraavat seikat saattavat olla äärimmäisen tärkeitä toimenpiteen onnistumisen kannalta:

   A. **Potilaan ammatti tai aktiviteetti.** Mikäli potilas on ammatissa tai toiminnassa, joka edellyttää raskaiden esineiden nostamista, lihasten rasitusta, kiertymistä, toistuvaa taivuttelua, kumartumista, juoksemista, runsasta kävelyä tai ruumiillista työtä, hänen ei tule palata näihin toimintoihin ennen kuin luu on täysin parantunut. Potilas ei ehkä pysty menestyksellisesti palaamaan näihin toimintoihin edes täydellisen parantumisen jälkeen.

   B. **Seniiliteetti, mielisairaus, alkoholismi tai huumeiden tai lääkkeiden väärinkäyttö.** Potilaan välinpitämättömyys laitteen käytön vaatimia tiettyjä rajoituksia ja varotoimenpiteitä kohtaan saattaa johtua muun muassa yllämainituista tiloista, mistä voi seurata implantaatin rikkoutuminen tai muita komplikaatioita.

   C. **Tietyt rappeuttavat sairaudet.** Joissain tapauksissa rappeuttava sairaus on saattanut edetä niin pitkälle implantaatin asentamisen ajankohtana, että se voi huomattavasti vähentää laitteen odotettua hyötyikää. Sellaisissa tapauksissa ortopedisia laitteita voidaan pitää ainoastaan viivästystekniikkana tai väliaikaisena hoitokeinona.

   D. **Yliherkkyys vierasesineille.** Kirurgin tulee tietää, ettei mikään leikkausta edeltävä koe voi täysin sulkea pois allergisen tai yliherkkyysreaktion mahdollisuutta. Potilaat voivat kehittää yliherkkyyden tai allergian vielä kauan implanttien asentamisen jälkeen.

   E. **Tupakointi.** Tupakoivilla potilailla on todettu valenivelen suurempi esiintymistiheys luusiirreleikkausten jälkeen. Lisäksi tupakoinnin on todettu aiheuttavan nikamavälilevyjen hajanaista rappeutumista. Tupakoinnin aiheuttama vierekkäisten segmenttien etenevä rappeutuminen voi myöhemmin johtaa kliiniseen epäonnistumiseen (uusiutuva kipu) jopa onnistuneen fuusion ja alustavan kliinisen parantumisen jälkeen.

**VAROITUS:** Jos luu ei fuusioidu odotetun ajan kuluessa, ruuvit voivat murtua näihin järjestelmiin kohdistuvan jatkuvan suuren kuormituksen vuoksi. Tämä on todettu potilailla, joilla luutuminen on viivästynyt tai jäänyt tapahtumatta tai joilla on muodostunut valenivel. Tämän vuoksi voidaan joutua suorittamaan järjestelmän revisio.

### VAROTOIMENPITEITÄ

1. **KIRURGISIA IMPLANTAATTEJA EI SAA KOSKAAN KÄYTTÄÄ UUDELLEEN.** Poistettua metalli-implantaattia ei saa koskaan asentaa uudelleen. Vaikka väline näyttää vahingoittumattomalta, siinä voi olla pieniä vikoja ja sisäisiä rasitusvammoja, jotka voivat johtaa ennenaikaiseen murtumiseen.
2. **IMPLANTAATIN OIKEA KÄSITTELY ON ERITTÄIN TÄRKEÄÄ.** Metalli-implantaattien muotoilu tulee suorittaa ainoastaan asianmukaisilla välineillä. Leikkaavan kirurgin tulee välttää laitteiden uurtamista, naarmuttamista tai edestakaista taivuttamista niitä muotoillessaan. Muutokset aiheuttavat pinnoitevikoja ja sisäisiä rasitteita, joista voi muodostua alkukohta implantaatin mahdolliselle murtumiselle. Implantaattia ei saa käyttää, jos sen epäillään vaurioituneen.

   Ruuvien liiallinen vääntäminen levyjä kiinnitettäessä voi aiheuttaa luun rikkoutumisen kierteiden särkyessä ja/tai ruuvien kiinnittymisen heikentymisen.
3. **RAKENTEEN TAIVUTTAMINEN.** Titaaniseoksesta valmistettuja komponentteja ei saa koskaan taivuttaa jyrkästi tai edestakaisin. Jos rakennetta muotoillaan liikaa, on parempi käyttää oikein muotoiltua uutta rakennetta sen sijaan, että liikaa taivutettua rakennetta väännettäisiin takaisin.
4. **IMPLANTAATIN POISTAMINEN PARANEMISEN JÄLKEEN.** Jos implantaattia ei poisteta sen tarkoitetun käytön jälkeen, seurauksena voi olla mikä tahansa seuraavista komplikaatioista: (1) syöpyminen ja paikallinen kudosreaktio tai kipu, (2) implantaatin liikkuminen uuteen asentoon, mistä voi seurata vamma, (3) leikkauksen jälkeisestä vammasta johtuvan lisävamman vaara, (4) taipuminen, löystyminen ja/tai murtuminen, minkä jälkeen poistaminen on epäkäytännöllistä tai vaikeaa, (5) laitteen aiheuttama kipu, epämukavuus tai oudot tuntemukset, (6) mahdollisen infektion vaaran lisääntyminen ja (7) luukato rasitussuojan vuoksi. Kirurgin tulee punnita vaarat ja hyödyt huolellisesti päättäessään implantaatin poistosta. Implantaatin poistoa tulisi seurata riittävä leikkauksen jälkeinen tarkkailu uuden murtuman tai deformiteetin ehkäisemiseksi. Jos potilas on vanhahko ja hänen aktiviteettitasonsa on alhainen, kirurgi voi päättää, ettei implantaattia poisteta, jolloin eliminoidaan toiseen leikkaukseen liittyvät vaarat.
5. **POTILAAN TULEE SAADA RIITTÄVÄT OHJEET.** Leikkauksen jälkihoito ja potilaan kyky ja halukkuus noudattaa ohjeita ovat eräitä tärkeimmistä seikoista luun onnistuneessa parantumisessa. Potilaalle täytyy kertoa implantaatin rajoitteista ja häntä on ohjattava rajoittamaan fyysisiä toimintoja, varsinkin nostamista ja kiertymisliikkeitä sekä kaikkea osallistumista urheiluun. Potilaan tulee ymmärtää, ettei metalli-implantaatti ole yhtä vahva kuin normaali, terve luu, vaan se voi löystyä, taipua ja/tai murtua, jos se joutuu liiallisen rasituksen alaiseksi varsinkin ennen luun täydellistä parantumista. Virheellisten liikkeiden vuoksi pois paikaltaan joutunut tai vahingoittunut implantaatti voi liikkua ja vahingoittaa hermoja tai verisuonia. Aktiivinen, heikko tai dementoitunut potilas, joka ei pysty asianmukaisesti käyttämään tukilaitteita, saattaa erityisesti olla vaarassa leikkauksen jälkihoidon aikana.

### MAHDOLLISIA HAITTAVAIKUTUKSIA

1. Yhteenliittymättömyys tai viivästynyt liittyminen.
2. Implantaatin taipuminen tai murtuminen. Implantaatin löystyminen.
3. Yliherkkyys metallille tai allerginen reaktio vierasesineelle.
4. Infektio, joko aikaisessa tai myöhemmässä vaiheessa.
5. Rasitussuojasta johtuva luun tiheyden väheneminen.
6. Laitteen aiheuttama kipu, epämukavuus tai oudot tuntemukset.
7. Leikkausvauriosta tai laitteesta johtuva hermovaurio. Hermostollisia vaikeuksia, joihin kuuluvat hermojuurisärky, hermojen liekaantuminen arpikudokseen, lihasten heikkous ja parestesia.
8. Verisuonten vahingoittuminen saattaa aiheuttaa katastrofisen tai kuolemaan johtavan verenvuodon. Väärin asennetut implantaatit, jotka ovat lähellä suuria valtimoita tai laskimoita saattavat kalvaa näitä suonia ja aiheuttaa katastrofisen verenvuodon leikkauksen jälkihoidon myöhäisvaiheessa.

9. Leikkauksen aikana sattuneet kovakalvon repeämät saattavat tehdä uuden leikkauksen tarpeelliseksi kovakalvon korjausta varten ja aiheuttaa kroonisen aivoselkäydinnesteen vuodon tai avanteen ja mahdollisen aivokalvotulehduksen.
10. Bursiitti (limapussitulehdus).
11. Halvaantuminen.
12. Ruokatorven puhkeaminen, kuluminen tai ärsyyntyminen.
13. Ruuvin ulostyöntyminen, minkä vuoksi implantaatti voi löystyä ja/tai joudutaan suorittamaan uusi leikkaus laitteen poistamiseksi.
14. Imusuonten vaurioituminen ja/tai imunesteen eksudaatio.
15. Selkäytimen loukkaantuminen tai vahingoittuminen.
16. Luurakenteiden murtuma.
17. Yhteen sulautuneiden selkänikamien tason viereisten segmenttien rappeutuminen tai epävakaisuus.
18. Kuolema.

**RAJOITETTU TAKUU JA VASTUUVAPAUSLAUSEKE: ALKUPERÄINEN OSTAJA SAA DEPUY SPINE -TUOTTEILLE MYÖNNETTÄVÄN RAJOITETUN TAKUUN, JOKA KATTAA VALMISTUS- JA MATERIAALIVIAT. KAIKKI MUUT TAKUUT JA VASTUUT, NIMENOMAISET TAI OLETETUT, MUKAAN LUETTUNA TAKUUT TUOTTEEN KAUPATTAVUUDESTA TAI SOPIVUUDESTA TIETTYYN TARKOITUKSEEN, TORJUTAAN PÄTEMÄTTÖMINÄ.**

**JOS VIIMEISIMMÄN PAINOKSEN/TARKENNUKSEN JA KONSULTOINNIN VÄLINEN AIKA ON ENEMMÄN KUIN KAKSI VUOTTA, PYYDÄ AJAN TASALLA OLEVIA TIETOJA DEPUY SPINEILTÄ NUMEROSTA 800 365 6633 (USA) TAI +1 508 880 8100.**

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**MERKKIEN TULKINTA**

| | | | |
|---|---|---|---|
| LOT ERÄKOODI | KERTAKÄYTTÖINEN | NONSTERILE EPÄSTERIILI | VALMISTAJA |
| REF CLUETTELONUMERO | XXXX-XX KÄYTETTÄVÄ ENNEN | STERILE R STERILOITU SÄDETYKSELLÄ | EC REP VALTUUTETTU EDUSTAJA EUROOPASSA |
| QTY MÄÄRÄ | KATSO KÄYTTÖOHJEITA | STERILE EO STERILOITU ETYLEENIOKSIDILLA | DIST JÄLLEENMYYJÄ |
| Rx Only Yhdysvaltain liittovaltion lain mukaan tämän laitteen saa myydä ainoastaan lääkäri tai lääkärin määräyksestä. | STERILE STERILI | MADE IN VALMISTUSMAA | SZ KOKO |

**MATERIAALI** MATL

| | | |
|---|---|---|
| A/T ACROFLEX™/Ti ACROFLEX™/titaani | PY Polyesteri | SS/RADEL®/ SRTA Ti Al Nitride Ruostumaton teräs/RADEL®/ titaanialumiininitridi |
| A Al Alumiini | P POLYMER Polymeeri | STA SS/Ti Al Nitride Ruostumaton teräs/ titaanialumiininitridi |
| A/P Al/PL Alumiini/muovi | P/CM PE/CoCrMo Polyeteeni/ kobolttikromimolybdeeni | S/U SS/ULTEM Ruostumaton teräs/Ultem |
| B/R Ba/RADEL® Barium/RADEL® | P/C POLYMER/CARBON FIBER COMPOSITE Polymeeri/hiilikuitukomposiitti | T Ti Titaani ja titaaniseokset |
| CaP CALCIUM PHOSPHATE Kalsiumfosfaatti | S SS Ruostumaton teräs | S/R SS/RADEL® Ruostumaton teräs/RADEL® |
| CM CoCrMo Kobolttikromimolybdeeni | S/A SS/Al Ruostumaton teräs/alumiini | R/T POLYOLEFIN RUBBER/Ti Polyolefiinikumi/titaani |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Kobolttikromimolybdeeni/ titaani/kalsiumfosfaatti | SBR SS/Ba/RADEL® Ruostumaton teräs/ barium/RADEL® | T/A Ti/Al Titaani/alumiini |
| F FOAM Vaahtomuovi | S/P SS/PHENOLIC Ruostumaton teräs/fenoli | Ti/UHMWPE/HA Titaani/suuren molekyylipainon omaava polyeteeni/ hydroksiapatiitti |
| HA Hydroksiapatiitti | S/PL SS/PL Ruostumaton teräs/muovi | SS/Ti Ruostumaton teräs/titaani |
| NiTi Ni/Ti Nikkeli/titaani | SRSI SS/RADEL®/ SILICONE Ruostumaton teräs/ RADEL®/silikoni | SS/Al/SILICONE Ruostumaton teräs/ alumiini/silikoni |
| PL Muovi | SRSN SS/RADEL®/ SILICONE/Ti Al Nitride Ruostumaton teräs/ RADEL®/silikoni/ titaanialumiininitridi | S/SI SS/SILICONE Ruostumaton teräs/silikoni |
| P/F PL/FOAM Muovi/vaahtomuovi | | |



fr

# SYSTÈME DE PLAQUES DE COMPRESSION ANTÉRIEURES PEAK

# SYSTÈME DE PLAQUES CERVICALES ANTÉRIEURES POLYAXIALES PEAK

# SYSTÈME DE STABILISATION DE LA RÉGION VENTRALE DES CERVICALES DOC

# SYSTÈME DE PLAQUES CERVICALES ANTÉRIEURES SLIM-LOC™

# SYSTÈME DE PLAQUES CERVICALES ANTÉRIEURES EAGLE™

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# SYSTÈME DE PLAQUES CERVICALES ANTÉRIEURES SKYLINE™

## REMARQUE IMPORTANTE À L'ATTENTION DES CHIRURGIENS

Les implants du système de stabilisation de la face antérieure des cervicales, comme tout autre dispositif de fixation interne, ont une durée de vie utile déterminée. L'activité physique du patient a un impact important sur cette durée de vie. Votre patient doit être informé que toute activité augmente le risque de relâchement, pliure ou cassure des composants de l'implant. Il est essentiel que le patient comprenne l'importance de restreindre ses activités pendant la période postopératoire et il est important d'examiner le patient après l'opération, pour évaluer le développement de la masse de l'arthrodèse et l'état des composants de l'implant. Même dans un cas de formation d'arthrodèse osseuse solide, les composants de l'implant peuvent néanmoins se plier, se casser ou se relâcher. Le patient doit donc être informé du fait que les composants de l'implant peuvent se plier, se casser ou se relâcher même s'il restreint ses activités.

En raison des limites imposées par les considérations anatomiques et les matériaux chirurgicaux modernes, les implants métalliques ne peuvent être faits pour durer indéfiniment. Ils ont pour but de fournir un support interne temporaire pendant la consolidation de l'arthrodèse. Les résultats de ces types d'implants risquent d'être nuls si aucune greffe d'os n'est faite ou si une pseudarthrose se développe.

Le chirurgien peut décider de retirer les implants après la formation d'une arthrodèse osseuse. La possibilité d'une seconde opération chirurgicale doit être envisagée avec le patient en précisant à ce dernier les risques qu'elle implique. Si les implants se cassent, la décision de les retirer doit être prise par le médecin, lequel doit considérer l'état du patient et les risques posés par la présence d'un implant cassé.

## DESCRIPTION

Le système de plaques de compression antérieures PEAK est formé d'un assortiment de plaques et de vis en alliage de titane. Les plaques sont disponibles en plusieurs longueurs de 26 à 94 mm de façon à pouvoir être adaptées sur un à quatre segments de fixation. Le système comprend également des vis à os cortical de 3,5 mm et des vis à os spongieux de 4 mm en alliage de titane, disponibles en différentes longueurs de 8 à 30 mm.

Le système de plaques cervicales polyaxiales antérieures PEAK est formé d'un assortiment de plaques et de vis en alliage de titane. Les plaques cervicales antérieures sont disponibles en différentes longueurs de 24 à 110 mm pour s'adapter sur un à quatre segments de fixation. Les vis à os spongieux sont offertes en diamètres de 4 mm et 4,35 mm. Elles sont entièrement filetées et sont disponibles en longueurs de 10 à 26 mm.

Le système de stabilisation de la face ventrale des cervicales DOC est un système composé de plates-formes, de plaques, de tiges et de vis en alliage de titane. Il est conçu pour aider les chirurgiens de la colonne vertébrale à corriger les défauts et l'instabilité de la colonne cervicale. Le système de stabilisation de la face ventrale des cervicales DOC, lorsqu'il est complètement assemblé, comporte une plaque ou deux tiges placées latéralement, liées par des plates-formes apposées sur la surface antérieure de la vertèbre. Le système est ancré à la vertèbre par des vis. L'implant fournit un appoint de stabilité à la colonne cervicale après une fusion cervicale antérieure. Selon la configuration de l'implant, il peut servir de structure rigide (port de la charge) ou dynamique (répartition de la charge).

Le système peut comprendre les types de composants suivants : tiges, plaques, plates-formes, vis à os internes et externes, vis à greffe et connecteurs de section. Tous les composants sont faits d'un alliage de titane pour implants conforme aux exigences de la norme ASTM F-136. Des assemblages préparés sont également disponibles pour faciliter le travail du

chirurgien. Ce sont des structures partielles préassemblées, constituées d'une plate-forme, d'un connecteur de section, de deux tiges et de deux vis de verrouillage.

**Plates-formes :** Les plates-formes sont conçues pour joindre les tiges et se fixer aux corps vertébraux avec des vis à os. On peut serrer toutes les plates-formes avec des vis à os pleines (pour fixation bicorticale) ou avec une combinaison de vis à os internes et externes (une vis à os externe creuse, utilisée avec une vis de verrouillage interne pleine pour les fixations unicorticales). La sélection des vis est à la discrétion du médecin. Toutes les plates-formes sont faites pour être utilisées avec deux tiges afin de former une structure.

Les plates-formes existent en modèles verrouillables ou non verrouillables. Les plates-formes verrouillables comportent des rallonges sur lesquelles des vis de verrouillage de plate-forme/connecteur de section peuvent être posées afin de fixer la plate-forme aux tiges. Les plates-formes verrouillables doivent être utilisées à l'extrémité de la structure opposée aux têtes de tiges.

Si vous préférez une configuration rigide à une configuration dynamique (avec répartition de la charge), une plate-forme verrouillable est nécessaire, adjacente aux têtes des tiges. Si vous préférez une configuration avec répartition de la charge, la plate-forme adjacente aux têtes des tiges n'est pas verrouillée aux tiges.

Plusieurs plates-formes sont conçues pour une insertion inclinée de la vis dans le corps vertébral. Elles existent sous forme verrouillable ou non verrouillable. Ces plates-formes comportent une ailette sur un côté, qui rejoint la vertèbre à partir de l'intérieur de l'espace du disque pour un meilleur positionnement et une meilleure fixation.

Différentes plates-formes sont conçues pour une insertion directe (perpendiculaire) de la vis dans le corps vertébral. Elles existent sous forme verrouillable ou non verrouillable.

Il existe un modèle de plate-forme permettant la fixation de la structure à un greffon intervertébral. Cette plate-forme comporte une fente horizontale et une niche sphérique afin de s'adapter aux variations des points d'entrée de la vis et de la trajectoire dans le greffon.

Le choix de plate-forme dépend de l'anatomie du patient de la préférence du chirurgien.

Le système de plaques cervicales antérieures SLIM-LOC™ consiste en une série de plaques et de vis en alliage de titane. Les plaques sont disponibles en différentes longueurs de 22 à 111 mm en configurations comportant 2, 3, 4, 5 ou 6 paires de trous de vis. Les vis SLIM-LOC existent en diamètre de 4,5 mm et peuvent être soit auto-foreuses de longueurs égales de 10 à 18 mm, soit auto-taraudeuses de longueurs égales de 10 à 26 mm. Des vis de plus grand diamètre (4,8 mm) sont également disponibles en longueurs de 12, 14 et 16 mm.

Le système de plaques cervicales antérieures EAGLE™ est formé d'un assortiment de plaques et de vis en alliage de titane. Les plaques sont disponibles avec deux à six paires de trous de vis, en différentes longueurs. Les vis sont disponibles en plusieurs tailles et géométries de pointes.

Le système de plaques cervicales antérieures SWIFT™ est fabriqué en alliage de titane et est constitué de plaques segmentées permettant l'établissement d'un greffon contrôlé de 2 mm au plus entre chaque segment. Les plaques sont disponibles avec deux à six paires de trous de vis, en différentes longueurs et en deux configurations, discectomie et corporectomie. Les vis sont disponibles en plusieurs tailles et géométries de pointes. Une vis pour greffe est disponible pour être utilisée das les plaques de corporectomie.

Le système de plaques cervicales antérieures UNIPLATE™ comprend des vis et des plaques en alliage de titane. Les plaques cervicales antérieures sont disponibles en différentes longueurs pour s'adapter à un ou deux segments de fixation. Les vis sont disponibles en plusieurs tailles et géométries de pointes.

Le système de plaques cervicales antérieures SKYLINE™ consiste en une série de plaques et de vis en alliage de titane. Les plaques sont disponibles avec deux à six paires de trous de vis, en différentes longueurs. Les vis sont disponibles en plusieurs tailles et géométries de pointes. Il existe des vis guidées et des vis variables afin de créer une configuration guidée, variable ou hybride.

## NETTOYAGE ET STÉRILISATION

Les implants des systèmes de stabilisation cervicale par plaque vissée sont livrés soit stériles, soit propres et non stériles. Assurez-vous que l'emballage des composants stériles est intact avant utilisation.

Dans le cas de produits non stériles, les procédures de stérilisation en milieu hospitalier recommandées par les normes ISO 8828 ou AORN doivent être respectées pour tous les composants.

Des tests ont été conduits et ont abouti aux RECOMMANDATIONS SUIVANTES POUR LA STÉRILISATION À LA VAPEUR :

| | |
|---|---|
| Cycle : | Prévide |
| Température : | 270 °F<br>132 °C |
| Durée d'exposition : | 6 minutes |

## EMPLOI

Le chirurgien doit non seulement maîtriser les techniques médicales et chirurgicales relatives à la pose de l'implant, mais doit également être au fait des limites mécaniques et métallurgiques des implants chirurgicaux métalliques. Les soins postopératoires sont extrêmement importants. Le patient doit être informé des limites des implants métalliques et doit veiller à ne pas imposer une charge pondérale ou une contrainte physique excessive sur le dispositif avant une guérison solide de l'os. Le patient doit également être averti que le non-respect des instructions postopératoires peut susciter l'échec de l'implant et éventuellement la nécessité d'une autre intervention chirurgicale pour le retrait de ce dernier.



Les composants du système d'implant vertébral DePuy Spine ne doivent pas être utilisés avec des composants provenant d'autres fabricants.

**Pour obtenir une translation verticale contrôlée (répartition de charge), il est essentiel de placer correctement les composants choisis.**

**Veuillez vous reporter au manuel traitant des méthodes chirurgicales pour obtenir des instructions appropriées.**

## INDICATIONS

**ATTENTION :** Selon la loi américaine, seuls les médecins sont autorisés à vendre ou à prescrire ce dispositif.

Les systèmes de plaques cervicales antérieures SLIM-LOC et SKYLINE™ sont indiqués pour la stabilisation de la colonne cervicale de C2 à C7, à l'aide d'une fixation à vis corticale unique sur la face antérieure des corps vertébraux. La pose antérieure d'une plaque vissée est spécifiquement indiquée, entre autres, pour les usages cliniques suivants : instabilité due à un traumatisme ; instabilité associée à la correction d'une lordose cervicale et d'une cyphose ; instabilité associée à une pseudarthrose à la suite d'une intervention échouée de la colonne cervicale ; instabilité associée à une restauration chirurgicale importante à la suite de tumeurs primitives ou de métastases malignes de la colonne cervicale ; instabilité associée à une corporectomie à un seul ou plusieurs niveaux lors de maladies dégénératives des disques avancées ; sténose du canal rachidien et myélopathie cervicale.

Le système de plaques de compression antérieures PEAK, le système de plaques cervicales polyaxiales antérieures PEAK, le système de stabilisation de la face ventrale des cervicales DOC, le système de plaques cervicales antérieures EAGLE, le système de plaques cervicales antérieures SWIFT et le système de plaques cervicales antérieures UNIPLATE sont conçus pour la fixation du corps intervertébral cervical antérieur. Ces systèmes sont indiqués pour les patients qui ont besoin de stabilité à la suite d'une fusion cervicale antérieure dans les conditions données ci-dessous. Les niveaux à considérer pour un tel traitement vont de C2 à T1.

Le système est indiqué, entre autres, pour la spondylite cervicale symptomatique, les traumatismes, les fractures, les cyphoses ou lordoses post-traumatiques, les tumeurs, les discopathies dégénératives (soit des douleurs dorsales d'origine discale avec dégénérescence du disque confirmée par les antécédents et la radiographie), une nouvelle intervention après une fusion échouée, ou une instabilité à la suite d'une intervention pour les conditions ci-dessus.

Le système de plaques cervicales antérieures UNIPLATE est également indiqué pour le traitement des sténoses vertébrales.

**AVERTISSEMENT :** Ces dispositifs ne sont pas homologués pour la fixation de vis aux éléments postérieurs (pédicules) de la colonne cervicale, thoracique ou lombaire.

## MOBILISATION POSTOPÉRATOIRE

Jusqu'à confirmation de la maturation de la masse de fusion par radiographie, l'immobilisation externe (par attelles ou plâtre) peut être recommandée, selon que le médecin la juge appropriée ou non.

Les directives à donner au patient pour minimiser toute contrainte sur les implants sont également importantes, afin de réduire le risque de complications cliniques pouvant accompagner l'échec de la fixation.

## CONTRE-INDICATIONS

- Toute infection active généralisée ou localisée à l'endroit prévu de l'implantation.
- Une ostéoporose grave peut empêcher la fixation appropriée des vis et, de ce fait, exclure l'utilisation de ce système ou de tout autre système d'instruments vertébraux.
- Patients dont on a démontré qu'ils pouvaient être traités, de façon sûre et prévisible, sans l'utilisation de dispositifs de fixation interne.
- Blessures ouvertes.

## CONTRE-INDICATIONS RELATIVES :

Tout élément ou tout état qui exclut totalement la possibilité de fusion (tel que cancer, dialyse, ostéopénie), l'obésité, certaines maladies dégénératives et la sensibilité aux corps étrangers, constitue une contre-indication relative.

## AVERTISSEMENTS, PRÉCAUTIONS ET COMPLICATIONS CONCERNANT LES DISPOSITIFS MÉTALLIQUES DE FIXATION INTERNE À USAGE TEMPORAIRE.

### AVERTISSEMENTS

Les avertissements, précautions et complications spécifiques indiqués ci-dessous doivent être compris par le chirurgien et expliqués au patient. Ces avertissements ne couvrent pas toutes les complications qui peuvent se présenter en chirurgie de façon générale, mais sont des considérations importantes et ayant trait aux dispositifs métalliques de fixation interne. Les risques chirurgicaux d'ordre général doivent être expliqués au patient avant l'intervention chirurgicale.

Les conditions connues créant des risques potentiels à la suite de l'utilisation de ce type de dispositif, et qui peuvent nécessiter une autre intervention sont, entre autres : fracture d'un composant du dispositif, perte de fixation, absence d'union, fracture de la vertèbre, lésion neurologique et lésions viscérales ou vasculaires.

1. **LE CHOIX DE L'IMPLANT APPROPRIÉ EST EXTRÊMEMENT IMPORTANT.** Les chances d'obtenir une fixation satisfaisante augmentent lorsque la sélection de la taille, de la forme et de la conception de l'implant est appropriée. Même si une soigneuse sélection de l'implant peut diminuer les risques, la taille et la forme des os humains tendent à limiter le choix de la taille, la forme et la solidité des implants. Les dispositifs métalliques de fixation interne ne peuvent pas supporter un degré d'activité égal à celui qui est normalement imposé à un os sain normal. On ne peut attendre d'aucun implant qu'il résiste indéfiniment à la contrainte que représente le poids total sans soutien artificiel.
2. **LES IMPLANTS PEUVENT SE ROMPRE LORSQU'ILS SONT SOUMIS À LA CHARGE CROISSANTE ASSOCIÉE À UNE UNION RETARDÉE OU INEXISTANTE.** Les appareils de fixation interne sont des dispositifs à répartition de charge utilisés pour obtenir un alignement en attendant la guérison normale. Si la guérison est retardée ou ne se produit pas, une cassure de l'implant peut être suscitée par la fatigue du métal. Le degré ou la réussite de l'union, le poids à soutenir et les niveaux d'activité dictent, entre autres, la longévité de l'implant. Les entailles, écorchures ou pliures infligées à l'implant pendant l'intervention chirurgicale sont également des facteurs d'échec précoce. Les patients doivent être bien informés des risques d'échec d'un implant.
3. **LE MÉLANGE DE MÉTAUX PEUT ENTRAÎNER LA CORROSION.** Il existe diverses formes de corrosion des métaux ; certaines se produisent sur les métaux implantés dans le corps par chirurgie. Une corrosion générale ou uniforme est présente sur tous les métaux et alliages implantés. Le coefficient d'attaque corrosive sur les implants métalliques est habituellement très faible grâce à la présence de pellicules passives sur leur surface. Le contact entre des métaux différents, tels que le titane et l'acier inoxydable, accélère le processus de corrosion de l'acier inoxydable et produit une attaque plus rapide. La présence de corrosion accélère souvent la fracture par fatigue des implants. La quantité de composés métalliques libérés dans le corps augmente alors en conséquence. Les dispositifs de fixation interne, tels que tiges, crochets, fils, etc., qui entrent en contact avec d'autres objets métalliques, doivent être composés du même métal ou de métaux compatibles.
4. **SÉLECTION DES PATIENTS.** Lors de la sélection des patients pour l'implantation de dispositifs de fixation interne, les facteurs suivants peuvent s'avérer d'une extrême importance pour la réussite définitive de la procédure :

   A. **La profession ou l'activité du patient.** Si la profession ou l'activité du patient exige qu'il soulève de lourdes charges, exerce un effort musculaire important, qu'il se tourne, se courbe, s'accroupisse, coure fréquemment, marche beaucoup ou travaille manuellement, il ne pourra pas reprendre ces activités avant la guérison complète de l'os. Même après la guérison complète, le patient peut ne pas être capable de reprendre ces activités sans problème.

   B. **État de sénilité, de maladie mentale, d'alcoolisme ou d'abus de drogues.** Ces conditions, entre autres, peuvent pousser le patient à ne pas tenir compte de certaines limites et précautions nécessaires quant à l'usage de l'appareil, provoquant l'échec de l'implant ou d'autres complications.

   C. **Certaines affections dégénératives.** Dans certains cas, la progression d'une maladie dégénérative peut avoir atteint un stade suffisamment avancé au moment de l'implantation pour que la vie utile de l'appareil en soit fortement diminuée. Dans de telles conditions, les dispositifs orthopédiques ne peuvent être considérés que comme une technique accordant un délai ou un remède temporaire.

   D. **Sensibilité aux corps étrangers.** Le chirurgien doit savoir qu'aucun test préopératoire ne peut exclure complètement la possibilité de sensibilité ou de réaction allergique. Des patients peuvent ne développer une sensibilité ou une allergie à l'implant qu'après un certain temps.

   E. **Consommation de tabac.** Il a été observé, dans le cas de patients fumeurs, des taux de pseudarthrose plus élevés à la suite d'interventions chirurgicales utilisant les greffons osseux. De plus, on a constaté que le tabac occasionnait une dégénérescence diffuse des disques intervertébraux. Une dégénérescence progressive des segments adjacents causée par le tabac peut entraîner un échec clinique tardif (douleur récurrente) même après une arthrodèse réussie et une amélioration clinique initiale.

**AVERTISSEMENT :** Si la fusion des os ne se produit pas au cours de la période prévue, les vis risquent de se rompre en raison de la charge prolongée et importante imposée sur ces dispositifs. Cette situation a été observée chez les patients présentant un retard de pseudarthrose, ou lors d'une fracture, et, dans ces cas, il sera nécessaire de revérifier l'intégrité de ces dispositifs.

## PRÉCAUTIONS

1. **LES IMPLANTS CHIRURGICAUX NE DOIVENT JAMAIS ÊTRE RÉUTILISÉS.** Un implant métallique retiré du patient ne doit jamais être réimplanté. Même si le dispositif semble en parfait état, il peut avoir de légers défauts et des traces internes de fatigue susceptibles de causer une rupture précoce.
2. **LA MANIPULATION CORRECTE DE L'IMPLANT EST EXTRÊMEMENT IMPORTANTE.** Le profilage d'implants métalliques ne doit être effectué qu'avec l'équipement approprié. Le chirurgien responsable doit éviter toute entaille, éraflure ou flexion inversée des dispositifs lors de leur profilage. Les altérations produisent des défauts du fini de surface et des contraintes internes qui peuvent entraîner la rupture de l'implant. N'utilisez pas l'implant si vous soupçonnez qu'il est endommagé.



Un serrage excessif des vis lors de l'installation de la plaque peut provoquer un relâchement des os, la dénudation des filets et/ou compromettre l'appui des vis.

3. **PLIAGE D'UNE STRUCTURE.** Les composants en alliage de titane ne devraient jamais subir des flexions prononcées ou inversées. Si une structure a été trop profilée, il est recommandé de profiler une nouvelle structure correctement, plutôt que d'effectuer une flexion inversée sur la structure trop profilée.
4. **RETRAIT DE L'IMPLANT APRÈS GUÉRISON.** Si le dispositif n'est pas retiré à la fin de son usage prévu, l'une ou l'autre des complications suivantes peuvent survenir : (1) corrosion, avec réaction des tissus ou douleur localisée ; (2) déplacement de la position de l'implant causant une blessure ; (3) risque de blessures supplémentaires à la suite d'un traumatisme postopératoire ; (4) pliure, relâchement et/ou rupture, pouvant rendre l'extraction peu avantageuse ou difficile ; (5) douleur, inconfort ou sensations anormales par suite de la présence du dispositif ; (6) augmentation possible du risque d'infection ; et (7) perte de densité osseuse due à l'effet bouclier anti-contrainte. Le chirurgien doit soigneusement faire la part des risques et avantages dans sa décision de retirer l'implant ou non. Le retrait de l'implant doit être suivi de soins postopératoires adéquats pour éviter toute nouvelle fracture ou difformité. Si le patient est relativement âgé et peu actif, le chirurgien peut choisir de ne pas retirer l'implant, éliminant ainsi les risques qu'implique une seconde opération.
5. **PRÉPARATION ADÉQUATE DU PATIENT.** Les soins postopératoires ainsi que la capacité et la volonté du patient de suivre les instructions comptent parmi les aspects les plus importants d'une guérison des os réussie. Le patient doit être prévenu des limites de l'implant, et informé de la nécessité de limiter et de réduire son activité physique, en particulier les mouvements de levage et de torsion et toute forme de pratique sportive. Il doit comprendre qu'un implant métallique n'est pas aussi solide qu'un os sain normal et qu'il peut se relâcher, se plier et/ou se casser sous des contraintes excessives, particulièrement en l'absence de guérison osseuse complète. Les implants qui se déplacent ou subissent des dommages par suite d'activités non appropriées peuvent provoquer des lésions des nerfs et des vaisseaux sanguins. Un patient actif, ou incapable d'utiliser correctement des dispositifs de support pondéral pour cause d'asthénie ou de démence encourt des risques importants pendant la réhabilitation postopératoire.

## COMPLICATIONS POSSIBLES

1. Absence ou retard de consolidation.
2. Pliure ou rupture de l'implant. Relâchement de l'implant.
3. Sensibilité au métal ou réaction allergique à un corps étranger.
4. Infection, précoce ou tardive.
5. Diminution de densité osseuse par l'effet bouclier anti-contrainte.
6. Douleur, inconfort ou sensations anormales par suite de la présence du dispositif.
7. Dommage nerveux dû au traumatisme chirurgical ou à la présence du dispositif. Difficultés neurologiques incluant une douleur radiculaire, attachement des tissus cicatriciels aux nerfs, faiblesse musculaire et paresthésie.
8. Des troubles vasculaires peuvent causer une hémorragie catastrophique ou fatale. Des implants mal positionnés à proximité d'artères ou de veines importantes peuvent éroder celles-ci et provoquer une hémorragie catastrophique à la fin de la période postopératoire.
9. Des déchirures durales en cours d'opération peuvent provoquer le besoin d'une autre opération réparatrice, une fuite de liquide céphalorachidien chronique ou une fistule artérioveineuse et une possibilité de méningite.
10. Bursite.
11. Paralysie.
12. Perforation, érosion ou irritation de l'œsophage.
13. Saillie de vis, pouvant entraîner une érosion de l'œsophage, un relâchement de l'implant et/ou une nouvelle opération pour le retrait du dispositif.
14. Lésions des vaisseaux lymphatiques et/ou exsudation de lymphe.
15. Interférence ou dommage à la moelle épinière.
16. Fracture des structures osseuses.
17. Changements dégénératifs ou instabilité de segments adjacents aux niveaux de l'arthrodèse vertébrale.
18. Mort.

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**TRADUCTION DES SYMBOLES**

| | | | |
|---|---|---|---|
| LOT NUMÉRO DE LOT | UN SEUL USAGE | NONSTERILE NON STÉRILE | FABRICANT |
| REF NUMÉRO DE CATALOGUE | XXXX-XX UTILISER AVANT LE | STERILE R STÉRILISATION PAR RADIATION | EC REP REPRÉSENTANT EUROPÉEN AGRÉÉ |
| QTY QUANTITÉ | VOIR LE MODE D'EMPLOI | STERILE EO STÉRILISATION PAR OXYDE D'ÉTHYLÈNE | DIST DISTRIBUÉ PAR |
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**MATÉRIAU** MATL

| | | |
|---|---|---|
| A/T ACROFLEX®/Ti ACROFLEX®/titane | P POLYMER Polymère | SS/RADEL®/ SRTA Ti Al Nitride Acier inoxydable/RADEL®/ nitrure d'aluminium et de titane |
| A Al Aluminium | P/CM PE/CoCrMo Polyéthylène/ cobalt-chrome-molybdène | STA SS/Ti Al Nitride Acier inoxydable/ nitrure d'aluminium et de titane |
| A/P Al/PL Aluminium/plastique | P/C POLYMER/CARBON FIBER COMPOSITE Matériau composite en fibres de carbone/polymère | S/U SS/ULTEM Acier inoxydable/ultem |
| B/R Ba/RADEL® Baryum/RADEL® | S SS Acier inoxydable | T Ti Titane et ses alliages |
| CaP CALCIUM PHOSPHATE Phosphate de calcium | S/A SS/Al Acier inoxydable/aluminium | S/R SS/RADEL® Acier inoxydable/RADEL® |
| CM CoCrMo Cobalt-chrome-molybdène | SBR SS/Ba/RADEL® Acier inoxydable/ baryum/RADEL® | R/T POLYOLEFIN RUBBER/Ti Caoutchouc polyoléfinique/titane |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Cobalt-chrome-molybdène/ titane/phosphate de calcium | S/P SS/PHENOLIC Acier inoxydable/ résine phénolique | T/A Ti/Al Titane/aluminium |
| F FOAM Mousse | S/PL SS/PL Acier inoxydable/plastique | Ti/UHMWPE/HA Titane/polyéthylène à poids moléculaire très élevé/ hydroxyapatite |
| HA Hydroxyapatite | SRSI SS/RADEL®/ SILICONE Acier inoxydable/ RADEL®/silicone | SS/Ti Acier inoxydable/titane |
| NIT Ni/Ti Nickel/titane | SRSN SS/RADEL®/ SILICONE/Ti Al Nitride Acier inoxydable/RADEL®/ silicone/nitrure d'aluminium et de titane | SS/Al/SILICONE Acier inoxydable/ aluminium/silicone |
| PL Plastique | | S/SI SS/SILICONE Acier inoxydable/silicone |
| P/F PL/FOAM Plastique/mousse | | |
| PY Polyester | | |



de

# PEAK ANTERIOR-KOMPRESSIONSPLATTENSYSTEM

# POLYAXIALES PEAK ANTERIOR-ZERVIKALPLATTENSYSTEM

# VENTRALES DOC ZERVIKAL-STABILISIERUNGSSYSTEM

# SLIM-LOC™ ANTERIOR-ZERVIKALPLATTENSYSTEM

# EAGLE™ ANTERIOR-ZERVIKALPLATTENSYSTEM

# SWIFT™ ANTERIOR-ZERVIKALPLATTENSYSTEM

# UNIPLATE™ ANTERIOR-ZERVIKALPLATTENSYSTEM

# SKYLINE™ ANTERIOR-ZERVIKALPLATTENSYSTEM

## WICHTIGER HINWEIS FÜR DEN OPERIERENDEN CHIRURGEN

Die Implantate des Anterior-Stabilisierungssystems sind wie alle temporären internen Fixiervorrichtungen nur auf begrenzte Zeit funktionsfähig. Der Aktivitätsgrad des Patienten wirkt sich stark auf die Nutzdauer aus. Alle Patienten müssen darüber informiert werden, dass Aktivitäten jeglicher Art das Risiko einer Lockerung, Verbiegung oder eines Bruchs des Implantats erhöhen. Es ist äußerst wichtig, die Patienten darin zu unterweisen, dass und wie sie ihre Aktivitäten während der postoperativen Periode einschränken sollen; weiterhin sollte eine postoperative Untersuchung am Patienten durchgeführt werden, um die Entwicklung der Fusionsmasse und den Status der Implantatkomponenten zu evaluieren. Auch wenn die gewünschte Knochenfusion auftritt, können sich Implantatkomponenten lockern, verbiegen oder brechen. Der Patient muss also darauf aufmerksam gemacht werden, dass die Implantatkomponenten sich auch bei beschränkter Aktivität lockern, verbiegen oder brechen können.

