PETITIONERS' DEMONSTRATIVE

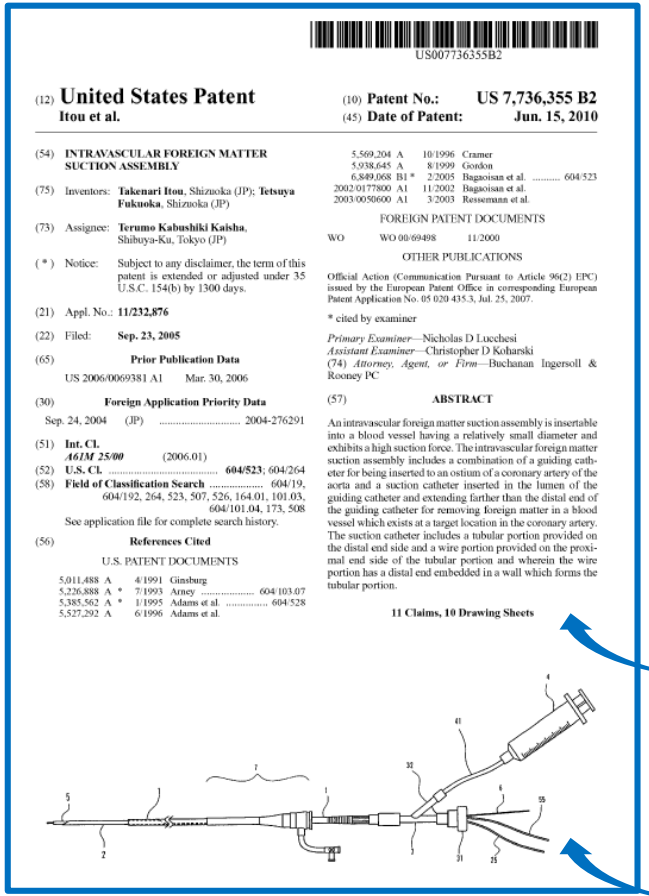
Medtronic, Inc. and Medtronic Vascular, Inc. v. Teleflex Innovations S.A.R.L.

CONCEPTION AND REDUCTION TO PRACTICE

IPR2020-00126, -00128, -00129, -00132,
-00134, -00135, -00137

March 8, 2021
ORAL HEARING

Conception and Reduction to Practice



US007736355B2

(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent: Jun. 15, 2010**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1300 days.

(21) Appl. No.: **11/232,876**

(22) Filed: **Sep. 23, 2005**

(65) **Prior Publication Data**

US 2006/0069381 A1 Mar. 30, 2006

(30) **Foreign Application Priority Data**

Sep. 24, 2004 (JP) 2004-276291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526, 164.01, 101.03, 604/101.04, 173, 508
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,011,488	A	4/1991	Ginsburg	
5,226,888	A *	7/1993	Arney	604/103.07
5,385,562	A *	1/1995	Adams et al.	604/528
5,527,292	A	6/1996	Adams et al.	
5,569,204	A	10/1996	Cramer	
5,938,645	A	8/1999	Gordon	
6,849,068	B1 *	2/2005	Bagaoisan et al.	604/523
2002/0177800	A1	11/2002	Bagaoisan et al.	
2003/0050600	A1	3/2003	Ressmann et al.	

FOREIGN PATENT DOCUMENTS

WO WO 00/69498 11/2000

OTHER PUBLICATIONS

Official Action (Communication Pursuant to Article 96(2) EPC) issued by the European Patent Office in corresponding European Patent Application No. 05 020 435.3, Jul. 25, 2007.

* cited by examiner

Primary Examiner—Nicholas D Lucchesi
Assistant Examiner—Christopher D Koharski
(74) *Attorney, Agent, or Firm*—Buchanan Ingersoll & Rooney PC

(57) **ABSTRACT**

An intravascular foreign matter suction assembly is insertable into a blood vessel having a relatively small diameter and exhibits a high suction force. The intravascular foreign matter suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery. The suction catheter includes a tubular portion provided on the distal end side and a wire portion provided on the proximal end side of the tubular portion and wherein the wire portion has a distal end embedded in a wall which forms the tubular portion.

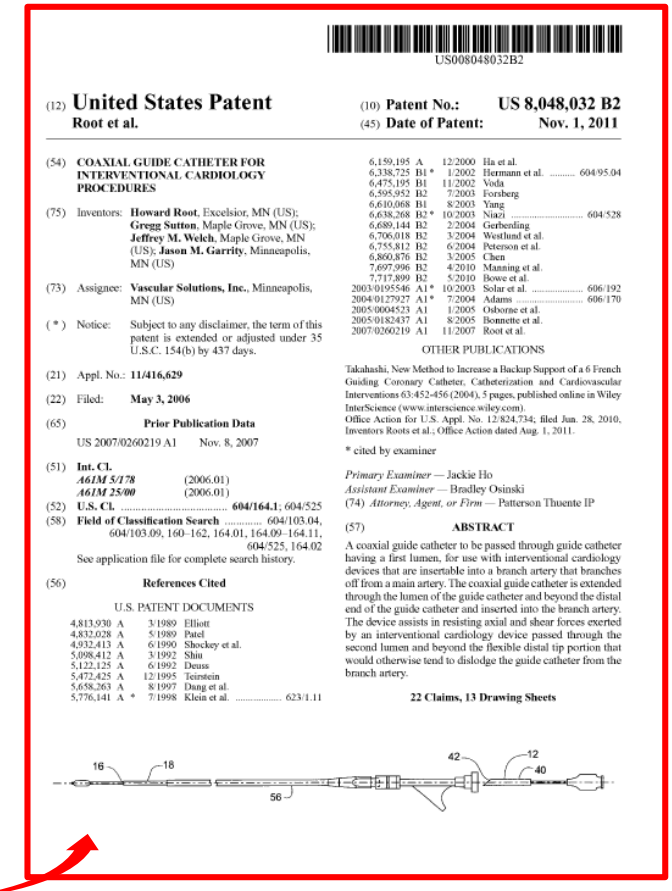
11 Claims, 10 Drawing Sheets

Filed: **Sep. 23, 2005**

Filed: **May 3, 2006**

Conception and Reduction to Practice before Itou

Conception before Itou and Diligence until Root



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 437 days.

(21) Appl. No.: **11/416,629**

(22) Filed: **May 3, 2006**

(65) **Prior Publication Data**

US 2007/0260219 A1 Nov. 8, 2007

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/164.1**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.09–164.11, 604/525, 164.02
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,813,930	A	3/1989	Elliott	
4,832,028	A	5/1989	Patel	
4,932,413	A	6/1990	Shockey et al.	
5,098,412	A	3/1992	Shiu	
5,122,125	A	6/1992	Deuss	
5,472,425	A	12/1995	Teirstein	
5,658,263	A	8/1997	Dang et al.	
5,776,141	A *	7/1998	Klein et al.	623/1.11
6,159,195	A	12/2000	Ha et al.	
6,338,725	B1 *	1/2002	Hermann et al.	604/95.04
6,475,195	B1	11/2002	Voda	
6,595,952	B2	7/2003	Forsberg	
6,610,068	B1	8/2003	Yang	
6,638,268	B2 *	10/2003	Niazi	604/528
6,689,144	B2	2/2004	Gerberding	
6,706,018	B2	3/2004	Westlund et al.	
6,755,812	B2	6/2004	Peterson et al.	
6,860,876	B2	3/2005	Chen	
7,697,996	B2	4/2010	Manning et al.	
7,717,899	B2	5/2010	Bowe et al.	
2003/0195546	A1 *	10/2003	Solar et al.	606/192
2004/0127927	A1 *	7/2004	Adams	606/170
2005/0004523	A1	1/2005	Osborne et al.	
2005/0182437	A1	8/2005	Bonnette et al.	
2007/0260219	A1	11/2007	Root et al.	

OTHER PUBLICATIONS

Takahashi, New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages, published online in Wiley InterScience (www.interscience.wiley.com).
Office Action for U.S. Appl. No. 12/824,734; filed Jun. 28, 2010, Inventors Roots et al.; Office Action dated Aug. 1, 2011.

* cited by examiner

Primary Examiner — Jackie Ho
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente IP

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

22 Claims, 13 Drawing Sheets

Teleflex cannot prove prior invention before Itou.

- Unclear conception timeline.
- No evidence corroborating assembly or testing of RX prototypes.
- Evidence showing VSI back-burnered RX and could not have reduced to practice before Itou.

Teleflex must prove prior invention.

Teleflex "must either **prove** (1) a conception and reduction to practice . . . or (2) a conception before the filing date of [Itou] combined with diligence."

REG Synthetic Fuels, LLC v. Neste Oil Oyj, 841 F.3d 954, 958 (Fed. Cir. 2016).

Teleflex bears "the burden of **going forward with evidence** . . . and **presenting persuasive argument** based on" that evidence."

Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375, 1379 (Fed. Cir. 2015).

If the Board is uncertain about the CRTP evidence, then **Teleflex has not satisfied its burden**.

Petitioners' CRTP Sur-Sur-Reply at 1-2.

Teleflex must prove prior invention claim-by-claim.

Teleflex must "establish prior [invention] of **every claim limitation**"—referencing claim-by-claim charts "fail[s] to meet this burden."

Gen. Access Sols., Ltd. v. Sprint Spectrum L.P., 811 F. App'x 654, 658 (Fed. Cir. 2020).

Petitioners' CRTP Reply at 2.

Conception

To prove conception, Teleflex must show "the formation, in the mind of the inventor of **a definite and permanent idea of the complete and operative invention**. . . . "Conception must include **every feature or limitation of the claimed invention**."

REG Synthetic Fuels, LLC v. Neste Oil Oyj, 841 F.3d 954, 962 (Fed. Cir. 2016).

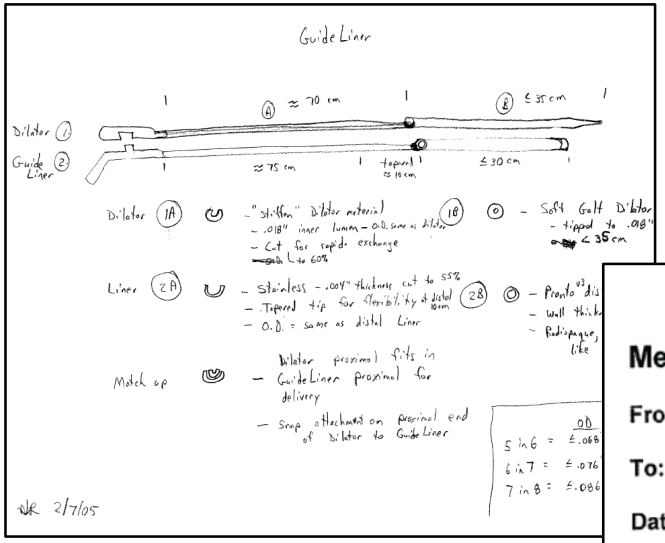
"[W]hen a party seeks to prove conception through an inventor's testimony **the party must proffer evidence, in addition to the inventor's own statements and documents, corroborating the inventor's testimony**."

Apator Miitors ApS v. Kamstrup A/S, 887 F.3d 1293, 1295 (Fed. Cir. 2018).

Petitioners' CRTP Reply at 3.

Teleflex cannot prove conception in early 2005.

Teleflex's Opening Brief: Three Conception Documents



LABORATORY NOTEBOOK

Notebook No.: 83

Assigned to: Gregg Sutton

Date: 10-21-04

Vascular Solutions, Inc.

Memo

From: Howard Root

To: GuideLiner DHF

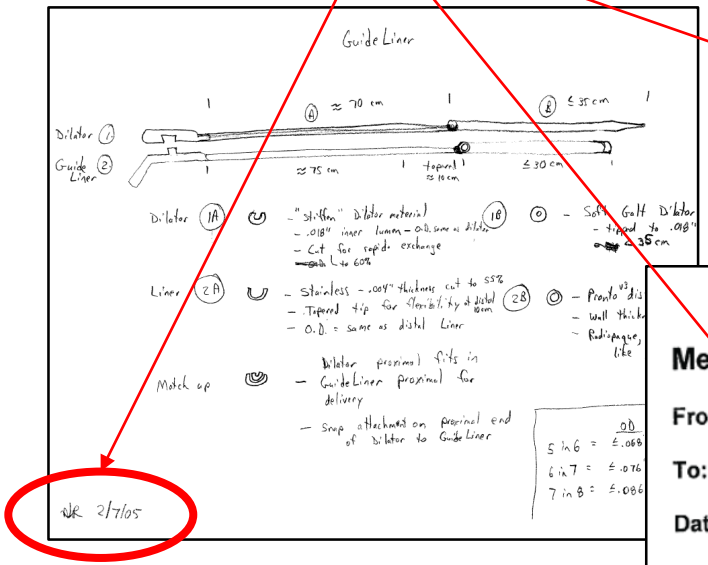
Date: February 4, 2005

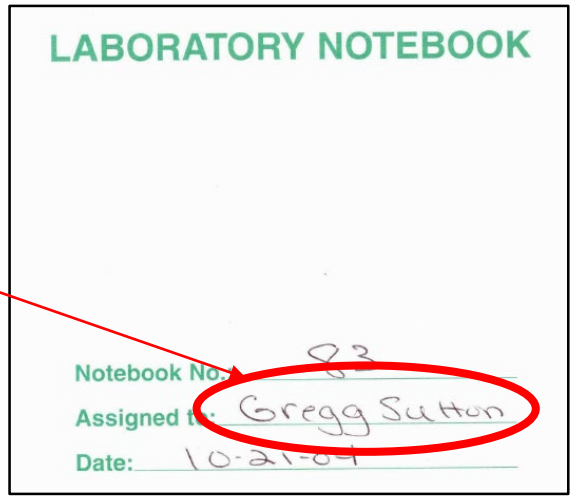
RE: **Market Feasibility for the GuideLiner catheters**

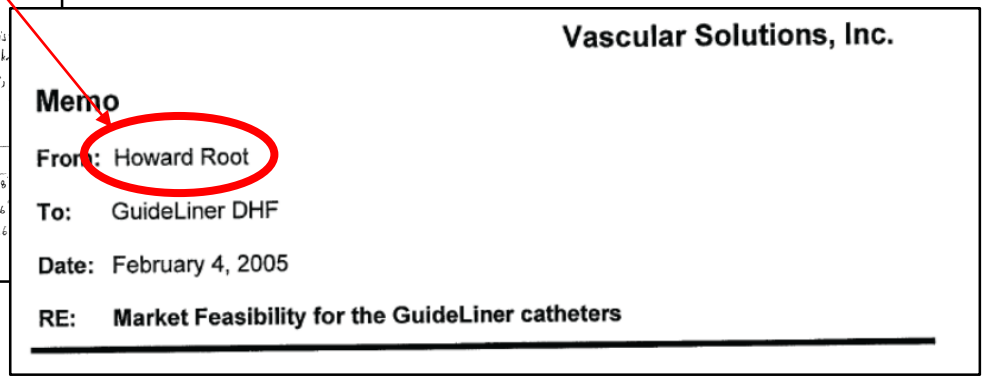
Ex-2002; Ex-2004; Ex-2127.

Teleflex cannot prove conception in early 2005.

Three Unwitnessed Inventor Documents







Ex-2002; Ex-2004; Ex-2127.

Teleflex cannot prove conception in early 2005.

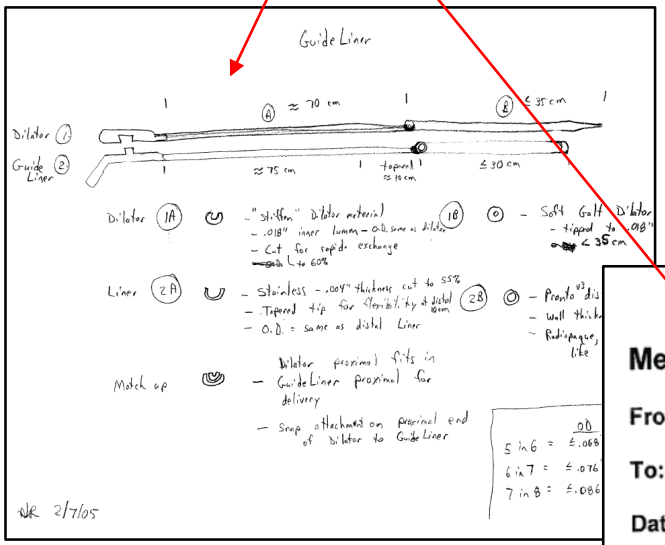
"We disagree with Patent Owners' contention that the [document] does not need corroboration because it is a physical exhibit. [It] is a document that has been authenticated only by the testimony of the inventors. **Thus, this document is one of the inventors' own statements and documents that depends solely on the inventor himself and, therefore, requires corroboration**."

Apple v. Yu, IPR2019-01258, 2021 WL 41670, at *19 (PTAB Jan. 5, 2021).

Petitioners' CRTP Sur-Sur-Reply at 2.

Teleflex cannot prove conception in early 2005.

No Side Opening



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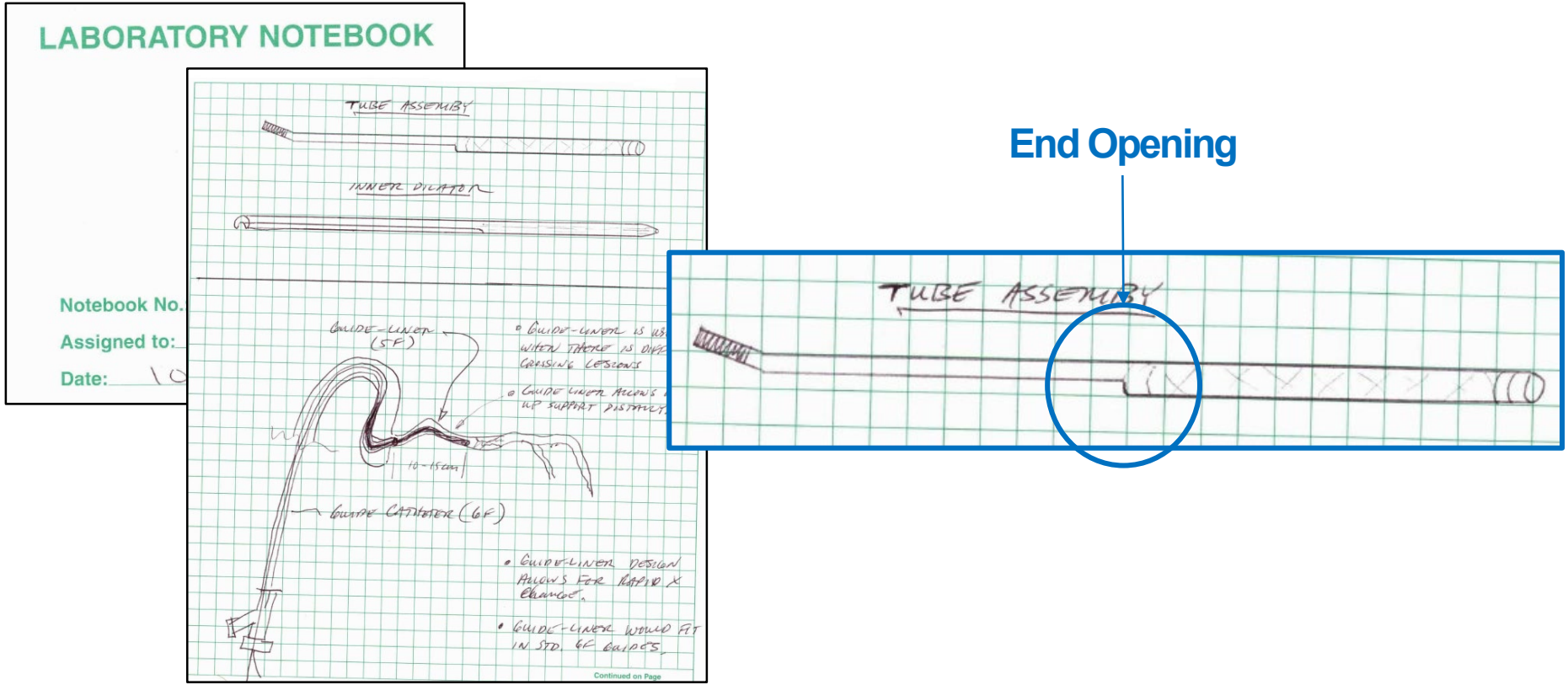
Ex-2002; Ex-2004; Ex-2127.

Teleflex cannot prove conception in early 2005.



Ex-2002; Ex-1755 ¶ 80.

Teleflex cannot prove conception in early 2005.

Sutton:

Q. Okay. And what's the -- does your -- let's go back to your invention disclosure, Exhibit 15. Does that show a transition in the collar?

A. No.

Q. Okay, okay. But it doesn't have a -- do you know what a -- a transition between the --

A. Yeah.

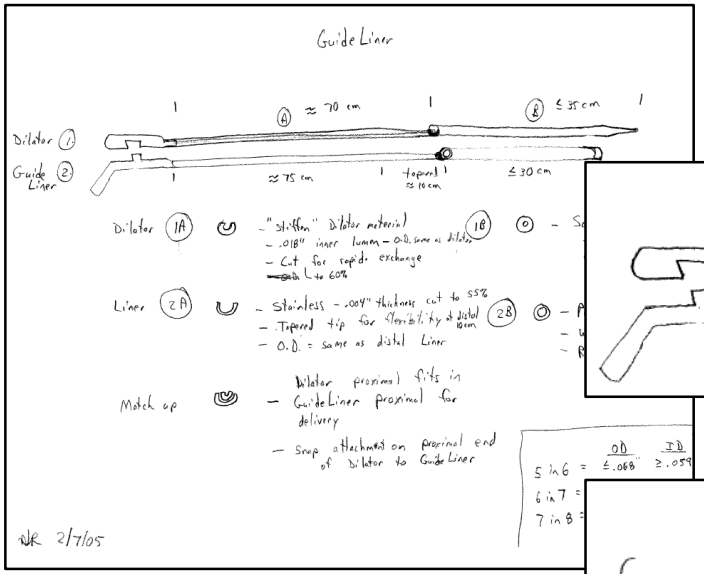
Q. It doesn't have a gradual transition --

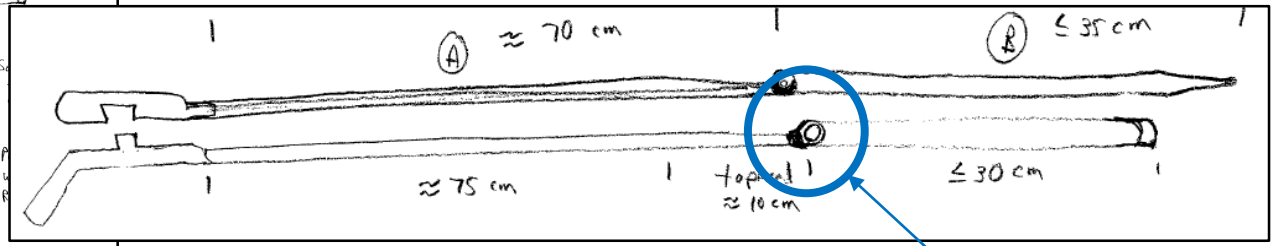
A. That's correct.

A. For -- for instance, I don't consider that a side opening, for one.

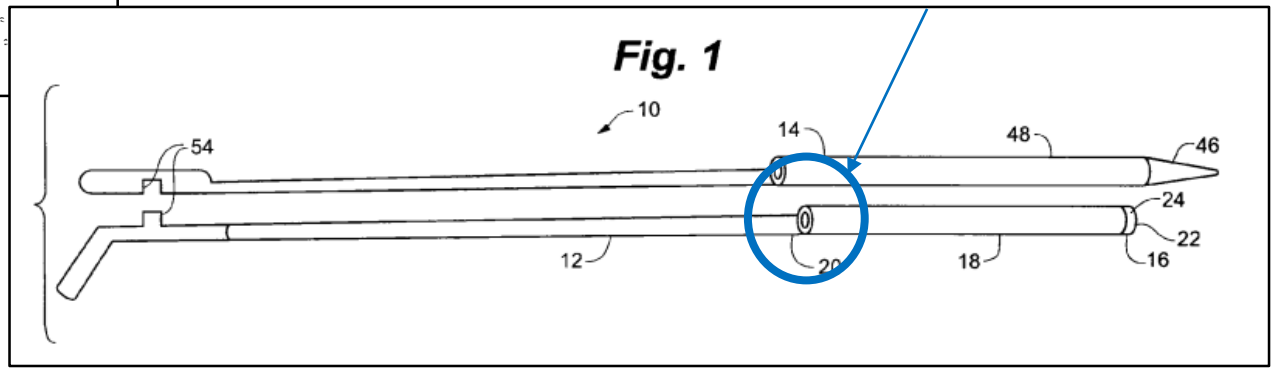
Ex-1108/1308/1708, 70:18-71:23, 79:14-80:24.

Teleflex cannot prove conception in early 2005.





End Opening



Ex-2004; Ex-1001, Fig. 1; Ex-1755 ¶ 83.

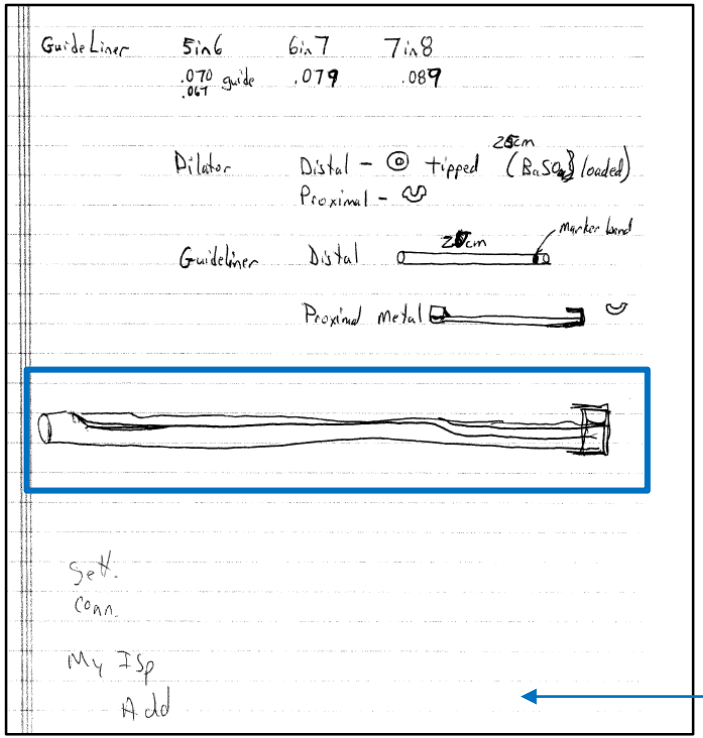
Teleflex cannot prove conception in early 2005.

Sutton:

> Figure 1. Again, that's not a transition opening, is it?
>
> **A. That's correct.**
>
> Q. That doesn't have a gradual transition?
>
> **A. No, it does not.**

Ex-1108/1308/1708, 73:19-23.

Teleflex cannot prove conception in early 2005.



Zalesky:

84. Mr. Root also testifies that the drawings on the third page of **Ex-2004** show a "side opening structure that is cut-away in several segments." **Ex-2118** ¶ 14. This drawing does not appear to correspond to any of the figures in the Root patents. **Ex-1001**. The drawing is quite crude; it is difficult to tell what it represents, if anything. It does not appear to show a side opening.

Undated

Ex-2004; Ex-1755 ¶ 84.

Teleflex cannot prove conception in early 2005.

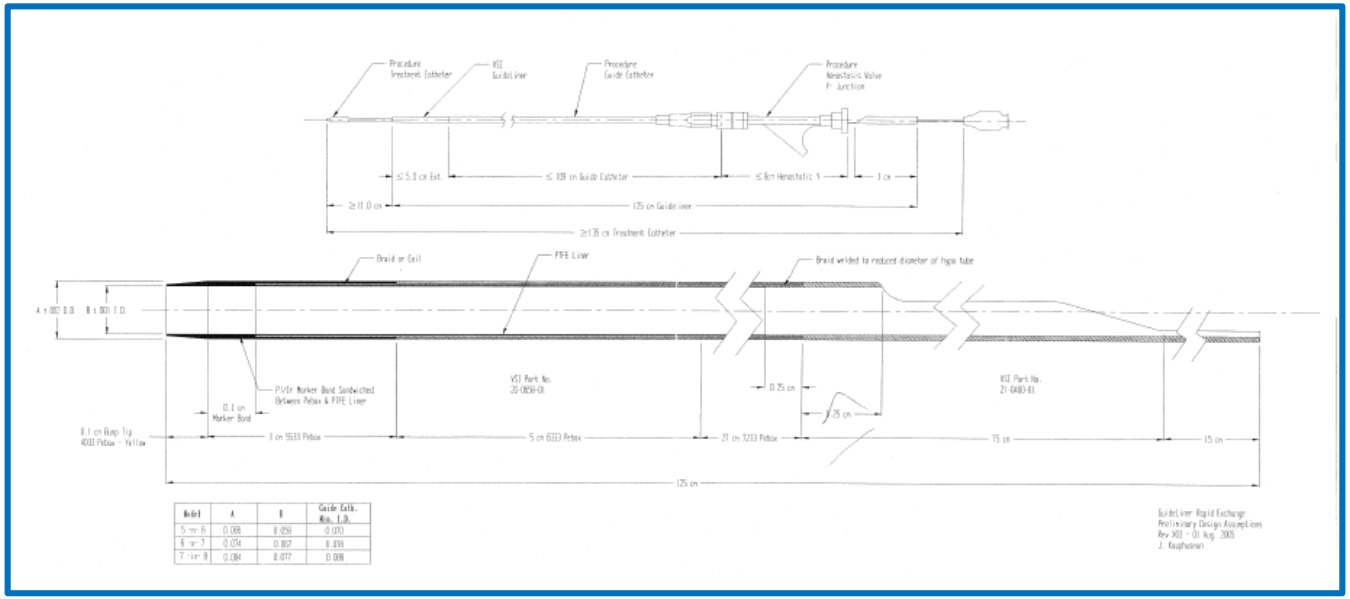
Sutton:

> A. I don't know. It's the first time I've seen this. It could be -- it could be anything, but it's kind of a poor drawing --

Ex-1108/1308/1708, 46:7-47:3.

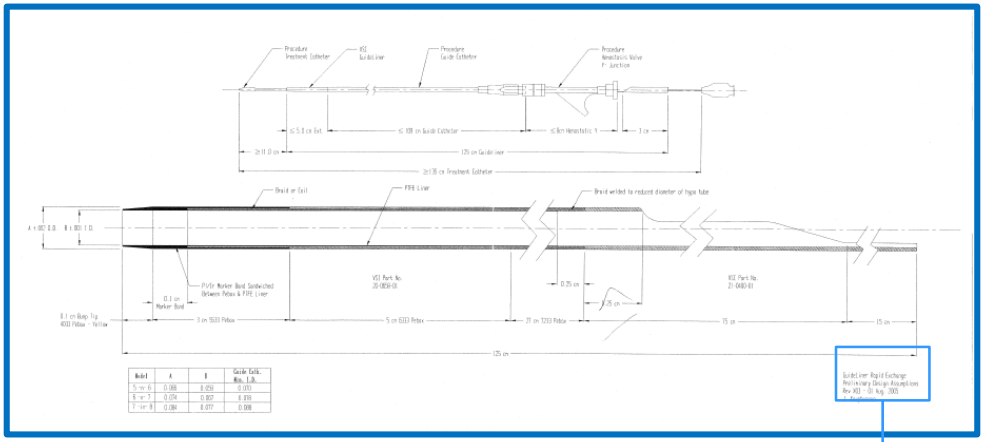
Teleflex cannot prove conception before August 2005.