Aufgrund der anatomisch bedingten Limitationen sowie der Eigenschaften moderner chirurgischer Werkstoffe ist es nicht möglich, Metallimplantate mit unbegrenzter Lebensdauer herzustellen. Ihr Zweck ist es, als temporäre innere Stütze zu dienen, während die Fusionsmasse sich festigt. Der Erfolg von Implantaten dieser Art ist besonders dann gefährdet, wenn kein Knochentransplantat verwendet wird, oder wenn eine Pseudoarthrose auftritt.

Nach erfolgter Knochenfusion kann es der Chirurg unter Umständen für angebracht halten, das Implantat wieder zu entfernen. Der Patient muss über die Möglichkeit eines eventuellen zweiten chirurgischen Eingriffs und die damit verbundenen Risiken informiert werden. Sollte ein Implantat brechen, muss der Arzt die Entscheidung treffen, ob das Implantat entfernt werden soll, wobei der Zustand des Patienten und die mit dem vorhandenen gebrochenen Implantat verbundenen Risiken abgewägt werden sollten.

## BESCHREIBUNG

Das PEAK Anterior-Kompressionsplattensystem besteht aus verschiedenen Platten und Schrauben mit Titanlegierung. Die Platten sind zum Aufnehmen von ein bis vier Fixierungselementen in verschiedenen Längen von 26 - 94 mm erhältlich. Das System ist außerdem mit kortikalen Schrauben (3,5 mm Durchmesser) und spongiösen Schrauben (4,0 mm Durchmesser) mit Titanlegierung ausgestattet, die in 8 mm - 30 mm Länge erhältlich sind.

Das polyaxiale PEAK Anterior-Zervikalplattensystem besteht aus verschiedenen Platten und Schrauben mit Titanlegierung. Die Anterior-Zervikalplatten sind zum Aufnehmen von ein bis vier Fixierungselementen in verschiedenen Längen von 24 mm bis 110 mm erhältlich. Die spongiösen Schrauben sind mit 4,0 mm und 4,35 mm Durchmesser erhältlich. Sie sind mit einem durchgehenden Gewinde versehen und zwischen 10 und 26 mm lang.

Das ventrale DOC Zervikalstabilisierungssystem ist ein aus Titanlegierung gefertigtes System mit Plattformen, Platten, Stäben und Schrauben, das Chirurgen bei der Korrektur von Wirbelsäulendefekten und bei der Wirbelsäulenstabilisierung hilft. In zusammengebauter Form umfasst das DOC-System eine Platte oder zwei seitlich montierte Stäbe, die durch vorne auf der Vertebra aufliegende Plattformen verbunden sind. Das System wird mit Schrauben an den Vertebrae verankert. Das Implantat bietet zusätzliche Stabilität für die Halswirbelsäule nach anterior-zervikaler Fusion. Je nach der Implantatkonfiguration kann das Implantat als steife (belastbare) oder dynamische (belastungsteilende) Konstruktion dienen.

Folgende Komponententypen sind für das System erhältlich: Stäbe, Platten, Plattformen, Innen- und Außenknochenschrauben, Transplantatschrauben und Querverbindungen. Alle Komponenten werden aus Titanlegierung von Implantatsqualität gemäß ASTM F-136 Spezifikationen hergestellt. Es gibt auch vorgefertigte Zusammenstellungen, die aus einer Plattform, einer Querverbindung, zwei Stäben und zwei Sicherungsschrauben bestehen.

**Plattform:** Die Plattformen sind so konzipiert, dass sie die Stäbe verbinden und mit Knochenschrauben an den Vertebralkörpern verankert werden können. Alle Plattformen lassen sich entweder mit Massiv-Schrauben (zur bikortikalen Befestigung) oder mit einer Kombination aus einer äußeren Knochenschraube und einer inneren Knochenschraube (eine hohle, äußere Knochenschraube mit einer massiven inneren Stellschraube zur unikortikalen Befestigung) verwenden. Der Arzt kann die Schrauben seiner Präferenz entsprechend wählen. Alle Plattformen sind zur Verwendung mit zwei Stäben für diese Konstruktion vorgesehen.

Die Plattformen sind in gesicherter und nicht gesicherter Ausführung erhältlich. Gesicherte Plattformen haben Verlängerungen, in die die Plattform-/ Querverbindungs-Sicherungsschrauben passen, mit denen die Plattformen an den Stäben befestigt sind. Gesicherte Plattformen müssen am Ende der Konstruktion, gegenüber den Stabköpfen, verwendet werden.

Wird eine steife Konstruktion einer dynamischen (d.h. belastungsteilenden) Konfiguration vorgezogen, muss auch neben den Stabköpfen eine gesicherte Plattform verwendet werden. Wird eine belastungsteilende Konfiguration gewünscht, wird die Plattform neben den Stabköpfen nicht an den Stäben gesichert.

Verschiedene Plattformen ermöglichen ein angewinkeltes Einsetzen der Schrauben in den Vertebralkörper. Diese gibt es sowohl in einer gesicherten als auch in einer nicht gesicherten Ausführung. Diese Plattformen haben eine Finnenvorrichtung auf einer Seite, die sich zur optimalen Positionierung und Befestigung von innen an den Vertebrae festhakt.

Einige Plattformen sind zur geraden Einführung (im rechten Winkel) der Schraube in den Wirbelkörper vorgesehen. Diese sind sowohl in einer gesicherten als auch in einer nicht gesicherten Ausführung erhältlich.

Ein Plattformdesign eignet sich zur Befestigung der Konstruktion an einem intervertebralen Knochenspan. Der horizontale Schlitz und eine kugelförmige Aushöhlung ermöglichen verschiedene Schraubeneinführungsstellen und Schraubrichtungen in das Transplantat.

Die Wahl der Plattform richtet sich nach der Präferenz des Arztes und der Anatomie des Patienten.

Das SLIM-LOC™ Anterior-Zervikalplattensystem besteht aus verschiedenen Platten und Schrauben mit Titanlegierung. Die Platten sind in den folgenden Längen erhältlich: 22 - 111 mm in Konfigurationen mit 2, 3, 4, 5 oder 6 Paar Schraubenlöchern. Die SLIM-LOC Schrauben haben einen Durchmesser von 4,5 mm und sind als selbstbohrende Ausführung in geraden Längen von 10 - 18 mm oder als selbstschneidende Ausführung in geraden Längen von 10 - 26 mm erhältlich. Schrauben mit größerem Durchmesser (4,8 mm) sind in den Längen 12, 14 und 16 mm erhältlich.

Das EAGLE™ Anterior-Zervikalplattensystem besteht aus verschiedenen Platten und Schrauben aus Titanlegierung. Die Platten sind mit zwei bis sechs Schraubenlöcherpaaren in verschiedenen Längen benlöcherpaaren in verschiedenen Längen erhältlich. Die Schrauben sind in verschiedenen Größen und Schraubspitzengeometrien erhältlich.

Das Swift™ Anterior-Zervikalplattensystem ist aus einer Titanlegierung gefertigt und besteht aus segmentierten Platten, die ein kontrolliertes Setzen des Transplantats bis zu 2 mm zwischen jedem Segment ermöglichen. Die Platten sind mit zwei bis sechs Schraubenlöcherpaaren in verschiedenen Längen und zwei Konfigurationen - Diskektomie und Korpektomie - erhältlich. Die Schrauben sind in verschiedenen Größen und Schraubspitzengeometrien erhältlich. Zur Anwendung in Korpektomieplatten steht eine Transplantat-schraube zur Verfügung.

Das UNIPLATE™ Anterior-Zervikalplattensystem besteht aus verschiedenen Platten und Schrauben mit Titanlegierung. Die Anterior-Zervikalplatten sind zum Aufnehmen von ein bis zwei Fixierungselemente in verschiedenen Längen erhältlich. Die Schrauben sind in verschiedenen Größen und Schraubspitzen-geometrien erhältlich.

Das SKYLINE™ Anterior-Zervikalplattensystem besteht aus verschiedenen Platten und Schrauben mit Titanlegierung. Die Platten haben zwei bis sechs Paar Schraubenlöcher verschiedener Längen. Die Schrauben sind in verschiedenen Größen und Schraubspitzengeometrien erhältlich. Es gibt unverstellbare und verstellbare Schrauben, mit denen unverstellbare, verstellbare sowie Misch-Konfigurationen möglich sind.

## REINIGUNG UND STERILISATION

Die Implantate des Zervikalplatten-Stabilisierungssystems werden entweder steril oder nur sauber aber unsteril geliefert. Bei sterilen Komponenten muss vor dem Gebrauch sichergestellt werden, dass die Packung unbeschädigt ist.

Für nicht sterile Komponenten sind die in ISO 8828 oder die vom AORN (US-Verband des OP-Personals) empfohlenen Sterilisationsverfahren für Krankenhäuser zu beachten.

Anhand von Tests wurde folgende EMPFEHLUNG FÜR DIE DAMPFSTERILISATION entwickelt:

| | |
|---|---|
| Zyklus | Vorvakuum |
| Temperatur | 132 °C (270 °F) |
| Anwendungszeit | 6 Min. |

## ANWENDUNG

Der Chirurg muss nicht nur mit den medizinischen und chirurgischen Aspekten des Implantats vertraut sein, sondern muss sich auch der mechanischen und metallurgischen Beschränkungen von chirurgischen Implantaten aus Metall bewusst sein. Die postoperative Versorgung ist äußerst wichtig. Der Patient ist auf die Beschränkungen der Metallimplantate hinzuweisen und in Bezug auf die Belastung und Stresseinwirkung auf die Vorrichtung vor fester Knochenheilung zu informieren. Der Patient ist ferner zu warnen, dass das Nichtbeachten der postoperativen Verhaltenshinweise zu einem Versagen des Implantats und möglicherweise zu zusätzlichen Operationen zu dessen Entfernung führen kann.

Die Komponenten des DePuy Spine Wirbelsäulensystems dürfen nicht zusammen mit Komponenten anderer Hersteller verwendet werden.



**Um eine kontrollierte vertikale Translation (Belastungsteilung) zu erzielen, ist die richtige Platzierung bestimmter Komponenten äußerst wichtig.**

**Siehe Handbuch zum chirurgischen Verfahren für spezifische Anweisungen.**

## INDIKATIONEN

**ACHTUNG:** Laut US-Bundesgesetz darf diese Vorrichtung nur durch einen Arzt oder auf ärztliche Verordnung verkauft werden.

Die Anterior-Zervikalplattensysteme SLIM-LOC und SKYLINE™ sind zur Stabilisierung der Halswirbelsäule von C2 bis C7 vorgesehen, wobei die Schrauben unikortikal am vorderen Teil der Wirbelkörper befestigt werden. Zu den spezifischen klinischen Indikationen für das Anterior-Platten-Verfahren gehören durch Trauma verursachte Instabilität, mit der Korrektur von zervikaler Lordose oder Kyphose verbundene Instabilität, Instabilität in Verbindung mit Pseudoarthrose aufgrund einer fehlgeschlagenen Halswirbelsäulenoperation, Instabilität in Verbindung mit extensiver rekonstruktiver Chirurgie für primäre Tumore oder metastatische bösartige Tumore der Halswirbelsäule, Instabilität in Verbindung mit Korpektomie auf einer oder mehreren Ebene(n) bei fortgeschrittener degenerativer Bandscheibenerkrankung, Stenose des Wirbelsäulenkanals und zervikale Myelopathie.

Das PEAK Anterior-Kompressionsplattensystem, das polyaxiale PEAK Anterior-Zervikalplattensystem, das ventrale DOC Zervikalstabilisierungssystem, das EAGLE Anterior-Zervikalplattensystem, das SWIFT Anterior-Zervikalplattensystem und das UNIPLATE Anterior-Zervikalplattensystem sind für die anterior-zervikale Wirbelkörperfixierung bestimmt. Diese Systeme eignen sich für Patienten, die nach einer anterior-zervikalen Fusion eine zusätzliche Stabilisierung für nachstehende Indikationen brauchen. Die vorgesehenen Behandlungsebenen liegen zwischen C2 und T1.

Zu den Indikationen gehören symptomatische zervikale Spondylose, Trauma, Fraktur, posttraumatische Kyphose oder Lordose, Tumor, degenerative Bandscheibenerkrankung (definiert als diskogene Schmerzen mit Degenerierung der Bandscheibe, die durch Krankengeschichte und Röntgenaufnahmen bestätigt sind), erneute Operation wegen fehlgeschlagener Fusion oder Instabilität nach Operation aufgrund einer der vorgenannten Indikationen.

Das UNIPLATE Anterior-Zervikalplattensystem ist auch für die Behandlung von Wirbelsäulenstenosen bestimmt.

**WARNUNG:** Diese Produkte sind nicht zum Festschrauben oder zur Befestigung an posterioren Elementen (Pedikeln) der Hals-, Brust- oder Lendenwirbelsäule zugelassen.

## POSTOPERATIVE MOBILISIERUNG

Bis das Ausreifen der Fusionsmasse durch Röntgenaufnahmen bestätigt ist, kann der Arzt u.U. eine externe Ruhestellung (z.B. mit einer Stütze) empfehlen.

Die Einweisung des Patienten, wie der Stress auf die Implantate reduziert werden kann, ist ebenfalls wichtig, um ein Wiederauftreten der klinischen Probleme aufgrund eines Versagens der Fixierung zu vermeiden.

## KONTRAINDIKATIONEN

- Aktive Systeminfektionen bzw. Infektion an der vorgesehenen Implantationsstelle.
- Starke Osteoporose kann eine adäquate Befestigung der Schrauben verhindern und dadurch die Verwendung dieser oder anderer Wirbelsäulenstützen ausschließen.
- Patienten, die bewiesenermaßen gefahrlos und mit abzusehendem Resultat ohne interne Befestigung behandelt werden können.
- Offene Wunden.

## RELATIVE KONTRAINDIKATIONEN:

Zu den relativen Kontraindikationen gehört jeder Grund oder jede Kondition, die die Möglichkeit einer Fusion völlig ausschließt (z.B. Krebs, Nierendialyse oder Osteopenie), Adipositas, bestimmte degenerative Krankheiten und Überempfindlichkeit Fremdkörpern gegenüber.

## WARNHINWEISE, VORSICHTSMASSNAHMEN UND NEBENWIRKUNGEN IN VERBINDUNG MIT TEMPORÄREN INTERNEN FIXIERVORRICHTUNGEN AUS METALL

### WARNUNGEN

Die folgenden spezifischen Warnhinweise, Vorsichtsmaßnahmen und Nebenwirkungen sollten vom Chirurgen verstanden und dem Patienten erklärt werden. Diese Warnhinweise schließen jedoch nicht alle jene Nebenwirkungen ein, die im allgemeinen mit Operationen in Verbindung gebracht werden und die auch wichtige Gesichtspunkte für interne Metallbefestigungsvorrichtungen darstellen. Allgemeine, mit Operationen verbundene Risiken sollten dem Patienten vor der Operation ebenfalls erklärt werden.

Potentielle Risiken, die mit der Verwendung dieses Produktes verbunden sind und zusätzliche Operationen möglich machen könnten, sind u.a.

der Bruch eines Produktteils, ein Lösen der Befestigung, mangelhafte Knochenfusion, Fraktur der Vertebra, neurologische sowie vaskuläre oder viszerale Verletzung.

1. **DIE KORREKTE WAHL EINES PASSENDEN IMPLANTATS IST VON GRÖSSTER WICHTIGKEIT.** Die Chancen für eine zufriedenstellende Fixation verbessern sich, wenn ein nach Größe, Form und Ausführung passendes Implantat für das Verfahren gewählt wird. Die richtige Auswahl kann zwar die Risiken mindern, andererseits wird die Form und Größe

des jeweiligen Implantats auch durch die Größe, Form und Stärke der menschlichen Knochen eingeschränkt. Interne Fixiervorrichtungen aus Metall können nicht denselben Beanspruchungen widerstehen wie normale gesunde Knochen. Kein Implantat kann der Erwartung entsprechen, dass es ungestützt einer vollen Gewichtsbelastung auf Dauer widerstehen kann.

2. **IMPLANTATE KÖNNEN BRECHEN, WENN SIE DURCH EINE VERSPÄTETE BZW. NICHT ERFOLGENDE HEILUNG ÜBERMÄSSIG BELASTET WERDEN.** Interne Fixiervorrichtungen dienen dazu, einen Teil der Belastung zu tragen und die Knochenausrichtung zu stützen, bis die normale Heilung eintritt. Bei verspäteter oder nicht erfolgender Heilung kann das Implantat aufgrund von Metallermüdung brechen. Die Lebensdauer des Implantats wird auch durch den Grad und Erfolg der Knochenfusion, die Gewichtsbelastung, den Aktivitätsgrad sowie andere Gegebenheiten beeinflusst. Während der Operation erfolgte Scharten, Kratzer oder Verbiegungen können ebenfalls eine verfrühte Funktionsuntüchtigkeit zur Folge haben. Alle Patienten müssen über das Risiko eines Versagens des Implantats voll unterrichtet werden.
3. **DIE VERWENDUNG VERSCHIEDENER METALLE KANN KORROSION VERURSACHEN.** Es gibt viele Arten von Korrosionsschäden, von denen teilweise auch die in der Humanchirurgie verwendeten Metalle betroffen sind. Allgemeine bzw. gleichmäßige Korrosion ist bei allen implantierten Metallen und Legierungen präsent, vollzieht sich jedoch gewöhnlich relativ langsam, da Implantatvorrichtungen aus Metall mit passivem Oberflächenfilm beschichtet sind. Berühren sich unterschiedliche Metalle, wie z.B. Titan und Edelstahl, beschleunigt sich beim Edelstahl der Korrosionsprozess. Bei Korrosion treten an den Implantaten auch schneller Ermüdungsfrakturen auf. Außerdem erhöht sich der Anteil der in den Körper abgegebenen Metallstoffe. Interne Fixiervorrichtungen, wie Stäbe, Haken, Drähte usw., die mit anderen Metallobjekten in Berührung kommen, müssen aus demselben oder einem kompatiblen Metall hergestellt sein.
4. **AUSWAHL DES PATIENTEN.** Bei der Wahl von Patienten für interne Fixiervorrichtungen sind die nachfolgend aufgeführten Faktoren von größter Wichtigkeit, um den Erfolg des Eingriffs zu gewährleisten.

   A. **Berufliche Tätigkeit und Aktivitätsgrad des Patienten.** Falls der Patient aus beruflichen oder anderen Gründen Tätigkeiten ausführt, die schweres Heben, Muskelbeanspruchung, Verdrehen, wiederholtes Beugen, Bücken, Laufen, viel Gehen oder Schwerarbeit erfordern, sollte der Patient diese Tätigkeiten erst wieder aufnehmen, wenn der Knochen vollständig geheilt ist. Selbst nach vollkommener Heilung kann es vorkommen, dass Patienten ihre frühere Tätigkeiten nicht mehr erfolgreich ausführen können.

   B. **Senilität, Geisteskrankheit, Alkoholismus oder Drogenmissbrauch.** Zustände dieser Art können dazu führen, dass Patienten die vorgeschriebenen Einschränkungen und Vorsichtsmaßnahmen nicht beachten, was das Versagen des Implantats oder andere Komplikationen nach sich ziehen kann.

   C. **Bestimmte Degenerationskrankheiten.** In manchen Fällen erweist sich der Degenerationsprozess zum Zeitpunkt der Implantation als bereits dermaßen fortgeschritten, dass eine bedeutend kürzere Nutzdauer der Vorrichtung zu erwarten ist. In derartigen Fällen sind orthopädische Vorrichtungen nur als Verzögerungstechnik oder temporäres Remedium zu betrachten.

   D. **Fremdkörperempfindlichkeit.** Es muss betont werden, dass die Möglichkeit einer Überempfindlichkeit oder allergischen Reaktion präoperativ nicht völlig ausgeschlossen werden kann. Derartige allergische Reaktionen können sich auch erst später entwickeln, nachdem die Implantate schon längere Zeit im Körper anwesend waren.

   E. **Rauchen.** Bei Rauchern werden nach Knochentransplantatprozeduren häufiger Pseudoarthroseerscheinungen beobachtet als bei anderen Patienten. Zudem hat sich erwiesen, dass Rauchen diffuse Bandscheibend egenerationen verursachen kann. Die durch Rauchen ausgelöste progressive Degeneration der benachbarten Knochensegmente kann zu späterem klinischem Fehlschlagen der Prozedur führen (chronische Schmerzen), selbst wenn die Fusion ursprünglich erfolgreich war und eine klinische Besserung festgestellt wurde.

**WARNHINWEIS:** Wenn die Knochenfusion nicht im erwarteten Zeitraum erfolgt, können die Schrauben aufgrund der hohen Dauerbelastung dieser Vorrichtungen brechen. Dies wurde in Patienten mit verzögerter Pseudoarthrose oder Nichtheilung beobachtet, wobei die Vorrichtung(en) ggf. geändert werden müssen.

## VORSICHTSMASSNAHMEN

1. **CHIRURGISCHE IMPLANTATE DÜRFEN AUF KEINEN FALL WIEDERVERWENDET WERDEN.** Ein entferntes Metallimplantat darf niemals erneut implantiert werden. Auch wenn die Vorrichtung unbeschädigt aussieht, können kleine Defekte und interne Stresskonzentrationen vorliegen, die zu einem baldigen Bruch führen können.
2. **DIE RICHTIGE BEHANDLUNG DES IMPLANTATS IST VON GRÖSSTER BEDEUTUNG.** Das Konturieren von Metallimplantaten darf nur mit den passenden Instrumenten ausgeführt werden. Der operierende Arzt muss darauf achten, dass beim Konturieren keine Scharten, Kratzer oder Knicke auftreten. Veränderungen verursachen Defekte der Oberflächenbeschichtung und interne Belastungsstellen, an denen sich im Verlauf der Zeit mögliche Bruchstellen entwickeln können. Bei Verdacht auf Beschädigung das Implantat nicht verwenden.

   Wenn die Schrauben beim Einsetzen der Platte zu fest angezogen werden, kann es zu einem Versagen des Knochens und einem ausgerissenen Gewinde kommen. Es müssen hierzu ggf. neue Schrauben gekauft werden.



3. **VERBIEGEN DER KONSTRUKTION.** Komponenten aus Titanlegierung dürfen nicht stark gebogen oder zurückgebogen werden. Falls eine Konstruktion zu stark konturiert wurde, empfiehlt es sich, eine neue Konstruktion richtig zu konturieren, anstatt die überkonturierte Konstruktion zurückzubiegen.
4. **ENTFERNEN DES IMPLANTATS NACH DER HEILUNG.** Wird die Vorrichtung nach Erfüllung des vorgesehenen Zwecks nicht entfernt, können folgende Komplikationen auftreten. (1) Korrosion, mit lokalen Gewebereaktionen oder Schmerzen; (2) Migration des Implantats mit nachfolgender Verletzung; (3) Risiko einer durch postoperatives Trauma verursachten zusätzlichen Verletzung; (4) Verbiegen, Lockern und/oder Brechen, wodurch eine spätere Entfernung erschwert oder verhindert werden könnte; (5) durch die Anwesenheit der Vorrichtung ausgelöste Schmerzen, Unbehagen oder abnorme Empfindungen; (6) erhöhtes Infektionsrisiko und (7) aufgrund von Nichtbeanspruchung erfolgender Knochenverlust. Der Chirurg sollte die Risiken sorgfältig gegen die Vorteile abwägen, bevor die Entscheidung bezüglich einer Implantatentfernung getroffen wird. Nach der Implantatentfernung sollte eine angemessene postoperative Überwachung erfolgen, um eine Neufraktur zu vermeiden. Bei älteren, relativ inaktiven Patienten kann es angebracht sein, das Implantat nicht zu entfernen, um die mit einer Reoperation verbundenen Risiken zu vermeiden.
5. **AUSREICHENDE UNTERWEISUNG DES PATIENTEN.** Die Nachversorgung des Patienten sowie seine Fähigkeit und Bereitschaft, die Anweisungen zu befolgen, gehören zu den wichtigsten Faktoren für eine erfolgreiche Heilung. Patienten müssen über die Beschränkungen des Implantats aufgeklärt werden und dazu angehalten werden, ihre körperlichen Tätigkeiten, insbesondere Heben, Drehbewegungen sowie jegliche Teilnahme an sportlichen Aktivitäten, einzuschränken. Es muss dem Patienten dargelegt werden, dass ein Metallimplantat weniger widerstandsfähig als ein normaler, gesunder Knochen ist, und dass es sich bei starker Beanspruchung lockern oder verbiegen und/oder brechen kann, insbesondere, wenn eine volle Heilung noch nicht erfolgt ist. Durch falsche Bewegung verschobene oder beschädigte Implantate können migrieren und Nerven- bzw. Gefäßverletzungen verursachen. Bei aktiven, aber geistesschwachen oder dementen Patienten, die unfähig sind, gewichtsstützende Vorrichtungen zweckmäßig zu gebrauchen, besteht während der postoperativen Rehabilitation ein besonders hohes Risiko.

## MÖGLICHE NEBENWIRKUNGEN

1. Keine Heilung/verzögerte Heilung.
2. Verbiegen oder Brechen des Implantats. Lockern des Implantats.
3. Metallüberempfindlichkeit, bzw. allergische Reaktionen auf Fremdkörper.
4. Infektion, früh oder verspätet auftretend.
5. Verminderte Knochendichte aufgrund von Nichtbeanspruchung.
6. Durch die Anwesenheit der Vorrichtung ausgelöster Schmerz, Unbehagen oder abnorme Empfindungen.
7. Durch chirurgisches Trauma oder die Anwesenheit der Vorrichtung ausgelöster Nervenschaden. Neurologische Komplikationen, einschließlich radikulärer Schmerz, Verwachsen von Nerven im Narbengewebe, Muskelschwäche und Parästhesie.
8. Eine Verletzung der Blutgefäße kann katastrophale oder tödliche Blutungen zur Folge haben. Schlecht positionierte Implantate, die sich neben großen Arterien oder Venen befinden, können eine Erosion dieser Gefäße verursachen. Dies kann in der späten postoperativen Phase katastrophale Blutungen nach sich ziehen.
9. Sollten während der Operation Dura-mater-Risse erfolgen, können weitere chirurgische Eingriffe erforderlich werden, um die Dura wieder zu reparieren, bzw. um eine chronische Liquor-Leckage, Fisteln oder eine Meningitis zu verhindern.
10. Bursitis.
11. Paralyse.
12. Ösophagusperforation, Erosion oder Reizung.
13. Herausdrehen der Schraube, was ein Lockern des Implantats und/oder eine Reoperation zur Entfernung der Vorrichtung zur Folge haben kann.
14. Verletzung der Lymphgefäße und/oder Lymph-Leckage.
15. Impingement-Syndrom bzw. Verletzungen des Rückenmarks.
16. Frakturen an Knochenstrukturen.
17. Degenerative Veränderungen oder Instabilität von Segmenten, die an die fusionierten Wirbelkörper angrenzen.
18. Tod.

**BESCHRÄNKTE GARANTIE UND HAFTUNGSAUSSCHLUSS: DEPUY SPINE PRODUKTE WERDEN DEM ERSTKÄUFER MIT EINER BESCHRÄNKTEN GARANTIE GEGEN MATERIAL- UND VERARBEITUNGSFEHLER VERKAUFT. ALLE ANDEREN AUSDRÜCKLICHEN ODER STILLSCHWEIGENDEN GEWÄHRLEISTUNGEN, EINSCHLIESSLICH ZUSAGEN IN BEZUG AUF DIE MARKTGÄNGIGKEIT ODER EIGNUNG FÜR EINEN BESTIMMTEN ZWECK, SIND HIERMIT AUSGESCHLOSSEN.**

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HERGESTELLT VON EINER DER FOLGENDEN FIRMEN:

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325 Paramount Drive
Raynham, MA 02767-0350 USA

DePuy Spine SÀRL
Chemin Blanc, 36
CH-2400 Le Locle, Schweiz

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Leeds LS11 8DT England

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**LEGENDE**

| | | | |
|---|---|---|---|
| LOT CHARGENNUMMER | NUR ZUR EINMALIGEN VERWENDUNG | NONSTERILE UNSTERIL | HERSTELLER |
| REF BESTELLNUMMER | XXXX-XX ZU VERWENDEN BIS | STERILE R STERILISATION DURCH GAMMASTRAHLEN | EC REP AUTORISIERTE VERTRETUNG FÜR EUROPA |
| QTY MENGE | | STERILE EO STERILISATION DURCH ETHYLENOXID | DIST VERTRIEB DURCH |
| Rx Only Laut Gesetz ist der Verkauf dieses Produkts in den USA nur auf ärztliche Anordnung gestattet. | SIEHE GEBRAUCHSANWEISUNG | MADE IN HERGESTELLT IN | SZ GRÖSSE |
| | STERILE STERIL | | |

**MATERIAL MATL**

| | | |
|---|---|---|
| A/T ACROFLEX®/Ti ACROFLEX®/Titan | PY Polyester | SS/RADEL®/ SRTA Ti Al Nitride Edelstahl/RADEL®/ Titanaluminiumnitrid |
| A Al Aluminium | P POLYMER Polymer | STA SS/Ti Al Nitride Edelstahl/Titanaluminiumnitrid |
| A/P Al/PL Aluminium/Kunststoff | P/CM PE/CoCrMo Polyethylen/ Kobalt-Chrom-Molybdän | S/U SS/ULTEM Edelstahl/Ultem |
| B/R Ba/RADEL® Barium/RADEL® | P/C POLYMER/CARBON FIBER COMPOSITE Polymer/ Kohlefaser-Verbundstoff | T Ti Titan und seine Legierungen |
| CaP CALCIUM PHOSPHATE Kalziumphosphat | S SS Edelstahl | S/R SS/RADEL® Edelstahl/RADEL® |
| CM CoCrMo Kobalt-Chrom-Molybdän | S/A SS/Al Edelstahl/Aluminium | R/T POLYOLEFIN RUBBER/Ti Polyolefin-Gummi/Titan |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Kobalt-Chrom-Molybdän/ Titan/Kalziumphosphat | S/Ba SS/Ba/RADEL® Edelstahl/Barium/RADEL® | T/A Ti/Al Titan/Aluminium |
| F FOAM Schaum | S/P SS/PHENOLIC Edelstahl/Phenolisch | Ti/UHMWPE/HA Titan/Polyethylen mit überdurchschnittlichem Molekulargewicht/Hydroxyapatit |
| HA Hydroxyapatit | S/PL SS/PL Edelstahl/Kunststoff | SS/Ti Edelstahl/Titan |
| Ni/Ti Ni/Ti Nickel/Titan | SRSI SS/RADEL®/ SILICONE Edelstahl/RADEL®/Silikon | SS/Al/SILICONE Edelstahl/Aluminium/Silikon |
| PL Kunststoff | SRSN SS/RADEL®/ SILICONE/Ti Al Nitride Edelstahl/RADEL®/Silikon/ Titanaluminiumnitrid | S/Si SS/SILICONE Edelstahl/Silikon |
| P/F PL/FOAM Kunststoff/Schaum | | |



el

# ΠΡΟΣΘΙΟ ΣΥΣΤΗΜΑ ΠΛΑΚΑΣ ΣΥΜΠΙΕΣΗΣ PEAK

# ΠΟΛΥΑΞΟΝΙΚΟ ΠΡΟΣΘΙΟ ΑΥΧΕΝΙΚΟ ΣΥΣΤΗΜΑ ΠΛΑΚΑΣ PEAK

# ΣΥΣΤΗΜΑ ΚΟΙΛΙΑΚΗΣ ΑΥΧΕΝΙΚΗΣ ΣΤΕΡΕΩΣΗΣ DOC

# SLIM-LOC™ ΠΡΟΣΘΙΟ ΑΥΧΕΝΙΚΟ ΣΥΣΤΗΜΑ ΠΛΑΚΑΣ

# ΠΡΟΣΘΙΟ ΑΥΧΕΝΙΚΟ ΣΥΣΤΗΜΑ ΠΛΑΚΑΣ EAGLE™

# ΠΡΟΣΘΙΟ ΑΥΧΕΝΙΚΟ ΣΥΣΤΗΜΑ ΠΛΑΚΑΣ SWIFT™

# ΠΡΟΣΘΙΟ ΑΥΧΕΝΙΚΟ ΣΥΣΤΗΜΑ ΠΛΑΚΑΣ UNIPLATE™

# ΠΡΟΣΘΙΟ ΑΥΧΕΝΙΚΟ ΣΥΣΤΗΜΑ ΠΛΑΚΑΣ SKYLINE™

## ΣΗΜΑΝΤΙΚΗ ΕΙΔΟΠΟΙΗΣΗ ΓΙΑ ΤΟ ΧΕΙΡΟΥΡΓΟ

Τα εμφυτεύματα Στερέωσης Πρόσθιου Αυχενικού Συστήματος, όπως και άλλες προσωρινές συσκευές εσωτερικής σταθεροποίησης, έχουν περιορισμένη διάρκεια χρήσης. Το επίπεδο δραστηριότητας του ασθενή ασκεί σημαντική επίδραση κατά την περίοδο χρήσης. Θα πρέπει να δοθούν οδηγίες στον ασθενή σχετικά με την αύξηση κινδύνου χαλάρωσης, λυγίσματος ή σπασίματος των εξαρτημάτων του εμφυτεύματος λόγω οποιασδήποτε δραστηριότητας. Είναι σημαντικό να συμβουλέψετε τον ασθενή σχετικά με τους περιορισμούς των δραστηριοτήτων τους κατά τη μετεγχειρητική περίοδο και να εξετάσετε τον ασθενή μετεγχειρητικά, για να αξιολογήσετε τη δημιουργία της μάζας συγκόλλησης και την κατάσταση των εξαρτημάτων του εμφυτεύματος. Ακόμη και αν δημιουργηθεί σταθερή συγκόλληση οστού, είναι δυνατόν να λυγίσουν, να σπάσουν ή να χαλαρώσουν τα εξαρτήματα του εμφυτεύματος. Γι' αυτό το λόγο, ο ασθενής θα πρέπει να γνωρίζει ότι μπορεί να λυγίσουν, να σπάσουν ή να χαλαρωθούν τα εξαρτήματα του εμφυτεύματος ακόμη και όταν τηρεί τους περιορισμούς δραστηριοτήτων.

Λόγω των περιορισμών που επιβάλλονται από την ανατομία και τα σύγχρονα χειρουργικά υλικά, τα μεταλλικά εμφυτεύματα δεν μπορούν να διατηρηθούν επ' αόριστον. Ο σκοπός τους είναι να παρέχουν προσωρινή εσωτερική υποστήριξη ενώ σταθεροποιείται η μάζα συγκόλλησης. Τα μοσχεύματα αυτού του τύπου είναι πιθανόν να αποτύχουν εάν δε χρησιμοποιηθεί μόσχευμα οστού ή εάν δημιουργηθεί ψευδάρθρωση.

Ο χειρουργός μπορεί να αποφασίσει την αφαίρεση αυτών των εμφυτευμάτων μετά τη δημιουργία συγκόλλησης οστού. Η πιθανότητα δεύτερης χειρουργικής επέμβασης πρέπει να συζητηθεί με τον ασθενή, και θα πρέπει να συζητηθούν επίσης οι κίνδυνοι που σχετίζονται με δεύτερη χειρουργική επέμβαση. Εάν σπάσουν όντως τα εμφυτεύματα, η απόφαση για την αφαίρεση τους πρέπει να ληφθεί από το γιατρό ο οποίος πρέπει να λάβει υπόψη επίσης την κατάσταση του ασθενή και τους κινδύνους που σχετίζονται με την παρουσία του σπασμένου εμφυτεύματος.

## ΠΕΡΙΓΡΑΦΗ

Το Πρόσθιο Σύστημα Πλάκας Συμπίεσης PEAK, αποτελείται από ποικίλες πλάκες και βίδες από κράμα τιτανίου. Οι πλάκες διατίθενται σε μήκη που κυμαίνονται από 26-94 χιλ. για να διευθετούν ένα έως τέσσερα τμήματα στερέωσης. Το σύστημα περιλαμβάνει επίσης 3,5 χιλ. φλοιώδεις και 4,0 χιλ. δικτυωτές βίδες από κράμα τιτανίου που διατίθενται σε μήκη που κυμαίνονται από 8 χιλ.-30 χιλ.

Το Πολυαξονικό Πρόσθιο Αυχενικό Σύστημα Πλάκας PEAK, αποτελείται από ποικίλες πλάκες και βίδες από κράμα τιτανίου. Οι πρόσθιες αυχενικές πλάκες διατίθενται σε μεγέθη από 24 χιλ. έως 110 χιλ. μήκους για να διευθετούν ένα έως τέσσερα τμήματα στερέωσης. Οι δικτυωτές βίδες διατίθενται σε διαμέτρους 4,0 χιλ. και 4,35 χιλ. Είναι πλήρως σπειρωτές και έχουν μήκη που κυμαίνονται από 10 χιλ. έως 26 χιλ.

Το Σύστημα Κοιλιακής Αυχενικής Στερέωσης DOC είναι ένα σύστημα που αποτελείται από πλατφόρμα, πλάκα, ράβδο και κοχλία από κράμα τιτανίου που βοηθά τους χειρουργούς σπονδυλικής στήλης στη διόρθωση ελαττωμάτων της αυχενικής μοίρας σπονδυλικής στήλης και στην στερέωση. Το Σύστημα Κοιλιακής Αυχενικής Στερέωσης DOC, στην πλήρως συναρμολογημένη μορφή του, αποτελείται από μία πλάκα ή δύο πλάγια τοποθετημένες ράβδους που ενώνονται με πλατφόρμες οι οποίες βρίσκονται πάνω στην πρόσθια σπονδυλική επιφάνεια. Το σύστημα αγκιστρώνεται στους σπονδύλους με κοχλίες. Το εμφύτευμα παρέχει συμπληρωματική σταθερότητα στην αυχενική μοίρα σπονδυλικής στήλης μετά από πρόσθια αγκύλωση. Ανάλογα με τη διαμόρφωση του εμφυτεύματος, μπορεί να λειτουργεί είτε ως άκαμπτη (με στήριξη φορτίου) είτε ως δυναμική (με κατανομή φορτίου) κατασκευή.

Οι ακόλουθοι τύποι εξαρτημάτων υπάρχουν στο σύστημα: Ράβδοι, Πλάκες, Πλατφόρμες, Εσωτερικοί και Εξωτερικοί Κοχλίες Οστών, Κοχλίες Μοσχεύματος και Εγκάρσιοι Συνδετήρες. Όλα τα εξαρτήματα του εμφυτεύματος είναι κατασκευασμένα από κράμα τιτανίου ποιότητας εμφυτεύματος που προσαρμόζεται στις προδιαγραφές ASTM F-136. Συναρμολογούμενες διατάξεις υπάρχουν επίσης για διευκόλυνση του χειρουργού. Αυτές είναι

προσυναρμολογημένες, τμηματικές κατασκευές αποτελούμενες από μία πλατφόρμα, ένα εγκάρσιο σύνδεσμο, δύο ράβδους και δύο ασφαλιστικούς κοχλίες.

**Πλατφόρμα:** Οι πλατφόρμες έχουν σχεδιαστεί για τη σύνδεση των Ράβδων και την αγκίστρωση στα σπονδυλικά σώματα με βίδες οστού. Όλες οι Πλατφόρμες μπορούν να χρησιμοποιηθούν είτε με Κοχλίες Συμπαγούς Οστού (για σταθεροποίηση δια μέσου αμφοτέρων των φλοιωδών τμημάτων του οστού) είτε με συνδυασμό εξωτερικών και εσωτερικών κοχλιών οστού (ένας κοίλος κοχλίας εξωτερικού οστού που χρησιμοποιείται με ένα συμπαγή εσωτερικό ασφαλιστικό κοχλία σχεδιασμένο για στερέωση σε ένα μόνο φλοιώδες τμήμα). Η επιλογή των κοχλιών γίνεται κατά την προτίμηση του γιατρού. Όλες οι πλατφόρμες έχουν σχεδιαστεί για να χρησιμοποιούνται με δύο ράβδους κατά το σχηματισμό της κατασκευής.

Οι πλατφόρμες διατίθενται σε ασφαλιζόμενα και μη ασφαλιζόμενα σχέδια. Οι ασφαλιζόμενες πλατφόρμες διαθέτουν προεκτάσεις που δέχονται ασφαλιστικούς κοχλίες πλατφόρμας/ εγκάρσιου συνδέσμου για τη στήριξη της πλατφόρμας στις ράβδους. Οι ασφαλιζόμενες πλατφόρμες χρειάζονται για χρήση στην άκρη της κατασκευής απέναντι από τις κεφαλές των ράβδων.

Εάν η άκαμπτη διαμόρφωση είναι προτιμότερη από τη δυναμική διαμόρφωση (δηλ. κατανομής φορτίου), πρέπει επίσης να χρησιμοποιηθεί μια ασφαλιζόμενη πλατφόρμα δίπλα στις κεφαλές των ράβδων. Εάν η διαμόρφωση κατανομής φορτίου είναι επιθυμητή, η πλατφόρμα δίπλα στις κεφαλές ράβδων δεν ασφαλίζεται στις ράβδους.

Διάφορες πλατφόρμες είναι σχεδιασμένες για γωνιώδη εισαγωγή της βίδας μέσα στο σπονδυλικό σώμα. Διατίθενται σε ασφαλιζόμενα και μη ασφαλιζόμενα σχέδια. Οι πλατφόρμες αυτές έχουν μια προεξοχή στη μία πλευρά η οποία αγκιστρώνει το σπόνδυλο εντός του χώρου του δίσκου για βέλτιστη τοποθέτηση και στερέωση.

Διάφορες πλατφόρμες είναι σχεδιασμένες για ευθεία (κάθετη) εισαγωγή του κοχλία μέσα στο σπονδυλικό σώμα. Διατίθενται σε ασφαλιζόμενα και μη ασφαλιζόμενα σχέδια.

Ένα σχέδιο πλατφόρμας υπάρχει για σταθεροποίηση της κατασκευής σε ένα μεσοσπονδύλιο μόσχευμα. Η πλατφόρμα αυτή διαθέτει οριζόντια σχισμή και σφαιρική υποδοχή για να επιτρέπει αποκλίσεις στο σημείο εισαγωγής κοχλία και την τροχιά μέσα στο μόσχευμα.

Η επιλογή πλατφόρμας βασίζεται στην προτίμηση του γιατρού και την ανατομία του ασθενή.

Το Πρόσθιο Αυχενικό Σύστημα Πλάκας SLIM-LOC™ αποτελείται από διάφορες πλάκες και κοχλίες από κράμα τιτανίου. Οι πλάκες διατίθενται σε μήκη που κυμαίνονται από 22-111 χιλ. σε διαμορφώσεις των 2, 3, 4, 5 ή 6 ζευγών οπών κοχλιών. Οι κοχλίες SLIM-LOC™ διατίθενται σε διάμετρο 4,5 χιλ. και διατίθενται ως διατρητικοί σε άρτια μεγέθη μηκών που κυμαίνονται από 10-18 χιλ. ή αυτοαναρρόφησης υγρού σε άρτια μεγέθη μηκών που κυμαίνονται από 10-26 χιλ. Διατίθενται κοχλίες μεγαλύτερων μεγεθών (4,8 χιλ.) σε μήκη 12. 14 και 16 χιλ.

Το Πρόσθιο Αυχενικό Σύστημα Πλάκας EAGLE™ αποτελείται από διάφορες πλάκες και κοχλίες από κράμα τιτανίου. Οι πλάκες διατίθενται με ζεύγη οπών κοχλιών δύο έως έξι, σε διάφορα μήκη. Οι κοχλίες διατίθενται σε διάφορα λεγέθη και γεωμετρίες άκρων κοχλιών.

Το Πρόσθιο Αυχενικό Σύστημα Πλάκας SWIFT™ έχει κατασκευαστεί από κράμα τιτανίου και αποτελείται από τμηματικές πλάκες που επιτρέπουν έως 2 χιλ. ελεγχόμενης σταθεροποίησης μοσχεύματος μεταξύ κάθε ενός από τα τμήματα. Οι πλάκες διατίθενται με ζεύγη οπών κοχλιών δύο έως έξι, σε διάφορα μήκη και σε δύο διαμορφώσεις δισκοτομής και σωματοτομής. Οι κοχλίες διατίθενται σε διάφορα μεγέθη και γεωμετρίες άκρων κοχλιών. Διατίθεται ένας κοχλίας μοσχεύματος για χρήση με πιρ πλάκες σωματοτομής.

Το Πρόσθιο Αυχενικό Σύστημα Πλάκας UNIPLATE™ αποτελείται από ποικιλία πλακών και βιδών κατασκευασμένων από κράμα τιτανίου. Οι πρόσθιες αυχενικές πλάκες διατίθενται σε διάφορα μήκη για να διευκολύνουν ένα με δύο τμήματα σταθεροποίησης. Οι βίδες διατίθενται σε διάφορα μεγέθη και γεωμετρίες άκρου.

Το Πρόσθιο Αυχενικό Σύστημα Πλάκας SKYLINE™ αποτελείται από διάφορες πλάκες και κοχλίες από κράμα τιτανίου. Οι πλάκες διαθέτουν δύο έως έξι ζεύγη οπών κοχλιών, σε διάφορα μήκη. Οι κοχλίες διατίθενται σε διάφορα μεγέθη και γεωμετρίες άκρου. Διατίθενται τόσο περιορισμένοι όσο και μεταβλητοί κοχλίες, για τη δημιουργία περιορισμένης, μεταβλητής ή υβριδικής διαμόρφωσης.

## ΚΑΘΑΡΙΣΜΟΣ ΚΑΙ ΑΠΟΣΤΕΙΡΩΣΗ

Τα εμφυτεύματα των Συστημάτων Αυχενικής Στερέωσης Πλάκας παρέχονται είτε αποστειρωμένα ή καθαρά και μη αποστειρωμένα. Για τα εξαρτήματα που παρέχονται αποστειρωμένα βεβαιωθείτε ότι η συσκευασία δεν έχει υποστεί ζημιά πριν από τη χρήση.

Για μη αποστειρωμένες συσκευές, πρέπει να ακολουθηθούν οι συνιστώμενες πρακτικές για όλα τα εξαρτήματα σύμφωνα με τις οδηγίες ISO 8828 ή AORN για αποστείρωση εντός του νοσοκομείου.

Ύστερα από δοκιμές καταρτίστηκαν οι παρακάτω ΣΥΣΤΑΣΕΙΣ ΓΙΑ ΑΠΟΣΤΕΙΡΩΣΗ ΜΕ ΑΤΜΟ:

| | |
|---|---|
| Κύκλος: | Προκατεργασία με κενό |
| Θερμοκρασία: | 270 °F<br>132 °C |
| Χρόνος Έκθεσης: | 6 λεπτά |

## ΧΡΗΣΗ

Ο χειρουργός θα πρέπει να έχει εμβριθή γνώση όχι μόνο σχετική με τις ιατρικές και χειρουργικές απόψεις των εμφυτευμάτων, αλλά θα πρέπει να γνωρίζει επίσης τους μηχανικούς και μεταλλουργικούς περιορισμούς των μεταλλικών χειρουργικών εμφυτευμάτων. Η μετεγχειρητική φροντίδα παίζει σημαντικό ρόλο. Ο ασθενής πρέπει να λάβει οδηγίες σχετικά με τους περιορισμούς του μεταλλικού εμφυτεύματος και να προειδοποιηθεί σχετικά με τη μεταφορά βάρους και τις



τάσεις του σώματος πάνω στη συσκευή πριν από τη σταθερή ίαση του οστού. Πρέπει να ειδοποιηθεί ο ασθενής ότι η μη τήρηση των μετεγχειρητικών οδηγιών μπορεί να καταλήξει σε αποτυχία του εμφυτεύματος και ενδεχόμενη ανάγκη μεταγενέστερα για πρόσθετη εγχείρηση για την αφαίρεση της συσκευής.

Τα εξαρτήματα του συστήματος σπονδυλικής στήλης της DePuy Spine δεν πρέπει να χρησιμοποιούνται με εξαρτήματα άλλων κατασκευαστών.

**Για να επιτευχθεί ελεγχόμενος κάθετος μετασχηματισμός συντεταγμένων (κατανομή φορτίου), η σωστή τοποθέτηση των επιλεγμένων εξαρτημάτων έχει ζωτική σημασία.**

**Ανατρέξτε στη χειρουργική τεχνική για τις ειδικές οδηγίες.**

## ΕΝΔΕΙΞΕΙΣ

**ΠΡΟΣΟΧΗ:** Το Δίκαιο των ΗΠΑ επιτρέπει την πώληση αυτών των συσκευών μόνο από γιατρούς ή με συνταγή γιατρού.

Το Πρόσθιο Αυχενικό Σύστημα Πλάκας SLIM-LOC και το Πρόσθιο Αυχενικό Σύστημα Πλάκας SKYLINE™ ενδείκνυνται για τη σταθεροποίηση των σπονδύλων C2 έως C7 της αυχενικής μοίρας της σπονδυλικής στήλης, χρησιμοποιώντας κοχλίες μονόπλευρης σταθεροποίησης στην πρόσθια επιφάνεια του σπονδυλικού σώματος. Οι ειδικές κλινικές ενδείξεις για την πρόσθια πλακοποίηση περιλαμβάνουν: αστάθεια προκαλούμενη από τραύμα, αστάθεια σχετιζόμενη με επιδιόρθωση αυχενικής λόρδωσης και παραμόρφωση από κύφωση, αστάθεια σχετιζόμενη με ψευδάρθρωση ως αποτέλεσμα προηγούμενης αποτυχημένης εγχείρησης στην αυχενική μοίρα σπονδυλικής στήλης, αστάθεια σχετιζόμενη με μείζον επαναδιορθωτική εγχείρηση για αρχικούς όγκους ή μεταστατικούς κακοήθεις όγκους της αυχενικής μοίρας σπονδυλικής στήλης, αστάθεια σχετιζόμενη με σωματική κοπή μονού ή πολλαπλών επιπέδων σε προηγμένης μορφής εκφυλιστική δισκοπάθεια, στένωση του καναλιού σπονδυλικής στήλης και αυχενική μυελοπάθεια.

Το Πρόσθιο Σύστημα Πλάκας Συμπίεσης PEAK, το Πολυαξονικό πρόσθιο αυχενικό σύστημα πλάκας PEAK, το Σύστημα Κοιλιακής Αυχενικής Στερέωσης DOC, το Πρόσθιο Αυχενικό Σύστημα Πλάκας EAGLE, το Πρόσθιο Αυχενικό Σύστημα Πλάκας SWIFT και το Πρόσθιο Αυχενικό Σύστημα Πλάκας UNIPLATE προορίζονται για πρόσθια αυχενική μεσοσπονδύλια στερέωση του σώματος. Αυτά τα συστήματα ενδείκνυνται για ασθενείς στους οποίους είναι επιθυμητή η σταθερότητα ύστερα από πρόσθια αυχενική αγκύλωση για τις ενδείξεις που αναφέρονται παρακάτω. Τα προβλεπόμενα επίπεδα για θεραπεία κυμαίνονται από το C2 ως το T1 (2ος Αυχενικός έως 1ος Θωρακικός σπόνδυλος).

Οι ενδείξεις περιλαμβάνουν συμπτωματική αυχενική σπονδύλωση, τραύμα, θλάση, μετατραυματική κύφωση ή λόρδωση, όγκο, εκφυλιστική δισκοπάθεια (που ορίζεται ως δισκογενής πόνος με εκφυλισμό του δίσκου που επαληθεύεται με τη μελέτη του ιστορικού και των ακτινογραφιών), επανεγχείρηση λόγω αποτυχημένης αγκύλωσης, ή αστάθειας μετά από εγχείρηση για τις παραπάνω ενδείξεις.

Το Πρόσθιο Αυχενικό Σύστημα Πλάκας UNIPLATE ενδείκνυται επίσης για τη θεραπεία στένωσης της σπονδυλικής στήλης.

**ΠΡΟΕΙΔΟΠΟΙΗΣΗ:** Αυτές οι συσκευές δεν εγκρίνονται για προσάρτηση ή στερέωση κοχλιών στα οπίσθια στοιχεία (συχένας του τόξου των σπονδύλων) της αυχενικής, της θωρακικής, ή της οσφυϊκής μοίρας της σπονδυλικής στήλης.

## ΜΕΤΕΓΧΕΙΡΗΤΙΚΗ ΚΙΝΗΤΟΠΟΙΗΣΗ

Ωσότου οι ακτινογραφίες επιβεβαιώσουν την επιτυχία της αγκύλωσης, ίσως συνιστάται εξωτερική ακινητοποίηση (π.χ. με νάρθηκα) κατά την κρίση του γιατρού.

Οι οδηγίες στον ασθενή για να μειώσει την τάση στα εμφυτεύματα είναι ένα εξίσου σημαντικό μέρος της προσπάθειας για αποφυγή δημιουργίας κλινικών προβλημάτων που πιθανόν να συνοδεύουν την αποτυχία της στερέωσης.

## ΑΝΤΕΝΔΕΙΞΕΙΣ

- Η ενεργός συστηματική μόλυνση ή η μόλυνση που εντοπίζεται στην περιοχή της επιδιωκόμενης εμφύτευσης.
- Η οξεία οστεοπόρωση μπορεί να αποτρέψει την επαρκή στερέωση των σπονδυλικών αγκίστρων και έτσι να αποκλείσουν τη χρήση αυτού ή άλλου συστήματος σπονδυλικών οργάνων.
- Ασθενείς που έχει αποδειχτεί ότι μπορούν να αντιμετωπίσουν με ασφαλή και προβλέψιμο τρόπο χωρίς εσωτερική στερέωση.
- Ανοιχτές πληγές.

## ΣΧΕΤΙΚΕΣ ΑΝΤΕΝΔΕΙΞΕΙΣ:

Οι σχετικές αντενδείξεις περιλαμβάνουν οποιονδήποτε παράγοντα ή πάθηση που αποκλείει τελείως την αγκύλωση (π.χ. καρκίνος, νεφρική ανεπάρκεια, ή οστεοπενία), παχυσαρκία, ορισμένα εκφυλιστική νοσήματα και ευαισθησία σε ξένα σώματα.

## ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ, ΠΡΟΦΥΛΑΞΕΙΣ, ΚΑΙ ΑΝΕΠΙΘΥΜΗΤΕΣ ΕΝΕΡΓΕΙΕΣ ΠΟΥ ΑΦΟΡΟΥΝ ΤΙΣ ΜΕΤΑΛΛΙΚΕΣ ΣΥΣΚΕΥΕΣ ΠΡΟΣΩΡΙΝΗΣ ΕΣΩΤΕΡΙΚΗΣ ΣΤΕΡΕΩΣΗΣ

### ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ

Ακολουθούν ειδικές προειδοποιήσεις, προφυλάξεις και ανεπιθύμητες ενέργειες που πρέπει να κατανοηθούν από το χειρουργό και να εξηγηθούν στον ασθενή. Αυτές οι προειδοποιήσεις δεν περιλαμβάνουν όλες τις ανεπιθύμητες ενέργειες που δύνανται να συμβούν γενικά κατά την εγχείρηση αλλά σημαντικά ζητήματα που είναι ειδικά για τις μετολλικές συσκευές εσωτερικής στερεώσης. Οι γενικοί κίνδυνοι εγχείρησης θα πρέπει να εξηγηθούν στον ασθενή πριν από την εγχείρηση.

Οι πιθανοί κίνδυνοι που συνδέονται με τη χρήση αυτού του συστήματος συσκευών, που μπορεί να απαιτήσουν επιπλέον εγχείρηση, περιλαμβάνουν: θλάση εξαρτήματος της συσκευής, απώλεια σταθεροποίησης, μη συνένωση, κάταγμα του σπονδύλου, νευρολογική κάκωση, και αγγειακή ή σπλαχνική κάκωση.

1. **Η ΣΩΣΤΗ ΕΠΙΛΟΓΗ ΤΟΥ ΜΟΣΧΕΥΜΑΤΟΣ ΕΙΝΑΙ ΠΟΛΥ ΣΗΜΑΝΤΙΚΗ.** Η πιθανότητα για ικανοποιητική στερέωση αυξάνεται με την επιλογή του κατάλληλου μεγέθους, μορφής, και σχήματος του εμφυτεύματος. Ενώ η σωστή επιλογή μπορεί να βοηθήσει στη μείωση κινδύνων, το μέγεθος και η μορφή των ανθρώπινων οστών ενέχει περιορισμούς στο μέγεθος, στη μορφή και στην ανθεκτικότητα των εμφυτευμάτων. Οι μεταλλικές εσωτερικές συσκευές στερέωσης δεν αντέχουν σε επίπεδα δραστηριότητας που είναι ίσα με αυτά στα οποία θέτονται τα φυσιολογικά υγιή οστά. Κανένα εμφύτευμα δεν είναι δυνατόν να αντέξει επ' αόριστον την ανυποστήρικτη τάση από τη πλήρη συγκράτηση βάρους.
2. **ΤΑ ΕΜΦΥΤΕΥΜΑΤΑ ΜΠΟΡΕΙ ΝΑ ΣΠΑΣΟΥΝ ΟΤΑΝ ΥΠΟΚΕΙΝΤΑΙ ΣΤΗΝ ΑΥΞΑΝΟΜΕΝΗ ΦΟΡΤΩΣΗ ΠΟΥ ΣΧΕΤΙΖΕΤΑΙ ΜΕ ΚΑΘΥΣΤΕΡΗΜΕΝΗ ΣΥΝΕΝΩΣΗ Ή ΜΗ ΣΥΝΕΝΩΣΗ.** Οι εσωτερικές συσκευές στερέωσης είναι συσκευές που μοιράζονται το φορτίο και οι οποίες χρησιμοποιούνται για να επιτευχθεί ευθυγράμμιση μέχρις ότου γίνει φυσιολογική ίαση. Εάν η ίαση καθυστερήσει, ή δεν γίνει, πιθανόν να σπάσει τελικά το εμφύτευμα λόγω καταπόνησης στο μέταλλο. Ο βαθμός ή η επιτυχία της συνένωσης, τα φορτία που δημιουργούνται από τη συγκράτηση βάρους και τα επίπεδα δραστηριότητας, μεταξύ άλλων καταστάσεων, θα υπαγορεύσουν τη μεγάλη διάρκεια ζωής του εμφυτεύματος. Οι εγκοπές, οι αμυχές ή οι στρεβλώσεις του εμφυτεύματος κατά τη διάρκεια της εγχείρησης πιθανόν να συμβάλουν επίσης στην πρώιμη αποτυχία. Οι ασθενείς θα πρέπει να είναι πλήρως καταρτισμένοι σχετικά με τους κινδύνους της αποτυχίας του εμφυτεύματος.
3. **Η ΑΝΑΜΙΞΗ ΜΕΤΑΛΛΩΝ ΠΙΘΑΝΟΝ ΝΑ ΠΡΟΚΑΛΕΣΕΙ ΔΙΑΒΡΩΣΗ.** Υπάρχουν πολλές μορφές ζημιάς λόγω διάβρωσης και πολλές από αυτές συμβαίνουν σε μέταλλα που εμφυτεύονται χειρουργικά σε ανθρώπους. Η γενική ή ενιαία διάβρωση παρουσιάζεται σε όλα τα εμφυτευμένα μέταλλα και κράματα. Ο ρυθμός διαβρωτικής προσβολής σε συσκευές μεταλλικών εμφυτευμάτων είναι συνήθως πολύ χαμηλός λόγω της παρουσίας των αδρανών επιστρώσεων στις επιφάνειες. Ανόμοια μέταλλα σε επαφή, όπως το τιτάνιο και ο ανοξείδωτος χάλυβας, επιταχύνουν τη διαδικασία διάβρωσης στον ανοξείδωτο χάλυβα και δημιουργείται πιο ραγδαία προσβολή. Η παρουσία διάβρωσης επιταχύνει συνήθως τη θλάση λόγω κόπωσης των εμφυτευμάτων. Θα αυξηθεί επίσης το ποσοστό μεταλλικών ενώσεων που απελευθερώνονται μέσα στο σώμα. Οι συσκευές εσωτερικής στερέωσης όπως οι ράβδοι, τα άγκιστρα, τα σύρματα, κλπ. που έρχονται σε επαφή με άλλα μεταλλικά αντικείμενα, πρέπει να είναι κατασκευασμένα από παρόμοια ή συμβατά μέταλλα.
4. **ΕΠΙΛΟΓΗ ΤΩΝ ΑΣΘΕΝΩΝ.** Όταν επιλέγετε ασθενείς για την εμφύτευση εσωτερικών συσκευών στερέωσης, οι ακόλουθοι παράγοντες μπορεί να είναι πολύ σημαντικοί στην τελική επιτυχία της επέμβασης:

   Α. **Το επάγγελμα και η δραστηριότητα του ασθενή.** Εάν ο ασθενής ασκεί επάγγελμα ή δραστηριότητα που περιλαμβάνει την άρση μεγάλου βάρους, ένταση στους μυς, στρέψεις, αλλεπάλληλες κάμψεις, σκυψίματα, τρέξιμο, πολύ περπάτημα ή χειρωνακτική εργασία, αή ασθενής δεν πρέπει να ξαναρχίσει αυτές τις δραστηριότητες μέχρις ότου να γίνει πλήρης ίαση του οστού. Ακόμη και με πλήρη ίαση, είναι πιθανόν να μην μπορεί να ξαναρχίσει ο ασθενής αυτές τις δραστηριότητες αποτελεσματικά.

   Β. **Παθήσεις λόγω γηρατειών, ψυχικών ασθενειών, αλκοολισμού ή χρήσης ναρκωτικών.** Αυτές οι παθήσεις, μεταξύ άλλων, μπορεί να κάνουν τον ασθενή να αγνοήσει ορισμένους απαραίτητους περιορισμούς και προφυλάξεις κατά τη χρήση αυτής της συσκευής, με αποτέλεσμα την αποτυχία του εμφυτεύματος ή άλλες επιπλοκές.

   Γ. **Μερικές εκφυλιστικές ασθένειες.** Σε ορισμένες περιπτώσεις, η πρόοδος εκφυλιστικής ασθένειας μπορεί να είναι τόσο προχωρημένη όταν γίνεται η εμφύτευση, που πιθανόν να μειώσει κατά πολύ την αναμενόμενη διάρκεια χρήσης της συσκευής. Σε τέτοιες περιπτώσεις, οι ορθοπεδικές συσκευές μπορούν να θεωρηθούν μόνο ως τεχνική επιβράδυνσης ή προσωρινή θεραπεία.

   Δ. **Ευαισθησία σε ξένα σώματα.** Ο χειρουργός ειδοποιείται ότι καμία προεγχειρητική εξέταση δεν μπορεί να αποκλείσει πλήρως την πιθανότητα ευαισθησίας ή την αλλεργική αντίδραση. Οι ασθενείς μπορεί να παρουσιάσουν ευαισθησία ή αλλεργία αφού τα εμφυτεύματα έχουν παραμείνει εντός του σώματες για ορισμένη χρονική περίοδο.

   Ε. **Κάπνισμα.** Σε ασθενείς που καπνίζουν έχουν παρατηρηθεί περισσότερα κρούσματα ψευδάρθρωσης μετά τις χειρουργικές επεμβάσεις όπου χρησιμοποιείται μόσχευμα οστού. Συμπληρωματικά, έχει αποδειχτεί ότι το κάπνισμα προκαλεί διάχυτη εκφύλιση των μεσοσπονδύλιων δίσκων. Η σταδιακή εκφύλιση των παρακείμενων τμημάτων που προκαλείται από κάπνισμα μπορεί να οδηγήσει σε μεταγενέστερη κλινική αποτυχία (υποτροπιάζοντα πόνο), ακόμη και μετά από επιτυχή αγκύλωση και αρχική κλινική βελτίωση.

**ΠΡΟΕΙΔΟΠΟΙΗΣΗ:** Εάν δεν γίνει στερέωση εντός του αναμενόμενου χρονικού διαστήματος, μπορεί να σπάσουν οι κοχλίες λόγω υψηλών και διαρκών φορτίων σε αυτές τις συσκευές. Αυτό έχει παρατηρηθεί σε ασθενείς με αργοπορημένη, ψευδάρθρωση ή μη συνένωση και μπορεί να έχει ως αποτέλεσμα την ανάγκη αποκατάστασης της συσκευής/των συσκευών.



## ΠΡΟΦΥΛΑΞΕΙΣ

1. **ΤΑ ΧΕΙΡΟΥΡΓΙΚΑ ΕΜΦΥΤΕΥΜΑΤΑ ΔΕΝ ΠΡΕΠΕΙ ΠΟΤΕ ΝΑ ΕΠΑΝΑΧΡΗΣΙΜΟΠΟΙΟΥΝΤΑΙ.** Ένα εκφυτευμένο μεταλλικό εμφύτευμα δεν πρέπει ποτέ να επανεμφυτευτεί. Ακόμη και αν η συσκευή φαίνεται ακέραια, μπορεί να έχει μικρά ελαττώματα και εσωτερικές καταπονήσεις που πιθανόν να οδηγήσουν σε γρήγορο σπάσιμο.
2. **Ο ΣΩΣΤΟΣ ΧΕΙΡΙΣΜΟΣ ΤΟΥ ΕΜΦΥΤΕΥΜΑΤΟΣ ΕΧΕΙ ΜΕΓΑΛΗ ΣΗΜΑΣΙΑ.** Η διαμόρφωση στα μεταλλικά εμφυτεύματα θα πρέπει να γίνεται μόνο με το σωστό εξοπλισμό. Ο χειρουργός θα πρέπει να αποφεύγει τη δημιουργία εγκοπών, αμυχών ή αντίθετης κάμψης όταν δημιουργεί τις καμπύλες. Οι τροποποιήσεις θα προκαλέσουν ελαττώματα στο φινίρισμα της επιφάνειας και εσωτερικές τάσεις που πιθανόν να γίνουν το κεντρικό σημείο της ενδεχόμενης θραύσης του εμφυτεύματος. Μη χρησιμοποιείτε το εμφύτευμα εάν υποψιάζεστε ότι υπάρχει βλάβη.

   Εάν εφαρμοστεί υπερβολική περιστροφή στους κοχλίες όταν τίθεται η πλάκα στη θέση της, μπορεί να προκαλέσει αποτυχία του οστού με αποτέλεσμα τα απογυμνωμένα σπειρώματα καιή παραμορφωμένους κοχλίες.
3. **ΚΑΜΨΗ ΤΗΣ ΚΑΤΑΣΚΕΥΗΣ.** Δεν πρέπει να κάμπτετε ποτέ εξαρτήματα από κράμα τιτανίου κατά οξεία ή αντίθετη γωνία. Εάν μια κατασκευή υπερκαμπυλωθεί συνιστάται η σωστή καμπύλωση νέας κατασκευής αντί της αντίστροφης κάμψης της υπερκαμπυλωμένης κατασκευής.
4. **ΑΦΑΙΡΕΣΗ ΤΟΥ ΕΜΦΥΤΕΥΜΑΤΟΣ ΜΕΤΑ ΤΗΝ ΙΑΣΗ.** Εάν η συσκευή δεν αφαιρεθεί αφού ολοκληρωθεί η ενδεικνυόμενη χρήση της, μπορεί να συμβεί οποιαδήποτε από τις ακόλουθες επιπλοκές: (1) Διάβρωση, με αντίδραση στον τοπικό ιστό, ή πόνο, (2) Μετατόπιση της θέσης εμφύτευσης με αποτέλεσμα τον τραυματισμό, (3) Κίνδυνος επιπρόσθετου τραυματισμού από μετεγχειρητικό τραύμα, (4) Στρέβλωση, χαλάρωση καιή θραύση, που μπορεί να καταστήσει την αφαίρεση άσκοπη ή δύσκολη, (5) Πόνο, δυσφορία, ή διαταραχή των αισθήσεων λόγω της παρουσίας της συσκευής, (6) Πιθανή αύξηση του κινδύνου λοίμωξης, και (7) Απώλεια οστού λόγω του φαινομένου "stress shielding". Ο χειρουργός θα πρέπει να υπολογίσει προσεκτικά τους κινδύνους έναντι των ωφεληματων όταν αποφασίζει εάν πρέπει να αφαιρέσει τη συσκευή. Η αφαίρεση του εμφυτεύματος θα πρέπει να ακολουθείται από επαρκή μετεγχειρητική φροντίδα για να αποφευχθεί η επανάληψη θλάσης. Εάν ο ασθενής είναι μεγάλος σε ηλικία και έχει χαμηλά επίπεδα δραστηριότητας, ο χειρουργός μπορεί να επιλέξει να μην αφαιρέσει τη συσκευή, εξαλείφοντας έτσι τους κινδύνους που σχετίζονται με τη δεύτερη εγχείρηση.
5. **ΔΩΣΤΕ ΕΠΑΡΚΕΙΣ ΟΔΗΓΙΕΣ ΣΤΟΝ ΑΣΘΕΝΗ.** Η μετεγχειρητική φροντίδα και η ικανότητα και προθυμία του ασθενή να ακολουθήσει τις οδηγίες είναι μεταξύ των πιο σημαντικών παραγόντων επιτυχημένης ίασης του οστού. Ο ασθενής πρέπει να κατανοήσει τους περιορισμούς του εμφυτεύματος, και να του δοθούν οδηγίες να περιορίσει και να περιστείλει τις σωματικές δραστηριότητες, ειδικά τις κινήσεις άρσης και συστροφής και οποιαδήποτε συμμετοχή σε αθλήματα. Ο ασθενής πρέπει να κατανοήσει ότι ένα μεταλλικό εμφύτευμα δεν είναι τόσο δυνατό όσο ένα φυσιολογικό υγιές οστό και μπορεί να χαλαρώσει, να λυγίσει καιή να σπάσει εάν ασκηθούν μεγάλες πιέσεις σε αυτό, ειδικά με την απουσία πλήρους οστικής ίασης. Ένας δραστήριος, εξασθενημένος, ή παράφρων ασθενής που δεν μπορεί να χρησιμοποιήσει κατάλληλα τις συσκευές υποστήριξης βάρους, μπορεί να διατρέχει ιδιαίτερο κίνδυνο κατά τη διάρκεια της μετεγχειρητικής ανάρρωσης.

## ΠΙΘΑΝΕΣ ΑΝΕΠΙΘΥΜΗΤΕΣ ΕΝΕΡΓΕΙΕΣ

1. Μη συνένωση, καθυστερημένη συνένωση.
2. Κάμψη ή θλάση του εμφυτεύματος. Χαλάρωση του εμφυτεύματος.
3. Ευαισθησία στο μέταλλο, ή αλλεργική αντίδραση σε ξένο σώμα.
4. Λοίμωξη, νωρίς ή αργότερα.
5. Μείωση οστικής πυκνότητας λόγω του φαινομένου "stress shielding".
6. Πόνος, δυσφορία ή διαταραχή των αισθήσεων λόψω της παρουσίας της συσκευής.
7. Βλάβη νεύρων λόγω χειρουργικού τραύματος ή παρουσία της συσκευής. Οι νευρολογικές δυσκολίες περιλαμβάνουν δυσλειτουργία των εντέρων καιή της ουροδόχου κύστης, ανικανότητα, παλίνδρομη εκσπερμάτωση, ριζικό πόνο, πρόσδεση των νεύρων σε ουλικό ιστό, μυϊκή αδυναμία και παραισθησία.
8. Η αγγειακή βλάβη μπορεί να οδηγήσει σε καταστρεπτική ή θανατηφόρα αιμορραγία. Εμφυτεύματα που δεν έχουν τοποθετηθεί σωστά δίπλα από μεγάλες αρτηρίες ή φλέβες, μπορεί να διαβρώσουν αυτά τα αγγεία και να προκαλέσουν καταστροφική αιμορραγία στη μεταγενέστερη μετεγχειρητική περίοδο.
9. Τα σχισίματα της σκληρής μήνιγγας που γίνονται κατά τη διάρκεια της εγχείρησης, μπορεί να έχουν σαν αποτέλεσμα την ανάγκη περαιτέρω εγχείρησης για την επισκευή της σκληρής μήνιγγας, μια χρόνια διαρροή CSF ή συρίγγιο και πιθανή μηνιγγίτιδα.
10. Θυλακίτιδα.
11. Παράλυση.
12. Διάτρηση, διάβρωση ή ερεθισμό του οισοφάγου.

13. Χαλάρωμα της βίδας προς τα έξω, που πιθανόν να οδηγήσει σε διάβρωση του οισοφάγου, χαλάρωση του εμφυτεύματος, στην επανεγχείρηση για την αφαίρεση της συσκευής ή σε συνδυασμό των παραπάνω.
14. Ζημιά στα λεμφικά αγγεία καιή εξίδρωση λεμφικού υγρού.
15. Πρόσκρουση ή ζημιά στη σπονδυλική στήλη.
16. Θλάση οστικών δομών.
17. Εκφυλιστικές αλλαγές ή αστάθεια σε τμήματα παρακείμενα στα τεχνητά αγκυλωμένα σπονδυλικά επίπεδα.
18. Θάνατος.

**ΠΕΡΙΟΡΙΣΜΕΝΗ ΕΓΓΥΗΣΗ ΚΑΙ ΑΠΟΚΗΡΥΞΗ: ΤΑ ΠΡΟΪΟΝΤΑ ΤΗΣ DEPUY SPINE ΠΩΛΟΥΝΤΑΙ ΜΕ ΠΕΡΙΟΡΙΣΜΕΝΗ ΕΓΓΥΗΣΗ ΣΤΟΝ ΑΡΧΙΚΟ ΑΓΟΡΑΣΤΗ ΕΝΑΝΤΙ ΕΛΑΤΤΩΜΑΤΩΝ ΣΤΗΝ ΕΡΓΑΣΙΑ ΤΟΥΣ ΚΑΙ ΣΤΑ ΥΛΙΚΑ ΤΟΥΣ. ΜΕ ΤΟ ΠΑΡΟΝ ΑΠΟΚΗΡΥΣΣΟΝΤΑΙ ΟΠΟΙΕΣΔΗΠΟΤΕ ΑΛΛΕΣ ΡΗΤΕΣ Ή ΕΝΝΟΟΥΜΕΝΕΣ ΕΓΓΥΗΣΕΙΣ, ΣΥΜΠΕΡΙΛΑΜΒΑΝΟΜΕΝΩΝ ΚΑΙ ΤΩΝ ΕΓΓΥΗΣΕΩΝ ΓΙΑ ΕΜΠΟΡΙΚΟΤΗΤΑ Ή ΚΑΤΑΛΛΗΛΟΤΗΤΑ.**

**ΕΑΝ ΕΧΟΥΝ ΠΕΡΑΣΕΙ ΠΕΡΙΣΣΟΤΕΡΟ ΑΠΟ ΔΥΟ ΕΤΗ ΜΕΤΑΞΥ ΤΗΣ ΗΜΕΡΟΜΗΝΙΑΣ ΕΚΔΟΣΗΣ/ΑΝΑΘΕΩΡΗΣΗΣ ΚΑΙ ΤΗΣ ΗΜΕΡΟΜΗΝΙΑΣ ΣΥΝΕΝΝΟΗΣΗΣ ΕΠΙΚΟΙΝΩΝΗΣΤΕ ΜΕ ΤΗΝ DEPUY SPINE, ΓΙΑ ΤΡΕΧΟΥΣΕΣ ΠΛΗΡΟΦΟΡΙΕΣ ΣΤΟΝ ΑΡΙΘΜΟ 800-365-6633 ή στο +1-508-880-8100.**

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DePuy Spine SÀRL
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**ΕΠΕΞΗΓΗΣΗ ΣΥΜΒΟΛΩΝ**

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|---|---|---|---|
| LOT ΑΡΙΘΜΟΣ ΠΑΡΤΙΔΑΣ | ΜΙΑΣ ΧΡΗΣΗΣ | NONSTERILE ΜΗ ΣΤΕΙΡΟ | ΚΑΤΑΣΚΕΥΑΣΤΗΣ |
| REF ΑΡΙΘΜΟΣ ΚΑΤΑΛΟΓΟΥ | XXXX-XX ΗΜΕΡΟΜΗΝΙΑ ΛΗΞΗΣ | STERILE R ΑΠΟΣΤΕΙΡΩΣΗ ΜΕ ΑΚΤΙΝΟΒΟΛΙΑ | EC REP ΕΞΟΥΣΙΟΔΟΤΗΜΕΝΟΣ ΑΝΤΙΠΡΟΣΩΠΟΣ ΓΙΑ ΤΗΝ ΕΥΡΩΠΗ |
| QTY ΠΟΣΟΤΗΤΑ | | STERILE EO ΑΠΟΣΤΕΙΡΩΣΗ ΜΕ ΟΞΕΙΔΙΟ ΤΟΥ ΑΙΘΥΛΕΝΙΟΥ | DIST ΔΙΑΝΕΜΕΤΑΙ ΑΠΟ ΤΗΝ |
| Rx Only Η ομοσπονδιακή νομοθεσία (των Η.Π.Α.) περιορίζει την πώληση της συσκευής αυτής σε ιατρούς ή κατόπιν εντολής ιατρού. | ΔΕΙΤΕ ΤΙΣ ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ | MADE IN ΧΩΡΑ ΚΑΤΑΣΚΕΥΗΣ | SZ ΜΕΓΕΘΟΣ |
| | STERILE ΣΤΕΙΡΟ | | |

**ΥΛΙΚΟ MATL**

| | | |
|---|---|---|
| A/T ACROFLEX™/Ti ACROFLEX™/Τιτάνιο | P POLYMER Πολυμερές | SS/RADEL™/ SRTA Ti Al Nitride Ανοξείδωτος χάλυβας/RADEL™/ Νιτρίδιο τιτανίου αλουμινίου |
| A Al Αλουμίνιο | P/CM PE/CoCrMo Πολυαιθυλένιο/Κοβάλτιο Χρώμιο Μολυβδαίνιο | STA SS/Ti Al Nitride Ανοξείδωτος χάλυβας/ Νιτρίδιο τιτανίου αλουμινίου |
| A/P Al/PL Αλουμίνιο/Πλαστικό | P/C POLYMER/CARBON FIBER COMPOSITE Πολυμερές/ Σύνθετο υλικό ανθρακονήματος | S/U SS/ULTEM Ανοξείδωτος χάλυβας/Ultem |
| B/R Ba/RADEL™ Βάριο/RADEL™ | S SS Ανοξείδωτος χάλυβας | T Ti Τιτάνιο και τα κράματά του |
| CaP CALCIUM PHOSPHATE Φωσφορικό ασβέστιο | S/A SS/Al Ανοξείδωτος χάλυβας/Αλουμίνιο | S/R SS/RADEL™ Ανοξείδωτος χάλυβας/RADEL™ |
| CM CoCrMo Κοβάλτιο Χρώμιο Μολυβδαίνιο | SBR SS/Ba/RADEL Ανοξείδωτος χάλυβας/ Βάριο/RADEL | R/T POLYOLEFIN RUBBER/Ti Καουτσούκ πολυολεφίνης/Τιτάνιο |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Κοβάλτιο Χρώμιο Μολυβδαίνιο/ Τιτάνιο/Φωσφορικό ασβέστιο | S/P SS/PHENOLIC Ανοξείδωτος χάλυβας/ Φαινολική ένωση | T/A Ti/Al Τιτάνιο/Αλουμίνιο |
| F FOAM Αφρώδες υλικό | S/PL SS/PL Ανοξείδωτος χάλυβας/Πλαστικό | Ti/UHMWPE/HA Τιτάνιο/Πολυαιθυλένιο υπερυψηλού μοριακού βάρους/Υδροξυαπατίτης |
| HA Υδροξυαπατίτης | SRSI SS/RADEL™/ SILICONE Ανοξείδωτος χάλυβας/ RADEL™/Σιλικόνη | SS/Ti Ανοξείδωτος χάλυβας/Τιτάνιο |
| NiTi Ni/Ti Νικέλιο/Τιτάνιο | SRSM SS/RADEL™/ SILICONE/Ti Al Nitride Ανοξείδωτος χάλυβας/RADEL™/ Σιλικόνη/Νιτρίδιο τιτανίου αλουμινίου | SS/Al/SILICONE Ανοξείδωτος χάλυβας/ Αλουμίνιο/Σιλικόνη |
| PL Πλαστικό | | S/SI SS/SILICONE Ανοξείδωτος χάλυβας/Σιλικόνη |
| P/F PL/FOAM Πλαστικό/Αφρώδες υλικό | | |
| PY Πολυεστέρας | | |



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# PEAK ELÜLSŐ KOMPRESSZIÓS LEMEZES RÖGZÍTŐKÉSZLET

# PEAK TÖBBTENGELYŰ ELÜLSŐ NYAKI LEMEZES RÖGZÍTŐKÉSZLET

# DOC ELÜLSŐ NYAKI RÖGZÍTŐRENDSZER

# SLIM-LOC™ ELÜLSŐ NYAKI LEMEZES RÖGZÍTŐKÉSZLET

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## FONTOS MEGJEGYZÉSEK AZ OPERÁLÓ ORVOS RÉSZÉRE

Az elülső nyaki rögzítő implantátumok hasznos élettartama más belső rögzítőeszközökhöz hasonlóan véges. A beteg fizikai aktivitásának mértéke jelentős hatással van az implantátum hasznos élettartamára. Tájékoztatni kell a beteget, hogy minden fizikai aktivitás növeli az implantátum elemei kilazulásának, elgörbülésének és törésének kockázatát. Elengedhetetlen fontosságú a betegek tájékoztatása a fizikai aktivitásnak a műtét utáni időszakban érvényes korlátozásáról, valamint a betegek posztoperatív vizsgálata a csontos fúzió létrejötte és az implantátum elemeinek állapota kapcsán. Szilárd csontos fúzió létrejötte ellenére is elgörbülhetnek, eltörhetnek vagy kilazulhatnak az implantátum elemei. Ezért a beteg figyelmét fel kell hívni arra, hogy az implantátum elemei a fizikai aktivitás korlátozásának betartása esetében is elgörbülhetnek, eltörhetnek vagy kilazulhatnak.