Teleflex's Sur-Reply:
New Conception Document



Ex-2022.

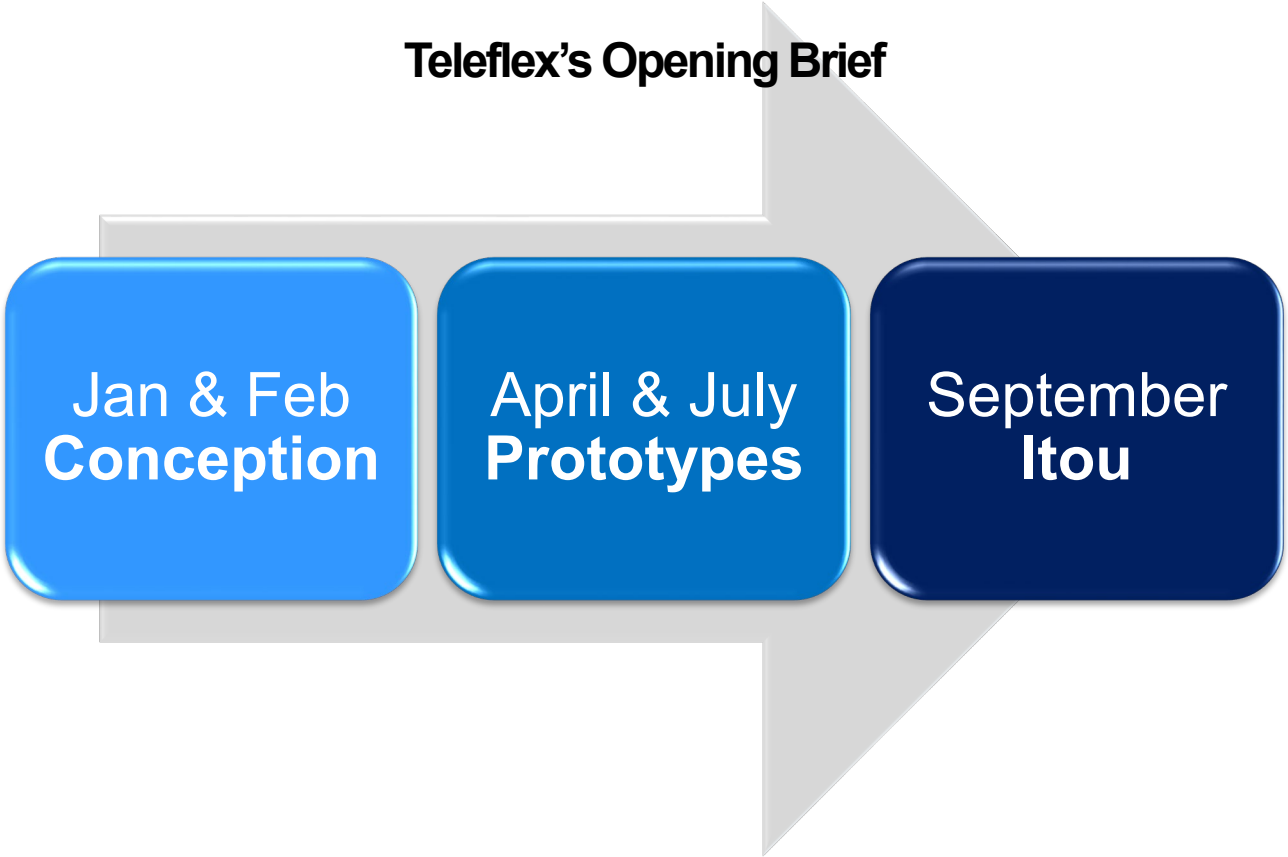
Teleflex cannot prove conception before August 2005.



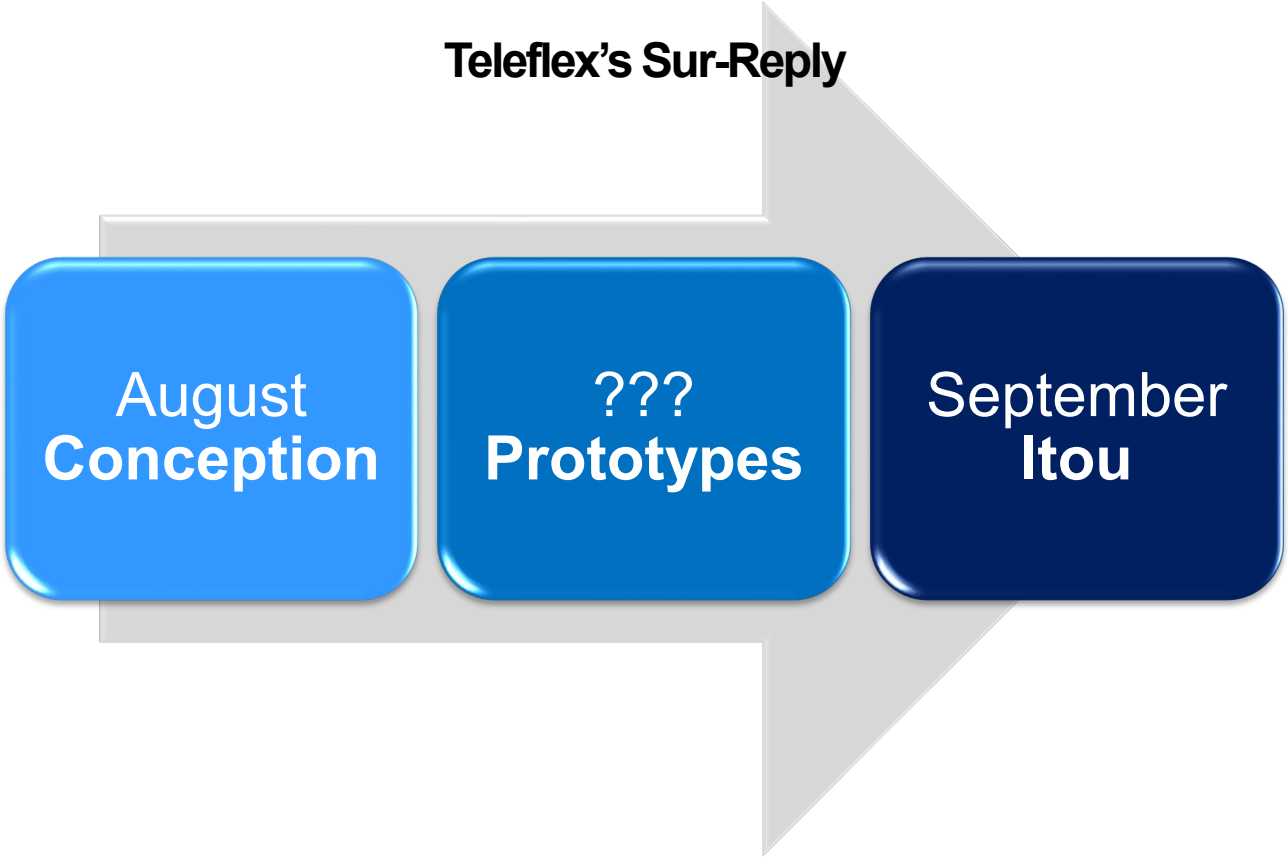
GuideLiner Rapid Exchange
Preliminary Design Assumptions
Rev X03 - 01 Aug. 2005
J. Kauphusman

Ex-2022.

Teleflex cannot prove conception before August 2005.



Teleflex cannot prove conception before August 2005.



Conception and Reduction to Practice

"Reduction to practice **follows conception**."

Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996).

Petitioners' CRTP Sur-Sur-Reply at 2.

Reduction to Practice

To prove reduction to practice, Teleflex must show:

"(1) **construction of an embodiment** . . . that met all the limitations of the [claimed invention];

(2) **determination that the invention would work for its intended purpose**; and

(3) the existence of **sufficient evidence to corroborate inventor testimony** regarding these events."

Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1169 (Fed. Cir. 2006).

Petitioners' CRTP Reply at 7-8.

Reduction to Practice: Constructing + Demonstrating

1. **Construct a prototype embodying the claimed invention.**

2. **Demonstrate that the invention would work for its intended purpose.**

Reduction to Practice: Constructing + Demonstrating

1. Construct a prototype embodying the claimed invention.

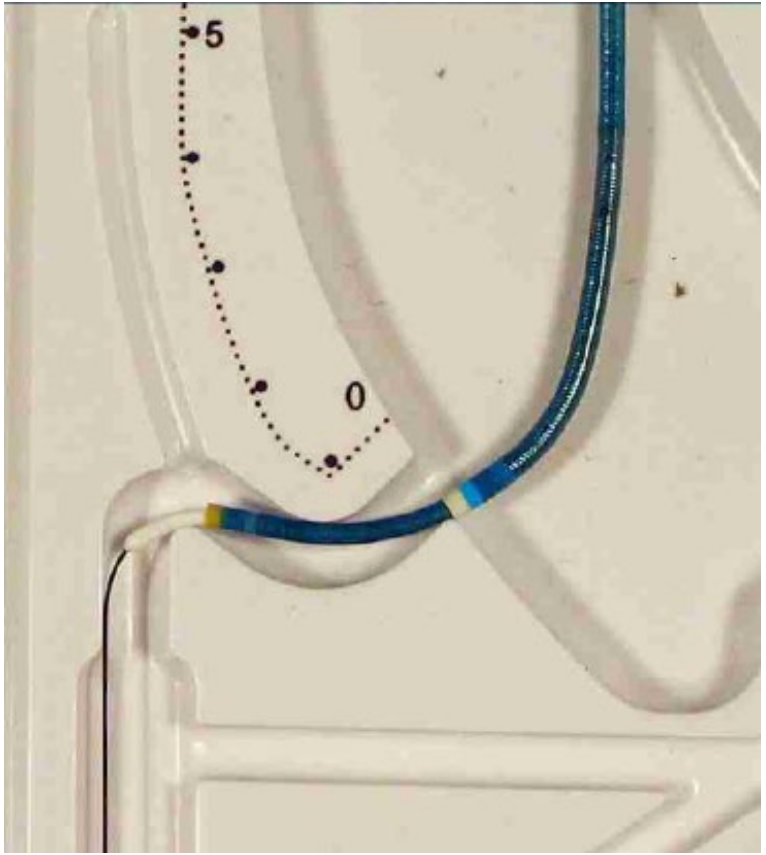
2. Demonstrate that the invention would work for its intended purpose.

VSI intended to develop an OTW GuideLiner.

OTW GEC

- Full-length lumen
- Mother-and-child

OTW Prototype Photo
VSI Slide Deck, July 2005



Ex-2129.

VSI intended to develop an OTW GuideLiner (Prior Art).

Memo

From: Howard Root

To: GuideLiner DHF

Date: June 23, 2005

RE: **Market Feasibili**

Market Feasibility of GuideLiner catheters

The placement of a smaller guide catheter through a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents has been described in the literature (Takahashi, "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," Catheterization and Cardiovascular Interventions 63:452-456 (2004)). This coaxial technique has been used in order to provide a safer method of deep seating the guide catheter. The danger of deep seating a normal guide catheter is that the guide is relatively stiff with a fixed curve, which can result in dissections of the coronary artery when advanced past the ostium. Using a smaller, and therefore more flexible, guide catheter (with either no curve or a very gentle curve) and placing it through the larger standard guide catheter can reduce this risk to the vessel. By safely deep seating the guide catheter, the physician can then have the added support for pushing a wire through a chronic total occlusion or advancing a balloon or stent through a tight stenosis.

Ex-2128.

VSI intended to develop an OTW GuideLiner.

Early on, *the* GuideLiner Device was OTW:

Memo

To: Design History File

From: James V. Kauphusman

CC: H. Root, G. Sutton, J. Welch, J. Garrity

Date: 19 April, 2005

Re: GuideLiner OTW meeting notes

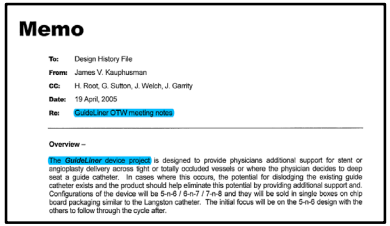
Overview –

The ***GuideLiner*** device project is designed to provide physicians additional support for stent or angioplasty delivery across tight or totally occluded vessels or where the physician decides to deep seat a guide catheter. In cases where this occurs, the potential for dislodging the existing guide catheter exists and the product should help eliminate this potential by providing additional support and. Configurations of the device will be 5-n-6 / 6-n-7 / 7-n-8 and they will be sold in single boxes on chip board packaging similar to the Langston catheter. The initial focus will be on the 5-n-6 design with the others to follow through the cycle after.

Ex-1759.

VSI intended to develop an OTW GuideLiner.

April 2005
Kauphusman meets with inventors re: GuideLiner OTW



Memo

To: Design History File
From: James V. Kauphusman
CC: H. Root, G. Sutton, J. Welch, J. Garrity
Date: 19 April, 2005
Re: GuideLiner OTW meeting notes

Overview –

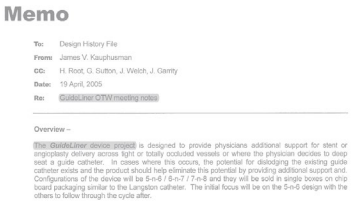
The GuideLiner device project is designed to provide physicians additional support for stent or angioplasty delivery across tight or totally occluded vessels or where the physician decides to deep seat a guide catheter. In cases where this occurs, the potential for dislodging the existing guide catheter exists and the product should help eliminate this potential by providing additional support and. Configurations of the device will be 5-in-8 / 6-in-7 / 7-in-8 and they will be sold in single boxes on chip board packaging similar to the Langston catheter. The initial focus will be on the 5-in-8 design with the others to follow through the cycle after.

Ex-1759.

VSI intended to develop an OTW GuideLiner.

April 2005
Kauphusman meets with inventors re: GuideLiner OTW

July 2005
Root presents GuideLiner OTW as "New Product on the Horizon"


Memo

To: Design History File
From: James V. Kauphusman
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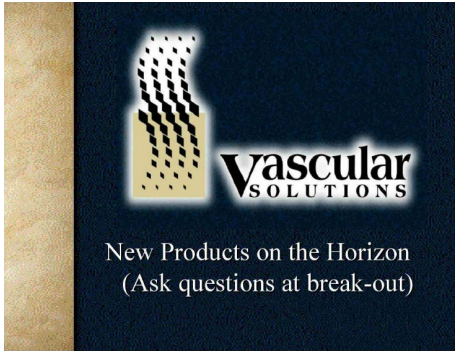
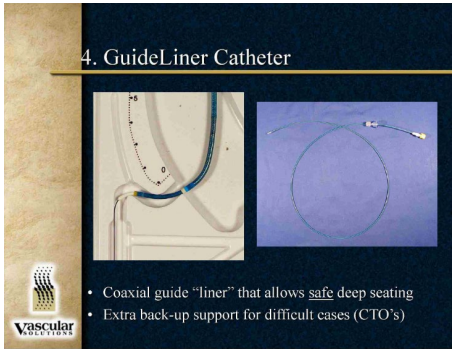
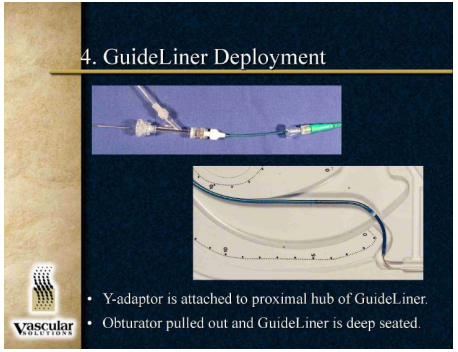
Date: 19 April, 2005
Re: GuideLiner OTW meeting notes

Overview –

The GuideLiner device project is designed to provide physicians additional support for stent or angioplasty delivery across tight or totally occluded vessels or where the physician decides to deep seat a guide catheter. In cases where this occurs, the potential for dislodging the existing guide catheter exists and the product should help eliminate this potential by providing additional support and. Configurations of the device will be 5+/-5 / 6+/-7 / 7+/-8 and they will be sold in single boxes on chip board packaging similar to the Langston catheter. The initial focus will be on the 5+/-5 design with the others to follow through the cycle after.







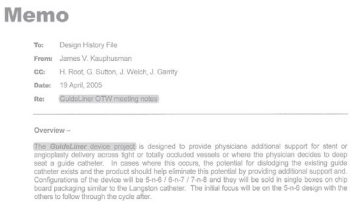
Ex-2129.

VSI intended to develop an OTW GuideLiner.

April 2005
Kauphusman meets with inventors re: GuideLiner OTW

July 2005
Root presents GuideLiner OTW as "New Product on the Horizon"

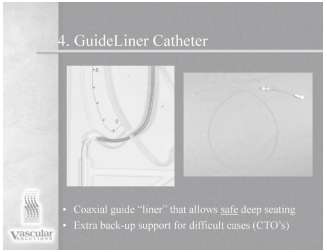
August / September / November 2005
Kauphusman tests GuideLiner OTW prototypes

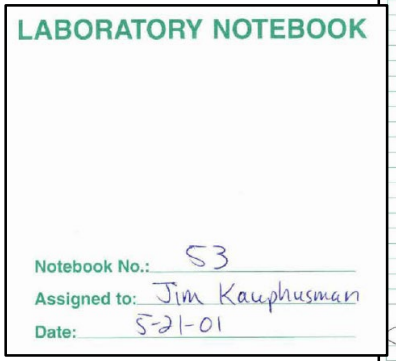

Memo

To: Design History File
From: James V. Kauphusman
CC: H. Root, G. Sutton, J. Welch, J. Garrity
Date: 19 April, 2005
Re: GuideLiner OTW meeting notes

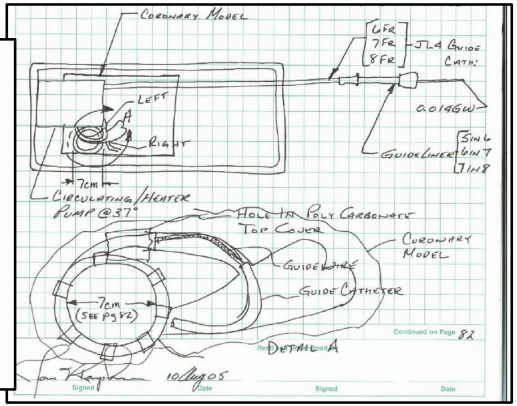
Overview –

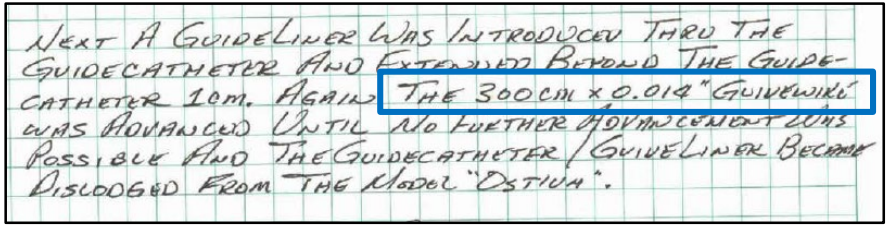
The GuideLiner device project is designed to provide physicians additional support for stent or angioplasty delivery across tight or totally occluded vessels or where the physician decides to deep seat a guide catheter. In cases where this occurs, the potential for dislodging the existing guide catheter exists and the product should help eliminate this potential by providing additional support and. Configurations of the device will be 5-in-6 / 6-in-7 / 7-in-8 and they will be sold in single boxes on chip board packaging similar to the Langston catheter. The initial focus will be on the 5-in-6 design with the others to follow through the cycle after.




LABORATORY NOTEBOOK

Notebook No.: 53
Assigned to: Jim Kauphusman
Date: 5-21-01

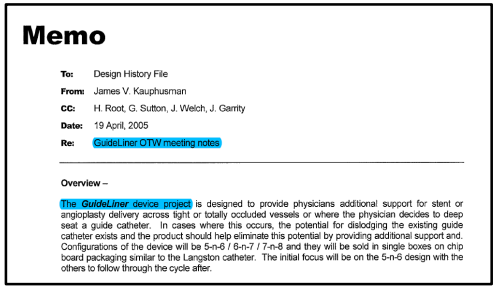



Next A GuideLiner was introduced thru the Guidecatheter and extended beyond the Guide-catheter 1cm. Again the 300cm x 0.014" Guidewire was advanced until no further advancement was possible and the Guidecatheter / GuideLiner became dislodged from the model "Ostium".

Ex-1760.

Teleflex kept OTW documents.

- **OTW** meetings.
- **OTW** photographs.
- **OTW** presentations.
- **OTW** laboratory notebook entries.
- **OTW** testing.



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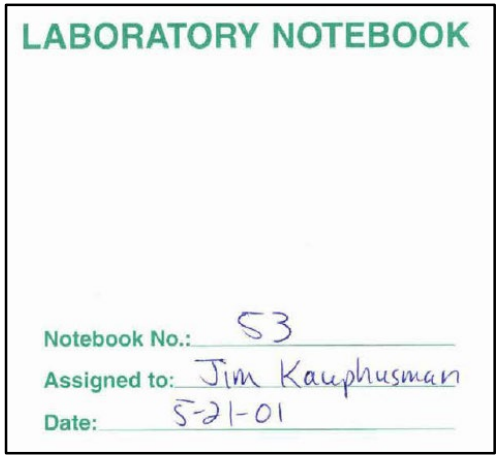
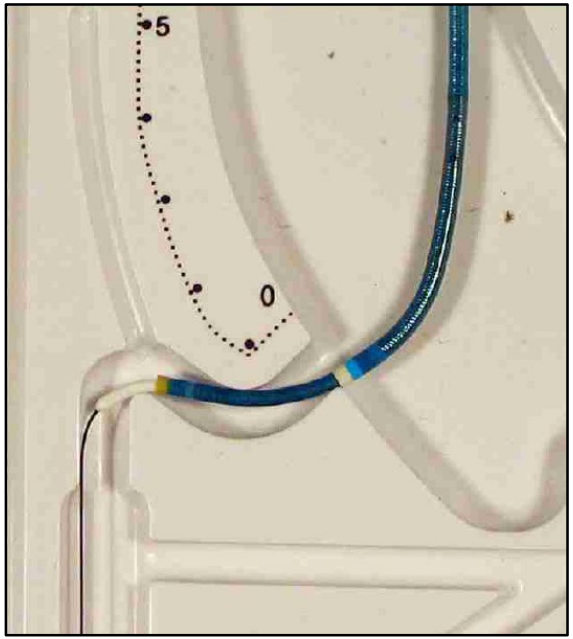
April 2005



LABORATORY NOTEBOOK

Notebook No.: 53
Assigned to: Jim Kauphusman
Date: 5-21-01

Summer / Fall 2005

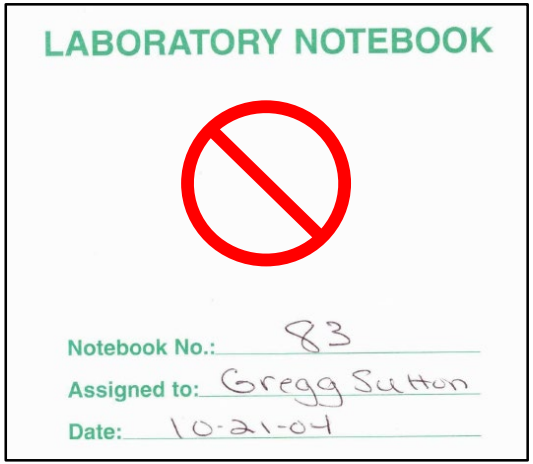


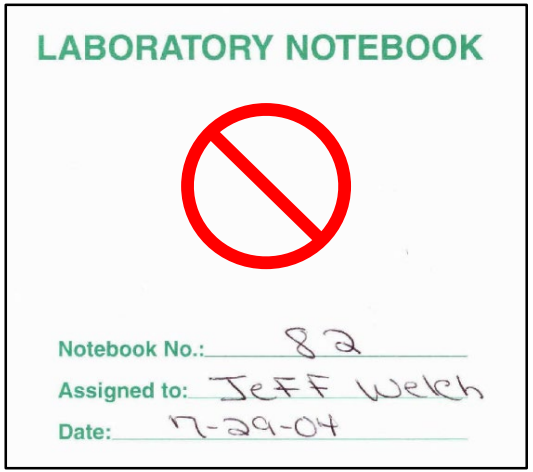
July 2005

Ex-1759; Ex-1760; Ex-2129.

Teleflex is missing key RX documents.

- **No** prototypes.
- **No** photographs.
- **No** assembly instructions.
- **No** laboratory notebook entries.
- **No** testing protocols.
- **No** testing notes / data / results.





Ex-1109/1309/1709; Ex-1758.

Teleflex is missing key RX documents.

Erb, a VSI technician and Teleflex's lead corroborating witness, shredded his notebook.

Erb:

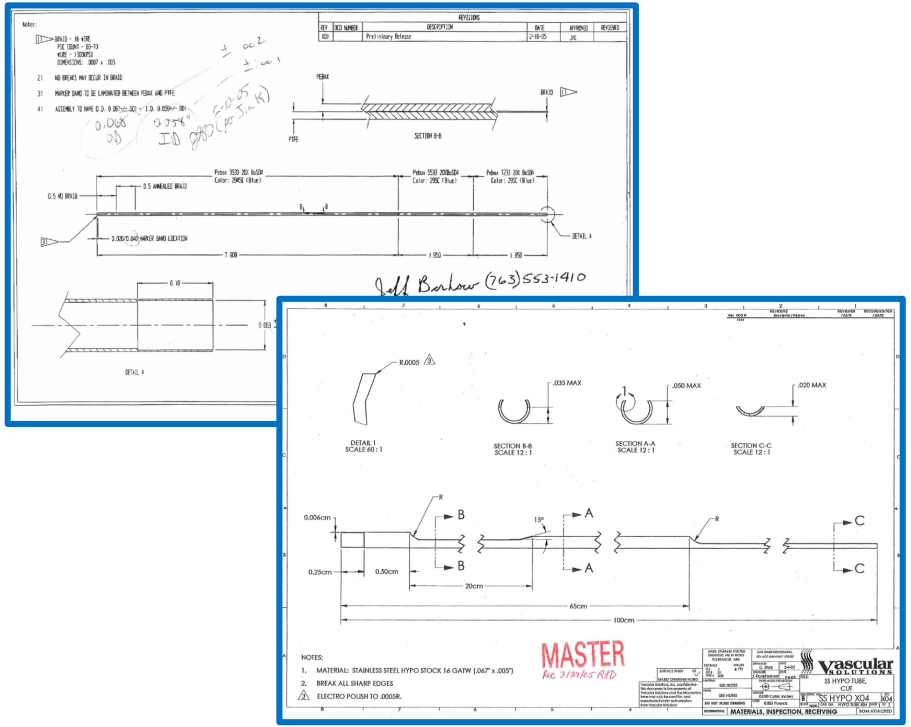
11 Q. When your notebook went missing, did you
12 report that?
13 A. Well, it didn't go missing. We were told we
14 no longer needed them. We went to an electronic
15 version or something. But I was no longer doing
16 testing, or that wasn't part of my role anymore.
17 So just housecleaning, I just got rid of whatever
18 prints and the notebook I had through the shredder
19 service that we did.

2 Q. And when you shredded your notebook, did you
3 start keeping records electronically?
4 A. No, I did not.
5 Q. So your testimony is that you then kept no
6 records, written or electronic, of your work at
7 Vascular Solutions?
8 A. Correct.

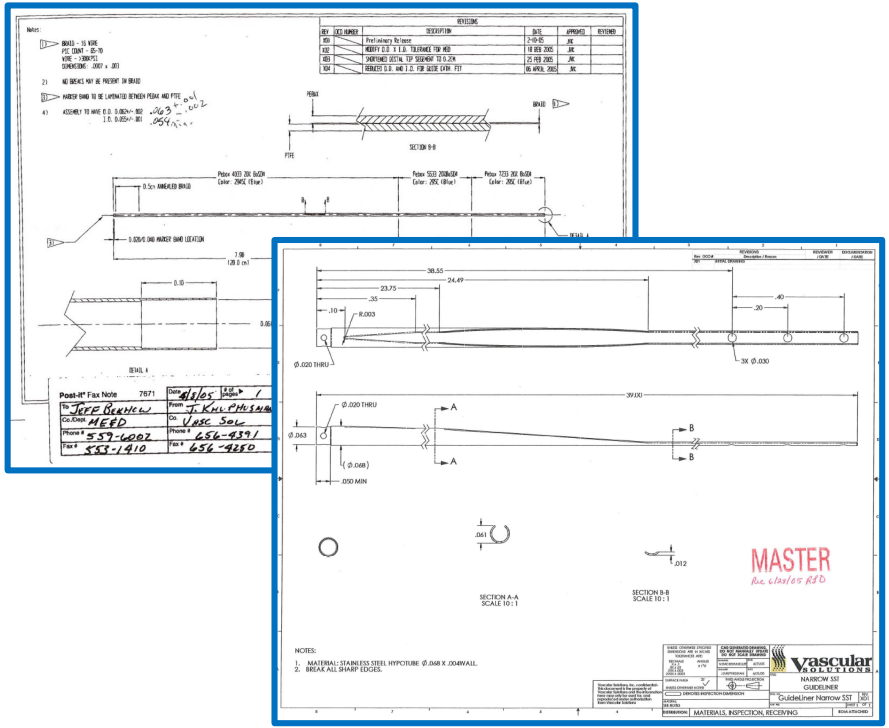
Ex-1756, 25:12-30:13, 33:2-8.

At most four documents matter.

“April Prototypes”



“July Prototypes”



Ex-2089; Ex-2113; Ex-2092; Ex-2114.

Teleflex cannot prove that VSI assembled RX prototypes.

Erb does not discuss assembling "April" components and "July" components.

> 8. As a machinist for the group, I worked on the early GuideLiner prototypes. Specifically, I machined-down the hypotubes that were used to form the proximal end of the early prototypes of that device. I personally made a special jig to hold the hypotubes and then used a vertical milling machine to cut the tubes along their length.

Ex-2122 ¶ 8.

Teleflex cannot prove that VSI assembled RX prototypes.

Erb lacks personal knowledge . . .

Sutton:

Q. What about, I believe you mentioned a Mr. Erb. Would you have expected him to keep a notebook during this time?

A. Steve was more of a machinist. I wouldn't have expected him to as much as the others.

Ex-1757, 43:10-14.

Teleflex cannot prove that VSI assembled RX prototypes.

. . . because Kauphusman and Mytty led the GuideLiner project.

Sutton:

Q. Okay. So who was the primary engineer working on the rapid exchange version? Let's start there.
A. Initially, mainly in the 2005 time frame, it was Jim Kauphusman.

Q. Do you know who specifically in the engineering department would have been involved in this process?
A. Well, Jim Kauphusman and Katie Mytty are specifically ones that I know of. There could have been more, but I don't remember specifically.

Ex-1757, 33:11-15, 70:14-19.

Teleflex cannot prove that VSI assembled RX prototypes.

No document corroborates assembling "April" components and "July" components.

Zalesky:

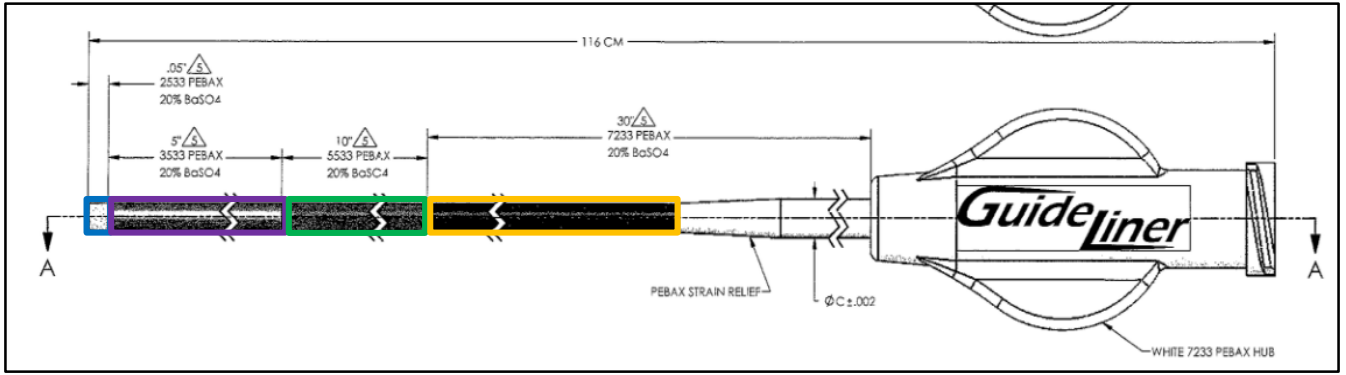
But my question is: Would it be reasonable for VSI to spend thousands of dollars on customized parts like those shown in 2089, 2113, 2092, and 2114, would it be reasonable for VSI to not assemble those parts together?

A. I agree that doesn't make a lot of sense, but I can certainly conceive of using those parts for other purposes, for other potential designs, through other exploratory concepts.

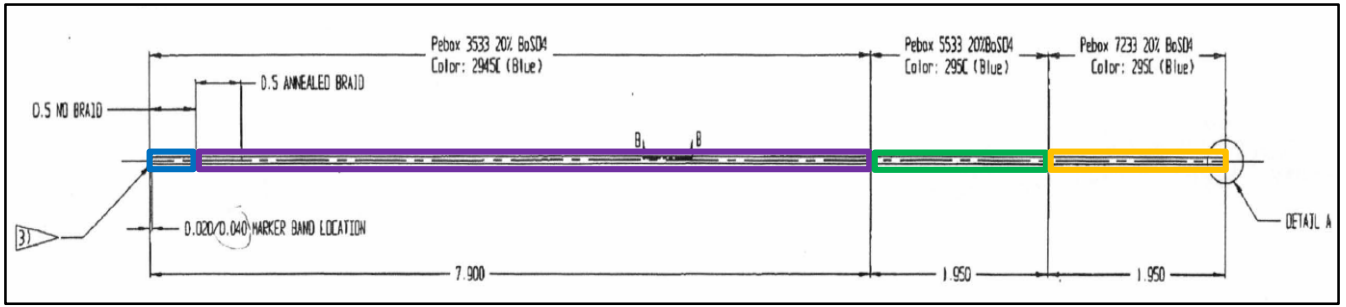
I just don't have any evidence that indicates how they were used or that they were assembled into any prototype.

Ex-2237, 208:14-25.

Distal sections bear a striking similarity to OTW drawings.



OTW Concept Drawing

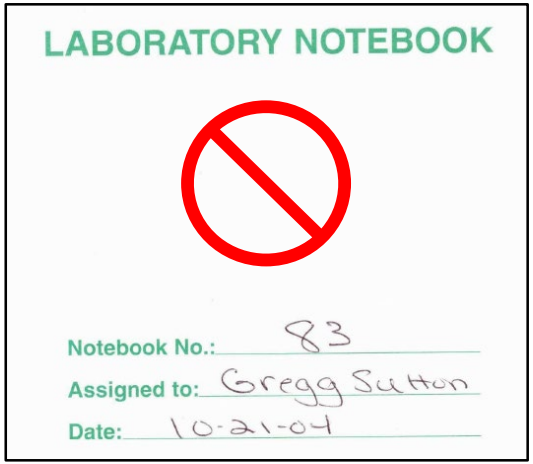


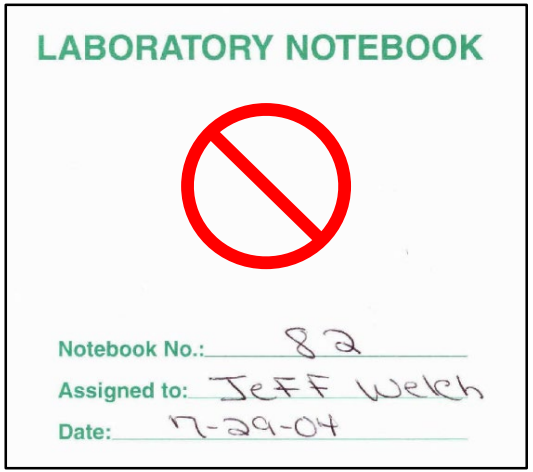
Distal Component

Ex-1763; Ex-2089.

Teleflex is missing key RX documents.

- **No** prototypes.
- **No** photographs.
- **No** assembly instructions.
- **No** laboratory notebook entries.
- **No** testing protocols.
- **No** testing notes / data / results.





Ex-1109/1309/1709; Ex-1758.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Reduction to practice: Constructing + Demonstrating

1. **Construct a prototype embodying the claimed invention.**

2. **Demonstrate that the invention would work for its intended purpose.**

Intended Purpose

Intended purpose: to increase backup support for accessing and crossing tough occlusions.

Intended Purpose

Sutton:

PROJECT GUIDE-LINER DEVICE Notebook No. _____ 1

Continued From Page _____

IDEA This idea relates to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions. The idea is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device. The new "guide within a guide" or "Guide Liner" is described below.

Ex-2002.

The parties agree on the intended purpose.

Teleflex:

> The intended purpose of the GuideLiner was to increase backup support for delivery of interventional cardiology devices, including procedures involving tough or chronic total occlusions. Exs-2002, -2003, -2024.

PO's CRTP Sur-Reply at 9.

The witnesses agree on how to test that intended purpose.

Intended purpose: to increase backup support for accessing and crossing tough occlusions.

Demonstrating whether the invention would work for that intended purpose: benchtop test simulating challenging anatomy.

The witnesses agree on how to test that intended purpose.

1. Set up benchtop model to simulate challenging anatomy.
2. Run prototype through and advance ICD to test navigating, accessing, and crossing.
3. Retrieve prototype in one piece.

Root agrees that demonstrating required certain testing.

1. **Set up benchtop model to simulate challenging anatomy.**

Root:

Q. Okay. I mean, first of all, I'll just ask again, you know, if you built one of these prototypes, in order to know that it worked for its intended purpose, did you even have to test it at all or would you know just from making it?

A. No. You would have to evaluate it. You would have to be able to have it in your hands and evaluate it in a simulated anatomy.

Q. So then in order to know it worked for its intended purpose, you would have to put it into a benchtop model; is that right?

A. Yeah. Benchtop model, you could define a lot of ways, but essentially, yes.

Ex-1762, 100:10-22.

Root agrees that demonstrating required certain testing.

1. Set up benchtop model to simulate challenging anatomy.
2. **Run prototype through and advance ICD to test navigating, accessing, and crossing.**

Root:

Q. And for what you talked about, basically extending a guide catheter, is the procedure what you think you'd have to do to basically get the guide catheter in and then put the GuideLiner through it and extend out of it? Does that make sense?

A. That's part of it, yes.

Q. And once you did that, in your view would you know that it works for its intended purpose?

A. You also should deliver a device through it to make sure that it goes through the guide catheter into the guide extension and out the distal end.

Ex-1762, 100:23-101:10.

Root agrees that demonstrating required certain testing.

1. Set up benchtop model to simulate challenging anatomy.
2. Run prototype through and advance ICD to test navigating, accessing, and crossing.
3. **Retrieve prototype in one piece.**

Root:

Q. So once you've done that, you've put it in the benchtop model and you've put a device through it, is that it? At that point do you know it works for its intended purpose?
A. Well, you need to retrieve it, so you would need to pull it back out.

Ex-1762, 101:14-19.

Root agrees that demonstrating required certain testing.

1. **Set up benchtop model to simulate challenging anatomy.**
2. **Run prototype through and advance ICD to test navigating, accessing, and crossing.**
3. **Retrieve prototype in one piece.**

Root:

So you would do a simulated procedure, so just like what they would do in the cath lab. And you would have your guide catheter in place. You'd put the GuideLiner over the wire into the simulated coronary artery. You'd deliver a stent through it. Then you'd pull the balloon without the stent back out, and then you would pull the GuideLiner out. And then you would confirm that this works as a rapid exchange guide extension.

Ex-1762, 101:19-102:3.

Keith expanded on what that testing should look like.

1. **Set up benchtop model to simulate challenging anatomy.**

Keith:

Q. Sure. So those -- and we've talked about those before, tight lesions, tortuous anatomy, et cetera.

Is it possible to test for those things in a benchtop model or to create those kinds of challenging coronary anatomy?

A. Yeah. I think one can simulate that fairly well in a bench model.

Q. What do you have to do -- I don't know how benchtop models work. I assume that they're pretty standard.

But how do you set up a benchtop model such that it's presenting challenging coronary anatomy?

A. Well, for example, I would set it up so that the simulated blood vessel has curvature in it versus being perfectly straight. And perhaps a restricted area that represents a lesion.

Ex-1764, 64:2-17.

Keith expanded on what that testing should look like.

1. Set up benchtop model to simulate challenging anatomy.
2. **Run prototype through and advance ICD to test navigating, accessing, and crossing.**

Keith:

Q. And it would be possible to see how a guide extension catheter like GuideLiner behaves under those circumstances?

A. Sure, that would be possible.

Q. For instance, you could see under those circumstances whether the guide catheter backs out?

A. You could, yep.

Q. Could you measure -- could you measure how much force it take to make it back out or, conversely, how much additional back-up support you're getting from the GuideLiner?

A. Again, one could measure that if one wanted to in -- in various ways, yes.

Q. And I think we already discussed you could observe whether there was any device hang-up, right?

A. Generally, yes.

Ex-1764, 66:1-13, 67:1-3.

Keith expanded on what that testing should look like.

1. Set up benchtop model to simulate challenging anatomy.
2. Run prototype through and advance ICD to test navigating, accessing, and crossing.
3. **Retrieve prototype in one piece.**

Keith:

Q. Sure. And you could also make observations about whether a GuideLiner prototype, for instance, had any kinking problems?

A. If it kinked, that could be an observable thing, yes.

Q. And after you had used a prototype setup like we discussed in tortuous anatomy with a tight lesion, you could see whether there was any issue with the connection between the distal and proximal portions on the way in or on the way out, right?

A. Yeah, those are things that could be observed as part of that testing if one wanted to.

Ex-1764, 66:14-25, 67:4-10.

Zalesky opined that demonstrating required certain testing.

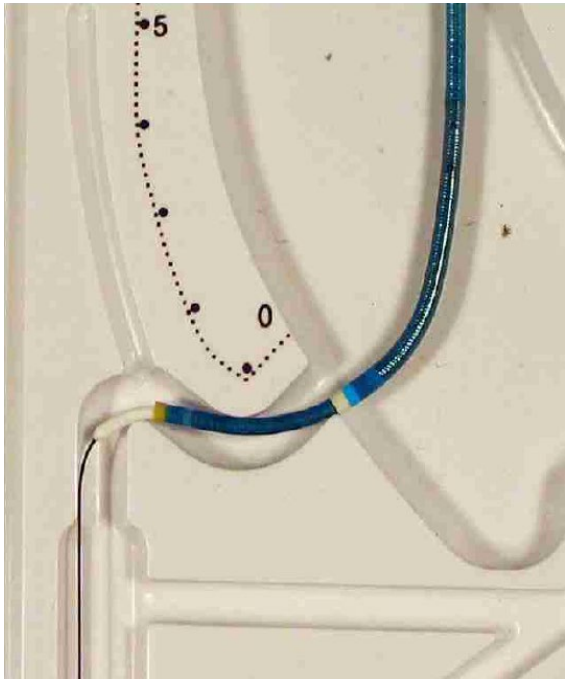
Zalesky:

235. It is possible to set up a benchtop model in a particular way to simulate challenging coronary anatomy, tortuous anatomy, or tough lesions. Not every "benchtop test" would allow an observer to judge whether a device would provide backup support for complex PCI procedures, allowing accessing and crossing tough or chronic occlusions. VSI needed to at least set up a benchtop model to simulate the anatomy the RX GuideLiner was intended to address and then (1) run the RX prototype through a guide catheter and out its distal end, (2) deliver an interventional cardiology device, and (3) retrieve the RX device in one piece.

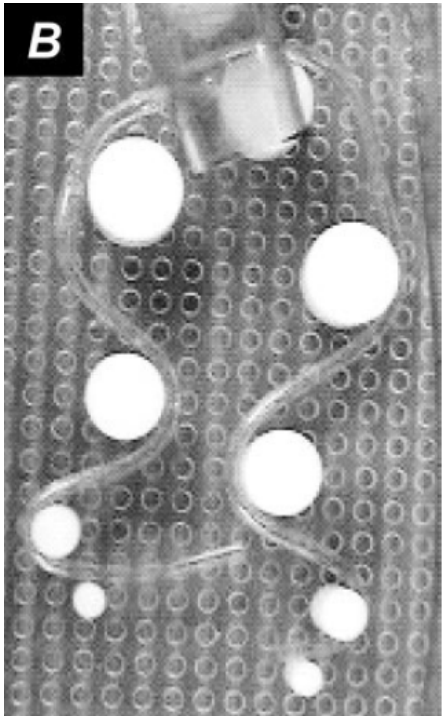
Ex-1755 ¶ 235.

Teleflex adduced zero RX testing evidence.

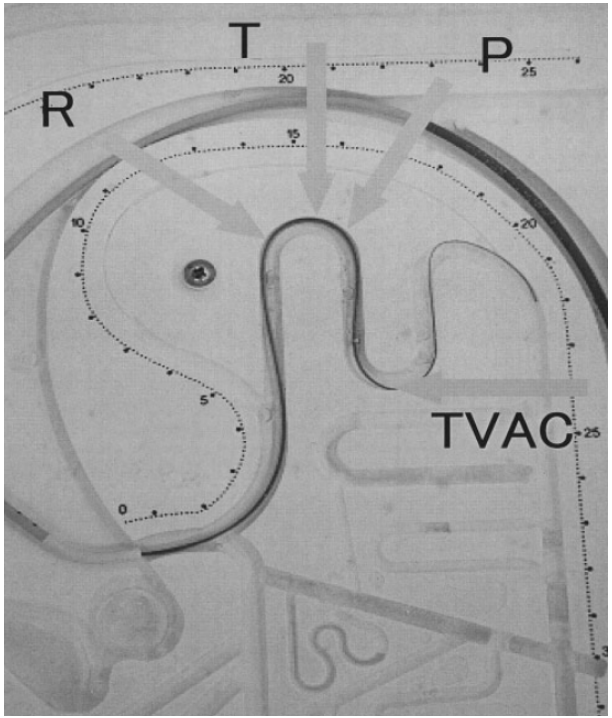
VSI Benchtop Model
July 2005



Takahashi
Demonstrating Increased
Backup Support



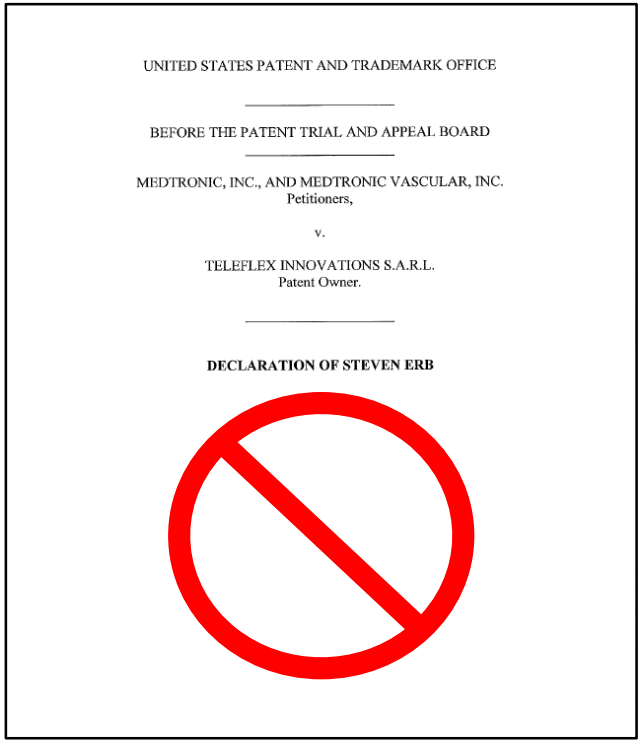
Sakurada
Demonstrating Improved
Crossing Ability



Ex-2129; Ex-1010; Ex-1055.

Teleflex adduced zero RX testing evidence.

Erb
VSI Technician



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

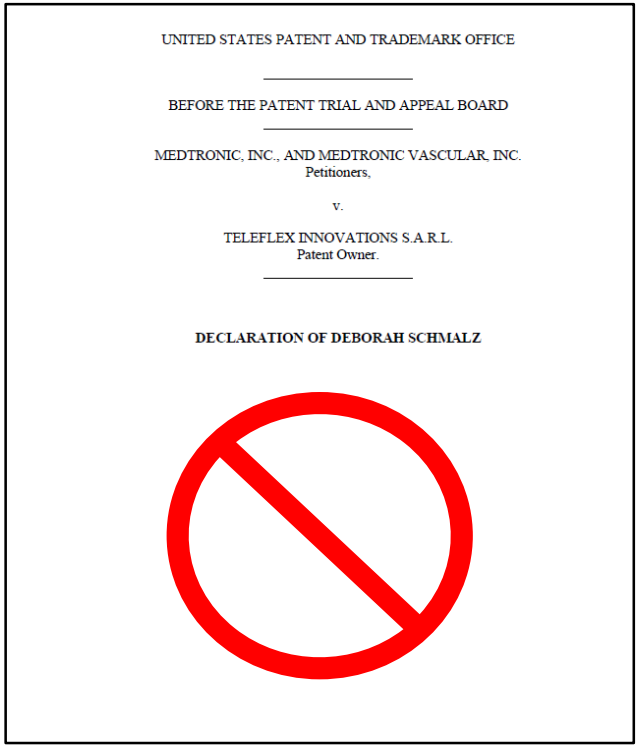
MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

DECLARATION OF STEVEN ERB

Schmalz
VSI VP of Regulatory



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Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

DECLARATION OF DEBORAH SCHMALZ

Ex-2122; Ex-2039.

Teleflex cannot prove that VSI tested RX prototypes.

Erb

VSI Technician

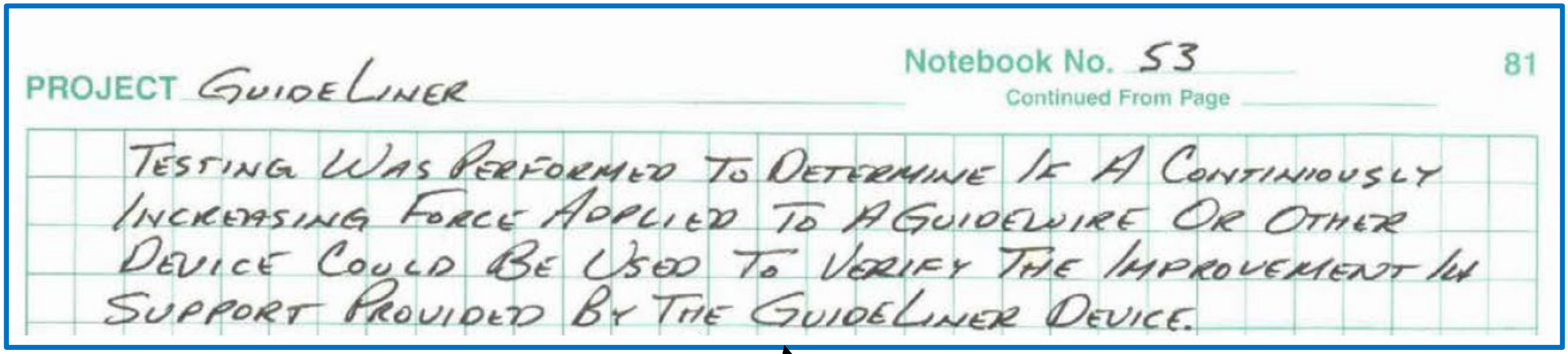
Q. When you say you were personally involved, what was your role?
A. I would have been standing there next to whoever was testing. So that would have been my personal role. Assisting, I guess would be the term.
Q. You were standing there or you were assisting?
A. Well, it would have been both. Whatever was required of me being a technician. So sometimes I may not -- may not have a role, but I would still be there just in case we needed something or -- also, it was exciting. I would be there just to see how it worked.

Q. Okay. Staying on paragraph 11, you've also written that you were aware of but not personally involved in tests of the GuideLiner prototypes involving the delivery of stents and balloons in a benchtop heart model, right?
A. Correct.

Ex-1756, 66:25-67:22, 71:11-73:20.

Teleflex cannot prove that VSI tested RX prototypes.

Kauphusman
GuideLiner Lead Engineer



PROJECT GUIDELINER

Notebook No. 53

81

Continued From Page

TESTING WAS PERFORMED TO DETERMINE IF A CONTINUOUSLY INCREASING FORCE APPLIED TO A GUIDEWIRE OR OTHER DEVICE COULD BE USED TO VERIFY THE IMPROVEMENT IN SUPPORT PROVIDED BY THE GUIDELINER DEVICE.

OTW Testing

Ex-1760 at 87.

Teleflex cannot prove that VSI tested RX prototypes.

Schmalz
VSI VP of Regulatory

Q. Understood. Now, you did not conceive of the GuideLiner rapid exchange invention; is that correct?
A. That is correct.
Q. And you did not personally build prototypes of the GuideLiner rapid exchange device; is that correct?
A. That is correct.
Q. And you did not personally test any prototypes of the GuideLiner rapid exchange device; is that correct?
A. That is correct.

Not a POSITA, no personal knowledge

Ex-1766, 34:11-35:1.

Teleflex cannot prove that VSI tested RX prototypes.

Schmalz
VSI VP of Regulatory

6. Exhibit 2024 is a Product Requirements document for the GuideLiner Catheter System, dated August 24, 2005. Such a document was created for products at the end of the concept development phase. In practice, this meant that a product must have been prototyped, thoroughly tested, and shown to work for its intended purpose before a Product Requirements document was created.

Ex-2039 ¶ 6.

Teleflex cannot prove that VSI tested RX prototypes.

- **No** reliable date.
- **No** author.
- **No** content.
- **No** electronic copy.
- **No** RX file name.
- **No** authenticator.

PRODUCT REQUIREMENTS:
GuideLiner Catheter System

Document Approvals:

Reviewer	J. Kauphusman	[illegible]
Documentation	J. Kujawa	[illegible]

3. REQUIREMENTS/SPECIFICATIONS

USER REQUIREMENTS	PRODUCT SPECIFICATIONS	TEST METHOD
3.1 Performance Requirements		
The catheter system must allow for advancement of the treatment catheter beyond (deeper) than using a guide catheter alone	?	?
The catheter system must be capable of withstanding normal insertion and removal forces through commonly used guide catheters and through the arterial system.		
The catheter system must slide inside the guide catheter and through the anticipated vasculature and be able to navigate the blood vessels without kinking.		
The catheter system must provide for an atraumatic entry into and travel through the blood vessel.		

Petitioners' Motion to Exclude Ex-2024; Ex-2024.

Teleflex cannot prove that VSI tested RX prototypes.

Teleflex cannot rely on the date on the face of the document "as proof of date[] of creation, modification, or publication"—**the date is inadmissible hearsay if Teleflex "has not established that the dates [on the face of the document] are automatically generated**."

See Standard Innovation Corp. v. Lelo, Inc., IPR2014-00148, Paper 41 at 18 (PTAB Apr. 23, 2015).

Petitioners' Motion to Exclude Ex-2024 at 3.

The Board needs to be able to assess testing evidence.

The Board judges "[t]he adequacy of a reduction to practice . . . by **what one of ordinary skill in the art would conclude from the results of the tests**."

Slip Track Sys., Inc. v. Metal-Lite, Inc., 304 F.3d 1256, 1265 (Fed. Cir. 2002).

The Board considers "**whether the testing in fact demonstrated a solution** to the problem intended to be solved by the invention."

Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994).

Petitioners' CRTP Sur-Sur-Reply at 12.

Predicting is not demonstrating.

"[E]vidence reflects that it was engaging in further testing and redesign and fully expected that the product would eventually work properly, **but what is required is not a mere basis for prediction but an actual demonstration**."

Tyco Healthcare Grp. v. Ethicon Endo-Surgery, Inc., 514 F. Supp. 2d 351, 361 (D. Conn. 2007).

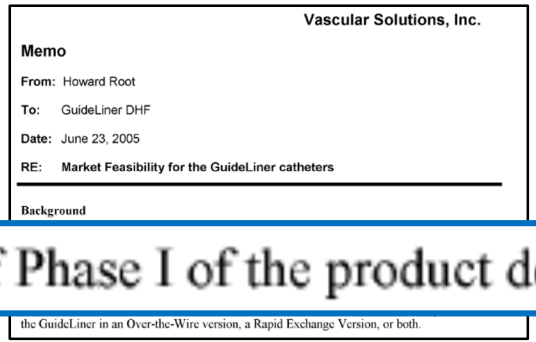
Petitioners' CRTP Reply at 26.

The Counter-Narrative

VSI did not reduce to practice before Itou.

2005

June 2005
Market Feasibility Memo



Vascular Solutions, Inc.

Memo

From: Howard Root

To: GuideLiner DHF

Date: June 23, 2005

RE: Market Feasibility for the GuideLiner catheters

Background

"As part of Phase I of the product development

the GuideLiner in an Over-the-Wire version, a Rapid Exchange Version, or both.

Zalesky:

172. Mr. Root discusses a market feasibility memo dated June 23, 2005, in which he discusses both an OTW and an RX version of the GuideLiner catheter. **Ex-2118** ¶ 37, citing **Ex-2017**. In my experience, assessing market feasibility is an early step in the Concept/Feasibility Phase, usually produced prior to any technical work. It provides justification for allocating resources to the prospective new project, and is usually among the very earliest entries into a DHF.

Ex-2128; Ex-1755 ¶ 172.

VSI did not reduce to practice before Itou.

2005

July 2005
RX Design TBD

Vascular Solutions, Inc.
Research & Development Update
July 2005

GuideLiner Device
A device for providing extra guide catheter back-up support during PTCA procedures.

“rapid exchange version to follow.”

Ex-2130.

VSI did not reduce to practice before Itou.

2005

August 2005 (?)
RX Product Requirements Incomplete

Zalesky:

196. A Product Requirements document is, in my experience, the very first significant document in a product's DHF, and it addresses the "design input" considerations prior to any preliminary designs, let alone fabrication of prototypes.

PRODUCT REQUIREMENTS:
GuideLiner Catheter System

Document Approvals:

Reviewer	J. Kauphusman	8/24/05
Documentation	J. Kujawa	8/24/05

3. REQUIREMENTS/SPECIFICATIONS

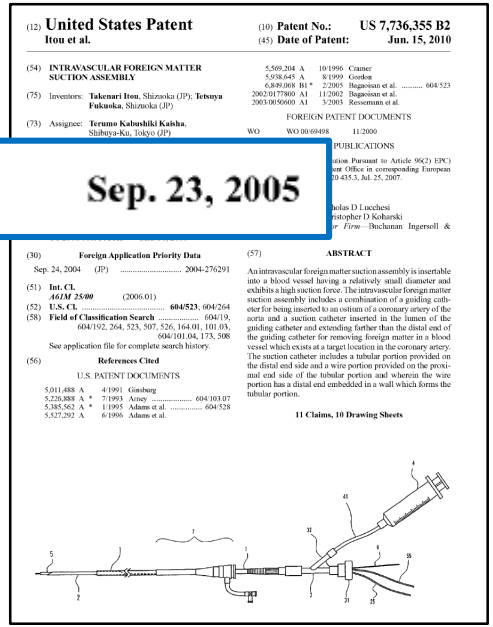
USER REQUIREMENTS	PRODUCT SPECIFICATIONS	TEST METHOD
3.1 Performance Requirements		
The catheter system must allow for advancement of the treatment catheter beyond (deeper) than using a guide catheter alone	?	?
The catheter system must be capable of withstanding normal insertion and removal forces through commonly used guide catheters and through the arterial system.		
The catheter system must slide inside the guide catheter and through the anticipated vasculature and be able to navigate the blood vessels without kinking.		
The catheter system must provide for an atraumatic entry into and travel through the blood vessel.		

Ex-2024; Ex-1755 ¶¶ 196-99.

VSI did not reduce to practice before Itou.

2005

September 2005
Itou



(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent: Jun. 15, 2010**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

Filed: **Sep. 23, 2005**

(30) **Foreign Application Priority Data**
Sep. 24, 2004 (JP) 2004-276291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526, 164.01, 101.03, 604/101.04, 173, 508
See application file for complete search history.

(56) **References Cited**
U.S. PATENT DOCUMENTS

5,011,488	A	4/1991	Ginsburg	
5,226,888	A *	7/1993	Arney	604/103.07
5,385,562	A *	1/1995	Adams et al.	604/528
5,527,292	A	6/1996	Adams et al.	
5,569,204	A	10/1996	Cramer	
5,938,645	A	8/1999	Gordon	
6,849,068	B1 *	2/2005	Bagaoisan et al.	604/523
2002/0177800	A1	11/2002	Bagaoisan et al.	
2003/0050600	A1	3/2003	Ressemann et al.	

FOREIGN PATENT DOCUMENTS
WO WO 00/69498 11/2000

PUBLICATIONS
...tion Pursuant to Article 96(2) EPC) ...nt Office in corresponding European ...20 435.3, Jul. 25, 2007.

...hodas D Lucchesi
...stopher D Kobarski
...r Firm—Buchanan Ingersoll &

(57) **ABSTRACT**

An intravascular foreign matter suction assembly is insertable into a blood vessel having a relatively small diameter and exhibits a high suction force. The intravascular foreign matter suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a suction catheter inserted in the lumen of the guiding catheter and extending further than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery. The suction catheter includes a tubular portion provided on the distal end side and a wire portion provided on the proximal end side of the tubular portion and wherein the wire portion has a distal end embedded in a wall which forms the tubular portion.

11 Claims, 10 Drawing Sheets

Ex-1007.

VSI did not reduce to practice before Itou.

December 2005
Additional Engineering Required

Vascular Solutions, Inc.
2006 Strategic Objectives

The over-the-wire version is expected to be launched in the U.S. and Germany [illegible]

"The rapid exchange version requires additional engineering and is not included in our 2006 forecasts."

Ex-2131.

VSI did not reduce to practice before Itou.

2005

December 2005
Additional Engineering Required

0370	12-2-2005	Guidelinner DVT - Build	Jim K	N/A	R.S. 2-17-06 Design Change Not completed
0371	12-2-2005	Guidelinner DVT - Build	Jim K	N/A	
0372	12-2-2005	Guidelinner DVT - Build	Jim K.	N/A	
0373	12-2-2005	Guidelinner DVT - Luer Assy.	Jim K.	N/A	
0374	12-2-2005	Guidelinner DVT - Luer Assy	Jim K.	N/A	
0375	12-2-2005	Guidelinner DVT - Luer Assy	Jim K.	N/A	

Sutton:

Q. What is design verification testing?

A. It's performance testing to verify the design works as intended.

Ex-1768, 14; 1757, 77:16-18.