Az anatómiai megfontolások és a modern sebészeti anyagok által támasztott korlátozások miatt nem lehet korlátlan ideig működőképes fémimplantátumokat készíteni. Ezek szerepe, hogy átmeneti belső támasztást nyújtsanak, amíg a csontos fúzió be nem fejeződik. Az ilyen típusú implantátumok nagyobb valószínűséggel válnak elégtelenné, ha a műtét során nem alkalmaznak csontgraftot vagy ha pseudoarthrosis alakul ki.

A csontos fúzió bekövetkezte után a sebész az implantátum eltávolítása mellett dönthet. Az újabb műtét lehetőségét meg kell beszélni a beteggel, és ki kell térni az újabb műtéttel kapcsolatos kockázatokra is. Ha az implantátum eltörik, az eltávolítására vonatkozó döntést az orvosnak kell meghoznia a beteg állapotának és a törött implantátum okozta kockázatoknak a figyelembevételével.

## LEÍRÁS

A PEAK elülső kompressziós lemezes rögzítőrendszer titánötvözetből készült lemezeket és csavarokat tartalmaz. A lemezek 26-94 mm-es, egy-négy szegmens rögzítésére alkalmas méretben kaphatók. A készlet ezen kívül tartalmaz titánötvözetből készült, 3,5 mm átmérőjű corticalis és 4,0 mm átmérőjű spongiosa csavarokat, 8 és 30 mm közötti hosszúságban.

A PEAK többtengelyű elülső nyaki lemezes rögzítőrendszer titánötvözetből készült lemezeket és csavarokat tartalmaz. Az elülső nyaki lemezek 24-110 mm-es, egy-négy szegmens rögzítésére alkalmas méretben kaphatók. 4,0 és 4,35 mm-es átmérőjű spongiosa csavarok kaphatók. A csavarok végig menetesek, és 10-26 mm hosszúak.

A DOC elülső nyaki rögzítőrendszer titánötvözetből készült platformokból, lemezekből, rudakból és csavarokból áll, és a nyaki gerinc defektusainak kezelésére és stabilizációjára szolgál. A DOC elülső nyaki rögzítőrendszer teljesen összeszerelt formájában egy lemezből vagy egy, a csigolyák elülső felszínén elhelyezkedő platform által összekapcsolt két, laterális elhelyezkedésű rúdból áll. A rendszer a csigolyákhoz csavarokkal rögzül. Az implantátum további stabilitást biztosít a nyaki gerincnek elülső cervicalis fúzió után. Az implantátum kialakításától függően szilárd (terhelésstabil) vagy dinamikus (részlegesen terhelésstabil) lehet.

A rendszer a következő elemekből áll: rudak, lemezek, platformok, külső és belső csontcsavarok, graftcsavarok és keresztösszekötő elemek. Mindegyik elem implantátum minőségű, az ASTM F-136 előírásoknak megfelelő titánötvözetből készült. A sebész munkájának megkönnyítése érdekében összeszerelt rendszerek is kaphatók. Ezek előre összeszerelt elemek, amelyek egy platformból, egy keresztösszekötő elemből, két rúdból és két rögzítőcsavarból állnak.

**Platform:** A platformok a rudak összekötésére és csontcsavarok segítségével a csigolyatestekhez történő rögzítésükre szolgálnak. Mindegyik platform alkalmas tömör csontcsavarok (bikortikális rögzítés) vagy külső és belső csontcsavarok kombinációja (üreges külső csontcsavar és tömör belső rögzítőcsavar unikortikális rögzítésre) alkalmazására.
A csavarok típusának megválasztása az orvos preferenciájától függ. Mindegyik platform két rúddal történő alkalmazásra szolgál.

Platformok zárható és nem zárható formában is kaphatók. A zárható platformokon olyan toldalék van, amely a platformot a rudakhoz rögzítő, a platform és a keresztösszekötő elem közötti rögzítőcsavarok befogadására alkalmas. Zárható platformok szükségesek a rudak fejvégével ellenlétes végén.

Ha szilárd megoldásra van szükség a dinamikus (részlegesen terhelésstabil) megoldás helyett, zárható platformot kell alkalmazni a rudak fejvégén is. Ha részlegesen terhelésstabil megoldásra van szükség, a rudak fejvégéhez csatlakozó platform nem rögzíthető a rudakhoz.

Különböző platformok állnak rendelkezésre a csavarnak a csigolyatesthez történő, különböző szögű rögzítéséhez. Ezek zárható és nem zárható formában is kaphatók. A platformok egyik oldalán taraj van, amely az elhelyezés és a rögzítés optimalizálása érdekében a csigolyáknak az intervertebralis rés felé tekintő felszínéhez támaszkodik.

Különböző platformok állnak rendelkezésre a csavarnak a csigolyatesthez merőlegesen történő rögzítéséhez. Ezek zárható és nem zárható formában is kaphatók.

Kapható olyan platform is, amely intervertebralis grafthoz történő rögzítésre alkalmas. Ezen a csavarok befogadására ívelt, vízszintes rés van kialakítva, amely lehetővé teszi, hogy a csavart különböző helyen és ívben lehessen a graftba csavarni.

A platform megválasztása az orvos döntésén és a beteg gerincének felépítésén múlik.

A SLIM-LOC™ elülső nyaki lemezes rögzítőrendszer titánötvözetből készült lemezeket és csavarokat tartalmaz. A lemezek hosszúsága 22 és 111 mm között változik, és 2, 3, 4, 5 vagy 6 pár csavar befogadására alkalmasak. A SLIM-LOC csavarok 4,5 mm átmérőjűek, az önfúró típusból 2 mm-enként 10-18 mm-es hosszúságban, az önmenetvágó típusból 2 mm-enként 10-26 mm hosszúságban kaphatók. Nagyobb (4,8 mm-es) átmérőjű csavarok 12, 14 és 16 mm-es hosszúságban kaphatók.

Az EAGLE™ elülső nyaki lemezes rögzítőrendszer titánötvözetből készült lemezeket és csavarokat tartalmaz. Kettő-hat lyukpárt tartalmazó lemezek kaphatók különböző méretekben. A csavarok különböző méretben és különböző kialakítású heggyel kaphatók.

A SWIFT™ elülső nyaki lemezes rendszer titánötvözetből készült, és szegmentált lemezekből áll, amelyek legfeljebb 2 mm-nyi ellenőrzött graftbeállítást tesznek lehetővé minden két szegmens között. Kettő-hat lyukpárt tartalmazó lemezek kaphatók különböző hosszúságban és kétféle (discectomiás és corpetomiás) kialakításban. A csavarok különböző méretben és különböző kialakítású heggyel kaphatók. A corpectommiás lemezekkel való használathoz graftcsavar is kapható.

A UNIPLATE™ elülső nyaki lemezes rögzítőrendszer titánötvözetből készült lemezeket és csavarokat tartalmaz. Az elülső nyaki lemezek különböző hosszúságú, egy és két szegmens rögzítésére alkalmas méretben kaphatók. A csavarok különböző méretben és különböző kialakítású heggyel kaphatók.

A SKYLINE™ elülső nyaki lemezes rögzítőrendszer titánötvözetből készült lemezeket és csavarokat tartalmaz. Kettő-hat lyukpárt tartalmazó lemezek kaphatók különböző méretekben. A csavarok különböző méretben és különböző kialakítású heggyel kaphatók. Kaphatók előre beállított beültetési mélységű és változtatható beültetési mélységű csavarok, amelyek segítségével létrehozható előre beállított mélységű, változtatható mélységű vagy a kettő kombinációját jelentő kialakítás is.

## TISZTÍTÁS ÉS STERILIZÁLÁS

A nyaki lemezes rögzítőrendszer elemeit sterilen, vagy tisztán, de nem sterilen szállítjuk. A steril alkatrészek esetében felhasználás előtt győződjön meg arról, hogy a csomagolás nem sérült.

Mindegyik nem steril összetevőt a kórházban, az IOS 8828 vagy az AORN ajánlásoknak megfelelően kell sterilizálni.

A vizsgálatok eredményei alapján következő AJÁNLÁSOK vonatkoznak A GŐZSTERILIZÁTORBAN TÖRTÉNŐ STERILIZÁCIÓRA:

| | |
|---|---|
| Ciklus | Elővákuum |
| Hőmérséklet | 270 °F<br>132 °C |
| Sterilizálás ideje | 6 perc |

## HASZNÁLAT

A sebésznek nem csak az implantáció belgyógyászati és sebészeti vetületeit kell alaposan ismernie, hanem tisztában kell lennie a fémimplantátumok mechanikai és gyártástechnológiai korlátaival is. Rendkívül fontos a posztoperatív gondozás. A betegnek el kell magyarázni a fémimplantátum korlátait, és figyelmeztetni kell a teljes csontos gyógyulás előtt a terhelés és az implantátumot érő stressz hatásaira. Figyelmeztetni kell a beteget arra, hogy a műtét utáni időszakra vonatkozó utasítások be nem tartása az implantátum elégtelenné válását okozhatja, valamint az eszköz eltávolítására szolgáló újabb műtétet tehet szükségessé.

A DePuy Spine gerincrögzítő rendszerek elemeit nem szabad más gyártók termékeivel együtt alkalmazni.

**A megfelelő függőleges irányú teherviselés érdekében döntő jelentőségű a kiválasztott alkatrészek megfelelő elhelyezése.**

**A műtéti technikára vonatkozó információk a műtéttechnikai használati utasításban találhatók.**

## JAVALLATOK

VIGYÁZAT! Az Amerikai Egyesült Államok törvényei ezen eszköz beszerzését csak orvosoknak, valamint orvosi rendeletre engedélyezik.

A SLIM-LOC és a SKYLINE™ elülső nyaki rögzítő lemezek használata a C2-C7 nyaki gerincszakaszon szükséges stabilizációs műtétek során javasolt, amikor a csigolyatestek elülső falán unikortikális csavaros rögzítést alkalmazunk. Az elülső lemezes rögzítés többek között az alábbi specifikus klinikai esetekben javasolt: trauma okozta instabilitás, a nyaki lordosis vagy kyphosis korrekciója által okozott instabilitás, korábbi sikertelen nyaki műtét okozta psuedoarthrosis miatti instabilitás,



a nyaki gerinc primer daganatai vagy áttétjei miatti műtét okozta instabilitás, előrehaladott degeneratív porckorongbetegség miatti porckorong-eltávolítás okozta instabilitás, a gerinccsatorna szűkülete, valamint nyaki myelopathia.

A PEAK elülső kompressziós lemezrendszer, a PEAK többtengelyű elülső nyaki gerincrögzítő rendszer, a DOC elülső nyaki stabilizációs rendszer, az EAGLE elülső nyaki lemezrendszer, a SWIFT elülső nyaki lemezrendszer és a UNIPLATE elülső nyaki lemezrendszer a nyaki gerinc csigolyatestjeinek elülső rögzítésére szolgál. E rendszerek alkalmazása javallt olyan betegek esetében, akiknél anterior nyaki gerincfúzió után a gerinc stabilizálására van szükség, az alább felsorolt indikációk mellett. A rögzítés a C2-től a T1 csigolyáig végezhető.

A kezelés javallatát tüneteket okozó nyaki spondylosis, trauma, törés, poszttraumás kyphosis vagy lordosis, daganatok, degeneratív porckorongbetegségek (porckorong eredetű hátfájdalom és a porckorong anamnézis és radiológiai vizsgálat által megerősített degenerációjának együttes jelenléte), sikertelen csigolyafúzió utáni ismételt műtét, valamint a fenti indikációk miatti műtét sikertelensége képezi.

A UNIPLATE elülső nyaki lemezes rögzítőrendszer gerincszűkület (spinal stenosis) kezelésére is használható.

**FIGYELMEZTETÉS:** Az eszköz alkalmazásának megfelelő voltát nem igazolták a cervicalis, thoracalis vagy lumbalis csigolyák hátsó komponenseihez (nyúlványok) történő csavaros rögzítésben.

## POSZTOPERATÍV MOBILIZÁCIÓ

Ameddig a fúzió (radiológiai vizsgálattal igazoltan) nem ment végbe, az orvos döntése alapján esetleg külső rögzítés javasolt (például fűzővel).

Ugyanennyire fontos része a rögzítés elégtelenné válásából következő szövődmények elkerülésére irányuló intézkedéseknek, hogy az orvos utasítsa a betegét az implantátumot érő terhelés csökkentésére.

## ELLENJAVALLATOK

- Aktív szisztémás fertőzések és a beültetés helyén elhelyezkedő fertőzések.
- A súlyos osteoporosis megakadályozhatja a csavarok megfelelő rögzülését, és ezzel kizárja e rendszer és a többi gerincrögzítő eszköz alkalmazását.
- Olyan betegek, akiknél bizonyíthatóan biztonsággal és kiszámíthatóan kezelhető az elváltozás belső rögzítés alkalmazása nélkül.
- Nyílt sebek.

## RELATÍV ELLENJAVALLATOK:

A beavatkozás relatív ellenjavallatát képezi minden olyan állapot vagy betegség (például rosszindulatú daganat, vesepótló kezelés vagy osteopaenia), amely teljes mértékben kizárja a csontos fúzió lehetőségét, valamint az elhízás, a degeneratív betegségek és az idegenanyag-túlérzékenység.

# A FÉMBŐL KÉSZÜLT IDEIGLENES IMPLANTÁTUMOK ALKALMAZÁSÁVAL KAPCSOLATOS FIGYELMEZTETÉSEK, ÓVINTÉZKEDÉSEK ÉS NEMKÍVÁNATOS HATÁSOK.

## FIGYELMEZTETÉSEK

A következő figyelmeztetéseket, óvintézkedéseket és nemkívánatos hatásokat a sebésznek figyelembe kell vennie, és el kell magyarázni a betegnek. A figyelmeztetések nem tartalmazzák az összes, a műtéttel általánosságban járó nemkívánatos hatást, hanem azok kifejezetten a fémből készült belső rögzítőberendezésekkel kapcsolatos megfontolások. A műtét előtt a beteggel ismertetni kell a műtét általános kockázatait.

Az eszköz alkalmazásával kapcsolatban felléphetnek a következő, műtétet szükségessé tevő szövődmények: a szerkezet alkatrészeinek törése, a rögzítés megszűnése, csigolyatörés, neurológiai károsodás, az erek és más szervek károsodása.

1. **RENDKÍVÜL FONTOS AZ IMPLANTÁTUM MEGFELELŐ MEGVÁLASZTÁSA.** A megfelelő rögzítés esélyét növeli az implantátum méretének, formájának és típusának megfelelő megválasztása. Az implantátum megfelelő megválasztása csökkentheti a kockázatokat, azonban az implantátumok méretét, alakját és erősségét korlátozza a csontok formája. A belső rögzítésre szolgáló fémeszközök nem alkalmasak akkora fizikai aktivitás által okozott terhelés elviselésére, mint a normális emberi csontok. Nem lehet egyetlen implantátumtól sem elvárni, hogy önmagában korlátlan ideig ellenálljon a teljes testtömeg által okozott erőbehatásnak.
2. **A CSONTOS FÚZIÓ KÉSÉSE VAGY ELMARADÁSA MIATT MEGNÖVEKEDETT TERHELÉS KÖVETKEZTÉBEN ELTÖRHETNEK AZ IMPLANTÁTUMOK.** A belső rögzítő berendezések célja a terhelés egy részének átvétele mindaddig, amíg a csontos gyógyulás be nem következik. Ha a gyógyulás késik vagy nem következik be, az implantátum a fém elfáradása következtében eltörhet. Az implantátum élettartamát többek között a csontos fúzió sikeressége és mértéke, a terhelés és a beteg fizikai aktivitása határozza meg. Az implantátum korai elégtelenné válásához hozzájárulhat az implantátum intraoperatív bevágása, megkarcolása és meggörbítése is. A betegeket teljes körűen tájékoztatni kell az implantátum elégtelenné válásának kockázatáról.
3. **A KÜLÖNBÖZŐ FÉMEK EGYÜTTES ALKALMAZÁSA KORRÓZIÓHOZ VEZETHET.** A korrózió sokféle formája létezik, és ezek közül számos előfordul az emberekbe beültetett eszközökön is. Általános, egyenletes korrózió minden beültetett fémen és ötvözeten megjelenik. A korrózió mértéke a fémimplantátumokon - a passzív felületi bevonatnak köszönhetően - általában igen csekély. Egymással érintkező, különböző fémek esetében, például titán és rozsdamentes acél érintkezésekor, a rozsdamentes acél korróziója felgyorsul. A korrózió következtében gyakran

korábban következik be az implantátumok fáradásos törése. A szervezetbe kerülő fémvegyületek mennyisége is növekszik. Azok a belső rögzítőeszközök, amelyek más fémtárgyakkal érintkezésbe kerülnek, például rudak, kampók, drótok stb., hasonló vagy kompatibilis anyagból kell, hogy álljanak.

4. **A BETEGEK KIVÁLASZTÁSA.** A belső rögzítőeszközökkel kezelendő betegek választásakor a következő tényezők rendkívüli jelentőséggel bírhatnak a beavatkozás sikere szempontjából.

   A. **A beteg foglalkozása és fizikai aktivitása.** Ha a beteg olyan foglalkozást vagy tevékenységet folytat, amely során nehéz tárgyakat emel, nagy izommunkát végez, törzsét forgatja, törzsét rendszeresen hajlítja, lehajol, fut, sokat gyalogol vagy fizikai munkát végez, nem folytathatja a munkát mindaddig, amíg csontjai tökéletesen össze nem forrtak. A teljes gyógyulás után sem biztos, hogy e tevékenységeket sikeresen el tudja majd végezni.

   B. **Szenilitás, elmebetegség, alkoholizmus és kábítószerhasználat.** Többek között e tényezők miatt a beteg figyelmen kívül hagyhatja a berendezés használatával kapcsolatos korlátozásokat és óvintézkedéseket, ami az implantátum elégtelenné válásához vagy egyéb szövődményekhez vezethet.

   C. **Bizonyos degeneratív betegségek.** Egyes esetekben a degeneratív betegségek progressziója olyannyira előrehaladott az implantáció időpontjában, hogy az jelentősen csökkentheti a szerkezet hasznos élettartamát. Ilyen esetekben az ortopédiai eszközök csak a betegség kimenetelét késleltető vagy ideiglenes gyógyulást biztosító módszernek tekinthetők.

   D. **Idegenanyag-túlérzékenység.** A sebésznek tudnia kell, hogy nem létezik olyan preoperatív vizsgálóeljárás, amely teljes mértékben kizárhatná a túlérzékenységet vagy az allergiás reakciót. Az implantátumok bizonyos ideig a testben való tartózkodása után túlérzékenység vagy allergia alakulhat ki.

   E. **Dohányzás.** Megfigyelték, hogy a dohányzó betegek körében gyakrabban fordul elő pseudoarthrosis csontgraft beültetésével végzett műtéteket követően. Ezenkívül kimutatták, hogy a dohányzás a csigolyaközti porckorongok diffúz degenerációját okozhatja. A környező struktúrák dohányzás által okozott progresszív degenerációja sikeres csontos fúzió és a tünetek kezdeti javulása után is vezethet késői klinikai elégtelenséghez (a fájdalom ismételt jelentkezéséhez).

**FIGYELMEZTETÉS:** Ha a fúzió az elvárható időn belül nem következik be, a csavarok eltörhetnek a tartós nagy terhelés következtében. Ezt megfigyelték elhúzódó vagy elmaradó csontgyógyulás, illetve álízület-képződés esetében; ez az eszköz(ök) revízióját teheti szükségessé.

## ÓVINTÉZKEDÉSEK

1. **AZ IMPLANTÁTUMOKAT SOHA NEM SZABAD ÚJRA FELHASZNÁLNI.** Az eltávolított fémimplantátumot soha nem szabad újra beültetni. Még ha az eszköz külsőleg épnek is tűnik, lehetséges, hogy tartalmaz kis sérüléseket és belső fáradásos károsodásokat, amelyek idő előtti töréséhez vezethetnek.

2. **RENDKÍVÜL FONTOS AZ IMPLANTÁTUM MEGFELELŐ KEZELÉSE.** A fémimplantátumok formázását csak a megfelelő eszközzel szabad végezni. A formázás során a sebésznek el kell kerülnie az implantátum megkarcolását és visszafelé történő hajlítását. Ellenkező esetben megsérülhet az eszköz felületi bevonata, valamint olyan belső feszültségek keletkezhetnek, amelyek az implantátum esetleges törésének gócpontjává válhatnak. Ne használja az implantátumot, ha lehetséges, hogy megsérült.

   A lemez rögzítése során a csavarok szükségesnél nagyobb mértékű megszorítása azt eredményezheti, hogy a csont károsodik, a menetek elkopnak és/vagy a csavar tartása gyengül.

3. **A SZERKEZET HAJLÍTÁSA.** A titánötvözetből készült alkatrészeket nem szabad túl nagy szögben, valamint visszafelé meghajlítani. Ha az alkatrészt a szükségesnél nagyobb mértékben hajlította meg, ajánlott új alkatrészt hajlítani, és nem visszahajlítani a túlhajlított darabot.

4. **AZ IMPLANTÁTUM GYÓGYULÁS UTÁNI ELTÁVOLÍTÁSA.** Ha az eszköz nem kerül eltávolításra hasznos életideje után, a következő szövődmények bármelyike előfordulhat: (1) Korrózió, lokális szöveti reakcióval és fájdalommal; (2) Az implantátum helyének megváltozása, ami sérülést okoz; (3) Posztoperatív traumából származó további sérülés veszélye; (4) Az implantátum elgörbülése, kilazulása és/vagy törése, ami megnehezítheti az eltávolítást; (5) Fájdalom, diszkomfort érzés vagy rendellenes érzetek a készülék jelenléte miatt; (6) A fertőzés nagyobb kockázata; (7) Csontvesztés a készülék által átvett terhelés miatt. A sebésznek az implantátum eltávolításáról meghozott döntése során gondosan mérlegelnie kell annak kockázatát és hasznát. Az implantátum eltávolítása után megfelelő posztoperatív gondozás szükséges az ismételt törés vagy elgörbülés elkerülése érdekében. Ha beteg idős és keveset mozog, a sebész dönthet az implantátum helyben hagyása mellett, ezzel elkerülhetők az újabb műtéttel járó kockázatok.

5. **A BETEGNEK ADOTT MEGFELELŐ UTASÍTÁSOK.** A csontok gyógyulásának sikeressége legfontosabb tényezői közé tartozik a posztoperatív gondozás, és az, hogy a beteg képes és hajlandó követni az orvos utasításait. A betegnek el kell magyarázni az implantátum korlátjait, és utasítani kell, hogy korlátoznia kell, illetve be kell szüntetnie bizonyos fizikai tevékenységeket, főleg az emelést, a törzs elfordítását, valamint mindenféle sporttevékenységet. A betegnek meg kell értenie, hogy egy fémimplantátum nem olyan erős, mint az egészséges csont, és túlzott terhelés esetén meglazulhat, elgörbülhet és/vagy eltörhet, főként ha még a csont nem gyógyult meg teljesen. A nem megfelelő fizikai tevékenység által más helyre kerülő vagy megsérült implantátumok vándorolhatnak a szervezetben, és megsérthetnek idegeket vagy ereket. A posztoperatív rehabilitáció során különösen nagy a szövődmények kockázata fizikailag aktív, debilis és demens személyek esetében, akik nem tudják megfelelően használni a gerinc terhelését csökkentő eszközöket.



## LEHETSÉGES NEMKÍVÁNATOS HATÁSOK

1. A csontos fúzió elmaradása vagy késése.
2. Az implantátum elgörbülése vagy törése. Az implantátum kilazulása.
3. Fémérzékenység vagy idegenanyag-túlérzékenység kialakulása.
4. Korai vagy késői fertőzés.
5. A csontsűrűség csökkenése azáltal, hogy az implantátum átveszi a terhelést.
6. Fájdalom, diszkomfort érzés, rendellenes érzetek az eszköz jelenléte miatt.
7. Idegsérülés műtéti trauma vagy a készülék jelenléte miatt. Neurológiai problémák, beleértve a gyöki fájdalmat, az idegek leszorítása hegszövetben, izomgyengeség, valamint paraesthesia.
8. Érsérülés következtében életveszélyes vagy halálos vérzés. A nagy artériák és vénák mellett elhelyezkedő, rosszul elhelyezett implantátumok az erek eróziójához és életveszélyes vérzéshez vezethetnek a késői posztoperatív időszakban.
9. A műtét közben a dura mater redőzése ismételt műtétet tehet szükségessé a dura plasztikája céljából, krónikus CSF-szivárgást vagy -fistulát okozhat, és meningitishez vezethet.
10. Bursitis.
11. Bénulás.
12. Nyelőcső-perforáció, erózió vagy irritáció.
13. A csavar kivándorlása, ami esetleg a nyelőcső eróziójához, az implantátum kilazulásához és/vagy az eszköz eltávolítását célzó reoperációhoz vezet.
14. Nyirokérsérülés és/vagy nyirokszivárgás.
15. A gerincvelő becsípődése vagy sérülése.
16. Csonttörés.
17. A fúzióval egyesített csigolyákkal szomszédos szegmentumok degenerációja vagy instabilitása.
18. Halál.

**A GARANCIA KORLÁTOZÁSA: A DEPUY SPINE TERMÉKEIÉRT KORLÁTOZOTT GARANCIÁT VÁLLAL AZ EREDETI VÁSÁRLÓ FELÉ AZ ANYAG- ÉS A GYÁRTÁSI HIBÁK TEKINTETÉBEN. MINDEN EGYÉB KIFEJEZETT ÉS HALLGATÓLAGOS GARANCIÁT ELHÁRÍTUNK, IDEÉRTVE A FORGALMAZHATÓSÁGRA ÉS AZ ALKALMAZHATÓSÁGRA VONATKOZÓ GARANCIÁT IS.**

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**A SZIMBÓLUMOK JELENTÉSE**

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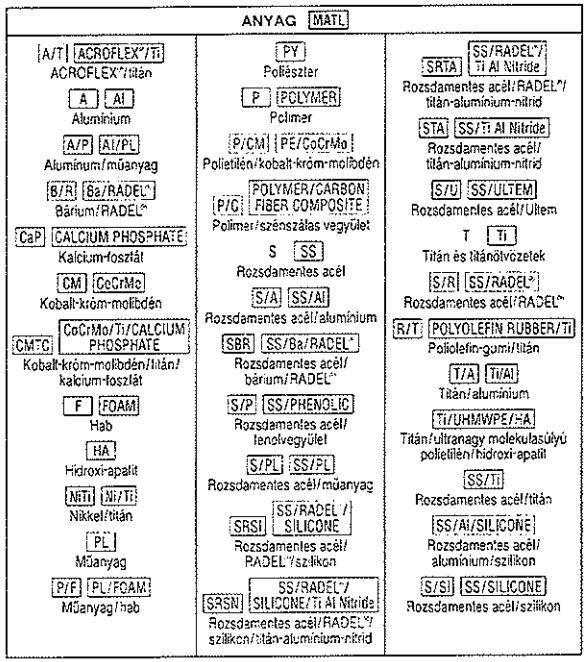


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# SISTEMA DI PIASTRE DI COMPRESSIONE ANTERIORI PEAK

# SISTEMA DI PIASTRE CERVICALI ANTERIORI MULTIASSIALE PEAK

# SISTEMA DI STABILIZZAZIONE CERVICALE VENTRALE DOC

# SISTEMA DI PIASTRE CERVICALI ANTERIORI SLIM-LOC™

# SISTEMA DI PIASTRE CERVICALI ANTERIORI EAGLE™

# SISTEMA DI PIASTRE CERVICALI ANTERIORI SWIFT™

# SISTEMA DI PIASTRE CERVICALI ANTERIORI UNIPLATE™

# SISTEMA DI PIASTRE CERVICALI ANTERIORI SKYLINE™

## AVVISO IMPORTANTE PER IL CHIRURGO

Gli impianti di sistemi di stabilizzazione cervicale anteriore, al pari di qualsiasi altro apparecchio temporaneo di fissazione interna, hanno una durata limitata su cui influisce in modo significativo il livello di attività del paziente. Il paziente deve essere informato del fatto che qualsiasi tipo di attività accresce il rischio di allentamento, curvatura o rottura dei componenti dell'impianto. È estremamente importante spiegare al paziente la necessità di limitare al massimo le attività nel periodo postoperatorio ed esaminarne le condizioni postoperatorie per valutare lo sviluppo della massa di fusione e lo stato dei componenti dell'impianto. Anche in caso di fusione ossea solida, i componenti dell'impianto potrebbero comunque allentarsi, piegarsi o rompersi. Il paziente va quindi informato che tale evenienza potrebbe verificarsi anche rispettando le limitazioni alle attività.



A causa delle limitazioni imposte da fattori anatomici e dagli attuali materiali chirurgici, gli impianti metallici non hanno una durata illimitata. Il loro scopo è fornire un supporto interno temporaneo durante il consolidamento della massa di fusione. Le probabilità di successo per questi tipi di impianti diminuiscono in assenza di innesto osseo o in caso di sviluppo di pseudoartrosi.

Una volta verificatasi la fusione ossea, il chirurgo può decidere di rimuovere l'impianto. La possibilità di un secondo intervento chirurgico deve essere valutata con il paziente, tenendo presenti i rischi che tale decisione può comportare. In caso di rottura di un impianto, la decisione della rimozione spetta al medico, che deve tenere presenti le condizioni del paziente e i rischi associati alla presenza di un impianto danneggiato.

## DESCRIZIONE

Il sistema di piastre di compressione anteriori PEAK è costituito da una varietà di piastre e viti in lega di titanio. Le piastre sono disponibili in lunghezze da 26 a 94 mm e presentano da uno a quattro segmenti di fissazione. Il sistema contiene inoltre viti in lega di titanio corticali da 3,5 mm e porose da 4 mm, disponibili in lunghezze da 8 a 30 mm.

Il sistema di piastre cervicali anteriori multiassiale PEAK è costituito da una varietà di piastre e viti in lega di titanio. Le piastre cervicali anteriori sono disponibili in dimensioni che vanno da 24 mm a 110 mm di lunghezza e presentano da uno a quattro segmenti di fissazione. Le viti porose sono disponibili in diametri di 4 e 4,35 mm. Tali viti sono completamente filettate e misurano da 10 a 26 mm di lunghezza.

Il sistema di stabilizzazione cervicale ventrale DOC è un sistema di viti, barre, piastre e piattaforme in lega di titanio in ausilio al chirurgo nella correzione dei difetti e nella stabilizzazione del tratto cervicale della colonna vertebrale. Quando è completamente montato, il sistema di stabilizzazione cervicale ventrale DOC consta di una piastra o di due barre collocate lateralmente, unite da piattaforme poste sulla superficie vertebrale anteriore. Il sistema è ancorato alle vertebre con viti. L'impianto aumenta la stabilità del tratto cervicale della colonna vertebrale in seguito a fusione cervicale anteriore. A seconda della configurazione, l'impianto può fungere da struttura rigida (sostentamento del carico) o dinamica (distribuzione del carico).

Il sistema comprende i seguenti tipi di elementi: barre, piastre, piattaforme, viti ossee interne ed esterne, viti a innesto e connettori trasversali. Tutti i componenti sono realizzati in lega di titanio per impianti, conforme alle specifiche ASTM F-136. Per agevolare il chirurgo, sono inoltre disponibili gruppi preassemblati costituiti da una piattaforma, un connettore trasversale, due barre e due viti di bloccaggio.

**Piattaforme:** le piattaforme servono per il collegamento delle barre e per l'ancoraggio ai corpi vertebrali con viti ossee. Tutte le piattaforme possono essere usate con viti ossee uniche (per la fissazione bicorticale) o con una combinazione di viti ossee interne ed esterne (una vite ossea esterna vuota usata con una vite di bloccaggio interna unica atta alla fissazione unicorticale). La scelta delle viti dipende dalle preferenze del chirurgo. Per formare la struttura, tutte le piattaforme utilizzano due barre.

Per le piattaforme sono disponibili configurazioni bloccabili e non bloccanti. Le piattaforme bloccabili sono dotate di estensioni su cui è possibile montare un insieme composto da piattaforma/viti di bloccaggio del connettore trasversale per fissare la piattaforma alle barre. Le piattaforme bloccabili devono essere usate all'estremità della struttura sul lato opposto alle teste delle barre.

Se si preferisce una configurazione rigida a una configurazione dinamica (ossia alla configurazione di distribuzione del carico), occorre usare anche una piattaforma bloccabile adiacente alle teste delle barre. Se si preferisce una configurazione di distribuzione del carico, la piattaforma adiacente alle teste delle barre non viene fissata alle barre.

Diverse piattaforme sono concepite per l'inserimento ad angolo della vite nel corpo vertebrale e sono disponibili in entrambe le configurazioni, bloccabile e non bloccante. Queste piattaforme sono dotate di un'aletta su un lato che si innesta nella vertebra dall'interno dell'area del disco per ottimizzare il posizionamento e la fissazione.

Diverse piattaforme sono concepite per l'inserimento perpendicolare della vite nel corpo vertebrale e sono disponibili in entrambe le configurazioni, bloccabile e non bloccante.

È disponibile un modello di piattaforma per la fissazione della struttura a un innesto intervertebrale. Questa piattaforma presenta una fessura orizzontale e una cavità sferica che consentono variazioni del sito di accesso e della traiettoria della vite nell'innesto.

La scelta delle piattaforme dipende dalle preferenze del chirurgo e dall'anatomia del paziente.

Il sistema di piastre cervicali anteriori SLIM-LOC™ è costituito da una varietà di piastre e viti in lega di titanio. Le piastre sono disponibili in lunghezze che vanno da 22 a 111 mm in configurazioni con 2, 3, 4, 5 o 6 paia di fori per viti. Le viti SLIM-LOC hanno un diametro di 4,5 mm e sono disponibili come autoperforanti in dimensioni di lunghezza regolari da 10 a 18 mm o autofilettanti in lunghezze regolari da 10 a 26 mm. Sono disponibili viti di diametro più grande (4,8 mm) in lunghezze da 12, 14 e 16 mm.

Il sistema di piastre cervicali anteriori EAGLE™ è costituito da una varietà di piastre e viti in lega di titanio. Le piastre sono disponibili con 2-6 paia di fori per viti, in varie lunghezze. Le viti sono disponibili in varie dimensioni e geometrie.

Il sistema di piastre cervicali anteriori SWIFT™ è prodotto in lega di titanio ed è costituito da piastre segmentate che consentono l'inserimento controllato di innesti di massimo 2 mm tra ciascun segmento. Le piastre sono disponibili con 2-6 paia di fori per viti, in varie lunghezze e due configurazioni, discectomia e corpectomia. Le viti sono disponibili in varie dimensioni e geometrie. È disponibile una vite per innesto da utilizzare nelle piastre per la corpectomia.

Il sistema di piastre cervicali anteriori UNIPLATE™ è costituito da una varietà di piastre e viti in lega di titanio. Le piastre cervicali anteriori sono disponibili in varie lunghezze in grado di accogliere uno o due segmenti di fissazione. Le viti sono disponibili in varie dimensioni e geometrie.

Il sistema di piastre cervicali anteriori SKYLINE™ è costituito da una varietà di piastre e viti in lega di titanio. Le piastre sono disponibili con 2-6 paia di fori per viti in varie lunghezze. Le viti sono disponibili in varie dimensioni e geometrie. Sono disponibili viti vincolate e variabili per creare una configurazione vincolata, variabile o ibrida.

## PULIZIA E STERILIZZAZIONE

Gli impianti di sistemi di stabilizzazione cervicale a piastre sono forniti sterili, o puliti ma non sterili. Per i componenti forniti sterili, prima dell'uso accertarsi che la confezione non sia danneggiata.

Con i dispositivi non sterili, adottare per tutti i componenti le procedure ISO 8828 o AORN consigliate per la sterilizzazione in ospedale.

I SEGUENTI CONSIGLI PER LA STERILIZZAZIONE A VAPOR D'ACQUA sono stati sviluppati sulla base di test condotti appositamente:

| | |
|---|---|
| Ciclo: | pre-aspirazione |
| Temperatura: | 132 °C<br>270 °F |
| Tempo di esposizione: | 6 min. |

## USO

Il chirurgo deve non solo possedere una conoscenza approfondita degli aspetti medici e chirurgici dell'impianto, ma deve anche essere consapevole delle limitazioni meccaniche e metallurgiche degli impianti chirurgici metallici. La cautela postoperatoria è estremamente importante. Il paziente deve essere informato delle limitazioni dell'impianto metallico e della necessità di astenersi dal sollevamento di pesi o dall'applicazione di eccessive sollecitazioni sull'impianto prima della saldatura dell'osso. Il paziente deve inoltre essere reso consapevole che la mancata osservanza delle istruzioni postoperatorie può determinare l'insuccesso dell'impianto e rendere necessario un altro intervento chirurgico per la rimozione dello stesso.

I componenti del sistema spinale DePuy Spine non vanno utilizzati con componenti di altre case produttrici.

**Il posizionamento corretto dei componenti selezionati è estremamente importante per ottenere una traslazione verticale controllata (distribuzione del carico).**

**Per istruzioni specifiche al riguardo, consultare il manuale delle tecniche chirurgiche.**

## INDICAZIONI

**ATTENZIONE:** le leggi statunitensi limitano la vendita di questo dispositivo ai medici o a individui in possesso di prescrizione medica.