VSI did not reduce to practice before Itou.

2006

May 2006
Design In Progress

Guide Liner Team Meeting
Date: May 2, 2006
Attendance: Julie Tapper, Jason Garrity, Dan Gabrielson, Bill Hughes, Deborah Neymark, Jon Hammond, Beti Jo Aichner, Jeff Welch, Vince Hackenmueller, Katie Mytty

"1) Review Initial Design and Intended Use"

Discussion:
Review Initial Design and Intended Use
[illegible] will be manufactured. 1) 5F for use with a 6F guide catheter and 2) 7F for use with a 8F

"prior to design lock"

Review product specs from original design
Harm/Hazard analysis (start at next meeting)
Design Concept
Product Requirements

Other Items:
None

Actions:
None

Root:

"Product Requirements" documents at VSI were used to begin the formal quality process for bringing a design frozen medical device product to market.

Ex-2109; Ex-2118 ¶ 54.

VSI did not reduce to practice before Itou.

April 2007
RX Design In Progress

R&D Device Idea List	04-30-2007 page 1

Idea Name	Prior	Project Leader	Concept Drawing	Design Freeze	Status / Comments
Varilase Bright Tip Rail 5000-85000-05019	1	J. Welch	4/20/07	TBD	~~Concept of ceramic 5mm rail complete~~ - Coors Tec quoting price and lead time for mold - Project review scheduled for today
Guide-Liner A guide catheter support device to aid in delivery of treatment catheters 5000-85000-05005	2	J. Welch	TBD	5/30/07	- Assembly of polymer shaft to NiTi backbone repeatability issues. - New adhesive with new LED light source being investigated - Assembly cost for GuideLiner with

Concept Drawing: TBD
Design Freeze: May 30, 2007

22. How strong is the bond between the metal collar and the guide extension on the GuideLiner?

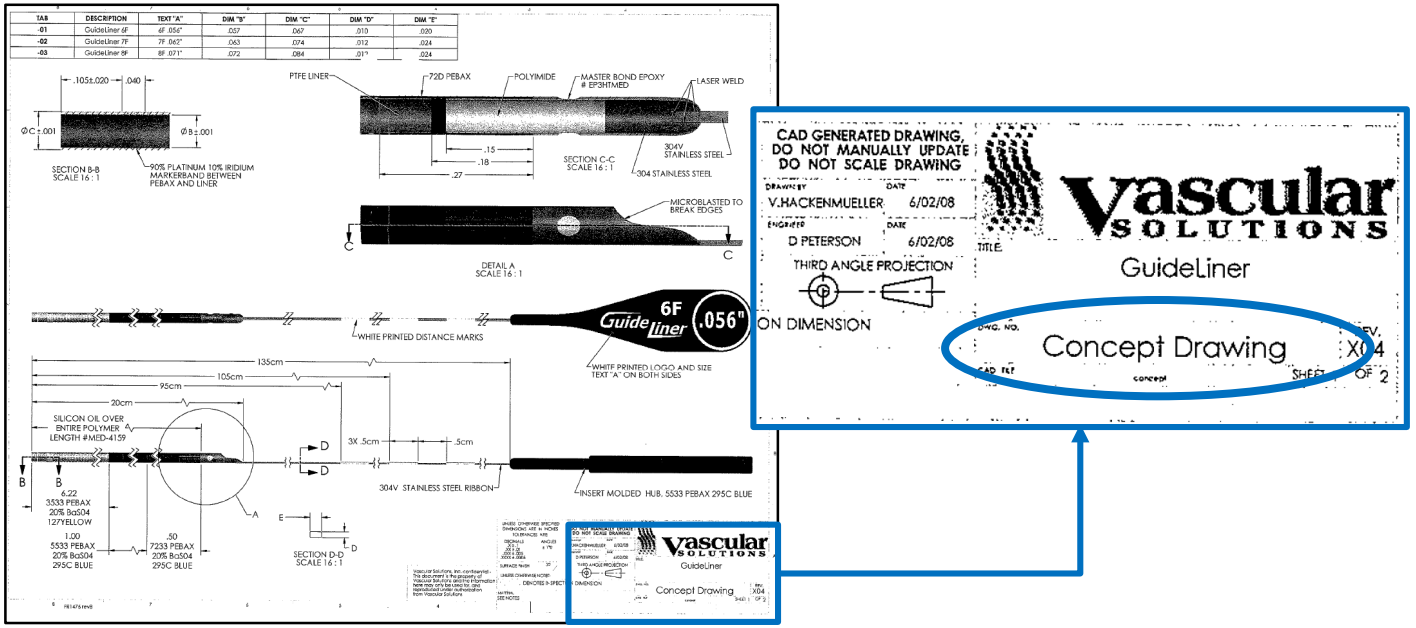
That is the part that took substantial engineering and testing. We did many pull tests on validation lots of the GuideLiner and the catheter would withstand at least a 3.5 lb. pull force. To give you some idea of what that feels like, that pull force is about the same as what it takes to lift a half-gallon of milk.

Ex-1769; Ex-1770.

VSI did not reduce to practice before Itou.

2008

June 2008
RX Concept Drawing



Ex-1765.

VSI did not reduce to practice before Itou.

July 2008
RX Design Pushed Out

Research & Development Update – July 2008
Jeff Welch (Devices) and Steve Penegor (Biologics)

GuideLiner
A coaxial liner for guide catheters to provide extra back-up support during PTCA procedures.

"timelines have been pushed out due to drastic design changes"

cost effective. We are planning on an August 2008 design freeze with a 510k submission in November 2008.

Ex-2132.

VSI did not reduce to practice before Itou.

2009

May 2009
RX Product Requirements Complete

PRODUCT REQUIREMENTS:
GuideLiner

Document Approvals:

Reviewer	Dean Peterson	5/4/09
Documentation	Laura Thomas	5/5/09

3. REQUIREMENTS/SPECIFICATIONS

USER REQUIREMENTS	PRODUCT SPECIFICATIONS	TEST METHOD
3.1 Performance Requirements		
The device(s) must pass through a guide catheter and into the vasculature without kinking or seizing.	3.1.1 The GuideLiner (6Fr, 7Fr, & 8Fr) shafts' distal 15cm must have a coil, and be capable of a 1" bend radius without kinking.	Design Specification TP1182
	3.1.2 The GuideLiner (6Fr, 7Fr, & 8Fr) shafts' distal 15cm must have a silicone coating.	Design Specification
	3.1.3 The GuideLiner (6Fr, 7Fr, & 8Fr) must be capable of advancing through a guide catheter that is placed in simulated anatomy until 10cm of the GuideLiner have extended pass the tip of the guide catheter.	TP1276
The device(s) must have a lubricious inner with the largest possible I.D. while maintaining structural integrity.	3.1.4 The PTFE lined inner diameter of the GuideLiner must be:	Print Verification

GuideLiner Size	Minimum I.D.
6F	.056"
7F	.062"
8F	.071"

3.1.3 The GuideLiner (6Fr, 7Fr, & 8Fr) must be capable of advancing through a guide catheter that is placed in simulated anatomy until 10cm of the GuideLiner have extended pass the tip of the guide catheter.

Ex-1767.

VSI did not reduce to practice before Itou.

2005

2006

2007

2008

2009

Phase I Feasibility

RX Design TBD

Prod. Reqs. Incomplete

Itou

Add'l Engineering Required

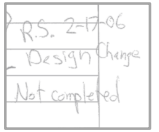
Initial Design Work Continues

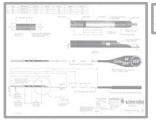
Assembly Issues

Concept Drawing

"Drastic Design Changes"

Prod. Reqs. Complete





Teleflex incorporates its claim-by-claim arguments by reference.

The Rule

(3) *Incorporation by reference; combined documents.* Arguments must not be incorporated by reference from one document into another document. Combined motions, oppositions, replies, or other combined documents are not permitted.

Teleflex's Opening Brief

Submitted herewith are Declarations testifying that, prior to September 2005, prototypes of the claimed invention were made and tested to confirm that they would work for their intended purpose. (Ex. 2118, ¶¶15-58; Ex. 2119, ¶¶6, 16-46; 2122, ¶¶5-13; 2039, ¶¶6-10.) Root's declaration also includes detailed charts that map the GuideLiner patent claims to the prototypes and establish that the prototypes contained all limitations of at least the claims for which Petitioner is relying on Itou.[5] (Ex. 2118, ¶¶78-82 and Appx. A-E; Ex. 2123, ¶28.)

>100 pages

37 C.F.R. § 42.6(a)(3); PO's CRTP Response at 22.

Teleflex cannot prove that VSI was diligent.

"[T]o antedate a reference, the applicant must not only have conceived the invention before the reference date, **but must have reasonably continued activity to reduce the invention to practice**."

ATI Techs. ULC v. Iancu, 920 F.3d 1362, 1369 (Fed. Cir. 2019).

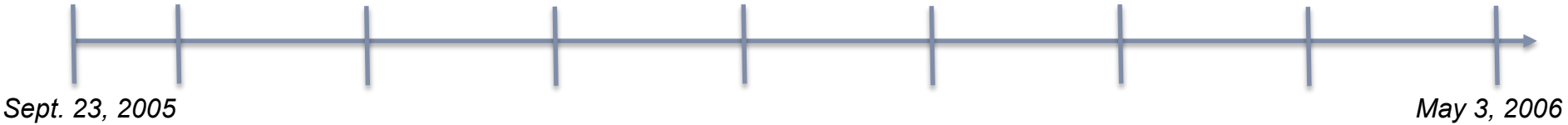
"Reasonable diligence must be shown **throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice**."

Perfect Surgical Techniques, Inc. v. Olympus Am., Inc., 841 F.3d 1004, 1007 (Fed. Cir. 2016).

Petitioners' CRTP Reply at 28.

Teleflex cannot prove that VSI was diligent.

Engineering Work



Teleflex cannot prove that VSI was diligent.

Root:

Q. So first question: Why was the over-the-wire listed as -- you're going to submit to approval for that first?
A. Because it was much easier to get regulatory approval and do the testing for the rapid -- or for the over-the-wire version.
Q. Okay. And this was October, and you were going to do that by December of 2005, right?
A. That was the plan.
Q. And why didn't that happen?
A. Well, we had some transition in personnel, and they didn't get their work done, and we needed to have a new team and we had new people coming in. We prioritized other projects ahead of the over-the-wire version.

Q. Got it. And so then the other piece there, it says, the rapid exchange version, you were going to do a 510(k) in the first quarter of 2006. Do you see that?
A. I see that.
Q. And this may be the same answers, but obviously you did not submit that in 2006, right?
A. Correct.
Q. And is it for the same reason; you had some transition and needed to have a new team for the rapid exchange version?
A. Correct, yeah. Mainly that.

Ex-1762, 131:3-133:3.

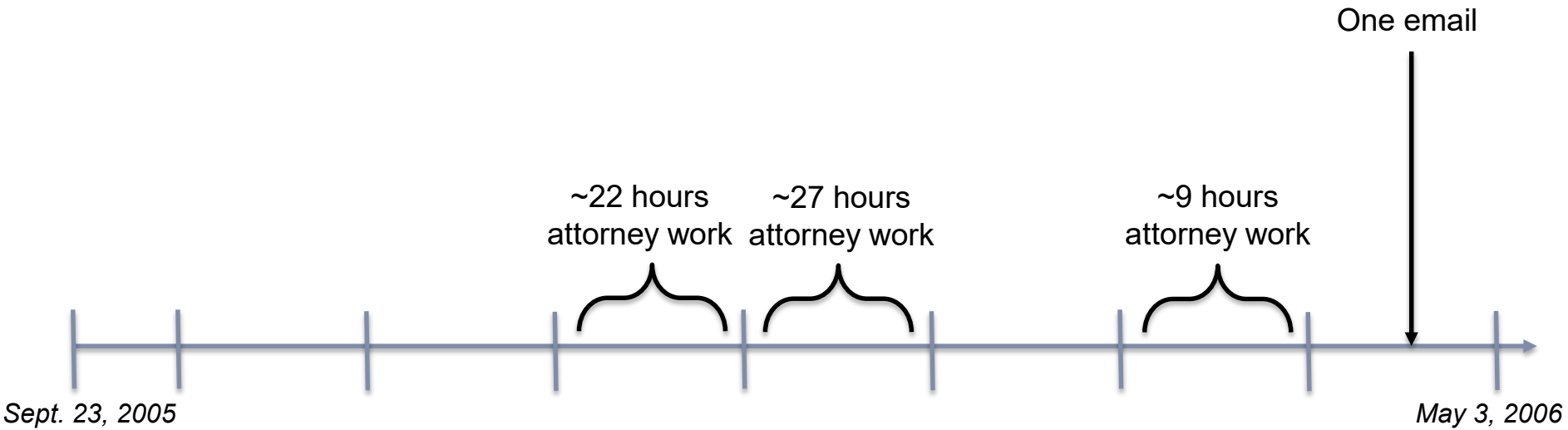
Teleflex cannot prove that VSI was diligent.

Parts Purchases

Ex-2104; Ex-2106; Ex-2107.

Teleflex cannot prove that VSI was diligent.

Prosecution Work



Ex-2098; Ex-2101; Ex-2103; Ex-2117.

Teleflex cannot prove that VSI was diligent.

Teleflex cannot prove prior invention.

US007736355B2

(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent: Jun. 15, 2010**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1300 days.

(21) Appl. No.: **11/232,876**

(22) Filed: **Sep. 23, 2005**

(65) **Prior Publication Data**

US 2006/0069381 A1 Mar. 30, 2006

(30) **Foreign Application Priority Data**

Sep. 24, 2004 (JP) 2004-276291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526, 164.01, 101.03, 604/101.04, 173, 508
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,011,488	A	4/1991	Ginsburg	
5,226,888	A *	7/1993	Arney	604/103.07
5,385,562	A *	1/1995	Adams et al.	604/528
5,527,292	A	6/1996	Adams et al.	
5,569,204	A	10/1996	Cramer	
5,938,645	A	8/1999	Gordon	
6,849,068	B1 *	2/2005	Bagaoisan et al.	604/523
2002/0177800	A1	11/2002	Bagaoisan et al.	
2003/0050600	A1	3/2003	Ressmann et al.	

FOREIGN PATENT DOCUMENTS

WO WO 00/69498 11/2000

OTHER PUBLICATIONS

Official Action (Communication Pursuant to Article 96(2) EPC) issued by the European Patent Office in corresponding European Patent Application No. 05 020 435.3, Jul. 25, 2007.

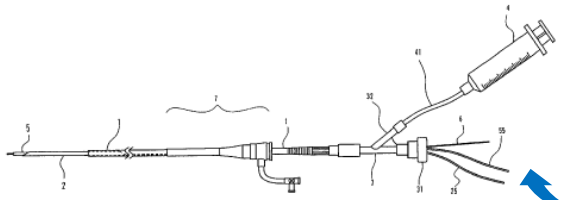
* cited by examiner

Primary Examiner—Nicholas D Lucchesi
Assistant Examiner—Christopher D Koharski
(74) *Attorney, Agent, or Firm*—Buchanan Ingersoll & Rooney PC

(57) **ABSTRACT**

An intravascular foreign matter suction assembly is insertable into a blood vessel having a relatively small diameter and exhibits a high suction force. The intravascular foreign matter suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery. The suction catheter includes a tubular portion provided on the distal end side and a wire portion provided on the proximal end side of the tubular portion and wherein the wire portion has a distal end embedded in a wall which forms the tubular portion.

11 Claims, 10 Drawing Sheets



Filed: **Sep. 23, 2005**

Filed: **May 3, 2006**

Conception and Reduction to Practice before Itou

Conception before Itou and Diligence until Root

US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 437 days.

(21) Appl. No.: **11/416,629**

(22) Filed: **May 3, 2006**

(65) **Prior Publication Data**

US 2007/0260219 A1 Nov. 8, 2007

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/164.1**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.09–164.11, 604/525, 164.02
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,813,930	A	3/1989	Elliott	
4,832,028	A	5/1989	Patel	
4,932,413	A	6/1990	Shockey et al.	
5,098,412	A	3/1992	Shiu	
5,122,125	A	6/1992	Deuss	
5,472,425	A	12/1995	Teirstein	
5,658,263	A	8/1997	Dang et al.	
5,776,141	A *	7/1998	Klein et al.	623/1.11
6,159,195	A	12/2000	Ha et al.	
6,338,725	B1 *	1/2002	Hermann et al.	604/95.04
6,475,195	B1	11/2002	Voda	
6,595,952	B2	7/2003	Forsberg	
6,610,068	B1	8/2003	Yang	
6,638,268	B2 *	10/2003	Niazi	604/528
6,689,144	B2	2/2004	Gerberding	
6,706,018	B2	3/2004	Westlund et al.	
6,755,812	B2	6/2004	Peterson et al.	
6,860,876	B2	3/2005	Chen	
7,697,996	B2	4/2010	Manning et al.	
7,717,899	B2	5/2010	Bowe et al.	
2003/0195546	A1 *	10/2003	Solar et al.	606/192
2004/0127927	A1 *	7/2004	Adams	606/170
2005/0004523	A1	1/2005	Osborne et al.	
2005/0182437	A1	8/2005	Bonnette et al.	
2007/0260219	A1	11/2007	Root et al.	

OTHER PUBLICATIONS

Takahashi, New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages, published online in Wiley InterScience (www.interscience.wiley.com).
Office Action for U.S. Appl. No. 12/824,734; filed Jun. 28, 2010, Inventors Roots et al.; Office Action dated Aug. 1, 2011.

* cited by examiner

Primary Examiner — Jackie Ho
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente IP

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

22 Claims, 13 Drawing Sheets

PETITIONERS' DEMONSTRATIVE

Medtronic, Inc. and Medtronic Vascular, Inc. v. Teleflex Innovations S.A.R.L.

IPR2020-00126, -00127, -00128, -00129, -00130,
-00132, -00134, -00135, -00136, -00137, -00138

March 8, 2021
ORAL HEARING

Agenda

Conception and Reduction to Practice

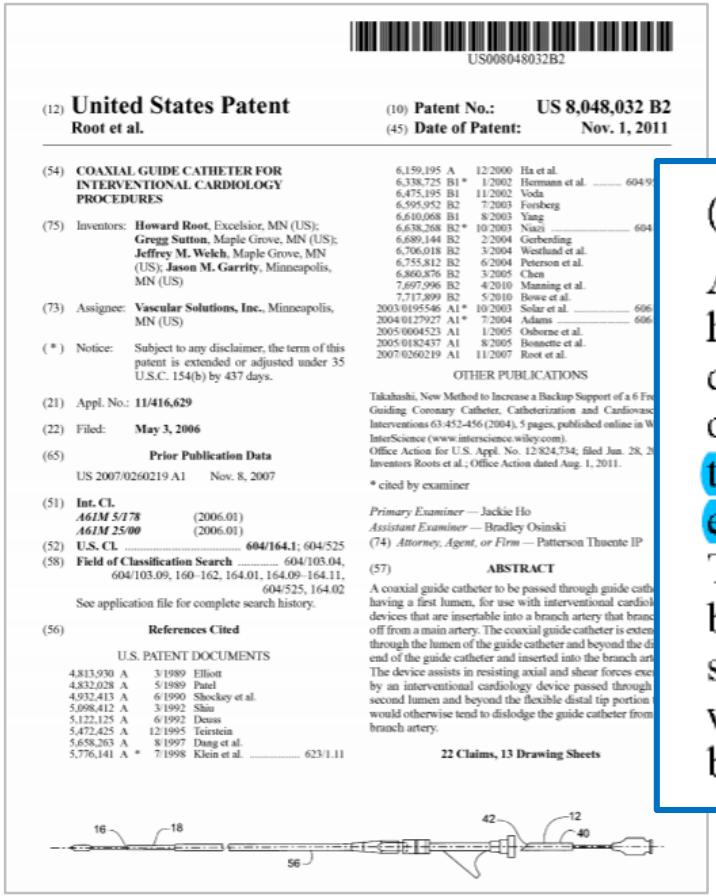
Merits

- Introduction
- Itou (IPR2020-00126, -00128, -00132, -00134, -00135, -00137)
- Ressemann (IPR2020-00134, -00138)
- Double Incline Claims
- Secondary Considerations
- Means-Plus-Function (IPR2020-00129)
- Kontos (IPR2020-00127, -00130, -00136)

Motions to Amend

INTRODUCTION

’032 Patent



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 437 days.

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(52) **U.S. Cl.** **604/164.1**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.09–164.11, 604/525, 164.02
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(56) **References Cited**

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5,098,412	A	3/1992	Shiu	
5,122,125	A	6/1992	Deuss	
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5,776,141	A *	7/1998	Klein et al.	623/1.11
6,159,195	A	12/2000	Ha et al.	
6,338,725	B1 *	1/2002	Hermann et al.	604/9
6,475,195	B1	11/2002	Voda	
6,595,952	B2	7/2003	Forsberg	
6,610,068	B1	8/2003	Yang	
6,638,268	B2 *	10/2003	Niazi	604
6,689,144	B2	2/2004	Gerberding	
6,706,018	B2	3/2004	Westlund et al.	
6,755,812	B2	6/2004	Peterson et al.	
6,860,876	B2	3/2005	Chen	
7,697,996	B2	4/2010	Manning et al.	
7,717,899	B2	5/2010	Bowe et al.	
2003/0195546	A1 *	10/2003	Solar et al.	606
2004/0127927	A1 *	7/2004	Adams	606
2005/0004523	A1	1/2005	Osborne et al.	
2005/0182437	A1	8/2005	Bonnette et al.	
2007/0260219	A1	11/2007	Root et al.	

OTHER PUBLICATIONS

Takahashi, New Method to Increase a Backup Support of a 6 Fr… Guiding Coronary Catheter, Catheterization and Cardiovasc… Interventions 63:452-456 (2004), 5 pages, published online in W… InterScience (www.interscience.wiley.com).
Office Action for U.S. Appl. No. 12/824,734; filed Jun. 28, 2… Inventors Roots et al.; Office Action dated Aug. 1, 2011.

* cited by examiner

Primary Examiner — Jackie Ho
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente IP

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide cath… having a first lumen, for use with interventional cardiol… devices that are insertable into a branch artery that branc… off from a main artery. The coaxial guide catheter is exten… through the lumen of the guide catheter and beyond the di… end of the guide catheter and inserted into the branch art… The device assists in resisting axial and shear forces exe… by an interventional cardiology device passed through … second lumen and beyond the flexible distal tip portion … would otherwise tend to dislodge the guide catheter from … branch artery.

22 Claims, 13 Drawing Sheets

(57) **ABSTRACT**

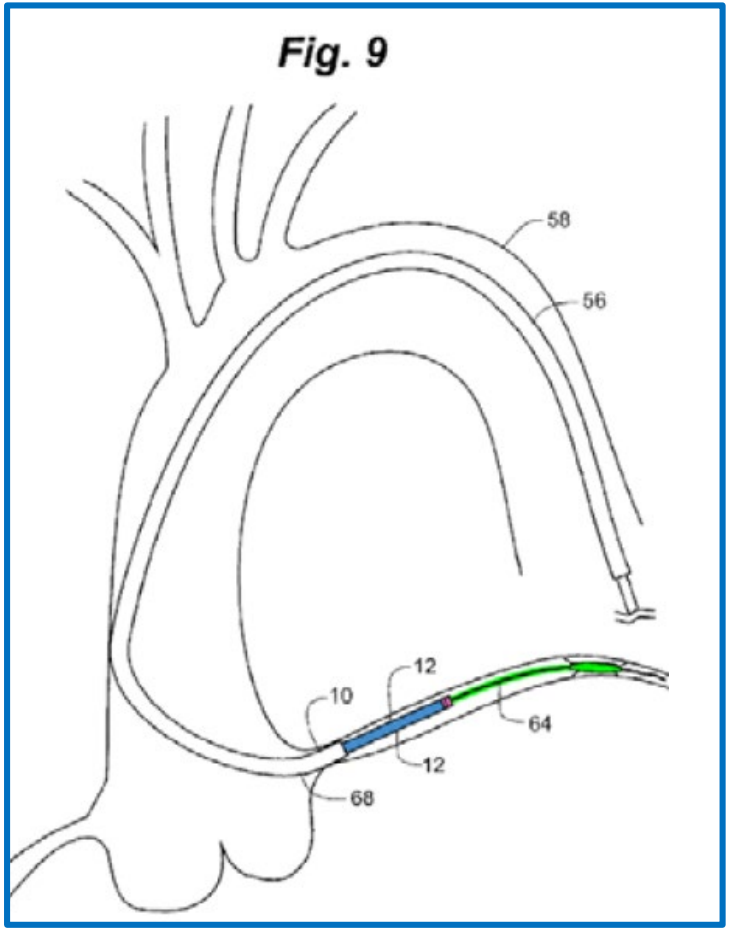
A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

IPR2020-00126, Ex-1001 at 1

’032 Patent

Coaxial guide catheter **12** is now ready to accept a treatment catheter such as a stent or balloon catheter. Referring to FIG. **9**, the combination of guide catheter **56** with coaxial guide catheter **12** inserted into ostium **60** of coronary artery **62** provides improved distal anchoring of guide catheter **56** and coaxial guide catheter **12**. The presence of coaxial guide catheter **12** within guide catheter **56** also provides stiffer back up support than guide catheter **56** alone. The combination of improved distal anchoring and stiffening of the guide catheter **56**/coaxial guide catheter **12** combination provides additional back up support to resist dislodging of guide catheter **56** from ostium **60** when force is applied to guidewire **64** to pass through stenotic lesion **66** or another lesion. In addition, the improved back up support assists in the positioning of a treating catheter that may include a stent or balloon.

IPR2020-00126, Ex-1001, 7:61-8:7; Fig. 9 (color added)



’032 Patent

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

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOTAPED DEPOSITION OF

HOWARD C. ROOT

DATE: November 13, 2020

TIME: 9:32 a.m. Central Time

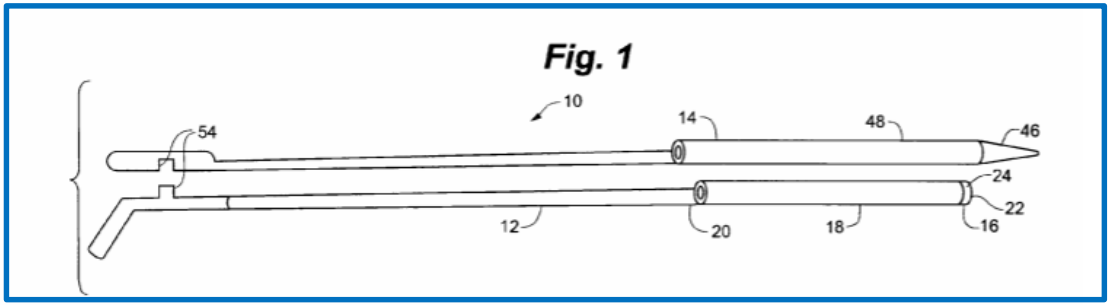
PLACE: Veritext Virtual Videoconference

REPORTED BY: PAULA K. RICHTER, RMR, CRR, CRC
(By videoconference)

Veritext Legal Solutions
www.veritext.com 888-391-3376
Medtronic Ex.1762
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

Q. Right. But in general, you didn't come up with guide extension; you didn't come up with rapid exchange. Your testimony is you came up with the combination of the two; is that right?

THE WITNESS: Yeah. We did not invent rapid exchange, and we did not invent guide extension, but we invented rapid exchange guide extension.



IPR2020-00127, Ex-1762 (Root Tr), 39:14-17, 19-22, Reply at 24; Ex-1001, Fig. 1

Takahashi

Basic Science Review

New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter

Saeko Takahashi,[1*] MD, Shigeru Saito,[1] MD, Shinji Tanaka,[1] MD, Yusuke Miyashita,[1] MD, Takaaki Shiono,[1] MD, Fumio Arai,[1] MD, Hiroshi Domae,[1] MD, Shutaro Satake,[1] MD, and Takenari Itoh,[2] PhD

A 6 Fr guiding catheter is commonly used in the percutaneous coronary intervention (PCI). However, one of the limitations of the 6 Fr guiding catheter is its weak backup support compared to a 7 or an 8 Fr guiding catheter. In this article, we present a new system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

Key words: five-in-six system; backup support; 6 Fr guiding catheter; chronic total occlusion

INTRODUCTION

Currently, a 6 Fr guiding catheter is commonly used in percutaneous coronary intervention (PCI), since its use can decrease access site complication, enable early ambulation, and reduce the consumption of the contrast dye [1–4]. Major limitations of a 6 Fr guiding catheter are the inner lumen is not big enough to accommodate bulky atherectomy devices, and its backup support is not strong compared to a 7 or an 8 Fr catheter. In this report, we demonstrate a new technique for PCI called the five-in-six system, which increases a backup support of a 6 Fr guiding catheter.

MATERIALS AND METHODS

The Five-in-Six System

The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A).

This 5 Fr Heartrail straight guiding catheter is 120 cm in length, whereas the 6 Fr guiding catheter is 100 cm. The 5 Fr Heartrail catheter has a very soft 13 cm end portion. This soft end portion can easily negotiate the tortuous coronary artery with the minimal damage and then it can be inserted more deeply into the artery. The inner lumen of the 5 Fr Heartrail catheter is 0.059′ in diameter; it can accept normal balloons or stent delivery systems less than 4.0 mm in diameter. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071′ in diameter to accommodate the 5 Fr Heartrail catheter; Launcher (Medtronic), Heartrail, and Radiguide (Terumo) guiding catheters can meet this inner lumen diameter.

In Vitro Experiments

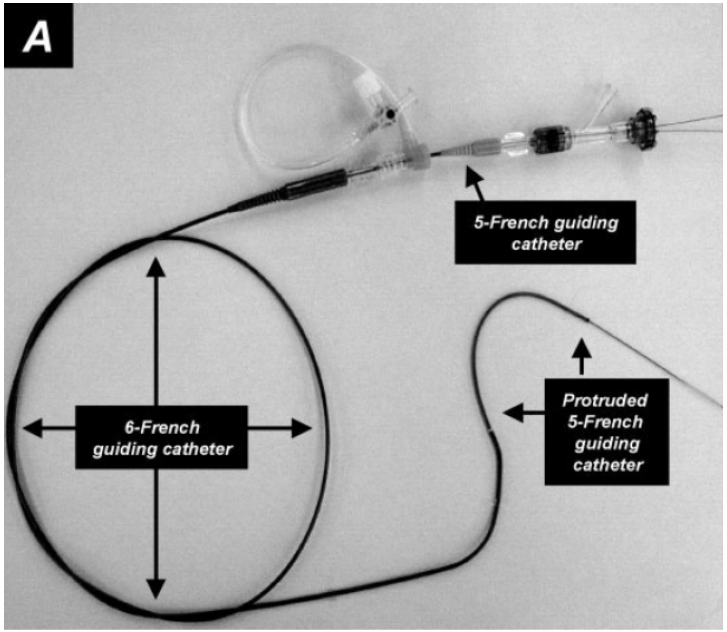
We measured the backup support of this five-in-six system in vitro using an experimental system. The artery model had three curves simulating tortuous coronary arteries. It was filled with water that was kept at 37°C (Fig. 1B). A guiding catheter was engaged into the ostium of the artery model. Then a rapid-exchange balloon catheter (Ryujin 2.5 × 20 mm; Terumo) was pushed into

[1]Division of Cardiology, Center of Shonan Kam... Japan [2]Research and ... tory, Terumo Corporat...

*Correspondence to: Dr. ... Catheterization Laborato... eral Hospital, 1202-1 Y... E-mail: saekot@wa2.so-...

Received 8 October 200...

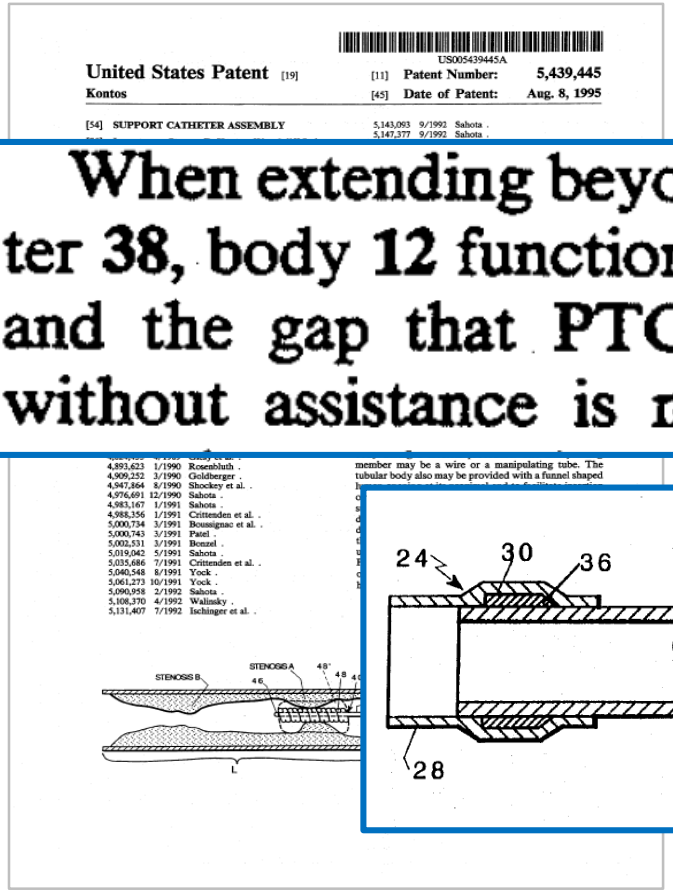
DOI 10.1002/ccd.20223
Published online in Wiley InterScience (www.interscience.wiley.com).



system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

IPR2020-00126, Ex-1010

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] **SUPPORT CATHETER ASSEMBLY**

5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .

4,893,623 1/1990 Rosenbluth .
4,909,252 3/1990 Goldberger .
4,947,864 8/1990 Shockey et al. .
4,976,691 12/1990 Sahota .
4,983,167 1/1991 Sahota .
4,988,356 1/1991 Crittenden et al. .
5,000,734 3/1991 Boussignac et al. .
5,000,743 3/1991 Patel .
5,002,531 3/1991 Bonzel .
5,019,042 5/1991 Sahota .
5,035,686 7/1991 Crittenden et al. .
5,040,548 8/1991 Yock .
5,061,273 10/1991 Yock .
5,090,958 2/1992 Sahota .
5,108,370 4/1992 Walinsky .
5,131,407 7/1992 Ischinger et al. .

member may be a wire or a manipulating tube. The tubular body also may be provided with a funnel shaped

STENOSIS B
STENOSIS A

When extending beyond the distal end of guide catheter **38**, body **12** functions as a guide catheter extension, and the gap that PTCA catheter **40** must negotiate without assistance is made much shorter. It will be

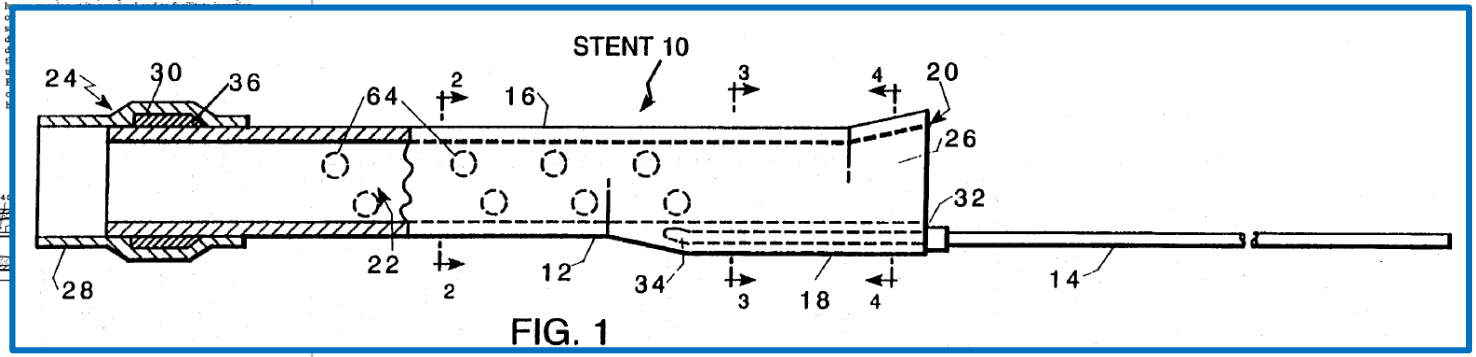


FIG. 1

Ex-1409, Fig. 1; 5:49-52

U.S. Patent No. 7,604,612 (Ressemann)

US007604612B2

(12) **United States Patent**
Ressemann et al.

(10) **Patent No.: US 7,604,612 B2**
(45) **Date of Patent: Oct. 20, 2009**

(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

(75) Inventors: **Thomas V Ressemann**, St. Cloud, MN (US); **Steven S Hackett**, Maple Grove, MN (US); **Andrew J Dusbabek**, Dayton, MN (US); **Dennis W Wahr**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical, Cardiology Division, Inc.**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 560 days.

(21) Appl. No.: **10/214,712**

(22) Filed: **Aug. 9, 2002**

(65) **Prior Publication Data**

US 2003/0050600 A1 Mar. 13, 2003

(51) **Int. Cl.**
A61M 29/00 (2006.01)

(52) **U.S. Cl.** **604/101.01**

(58) **Field of Classification Search** 604/101.04, 604/284, 524, 96.01, 101.01, 101.03–101.05, 604/102.01–102.03, 103.06–103.08; 606/191, 606/194

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,522,195 A * 6/1985 Schiff 600/18
4,655,746 A 4/1987 Daniels et al.
4,696,668 A * 9/1987 Wilcox 604/28
4,784,636 A 11/1988 Rydell
4,883,460 A 11/1989 Zanetti
4,921,478 A 5/1990 Solano et al.

(Continued)

FOREIGN PATENT DOCUMENTS

EP 0 427 429 A2 5/1991

(Continued)

OTHER P

Kachel, Reiner, M.D., "Results Arteries," J. Endovas Surg. 19

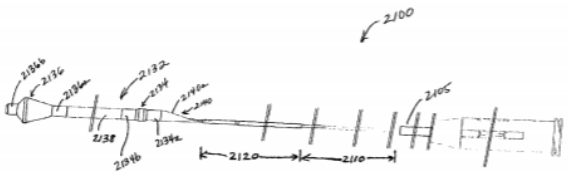
(C

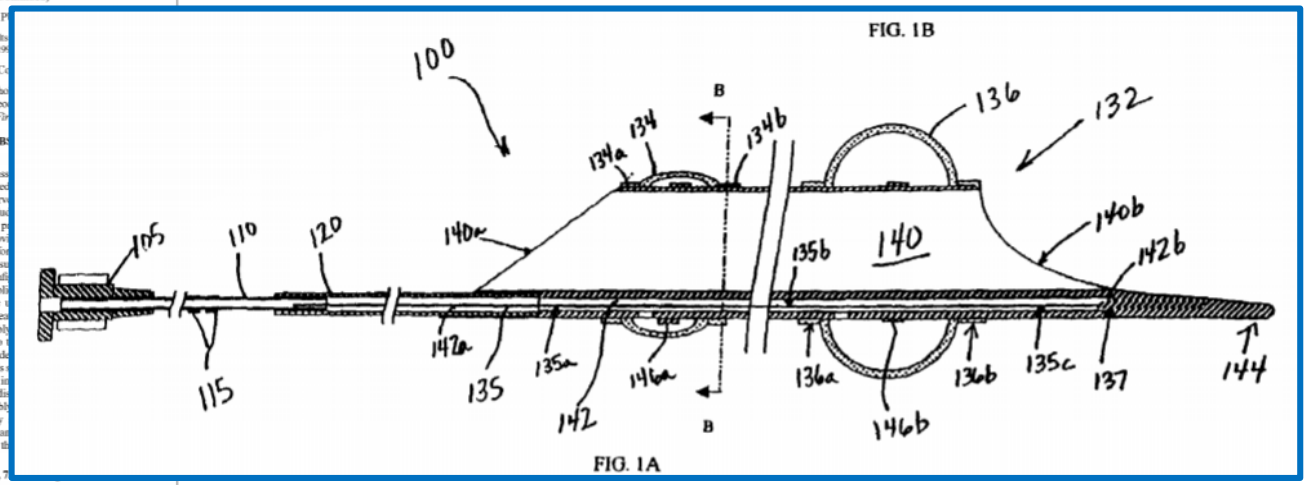
Primary Examiner—Nichc
Assistant Examiner—Theo
(74) *Attorney, Agent, or Fir*

(57) ABS

An evacuation sheath ass occluded vessels which re tion during vascular interv tion sheath assembly inclu evacuation lumen having p mal sealing surface is provi tube and is configured to fo catheter. A distal sealing su tion of the tube and is confi vessel. Obturator assembl blies are provided to be assembly. A method of trea evacuation sheath assembl tion sheath assembly into catheter. Normal antegrad proximate to the stenosis is Retrograde blood flow is i carry embolic material da evacuation sheath assembl grade flow, the coronary occluded. Alternatively, a while flow is occluded at th

15 Claims, 7





IPR2020-00126, Ex-1008, Fig. 1A

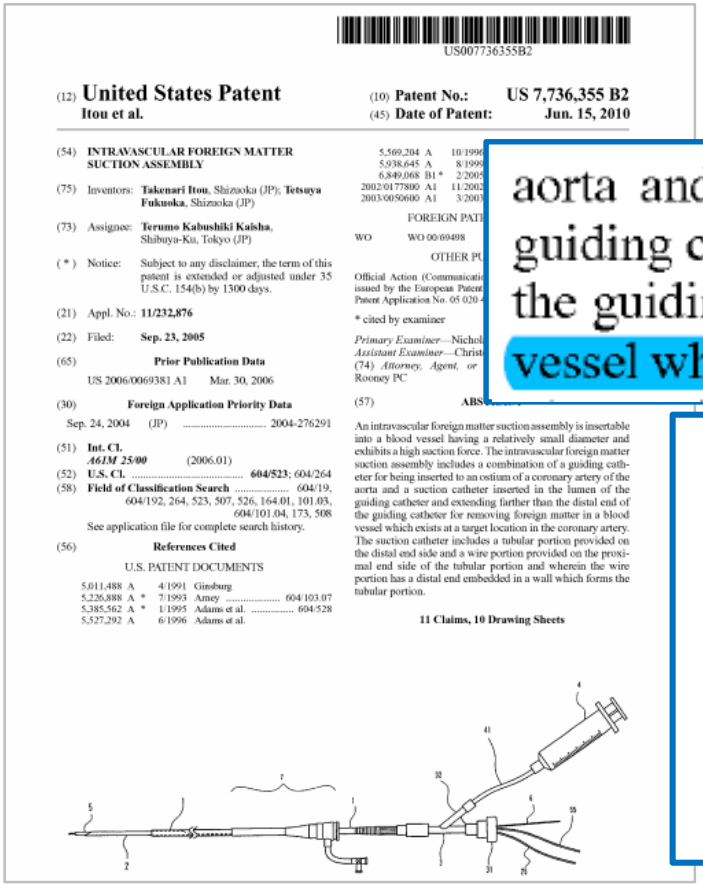
U.S. Patent No. 7,604,612 (Ressemann)

As embodied herein and shown in FIG. **1**A, an evacuation sheath assembly **100** is provided. Evacuation sheath assembly **100** includes an evacuation head and a shaft. As embodied herein and shown in FIG. **5**A, the evacuation sheath assembly **100** is sized to fit inside a guide catheter to advance a distal end of the evacuation sheath assembly into a blood vessel to treat a stenosis.

Additionally, although the method of use of the evacuation sheath assembly will be described with respect to placing a stent within a vessel, the evacuation sheath assembly **100** can be used during other therapies, such as angioplasty, atherectomy, thrombectomy, drug delivery, radiation, and diagnostic procedures.

IPR2020-00126, Ex-1008, 6:18-26, 29-34

U.S. Pat. No. 7,736,355 (Itou)



US007736355B2

(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent: Jun. 15, 2010**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1300 days.

(21) Appl. No.: **11/232,876**

(22) Filed: **Sep. 23, 2005**

(65) **Prior Publication Data**

US 2006/0069381 A1 Mar. 30, 2006

(30) **Foreign Application Priority Data**

Sep. 24, 2004 (JP) 2004-276291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526, 164.01, 101.03, 604/101.04, 173, 508
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,011,488 A 4/1991 Ginsburg
5,226,888 A * 7/1993 Arney 604/103.07
5,385,562 A * 1/1995 Adams et al. 604/528
5,527,292 A 6/1996 Adams et al.

5,569,204 A 10/1996
5,938,645 A 8/1999
6,849,068 B1 * 2/2005
2002/0177800 A1 11/2002
2003/0050600 A1 3/2003

FOREIGN PATE

WO WO 00/69498

OTHER PU

Official Action (Communicati
issued by the European Patent
Patent Application No. 05 020

* cited by examiner

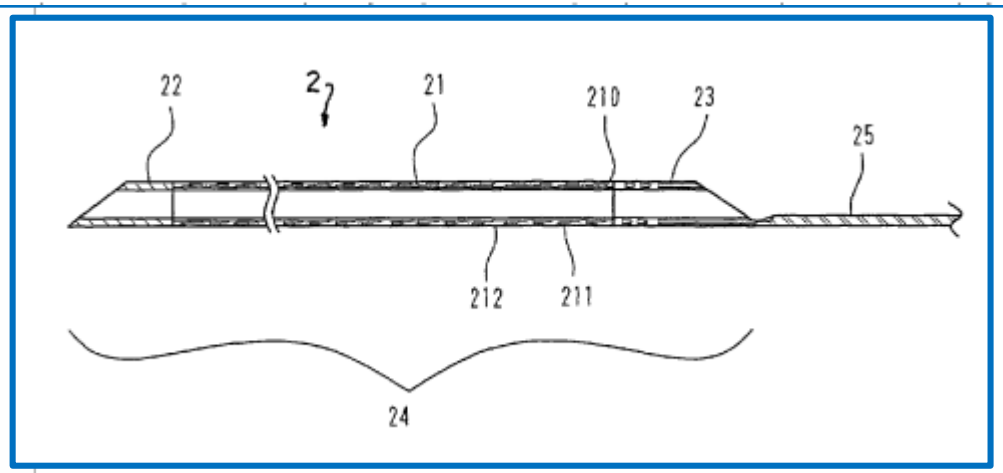
Primary Examiner—Nichol
Assistant Examiner—Christ
(74) *Attorney, Agent, or* Rooney PC

(57) ABS

An intravascular foreign matter suction assembly is insertable into a blood vessel having a relatively small diameter and exhibits a high suction force. The intravascular foreign matter suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery. The suction catheter includes a tubular portion provided on the distal end side and a wire portion provided on the proximal end side of the tubular portion and wherein the wire portion has a distal end embedded in a wall which forms the tubular portion.

11 Claims, 10 Drawing Sheets

aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery.

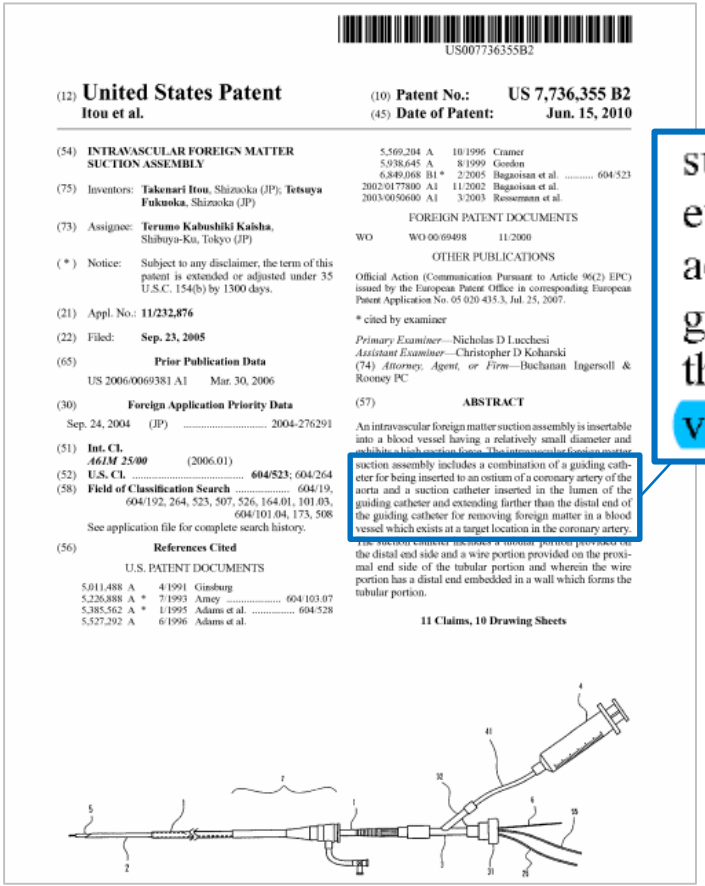


IPR2020-00126, Ex-1007, Abstract; Fig. 3

ITOU

IPR2020-00126, -00128, -00132, -00134, -00135, -00137

Itou



US007736355B2

(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent: Jun. 15, 2010**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1300 days.

(21) Appl. No.: **11/232,876**

(22) Filed: **Sep. 23, 2005**

(65) **Prior Publication Data**

US 2006/0069381 A1 Mar. 30, 2006

(30) **Foreign Application Priority Data**

Sep. 24, 2004 (JP) 2004-276291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526, 164.01, 101.03, 604/101.04, 173, 508
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,011,488	A	4/1991	Ginsburg	
5,226,888	A *	7/1993	Arney	604/103.07
5,385,562	A *	1/1995	Adams et al.	604/528
5,527,292	A	6/1996	Adams et al.	
5,569,204	A	10/1996	Cramer	
5,938,645	A	8/1999	Gordon	
6,849,068	B1 *	2/2005	Bagaoisan et al.	604/523
2002/0177800	A1	11/2002	Bagaoisan et al.	
2003/0050600	A1	3/2003	Ressemann et al.	

FOREIGN PATENT DOCUMENTS

WO WO 00/69498 11/2000

OTHER PUBLICATIONS

Official Action (Communication Pursuant to Article 96(2) EPC) issued by the European Patent Office in corresponding European Patent Application No. 05 020 435.3, Jul. 25, 2007.

* cited by examiner

Primary Examiner—Nicholas D Lucchesi
Assistant Examiner—Christopher D Koharski
(74) *Attorney, Agent, or Firm*—Buchanan Ingersoll & Rooney PC

(57) **ABSTRACT**

An intravascular foreign matter suction assembly is insertable into a blood vessel having a relatively small diameter and exhibits a high suction force. The intravascular foreign matter suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery. The suction catheter includes a tubular portion provided on the distal end side and a wire portion provided on the proximal end side of the tubular portion and wherein the wire portion has a distal end embedded in a wall which forms the tubular portion.

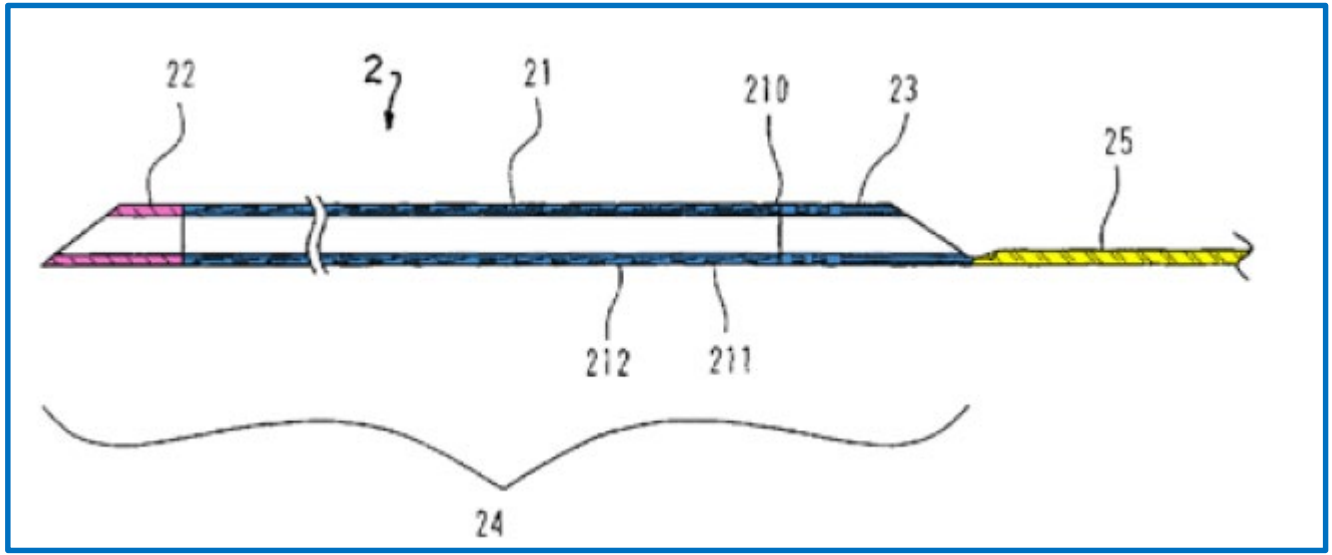
11 Claims, 10 Drawing Sheets

suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery.

IPR2020-00126, Ex-1007, Abstract

Itou

More preferably, the suction catheter includes a tubular portion provided on the distal side and a solid wire-like portion provided on the proximal side and having a distal end embedded in a wall which forms the tubular portion. Further,



IPR2020-00126, Ex-1007, Fig. 3 (color added); 2:12-15

Itou

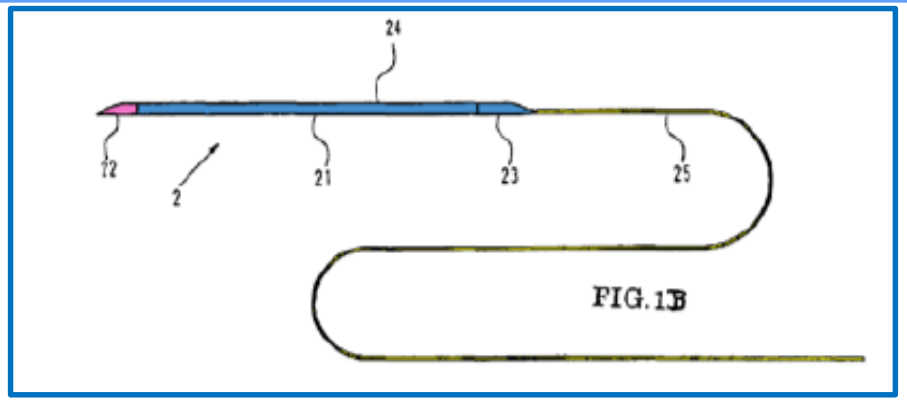
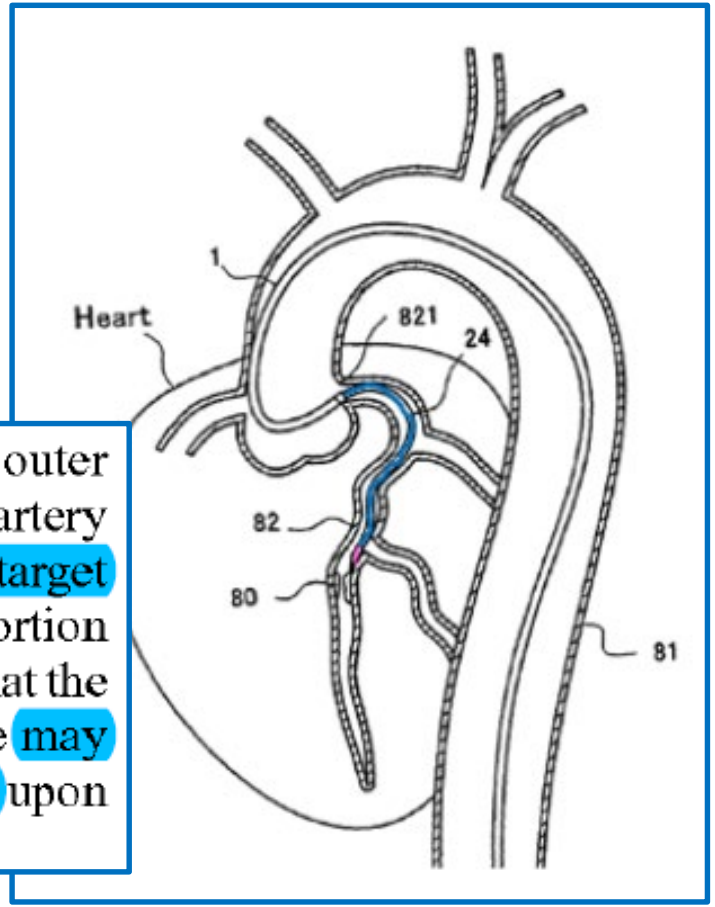


FIG. 1B

The tubular portion **24** of the suction catheter **2** has an outer diameter with which it can be inserted into the coronary artery **82** and is introduced along the guide wire **6** to the target location **80** positioned at a deep location. The tubular portion **24** is designed so as to have a sufficient axial length so that the proximal end of the tubular portion **24** in an open state may not leap out from the distal end of the guiding catheter **1** upon such introduction of the tubular portion **24**.



IPR2020-00137

RE47,379 claims	Instituted Ground	References
25-26, 29-31, 33-40, 42-43, 45	1	Itou
26, 38-40, 43-45	2	Itou, Ressemann
32	3	Itou and knowledge of a POSITA
44	4	Itou, Kataishi
44	5	Itou, Enger

Claims addressed in Patent Owner's Response

- 44

Unrebutted claims: 25-26, 29-31, 33-40, 42-43, 45

RE45,760 claims	Instituted Ground	References
25-31, 33-38, 41, 42, 44, 47	1	Itou
25, 30, 32, 39, 40	2	Itou, Ressemann
32	3	Itou, Kataishi
32	4	Itou, Enger

Claims addressed in Patent Owner's Response

- Dependent claims 32, 39

Unrebutted claims: 25-31, 33-38, 40-42, 44, 47

RE45,760 claims	Instituted Ground	References
48, 51, 53	1	Itou
48, 51, 53	2	Itou, Ressemann
52	3	Itou and knowledge of a POSITA
48, 51, 53	4	Ressemann

Claims addressed in Patent Owner's Response

- Ground 4 only (claims 48, 51, 53)

Unrebutted claims: Grounds 1-3 (claims 48, 51-53)

IPR2020-00126

8,048,032 claims	Instituted Ground	References
1-19, 22	1	Itou
3, 13, 14	2	Itou, Ressemann
20	3	Itou, Berg

Claims addressed in Patent Owner's Response

- Independent claims 1, 11
- Dependent claims 3, 6, 13, 14

Unrebutted claims: 2, 4, 5, 7-12, 15-19, 20, 22

IPR2020-00128

RE45,380 claims	Instituted Ground	References
1-4, 6-10, 12-20, 23	1	Itou
3, 14,15	2	Itou, Ressemann
21	3	Itou, Berg

Claims addressed in Patent Owner's Response

- Independent claims 1, 12
- Dependent claims 3, 14, 15

Unrebutted claims: 2, 4, 6-10, 13, 16-20, 21

IPR2020-00135

RE45,776 Claims	Instituted Ground	References
25-27, 29-33, 35-37, 41-45, 47-49	1	Itou
39, 49	2	Itou and knowledge of a POSITA
36-37, 52-56	3	Itou, Kataishi and knowledge of a POSITA
32, 36-38, 46, 52-56	4	Itou, Ressemann and knowledge of a POSITA
52-56	5	Itou, Enger and knowledge of a POSITA

Claims addressed in Patent Owner's Response

- Independent claims 25, 52, 53, 56
- Dependent claims 32, 36, 37, 39, 46

Unrebutted claims: 26-27, 29-31, 33, 35, 38, 41-45, 47-49, 54-55

IPR2020-00126, -00128, -00132, -00135, -00137

- "*interventional cardiology devices*"
  - Claim Construction (IPR2020-00126, -00128, -00135)
  - Itou Receives interventional cardiology devices

***

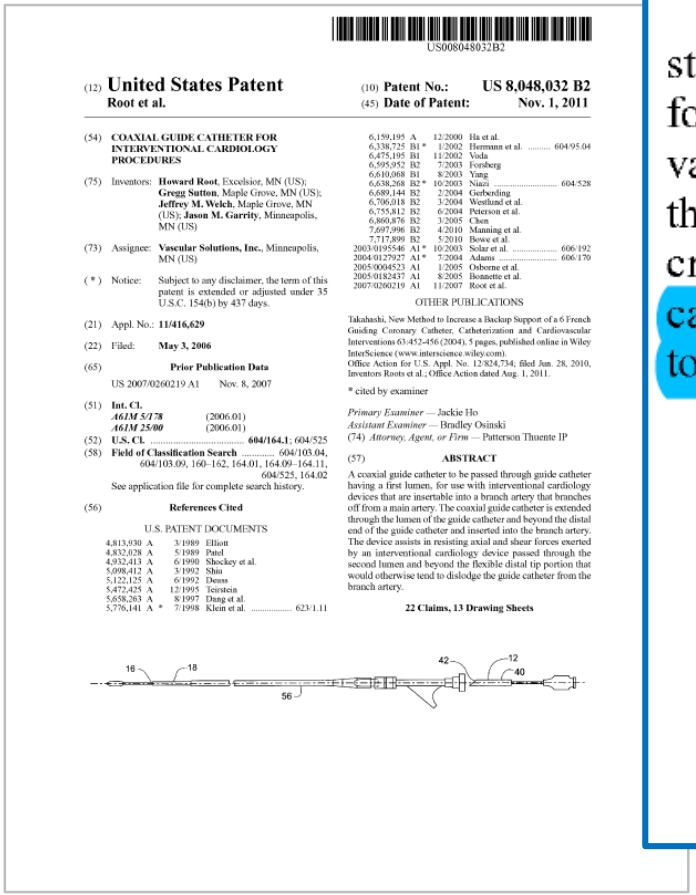
- Itou discloses a "*flexible cylindrical distal tip portion*" (claim 6, '032 patent) (IPR2020-00126)
- Itou discloses an *"inclined region that tapers into a non-inclined region"* (claim 32, '776 patent) (IPR2020-00135)

- "*interventional cardiology devices*"
  - Claim Construction (independent claims)
  - Itou Receives interventional cardiology devices

***

- Itou discloses a "*flexible cylindrical distal tip portion*" (claim 6, '032 patent) (IPR2020-00126)
- Itou discloses an *"inclined region that tapers into a non-inclined region"* (claim 32, '776 patent) (IPR2020-00135)

"interventional cardiology devices"



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 437 days.