Il sistema di piastre cervicali anteriori SLIM-LOC e il sistema di piastre cervicali anteriori SKYLINE™ sono indicati per la stabilizzazione della colonna cervicale da C2 a C7 mediante l'impiego di fissazione monocorticale a vite alla superficie anteriore dei corpi vertebrali. Le indicazioni cliniche specifiche per la placcatura anteriore includono: instabilità causata da trauma; instabilità associata alla correzione della lordosi cervicale e deformità per cifosi; instabilità associata a pseudoartrosi dovuta a precedenti interventi chirurgici malriusciti alla colonna cervicale; instabilità associata a chirurgia ricostruttiva principale per tumori primari o tumori maligni metastatici della colonna cervicale; instabilità associata a corpectomia singola o multilivello in malattie del disco degenerative avanzate, stenosi del canale spinale e mielopatia cervicale.

Il sistema di piastre di compressione anteriori PEAK, il sistema di piastre cervicali anteriori multiassiale PEAK, il sistema di stabilizzazione cervicale ventrale DOC, il sistema di piastre cervicali anteriori EAGLE, il sistema di piastre cervicali anteriori SWIFT e il sistema di piastre cervicali anteriori UNIPLATE sono indicati per la fissazione del corpo intervertebrale cervicale anteriore in pazienti in cui si richiede la stabilità in seguito a fusione cervicale anteriore per le indicazioni riportate nel seguito. I livelli previsti per il trattamento comprendono il tratto da C2 a T1.

Le indicazioni includono spondilosi cervicale sintomatica, trauma, fratture, cifosi o lordosi post-traumatica, tumore, discopatia degenerativa (definita come dorsalgia discogena con degenerazione del disco confermata da anamnesi e radiografie), ripetizione dell'intervento per mancata fusione o instabilità a seguito di intervento chirurgico per le indicazioni suddette.

Il sistema di piastre cervicali anteriori UNIPLATE è inoltre indicato per il trattamento della stenosi spinale.

**AVVERTENZA:** questi dispositivi non sono approvati per il fissaggio di viti o fissazione agli elementi posteriori (peduncoli) della colonna cervicale, toracica o lombare.

## IMMOBILIZZAZIONE POSTOPERATORIA

Finché la maturazione della fusione non viene confermata mediante raggi X, potrebbe essere opportuno ricorrere a un'immobilizzazione esterna (fasciatura o gesso), a discrezione del chirurgo.

Al pari di altri aspetti del decorso postoperatorio atti a prevenire l'insorgenza di problemi clinici che potrebbero pregiudicare la riuscita della fissazione, è importante fornire al paziente istruzioni per la riduzione delle sollecitazioni sugli impianti.

## CONTROINDICAZIONI

- Infezioni sistemiche attive o infezioni localizzate nel sito previsto per l'impianto.
- Osteoporosi grave tale da impedire la corretta fissazione delle viti e quindi precludere l'uso di questo o di altri sistemi di fissazione della colonna vertebrale.
- Possibilità accertata di trattare il paziente in modo sicuro e con risultati certi senza fissazione interna.
- Ferite aperte.



## CONTROINDICAZIONI RELATIVE

Le controindicazioni relative comprendono patologie o condizioni che precludono totalmente la possibilità di fusione (ad esempio, cancro, dialisi renale od osteopenia), obesità, alcune malattie degenerative e sensibilità ai corpi estranei.

## AVVERTENZE, PRECAUZIONI ED EFFETTI INDESIDERATI RELATIVI AD APPARECCHI METALLICI DI FISSAZIONE INTERNA

### AVVERTENZE

Di seguito sono riportate avvertenze, precauzioni e indicazioni di effetti indesiderati particolari che devono essere comprese dal chirurgo e spiegate al paziente. Queste indicazioni non comprendono tutti gli effetti indesiderati che possono insorgere negli interventi chirurgici in generale, ma si riferiscono specificamente agli apparecchi metallici di fissazione interna. I rischi associati agli interventi chirurgici in generale devono essere illustrati al paziente prima dell'intervento chirurgico.

I rischi potenziali associati all'uso di questo sistema che potrebbero richiedere un ulteriore intervento chirurgico comprendono: rottura dei componenti dell'apparecchio, perdita di fissazione, mancata unione, rottura della vertebra, lesioni neurologiche, vascolari o viscerali.

1. **UNA CORRETTA SCELTA DELL'IMPIANTO È ESTREMAMENTE IMPORTANTE.** La fissazione ha maggiori probabilità di successo se viene scelto un impianto di dimensioni, forma e struttura adeguate. Se una scelta corretta può contribuire a ridurre i rischi, le dimensioni e la forma delle ossa umane pongono dei limiti alle dimensioni, alla forma e alla resistenza degli impianti. Gli apparecchi metallici di fissazione interna non sono in grado di sopportare livelli di attività pari a quelli sostenuti da un osso sano. Nessun impianto può sopportare a tempo indefinito il sostentamento dell'intero peso corporeo senza adeguati strumenti di sostegno.
2. **GLI IMPIANTI POSSONO ROMPERSI SE SOGGETTI A UN AUMENTO DEL CARICO ASSOCIATO A UN'UNIONE RITARDATA O A UNA MANCATA UNIONE.** Gli strumenti di fissazione interna sono apparecchi con distribuzione del carico impiegati per ottenere l'allineamento fino al momento della guarigione. Se la guarigione è ritardata o non si verifica, l'impianto può rompersi per usura del metallo. Il grado di successo dell'unione, i carichi prodotti dal sostentamento del peso e i livelli di attività, determinano, insieme ad altre condizioni, la durata dell'impianto. Scalfiture, graffi o curvature dell'impianto durante l'intervento chirurgico possono inoltre contribuire a un precoce deterioramento dell'impianto. I pazienti devono essere debitamente informati della possibilità di deterioramento dell'impianto.
3. **L'IMPIEGO DI METALLI DIVERSI PUÒ PROVOCARE CORROSIONE.** Esistono molte forme di corrosione, e alcune di queste si verificano anche in apparecchiature metalliche impiantate chirurgicamente in pazienti umani. Una forma di corrosione generale o uniforme è presente su tutti i metalli e le leghe impiantati. La percentuale di attacco corrosivo su apparecchi metallici per impianto è generalmente molto bassa grazie alla presenza di pellicole di superficie passive. Il contatto tra metalli diversi, come il titanio e l'acciaio inox, accelera il processo di corrosione dell'acciaio inox rendendo più rapido l'attacco corrosivo. La presenza di corrosione accelera spesso la rottura per usura dell'impianto e accresce inoltre il numero di composti metallici rilasciati nel sistema corporeo. Le apparecchiature di fissazione interna, quali barre, ganci, fili e così via, sottoposte al contatto con altri oggetti metallici devono essere costituite da metalli simili o compatibili.
4. **CRITERI DI SCELTA DEL PAZIENTE.** Nella scelta del paziente a cui applicare un apparecchio di fissazione interna, i seguenti fattori possono essere di estrema importanza per il successo finale dell'intervento.

   A. **Occupazione o attività del paziente.** Se il paziente svolge un'occupazione o attività che prevede sollevamento di pesi, sforzi muscolari, torsioni, piegamenti ripetitivi, flessioni, corse, lunghe passeggiate o lavoro manuale, non potrà esercitare tali attività fino alla completa saldatura dell'osso. Anche in caso di completa guarigione, il paziente potrebbe non essere più in grado di svolgere appieno tali attività.

   B. **Condizioni di senilità, infermità mentale, alcolismo o consumo di narcotici.** Queste e altre condizioni possono indurre il paziente a ignorare alcune limitazioni e precauzioni necessarie nell'utilizzo dell'apparecchio, provocando il fallimento dell'impianto o altre complicanze.

   C. **Alcune malattie degenerative.** In alcuni casi, al momento dell'impianto la malattia degenerativa potrebbe aver raggiunto uno stato talmente avanzato da ridurre in modo sostanziale la normale durata dell'apparecchio. In questi casi gli apparecchi ortopedici sono da considerare soltanto una tecnica dilatoria o un rimedio temporaneo.

   D. **Sensibilità ai corpi estranei.** Il chirurgo deve sapere che nessun test preoperatorio può escludere completamente la possibilità di sensibilità o reazioni allergiche. I pazienti possono sviluppare sensibilità o allergie anche a distanza di tempo dall'intervento di impianto.

   E. **Fumo.** Nei pazienti fumatori sono state riscontrate percentuali più alte di pseudoartrosi in seguito a trattamenti chirurgici in cui vengono utilizzati innesti ossei. È stato inoltre dimostrato che il fumo provoca una degenerazione diffusa dei dischi intervertebrali. La degenerazione progressiva dei segmenti adiacenti provocata dal fumo può provocare l'insuccesso clinico finale (dolore ricorrente) anche a fusione avvenuta e a seguito di iniziali progressi clinici.

**AVVERTENZA:** se la fusione ossea non avviene entro un periodo di tempo ragionevole, le viti potrebbero rompersi a causa dell'elevato peso di carico degli apparecchi. Ciò è stato notato in pazienti con pseudoartrosi ritardata o con mancata fusione e può rendere necessaria una revisione degli apparecchi.

## PRECAUZIONI

1. **GLI IMPIANTI CHIRURGICI NON DEVONO MAI ESSERE RIUTILIZZATI.** Un impianto metallico espiantato non deve mai essere reimpiantato. Anche se l'apparecchio non sembra danneggiato, può presentare piccoli difetti e punti deboli che potrebbero provocarne una rapida rottura.
2. **UN CORRETTO TRATTAMENTO DELL'IMPIANTO È ESTREMAMENTE IMPORTANTE.** La sagomatura degli impianti metallici va eseguita esclusivamente con strumenti adeguati. In fase di sagomatura, il chirurgo deve evitare di incidere, graffiare o piegare controsenso gli apparecchi. Qualsiasi alterazione causerà difetti alle parti di superficie e punti deboli interni che in seguito possono provocare un'eventuale rottura dell'impianto. In caso di dubbio sulla sua integrità, non utilizzare l'impianto.

   Un'eccessiva torsione applicata alle viti durante la sistemazione della piastra può causare un indebolimento dell'osso provocando la rottura della filettatura e/o compromettendo la presa delle viti.
3. **CURVATURA DELLA STRUTTURA.** I componenti in lega di titanio non devono mai essere piegati eccessivamente o controsenso. In caso di eccessiva sagomatura di una struttura, si consiglia di sagomarne correttamente una nuova anziché tentare di riparare la struttura sagomata in modo errato.
4. **RIMOZIONE DELL'IMPIANTO A GUARIGIONE AVVENUTA.** Se una volta espletata la propria funzione l'apparecchio non viene rimosso, possono verificarsi le seguenti complicanze: (1) corrosione, con reazioni tessutali localizzate o dolore; (2) spostamento dell'impianto con conseguenti lesioni; (3) rischio di ulteriori lesioni da trauma postoperatorio; (4) curvatura, allentamento e/o rottura dell'apparecchio tali da rendere complicata o impossibile la rimozione; (5) dolore, fastidio o sensazioni anomale dovuti alla presenza dell'apparecchio; (6) possibile rischio di infezione e (7) riduzione ossea dovuta a protezione da sforzo. Prima di decidere di rimuovere l'impianto, il chirurgo deve valutarne attentamente i pro e i contro. La rimozione dell'impianto deve essere seguita da un adeguato trattamento postoperatorio al fine di evitare nuove eventuali fratture o deformità. Se il paziente è anziano e ha un basso livello di attività, il chirurgo può decidere di non rimuovere l'impianto, eliminando in questo modo i rischi connessi a un secondo intervento chirurgico.
5. **ISTRUIRE ADEGUATAMENTE IL PAZIENTE.** La cautela postoperatoria, unita alla buona volontà del paziente nel seguire le istruzioni fornite dal chirurgo, sono fra gli aspetti più importanti per una completa guarigione dell'osso. Il paziente deve essere reso consapevole delle limitazioni imposte dall'impianto e persuaso a ridurre l'attività fisica, in particolare i movimenti che implicano torsione o sollevamento di pesi, nonché la pratica di qualsiasi tipo di sport. Il paziente deve comprendere che un impianto metallico non è altrettanto resistente di un osso sano e che quindi potrebbe allentarsi, piegarsi e/o rompersi in caso di sollecitazioni eccessive, soprattutto in assenza di una completa guarigione dell'osso. Impianti spostati o danneggiati da attività improprie possono danneggiare nervi o vasi sanguigni. Un paziente attivo, debilitato o demente non in grado di usare in modo corretto apparecchi ortopedici per il sostentamento del peso, è particolarmente a rischio durante la riabilitazione postoperatoria.

## POSSIBILI EFFETTI INDESIDERATI

1. Ritardo nell'unione o mancata unione.
2. Curvatura, rottura o allentamento dell'impianto.
3. Sensibilità al metallo o reazione allergica a un corpo estraneo.
4. Infezione, precoce o ritardata.
5. Diminuzione della densità ossea dovuta alla protezione da sforzo.
6. Dolore, fastidio o sensazioni anomale dovuti alla presenza dell'apparecchio.
7. Danni neurologici dovuti al trauma chirurgico o alla presenza dell'apparecchio. I problemi neurologici includono dolore radicolare, contatto di nervi con il tessuto della cicatrice, debolezza muscolare e parestesia.
8. Danni vascolari potrebbero provocare emorragie gravi o letali. Impianti mal posizionati adiacenti a grandi arterie o vene potrebbero corrodere questi vasi e provocare gravi emorragie nel tardo periodo postoperatorio.
9. Lacerazioni durali durante l'intervento chirurgico potrebbero rendere necessario un ulteriore intervento per la riparazione della dura e causare fistole o perdita cronica di liquido cerebrospinale e possibili meningiti.
10. Borsite.
11. Paralisi.
12. Perforazione, corrosione o irritazione dell'esofago.
13. Svitamento della vite, con possibile lesione esofagea, allentamento dell'impianto e/o ulteriore operazione per la rimozione dell'apparecchio.
14. Danni ai vasi linfatici e/o essudazione dei fluidi linfatici.
15. Ripercussioni o danni al midollo spinale.
16. Frattura di strutture ossee.
17. Mutamenti degenerativi o instabilità nei segmenti adiacenti ai livelli vertebrali fusi.
18. Decesso.

**GARANZIA LIMITATA ED ESONERO DA RESPONSABILITÀ: I PRODOTTI DEPUY SPINE SONO VENDUTI ALL'ACQUIRENTE CON UNA GARANZIA LIMITATA RELATIVA A DIFETTI DI FABBRICAZIONE E DEI MATERIALI. NON SONO PREVISTE ALTRE GARANZIE ESPLICITE O IMPLICITE, INCLUSE LE GARANZIE DI COMMERCIABILITÀ O IDONEITÀ.**



**SE SONO TRASCORSI PIÙ DI DUE ANNI TRA LA DATA DELLA PUBBLICAZIONE/REVISIONE E LA DATA DELLA CONSULTAZIONE, RIVOLGERSI A DEPUY SPINE PER INFORMAZIONI AGGIORNATE CHIAMANDO IL NUMERO VERDE 800-365-6633 (valido negli U.S.A.) o il numero +1-508-880-8100.**

PRODOTTO DA UNA DELLE SEGUENTI AZIENDE:

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767-0350 Stati Uniti

DePuy Spine SÀRL
Chemin Blanc, 36
CH-2400 Le Locle, Svizzera

DISTRIBUITO NEGLI STATI UNITI DA:
DePuy Spine, Inc.
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Codman SÀRL
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CH-2400 Le Locle, Svizzera CE 0424

RAPPRESENTANTE AUTORIZZATO IN EUROPA:
DePuy International, Ltd.
St. Anthony's Road
Leeds LS11 8DT Regno Unito

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### TRADUZIONE DEI SIMBOLI

| | | | |
|---|---|---|---|
| LOT NUMERO LOTTO | MONOUSO | NONSTERILE NON STERILE | PRODUTTORE |
| REF NUMERO DI CATALOGO | XXXX-XX SCADENZA | STERILE R STERILIZZAZIONE TRAMITE IRRADIAZIONE | EC REP DISTRIBUTORE AUTORIZZATO PER L'EUROPA |
| QTY QUANTITÀ | CONSULTARE LE ISTRUZIONI PER L'USO | STERILE EO STERILIZZAZIONE CON OSSIDO DI ETILENE | DIST DISTRIBUITO DA |
| Rx Only La legislazione federale americana prevede la vendita di questo dispositivo ai soli medici o dietro richiesta medica. | STERILE STERILE | MADE IN PRODOTTO IN | SZ DIMENSIONE |

**MATERIALE** MATL

| | | |
|---|---|---|
| A/T ACROFLEX™/Ti ACROFLEX™/titanio | PY Poliestere | SS/RADEL™/Y SRTA Ti Al Nitride Acciaio inox/RADEL™/ titanio nitruro di alluminio |
| A Al Alluminio | P POLYMER Polimero | STA SS/Ti Al Nitride Acciaio inox/ titanio nitruro di alluminio |
| A/P Al/PL Alluminio/plastica | P/CM PE/CoCrMo Polietilene/ cobalto cromo molibdeno | S/U SS/ULTEM Acciaio inox/Ultem |
| B/R Ba/RADEL™ Bario/RADEL™ | P/C POLYMER/CARBON FIBER COMPOSITE Composto di polimero/ fibra di carbonio | T Ti Titanio e relative leghe |
| CaP CALCIUM PHOSPHATE Fosfato di calcio | S SS Acciaio inox | S/R SS/RADEL™ Acciaio inox/RADEL™ |
| CM CoCrMo Cobalto cromo molibdeno | S/A SS/Al Acciaio inox/alluminio | R/T POLYOLEFIN RUBBER/Ti Gomma poliolefinica/titanio |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Cobalto cromo molibdeno/ titanio/fosfato di calcio | SBR SS/Ba/RADEL™ Acciaio inox/Bario/RADEL™ | T/A Ti/Al Titanio/alluminio |
| F FOAM Gomma spugnosa | S/P SS/PHENOLIC Acciaio inox/Fenolo | Ti/UHMWPE/HA Titanio/polietilene con peso molecolare ultra-elevato/ idrossiapatite |
| HA Idrossiapatite | S/PL SS/PL Acciaio inox/plastica | SS/Ti Acciaio inox/titanio |
| NiTi Ni/Ti Nichel/titanio | SRSI SS/RADEL™/Y SILICONE Acciaio inox/RADEL™/silicone | SS/Al/SILICONE Acciaio inox/alluminio/silicone |
| PL Plastica | SRSN SS/RADEL™/Y SILICONE/Ti Al Nitride Acciaio inox/RADEL™/silicone/ titanio nitruro di alluminio | S/SI SS/SILICONE Acciaio inox/silicone |
| P/F PL/FOAM Plastica/gomma spugnosa | | |

pl

# PŁYTKOWY SYSTEM DO STABILIZACJI PRZEDNIEJ PEAK

# WIELOOSIOWY PŁYTKOWY SYSTEM DO PRZEDNIEJ STABILIZACJI ODCINKA SZYJNEGO PEAK

# SYSTEM STABILIZACJI DOLNEJ PARTII KRĘGÓW SZYJNYCH DOC

# PŁYTKOWY SYSTEM DO PRZEDNIEJ STABILIZACJI ODCINKA SZYJNEGO SLIM-LOC™

# PŁYTKOWY SYSTEM DO PRZEDNIEJ STABILIZACJI ODCINKA SZYJNEGO EAGLE™

# PŁYTKOWY SYSTEM DO PRZEDNIEJ STABILIZACJI ODCINKA SZYJNEGO SWIFT™

# PŁYTKOWY SYSTEM DO PRZEDNIEJ STABILIZACJI ODCINKA SZYJNEGO UNIPLATE™

# PŁYTKOWY SYSTEM DO PRZEDNIEJ STABILIZACJI ODCINKA SZYJNEGO SKYLINE™

## ISTOTNA UWAGA DLA OPERUJĄCEGO CHIRURGA

Implanty systemu do przedniej stabilizacji odcina szyjnego, podobnie jak inne narzędzia do unieruchomiania złamanych kości, mają ograniczoną żywotność. Na trwałość implantów ma istotny wpływ poziom aktywności fizycznej pacjenta. Pacjent musi wiedzieć, że każda aktywność fizyczna zwiększa ryzyko poluzowania się, wygięcia lub pęknięcia elementów implantu. Należy koniecznie poinformować pacjenta o ograniczeniach aktywności fizycznej w okresie pooperacyjnym i przeprowadzać badania w celu oszacowania postępu zrostu i stanu elementów implantu. Nawet jeśli nastąpił prawidłowy zrost kostny, elementy implantu mogą ulec pęknięciu, zakrzywieniu lub poluzowaniu. Pacjent musi wiedzieć, że istnieje ryzyko poluzowania się, wygięcia lub pęknięcia elementów implantu nawet przy przestrzeganiu ograniczeń aktywności fizycznej.

Z przyczyn natury anatomicznej oraz ze względu na ograniczenia nowoczesnych materiałów chirurgicznych skuteczność metalowych implantów jest ograniczona w czasie. Ich przeznaczeniem jest zapewnienie tymczasowego wsparcia podczas zrastania się kości. Tego typu implanty mogą zawieść, jeśli nie korzysta się z przeszczepu kostnego lub jeśli rozwinie się choroba rzekomego zwyrodnieniowa stawów.

Chirurg może zdecydować się na chirurgiczne usunięcie implantów po zrośnięciu się kości.

Należy omówić z pacjentem możliwość przeprowadzenia drugiej operacji oraz ryzyko z nią związane. W przypadku pęknięcia implantów decyzję o ich usunięciu musi podjąć lekarz, który dokonuje rozpoznania stanu pacjenta i ryzyka związanego z obecnością pękniętego implantu.

## OPIS

Płytkowy system do stabilizacji przedniej PEAK składa się z zestawu płytek i śrub ze stopu tytanowego. Płytki są dostępne w długościach od 26 do 94 mm, co pozwala na objęcie od 1 do 4 segmentów usztywnianych. System zawiera również śruby ze stopu tytanowego do kości korowej o średnicy 3,5 mm oraz do kości gąbczastej o średnicy 4,0 mm. Są one dostępne w długościach od 8 mm do 30 mm.

Wieloosiowy płytkowy system do przedniej stabilizacji odcinka szyjnego PEAK składa się z zestawu płytek i śrub ze stopu tytanowego. Płytki do przedniej stabilizacji odcinka szyjnego są dostępne w długościach od 24 do 110 mm, co pozwala na objęcie od 1 do 4 segmentów usztywnianych. Śruby do kości gąbczastej mogą mieć średnice 4,0 mm i 4,35 mm. Są one w pełni gwintowane i mają długości od 10 mm do 26 mm.

System stabilizacji przedniej kręgów szyjnych DOC jest systemem zawierającym platformę, płytki, pręty i śruby ze stopu tytanowego. Jest on stosowany przy korekcji wad szyjnego odcinka kręgosłupa i jego stabilizacji. System stabilizacji przedniej kręgów szyjnych DOC, w pełnym zestawie, składa się z płytki lub dwóch bocznie ustawionych prętów połączonych platformami, które leżą na przedniej powierzchni kręgów. Cały system jest przymocowany do kręgów śrubami. Po zrośnięciu się kręgów szyjnych implant zapewnia dodatkową stabilność szyjnego odcinka kręgosłupa. W zależności od konfiguracji implantu może on służyć jako sztywna (nośna) lub pół-sztywna (współdzieląca ciężar) konstrukcja.

W tym systemie dostępne są następujące typy elementów: pręty, płytki, platformy, wewnętrzne i zewnętrzne śruby do kości, śruby do przeszczepu i złącza krzyżowe. Wszystkie elementy są produkowane ze stopu tytanowego przeznaczonego do implantów zgodnego z normami ASTM F-136. W celu zapewnienia wygody chirurga dostępne są również różne zestawy. Są to uprzednio złożone częściowe konstrukcje składające się z jednej platformy, jednego złącza krzyżowego, dwóch prętów i dwóch śrub blokujących.



**Platforma:** Platformy są przeznaczone do łączenia prętów z kręgami za pomocą śrub do kości. Wszystkie platformy mogą być używane albo ze śrubami do litej kości (dwukorowe usztywnienie), albo z zewnętrznymi i wewnętrznymi śrubami do kości (pusta w środku zewnętrzna śruba do kości używana z wewnętrzną śrubą blokującą do usztywnień dwukorowych). Wybór śrub należy do lekarza. Wszystkie platformy są zaprojektowane do stosowania z dwoma prętami, tworząc jedną konstrukcję.

Dostępne są platformy zamykane i niezamykane. Zamykane platformy mają przedłużenia pasujące do śrub blokujących do platform oraz śrub złącz krzyżowych używanych do przymocowywania platformy do prętów. Platformy zamykane są wymagane w przypadku stosowania przy końcówkach konstrukcji naprzeciwko główek prętów.

Jeśli względem konstrukcji dynamicznej (współdzielącej ciężar) preferowana jest konstrukcja sztywna, platforma zamykana musi być również stosowana w sąsiedztwie z główkami prętów. Jeśli preferowana jest konstrukcja współdzieląca ciężar, platforma przylegająca do główek prętów nie jest przymocowana do prętów.

Różne platformy są tak zaprojektowane, że wymagają wkręcenia śruby pod kątem do trzonu kręgu. Dostępne są one w wersji zamykanej i niezamykanej. Platformy te po jednej stronie mają stateczniki, który sprzęga się z kręgiem od wewnątrz przestrzeni krążka w celu uzyskania optymalnej pozycji i usztywnienia.

Różne platformy są tak zaprojektowane, że wymagają wkręcenia śruby pod kątem prostym do trzonu kręgu. Dostępne są one w wersji zamykanej i niezamykanej.

Jeden z typów platform służy do mocowania konstrukcji do przeszczepu międzykręgowego. Platforma ta ma poziomą szczelinę i kuliste gniazdo ułatwiające wprowadzanie śrub z różnych stron i w różnych miejscach.

Wybór platformy należy do lekarza i zależy od budowy anatomicznej pacjenta.

Płytkowy system do przedniej stabilizacji odcinka szyjnego SLIM-LOC™ składa się z zestawu płytek i śrub ze stopu tytanowego. Dostępne są płytki o długościach od 22 do 111 mm z układem 2., 3., 4., 5. lub 6. par otworów na śruby. Śruby SLIM-LOC o średnicy 4,5 mm są dostępne jako śruby samowiercące o długościach odpowiadających liczbom parzystym z zakresu od 10 do 18 mm lub śruby samogwintujące o długościach odpowiadających liczbom parzystym z zakresu od 10 do 26 mm. Śruby o większej średnicy (4,8 mm) są dostępne w następujących rozmiarach: 12, 14 i 16 mm.

Płytkowy system do przedniej stabilizacji odcinka szyjnego EAGLE™ zawiera zestaw płytek i śrub ze stopu tytanowego. Płytki są dostępne w wersjach zawierających od dwóch do sześciu par otworów na śruby oraz w różnych długościach. Śruby są dostępne w różnych rozmiarach i z różną geometrią końcówek.

Płytkowy system do przedniej stabilizacji odcinka szyjnego SWIFT™ jest wykonany ze stopu tytanu i składa się z segmentowanych płytek, które umożliwiają kontrolowane osadzenie przeszczepu o grubości do 2 mm między poszczególnymi segmentami. Płytki są dostępne w wersjach zawierających od dwóch do sześciu par otworów na śruby, w różnych długościach i w dwóch konfiguracjach: do stabilizacji po usunięciu krążka międzykręgowego lub trzonu kręgu. Śruby są dostępne w różnych rozmiarach i z różną geometrią końcówek. Do zastosowań z płytkami do stabilizacji po usunięciu trzonu kręgu dostępna jest śruba do przeszczepu.

Płytkowy system do przedniej stabilizacji odcinka szyjnego UNIPLATE™ zawiera zestaw płytek i śrub ze stopu tytanowego. Płytki do przedniej stabilizacji odcinka szyjnego są dostępne w różnych długościach, co pozwala na pokrycie od 1 do 2 segmentów usztywnianych. Śruby są dostępne w różnych rozmiarach i z różną geometrią końcówek.

Płytkowy system do przedniej stabilizacji odcinka szyjnego SKYLINE™ zawiera zestaw płytek i śrub ze stopu tytanowego. Płytki są dostępne w wersjach zawierających od dwóch do sześciu par otworów na śruby oraz w różnych długościach. Śruby są dostępne w różnych rozmiarach i z różną geometrią końcówek. Dostępne są zarówno śruby ryglujące, jak i nieryglujące, co umożliwia utworzenie konfiguracji sztywnej, relatywnie sztywnej lub hybrydowej.

## CZYSZCZENIE I STERYLIZACJA

Dostarczane implanty płytkowych systemów do stabilizacji kręgów szyjnych są albo jałowe, albo czyste, lecz niejałowe. W przypadku elementów jałowych przed użyciem należy sprawdzić, czy opakowanie nie zostało uszkodzone.

W przypadku narzędzi niejałowych dla wszystkich elementów należy stosować zalecane procedury sterylizacji szpitalnej zgodne z normami ISO 8828 lub AORN.

W celu opracowania następujących ZALECEŃ DO STERYLIZACJI PAROWEJ zostały przeprowadzone odpowiednie testy:

| Cykl | Przedpróżnia |
|---|---|
| Temperatura | 270°F<br>132°C |
| Czas ekspozycji | 6 min |

## SPOSÓB UŻYCIA

Chirurg musi mieć nie tylko szczegółową wiedzę o medycznych i chirurgicznych aspektach stosowania implantu, lecz również musi być świadomy ograniczeń wynikających z mechanicznych i materiałowych właściwości metalowych implantów chirurgicznych. Bardzo ważna jest opieka pooperacyjna. Pacjenta należy poinformować o ograniczeniach metalowego implantu i ostrzec przed nadmiernym naciskiem i przenoszeniem ciężaru ciała na implant, zanim nie nastąpi całkowity zrost kości. Pacjent musi wiedzieć, że niestosowanie się do zaleceń pooperacyjnych może doprowadzić do wystąpienia problemów z implantem, który trzeba będzie usunąć, wykonując dodatkowy zabieg chirurgiczny.

Elementy systemu DePuy Spine nie powinny być używane z elementami pochodzącymi od innych producentów.

**W celu osiągnięcia kontrolowanego pionowego przesuwu (współdzielenia ciężaru) istotne jest prawidłowe ustawienie wybranych elementów.**

**Szczegółowe instrukcje można znaleźć w podręczniku techniki chirurgicznej.**

## WSKAZANIA

**UWAGA:** Prawo USA zezwala na sprzedaż niniejszego urządzenia wyłącznie przez lekarza lub na jego zamówienie.

Płytkowe systemy do przedniej stabilizacji odcinka szyjnego SLIM-LOC i SKYLINE™ są przeznaczone do stabilizacji szyjnego odcinka kręgosłupa od C2 do C7 przy użyciu mocowania za pomocą śrub jednokorowych do przedniej powierzchni trzonów kręgów. Szczególne wskazania kliniczne do zastosowania przedniej stabilizacji za pomocą płytek to: niestabilność spowodowana urazem, niestabilność związana z korekcją lordozy szyjnej i deformacji kifozy, niestabilność związana z wytworzenie stawu rzekomego w wyniku wcześniejszego nieudanego zabiegu na odcinku szyjnym kręgosłupa, niestabilność związana z poważną operacją odtwórczą z powodu guzów pierwotnych lub przerzutowych nowotworów złośliwych w obrębie kręgosłupa szyjnego, niestabilność związana z jedno- lub wielopoziomowym wycięciem trzonu kręgu w zaawansowanej chorobie zwyrodnieniowej krążka, zwężeniach kanału kręgowego i mielopatii szyjnej.

Płytkowy system do stabilizacji przedniej PEAK, wieloosiowy płytkowy system do stabilizacji odcinka szyjnego PEAK, system stabilizacji przedniej kręgów szyjnych DOC, płytkowy system do przedniej stabilizacji odcinka szyjnego EAGLE, płytkowy zestaw do przedniej stabilizacji odcinka szyjnego SWIFT i płytkowy zestaw do przedniej stabilizacji odcinka szyjnego UNIPLATE są przeznaczone do przedniego usztywnienia kręgosłupa w odcinku szyjnym. Te systemy są zalecane pacjentom, w przypadku których po zrośnięciu się kości kręgów szyjnych w związku ze wskazaniami podanymi poniżej pożądana jest stabilność. Zalecany zakres poziomów leczenia to C2-T1.

Wskazania to symptomatyczna spondyloza kręgów szyjnych, uraz, złamanie, pourazowa kifoza lub lordoza, guz, zwyrodnieniowa choroba krążka (definiowana jako ból pochodzący od krążka wraz ze zwyrodnieniem krążka poparte dowodami z historii choroby pacjenta i badań radiograficznych), ponowna operacja ze względu na nieudany zrost kości lub niestabilność po operacji związana z powyższymi wskazaniami.

Płytkowy system do przedniej stabilizacji odcinka szyjnego UNIPLATE przeznaczony jest także do leczenia zwężenia kanału kręgowego.

**OSTRZEŻENIE:** Te systemy nie nadają się do przytwierdzania śrub do tylnych elementów (szypułek) kręgosłupa na odcinku szyjnym, piersiowym lub lędźwiowym.

## MOBILIZACJA POOPERACYJNA

Dopóki prześwietlenie rentgenowskie nie potwierdzi rozwoju masy zrostowej, lekarz może zalecić zastosowanie zewnętrznego unieruchomienia (na przykład szelek).

Poinstruowanie pacjenta o konieczności nieprzeciążania implantów jest jednym ze sposobów uniknięcia problemów klinicznych, które mogą towarzyszyć nieudanej próbie zespolenia kości.

## PRZECIWWSKAZANIA

- Aktywne zakażenie ogólnoustrojowe lub zakażenie w okolicach planowanej implantacji.
- Ciężka osteoporoza jest przeciwwskazaniem, gdyż może uniemożliwić odpowiednie usztywnienie i w ten sposób wyklucza zastosowanie tego lub innych systemów stosowanych w leczeniu kręgosłupa.
- Pacjenci, którzy mogą być leczeni w sposób bezpieczny i przewidywalny bez usztywnienia wewnętrznego.
- Rany otwarte.

## WZGLĘDNE PRZECIWSKAZANIA:

Względne przeciwwskazania to wszelkie problemy lub stany, które całkowicie wykluczają możliwość zrostu (np. rak, dializa lub osteopenia), otyłość, pewne choroby zwyrodnieniowe i nadwrażliwość na ciała obce.

## OSTRZEŻENIA, ŚRODKI OSTROŻNOŚCI I DZIAŁANIA NIEPOŻĄDANE ZWIĄZANE Z UŻYWANIEM TYMCZASOWYCH METALOWYCH ELEMENTÓW DO ZESPALANIA KOŚCI

### OSTRZEŻENIA

Poniżej podano szczególne ostrzeżenia, środki ostrożności i działania niepożądane, z którymi chirurg powinien się zapoznać i które powinien wyjaśnić pacjentowi.

Ostrzeżenia nie obejmują wszystkich działań niepożądanych, które mogą się pojawić przy każdej operacji, lecz dotyczą konkretnie metalowych elementów do zespalania kości. Przed operacją należy wyjaśnić pacjentowi ogólne niebezpieczeństwo związane z zabiegiem.

Potencjalne problemy związane ze stosowaniem tego systemu mogące prowadzić do konieczności przeprowadzenia dodatkowego zabiegu chirurgicznego to: złamania elementów urządzeń, brak usztywnienia, brak zrostu, złamanie kręgu, uszkodzenia neurologiczne i naczyniowe oraz uszkodzenia narządów wewnętrznych.

1. **BARDZO WAŻNY JEST ODPOWIEDNI DOBÓR IMPLANTU.** Możliwość udanego zespolenia kości wzrasta, jeżeli wybrano implant o odpowiednim rozmiarze, kształcie i wzorze. Odpowiedni wybór może zminimalizować ryzyko, natomiast kształt i wielkość kości ludzkich ogranicza rozmiar, kształt i wytrzymałości implantu. Metalowe elementy zespalające nie wytrzymują poziomu aktywności, jakiemu poddawane są zdrowe kości człowieka. Nie można oczekiwać, aby jakikolwiek implant wytrzymywał



w nieskończoność bezpośredni nacisk związany z utrzymywaniem całego ciężaru ciała.

2. **IMPLANTY MOGĄ PĘKAĆ, GDY NARAŻONE SĄ NA ROSNĄCE PRZECIĄŻENIE ZWIĄZANE Z OPÓŹNIONYM ZROSTEM LUB NIEZRASTANIEM SIĘ KOŚCI.** Wewnętrzne urządzenia zespalające przejmują część obciążenia i używane są do podtrzymywania kości aż do pełnego ich zrostu. Jeśli zrastanie jest opóźnione lub nie następuje, implant może pęknąć z powodu zmęczenia metalu. Trwałość implantu zależy od stopnia zrastania się kości, nacisku ciężaru ciała i aktywności fizycznej. Wyszczerbienia, zarysowania lub zgięcia implantu w czasie operacji mogą przyczynić się do niepowodzenia we wczesnym okresie pooperacyjnym. Pacjenci powinni być dokładnie poinformowani o ryzyku wystąpienia problemów z implantem.
3. **UŻYWANIE RÓŻNYCH METALI W POŁĄCZENIU MOŻE SPOWODOWAĆ KOROZJĘ.** Istnieje wiele form korozji; niektóre spośród nich zachodzą w elementach metalowych implantowanych u ludzi. Korozja ogólna, inaczej jednorodna, występuje w przypadku wszystkich wszczepianych metali i stopów. Szybkość korozji metalowych implantów jest zwykle bardzo mała ze względu na obecność pasywnej warstwy ochronnej. Stykanie się różnych metali, na przykład tytanu i stali nierdzewnej, przyspiesza proces korozji stali nierdzewnej. Obecność korozji często przyspiesza pękanie zmęczeniowe implantów. Rośnie też ilość związków metali uwalnianych do organizmu. Elementy systemów usztywniających kości (takie jak pręty, haki, druty itp.), które stykają się z innymi obiektami metalowymi, muszą być wykonane z podobnych lub kompatybilnych materiałów.
4. **DOBÓR PACJENTÓW.** Ogromne znaczenie dla ostatecznego sukcesu zabiegu mogą mieć następujące warunki doboru pacjentów do implantacji:

   A. **Zawód lub aktywność pacjenta.** Jeśli pacjent wykonuje zawód lub czynności wymagające podnoszenia ciężarów, napinania mięśni, skręcania ciała, wielokrotnego schylania się, przyjmowania pozycji zgarbionej, biegania, pokonywania pieszo dużych odległości lub wykonywania pracy fizycznej, nie powinien podejmować tych czynności, zanim kość w pełni się nie zrośnie. Nawet gdy kość całkowicie się zrośnie, pacjent może nie być zdolny do podjęcia tych czynności.

   B. **Podeszły wiek, choroba umysłowa, alkoholizm lub narkomania.** Między innymi te stany mogą sprawić, że pacjent będzie ignorował pewne ważne ograniczenia i środki ostrożności związane z użyciem implantów, przyczyniając się do uszkodzenia implantu lub innych powikłań.

   C. **Niektóre choroby zwyrodnieniowe.** W niektórych przypadkach postęp choroby zwyrodnieniowej może być w momencie wszczepienia implantu tak zaawansowany, że będzie w znacznym stopniu ograniczać przewidywaną trwałość implantu. W takich przypadkach zastosowanie elementów ortopedycznych można uznać jedynie za technikę opóźniającą postęp schorzenia lub środek tymczasowy.

   D. **Nadwrażliwość na ciała obce.** Przypominamy, że żaden test przeprowadzony przed operacją nie jest w stanie całkowicie wykluczyć możliwości wystąpienia reakcji alergicznych czy występowania nadwrażliwości. Nadwrażliwość lub alergia może pojawić się u pacjenta dopiero po upływie pewnego czasu od wszczepienia implantu.

   E. **Palenie.** Zaobserwowano, że u pacjentów palących częściej dochodziło do wytworzenia stawu rzekomego po zabiegach z zastosowaniem przeszczepu kostnego. Dodatkowo zaobserwowano, że palenie powoduje zwyrodnienie międzykręgowych krążków. Postępujące zwyrodnienie sąsiadujących segmentów powodowane paleniem może prowadzić do późnego niepowodzenia klinicznego (powracający ból) nawet po udanym zrośnięciu się kości i początkowej poprawie klinicznej.

**OSTRZEŻENIE:** Jeśli zrost kości nie nastąpi w oczekiwanym czasie, śruby mogą ulec pęknięciu z powodu dużego i ciągłego nacisku powodowanego przez te urządzenia. Zaobserwowano to u pacjentów z opóźnionym zrostem, wytworzonym stawem rzekomym lub brakiem zrostu, co może wymagać korekcji urządzenia.