(21) Appl. No.: **11/416,629**

(22) Filed: **May 3, 2006**

(65) **Prior Publication Data**

US 2007/0260219 A1 Nov. 8, 2007

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/164.1**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.09–164.11, 604/525, 164.02
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,813,930	A	3/1989	Elliott
4,832,028	A	5/1989	Patel
4,932,413	A	6/1990	Shockey et al.
5,098,412	A	3/1992	Shiu
5,122,125	A	6/1992	Deems
5,472,425	A	12/1995	Teirstein
5,658,263	A	8/1997	Dang et al.
5,776,141	A *	7/1998	Klein et al. 623/1.11
6,159,195	A	12/2000	Ha et al.
6,338,725	B1 *	1/2002	Hermann et al. 604/95.04
6,475,195	B1	11/2002	Voda
6,595,952	B2	7/2003	Forsberg
6,610,068	B1	8/2003	Yang
6,638,268	B2 *	10/2003	Niazi 604/528
6,689,144	B2	2/2004	Gerberding
6,706,018	B2	3/2004	Westlund et al.
6,755,812	B2	6/2004	Peterson et al.
6,860,878	B2	3/2005	Chen
7,697,996	B2	4/2010	Manning et al.
7,717,899	B2	5/2010	Bowe et al.
2003/0195546	A1 *	10/2003	Solar et al. 606/192
2004/0127927	A1 *	7/2004	Adams 606/170
2005/0004523	A1	1/2005	Osborne et al.
2005/0182437	A1	8/2005	Bonnette et al.
2007/0260219	A1	11/2007	Root et al.

OTHER PUBLICATIONS

Takahashi, New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages, published online in Wiley InterScience (www.interscience.wiley.com).
Office Action for U.S. Appl. No. 12/824,734, filed Jun. 28, 2010, Inventors Roots et al.; Office Action dated Aug. 1, 2011.

* cited by examiner

Primary Examiner — Jackie Ho
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente IP

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

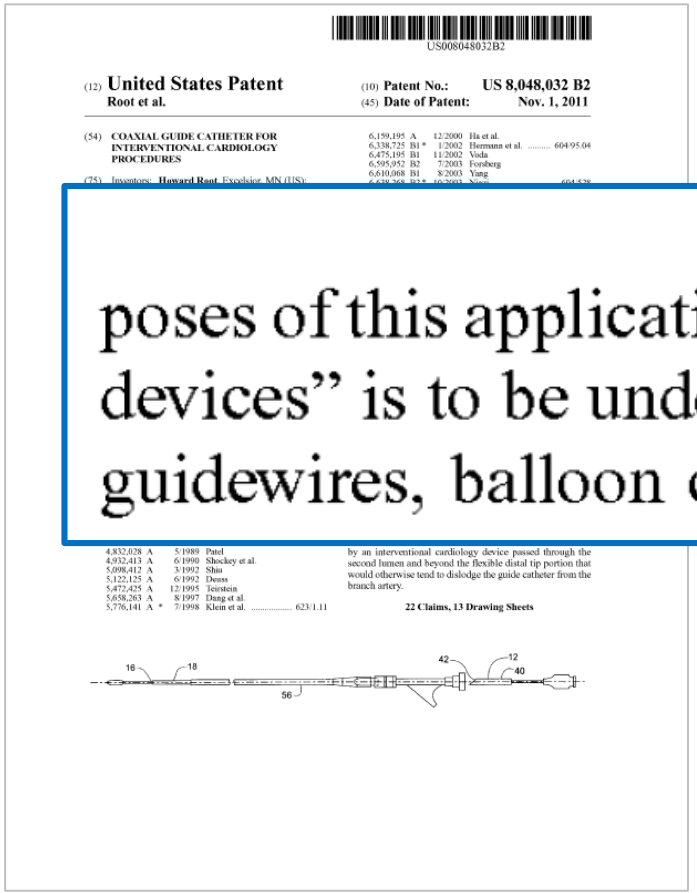
22 Claims, 13 Drawing Sheets

1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

Ex-1001, claim 1 ('032 patent)

“interventional cardiology devices”



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

6,159,195 A 12/2000 Ha et al.
6,338,725 B1 * 1/2002 Hermann et al. 604/95.04
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6,595,952 B2 7/2003 Forsberg
6,610,068 B1 8/2003 Yang

4,832,028 A 5/1989 Patel
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5,098,412 A 3/1992 Shiu
5,122,125 A 6/1992 Deniss
5,472,425 A 12/1995 Teirstein
5,658,263 A 8/1997 Dang et al.
5,776,141 A * 7/1998 Klein et al. 623/1.11

by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

22 Claims, 13 Drawing Sheets

16 18 42 12 40 56

For the purposes of this application, the term “interventional cardiology devices” is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters.

Ex-1001, 1:17-21

"interventional cardiology devices"

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Having considered the parties' positions and evidence of record, we determine that the term "interventional cardiology devices" refers to at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters. In the context of independent claims 1 and 11, the lumen of the recited guide catheter must be sized to receive at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters.

"interventional cardiology devices"

Institution Decision	Teleflex Proposal
• " . . . at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloons, stents and stent catheters;" • ". . . we do not construe the claims to require that more than one . . . be simultaneously insertable . . . "	• " . . . **at least four** of the most common coronary devices - - - guidewires, balloons, stents and stent catheters;" and • "any other device that is delivered beyond the end of the device for use with a standard guide catheter to a location in the cardiac vasculature requiring treatment, **to provide treatment** to that location."
IPR2020-00126, Paper 22, 12-13.	IPR2020-00126, POR, 11.

"interventional cardiology devices"

coronary arteries that branch off from the aorta. For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters. In

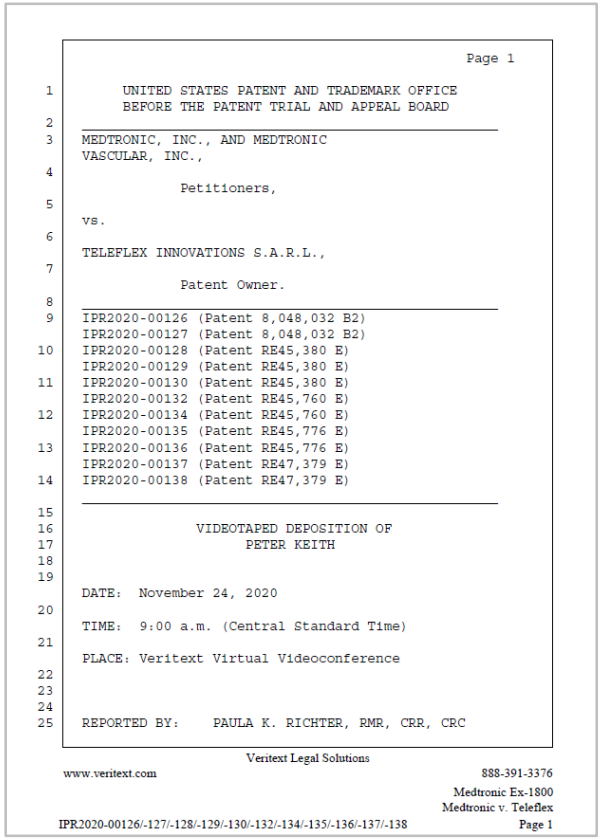
Once the tapered inner catheter is removed a cardiac treatment device, such as a guidewire, balloon or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. As described below, the

ing injections through existing Y adapters. Finally, the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel.

from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**.

IPR2020-00126, Ex-1001, 1:17-21; 4:30-31; 5:9-12; 9:59-61

“interventional cardiology devices”



Page 1

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

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOTAPED DEPOSITION OF
PETER KEITH

DATE: November 24, 2020

TIME: 9:00 a.m. (Central Standard Time)

PLACE: Veritext Virtual Videoconference

REPORTED BY: PAULA K. RICHTER, RMR, CRR, CRC

Veritext Legal Solutions
www.veritext.com 888-391-3376

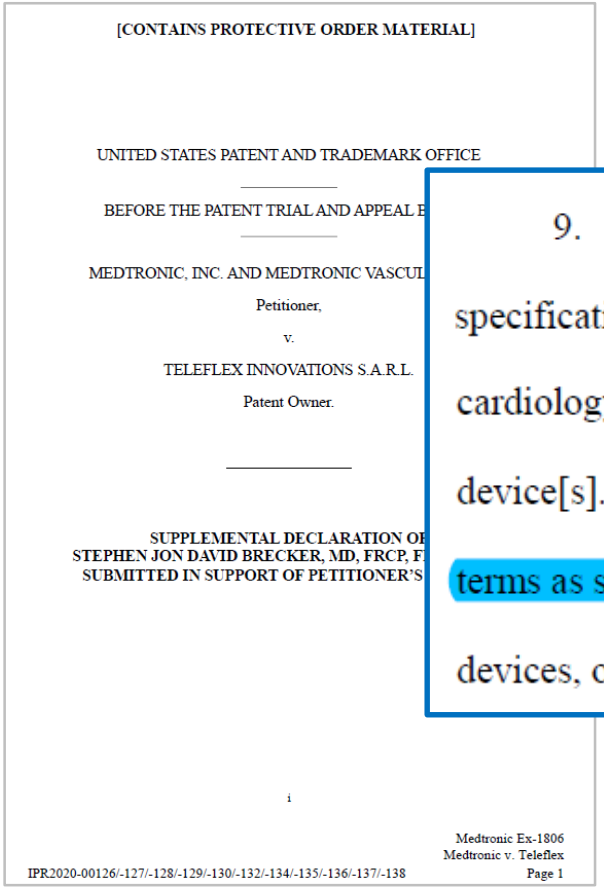
Medtronic Ex-1800
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

20 Q. Okay. So is it fair to say in that time
21 frame there were standard coronary devices that
22 provided treatment and others that did not provide
23 treatment?
24 A. Sure. In the context of what I just
25 described, I think that's -- you know, that's a --
1 that's one way to look at it, yes.

IPR2020-00126, Ex-1800 (Keith Tr.) 63:20-64:1

“interventional cardiology devices”



[CONTAINS PROTECTIVE ORDER MATERIAL]

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL B

MEDTRONIC, INC. AND MEDTRONIC VASCUL

Petitioner,

v.

TELEFLEX INNOVATIONS S.A.R.L.

Patent Owner.

SUPPLEMENTAL DECLARATION OF
STEPHEN JON DAVID BRECKER, MD, FRCP, F
SUBMITTED IN SUPPORT OF PETITIONER'S

i

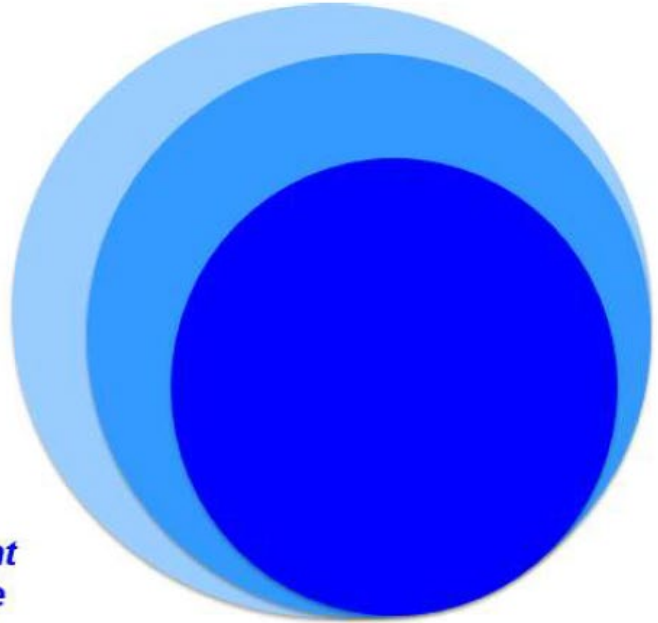
Medtronic Ex-1806
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

9. I understand Teleflex's argument to be, in part, that the patent specification uses the terms "cardiac treatment device" and "interventional cardiology treatment device" interchangeably with "interventional cardiology device[s]." POR, 12 (IPR2020-00126). I disagree that the patent uses these three terms as synonyms. The specification does not limit its discussion to treatment devices, or even to treatment devices and catheters that deliver those devices.

IPR2020-00126, Ex-1806 (Supplemental Brecker Decl.)

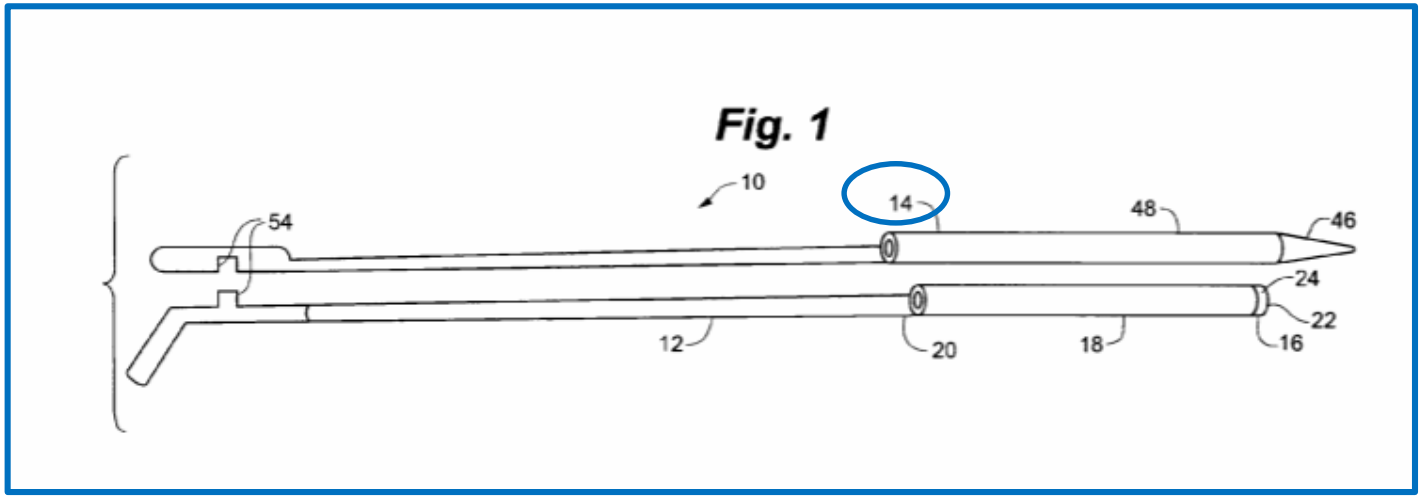
"interventional cardiology devices"

12. As illustrated below, an "interventional cardiology treatment device" is but a subset of "interventional cardiology device(s)."



IPR2020-00126, Ex-1806 (Supplemental Brecker Decl.)

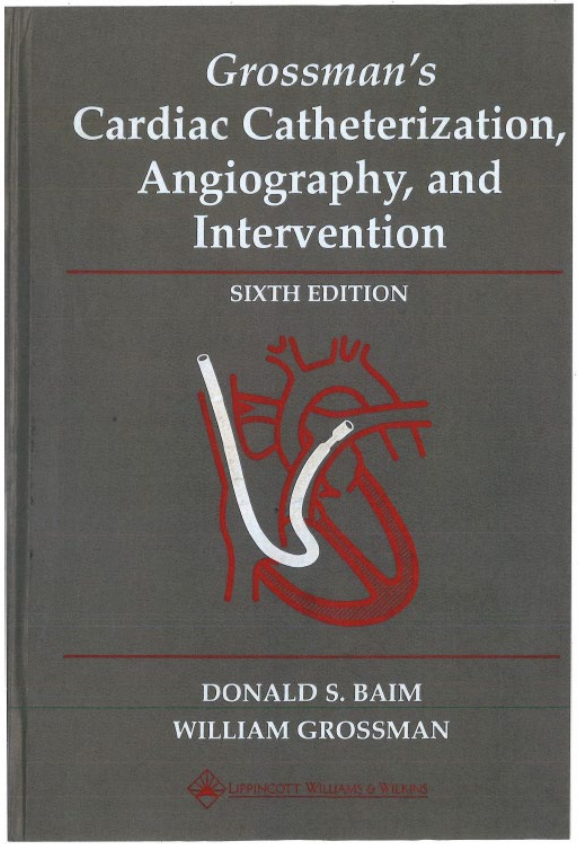
“interventional cardiology devices”



Once the tapered inner catheter is removed a cardiac treatment device, such as a guidewire, balloon or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. As described below, the

IPR2020-00126, Ex-1001, Fig. ; 4:30-34

“interventional cardiology devices”

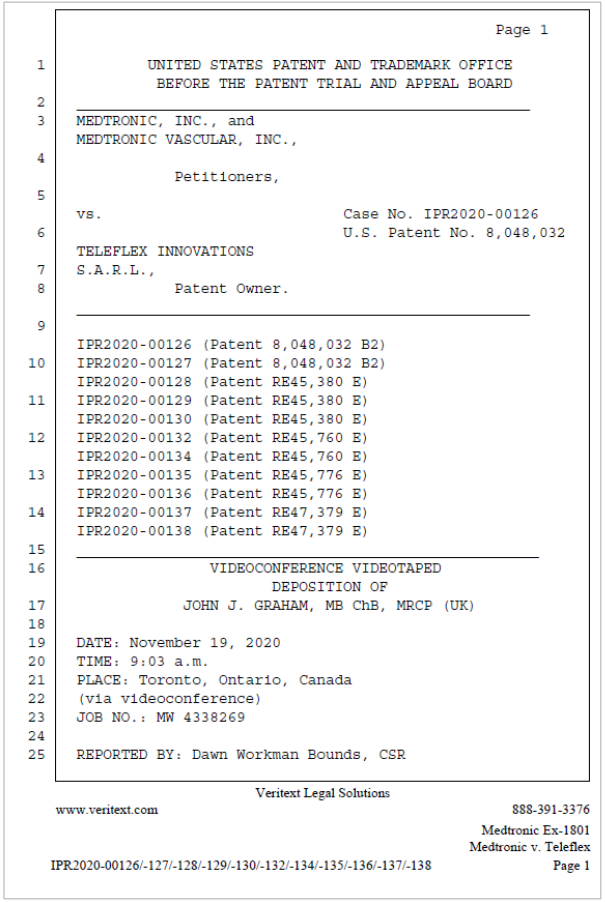


EQUIPMENT

A coronary angioplasty system consists of three basic components (Fig. 23.2): (a) a guiding catheter, which provides stable access to the coronary ostium, a route for contrast administration, and a conduit for the advancement of the dilatation equipment; (b) a leading guidewire that can be passed through the guiding catheter, across the target lesion, and well into the distal coronary vasculature to provide a rail over which a series of therapeutic devices can be advanced; and (c) a nonelastomeric balloon dilatation catheter filled with liquid contrast medium. Technol-

IPR2020-00126, Ex-1015a, 94, Reply at 5 (citing text shown above)

“interventional cardiology devices”



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

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020-00126
U.S. Patent No. 8,048,032

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
JOHN J. GRAHAM, MB ChB, MRCP (UK)

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338269

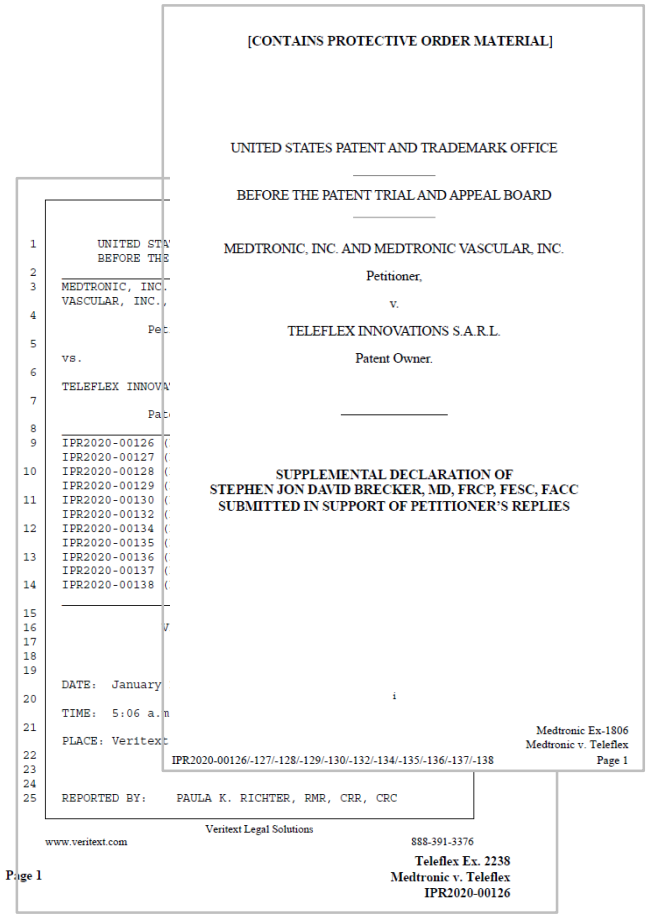
REPORTED BY: Dawn Workman Bounds, CSR

15 Q. So as you sit here today, you can't think of an
16 example where you've used just a guide wire in a
17 premeditative way to treat a lesion or occlusion, right?
18 A. As the sole treatment, no.
19 Q. And it's used in conjunction, the guide wire,
20 with a stent or a balloon --
21 A. True.
22 Q. -- usually, correct?
23 A. That is correct.

IPR2020-00126, Ex-1801 (Graham Tr.), 89:15-23

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

“interventional cardiology devices”



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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.

Petitioner,

v.

TELEFLEX INNOVATIONS S.A.R.L.

Patent Owner.

IPR2020-00126
IPR2020-00127
IPR2020-00128
IPR2020-00129
IPR2020-00130
IPR2020-00132
IPR2020-00134
IPR2020-00135
IPR2020-00136
IPR2020-00137
IPR2020-00138

SUPPLEMENTAL DECLARATION OF
STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

DATE: January

TIME: 5:06 a.m

PLACE: Veritext

REPORTED BY: PAULA K. RICHTER, RMR, CRR, CRC

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Medtronic Ex-1806
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

Teleflex Ex. 2238
Medtronic v. Teleflex
IPR2020-00126

Page 1

13. Only a subset of the devices specifically identified in the specification provide treatment. A guidewire does not provide treatment. It instead “provide[s] a rail over which a series of therapeutic devices can be advanced.” Ex-1015, 95. Dr. Graham’s testimony supports this. He acknowledges that a guidewire is used in conjunction with a stent or balloon in order to treat an occlusion. Ex-1801, 89:2-23.

Ex-1806, Reply at 5

1	A. It doesn't define that the blockage is now 90	05:30:22
2	percent. All that you are seeing is some distal	05:30:27
3	penetration of contrast into the distal vessel.	05:30:33
4	Q. Okay. And does that indicate that some blood	05:30:41
5	flow has been restored?	05:30:48
6	A. Yes.	05:30:49
7	Q. And is that a bad thing?	05:30:49
8	A. No, it is not a bad thing.	05:30:54

Ex-2238 (Brecker Tr.), 20:21-21:8, Sur-Reply at 6-7

IPR2020-00126, -00128, -00132, -00135, -00137

- "*interventional cardiology devices*"
  - Claim Construction (-00126, -00128, -00135)
  - Itou Receives interventional cardiology devices

***

- Itou discloses a "*flexible cylindrical distal tip portion*" (claim 6, '032 patent) (IPR2020-00126)
- Itou discloses an *"inclined region that tapers into a non-inclined region"* (claim 32, '776 patent) (IPR2020-00135)

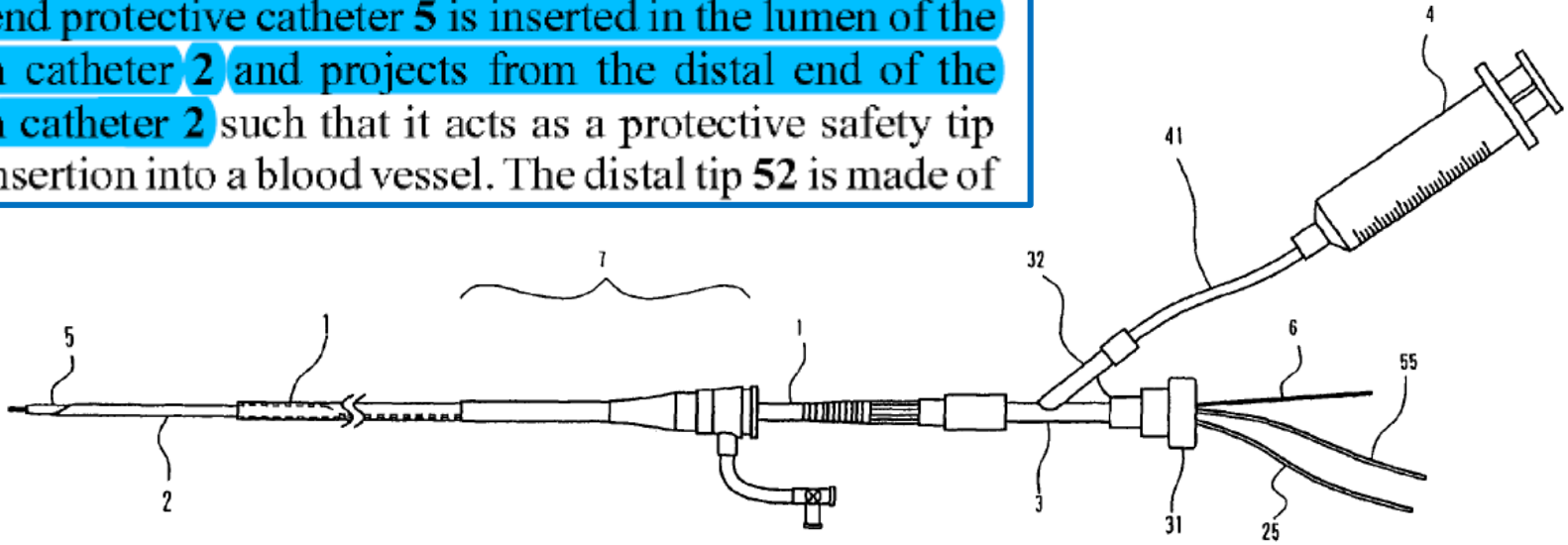
Itou Receives "*interventional cardiology devices*"

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Petitioner demonstrates that the tubular portion of Itou's device has an inner diameter through which both guide wire 6 and protective catheter 5 may be inserted. Pet. 25–26 (providing the inner diameters of suction catheter 2) (citing Ex. 1007, Table 1, Fig. 5). Patent Owner does not dispute this evidence, but contends a "protective catheter" and "guide wire" are not "balloon catheters, stents, and stent catheters." Prelim. Resp. 32.

Itou Receives "*interventional cardiology devices*"

end side wire-like portion **55** formed from a metal wire. The distal end protective catheter **5** is inserted in the lumen of the suction catheter **2** and projects from the distal end of the suction catheter **2** such that it acts as a protective safety tip upon insertion into a blood vessel. The distal tip **52** is made of



The lumen of the tubular body portion **51** of the distal end protective catheter **5** has a size sufficient to receive the guide wire **6** of FIG. **1**F therein.

IPR2020-00126, Ex-1007, 4:48-51, 61-63; Fig. 5; *and see* Table 1

Itou Receives "*interventional cardiology devices*"

> As explained above, "interventional cardiology devices" is defined in the specification and, as used in claims 1 and 11, requires that at least the set of four common interventional cardiology devices—guidewires, balloon catheters, stents, and stent catheters—are insertable.

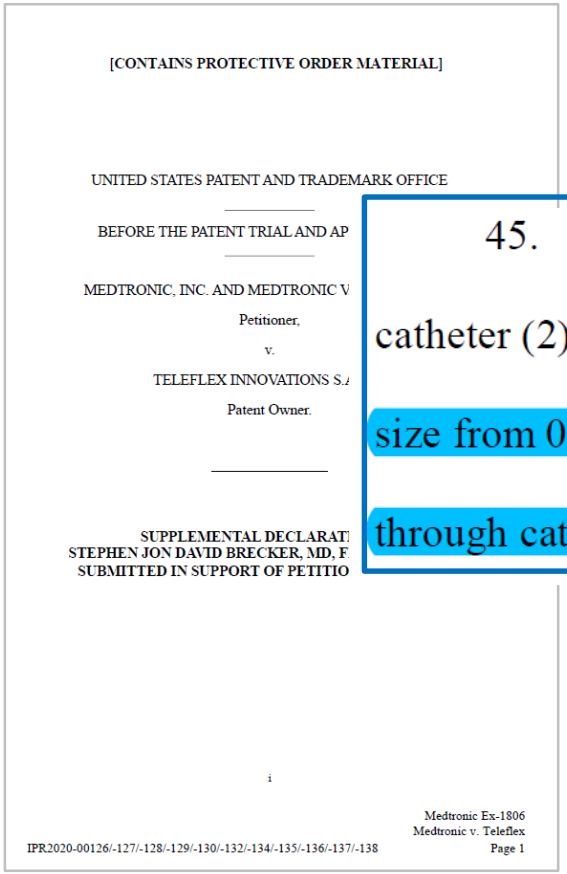
IPR2020-00126, Paper 44 (POR), 19-20

Itou Receives "*interventional cardiology devices*"

> And Itou's pushwire reduces the *effective size* of Itou's opening by about 22%, from 0.059 inches to around 0.046 inches. *Id.*; Ex-2145, ¶¶ 122-23.

IPR2020-00126, Paper 44 (POR), 21

Itou Receives "*interventional cardiology devices*"



[CONTAINS PROTECTIVE ORDER MATERIAL]

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND AP

MEDTRONIC, INC. AND MEDTRONIC V

Petitioner,

v.

TELEFLEX INNOVATIONS S.

Patent Owner.

SUPPLEMENTAL DECLARAT
STEPHEN JON DAVID BRECKER, MD, F
SUBMITTED IN SUPPORT OF PETITIO

i

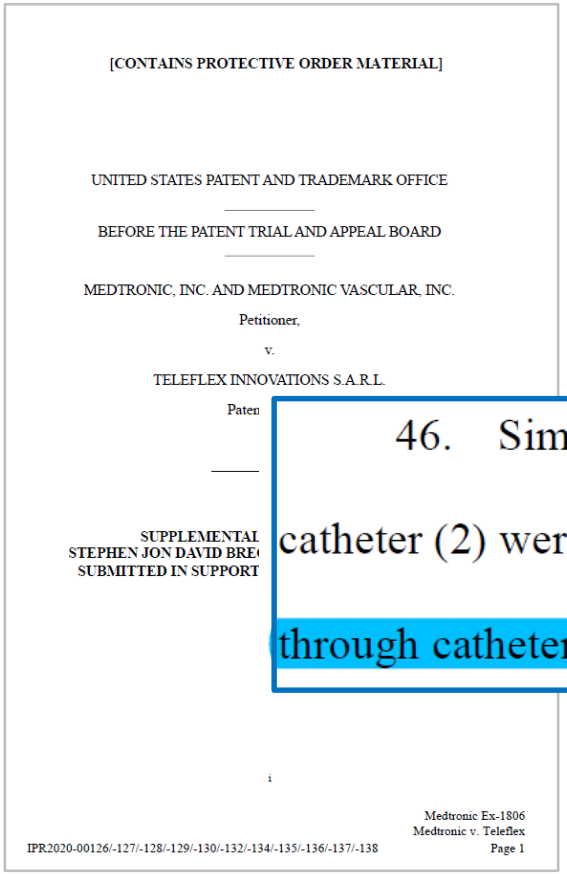
Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

45. Itou teaches that guidewire (6) is insertable through the lumen of catheter (2). Ex-1007, Fig. 5; 4:64-65; 5:11-20. Guidewires were known to range in size from 0.010 to 0.018 inches. Ex-1015, 98. They would therefore be insertable through catheter (2) even if its "effective size" were 0.046 inches.

IPR2020-00126, Ex-1806 (Supplemental Brecker Decl.)

Itou Receives "*interventional cardiology devices*"



[CONTAINS PROTECTIVE ORDER MATERIAL]

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.

Petitioner,

v.

TELEFLEX INNOVATIONS S.A.R.L.

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SUPPLEMENTAL
STEPHEN JON DAVID BRE
SUBMITTED IN SUPPORT

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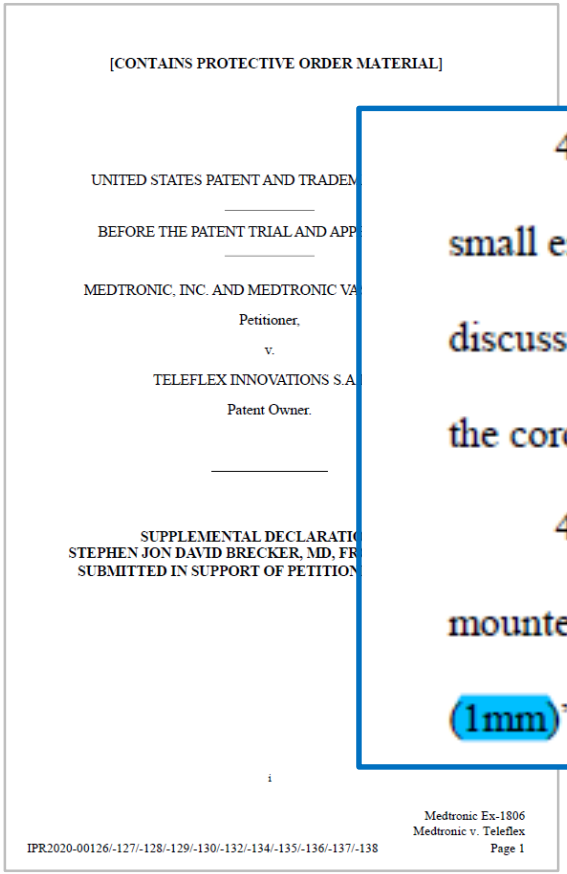
Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

46. Similarly, even if the "effective size" of the opening to the lumen of catheter (2) were 0.046 inches, angioplasty catheters were known to be insertable through catheters with lumen of 0.045 inches. Ex-1009, 4:49-63; Ex-1833, 1.

IPR2020-00126, Ex-1806 (Supplemental Brecker Decl.)

Itou Receives "*interventional cardiology devices*"



[CONTAINS PROTECTIVE ORDER MATERIAL]

UNITED STATES PATENT AND TRADEM

BEFORE THE PATENT TRIAL AND APP

MEDTRONIC, INC. AND MEDTRONIC VA

Petitioner,

v.

TELEFLEX INNOVATIONS S.A

Patent Owner.

SUPPLEMENTAL DECLARATI
STEPHEN JON DAVID BRECKER, MD, FR
SUBMITTED IN SUPPORT OF PETITION

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Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

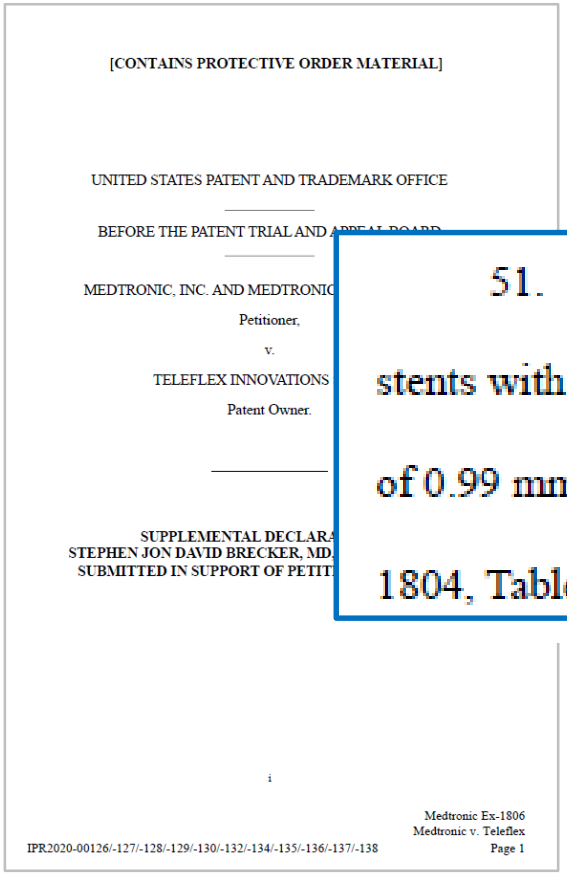
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

47. There were also a variety of stents with crossing profiles that were small enough to be advanced through a lumen of 0.046 inches (1.16 mm) that I discuss below. Necessarily, each of the stents that are discussed were advanced into the coronary vasculature on a "stent catheter."

48. Baim explains that "[a]ll current slotted tube designs are 'bare mounted' on a delivery balloon, with deflated profiles smaller than 0.040-in. (1mm)" Ex-1015, 189.

IPR2020-00126, Ex-1806 (Supplemental Brecker Decl.)

Itou Receives "*interventional cardiology devices*"



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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC

Petitioner,

v.

TELEFLEX INNOVATIONS

Patent Owner.

SUPPLEMENTAL DECLARA
STEPHEN JON DAVID BRECKER, MD.
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Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

51. And an article by Colombo described several balloon-expandable stents with crossing profiles well under 0.046 inches, including those with profiles of 0.99 mm (0.038 inch), 0.93 mm (0.036 inch) and 0.84 mm (0.033 inch)). Ex-1804, Table 1; Fig. 3.

IPR2020-00126, Ex-1806 (Supplemental Brecker Decl.)

Itou Receives "*interventional cardiology devices*"

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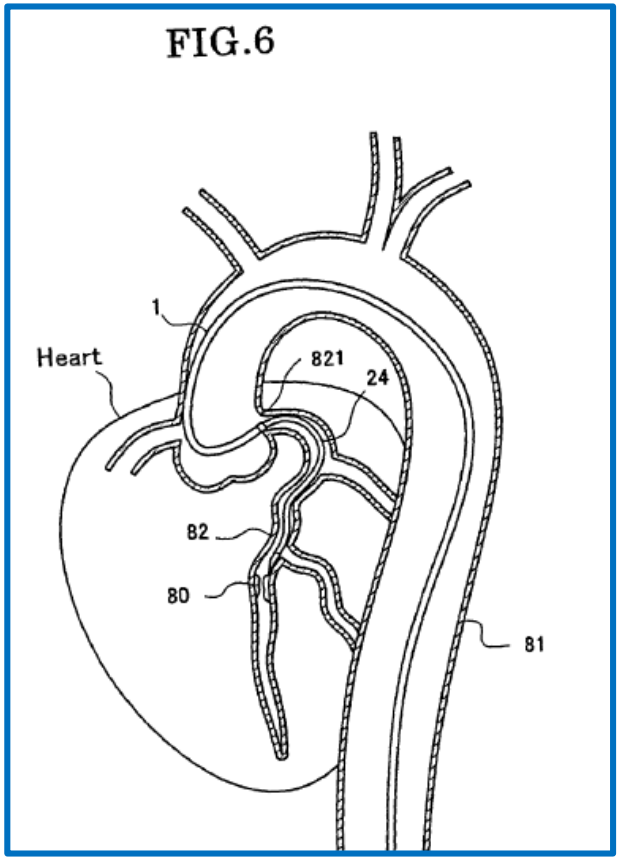
42. Moreover, even if Itou's proximal opening was obstructed by wire 25 so that the "effective size" of catheter 2's opening went from 0.059 inches (1.5mm) to 0.046 inches (1.16 mm) as Patent Owner and Mr. Keith allege (it is not), such an opening is still large enough to receive a standard coronary stent.

43. By the early 2000s, standard coronary stents, guidewires, balloon catheters, and stent catheters were available with an outer diameter sufficient to pass through Itou's allegedly constricted opening of 0.046 inches. *See* Ex-1015,

Medtronic Ex-1807
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

IPR2020-00126, Ex-1807 (Jones Decl.)

Itou Receives "*interventional cardiology devices*"



Itou Receives "*interventional cardiology devices*"

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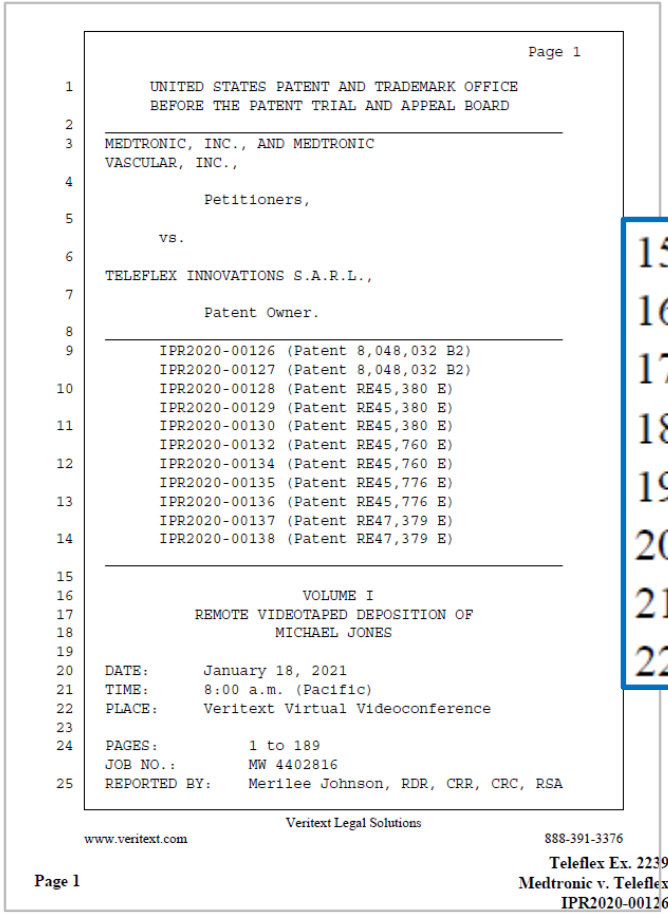
46. For the reasons stated above, it is my opinion that the lumen of Itou's suction catheter 2 is suitable for receiving a stent catheter once catheter 2 has been advanced through a guide catheter and has been partially extended from the guide catheter's distal end, and when the proximal opening of catheter 2's tubular portion is still within the guide catheter.

Medtronic Ex-1807
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

IPR2020-00126, Ex-1807 (Jones Decl.)

Itou Receives "*interventional cardiology devices*"



Page 1

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

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VOLUME I
REMOTE VIDEOTAPED DEPOSITION OF
MICHAEL JONES

DATE: January 18, 2021
TIME: 8:00 a.m. (Pacific)
PLACE: Veritext Virtual Videoconference

PAGES: 1 to 189
JOB NO.: MW 4402816
REPORTED BY: Merilee Johnson, RDR, CRR, CRC, RSA

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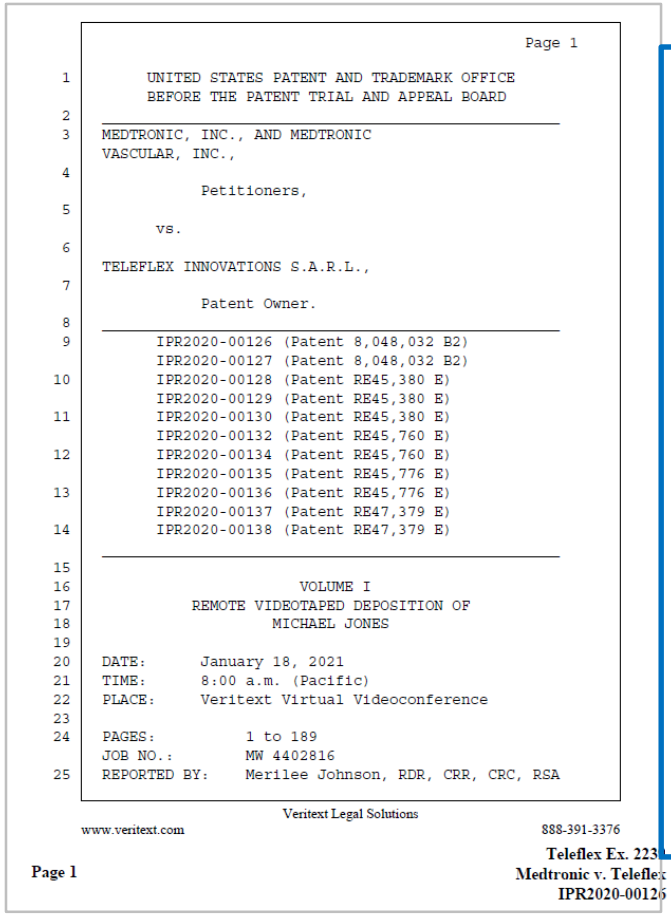
Page 1

Teleflex Ex. 2239
Medtronic v. Teleflex
IPR2020-00126

15 Q. And just so we're clear: Is it your
16 opinion that all of the stents, including the
17 largest .042 stent, would be able to travel from
18 outside the body along Itou's wire 25 and through
19 Itou's tubular portion and into the vasculature if
20 Itou was in what we called earlier the straight
21 configuration?
22 A. Yes.

IPR2020-00126, Ex-2239 (Jones Tr.), 180:5-22, Paper 114 at 4, n.2

Itou Receives "*interventional cardiology devices*"



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UNITED STATES PATENT AND TRADEMARK OFFICE
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IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VOLUME I
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Page 1

Teleflex Ex. 223[illegible]
Medtronic v. Teleflex
IPR2020-00126

And so same question, as far as passing along the wire and into the tubular structure and through the tubular structure. Would your answer change at all, given, you know, the discussion you had earlier today about the thickness of the wire?

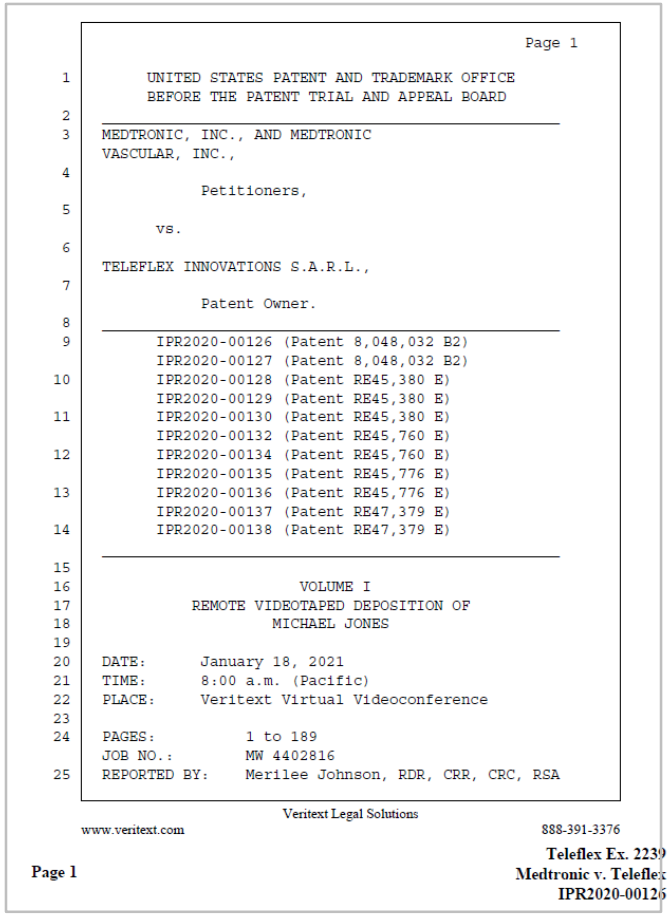
A. No. It wouldn't.

Q. And why is that, if you don't mind?

A. The thickness of the wire and its proximity to the rear opening, the opening still remains -- even with the worst case of the wire extruded into the opening, the opening still remains .046 of an inch. And all of these stents listed here, the largest being .042, should go into that opening without a problem.

IPR2020-00126, Ex-2239 (Jones Tr.), 181:2-15, Paper 114 at 4, n.2

Itou Receives "*interventional cardiology devices*"



Page 1

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

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

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IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VOLUME I
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MICHAEL JONES

DATE: January 18, 2021
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PLACE: Veritext Virtual Videoconference

PAGES: 1 to 189
JOB NO.: MW 4402816
REPORTED BY: Merilee Johnson, RDR, CRR, CRC, RSA

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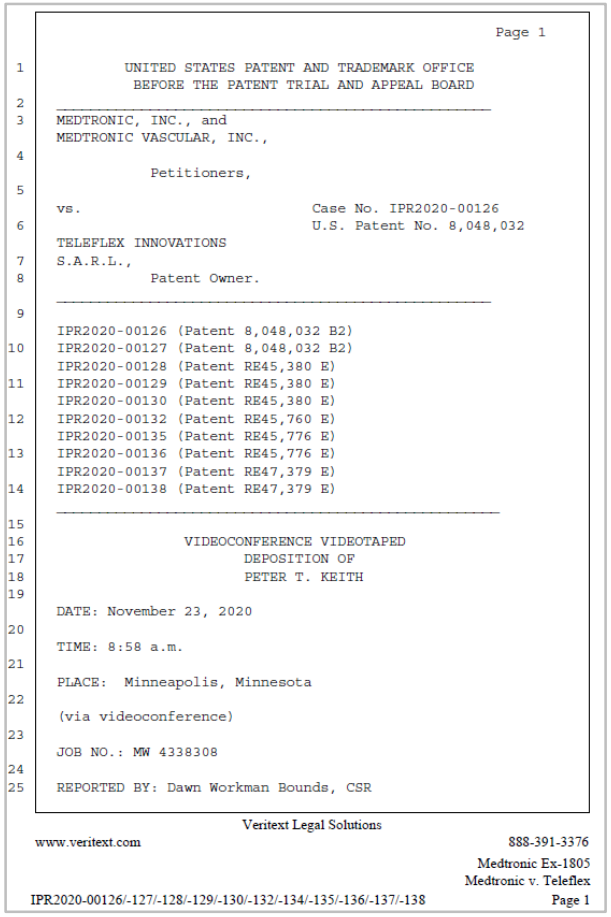
Page 1

Teleflex Ex. 2239
Medtronic v. Teleflex
IPR2020-00126

16 Q. Okay. So is it your opinion that in all
17 circumstances Itou's tubular portion could receive
18 a -- at least a .042-inch stent, or smaller?
19 A. Yes.
20 Q. And would you need to run any testing to
21 confirm that?
22 A. No, not around .042 or smaller.

Itou Receives "*interventional cardiology devices*"



Page 1

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

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020-00126
U.S. Patent No. 8,048,032

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
PETER T. KEITH

DATE: November 23, 2020

TIME: 8:58 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338308

REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex-1805
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

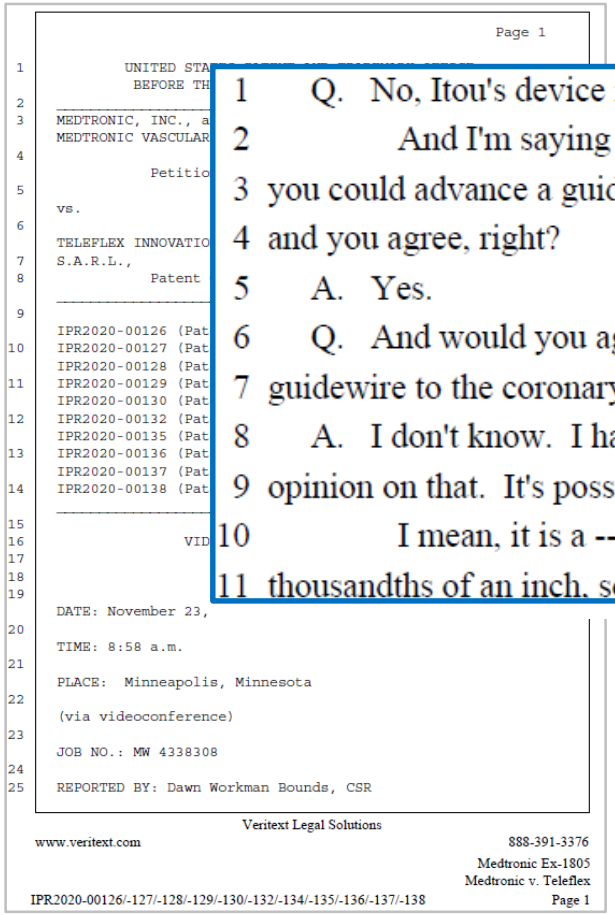
My question is: In this configuration, as shown in figure 6, is there any reason that a guidewire of 0.014 inches couldn't be advanced through guide catheter 1 into the lumen of catheter 2, which is tubular portion 24?

A. Well, it certainly isn't taught to do that.

Q. As you sit here today, is there a reason that you can think of that that -- that the structure of Itou isn't sufficient to receive a guidewire with a diameter of 0.014 inches?

A. I -- I don't have a particular opinion on that.

Itou Receives "*interventional cardiology devices*"



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IPR2020-00138 (Pat

VID

DATE: November 23,

TIME: 8:58 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338308

REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex-1805
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

1 Q. No, Itou's device is there.
2 And I'm saying you'd agree with me that
3 you could advance a guidewire into the guide catheter;
4 and you agree, right?
5 A. Yes.
6 Q. And would you agree that you could advance that
7 guidewire to the coronary ostium?
8 A. I don't know. I haven't really formed an
9 opinion on that. It's possible, but I don't know.
10 I mean, it is a -- it's only 14
11 thousandths of an inch, so it is a pretty small device.

12 Q. Could you at least advance it to the opening of
13 tubular portion 24?
14 A. To the opening, yeah, you probably could get
15 that far.
16 Q. Could you advance it into the opening of
17 tubular portion 24?
18 A. I don't know. Sometimes maybe. I haven't
19 really thought about it.

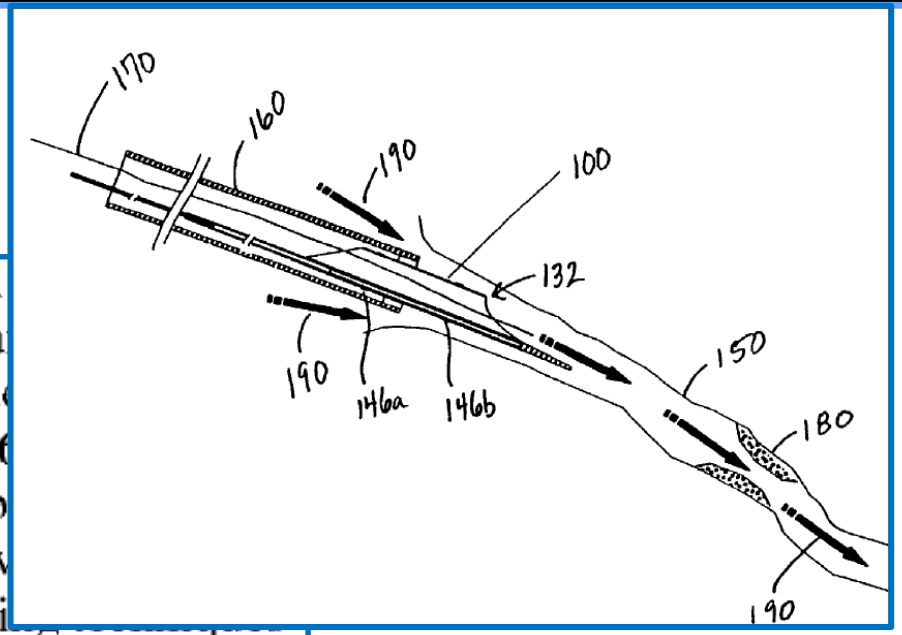
Itou Receives "*interventional cardiology devices*"

3. The device of claim **2** wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

IPR2020-00126, Ex-1001

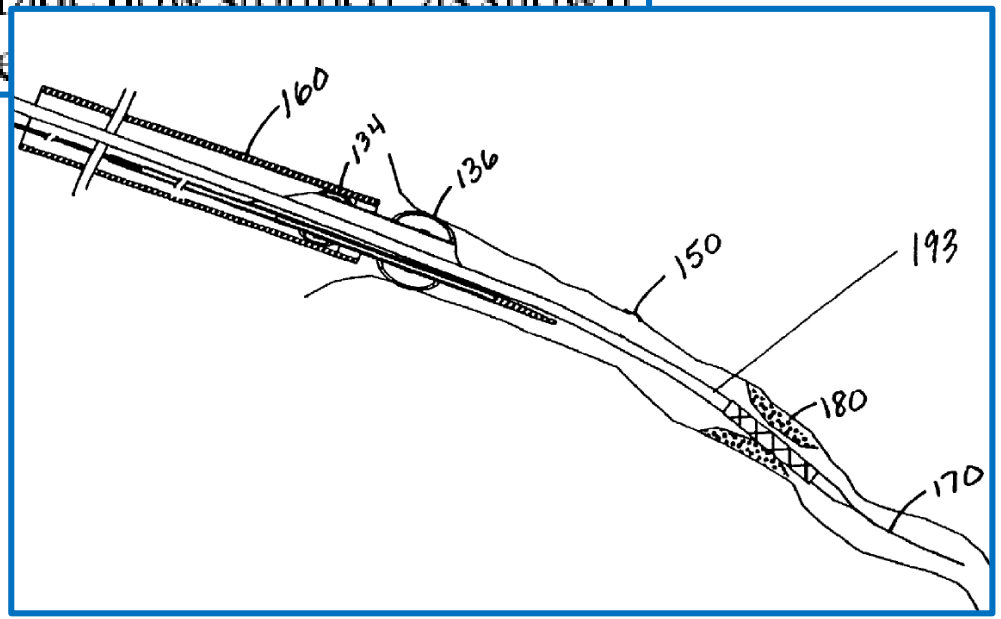
Ressemann

As shown in FIG. **6**B, the evacuation sheath
then is advanced over the guide wire **170** a
within the vessel **150** with the distal radiopaqu
distal of the distal tip of the guiding catheter **16**
the vessel **150**) and the proximal marker **146***a* p
distal tip of the guiding catheter **160** (i.e., w
160), as determined through appropriate imagi
known in the art. Alternatively, the guide catheter **160** may be positioned within the ostium of the target vessel, and the evacuation sheath assembly **100** may be advanced through the catheter and beyond a major side branch of the target vessel.



Ressemann

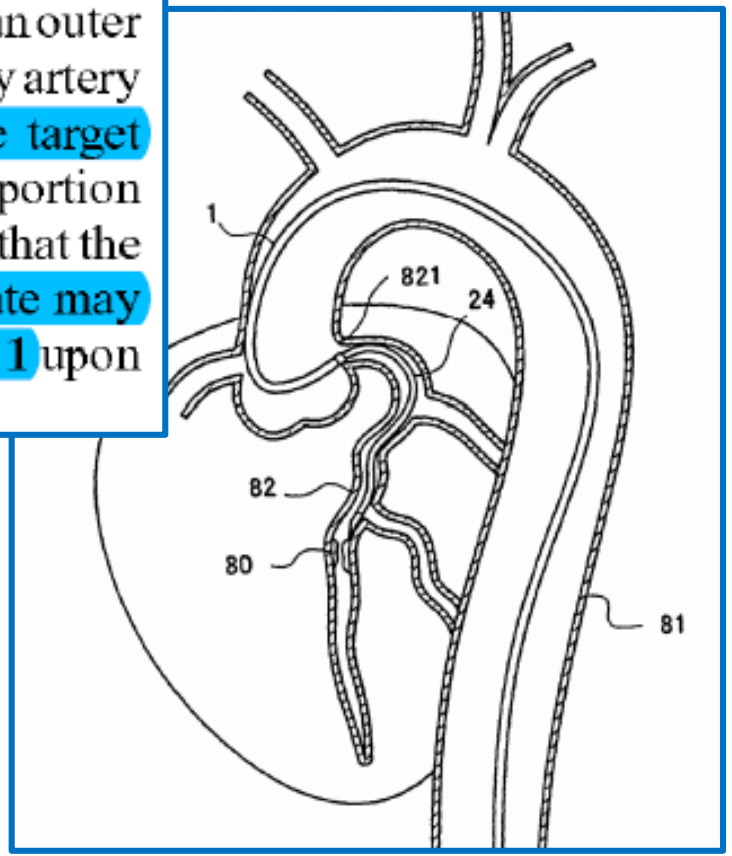
all seals are again established. With all seals in place, a therapeutic device such as a stent delivery system **193** is advanced across the stenosis **180** with antegrade flow stopped, as shown in FIG. **6**E. The touhy borst valve



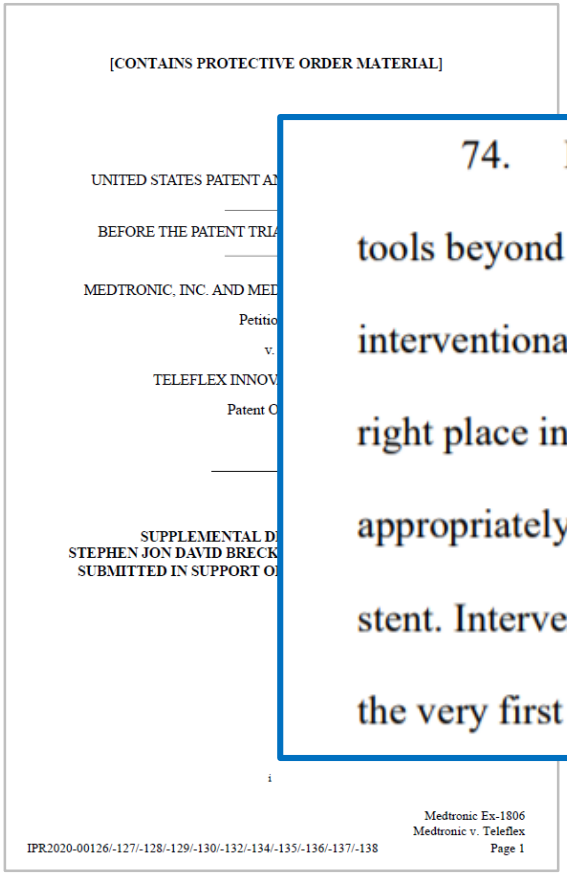
IPR2020-00126, Ex-1008 (Ressemann), 13:15-16, 57-60; Fig. 6E

Itou Receives "*interventional cardiology devices*"

The tubular portion **24** of the suction catheter **2** has an outer diameter with which it can be inserted into the coronary artery **82** and is introduced along the guide wire **6** to the target location **80** positioned at a deep location. The tubular portion **24** is designed so as to have a sufficient axial length so that the proximal end of the tubular portion **24** in an open state may not leap out from the distal end of the guiding catheter **1** upon such introduction of the tubular portion **24**.