### ŚRODKI OSTROŻNOŚCI

1. **IMPLANTY CHIRURGICZNE NIE NADAJĄ SIĘ DO PONOWNEGO UŻYCIA.** Eksplantowany metalowy implant nie powinien być nigdy ponownie implantowany. Nawet jeśli urządzenie wydaje się być nieuszkodzone, może posiadać drobne wady i ślady użycia, które mogą prowadzić do wczesnego uszkodzenia.
2. **BARDZO WAŻNE JEST ODPOWIEDNIE POSTĘPOWANIE Z IMPLANTEM.** Konturowanie metalowych implantów powinno być przeprowadzane wyłącznie przy użyciu odpowiedniego oprzyrządowania. Operujący chirurg powinien unikać wyszczerbienia, zarysowania czy wygięcia urządzenia do tyłu w czasie konturowania. Zmiany mogą doprowadzić do defektów powierzchni lub wewnętrznych napięć, co może być głównym powodem ewentualnego uszkodzenia implantu. Nie stosować, jeśli istnieje możliwość uszkodzenia implantu.

   Dokręcanie śrub zbyt dużym momentem obrotowym podczas osadzania płytki może spowodować uszkodzenie kości, przyczyniając się do zerwania gwintu i/lub upośledzenia umocowania śruby.
3. **ZGINANIE KONSTRUKCJI.** Elementy ze stopu tytanowego nie powinny być mocno zginane lub wyginane do tyłu. Jeśli konstrukcja jest nadmiernie skonturowana, raczej zaleca się użycie nowej konstrukcji, którą należy poprawnie skonturować, niż użycie tej samej poprzez odgięcie nadmiernie skonturowanej konstrukcji.
4. **USUNIĘCIE IMPLANTU PO ZROŚNIĘCIU SIĘ KOŚCI.** Jeśli urządzenie nie zostanie usunięte po zakończeniu swojej pracy, mogą wystąpić następujące komplikacje: (1) korozja z miejscowym odczynem tkankowym lub bólem; (2) przemieszczanie się implantu powodujące rany; (3) ryzyko dodatkowego uszkodzenia w wyniku pooperacyjnego urazu; (4) zgięcie, poluzowanie i/lub pęknięcie, co

może utrudnić wyjęcie implantu; (5) ból, dyskomfort lub nietypowe odczucia spowodowane obecnością urządzenia; (6) możliwe zwiększone ryzyko infekcji; (7) zanik kości spowodowany nadwyrężeniem. Chirurg powinien dokładnie rozważyć zarówno ryzyko, jak i korzyści płynące z usunięcia implantu z ciała. Po usunięciu implantu należy zapewnić pooperacyjną opiekę w celu uniknięcia ponownego złamania lub deformacji. Jeśli pacjent jest w podeszłym wieku i jego poziom aktywności jest niski, chirurg może zadecydować o pozostawieniu implantu, redukując w ten sposób ryzyko związane z kolejnym zabiegiem.

5. **DOKŁADNE INSTRUOWANIE PACJENTA.** Wśród najważniejszych aspektów udanego leczenia kości są opieka pooperacyjna oraz chęć i umiejętność pacjenta do przestrzegania zaleceń. Pacjenta należy uświadomić o ograniczeniach związanych z implantem i zalecić mniej aktywności fizycznej, szczególnie ograniczyć podnoszenie ciężarów, wykonywanie ruchów skręcających i uprawianie wszelkich sportów. Pacjent powinien zrozumieć, iż metalowy implant nie jest tak wytrzymały jak zdrowa kość i może się poluzować, wygiąć i/lub złamać, jeśli wymaga się od niego zbyt dużo, szczególnie wtedy, gdy kość nie jest jeszcze całkowicie zrośnięta. Implanty przemieszczone lub uszkodzone z powodu nadwyrężenia mogą się przemieścić i uszkodzić nerwy lub naczynia krwionośne. Aktywny, osłabiony lub otępiały pacjent, który nie potrafi poprawnie korzystać z urządzeń podtrzymujących wagę, może być narażony na niebezpieczeństwo w czasie pooperacyjnej rehabilitacji.

## MOŻLIWE DZIAŁANIA NIEPOŻĄDANE

1. Brak zrostu, zrost opóźniony.
2. Wygięcie lub złamanie implantu. Poluzowanie implantu.
3. Nadwrażliwość na metale lub reakcja alergiczna na ciała obce.
4. Infekcja, wczesna lub późna.
5. Zmniejszenie gęstości kości spowodowane nadwyrężeniem.
6. Ból, dyskomfort lub nietypowe odczucia związane z obecnością implantu.
7. Uszkodzenie nerwu związane z urazem operacyjnym lub obecnością implantu. Trudności neurologiczne, w tym ból korzeniowy, wciąganie nerwów w tkankę blizny, osłabienie mięśniowe i parestezje.
8. Uszkodzenie naczyń może wywołać niebezpieczne lub śmiertelne krwawienie. Nieprawidłowo umiejscowione implanty leżące obok dużych tętnic lub żył mogą uszkadzać naczynia krwionośne i powodować niebezpieczne krwawienia w późnym okresie pooperacyjnym.
9. Pęknięcie opony twardej w czasie zabiegu może oznaczać potrzebę przeprowadzenia kolejnego zabiegu na oponie twardej, przewlekły wyciek płynu mózgowo-rdzeniowego lub przetoka oraz możliwość zapalenia opon.
10. Zapalenie kaletki maziowej.
11. Paraliż.
12. Przebicie, nadżerka lub podrażnienie przełyku.
13. Wykręcenie się śruby mogące prowadzić do poluzowania implantu i/lub konieczności przeprowadzenia ponownego zabiegu w celu usunięcia elementu.
14. Uszkodzenie naczyń limfatycznych i/lub wysięk płynu limfatycznego.
15. Naruszenie lub uszkodzenie rdzenia kręgowego.
16. Złamanie struktur kostnych.
17. Zwyrodniałe zmiany lub niestabilność w segmentach sąsiadujących z leczonymi poziomami kręgów.
18. Zgon.

**OŚWIADCZENIE O OGRANICZONEJ GWARANCJI: PRODUKTY FIRMY DEPUY SPINE SĄ SPRZEDAWANE Z OGRANICZONĄ GWARANCJĄ DLA PIERWOTNEGO NABYWCY DOTYCZĄCĄ JEDYNIE WAD PRODUKCYJNYCH I MATERIAŁOWYCH. FIRMA DEPUY SPINE WYKLUCZA ODPOWIEDZIALNOŚĆ Z TYTUŁU WSZELKICH GWARANCJI, ZARÓWNO WYRAŹNYCH, JAK I DOROZUMIANYCH, KTÓRE DOTYCZYĆ MOGĄ NINIEJSZEGO PRODUKTU.**

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**TŁUMACZENIE SYMBOLI**

| | | | |
|---|---|---|---|
| LOT NUMER PARTII | DO UŻYTKU JEDNORAZOWEGO | NONSTERILE NIEJAŁOWY | PRODUCENT |
| REF NUMER W KATALOGU | XXXX-XX UŻYĆ DO | STERILE R STERYLIZACJA POPRZEZ NAŚWIETLANIE | EC REP AUTORYZOWANY PRZEDSTAWICIEL W EUROPIE |
| QTY ILOŚĆ | PATRZ: INSTRUKCJA UŻYCIA | STERILE EO STERYLIZACJA TLENKIEM ETYLENU | DIST DYSTRYBUTOR |
| Rx Only Zgodnie z prawem federalnym (USA) urządzenie to może być sprzedawane wyłącznie przez lub na zlecenie lekarza. | STERILE JAŁOWY | MADE IN WYPRODUKOWANO W | SZ ROZMIAR |

**MATERIAŁ MATL**

| | | |
|---|---|---|
| A/T AcroFlex®/Ti AcroFlex®/Tytan | PY Poliester | SS/RADEL®/ SRTA Ti Al Nitride Stal nierdzewna/RADEL®/ Azotek tytanowo-aluminiowy |
| A Al Aluminium | P POLYMER Polimer | STA SS/Ti Al Nitride Stal nierdzewna/ Azotek tytanowo-aluminiowy |
| A/P Al/PL Aluminium/Tworzywo sztuczne | P/CM PE/CoCrMo Polietylen/ Kobalt chrom molibden | S/U SS/ULTEM Stal nierdzewna/Ultem |
| B/R Ba/RADEL® Bar/RADEL® | P/C POLYMER/CARBON FIBER COMPOSITE Polimer/Włókno węglowe | T Ti Tytan i jego stopy |
| CaP CALCIUM PHOSPHATE Fosforan wapnia | S SS Stal nierdzewna | S/R SS/RADEL® Stal nierdzewna/RADEL® |
| CM CoCrMo Kobalt chrom molibden | S/A SS/Al Stal nierdzewna/Aluminium | R/T POLYOLEFIN RUBBER/Ti Guma poliolefinowa/Tytan |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Kobalt chrom molibden/Tytan/ Fosforan wapnia | SBR SS/Ba/RADEL® Stal nierdzewna/Bar/RADEL® | T/A Ti/Al Tytan/Aluminium |
| F FOAM Pianka | S/P SS/PHENOLIC Stal nierdzewna/Fenoplasty | Ti/UHMWPE/HA Tytan/Polietylen o bardzo dużej masie cząsteczkowej/ Hydroksyapatyt |
| HA Hydroksyapatyt | S/PL SS/PL Stal nierdzewna/ Tworzywo sztuczne | SS/Ti Stal nierdzewna/Tytan |
| NiTi Ni/Ti Nikiel/Tytan | SRSI SS/RADEL®/ SILICONE Stal nierdzewna/ RADEL®/Silikon | SS/Al/SILICONE Stal nierdzewna/ Aluminium/Silikon |
| PL Tworzywo sztuczne | SRSN SS/RADEL®/ SILICONE/Ti Al Nitride Stal nierdzewna/ RADEL®/Silikon/Azotek tytanowo-aluminiowy | S/SI SS/SILICONE Stal nierdzewna/Silikon |
| P/F PL/FOAM Tworzywo sztuczne/Pianka | | |

pt

# SISTEMA DE PLACA DE COMPRESSÃO ANTERIOR PEAK

# SISTEMA DE PLACA POLIAXIAL DA CERVICAL ANTERIOR PEAK

# SISTEMA DE ESTABILIZAÇÃO DA CERVICAL VENTRAL DOC

# SISTEMA DE PLACA DA CERVICAL ANTERIOR SLIM-LOC™

# SISTEMA DE PLACA DA CERVICAL ANTERIOR EAGLE™

# SISTEMA DE PLACA DA CERVICAL ANTERIOR SWIFT™

# SISTEMA DE PLACA DA CERVICAL ANTERIOR UNIPLATE™

# SISTEMA DE PLACA DA CERVICAL ANTERIOR SKYLINE™

## NOTA IMPORTANTE PARA O CIRURGIÃO PRINCIPAL

Os implantes do Sistema de Estabilização da Cervical Anterior, como qualsquer outros dispositivos internos de fixação temporários, têm um período de vida útil finito. O nível de actividade física do paciente tem um impacto significativo neste período de vida útil. O seu paciente terá de ser informado de que qualquer actividade física aumentará o risco de afrouxamento, dobra ou quebra dos componentes do implante. É essencial instruir os pacientes sobre as restrições à actividade física necessárias durante o período pós-operatório, sendo igualmente importante um exame pós-operatório do paciente para avaliar o desenvolvimento da massa de fusão e o estado dos componentes do implante. Mesmo que ocorra uma fusão sólida do osso, os componentes do implante poderão ainda assim dobrar, quebrar ou afrouxar. Por esta razão, o paciente deverá ser alertado para o facto de que os componentes poderão quebrar, dobrar ou afrouxar mesmo se as restrições à actividade forem cumpridas.

Devido às limitações impostas pelas considerações anatómicas e pelos materiais cirúrgicos modernos, os implantes metálicos não podem ser fabricados para durarem indefinidamente. A sua função é a de proporcionar suporte interno temporário enquanto a massa de fusão se consolida. Estes tipos de implantes têm maior probabilidade de falhar se não se utilizar um enxerto ósseo ou se ocorrer uma pseudo-artrose.

O cirurgião poderá determinar a necessidade de remover estes implantes após a ocorrência da fusão do osso. A possibilidade de um segundo procedimento cirúrgico deverá ser discutida com o paciente, bem como os respectivos riscos associados. Se os implantes quebrarem, a decisão de os remover deverá ser tomada pelo médico, tendo em consideração o estado do paciente e os riscos associados à presença do implante quebrado.

## DESCRIÇÃO

O Sistema de Placa de Compressão Anterior PEAK consiste num conjunto de placas e parafusos de liga de titânio. As placas existem em vários comprimentos, entre 26-94 mm, de modo a incluir entre um e quatro segmentos de fixação. O sistema também inclui parafusos de liga de titânio corticais de 3,5 mm e esponjosos de 4,0 mm, que existem em vários comprimentos, entre 8-30 mm.

O Sistema de Placa Poliaxial da Cervical Anterior PEAK consiste num conjunto de placas e parafusos de liga de titânio. As placas da cervical anterior variam em tamanho, entre 24-110 mm de comprimento, de modo a incluir entre um e quatro segmentos de fixação. Os parafusos esponjosos existem com diâmetros de 4,0 mm e 4,35 mm. São totalmente roscados, com comprimentos entre 10-26 mm.

O Sistema de Estabilização da Cervical Ventral DOC consiste num sistema com uma plataforma, placa, vareta e parafusos de liga de titânio, utilizado para ajudar os cirurgiões da coluna vertebral na correcção de defeitos e estabilização da coluna cervical. O Sistema de Estabilização da Cervical Ventral DOC, na sua forma completamente montada, consiste numa placa ou em duas varetas colocadas lateralmente unidas pelas plataformas que se encontram na superfície vertebral anterior. O sistema é fixado às vértebras com parafusos. O implante fornece a estabilidade suplementar à coluna cervical após uma fusão cervical anterior. Dependendo da configuração do implante, pode funcionar como uma construção rígida (com apoio de carga) ou dinâmica (com partilha de carga).

Existem os seguintes tipos de componentes no sistema: Varetas, Placas, Plataformas, Parafusos Ósseos Internos e Externos, Parafusos de Enxertos e Conectores Transversais. Todos os componentes são fabricados com liga de titânio de grau para implantes, em conformidade com as especificações ASTM F-136. Também existem montagens para a conveniência do cirurgião. Estas são construções parciais previamente montadas que consistem numa plataforma, num conector transversal, em duas varetas e em dois parafusos de fixação.

**Plataforma:** As plataformas são concebidas para ligar as varetas e a âncora aos corpos vertebrais por meio de parafusos ósseos. Todas as plataformas podem ser utilizadas com parafusos para osso sólido (para fixação bicortical) ou com uma combinação de parafusos ósseos externos e internos (um parafuso ósseo externo oco utilizado com um parafuso de fixação interno sólido para fixação unicortical). A selecção



do parafuso é determinada segundo a preferência do médico. Todas as plataformas são concebidas para serem utilizadas com as duas varetas para dar forma à construção.

As plataformas existem em designs fixáveis e não fixáveis. As plataformas fixáveis têm extensões que aceitam parafusos de fixação de plataforma/conector transversal para fixar a plataforma às varetas. As plataformas fixáveis são necessárias para utilizar nas extremidades da construção oposta às cabeças das varetas.

Se for preferida uma configuração rígida em vez de uma configuração dinâmica (isto é, de partilha de carga), também deve ser utilizada uma plataforma fixável junto às cabeças das varetas. Se for desejada uma configuração de partilha de carga, a plataforma junto às cabeças das varetas não se prende às varetas.

São concebidas várias plataformas para inserção angular do parafuso no corpo vertebral. Existem em designs fixáveis e não fixáveis. Estas plataformas têm uma aleta num dos lados que acopla a vértebra no interior do espaço do disco, com vista a um posicionamento e fixação ideais.

São concebidas várias plataformas para a inserção direita (perpendicular) do parafuso no corpo vertebral. Estas plataformas existem em designs fixáveis e não fixáveis.

Existe um design de plataforma para fixação da construção num enxerto intervertebral. Esta plataforma comporta um encaixe horizontal e um ninho esférico para permitir a variação no local de entrada do parafuso e na trajectória para o enxerto.

A selecção da plataforma é baseada na preferência do médico e na anatomia do paciente.

O Sistema de Placa da Cervical Anterior SLIM-LOC™ consiste num conjunto de placas e parafusos de liga de titânio. As placas existem em comprimentos que variam entre 22-111 mm, em configurações com 2, 3, 4, 5 ou 6 pares de orifícios de parafusos. Os parafusos SLIM-LOC™ existem com diâmetros de 4,5 mm, como parafusos ponta broca em comprimentos uniformes entre 10-18 mm ou parafusos auto-roscantes em comprimentos uniformes entre 10-26 mm. Os parafusos de diâmetros maiores (4,8 mm) existem com os comprimentos 12, 14 e 16 mm.

O Sistema de Placa da Cervical Anterior EAGLE™ consiste num conjunto de placas e parafusos de liga de titânio. As placas estão disponíveis com dois a seis pares de orifícios de parafusos, em vários comprimentos. Os parafusos estão disponíveis em vários tamanhos e geometrias de pontas.

O Sistema de Placa da Cervical Anterior SWIFT™ é feito de liga de titânio e consiste em placas segmentadas que permitem até 2 mm de ajuste controlado do enxerto entre cada um dos segmentos. As placas estão disponíveis com dois a seis pares de orifícios de parafusos, em vários comprimentos e duas configurações, discectomia e corpectomia. Os parafusos estão disponíveis em vários tamanhos e geometrias de pontas. Existe um parafuso de enxerto para utilizar nas placas de corpectomia.

O Sistema de Placa da Cervical Anterior UNIPLATE™ consiste num conjunto de placas e parafusos de liga de titânio. As placas da cervical anterior estão disponíveis em vários comprimentos para acomodar um a dois segmentos de fixação. Os parafusos estão disponíveis em vários tamanhos e geometrias de pontas.

O Sistema de Placa da Cervical Anterior SKYLINE™ consiste num conjunto de placas e parafusos de liga de titânio. As placas possuem dois a seis pares de orifícios de parafusos, em vários comprimentos. Os parafusos estão disponíveis em vários tamanhos e geometrias de pontas. Estão disponíveis parafusos limitados e variáveis para criar uma configuração limitada, variável ou híbrida.

## LIMPEZA E ESTERILIZAÇÃO

Os implantes dos Sistemas de Estabilização por Placas Cervicais são fornecidos esterilizados ou limpos e não esterilizados. Para os componentes fornecidos esterilizados, antes de os utilizar, certifique-se de que a embalagem não está danificada.

Para os dispositivos não esterilizados, devem ser seguidas, para todos os componentes, as práticas recomendadas da ISO 8828 ou da AORN para a esterilização hospitalar.

Foram realizados testes para desenvolver as seguintes RECOMENDAÇÕES PARA A ESTERILIZAÇÃO A VAPOR:

| | |
|---|---|
| Ciclo | Pré-vácuo |
| Temperatura | 132 °C<br>270 °F |
| Tempo de exposição | 6 minutos |

## UTILIZAÇÃO

O cirurgião deve ter um conhecimento completo dos aspectos médicos e cirúrgicos do implante, e deve estar ciente das limitações mecânicas e metalúrgicas do implante cirúrgico metálico. Os cuidados pós-operatórios são extremamente importantes. O paciente deve ser instruído sobre as limitações do implante metálico e advertido a respeito do apoio de peso e esforços do corpo sobre o dispositivo antes da sólida consolidação óssea. O paciente deve ser advertido de que o não cumprimento das instruções pós-operatórias poderá levar a uma falha do implante e à possível necessidade de uma cirurgia adicional para remover o dispositivo.

Os componentes espinais do sistema DePuy Spine não devem ser usados com componentes de outros fabricantes.

**A fim de obter uma translação vertical controlada (partilha de carga), é fundamental a colocação correcta dos componentes seleccionados.**

**Consulte o manual de técnicas cirúrgicas para obter instruções específicas.**

## INDICAÇÕES

**ATENÇÃO:** A lei dos Estados Unidos limita a venda deste dispositivo a médicos ou por receita destes.

O Sistema de Placa da Cervical Anterior SLIM-LOC e o Sistema de Placa da Cervical Anterior SKYLINE™ estão indicados para a estabilização da coluna cervical, da C2 à

C7, empregando a fixação por meio de parafusos unicorticais na face anterior dos corpos vertebrais. As indicações clínicas específicas relativas à colocação de placas na cervical anterior incluem: instabilidade causada por traumatismo, instabilidade associada à correcção de deformação por lordose e cifose cervical, instabilidade associada à pseudoartrose como resultado de uma cirurgia falhada à coluna cervical, instabilidade associada a grandes cirurgias reconstrutivas para tumores primários ou tumores malignos metastáticos da coluna cervical, instabilidade associada à corpectomia de nível único ou múltiplo na doença degenerativa discal avançada, na estenose do canal da coluna e na mielopatia cervical.

O Sistema de Placa de Compressão Anterior PEAK, o Sistema de Placa Poliaxial da Cervical Anterior PEAK, o Sistema de Estabilização da Cervical Ventral DOC, o Sistema de Placa da Cervical Anterior EAGLE, o Sistema de Placa da Cervical Anterior SWIFT e o Sistema de Placa da Cervical Anterior UNIPLATE destinam-se à fixação do corpo intervertebral cervical anterior. Estes sistemas estão indicados para os pacientes nos quais é desejada uma estabilidade após fusão cervical anterior para as indicações listadas abaixo. Os níveis previstos para o tratamento variam entre C2 e T1.

As indicações incluem espondilose cervical sintomática, traumatismo, fractura, lordose ou cifose pós-traumática, tumor, doença degenerativa discal (definida como dor discogénica com degeneração do disco confirmada pela história clínica e por estudos radiográficos), nova cirurgia por falha da fusão ou instabilidade após uma cirurgia para as indicações acima mencionadas.

O Sistema de Placa da Cervical Anterior UNIPLATE também está indicado para o tratamento da estenose da coluna.

**ADVERTÊNCIA:** Estes dispositivos não estão aprovados para conexão ou fixação de parafusos aos elementos posteriores (apófises) da coluna cervical, torácica ou lombar.

## MOBILIZAÇÃO PÓS-OPERATÓRIA

Até que a consolidação da fusão seja confirmada por exames radiográficos, pode ser recomendada a utilização de uma imobilização externa (como a utilização de suporte), baseada no critério do médico.

As instruções ao paciente para reduzir o esforço nos implantes constituem uma parte igualmente importante da tentativa de evitar a ocorrência dos problemas clínicos que podem acompanhar a falha da fixação.

## CONTRA-INDICAÇÕES

- Infecção sistémica activa ou uma infecção localizada no local de implantação pretendido.
- A osteoporose severa pode impedir a fixação adequada dos parafusos e, assim, impossibilitar a utilização deste ou de qualquer outro sistema de instrumentação da coluna vertebral.
- Pacientes que mostraram poderem ser tratados com segurança e previsibilidade sem uma fixação interna.
- Feridas abertas.

## CONTRA-INDICAÇÕES RELATIVAS:

As contra-indicações relativas incluem qualquer entidade ou condição que impeça totalmente a possibilidade de fusão (por exemplo, cancro, diálise renal ou osteopenia), obesidade, determinadas doenças degenerativas e sensibilidade a corpos estranhos.

## ADVERTÊNCIAS, PRECAUÇÕES E EFEITOS ADVERSOS RELATIVOS AOS DISPOSITIVOS METÁLICOS TEMPORÁRIOS DE FIXAÇÃO INTERNA

### ADVERTÊNCIAS

Seguem-se advertências, precauções e efeitos adversos específicos que devem ser compreendidos pelo cirurgião e devem ser explicados ao paciente. Estas advertências não incluem todos os efeitos adversos que podem ocorrer com a cirurgia de um modo geral, mas são considerações importantes, específicas dos dispositivos metálicos de fixação interna. Os riscos cirúrgicos gerais devem ser explicados ao paciente antes da cirurgia.

Os riscos potenciais relacionados com a utilização deste sistema de dispositivo, que podem requerer cirurgia adicional, incluem: quebra de um componente do dispositivo, perda da fixação, não-união, fractura da vértebra, lesão neurológica e lesão vascular ou visceral.

1. **É EXTREMAMENTE IMPORTANTE SELECCIONAR-SE O IMPLANTE CORRECTO.** O potencial para uma fixação satisfatória aumenta ao seleccionar-se um implante de tamanho, forma e design apropriados. Enquanto que a selecção apropriada pode ajudar a minimizar os riscos envolvidos, o tamanho dos ossos humanos apresenta limitações ao tamanho, forma e força dos implantes. Os dispositivos metálicos internos de fixação não podem suportar níveis de actividade idênticos aos suportados por um osso saudável. Não se pode esperar que nenhum implante suporte indefinidamente o esforço não apoiado de todo o peso corporal.
2. **OS IMPLANTES PODEM QUEBRAR QUANDO SUJEITOS A UM AUMENTO DE CARGA ASSOCIADO A UMA NÃO-UNIÃO OU UNIÃO RETARDADA.** Os dispositivos de fixação interna são dispositivos de partilha de carga, usados para obter um alinhamento até à consolidação normal. Se a consolidação for tardia ou se não ocorrer, o implante poderá eventualmente quebrar devido a um esforço excessivo do metal. O grau de sucesso da união, as cargas produzidas pelo peso corporal e os níveis de actividade estabelecerão, entre outras condições, a longevidade do implante. Entalhes, riscos ou dobras ocorridos no implante durante a cirurgia também podem contribuir para uma falha prematura do mesmo. Os pacientes deverão ser completamente informados sobre os riscos de uma falha do implante.
3. **A MISTURA DE METAIS PODERÁ CAUSAR CORROSÃO.** Existem muitos tipos de danos por corrosão, e vários destes ocorrem especificamente em metais implantados cirurgicamente em seres humanos. A corrosão geral ou uniforme está presente em todos os metais e ligas implantados. A taxa de ataque corrosivo dos metais implantados normalmente é muito baixa, devido à presença de películas passivas de superfície. Metais dissimilares em contacto, tais como titânio e aço inoxidável, aceleram o processo de corrosão do aço inoxidável, ocorrendo assim um ataque mais rápido. A presença de corrosão acelera frequentemente as quebras devidas à fadiga dos materiais dos implantes. A quantidade de compostos metálicos libertados no organismo também aumentará. Os dispositivos internos de fixação, tais como varetas, ganchos, fios, etc., que entram em contacto com outros objectos metálicos, deverão ser feitos do mesmo metal ou de um metal compatível.
4. **SELECÇÃO DE PACIENTES.** Ao seleccionar pacientes para implantação de dispositivos internos de fixação, os seguintes factores são de extrema importância para o eventual sucesso do procedimento:

   A. **A actividade profissional ou ocupação do paciente.** Se o paciente estiver envolvido numa ocupação ou actividade profissional que envolva o levantamento de objectos pesados, esforço muscular, torção, inclinação repetitiva, agachar-se, correr, caminhadas substanciais ou trabalho manual, estas actividades não deverão ser retomadas até o osso estar completamente consolidado. Mesmo com uma consolidação completa, o paciente poderá ainda assim não ser capaz de retomar estas actividades com êxito.

   B. **Condições de senilidade, doença mental, alcoolismo ou uso de drogas.** Estas condições, entre outras, podem fazer com que o paciente ignore certas limitações e precauções necessárias relativas ao uso deste dispositivo, causando uma falha do implante ou outras complicações.

   C. **Certas doenças degenerativas.** Em alguns casos, o estado de uma doença degenerativa poderá estar tão avançado na altura do implante, que significaria uma diminuição substancial do período de vida útil do implante. Em tais casos, os dispositivos ortopédicos apenas podem ser considerados como uma técnica de retardamento ou como uma solução temporária.

   D. **Sensibilidade a corpos estranhos.** O cirurgião deverá saber que nenhum teste pré-operatório poderá excluir completamente a possibilidade de sensibilidade ou de uma reacção alérgica. Os pacientes podem desenvolver este tipo de alergias ou sensibilidade após os implantes estarem dentro do corpo durante um certo período de tempo.

   E. **Tabagismo.** Os pacientes com hábitos tabagistas parecem apresentar taxas mais altas de pseudo-artrose, a seguir aos procedimentos cirúrgicos onde se utilizou um enxerto ósseo. Adicionalmente, o hábito de fumar demonstrou causar uma degenerescência difusa dos discos intervertebrais. A degenerescência progressiva dos segmentos adjacentes causada pelo fumo poderá provocar uma falha clínica tardia (dor recorrente), mesmo após uma fusão bem-sucedida e uma melhoria clínica inicial.

**ADVERTÊNCIA:** Se a fusão óssea não ocorrer no período de tempo previsto, os parafusos podem quebrar-se devido à elevada e sustentada carga destes dispositivos. Esta situação tem sido observada em pacientes com pseudo-artrose tardia ou não-união e pode resultar na necessidade de rever o(s) dispositivo(s).

### PRECAUÇÕES

1. **OS IMPLANTES CIRÚRGICOS NUNCA DEVEM SER REUTILIZADOS.** Um implante de metal explantado nunca deve ser reimplantado. Mesmo que o dispositivo não pareça danificado, este pode conter pequenos defeitos e padrões internos de fadiga do material que podem levar a uma ruptura precoce.
2. **A MANIPULAÇÃO CORRECTA DO IMPLANTE É EXTREMAMENTE IMPORTANTE.** Apenas deve ser feito um contorno num implante de metal com o equipamento apropriado. O cirurgião principal deve evitar entalhar, riscar ou dobrar para trás o implante durante a aplicação de um contorno. As alterações produzirão defeitos no revestimento da superfície e fadigas internas que se podem transformar no ponto fulcral para a eventual ruptura do implante. Não utilize o implante caso haja suspeita de danos.

   Ao assentar a placa, os parafusos demasiado apertados poderão causar a falha do osso, resultando em roscas gastas e/ou numa fixação comprometida dos parafusos.
3. **DOBRA DA CONSTRUÇÃO.** Os componentes de liga de titânio não devem nunca ser dobrados em ângulo agudo ou dobrados para trás. Se uma construção sofrer um contorno excessivo, recomenda-se que uma construção nova seja contornada correctamente, em vez de dobrar para trás a construção com contorno excessivo.
4. **REMOÇÃO DO IMPLANTE APÓS A CONSOLIDAÇÃO.** Se o dispositivo metálico não for removido após a conclusão da sua utilização prevista, podem ocorrer algumas das seguintes complicações: (1) Corrosão, com reacção do tecido ou dor localizada; (2) Migração da posição do implante resultando numa lesão; (3) Risco de lesão adicional por traumatismo pós-operatório; (4) Dobra, afrouxamento e/ou ruptura, que poderiam tornar a remoção pouco prática ou difícil; (5) Dor, desconforto, ou sensações anormais devido à presença do dispositivo; (6) Possível risco aumentado de infecção; e (7) Perda óssea devido à protecção contra os esforços. O cirurgião deve pesar com cuidado os riscos e os benefícios ao decidir da remoção do implante. A remoção do implante deve ser seguida pelo tratamento pós-operatório adequado para evitar uma nova fractura ou deformação. Se, por exemplo, o paciente for mais idoso e tiver um nível de actividade baixo, o cirurgião pode decidir não remover o implante, eliminando, assim, os riscos inerentes a uma segunda cirurgia.

5. **INSTRUA ADEQUADAMENTE O PACIENTE.** Os cuidados pós-operatórios e a capacidade e a vontade do paciente em seguir as instruções são dos aspectos mais importantes para uma consolidação óssea bem-sucedida. O paciente deve estar ciente das limitações do implante e ser instruído para limitar e restringir actividades físicas, em especial movimentos de elevação e de rotação e a participação em desportos de qualquer tipo. O paciente deve compreender que a fixação do implante não é tão forte quanto o osso saudável normal e que poderá ocorrer um afrouxamento, dobra e/ou ruptura se forem exercidas exigências excessivas na ausência de consolidação óssea completa. Os implantes deslocados ou danificados por actividades indevidas podem migrar, e lesionar os nervos ou os vasos sanguíneos. Um paciente activo, debilitado ou mentalmente perturbado que não possa utilizar correctamente os dispositivos para apoio do peso pode estar particularmente em risco durante a reabilitação pós-operatória.

## EFEITOS ADVERSOS POSSÍVEIS

1. Não-união, união tardia.
2. Dobragem ou quebra do implante. Libertação do implante.
3. Sensibilidade ao metal ou reacção alérgica a um corpo estranho.
4. Infecção, precoce ou tardia.
5. Diminuição da densidade óssea devido à protecção contra o esforço.
6. Dor, desconforto ou sensação anormal devido à presença do dispositivo.
7. Danos aos nervos devido a traumatismo cirúrgico ou à presença do dispositivo. Dificuldades neurológicas, incluindo dor radicular, adesão dos nervos à cicatriz, enfraquecimento muscular e parestesia.
8. Danos vasculares poderão resultar numa hemorragia catastrófica ou mesmo fatal. Implantes mal colocados adjacentes a grandes artérias ou veias poderão desgastar estes vasos e causar uma hemorragia no período pós-operatório tardio.
9. As lacerações da dura mater ocorridas durante a cirurgia poderão resultar na necessidade de cirurgia adicional para correcção da dura mater, um vazamento crónico ou fístula de CSF (líquido cefalorraquidiano) e possível meningite.
10. Bursite.
11. Paralisia.
12. Perfuração, erosão ou irritação do esófago.
13. Recuo do parafuso, possivelmente levando à libertação do implante, e/ou a uma nova operação para remover o dispositivo.
14. Danos aos vasos linfáticos e/ou à exsudação do fluido linfático.
15. Prejuízos ou danos na espinal medula.
16. Fractura de estruturas ósseas.
17. Alterações degenerativas ou instabilidade nos segmentos adjacentes aos níveis vertebrais fundidos.
18. Morte.

**GARANTIA LIMITADA E RENÚNCIA: OS PRODUTOS DEPUY SPINE SÃO VENDIDOS AO COMPRADOR ORIGINAL COM UMA GARANTIA LIMITADA CONTRA DEFEITOS DE FABRICO E DE MATERIAL. QUAISQUER OUTRAS GARANTIAS EXPRESSAS OU IMPLÍCITAS, INCLUINDO GARANTIAS DE COMERCIALIZAÇÃO E ADEQUAÇÃO A DETERMINADO FIM, SÃO AQUI RENUNCIADAS.**

**SE TIVEREM DECORRIDO MAIS DE DOIS ANOS ENTRE A DATA DE EMISSÃO/REVISÃO E A DATA DA CONSULTA, CONTACTE A DEPUY SPINE PARA OBTER INFORMAÇÕES ACTUALIZADAS, ATRAVÉS DO NÚMERO: 800-365-6633 (NOS EUA) OU +1-508-880-8100.**

FABRICADO POR UMA DAS SEGUINTES ENTIDADES:

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325 Paramount Drive, Raynham, MA 02767-0350 EUA

DePuy Spine SÀRL
Chemin Blanc, 36, CH-2400 Le Locle, Suíça

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St. Anthony's Road, Leeds LS11 8DT Reino Unido

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**LEGENDA**

| | | | |
|---|---|---|---|
| LOT NÚMERO DE LOTE | UTILIZAÇÃO ÚNICA | NONSTERILE NÃO ESTERILIZADO | FABRICANTE |
| REF NÚMERO DE CATÁLOGO | XXXX-XX VALIDADE | STERILE R ESTERILIZAÇÃO POR IRRADIAÇÃO | EC REP REPRESENTANTE AUTORIZADO NA EUROPA |
| QTY QUANTIDADE | VER AS INSTRUÇÕES DE UTILIZAÇÃO | STERILE EO ESTERILIZAÇÃO POR ÓXIDO DE ETILENO | DIST DISTRIBUÍDO POR |
| Rx Only A lei federal (dos Estados Unidos) só permite a venda deste dispositivos a médicos ou sob receita destes. | STERILE ESTERILIZADO | MADE IN FABRICADO EM | SZ TAMANHO |



**MATERIAL** MATL

| | | |
|---|---|---|
| A/T ACROFLEX™/Ti ACROFLEX™/Titânio | PY Poliéster | SS/RADEL™/ SRTA Ti Al Nitride Aço inoxidável/RADEL™/ Nitreto de titânio de alumínio |
| A Al Alumínio | P POLYMER Polímero | STA SS/Ti Al Nitride Aço inoxidável/ Nitreto de titânio aluminio |
| A/P Al/PL Alumínio/Plástico | P/CM PE/CoCrMo Polietileno/ Cobalto Crômio Molibdeno | S/U SS/ULTEM Aço inoxidável/Ultem |
| B/R Ba/RADEL™ Bário/RADEL™ | P/C POLYMER/CARBON FIBER COMPOSITE Composto de fibra de carbono/ Polímero | T Ti Titânio e respectivas ligas |
| CaP CALCIUM PHOSPHATE Fosfato de cálcio | S SS Aço inoxidável | S/R SS/RADEL Aço inoxidável/RADEL™ |
| CM CoCrMo Cobalto Crômio Molibdeno | S/A SS/Al Aço inoxidável/Alumínio | R/T POLYOLEFIN RUBBER/Ti Borracha poliolefina/Titânio |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Cobalto Crômio Molibdeno/ Titânio/Fosfato de cálcio | SBR SS/Ba/RADEL™ Aço inoxidável/Bário/RADEL™ | T/A Ti/Al Titânio/Alumínio |
| F FOAM Espuma | S/P SS/PHENOLIC Aço inoxidável/Fenólico | Ti/UHMWPE/HA Titânio/Polietileno de peso molecular ultra elevado/ Hidroxiapatita |
| HA Hidroxiapatita | S/PL SS/PL Aço inoxidável/Plástico | SS/Ti Aço inoxidável/Titânio |
| NiTi Ni/Ti Níquel/Titânio | SRSI SS/RADEL™/ SILICONE Aço inoxidável/ RADEL™/Silicone | SS/Al/SILICONE Aço inoxidável/ Alumínio/Silicone |
| PL Plástico | SRSN SS/RADEL™/ SILICONE/Ti Al Nitride Aço inoxidável/RADEL™/ Silicone/Nitreto de titânio de alumínio | S/SI SS/SILICONE Aço inoxidável/Silicone |
| P/F PL/FOAM Plástico/Espuma | | |

es

# SISTEMA DE PLACAS ANTEROCOMPRESORAS PEAK

# SISTEMA DE PLACAS POLIAXIALES ANTEROCERVICALES PEAK

# SISTEMA PARA ESTABILIZACIÓN VENTROCERVICAL DOC

# SISTEMA DE PLACAS ANTEROCERVICALES SLIM-LOC™

# SISTEMA DE PLACAS ANTEROCERVICALES EAGLE™

# SISTEMA DE PLACAS ANTEROCERVICALES SWIFT™

# SISTEMA DE PLACAS ANTEROCERVICALES UNIPLATE™

# SISTEMA DE PLACAS ANTEROCERVICALES SKYLINE™

## NOTA IMPORTANTE PARA EL CIRUJANO A CARGO DE LA OPERACIÓN

Los implantes del Sistema para Estabilización Anterocervical, al igual que cualquier otro dispositivo de fijación interna, tienen una vida útil limitada. El nivel de actividad del paciente tiene un impacto significativo en la vida útil. El paciente debe estar informado de que cualquier actividad aumenta el riesgo de que los componentes del implante se aflojen, se doblen o se rompan. Es esencial instruir a los pacientes respecto a restricciones en sus actividades durante el período postoperatorio y examinar al paciente después de la operación para evaluar el desarrollo de la masa de fusión y el estado

de los componentes del implante. Aun en el caso de que se produzca una fusión ósea sólida, los componentes del implante pueden doblarse, romperse o aflojarse. Por lo tanto, el paciente debe saber que los componentes del implante pueden doblarse, romperse o aflojarse aun cuando cumpla con restringir su actividad.

Debido a las limitaciones impuestas por las consideraciones anatómicas y los materiales quirúrgicos modernos, los implantes metálicos no pueden tener una duración indefinida. Su propósito es proporcionar soporte interno temporal mientras la masa de fusión se está consolidando. Es más factible que fallen estos tipos de implantes si no se utiliza un injerto óseo o si se desarrolla una seudoartrosis.

El cirujano puede determinar la necesidad de retirar estos implantes después de producirse la fusión ósea. Debe evaluarse con el paciente la posibilidad de un segundo procedimiento quirúrgico y los riesgos asociados. Si los implantes se rompen, el médico debe tomar la decisión de retirarlos, tomando en consideración el estado del paciente y los riesgos asociados con la presencia del implante roto.

## DESCRIPCIÓN

El Sistema de Placas Anterocompresoras PEAK consiste en un surtido de placas y tornillos de aleación de titanio. Las placas están disponibles en longitudes de 26 mm a 94 mm para acomodar de uno a cuatro segmentos de fijación. El sistema también incluye tornillos corticales de 3,5 mm y cancelosos de 4 mm de aleación de titanio que están disponibles en longitudes de 8 mm a 30 mm.

El Sistema de Placas Poliaxiales Anterocervicales PEAK consiste en un surtido de placas y tornillos de aleación de titanio. Las placas anterocervicales varían en longitud de 24 mm a 110 mm para acomodar de uno a cuatro segmentos de fijación. Los tornillos cancelosos están disponibles en diámetros de 4 mm y 4,35 mm; los hay completamente roscados y sus longitudes varían de 10 mm a 26 mm.

El Sistema para Estabilización Ventrocervical DOC es un sistema de tornillo, varilla, placa y plataforma de aleación de titanio que se utiliza para asistir a los cirujanos de la espina dorsal en la corrección de defectos y estabilización de la columna cervical. El Sistema para Estabilización Ventrocervical DOC, en su forma completamente ensamblada, consta de una placa o dos varillas colocadas lateralmente unidas por plataformas sobre la superficie anterovertebral. El sistema se sujeta a las vértebras mediante tornillos. El implante proporciona estabilidad suplementaria a la columna cervical después de la fusión anterocervical. Dependiendo de la configuración del implante, podría servir como una estructura rígida (que soporte la carga) o dinámica (que comparta la carga).

Los componentes siguientes están disponibles en el sistema: varillas, placas, plataformas, tornillos óseos externos e internos, tornillos de injerto y conectores transversales. Todos los componentes se fabrican de aleación de titanio de calidad para implantes conforme a las especificaciones ASTM F-136. Para conveniencia del cirujano también hay disponibles sistemas ensamblados. Estos son estructuras parcialmente ensambladas que constan de una plataforma, un conector transversal, dos varillas y dos tornillos de fijación.

**Plataforma:** Las plataformas están diseñadas para conectar las varillas y anclajes a los cuerpos vertebrales con los tornillos óseos. Todas las plataformas se pueden usar con tornillos óseos sólidos (para fijación bicortical) o con la combinación de tornillos óseos externo e interno (un tornillo óseo externo hueco que se utiliza con un tornillo de fijación interno sólido diseñado para fijación unicortical). La selección de los tornillos es determinada por el médico según su preferencia. Todas las plataformas están diseñadas para formar la estructura con dos varillas.

Las plataformas están disponibles en diseños fijable y no fijable. Las plataformas fijables tienen extensiones que aceptan tornillos de fijación del conector transversal o de plataforma para fijar la plataforma a las varillas. Las plataformas fijables son necesarias para el extremo de la estructura opuesto a las cabezas de las varillas.

Si se prefiere una configuración rígida en vez de una configuración dinámica (es decir, con carga compartida), también se debe utilizar una plataforma fijable adyacente a las cabezas de las varillas. Si se desea una configuración con carga compartida, la plataforma adyacente a las cabezas de las varillas no se fija a las varillas.

Varias plataformas están diseñadas para la inserción angulada del tornillo en el cuerpo vertebral. Están disponibles en diseños fijables y no fijables. Estas plataformas tienen una aleta en un lado, la cual se engancha a la vértebra desde dentro del espacio del disco para un posicionamiento y fijación óptimos.

Varias plataformas están diseñadas para la inserción recta (perpendicular) del tornillo en el cuerpo vertebral. Están disponibles en diseños fijables y no fijables.

Existe un diseño de plataforma para la fijación de la estructura a un injerto intervertebral. Esta plataforma tiene una ranura horizontal y un nido esférico para acomodar la variación del lugar de entrada del tornillo y la trayectoria en el injerto.

La selección de las plataformas se basa en la anatomía del paciente y la preferencia del médico.

El Sistema de Placas Anterocervicales SLIM-LOC™ consiste en un surtido de placas y tornillos de aleación de titanio. Las placas están disponibles en longitudes que varían de 22 mm a 111 mm en configuraciones con 2, 3, 4, 5 ó 6 pares de agujeros para tornillos. Los tornillos SLIM-LOC están disponibles en diámetros de 4,5 mm con puntas perforadoras en longitudes pares de 10 mm a 18 mm o con puntas de punción en longitudes pares de 10 mm a 26 mm. Tornillos con diámetros de mayor tamaño (4,8 mm) están disponibles en longitudes de 12 mm, 14 mm y 16 mm.

El Sistema de Placas Anterocervicales EAGLE™ consiste en un surtido de placas y tornillos de aleación de titanio. Las placas están disponibles con dos a seis pares de agujeros para tornillos, en varias longitudes. Los tornillos están disponibles en varios tamaños y con distintas puntas.



El Sistema de Placas Anterocervicales SWIFT™ está hecho de aleación de titanio y consiste en placas diseñadas en segmentos, lo cual permite que se coloquen de manera controlada injertos de hasta 2 mm entre cada segmento. Las placas están disponibles con dos a seis pares de agujeros para tornillos, en varias longitudes y en dos configuraciones: discectomía y corpectomía. Los tornillos están disponibles en varios tamaños y con distintas puntas. Un tornillo de injertos está disponible para las placas de corpectomía.

El Sistema de Placas Anterocervicales UNIPLATE™ consiste en un surtido de placas y tornillos de aleación de titanio. Las placas anterocervicales están disponibles en varias longitudes para acomodar de uno a dos segmentos de fijación. Los tornillos están disponibles en varios tamaños y con distintas puntas.

El Sistema de Placas Anterocervicales SKYLINE™ consiste en un surtido de placas y tornillos de aleación de titanio. Las placas están disponibles con dos a seis pares de agujeros para tornillos, en varias longitudes. Los tornillos están disponibles en varios tamaños y con distintas puntas. Se ofrecen tornillos restringidos y variables para crear una configuración restringida, variable o híbrida.

## LIMPIEZA Y ESTERILIZACIÓN

Los implantes de los Sistemas para Estabilización con Placas Cervicales se suministran ya sea estériles, o limpios y no estériles. Para los componentes proporcionados estériles, debe asegurarse de que el paquete no esté dañado antes del uso.

Para los dispositivos no estériles, deben seguirse las prácticas ISO 8828 o AORN recomendadas para la esterilización de todos los componentes en el hospital.

Se realizaron pruebas para desarrollar las siguientes RECOMENDACIONES PARA LA ESTERILIZACIÓN AL VAPOR:

| | |
|---|---|
| Ciclo: | Prevacío |
| Temperatura: | 270 °F<br>132 °C |
| Tiempo de exposición: | 6 min. |

## USO

El cirujano debe tener amplio conocimiento de los aspectos médicos y quirúrgicos de los implantes quirúrgicos, así como conocimiento de las limitaciones mecánicas y metalúrgicas de los implantes quirúrgicos metálicos. El cuidado postoperatorio es sumamente importante. Se deben indicar al paciente las limitaciones de los implantes metálicos y advertir acerca de los efectos de cargar peso y de los esfuerzos del cuerpo sobre el dispositivo antes de la curación ósea completa. Se debe advertir al paciente que el no cumplir con las instrucciones postoperatorias podría ocasionar el fracaso del implante y la posible necesidad de una cirugía adicional para retirar el dispositivo.

Los componentes de los sistemas espinales DePuy Spine no deben usarse con componentes de otros fabricantes.

**Para obtener una traslación vertical controlada (carga compartida), es muy importante la ubicación correcta de los componentes seleccionados.**

**Para obtener instrucciones específicas, por favor consulte el manual de técnicas quirúrgicas.**

## INDICACIONES

**PRECAUCIÓN:** Las leyes federales de EE.UU. restringen la venta de estos dispositivos exclusivamente al médico o bajo orden médica.

El Sistema de Placas Anterocervicales SLIM-LOC y el Sistema de Placas Anterocervicales SKYLINE™ están indicados para la estabilización de la columna cervical de C2 a C7, empleando fijación unicortical con tornillos en las caras anteriores de los cuerpos vertebrales. Las indicaciones clínicas específicas para las placas de fijación anterior incluyen: inestabilidad causada por trauma; inestabilidad asociada con la corrección de las anormalidades cervicales lordosis y cifosis; inestabilidad asociada con seudoartrosis, resultado de un fracaso quirúrgico de la columna cervical; inestabilidad asociada con reconstrucción quirúrgica extensa para tumores primarios o tumores malignos metastáticos de la columna cervical; inestabilidad asociada con corpectomía de uno o múltiples niveles por trastorno degenerativo avanzado de disco, estenosis del canal espinal y mielopatía cervical.

El Sistema de Placas Anterocompresoras PEAK, el Sistema de Placas Poliaxiales Anterocervicales PEAK, el Sistema de Estabilización Ventrocervical DOC, el Sistema de Placas Anterocervicales EAGLE, el Sistema de Placas Anterocervicales SWIFT y el Sistema de Placas Anterocervicales UNIPLATE están indicados para la fijación intervertebral anterocervical. Estos sistemas son para pacientes que requieran estabilidad después de la fusión anterocervical para las indicaciones listadas a continuación. Los niveles de tratamiento abarcan de C2 a T1.

Las indicaciones incluyen espondilosis cervical sintomática, trauma, fractura, cifosis o lordosis postraumática, tumor, trastorno degenerativo de disco (definido como dolor discogénico con degeneración del disco confirmado por historial y estudios radiográficos), cirugía subsiguiente al fracaso de fusión, o inestabilidad después de una cirugía asociada con las indicaciones anteriores.

El Sistema de Placas Anterocervicales UNIPLATE también está indicado para el tratamiento de estenosis de la médula espinal.

**ADVERTENCIA:** Estos dispositivos no han sido aprobados para uso de tornillo ni fijación a los elementos posteriores (pedículos) de la columna cervical, torácica o lumbar.

## MOVILIZACIÓN POSTOPERATORIA

Hasta que se confirme la maduración de la fusión por medio de examen radiográfico, se recomienda inmovilización externa (tal como entabillado), a juicio del médico.

De igual importancia para lograr el objetivo de evitar los problemas clínicos que pueden acompañar la ausencia de fijación, son las instrucciones que reciba el paciente respecto a la reducción de esfuerzo en los implantes.

## CONTRAINDICACIONES

- Una infección sistémica activa o infección localizada en el lugar propuesto del implante.
- Una osteoporosis severa puede impedir la fijación adecuada de los tornillos e impedir el uso de éstos o de cualquier otro sistema de instrumentos para la espina dorsal.
- Pacientes que se puedan tratar con seguridad y previsiblemente sin fijación interna.
- Heridas abiertas.

## CONTRAINDICACIONES RELATIVAS:

Las contraindicaciones relativas incluyen cualquier entidad o condición que excluya totalmente la posibilidad de fusión (por ejemplo, cáncer, diálisis de los riñones u osteopenia), obesidad, ciertas enfermedades degenerativas y sensibilidad a cuerpos extraños.

## ADVERTENCIAS, PRECAUCIONES Y EFECTOS ADVERSOS CONCERNIENTES A LOS DISPOSITIVOS METÁLICOS TEMPORALES DE FIJACIÓN INTERNA.

### ADVERTENCIAS

A continuación se proporcionan las advertencias, precauciones y efectos adversos específicos que deben ser entendidos por el cirujano y explicados al paciente. Estas advertencias no incluyen todos los efectos adversos que pueden ocurrir con las cirugías en general, pero son consideraciones importantes específicas para dispositivos metálicos de fijación interna. Los riesgos quirúrgicos generales deben ser explicados al paciente antes de la cirugía.

Los riesgos potenciales identificados con el uso de este sistema de dispositivos que pueden requerir cirugía adicional incluyen: fractura de componentes del dispositivo, pérdida de la fijación, falta de unión, fractura de la vértebra, lesión neurológica y lesión vascular o visceral.

1. **ES MUY IMPORTANTE REALIZAR UNA SELECCIÓN CORRECTA DEL IMPLANTE.** Si se selecciona un implante del tamaño, forma y diseño apropiado, aumentará la posibilidad de que se produzca una fijación satisfactoria. Aunque una selección apropiada puede ayudar a reducir al mínimo los riesgos, el tamaño y la forma de los huesos humanos pueden limitar el tamaño, la forma y la resistencia de los implantes. Los dispositivos metálicos de fijación interna no resisten los mismos niveles de actividad que los huesos saludables y normales. No se puede esperar que un implante soporte indefinidamente, sin apoyo, el esfuerzo del peso total.
2. **LOS IMPLANTES PUEDEN ROMPERSE CUANDO SE SOMETEN A UNA MAYOR CARGA ASOCIADA CON UNA UNIÓN RETARDADA O FALTA DE UNIÓN.** Los dispositivos de fijación interna son dispositivos que comparten la carga y se utilizan para obtener una alineación hasta que se produzca la curación normal. Si la curación se retrasa, o no se produce, es posible que el implante se rompa con el tiempo debido a la fatiga metálica. El grado o éxito de la unión, las cargas producidas por el soporte del peso y los niveles de actividad, entre otras condiciones, determinarán la duración del implante. Las muescas, los rasguños o el doblamiento del implante durante la cirugía también pueden contribuir a una falla prematura. Los pacientes deben ser debidamente informados de los riesgos de fracaso del implante.
3. **LA COMBINACIÓN DE METALES PUEDE CAUSAR CORROSIÓN.** Existen muchas formas de daño por corrosión y algunas de éstas ocurren en los metales implantados quirúrgicamente en seres humanos. La corrosión general o uniforme está presente en todas las aleaciones y metales implantados. La proporción del ataque corrosivo en dispositivos metálicos de implante generalmente es muy baja debido a la presencia de películas superficiales pasivas. El contacto entre metales diferentes, tal como entre el titanio y el acero inoxidable aceleran el proceso de corrosión del acero inoxidable y se produce un ataque más rápido. La presencia de corrosión, generalmente, acelera la fractura por fatiga de los implantes. También aumentará la cantidad de compuestos metálicos liberados en el sistema del cuerpo. Los dispositivos de fijación interna, tales como varillas, ganchos, cables, etc., que entran en contacto con otros objetos metálicos deben estar fabricados con metales parecidos o compatibles.
4. **SELECCIÓN DEL PACIENTE.** Al seleccionar los pacientes para implante de dispositivos de fijación interna, los siguientes factores pueden ser muy importantes para el futuro éxito del procedimiento.

   A. **La ocupación o actividad del paciente.** Si el paciente participa en una ocupación o actividad que incluye levantar cargas pesadas, esfuerzo muscular, vueltas, flexiones repetidas, agacharse, correr, caminar largas distancias o labores manuales, el paciente no debe realizar estas actividades hasta que el hueso esté completamente curado. Aun después de una curación completa, es posible que el paciente no pueda volver a realizar exitosamente estas actividades.

   B. **Senilidad, enfermedad mental, alcoholismo o abuso de drogas.** Estas condiciones, entre otras, pueden causar que el paciente ignore ciertas limitaciones y precauciones necesarias en el uso del dispositivo, conduciendo al fracaso del implante u otras complicaciones.

   C. **Ciertas enfermedades degenerativas.** En algunos casos, la progresión de una enfermedad degenerativa puede estar tan avanzada al momento del implante que puede disminuir significativamente la vida útil prevista del dispositivo. En dichos casos, los dispositivos ortopédicos sólo pueden considerarse una técnica dilatoria o remedio temporal.

   D. **Sensibilidad a cuerpos extraños.** Se le señala al cirujano que ninguna prueba preoperatoria puede excluir completamente la posibilidad de una reacción alérgica o de sensibilidad. Los pacientes pueden desarrollar sensibilidad o alergia después de que los implantes hayan estado por un tiempo en el cuerpo.

   E. **Fumadores.** Se ha observado que los pacientes que fuman experimentan tasas más altas de seudoartrosis después de procedimientos quirúrgicos donde se utilizó injerto óseo. Además, se ha demostrado que el fumar causa degeneración difusa de los discos intervertebrales. La degeneración progresiva de los segmentos adyacentes que causa el fumar puede conducir a una falla clínica posterior (dolor recurrente) aun después de una fusión exitosa y una mejora clínica inicial.

**ADVERTENCIA:** Si la fusión ósea no ocurre dentro del período de tiempo previsto, los tornillos pueden romperse debido a la alta carga sostenida por estos dispositivos, lo cual ha sido observado en los pacientes con seudoartrosis retardada o falta de unión y puede resultar en que se precise revisar el o los dispositivos.

### PRECAUCIONES

1. **LOS IMPLANTES QUIRÚRGICOS JAMÁS DEBEN REUTILIZARSE.** Un implante metálico explantado nunca debe reimplantarse. Aunque parezca que el dispositivo está intacto, puede tener defectos pequeños y patrones de esfuerzo interno que pueden conducir a una rotura prematura.
2. **ES MUY IMPORTANTE MANIPULAR CORRECTAMENTE EL IMPLANTE.** Las alteraciones del contorno de los implantes metálicos sólo deben realizarse con equipo apropiado. El cirujano encargado de la operación debe evitar cualquier muesca, rasguño o doblado inverso de los dispositivos al realizar alteraciones del contorno. Las alteraciones producirán defectos en el acabado de la superficie y esfuerzos internos que pueden convertirse en el punto céntrico de una rotura futura del implante. No se debe usar el implante si se sospecha que está dañado.

   Si se aplica un exceso de torsión a los tornillos al asentar la placa puede ocasionar el deterioro del hueso, lo cual podría estropear las roscas o comprometer el alcance del tornillo.
3. **DOBLADO DE LA ESTRUCTURA.** Los componentes de aleación de titanio nunca deben doblarse en un ángulo agudo ni doblarse hacia atrás. Si una estructura se sobrecontornea, se recomienda contornear una estructura nueva en lugar de volver a doblar la estructura sobrecontorneada.
4. **RETIRO DEL IMPLANTE DESPUÉS DE LA CURACIÓN.** Si el dispositivo no se retira una vez finalizado su uso indicado, puede presentarse cualquiera de las siguientes complicaciones: (1) corrosión, con dolor o reacción localizada del tejido; (2) migración de la posición del implante resultando en lesión; (3) riesgo de lesión adicional debido a trauma postoperatorio; (4) doblado, aflojamiento y/o rotura, lo cual dificultaría o impediría el retiro; (5) dolor, molestia o sensaciones anormales debido a la presencia del dispositivo; (6) posible aumento del riesgo de infección; y (7) pérdida ósea debido a la protección de esfuerzo. El cirujano debe ponderar cuidadosamente los riesgos frente a los beneficios al decidir el retiro del implante. Después del retiro del implante, el paciente debe observar un cuidado postoperatorio adecuado para evitar otra fractura o deformidad. Si el paciente es de edad avanzada y tiene un bajo nivel de actividad, el cirujano puede decidir no retirar el implante, eliminando de esta manera los riesgos asociados con una segunda cirugía.
5. **PROPORCIONE LAS INSTRUCCIONES ADECUADAS AL PACIENTE.** El cuidado postoperatorio, y la capacidad y voluntad del paciente para seguir las instrucciones, son algunos de los aspectos más importantes para la curación exitosa del hueso. El paciente debe conocer las limitaciones del implante y se le debe indicar que limite y restrinja las actividades físicas, especialmente los movimientos de levantamiento y giro y cualquier tipo de participación en deportes. El paciente debe entender que un implante metálico no es tan fuerte como el hueso saludable y normal, y puede aflojarse, doblarse y/o romperse si se somete a demandas excesivas, especialmente en ausencia de una curación completa del hueso. Los implantes desplazados o dañados por actividades indebidas podrían migrar y dañar los nervios o vasos sanguíneos. Un paciente activo, debilitado o demente que no puede usar apropiadamente dispositivos de soporte de peso puede estar particularmente en riesgo durante la rehabilitación postoperatoria.

### EFECTOS ADVERSOS POSIBLES

1. Falta de unión, unión retardada.
2. Doblado o fractura del implante. Aflojamiento del implante.
3. Sensibilidad al metal, o reacción alérgica a un cuerpo extraño.
4. Infección, al poco tiempo o posteriormente.
5. Menor densidad ósea debido a la protección de esfuerzo.
6. Dolor, molestia o sensaciones anormales debido a la presencia del dispositivo.
7. Daño neurológico debido a trauma quirúrgico o a la presencia del dispositivo. Dificultades neurológicas incluyendo dolor radical, conexión de nervios en tejido cicatrizante, debilidad muscular y parestesia.
8. El daño vascular puede resultar en hemorragia catastrófica o mortal. Los implantes en posición incorrecta adyacentes a venas o arterias importantes pueden dañar estos vasos y causar hemorragia catastrófica en el último período postoperatorio.
9. Las rasgaduras durales ocurridas durante la cirugía pueden resultar en la necesidad de otra cirugía para reparación dural, un derrame crónico del líquido cefalorraquídeo o fístula y posiblemente meningitis.
10. Bursitis.
11. Parálisis.
12. Perforación, erosión o irritación esofágica.

13. Retroceso del tornillo, lo cual puede conducir a daño esofágico, aflojamiento del implante y/u otra operación para retirar el dispositivo.
14. Daño a los vasos linfáticos y/o exudación del fluido linfático.
15. Presión o daño de la médula espinal.
16. Fractura de estructuras óseas.
17. Cambios degenerativos o inestabilidad en segmentos adyacentes a niveles vertebrales fusionados.
18. Muerte.

**GARANTÍA LIMITADA Y DESCARGO DE RESPONSABILIDAD: LOS PRODUCTOS DEPUY SPINE SE VENDEN AL COMPRADOR ORIGINAL CON UNA GARANTÍA LIMITADA CONTRA DEFECTOS DE MATERIALES Y FABRICACIÓN. POR EL PRESENTE, SE NIEGA CUALQUIER OTRA GARANTÍA EXPRESA O IMPLÍCITA, DE USO GENERAL O ESPECÍFICO.**

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**TRADUCCIÓN DE SÍMBOLOS**

| | | | |
|---|---|---|---|
| LOT NÚMERO DE LOTE | PARA UN SOLO USO | NONSTERILE NO ESTÉRIL | FABRICANTE |
| REF NÚMERO DE CATÁLOGO | XXXX-XX FECHA DE CADUCIDAD | STERILE R ESTERILIZADO POR IRRADIACIÓN | EC REP REPRESENTANTE EUROPEO AUTORIZADO |
| QTY CANTIDAD | | STERILE EO ESTERILIZADO CON ÓXIDO DE ETILENO | DIST DISTRIBUIDO POR |
| Rx Only La ley federal de los EE.UU. solo autoriza la venta de este dispositivo a un médico o bajo receta médica. | VEA LAS INSTRUCCIONES DE USO | MADE IN FABRICADO EN | SZ TAMAÑO |
| | STERILE ESTÉRIL | | |

**MATERIAL** MATL

| | | |
|---|---|---|
| A/T ACROFLEX™/Ti ACROFLEX™/Titanio | P POLYMER Polímero | SS/RADEL™ SRTA Ti Al Nitride Acero inoxidable/RADEL™/ Nitruro de titanio y aluminio |
| A Al Aluminio | P/CM PE/CoCrMo Polietileno/ Cobalto cromo molibdeno | STA SS/Ti Al Nitride Acero inoxidable/ Nitruro de titanio y aluminio |
| A/P Al/PL Aluminio/Plástico | P/C POLYMER/CARBON FIBER COMPOSITE Polímero/Compuesto de fibra de carbono | S/U SS/ULTEM Acero inoxidable/Ultem |
| B/R Ba/RADEL Bario/RADEL | S SS Acero inoxidable | T Ti Titanio y sus aleaciones |
| CaP CALCIUM PHOSPHATE Fosfato de calcio | S/A SS/Al Acero inoxidable/Aluminio | S/R SS/RADEL™ Acero inoxidable/RADEL™ |
| CM CoCrMo Cobalto cromo molibdeno | S/BR SS/Ba/RADEL™ Acero inoxidable/ Bario/RADEL | R/T POLYOLEFIN RUBBER/Ti Goma de poliolefina/Titanio |
| CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Cobalto cromo molibdeno/ Titanio/Fosfato de calcio | S/P SS/PHENOLIC Acero inoxidable/ Resina fenólica | T/A Ti/Al Titanio/Aluminio |
| F FOAM Espuma | S/PL SS/PL Acero inoxidable/Plástico | Ti/UHMWPE/HA Titanio/Polietileno de peso molecular ultra-alto/ Hidroxiapatita |
| HA Hidroxiapatita | SRSI SS/RADEL™/ SILICONE Acero inoxidable/ RADEL™/Silicona | SS/Ti Acero inoxidable/Titanio |
| Ni/Ti Ni/Ti Níquel/Titanio | SRSN SS/RADEL™/ SILICONE/Ti Al Nitride Acero inoxidable/RADEL™/ Silicona/Nitruro de titanio y aluminio | SS/Al/SILICONE Acero inoxidable/ Aluminio/Silicona |
| PL Plástico | | S/SI SS/SILICONE Acero inoxidable/Silicona |
| P/F PL/FOAM Plástico/Espuma | | |
| PY Poliéster | | |



SV

# PEAK FRÄMRE TRYCKPLATTESYSTEM

# PEAK POLYAXIELLT FRÄMRE CERVIKALPLATTESYSTEM

# DOC VENTRALT CERVIKALSTABILISERINGS-SYSTEM

# SLIM-LOC™ FRÄMRE CERVIKALPLATTESYSTEM

# EAGLE™ FRÄMRE CERVIKALPLATTESYSTEM

# SWIFT™ FRÄMRE CERVIKALPLATTESYSTEM

# UNIPLATE™ FRÄMRE CERVIKALPLATTESYSTEM

# SKYLINE™ FRÄMRE CERVIKALPLATTSYSTEM

## VIKTIG INFORMATION TILL DEN OPERERANDE KIRURGEN

Det främre cervikala stabiliseringsimplantatet har, liksom andra interna fixationsenheter, en begränsad livslängd. Patientens aktivitetsnivå har mycket stor betydelse för denna livslängd. Patienten måste upplysas om att alla aktiviteter ökar risken för lossning, böjning, eller brott på implantatkomponenterna. Det är nödvändigt att upplysa patienter om restriktioner med avseende på deras aktiviteter under den postoperativa tiden och att undersöka patienten postoperativt för att utvärdera fusionsmassans utveckling och implantatkomponenternas status. Även om massiv benfusion äger rum kan implantatkomponenter böja sig, gå sönder eller lossna. Patienten måste därför göras medveten om att implantatkomponenter kan böja sig, gå sönder eller lossna trots att aktivitetsrestriktioner efterlevs.

Till följd av de begränsningar som anatomiska hänsynstaganden och moderna kirurgiska material medför, kan metallimplantat inte hålla i all oändlighet. Deras syfte är att utgöra ett tillfälligt internt stöd under tiden som fusionsmassan förtätas. Sannolikheten för att dessa typer av implantat ska misslyckas ökar om inget bentransplantat används eller om en pseudartros utvecklas.

Kirurgen kan besluta sig för att ta bort dessa implantat när benfusion föreligger. Risken för ett andra kirurgiskt ingrepp, liksom de risker som är förbundna med ett andra kirurgiskt ingrepp, måste tas upp med patienten. Om implantaten skulle gå sönder, måste beslutet att ta ut dem fattas av läkaren, som måste beakta patientens tillstånd och de risker som är förbundna med att det trasiga implantatet sitter kvar.

## BESKRIVNING

PEAK främre tryckplattesystem består av ett antal olika plattor och skruvar av titanlegering. Plattorna finns i längder på från 26 till 94 mm, med plats för från ett till fyra fixationssegment. I systemet ingår även 3,5 mm kortikala och 4,0 mm spongiösa titanlegeringsskruvar, i längder på från 8 till 30 mm.

PEAK polyaxiella främre cervikalplattesystem består av ett antal olika plattor och skruvar av titanlegering. De främre cervikalplattorna finns i längder på från 24 till 110 mm, med plats för från ett till fyra fixationssegment. De spongiösa skruvarna finns med diametrar på 4,0 och 4,35 mm. De är helgängade och finns i längder på från 10 till 26 mm.

Det ventrala cervikala stabiliseringssystemet DOC är ett titanlegeringssystem med plattform, platta, stav och skruvsystem som spinalkirurger använder som hjälpmedel vid korrigering av halsryggradsdefekter och för stabilisering. Det ventrala cervikala stabiliseringssystemet DOC består i fullständigt monterad form av en platta eller två sidställda stavar, förenade av plattformar som ligger på den främre vertebralytan. Systemet är förankrat till vertebra med skruvar. Implantatet ger ytterligare stabilitet åt halsryggraden efter främre cervikal fusion. Beroende på implantatkonfigurationen, kan det användas som antingen en fast (helbärande) eller en dynamisk (delbärande) konstruktion.

Följande typer av komponenter ingår i systemet: stavar, plattor, plattformar, inre och yttre benskruvar, transplantatskruvar och tvärförbindningar. Alla komponenter är tillverkade av titanlegering av implantatkvalitet, som uppfyller kraven i ASTM F-136-specifikationerna. Delmontage finns också tillgängliga för att förenkla processen för kirurgen. Dessa utgör förmonterade delkonstruktioner bestående av en plattform, en tvärförbindning, två stavar och två låsskruvar.

**Plattform:** Plattformarna är avsedda att binda samman stavarna och förankra dem vid vertebralkropparna med benskruvar. Alla plattformar kan användas med antingen massiva benskruvar (för bikortikal fixation), eller med en kombination av yttre och inre benskruvar (en ihålig yttre benskruv som används tillsammans med en massiv inre låsskruv avsedd för unikortikal fixation). Skruvvalet beror på vad läkaren föredrar. Alla plattformar är avsedda att bilda konstruktionen tillsammans med två stavar.

Plattformar finns i låsande respektive icke-låsande utföranden. Låsande plattformar har förlängningar för plattforms/tvärförbindningslåsskruvar, för att fästa plattformen vid stavarna. Låsande plattformar erfordras i den andra änden av konstruktionen, mitt emot stavhuvudena.

Om en stabil konfiguration föredras framför en dynamisk (d.v.s. dellastbärande) konfiguration, måste en låsbar plattform också användas i direkt anslutning till stavhuvudena. Om en dellastbärande konfiguration önskas, låses inte plattformen i direkt anslutning till stavhuvudena vid stavarna.

Olika plattformar finns för vinklat införande av skruven i den vertebrala kroppen. De finns i såväl låsande som icke-låsande utföranden. Dessa plattformar har en slags fena på den ena sidan, vilken förankrar vertebra inifrån diskutrymmet, för optimal placering och fixation.

Olika plattformar finns för rakt (vertikalt) skruvinförande i den vertebrala kroppen. De finns i såväl låsande som icke-låsande utförande.

Ett plattformsutförande finns för fixation av konstruktionen till ett intervertebralt transplantat. Denna plattform har en horisontell skåra och klotformad kapsling, för att ge utrymme för variationer i skruvfästet och i rörelseleden in i transplantatet.

Valet av plattform baseras på läkarens bedömning och patientanatomin.

SLIM-LOC™ främre cervikalplattesystem består av ett antal olika plattor och skruvar av titanlegering. Plattorna finns i längder på från 22 till 111 mm och i konfigurationer med 2, 3, 4, 5 eller 6 par skruvhål. SLIM-LOC-skruvarna finns med 4,5 mm diameter, antingen som självborrande i jämna längder på från 10 till 18 mm, eller som självgängande i jämna längder på från 10 till 26 mm. Skruvar med större diameter (4,8 mm) finns i längder på 12, 14 och 16 mm.

EAGLE™ främre cervikalplattesystem består av ett antal olika plattor och skruvar av titanlegering. Plattorna finns med en till sex par skruvhål, i olika länder. Skruvarna finns i olika storlekar och med olika skruvspetsgeometrier.

SWIFT™ främre cervikalplattesystem tillverkas av titanlegering och består av segmenterade plattor som låter upp till 2 mm av kontrollerat transplantat placeras mellan varje segment. Plattorna finns med ett till sex par skruvhål, i olika längder samt i två konfigurationer, för diskektomi och korpektomi. Skruvarna finns i olika storlekar och med olika skruvspetsgeometrier. En graftskruv finns tillgänglig för användning i korpectomiplattorna.

UNIPLATE™ främre cervikalplattesystem består av ett antal olika plattor och skruvar i titanlegering. De främre cervikalplattorna finns med olika längder, för ett eller två fixationssegment. Skruvarna finns i olika storlekar och med olika spetsgeometrier.

SKYLINE™ främre cervikalplattsystem består av ett antal olika plattor och skruvar av titanlegering. Plattorna finns i olika längder med två till sex par skruvhål. Skruvarna finns i olika storlekar och med olika skruvspetsgeometrier. Både fixerade och reglerbara skruvar finns för att skapa en fast, reglerbar eller hybrid konfiguration.

## RENGÖRING OCH STERILISERING

Implantat bestående av det cervikala plattstabiliseringssystemet levereras antingen sterila eller rena och icke-sterila. Kontrollera före användning att förpackningen inte är skadad när det gäller komponenter som tillhandahålls sterila.

När det gäller icke-sterila anordningar ska de i ISO 8828 eller AORN rekommenderade förfarandena för sterilisering vid sjukhuset följas för alla komponenter.

Tester utfördes för att ta fram följande REKOMMENDATIONER FÖR ÅNGSTERILISERING:

| | |
|---|---|
| Cykel | Förvakuum |
| Temperatur | 132 °C (270 °F) |
| Exponeringstid | 6 min. |

## ANVÄNDNING

Kirurgen måste inte bara vara väl förtrogen med de medicinska och kirurgiska aspekterna av implantatet, utan också vara medveten om de mekaniska och metallurgiska begränsningarna hos metalliska kirurgiska implantat. Den postoperativa vården är ytterst viktig. Patienten måste få anvisningar om metallimplantatets begränsningar och varnas för tunga lyft och kroppslig belastning på anordningen före ordentlig benläkning. Patienten bör varnas för att bristfällig efterlevnad av de postoperativa anvisningarna kan leda till att implantatet upphör att fungera, vilket i sin tur kan kräva ytterligare kirurgi för att avlägsna det.

DePuy Spine-spinalsystemkomponenter skall inte användas tillsammans med spinalsystemkomponenter från andra tillverkare.

**En korrekt placering av utvalda komponenter är av allra största betydelse för att få kontrollerad vertikal upptagning (delbärande).**

**Se handboken med de kirurgiska metoderna för detaljerade anvisningar.**

## INDIKATIONER

OBSERVERA: Enligt amerikansk (USA) lagstiftning får denna anordning endast säljas av läkare eller på läkares order.

SLIM-LOC främre cervikalplattesystem och SKYLINE™ främre cervikalplattsystem indikeras för stabilisering av halsryggraden från C2 till C7, med hjälp av unikortikal skruvfixation på vertebralelementens främre yta. De specifika kliniska indikationerna för användning av främre plattor innefattar följande: instabilitet till följd av trauma; instabilitet i samband med korrigering av cervikal lordos och kyfosdeformitet; instabilitet i samband med pseudoartros till följd av tidigare misslyckad halsryggradskirurgi; instabilitet i samband med mer omfattande rekonstruktiv kirurgi för primärtumörer eller metastatiska, maligna tumörer på halsryggraden; instabilitet i samband med en- eller flernivåkorpektomi vid framskriden, degenerativ diskåkomma, spinalkanalstenos och cervikalmyelopati.

PEAK främre tryckplattesystem, PEAK polyaxiella främre cervikalplattesystem, det ventrala cervikala stabiliseringssystemet DOC, EAGLE främre cervikalplattesystem, SWIFT främre cervikalplattesystem och UNIPLATE främre cervikalplattesystem är avsedda för främre cervikal intervertebral kroppsfixation. Dessa system är avsedda för patienter för vilka stabilitet önskas efter främre cervikalfusion, vid de indikationer som följer nedan. De avsedda behandlingsnivåerna går från C2 till T1.



Indikationerna innefattar symptomatisk cervikal spondylos, trauma, fraktur, posttraumatisk kyfos eller lordos, tumör, degenerativ disksjukdom (definierad som diskogen smärta, med degenerering av disken bekräftad av anamnes och radiografiska undersökningar), ny operation till följd av utebliven fusion, eller instabilitet efter kirurgi för ovanstående indikationer.

UNIPLATE främre cervikalplattesystem indikeras dessutom för behandling av spinalstenos.

VARNING: Dessa anordningar är inte godkända för skruvfästning eller för fästning vid de bakre cervikal-, bröstkorgs- eller ländryggradselementen (stjälkarna).

## POSTOPERATIV MOBILISERING

Tills dess att fusionsmognad har bekräftats genom radiografisk undersökning, kan extern immobilisering (exempelvis stagning) komma att rekommenderas utifrån läkarens bedömning.

Patientinstruktioner avseende minskad belastning på implantatet, utgör lika viktiga delar av ansträngningarna för att undvika uppkomsten av de kliniska problem som kan åtföljа utebliven fixation.

## KONTRAINDIKATIONER

- Aktiv systemisk infektion, eller en infektion vid platsen för den tänkta implantationen.
- Svår osteoporos kan förhindra tillräcklig fixering av skruvar, och därmed utesluta användningen av detta eller något annat spinalinstrumentsystem.
- Patienter som visat sig vara säkert och förutsägbart behandlade utan intern fixation.
- Öppna sår.

## RELATIVA KONTRAINDIKATIONER:

De relativa kontraindikationerna innefattar varje enhet eller tillstånd som helt och hållet utesluter möjligheten till fusion (t.ex. cancer, njurdialys eller osteopeni), fetma, vissa degenerativa sjukdomar, samt känslighet för främmande kroppar.

## VARNINGAR, SÄKERHETSÅTGÄRDER OCH BIVERKNINGAR RÖRANDE TILLFÄLLIGA METALLISKA INTERNA FIXATIONSANORDNINGAR.

### VARNINGAR

Nedan följer specifika varningar, säkerhetsåtgärder och biverkningar som kirurgen måste vara medveten om och som måste förklaras för patienten. Dessa varningar innefattar inte alla de negativa effekter som kan uppträda vid kirurgi i allmänhet, utan utgör viktiga beaktanden med särskilt avseende på interna fixationsenheter av metall. Allmänna kirurgiska risker ska förklaras för patienten före kirurgi.

De potentiella risker som identifierats vid användning av detta system, vilka kan kräva ytterligare kirurgi, innefattar: komponentbrott i anordningen, fixationsbortfall, utebliven läkning, vertebralfraktur, neurologisk skada, samt vaskulär eller invärtes skada.

1. **KORREKT IMPLANTATVAL ÄR YTTERST VIKTIGT.** Chanserna för tillfredsställande fixation ökas genom val av rätt implantatstorlek, -form och -utförande. Rätt val kan bidra till att minimera riskerna, men storleken och formen på patientens ben medför begränsningar av implantatets storlek, form och styrka. Interna fixationsenheter av metall står inte emot samma aktivitetsnivåer som normala, friska ben kan utsättas för. Inget implantat kan förväntas stå emot belastningen av full vikt i all oändlighet.
2. **IMPLANTAT KAN GÅ SÖNDER OM DE UTSÄTTS FÖR DE YTTERLIGARE BELASTNINGAR SOM ÄR FÖRBUNDNA MED FÖRDRÖJD LÄKNING ELLER UTEBLIVEN LÄKNING.** Anordningar för intern fixation är dellastbärande och används för att erhålla inriktning tills normal läkning äger rum. Om läkningen fördröjs, eller inte äger rum, kan implantatet till slut gå sönder till följd av metallutmattning. Läkningsgraden eller läkningens framgång, belastningar till följd av tunga bördor samt aktivitetsnivåer kommer, tillsammans med andra förhållanden, att vara avgörande för implantatets livslängd. Hack, repor eller böjning av implantatet under det kirurgiska ingreppet kan också bidra till att det förlorar sin funktion i förtid. Patienterna ska informeras till fullo om att implantatet kan upphöra att fungera.
3. **ATT BLANDA METALLER KAN FÖRORSAKA KORROSION.** Det finns många typer av korrosionsskador, och flera av dessa uppträder på metaller som implanteras kirurgiskt i människor. Allmän korrosion föreligger på alla implanterade metaller och legeringar. Korrosionsangreppets utbredningshastighet på metalliska implantatanordningar är vanligtvis mycket låg till följd av närvaron av passiva ytskikt. Olikartade metaller i kontakt med varandra, såsom titan och rostfritt stål, skyndar på korrosionsprocessen för rostfritt stål och snabbare angrepp äger rum. Förekomsten av korrosion skyndar många gånger på utmattningsbrott hos implantat. Den mängd metallföreningar som avges in i kroppssystemet kommer också att öka. Interna fixationsenheter, såsom stavar, krokar, trådar, etc., som kommer i kontakt med andra metallföremål, måste vara tillverkade av likartade eller kompatibla material.
4. **PATIENTURVAL.** Vid val av patienter för interna fixationsenheter, kan följande faktorer vara oerhört viktiga för förfarandets slutgiltiga framgång:

   A. **Patientens yrke eller verksamhet.** Om patienten har ett yrke eller ägnar sig åt en verksamhet som innefattar tunga lyft, muskelansträngningar, vridning, upprepad böjning, framåtlutning, löpning, långa sammanlagda gångsträckor, eller kroppsarbete, ska han/hon inte återvända till yrket eller verksamheten förrän benet har läkt till fullo. Även efter fullständig läkning, kan patienten eventuellt inte återvända till den tidigare verksamheten framgångsrikt.

B. **Ett allmäntillstånd karakteriserat av senilitet, mentalsjukdom, alkoholism eller drogmissbruk.** Dessa tillstånd, bland andra, kan leda till att patienten åsidosätter vissa nödvändiga begränsningar och säkerhetsåtgärder vid användningen av anordningen, vilket kan leda till att implantatets funktion går förlorad eller till andra komplikationer.

C. **Vissa degenerativa sjukdomar.** I vissa fall kan en degenerativ sjukdoms utbredning ha gått så långt vid implantationstidpunkten, att den i väsentlig grad kan komma att sätta ner anordningens förväntade livslängd. Under sådana förhållanden kan ortopediska anordningar endast betraktas som en fördröjningsteknik eller en tillfällig bot.

D. **Känslighet för främmande kroppar.** Kirurgen varnas för att ingen preoperativ test helt och hållet kan eliminera risken för överkänslighet eller allergisk reaktion. Patienten kan utveckla överkänslighet eller allergi efter det att implantatet har funnits i kroppen under en viss tid.

E. **Rökning.** Det har visat sig att patienter som röker oftare drabbas av pseudartros efter kirurgiska ingrepp där bentransplantat används. Rökning har dessutom visat sig orsaka diffus degenerering av intervertebralbrosk. Progressiv degenerering av intilliggande segment, förorsakad av rökning, kan leda till sen klinisk svikt (återkommande smärta) även efter framgångsrik fusion och initial klinisk förbättring.

**VARNING:** Om benfusion inte sker inom den förväntade tidsperioden kan skruvarna komma att brista till följd av alltför stor och ihållande belastning av anordningarna. Detta har konstaterats hos patienter med fördröjning, pseudoartros eller utebliven läkning, och kan leda till behov av revidering av anordningen eller anordningarna.

## SÄKERHETSÅTGÄRDER

1. **KIRURGISKA IMPLANTAT FÅR ALDRIG ÅTERANVÄNDAS.** Ett uttaget metallimplantat ska aldrig implanteras på nytt. Även om anordningen tycks vara oskadad så kan den ha små defekter och inre spänningsmönster, som kan leda till att den förlorar sin funktion i förtid.
2. **KORREKT HANTERING AV IMPLANTATET ÄR YTTERST VIKTIGT.** Formning av metallimplantat ska endast utföras med rätt utrustning. Den opererande kirurgen ska undvika att hacka, repa eller böja implantatet bakåt vid formning. Dylika ändringar orsakar ytdefekter och inre spänningar, som kan komma att bestämma den punkt där implantatet till slut kommer att gå av. Använd inte implantat vid misstanke om skador.

   Om dessa skruvar utsätts för alltför höga moment när plattan sätts på plats kan benfel uppstå, vilket kan resultera i förstörda gängor och/eller nedsatt skruvprestanda.
3. **BÖJNING AV KONSTRUKTIONEN.** Titanlegeringskomponenter ska aldrig böjas skarpt eller böjas bakåt. Om en konstruktion har formats för mycket rekommenderar vi att en ny konstruktion ges rätt form, snarare än tillbakaböjning av den alltför formade konstruktionen.
4. **BORTTAGNING AV IMPLANTATET EFTER LÄKNING.** Om anordningen inte tas ut när den uppfyllt sin avsedda funktion, kan någon av följande komplikationer tillstöta: (1) Korrosion, med lokaliserad vävnadsreaktion eller smärta; (2) Migration av implantatpositionen som leder till skador; (3) Risk för ytterligare skador från postoperativt trauma; (4) Böjning, lossning, och/eller brott, som kan göra uttagning ogenomförbar eller besvärlig; (5) Smärta, obehag, eller onormala förnimmelser till följd av att anordningen sitter på plats; (6) Eventuellt ökad infektionsrisk; och (7) Benförlust till följd av belastningstäckning. Kirurgen bör noga väga riskerna mot fördelarna vid beslut om huruvida implantatet ska tas ut. Implantatuttagning ska följas av lämplig postoperativ behandling, för att undvika ny fraktur eller deformitet. Om patienten är äldre och har en låg aktivitetsnivå, kan kirurgen välja att inte ta ut implantatet, och därmed eliminera de risker som ett andra kirurgiskt ingrepp innebär.
5. **INFORMERA PATIENTEN TILLRÄCKLIGT.** Den postoperativa vården, och patientens möjlighet och vilja att följa anvisningarna, är några av de allra viktigaste aspekterna av framgångsrik benläkning. Patienten måste informeras om implantatets begränsningar, och uppmanas att begränsa de fysiska aktiviteterna, särskilt lyft- och vridrörelser och allt slags idrottsutövande. Patienten ska göras medveten om att ett metalliskt implantat inte är lika starkt som ett normalt friskt ben, och att det kan komma att lossna, böjas och/eller gå sönder om alltför höga krav ställs på det, särskilt i frånvaro av fullständig benläkning. Implantat som ändrat läge eller skadats på grund av olämpliga aktiviteter kan komma att migrera och skada nerverna eller blodkärlen. En aktiv, försvagad, eller psykiskt sjuk patient, som inte på korrekt sätt kan använda hjälpmedel för avlastning, löper troligtvis de allra största riskerna vid postoperativ rehabilitering.

## EVENTUELLA BIVERKNINGAR

1. Utebliven läkning, fördröjd läkning.
2. Böjning eller brott på implantatet. Implantatlossning.
3. Metallöverkänslighet, eller allergisk reaktion på en främmande kropp.
4. Infektion, tidig eller sen.
5. Försämring av bentätheten till följd av belastningstäckning.
6. Smärta, obehag, eller onormala förnimmelser till följd av att anordningen sitter på plats.
7. Nervskador till följd av kirurgiskt trauma eller att anordningen sitter på plats. Neurologiska svårigheter innefattande radikulär smärta, nervbegränsning i ärrvävnad, muskelsvaghet och parestesi.



8. Vaskulära skador kan leda till katastrofal eller fatal blödning. Felplacerat implantat, i omedelbar närhet till stora artärer eller vener, kan komma att erodera dessa kärl och förorsaka katastrofal blödning under den sena postoperativa perioden.
9. Durala rupturer uppkomna under kirurgin kan leda till behov av ytterligare kirurgi för durala reparationer, ett kroniskt cerebrospinalvätskeläckage eller fistel, samt eventuell meningit.
10. Bursit.
11. Paralys.
12. Esofagusperforation, erosion eller irritation.
13. Skruvlossning, vilket eventuellt kan leda till esofaguserosion, implantatlossning, och/eller ny operation för att ta ut anordningen.
14. Skador på lymfkärlen och/eller lymfvätskeexsudation.
15. Ryggmärgsintrång eller -skada.
16. Brott i benstrukturer.
17. Degenerativa förändringar eller instabilitet i segment i omedelbar närhet till sammansmälta vertebralnivåer.
18. Dödsfall.

**BEGRÄNSAD GARANTI OCH ANSVARSFRISKRIVNING: DEPUY SPINE-PRODUKTER TÄCKS AV EN BEGRÄNSAD GARANTI SOM GÄLLER FÖR DEN FÖRSTA KÖPAREN, MED AVSEENDE PÅ BRISTFÄLLIGT ARBETSUTFÖRANDE OCH DEFEKTA MATERIAL. VARJE ANNAN UTTRYCKLIG ELLER UNDERFÖRSTÅDD GARANTI, INNEFATTANDE GARANTIER MED AVSEENDE PÅ SÄLJBARHET ELLER LÄMPLIGHET, AVVISAS HÄRMED.**

**OM MER ÄN TVÅ ÅR HAR GÅTT MELLAN PUBLICERINGS/REVIDERINGSDAGEN OCH KONSULTATIONSDAGEN SKA DEPUY SPINE KONTAKTAS FÖR AKTUELL INFORMATION på telefon +1-508-880-8100.**

TILLVERKAD AV EN AV FÖLJANDE:

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767-0350 USA

DePuy Spine SÀRL
Chemin Blanc, 36
CH-2400 Le Locle, Schweiz

DISTRIBUERAD I USA AV:
DePuy Spine, Inc.
325 Paramount Drive, Raynham, MA 02767-0350 USA

DISTRIBUERAD I EUROPA AV:
Codman SÀRL
Rue DeJaluse, CH-2400 Le Locle, Schweiz CE 0424

AUKTORISERAD EUROPEISK REPRESENTANT:
DePuy International, Ltd.
St. Anthony's Road, Leeds LS11 8DT Storbritannien

REVIDERAD I MAJ 2006.
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**SYMBOLNYCKEL**

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| LOT PARTINUMMER | FÖR ENGÅNGSBRUK | NONSTERILE OSTERIL | TILLVERKARE |
| REF KATALOGNUMMER | XXXX-XX TANVÄNDES FÖRE | STERILE R STERILISERAD MED STRÅLNING | EC REP AUKTORISERAD EUROPEISK REPRESENTANT |
| QTY ANTAL | SE BRUKSANVISNING | STERILE EO STERILISERAD MED ETYLENOXID | DIST DISTRIBUERAD AV |
| Rx Only Enligt amerikansk federal lagstiftning får denna anordning endast säljas av eller på order av läkare. | STERILE STERIL | MADE IN TILLVERKAD I | SZ STORLEK |

**MATERIAL** MATL

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| A/T ACROFLEX™/Ti ACROFLEX™/titan<br>A Al Aluminium<br>A/P Al/PL Aluminium/plast<br>B/R Ba/RADEL™ Barium/RADEL™<br>CaP CALCIUM PHOSPHATE Kalciumfosfat<br>CM CoCrMo Kobolt-krom-molybden<br>CMTC CoCrMo/Ti/CALCIUM PHOSPHATE Kobolt-krom-molybden/titan/kalciumfosfat<br>F FOAM Skumplast<br>HA Hydroxiapatit<br>NiTi Ni/Ti Nickel/titan<br>PL Plast<br>P/F PL/FOAM Plast/skumplast | PY Polyester<br>P POLYMER Polymer<br>P/CM PE/CoCrMo Polyetylen/kobolt-krom-molybden<br>P/C POLYMER/CARBON FIBER COMPOSITE Polymer/kolfiberkomposit<br>S SS Rostfritt stål<br>S/A SS/Al Rostfritt stål/aluminium<br>SBR SS/Ba/RADEL™ Rostfritt stål/barium/RADEL™<br>S/P SS/PHENOLIC Rostfritt stål/fenol<br>S/PL SS/PL Rostfritt stål/plast<br>SRSI SS/RADEL™/ SILICONE Rostfritt stål/RADEL™/silikon<br>SRSN SS/RADEL™/ SILICONE/Ti Al Nitride Rostfritt stål/RADEL™/silikon/titan-aluminium-nitrid | SRTA SS/RADEL™/ Ti Al Nitride Rostfritt stål/RADEL™/titan-aluminium-nitrid<br>STA SS/Ti Al Nitride Rostfritt stål/titan-aluminium-nitrid<br>S/U SS/ULTEM Rostfritt stål/ultem<br>T Ti Titan och titanlegeringar<br>S/R SS/RADEL™ Rostfritt stål/RADEL™<br>R/T POLYOLEFIN RUBBER/Ti Polyolefingummi/titan<br>T/A Ti/Al Titan/aluminium<br>Ti/UHMWPE/HA Titan/polyetylen med ultrahög molekylvikt/hydroxiapatit<br>SS/Ti Rostfritt stål/titan<br>SS/Al/SILICONE Rostfritt stål/aluminium/silikon<br>S/Si SS/SILICONE Rostfritt stål/silikon |

**Media Contact:** Thomas Listerman
WeissComm Partners
415-946-1070
tlisterman@wcpglobal.com

## PEAK Surgical Receives 510(k) Clearance to Market PEAK® Surgery System for Use in General Surgery

*-- Tissue Dissection System Represents Important Advance in Radiofrequency Surgical Technologies --*

PALO ALTO, Calif. (July 24, 2008) – PEAK Surgical, Inc., a medical device company that has developed a new tissue dissection system based on a proprietary technology, today announced that the U.S. Food and Drug Administration has granted the company 510(k) clearance to market its PEAK® Surgery System for use in general surgery. The PEAK Surgery System combines the PULSAR™ Generator, which supplies pulsed plasma radiofrequency energy, with the PEAK PlasmaBlade™ 4.0, a low-temperature surgical cutting and coagulation tool. This tissue dissection system will be commercially available next month.

"With the introduction of the PlasmaBlade, general surgeons now have access to a single surgical tool that cuts tissue as precisely as a scalpel and controls bleeding as effectively as traditional electrosurgery without causing extensive collateral thermal damage to tissues," said John Tighe, chief executive officer of PEAK Surgical.

In preparation for the commercialization of the PEAK Surgery System, the company launched a redesigned corporate Web site, which can be accessed at www.peaksurgical.com. The Web site provides detailed information about all of the components of the PEAK Surgery System, including a cart and wireless foot switch, as well as video, a brochure, fact sheets, product images, scientific literature and surgeon testimonials, among other information.

**Benefits of the PlasmaBlade and PULSAR Generator**

For decades, surgeons have relied on scalpels to cut skin and delicate tissues and used electrosurgical devices to cut and coagulate fat and other thicker, tougher tissues. Although scalpels precisely cut tissue, they do not control bleeding. Electrosurgical devices, on the other hand, cut efficiently and control bleeding but can cause extensive thermal damage to surrounding tissue. In cases where the risk of collateral damage or scarring from electrosurgery is considered to be unacceptable, surgeons must use both a traditional scalpel for cutting and an electrosurgery device for coagulation. The PlasmaBlade combines into a single surgical tool the precision of a scalpel and the bleeding control of a traditional electrosurgery device.

Unlike most radiofrequency-based surgical products that use continuous voltage waveforms to cut tissue, the PULSAR Generator supplies pulsed plasma-mediated electrical discharges through the PlasmaBlade. Because the radiofrequency is provided in short on-and-off pulses and the blade contains highly insulated electrodes, the PlasmaBlade cuts tissue at an average temperature that is half that of a conventional electrosurgery device and can be as low as 50 degrees Centigrade. This temperature reduction results in reduced heat transfer and half the

EXHIBIT
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PENGAD 800-631-6989

damage to surrounding tissues compared with traditional electrosurgical devices. The PlasmaBlade also can dissect tissue in a wet or dry surgical field.

The pulsed plasma-mediated discharges and electrode insulation techniques were originally developed at the Hansen Experimental Physics Laboratory and Department of Ophthalmology at Stanford University.

"Surgeons typically must switch between a scalpel and a traditional electrosurgery device depending on the surgical field and type of tissue they are cutting," said Dr. Thomas M. Krummel, professor and chair of surgery at Stanford University School of Medicine. "I believe the PlasmaBlade has the potential to revolutionize the way surgery is performed because it eliminates the need to change from one surgical tool to another as a surgeon cuts through all types of soft tissue, including skin, fat and muscle. It also has the ability to cut in a wet or dry surgical field, an advancement over most electrosurgical tools in use today."

**PlasmaBlade Study Results**

Results of a preclinical surgical incision healing study of the PlasmaBlade presented in an oral presentation at the American College of Surgeons' Annual Clinical Congress in October 2007 demonstrated that it efficiently cut tissue with effective bleeding control and minimal thermal damage compared with standard surgical techniques. The PlasmaBlade reduced bleeding by 60 percent compared with a scalpel, while providing the same positive wound healing profile of minimal scarring and inflammation. In addition, surgical incision healing and strength were significantly improved with the PlasmaBlade compared with traditional electrosurgical devices.

Additional preclinical studies of the PEAK Surgery System are underway. PEAK Surgical is exploring the applicability of its technology across numerous surgical fields beyond general surgery, including cardiothoracic, gynecologic, plastic and reconstructive and neurosurgery. The company believes the technology may have applications in more than 2 million surgical procedures each year.

**About PEAK Surgical, Inc.**

PEAK Surgical, Inc. is a medical device company that has developed the PEAK® Surgery System, a new tissue dissection system based on a proprietary technology that represents an evolutionary leap in the advancement of radiofrequency surgical technologies. The PEAK Surgery System consists of the PEAK PlasmaBlade™ 4.0, a disposable cutting tool that offers the exacting control of a scalpel and the bleeding control of traditional electrosurgery without the extensive collateral damage, and the PULSAR™ Generator, which supplies pulsed plasma radiofrequency energy to the PlasmaBlade. The PEAK Surgery System is cleared for use in general surgery in the United States. The company is exploring the applicability of this technology across additional surgical fields, including cardiothoracic, gynecologic, plastic and reconstructive, and neurosurgery. For more information, please visit www.peaksurgical.com.

# # #

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2008

PEAK Surgical, Inc.
% Grace A. Carlson, MD
2464 Embarcadero Way
Palo Alto, California 94303

Re: K073057
Trade/Device Name: PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 20, 2008
Received: June 23, 2008

Dear Dr. Carlson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073057 p. 1 of 1

## Indications for Use

510(k) Number (if known): _____

Device Name: PULSAR™ Generator and
PEAK PlasmaBlade™ Tissue Dissection Device

Indications for Use:

The PULSAR Generator with the PEAK PlasmaBlade Tissue Dissection Device is intended to be used for cutting and coagulation of soft tissue during surgical procedures.

| | | |
|---|---|---|
| Prescription Use __X__<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number_____

# Certificate

# Full Quality Assurance

## No. CE 540861

Issued to:

**PEAK Surgical, Inc.**
**2464 Embarcadero Way**
**Palo Alto**
**California**
**94303**
**USA**

In respect of:

**Design, development and manufacture of the PEAK PULSAR electrosurgical generator, PULSAR wireless footswitch, and PlasmaBlade tissue dissection devices**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

David Ford, Managing Director, BSI Product Services

First Issued: **16 Jan 2009** Date: **16 Jan 2009**

Expiration Date: **15 Jan 2014**



*Conditions of Approval*
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

*raising standards worldwide™*

PENGAD 800-631-6989 EXHIBIT Pe Puy 11

BSI

# Certificate

# List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 540861**

Date: **16 Jan 2009**

Issued to: **PEAK Surgical, Inc.**
**Palo Alto**
**USA**

| Subcontractor | Service(s) supplied |
|---|---|
| Paragon MedSystems LLC<br>15920 BernardoCentre Drive<br>San Diego,<br>California<br>USA<br>92127 | Manufacture |
| Sterigenics<br>4900 Gifford Avenue<br>Los Angeles<br>California<br>USA<br>90058 | Sterilization |



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PEAK0981

# Certificate

# History of Quality Assurance Certificate

**Certificate No:** CE 540861
**Issue Date:** 16 Jan 2009
**Issued to:** PEAK Surgical, Inc.
Palo Alto
USA

| Date | Reference Number | Action |
|---|---|---|
| 16 January 2009 | 7252159 | First issue |



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PEAK0982

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 03 2008

Peak Surgical, Inc.
% Grace A. Carlson, MD
Consultant, Regulatory and Clinical Affairs
2464 Embarcadero Way
Palo Alto, California 94303

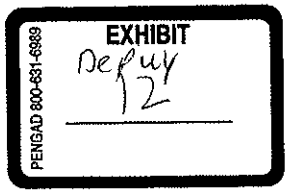
Re: K082786
Trade/Device Name: PEAK Surgery System (PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection Devices
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 22, 2008
Received: September 23, 2008

Dear Dr. Carlson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set



forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K082786

Device Name: PEAK Surgery System (PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection Devices

Indications for Use:

The PEAK Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mrm

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K082786

Media Contact: Jani Bergan
WeissComm Partners
415-946-1064
jbergan@wcpglobal.com

## PEAK Surgical Names John Cifarelli Vice President, Sales

*Seasoned Executive Ready To Develop Sales Team*

PALO ALTO, Calif. (April 15, 2008) – PEAK Surgical, Inc., a medical device company that is developing a new category of tissue dissection systems based on a proprietary technology, has selected John Cifarelli to establish and lead the company's sales team as its vice president of sales. Cifarelli and his team will sell the company's PEAK® Surgery System once the pre-market notification (510k) has been cleared by the U.S. Food and Drug Administration.

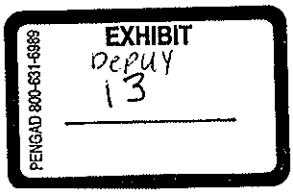
"John is a seasoned medical device executive with more than 20 years in the industry. Not only is he a proven leader, having managed sales, marketing, field engineers and customer service groups, but he also has developed key partnerships that have maximized product revenue," said John Tighe, president and chief executive officer of PEAK Surgical. "We are confident that John will help us create and grow a top-notch sales force with the experience necessary to quickly commercialize our PEAK Surgery System."

Cifarelli joins PEAK Surgical from NeoGuide Systems, Inc., a developer of technology to prevent and treat colorectal cancer, where he served as vice president of sales. Prior to that, he was executive vice president of sales and marketing for CDx Laboratories, Inc., a specialty pathology laboratory focused on gastroenterology and otolaryngology. Before joining CDx Laboratories, he spent 18 years at Olympus America, where he held several positions, including vice president and general manager of the Surgical Products Group. In that position, he created strategies that resulted in significant growth and profitability.

"I am excited to work with the PEAK Surgical management team to help them bring the PEAK Surgery System to market because I believe it has great potential to revolutionize the way surgery is performed today," Cifarelli said.

Cifarelli began his career as a sales representative at C.R. Bard in the urology division and at the 3M Company. He has consulted for several medical device companies, developing business plans, sales channels and marketing strategies. He holds a bachelor of science degree from Marist College.

**About PEAK Surgical, Inc.**
PEAK Surgical, Inc. is a medical device company that has developed the PEAK® Surgery System, a new tissue dissection system based on a proprietary technology that represents an important advance in radiofrequency surgical technologies. The PEAK Surgery System consists of the PEAK PlasmaBlade™, a family of disposable cutting devices that offer the exacting control of a scalpel and the bleeding control of traditional electrosurgery without extensive



collateral damage, and the PULSAR® Generator, which supplies pulsed plasma radiofrequency energy to the PlasmaBlade. The PEAK Surgery System is cleared for use in general, plastic and reconstructive, ENT, gynecologic, orthopedic, arthroscopic, spinal and neurological surgical procedures in the United States, and for use in general surgery in the EU. For more information, please visit www.peaksurgical.com.

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# # #

October 17, 2006

VIA FAX

Jennifer Lee Taylor, Esq.
Morrison & Foerster
425 Market Street
San Francisco, CA 94105-2482

Re: Trademark PEAK

Dear Ms. Taylor:

We reply to your letter dated September 18, 2006 requesting whether our client, Carl Zeiss AG, would either submit for cancellation, or assign to Peak Surgical, Inc., Zeiss' Canadian, Mexican, German, Irish, Australian and International registrations of the trademark PEAK.

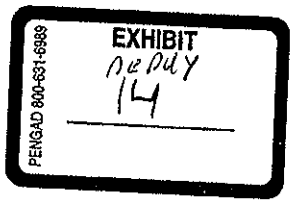
Our client has informed us that, in the spirit of cooperation, it is willing to assign all those registrations to Peak Surgical provided that it reimburses our client for the official fees and attorneys' fees for the assignment of the Canadian, Mexican, Irish and Australian registrations.

Please let me know if this arrangement is acceptable to your client.

Very truly yours,

V. T. Giordano

VTG/jf



December 1, 2006

VIA FAX

Jennifer Lee Taylor, Esq.
Morrison & Foerster
425 Market Street
San Francisco, CA 94105-2482

Re: Trademark PEAK

Dear Ms. Taylor:

Our client, Carl Zeiss AG, has consented to your request that you prepare a global assignment of its PEAK registrations to Peak Surgical, Inc.

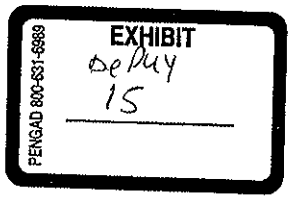
Attached is a schedule listing all its PEAK registrations, and a pending application in Brazil (which I assume your client will also want to acquire).

Please send us the appropriate documents in due course.

Very truly yours,

V. T. Giordano

VTG/jf
Enc.



MORRISON | FOERSTER

425 MARKET STREET
SAN FRANCISCO
CALIFORNIA 94105-2482
TELEPHONE:415.268.7000
FACSIMILE:415.268.7522
WWW.MOFO.COM

MORRISON & FOERSTER LLP
NEW YORK, SAN FRANCISCO,
LOS ANGELES, PALO ALTO,
SAN DIEGO, WASHINGTON, D.C.
DENVER, NORTHERN VIRGINIA,
ORANGE COUNTY, SACRAMENTO,
WALNUT CREEK, CENTURY CITY
TOKYO, LONDON, BEIJING,
SHANGHAI, HONG KONG,
SINGAPORE, BRUSSELS

September 18, 2006

Writer's Direct Contact
415.268.6538
JTaylor@mofo.com

By UPS

NOTHING ENTERED
IN DOCKET

Vito T. Giordano
Von Maltitz Derenberg Kunin Janssen & Giordano
60 East 42nd Street
New York, NY 10165

Re: PEAK Trademark
Our Ref.: 59599-6001.000

Dear Mr. Giordano:

I am contacting you because you are listed as the attorney of record for various U.S. trademark filings for Carl Zeiss AG.

Morrison & Foerster LLP represents Peak Surgical, Inc. in connection with its intellectual property matters. Peak Surgical, Inc. currently holds a license from Stanford University under which Peak Surgical is permitted to use a particular patented technology (a medical device used for tissue cutting, tissue resectioning, hemostasis, and coagulation of blood vessels ), as well as to use and to file applications to register the PEAK trademark in connection with the medical device.

Carl Zeiss AG previously held an exclusive license to the patented technology (the license began on December 15, 1999 and concluded on August 17, 2004). During the period of the license, Carl Zeiss AG was permitted to use the PEAK trademark as long as it was actively marketing and selling products displaying the trademark. It appears that Carl Zeiss AG also proceeded to register the PEAK trademark in a number of countries for use in connection with the licensed technology, as listed below:

1. Canadian registration for PEAK for avalanche knives.

2. Mexican registration for PEAK for surgical instruments.

3. German registration for PEAK for surgical instruments.

4. Irish registration for PEAK for unspecified medical devices.

EXHIBIT
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5. Australian registration for PEAK for unspecified medical devices.

6. International Registration for PEAK for unspecified medical devices in the following countries: Austria, Benelux, Switzerland, Spain, Italy, Portugal, Denmark Finland, Greece and Sweden.

After entering into its agreement with Stanford University, Peak Surgical commenced applying to register the PEAK trademark for use in connection with the medical device in a number of countries. We are concerned that some of the registrations owned by Carl Zeiss may be cited against the Peak Surgical applications.

Because Carl Zeiss is no longer permitted to use the PEAK name in connection with the device, Dr. Grace Carlson of Peak Surgical contacted Dr. Hans-Joachim Miesner at Carl Zeiss in July to determine if the PEAK registrations could either be submitted for cancellation or assigned to Peak Surgical. Despite several e-mail messages from Dr. Miesner, my client has not received a substantive response to her inquiry.

I am writing today to determine if you could provide us with the name of a contact in the Carl Zeiss AG legal department to whom we can address our inquiry. My client is anxious to resolve this issue as quickly as possible so that it can be sure that it will be able to use and register the PEAK trademark in the relevant jurisdictions.

I look forward to your response.

Very truly yours,

Jennifer Lee Taylor

S9599-0500.000

VON MALTITZ, DERENBERG, KUNIN, JANSSEN & GIORDANO

60 EAST 42ND STREET
NEW YORK, N. Y. 10165

TELEPHONE (212) 661-1400
FAX (212) 370-1819

October 17, 2006

VIA FAX

Jennifer Lee Taylor, Esq.
Morrison & Foerster
425 Market Street
San Francisco, CA 94105-2482

TRADEMARK DOCKET
OCT 18 2006

Re: Trademark PEAK

Dear Ms. Taylor:

We reply to your letter dated September 18, 2006 requesting whether our client, Carl Zeiss AG, would either submit for cancellation, or assign to Peak Surgical, Inc., Zeiss' Canadian, Mexican, German, Irish, Australian and International registrations of the trademark PEAK.

Our client has informed us that, in the spirit of cooperation, it is willing to assign all those registrations to Peak Surgical provided that it reimburses our client for the official fees and attorneys' fees for the assignment of the Canadian, Mexican, Irish and Australian registrations.

Please let me know if this arrangement is acceptable to your client.

Very truly yours,

V. T. Giordano

V. T. Giordano

VTG/jf

EXHIBIT
DePuy
17
PENGAD 800-631-6989

MORRISON | FOERSTER

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TELEPHONE: 415.268.7000
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MORRISON & FOERSTER LLP
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ORANGE COUNTY, SACRAMENTO,
WALNUT CREEK, CENTURY CITY
TOKYO, LONDON, BEIJING,
SHANGHAI, HONG KONG,
SINGAPORE, BRUSSELS

October 19, 2006

Writer's Direct Contact
415.268.6538
JTaylor@mofo.com

By Facsimile

Vito T. Giordano
Von Maltitz Derenberg Kunin Janssen & Giordano
60 East 42nd Street
New York, NY 10165

Re: PEAK Trademark
Our Ref.: 59599-6001.000

Dear Mr. Giordano:

Thank you for your letter of October 17, 2006.

My client was delighted to hear that Carl Zeiss AG would assign the PEAK trademark registrations to it, and agrees to reimburse your client for any official fees and attorneys' fees for the assignments.

Since I sent you my letter of September 18, 2006, we have learned that Carl Zeiss AG also has a pending application for PEAK in Brazil. We have been told that it will be cited against my client's Brazilian applications for PEAK. To simplify matters, can you provide me with a list of PEAK trademark applications and registrations owned by Carl Zeiss AG? I can then prepare a global assignment document for signature by Carl Zeiss and I can also contact associates in the relevant countries to determine what other documents, if any, will be required to record the assignments.

Thank you for your assistance in this matter.

Very truly yours,

Jennifer Lee Taylor

NOTHING ENTERED
IN DOCKET

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sf-2213051

S9599-6000.000

VON MALTITZ, DERENBERG, KUNIN, JANSSEN & GIORDANO

60 EAST 42ND STREET
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TELEPHONE (212) 661-1400
FAX (212) 370-1819

December 1, 2006

VIA FAX

Jennifer Lee Taylor, Esq.
Morrison & Foerster
425 Market Street
San Francisco, CA 94105-2482

Re: Trademark PEAK

Dear Ms. Taylor:

Our client, Carl Zeiss AG, has consented to your request that you prepare a global assignment of its PEAK registrations to Peak Surgical, Inc.

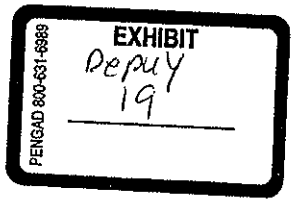
Attached is a schedule listing all its PEAK registrations, and a pending application in Brazil (which I assume your client will also want to acquire).

Please send us the appropriate documents in due course.

Very truly yours,

V. T. Giordano

VTG/jf
Enc.



| Mark | Country | Application No. | Registration No. | Expiry Date |
|---|---|---|---|---|
| PEAK | Germany | | 30087001 | 30.11.2010 |
| PEAK | International (Austria, Benelux, Spain, Italy, Portugal, Switzerland, Denmark, Finland, Greece, Great Britain, Sweden) | | 762103 | 19.06.2011 |
| PEAK | Argentina | | 1886102 | 19.09.2012 |
| PEAK | Australia | | 866873 | 20.02.2011 |
| PEAK | Brazil | 823700895 | | |
| PEAK | Canada | | 606803 | 01.04.2019 |
| PEAK | Ireland | | 223368 | 20.02.2011 |
| PEAK | Mexico | | 815515 | 03.04.2011 |
| PEAK | USA | | 2679873 | 28.01.2013 |

24/11/2006 12:45 CARL - 'SS,OBERKOCHEN K-RP → 00012123701P19 NUM156 P002

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SINGAPORE, BRUSSELS

December 21, 2006

Writer's Direct Contact
415.268.6538
JTaylor@mofo.com

*By Overnight Delivery*

V. T. Giordano
von Maltitz, Derenberg, Kunin, Janssen & Giordano
60 East 42nd Street
New York, NY 10165

**Re: Assignment of PEAK registrations (and pending application) from Carl Zeiss AG to PEAK Surgical, Inc.**

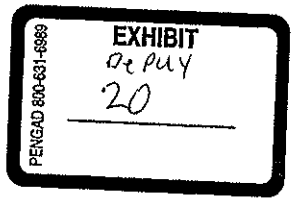
Dear Mr. Giordano:

Thank you for your letter of December 1, 2006, in which you confirmed the consent of your client, Carl Zeiss AG ("Carl Zeiss"), to globally assign its PEAK registrations to our client, PEAK Surgical, Inc. ("PEAK Surgical"). As you assumed, PEAK Surgical would also like to acquire the rights to the pending trademark application in Brazil.

Enclosed please find the following documents in connection with the global assignment of the PEAK mark registrations (and related pending application) to PEAK Surgical:

1. *Assignment*. Four (4) copies of the Assignment are enclosed, as it is our understanding that an original Assignment must be filed in Argentina, Brazil, and Mexico. Each Assignment has been signed by PEAK Surgical and must be signed by Carl Zeiss. The Assignment is dated 2007, as we expected that your client would not sign it before the new year begins. Please note that the Assignments for the marks registered (or pending registration) in Argentina, Brazil, and Mexico must be notarized and legalized.

2. *Form MM5*. The Form MM5 must be submitted to the World Intellectual Property Organization in order to effect the assignment of the International registration of the PEAK mark. Carl Zeiss must complete section 8 of the Form MM5. Please note that PEAK Surgical has signed section 5 of the Form MM5.



Please arrange for your client to execute the forms, and to notarize and legalize them where required. I believe that your client intends to submit some of the forms directly to the appropriate trademark offices and that we will handle the remainder. Please confirm the countries to which your client prefers to submit the forms. Do not hesitate to contact me if you have questions or need any assistance in this matter.

Sincerely,

Jennifer Lee Taylor

Enclosures

## ASSIGNMENT

**WHEREAS**, Carl Zeiss AG, a German corporation with its principal place of business located at 73447 Oberkochen, Germany ("**Assignor**"), is the sole owner of all rights, title and interest in and to the trademarks listed in the attached **Exhibit A** (the "**Trademarks**"); and

**WHEREAS**, Assignor wishes to assign all rights, title and interest in and to the Trademarks to PEAK Surgical, Inc., a Delaware corporation with its principal place of business located at 2464 Embarcadero Way, Palo Alto, CA 94303 ("**Assignee**"), and Assignee wishes to accept such assignment;

**NOW, THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Assignor hereby assigns, grants, transfers and conveys (and agrees to assign, grant, transfer and convey) to Assignee, its successors and assigns all right, title and interest throughout the world in and to the Trademarks, together with all national, foreign, state and common law registrations, applications for registration and renewals and extensions thereof; all goodwill associated therewith; and all benefits, privileges, causes of action and remedies relating to any of the foregoing, whether before or hereafter accrued (including, without limitation, the exclusive rights to apply for and maintain all such registrations, renewals and/or extensions; to sue for all past, present or future infringements or other violations of any rights in the Trademarks; and to settle and retain proceeds from any such actions).

Assignor also agrees to execute such written instruments, extend such other cooperation and perform such other acts as may be necessary, in the opinion of Assignee, to register a trademark or otherwise enforce Assignee's rights in the Trademarks; and Assignor hereby irrevocably appoints Assignee and any of its officers as Assignor's attorney in fact to undertake such acts in Assignor's name.

This assignment agreement constitutes the entire agreement between Assignor and Assignee concerning the subject matter hereof and supersedes all prior or contemporaneous discussions, communications and agreements, whether oral or written, between Assignor and Assignee relating to the subject matter hereof.

**IN WITNESS THEREOF**, the Assignor has executed this document by the name of its duly authorized officer, as of _____, 2007.

**CARL ZEISS AG**

By: _____

Name: _____

Title: _____

**PEAK SURGICAL, INC.**

By: Grace A Carlson MD

Name: Grace A. Carlson

Title: VP Regulatory + Clinical Affairs

## EXHIBIT A

## TRADEMARKS

| Mark | Country | Application No. | Registration No. | Expiry Date |
|---|---|---|---|---|
| PEAK | Germany | | 30087001 | 30.11.2010 |
| PEAK | International (Austria, Benelux, Spain, Italy, Portugal, Switzerland, Denmark, Finland, Greece, Great Britain, Sweden) | | 762103 | 19.06.2011 |
| PEAK | Argentina | | 1886102 | 19.09.2012 |
| PEAK | Australia | | 866873 | 20.02.2011 |
| PEAK | Brazil | 823700895 | | |
| PEAK | Canada | | TMA606803 | 01.04.2019 |
| PEAK | Ireland | | 223368 | 19.02.2011 |
| PEAK | Mexico | | 815515 | 03.04.2011 |
| PEAK | USA | | 2679873 | 28.01.2013 |

RECEIVED
JAN 30 2007
J. TAYLOR
S9599-6000.000

Carl Zeiss AG 73446 Oberkochen

MORRISON FOERSTER
Attn.: Mrs. Jennifer Lee Taylor
425 Market Street
San Francisco
California 94105-2482
USA

Division/Dept.: Corporate Legal Affairs
Your contact: Mrs. Bolsinger

Carl Zeiss AG

Carl-Zeiss-Strasse 22
73447 Oberkochen
Germany

Phone: +49 73 64 20-2225
Fax: +49 73 64 20-3911
E-mail: c.bolsinger@zeiss.de
I W 473 USA

Your ref.:
Yours of:
Our ref.: Boi/Eder
Date: 23.1.2007

## "PEAK" Trademarks

Dear Mrs. Taylor:

Mr. Giordano conveyed your letter of December 21, 2006 to me. Before arranging for signature of the assignment forms I need some more information.

You sent us four copies of the assignment, executed by PEAK Surgical Inc. Do you expect us to have three forms (for Argentina, Brazil and Mexico) signed, notarized and legalized? If the remaining assignment form is the "overall" one, can we keep that in our file?

We will arrange for signature of form MM5 and submission to WIPO. Moreover we believe it would be prudent that we arrange for the assignment of the German registration and inform our foreign trademark attorneys that we have assigned the "PEAK" trademark to PEAK Surgical Inc. and that you will get into contact with them regarding the assignment procedure; do you agree?

Best regards
Carl Zeiss AG
Corporate Legal Affairs
Claudia Bolsinger

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ORANGE COUNTY, SACRAMENTO,
WALNUT CREEK, CENTURY CITY

TOKYO, LONDON, BEIJING,
SHANGHAI, HONG KONG,
SINGAPORE, BRUSSELS

January 30, 2007

Writer's Direct Contact
415.268.6538
JTaylor@mofo.com

*Via Air Mail*

Claudia Bolsinger
Carl Zeiss AG
Carl-Zeiss-Strasse 22
73447 Oberkochen
Germany

Re: Assignment of PEAK Trademark Registrations

Dear Mrs. Bolsinger:

We received your letter requesting further information regarding the forms necessary to assign the PEAK trademark registrations to our client, PEAK Surgical, Inc.

With respect to the assignment agreements for Argentina, Brazil, and Mexico, we would greatly appreciate it if you would have those assignments signed by Carl Zeiss AG, and then notarized and legalized.

The remaining assignment is for your records. Please send a copy of the fully executed assignment to my attention.

Finally, we would be delighted to work with your foreign trademark attorneys on the German registration. After you have arranged for the assignment of the German registration, please give us the contact information for your foreign trademark attorneys and their reference number for the matter.

Should you have any further questions, please do not hesitate to contact me.

Sincerely,

Jennifer Lee Taylor

sf-2262411

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PENGAD 800-631-6989