Itou Receives "*interventional cardiology devices*"



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UNITED STATES PATENT A

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MEDTRONIC, INC. AND MED

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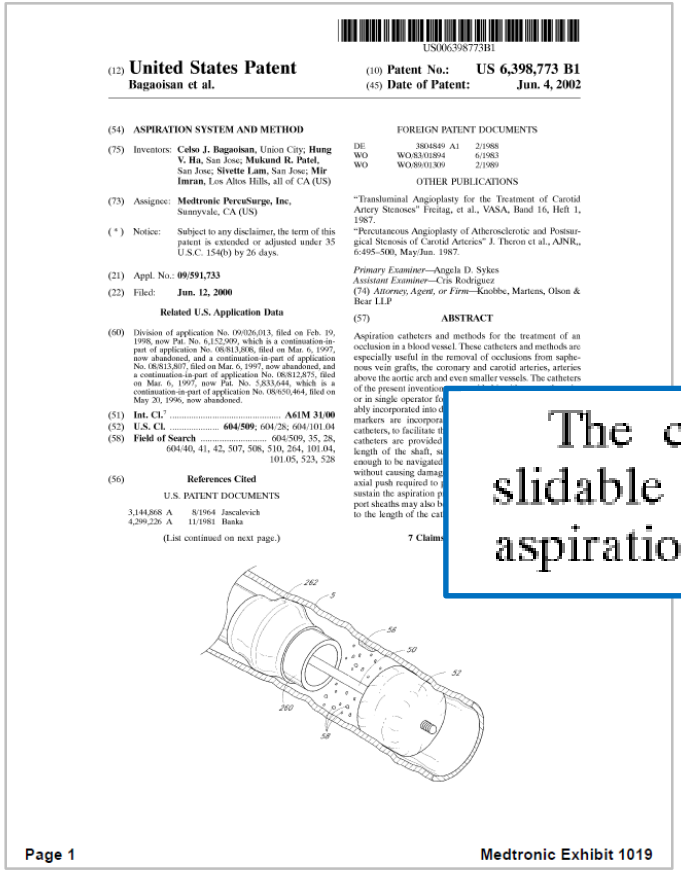
Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

74. From the very beginning, interventional cardiologists have adapted tools beyond the indication for which they were designed. Innovation is in an interventional cardiologist's DNA. If a suction catheter is positioned within the right place in the vasculature to deliver a balloon or stent—and is sized appropriately—it would not be a big step to use the catheter to deploy a balloon or stent. Interventional cardiologists have made these types of adaptations of use from the very first intervention ever carried out.

IPR2020-00126, Ex-1806 (Supplemental Brecker Decl.)

Itou Receives "*interventional cardiology devices*"



US006398773B1

(12) **United States Patent**
Bagaoisan et al.

(10) **Patent No.: US 6,398,773 B1**
(45) **Date of Patent: Jun. 4, 2002**

(54) **ASPIRATION SYSTEM AND METHOD**

(75) Inventors: **Celso J. Bagaoisan**, Union City; **Hung V. Ha**, San Jose; **Mukund R. Patel**, San Jose; **Sivette Lam**, San Jose; **Mir Imran**, Los Altos Hills, all of CA (US)

(73) Assignee: **Medtronic PercuSurge, Inc.**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 26 days.

(21) Appl. No.: **09/591,733**

(22) Filed: **Jun. 12, 2000**

Related U.S. Application Data

(60) Division of application No. 09/026,013, filed on Feb. 19, 1998, now Pat. No. 6,152,909, which is a continuation-in-part of application No. 08/813,808, filed on Mar. 6, 1997, now abandoned, and a continuation-in-part of application No. 08/813,807, filed on Mar. 6, 1997, now abandoned, and a continuation-in-part of application No. 08/812,875, filed on Mar. 6, 1997, now Pat. No. 5,833,644, which is a continuation-in-part of application No. 08/650,464, filed on May 20, 1996, now abandoned.

(51) **Int. Cl.**[7] **A61M 31/00**

(52) **U.S. Cl.** **604/509**; 604/28; 604/101.04

(58) **Field of Search** 604/509, 35, 28, 604/40, 41, 42, 507, 508, 510, 264, 101.04, 101.05, 523, 528

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,144,868 A 8/1964 Jasculevich
4,299,226 A 11/1981 Banka

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

DE 3804849 A1 2/1988
WO WO 83/01894 6/1983
WO WO 89/01309 2/1989

OTHER PUBLICATIONS

"Transluminal Angioplasty for the Treatment of Carotid Artery Stenoses" Freitag, et al., VASA, Band 16, Heft 1, 1987.
"Percutaneous Angioplasty of Atherosclerotic and Postsurgical Stenosis of Carotid Arteries" J. Theron et al., AJNR, 6:495–500, May/Jun. 1987.

Primary Examiner—Angela D. Sykes
Assistant Examiner—Cris Rodriguez
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

Aspiration catheters and methods for the treatment of an occlusion in a blood vessel. These catheters and methods are especially useful in the removal of occlusions from saphenous vein grafts, the coronary and carotid arteries, arteries above the aortic arch and even smaller vessels. The catheters of the present invention
or in single operator fo
ably incorporated into d
markers are incorpora
catheters, to facilitate th
catheters are provided
length of the shaft, s
enough to be navigated
without causing damag
axial push required to
sustain the aspiration p
port sheaths may also b
to the length of the cat

7 Claim

Page 1

Medtronic Exhibit 1019

> The catheters are preferably sized so as to allow the slidable insertion of a therapy catheter through the main aspiration lumen of the aspiration catheter.

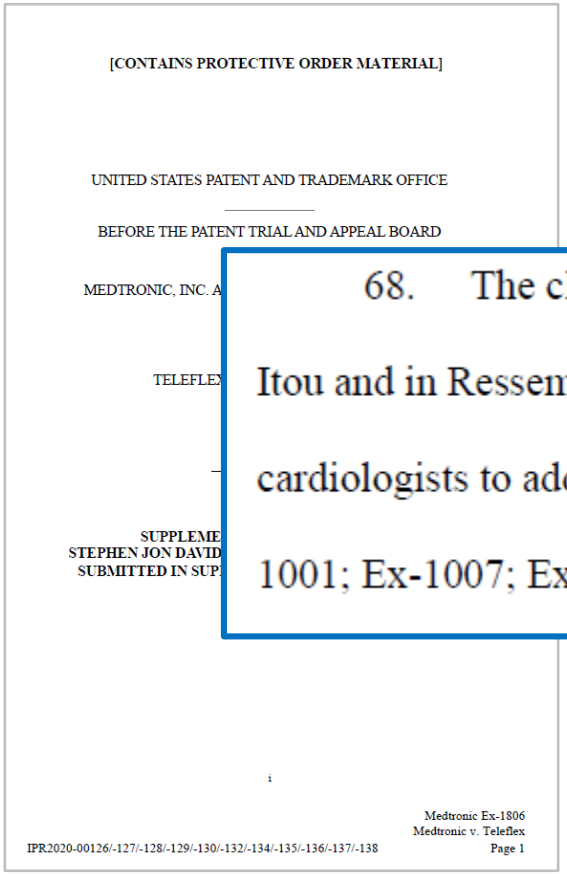
IPR2020-00126, Ex-1019 (Bagaoisan), 3:3-4, Petition at 69

Itou Receives "*interventional cardiology devices*"

A. So the distal portion of the GuideLiner is a round tube, wide open. We wanted the thinnest wall possible. We want it to flex within the coronary artery, but we want it to have column support so you could push it and it doesn't buckle or kink. And that same requirement for the round tube exists in the Pronto, which is an aspiration catheter trying to extract clot from the coronary artery, and so you're having a big, wide open lumen that goes down the coronary artery, combined with that aspiration on the back end to extract the clot in acute MI or heart attack patients.

IPR2020-00126, Ex-1762 (Root Tr), 46:9-20, Reply at 13

Itou Receives "*interventional cardiology devices*"



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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

68. The claims of the Teleflex patent, as well as the devices disclosed in Itou and in Ressemann are all coronary catheters used by interventional cardiologists to address the problem of occlusions in the coronary vasculature. Ex-1001; Ex-1007; Ex-1008.

IPR2020-00126, Ex-1806 (Supplemental Brecker Decl.)

Itou Receives "*interventional cardiology devices*"

Claims 1 and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (USPN5,385,562). Adams et al. discloses a guide catheter system for an angioplasty balloon catheter.

Regarding claims 1 and 7-12, Adams et al. discloses an catheter capable of being an intravascular foreign matter suction assembly (Figure 2, 14) for sucking foreign

IPR2020-00126, Ex-1021 (Itou's prosecution history), 3-4, Petition at 72

Itou Receives "*interventional cardiology devices*"

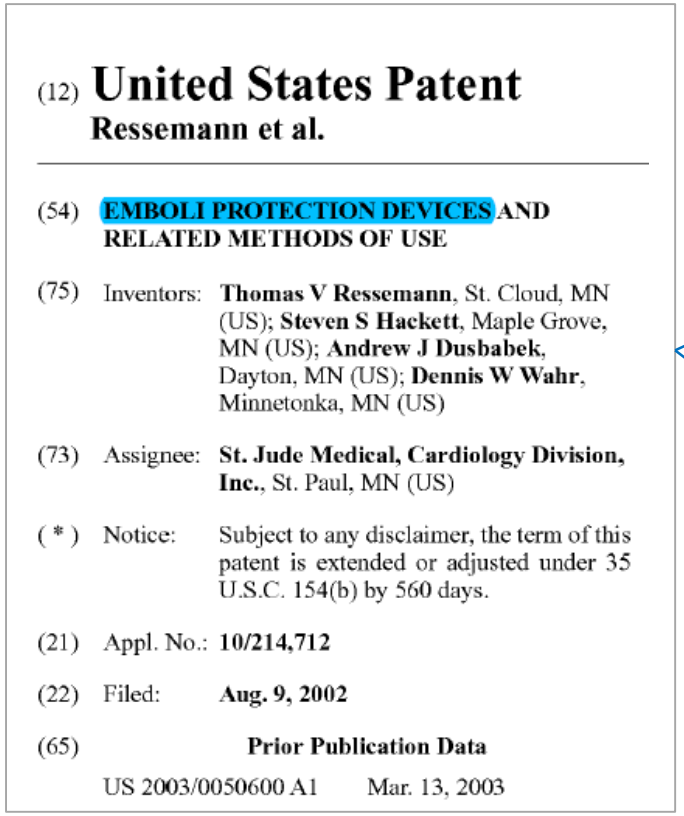
However, Bagaoisan et al. teaches an aspiration catheter.

Regarding claims 3-5, Bagaoisan et al. teaches an aspiration catheter (10, Figure) with a suction lumen that has a source of negative pressure (col 7, ln 35-55) attached to a branched connector (14).

At the time of the invention, it would have been obvious to add a source of negative pressure to the device of Adams et al. in order to suction out potentially harmful emboli created during an angioplasty procedure. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Bagaoisan et al. (cols 1-2).

IPR2020-00126, Ex-1021 (Itou's prosecution history), 5, Petition at 72

Ressemann



(12) **United States Patent**
Ressemann et al.

(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

(75) Inventors: **Thomas V Ressemann**, St. Cloud, MN (US); **Steven S Hackett**, Maple Grove, MN (US); **Andrew J Dusbabek**, Dayton, MN (US); **Dennis W Wahr**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical, Cardiology Division, Inc.**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 560 days.

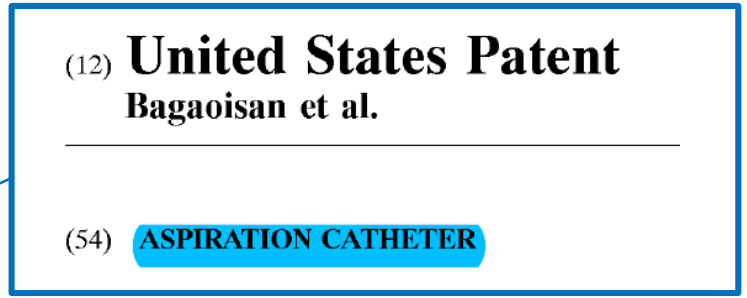
(21) Appl. No.: **10/214,712**

(22) Filed: **Aug. 9, 2002**

(65) **Prior Publication Data**

US 2003/0050600 A1 Mar. 13, 2003

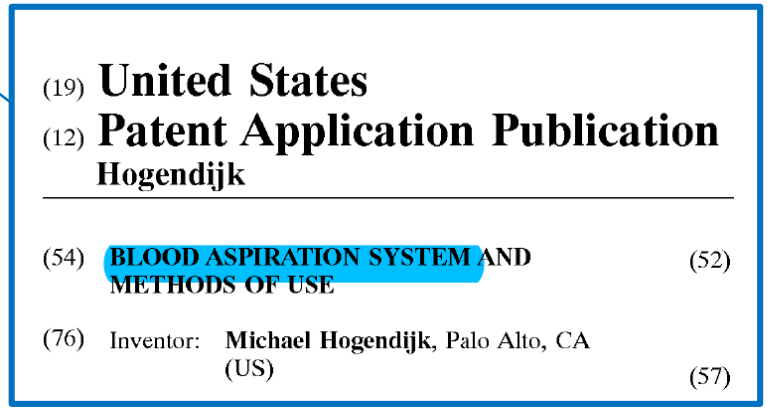
Ex-1008



(12) **United States Patent**
Bagaoisan et al.

(54) **ASPIRATION CATHETER**

Ex-1808



(19) **United States**
(12) **Patent Application Publication**
Hogendijk

(54) **BLOOD ASPIRATION SYSTEM AND METHODS OF USE**

(52)

(76) Inventor: **Michael Hogendijk**, Palo Alto, CA (US)

(57)

Ex-1809

IPR2020-00126

Itou Receives "*interventional cardiology devices*"

72. I am additionally aware that Teleflex has argued that a POSITA would never use Itou's catheter (2) to both deliver an interventional cardiology device (other than distal end protective catheter (5) or a guidewire). POR, 30 (IPR2020-00126). Their position is that if residual debris is left in a catheter that catheter must be removed from the patient and flushed, outside of the body, before it can be used to deliver a stent.

73. While that might be the order of steps an interventional cardiologist would use, it would not necessarily always be the case. If there was good suctioning and backflush with little evidence of debris, (s)he would be confident there was no material in the catheter, and had the motivation to use the catheter to deliver a balloon or stent.

Itou Receives "*interventional cardiology devices*"

TABLE 1

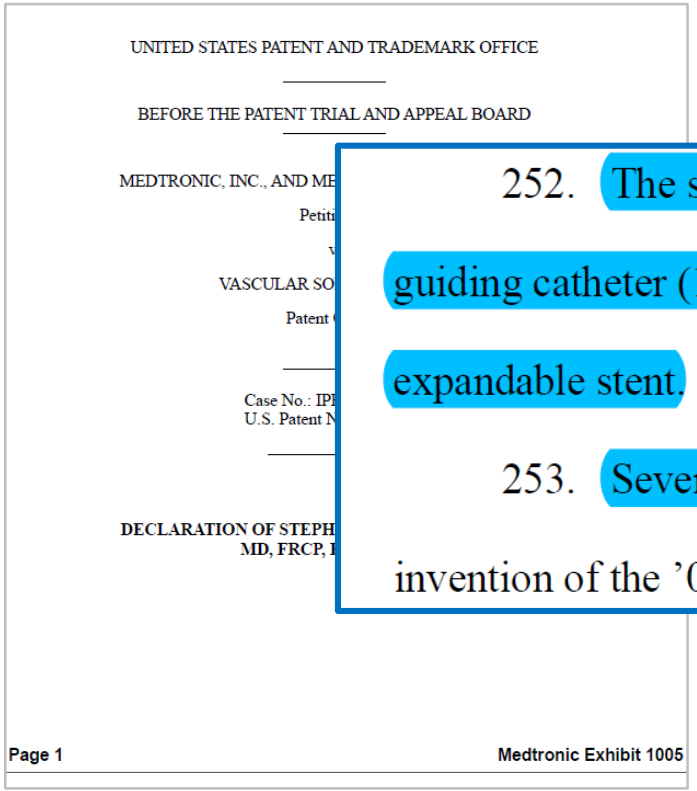
Name of device	Overall length (mm)	Outer diameter (mm)	Inner diameter (mm)
Guiding catheter 1	1000	2.06	1.8
Suction catheter 2 (tubular portion)	150	1.72	1.5
Suction catheter 2 (wire-like portion)	1100	0.45	—
Distal end protective catheter 5 (tubular portion)	20	1.35	0.5
Distal end protective catheter 5 (wire-like portion)	1300	0.45	—

DECLARATION OF STEPHEN JON D
MD, FRCP, FESC, FAC

250. Thus, prior art catheters with inner lumen diameters of 1.54, 1.1, and 1.33 mm had been successfully used for balloon angioplasty procedures.

Page 1 Medtronic Exhibit 1005

Itou Receives "*interventional cardiology devices*"



UNITED STATES PATENT AND TRADEMARK OFFICE

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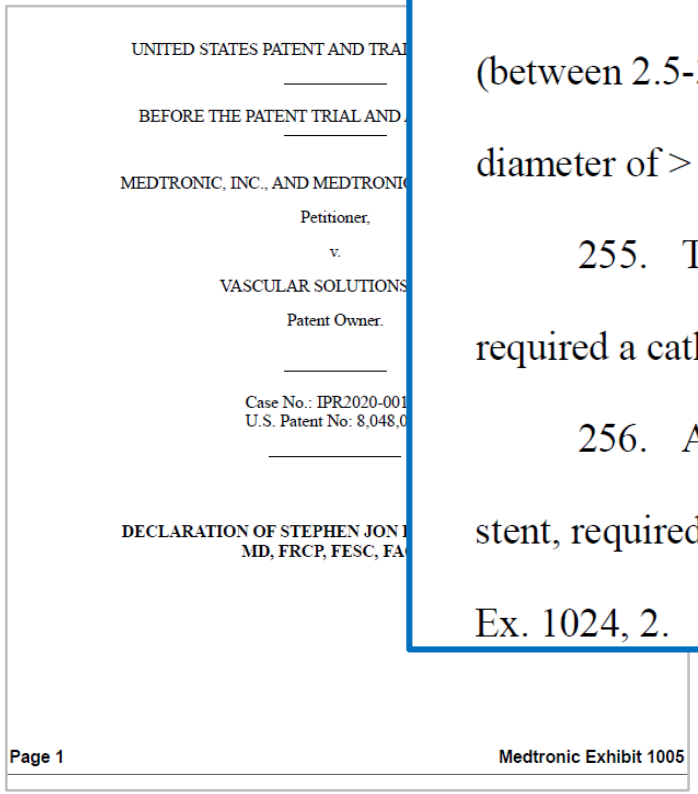
MD, FRCP, I

Page 1 Medtronic Exhibit 1005

252. The structure of suction catheter (2) allowed it to be inserted into guiding catheter (1), and—as taught by Ressemann—used to receive a balloon-expandable stent.

253. Several such stents were available at the time of the purported invention of the '032 patent.

Itou Receives "*interventional cardiology devices*"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BEFORE THE PATENT TRIAL AND

MEDTRONIC, INC., AND MEDTRONI

Petitioner,

v.

VASCULAR SOLUTIONS

Patent Owner.

Case No.: IPR2020-001
U.S. Patent No: 8,048,0

DECLARATION OF STEPHEN JON
MD, FRCP, FESC, FA

Page 1 Medtronic Exhibit 1005

254. A Cordis stent, the Cypher™ Sirolimus-eluting coronary stent (between 2.5-3.0 mm on an RX delivery system) required a catheter with an inner diameter of > 0.056 in. (1.4 mm). Ex. 1022, 3.

255. The Medtronic Driver™ stent, on either an OTW or RX system, required a catheter with an inner diameter of 0.056 inches (1.4 mm). Ex. 1023, 9.

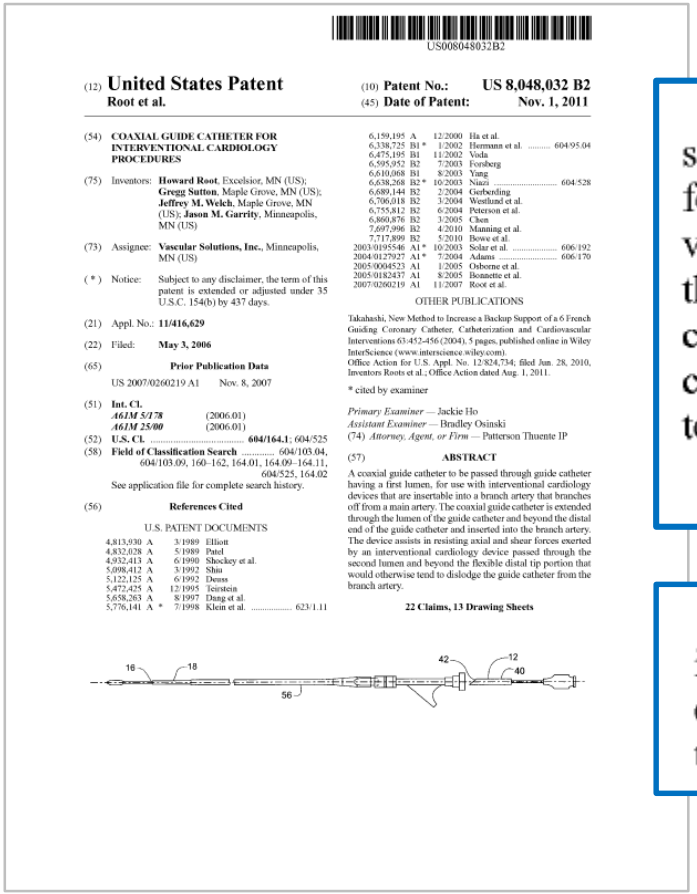
256. A Boston Scientific stent, the TAXUS™ Express²™ Paclitaxel-eluting stent, required a catheter with an inner diameter of ≥ 0.058 in. (1.47 mm). Ex. 1024, 2.

IPR2020-00126

- "*interventional cardiology devices*"
  - Claim Construction (IPR2020-00126, -00128, -00135)
  - Itou Receives interventional cardiology devices

***

- Itou discloses a "*flexible cylindrical distal tip portion*" (claim 6, '032 patent)
- Itou discloses an *"inclined region that tapers into a non-inclined region"* (claim 32, '776 patent) (IPR2020-00135)



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 437 days.

(21) Appl. No.: **11/416,629**

(22) Filed: **May 3, 2006**

(65) **Prior Publication Data**

US 2007/0260219 A1 Nov. 8, 2007

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/164.1**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.09–164.11, 604/525, 164.02
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,813,930	A	3/1989	Elliott	
4,832,028	A	5/1989	Patel	
4,932,413	A	6/1990	Shockey et al.	
5,098,412	A	3/1992	Shiu	
5,122,125	A	6/1992	Deuss	
5,472,425	A	12/1995	Teirstein	
5,658,263	A	8/1997	Dang et al.	
5,776,141	A *	7/1998	Klein et al.	623/1.11
6,159,195	A	12/2000	Ha et al.	
6,338,725	B1 *	1/2002	Hermann et al.	604/95.04
6,475,195	B1	11/2002	Voda	
6,595,952	B2	7/2003	Forsberg	
6,610,068	B1	8/2003	Yang	
6,638,268	B2 *	10/2003	Niazi	604/528
6,689,144	B2	2/2004	Gerberding	
6,706,018	B2	3/2004	Westlund et al.	
6,755,812	B2	6/2004	Peterson et al.	
6,860,878	B2	3/2005	Chen	
7,697,996	B2	4/2010	Manning et al.	
7,717,899	B2	5/2010	Bowe et al.	
2003/0195546	A1 *	10/2003	Solar et al.	606/192
2004/0127927	A1 *	7/2004	Adams	606/170
2005/0004523	A1	1/2005	Osborne et al.	
2005/0182437	A1	8/2005	Bonnette et al.	
2007/0260219	A1	11/2007	Root et al.	

OTHER PUBLICATIONS

Takahashi, New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages, published online in Wiley InterScience (www.interscience.wiley.com).
Office Action for U.S. Appl. No. 12/824,734; filed Jun. 28, 2010, Inventors Roots et al.; Office Action dated Aug. 1, 2011.

* cited by examiner

Primary Examiner — Jackie Ho
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente IP

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

22 Claims, 13 Drawing Sheets

1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

a flexible tip portion defining a tubular structure having a

6. The device of claim **1** wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

Ex-1001, claim 6 ('032 patent)

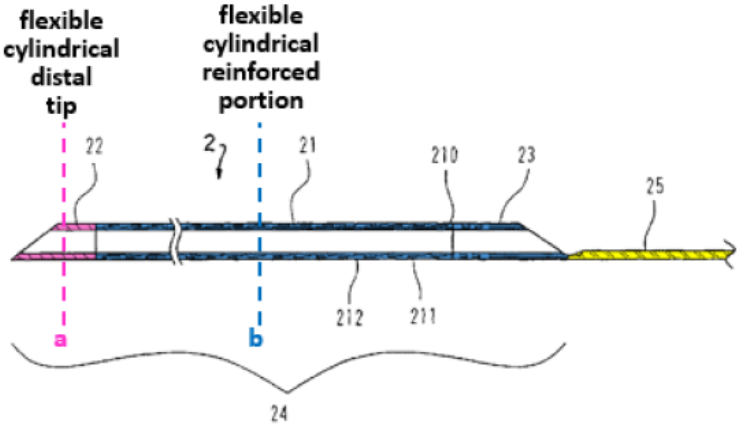
Itou Discloses a "*flexible cylindrical distal tip portion*"

TABLE 1

Name of device	Overall length (mm)	Outer diameter (mm)	Inner diameter (mm)
Guiding catheter 1	1000	2.06	1.8
Suction catheter 2 (tubular portion)	150	1.72	1.5
Suction catheter 2 (wire-like portion)	1100	0.45	—
Distal end protective catheter 5 (tubular portion)	20	1.35	0.5
	1300	0.45	—

More preferably, the suction catheter includes a tubular portion provided on the distal side and a solid wire-like portion provided on the proximal side and having a distal end embedded in a wall which forms the tubular portion. Further, the tubular portion of the suction catheter has a soft tip whose distal end is flexible in order to reduce the damage to the blood vessel, and includes a reinforcing member so that, even where

Itou Discloses a "*flexible cylindrical distal tip portion*"



Ex-1007, Fig. 3 (color and annotations added).

Tip 22 (pink) is cylindrical as a cross section taken through line (a) is circular, reflected by tubular portion (24) having an inner ***diameter***. Ex-1007, Table 1, Fig. 7B; Ex-1005, ¶ 202. Thus, tip 22 is a "flexible cylindrical distal tip portion." Ex-1005, ¶ 202.

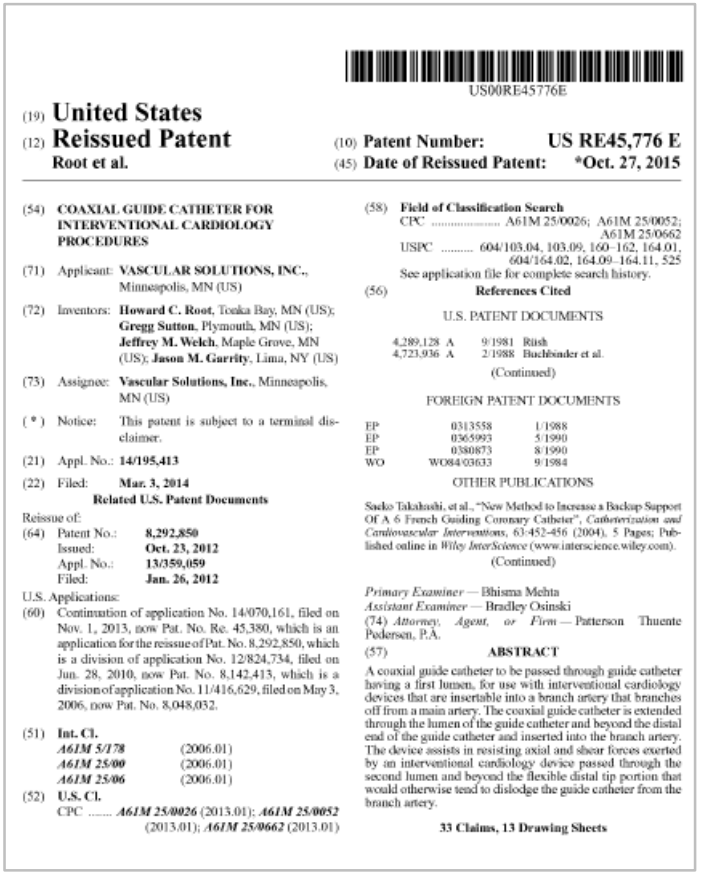
IPR2020-00126, Paper 1 (Petition), 45; *and see* Ex-1005 (Brecker Decl.), ¶ 202.

IPR2020-00135

- "*interventional cardiology devices*"
  - Claim Construction (IPR2020-00126, -00128, -00135)
  - Itou Receives interventional cardiology devices

***

- Itou discloses a "*flexible cylindrical distal tip portion*" (claim 6, '032 patent) (IPR2020-00126)
- Itou discloses an *"inclined region that tapers into a non-inclined region"* (claim 32, '776 patent)



US00RE45776E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE45,776 E**
(45) **Date of Reissued Patent: *Oct. 27, 2015**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **VASCULAR SOLUTIONS, INC.**, Minneapolis, MN (US)

(72) Inventors: **Howard C. Root**, Tonka Bay, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Lima, NY (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/195,413**

(22) Filed: **Mar. 3, 2014**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,059**
Filed: **Jan. 26, 2012**

U.S. Applications:
(60) Continuation of application No. 14/070,161, filed on Nov. 1, 2013, now Pat. No. Re. 45,380, which is an application for the reissue of Pat. No. 8,292,850, which is a division of application No. 12/824,734, filed on Jun. 28, 2010, now Pat. No. 8,142,413, which is a division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)
A61M 25/06 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 25/0026*** (2013.01); ***A61M 25/0052*** (2013.01); ***A61M 25/0662*** (2013.01)

(58) **Field of Classification Search**
CPC A61M 25/0026; A61M 25/0052; A61M 25/0662
USPC 604/103.04, 103.09, 160–162, 164.01, 604/164.02, 164.09–164.11, 525
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,289,128 A 9/1981 Rüsh
4,723,936 A 2/1988 Buchbinder et al.
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0313558 1/1988
EP 0365993 5/1990
EP 0380873 8/1990
WO WO84/03633 9/1984

OTHER PUBLICATIONS

Saeko Takahashi, et al., "New Method to Increase a Backup Support Of A 6 French Guiding Coronary Catheter", *Catheterization and Cardiovascular Interventions*, 63:452-456 (2004), 5 Pages; Published online in *Wiley InterScience* (www.interscience.wiley.com).
(Continued)

Primary Examiner — Bhisma Mehta
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente Pedersen, P.A.

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

33 Claims, 13 Drawing Sheets

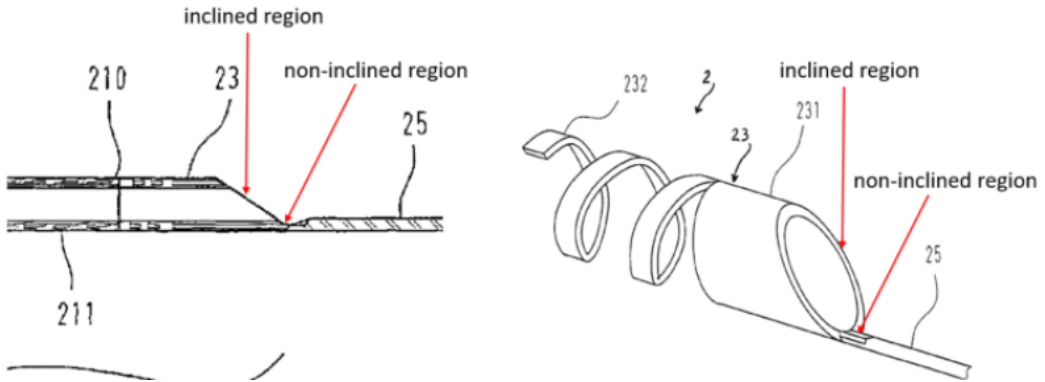
25. A guide extension catheter for use with a guide catheter, comprising:
a substantially rigid segment;
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination

36. The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.

Ex-1001, claim 36 ('776 patent)

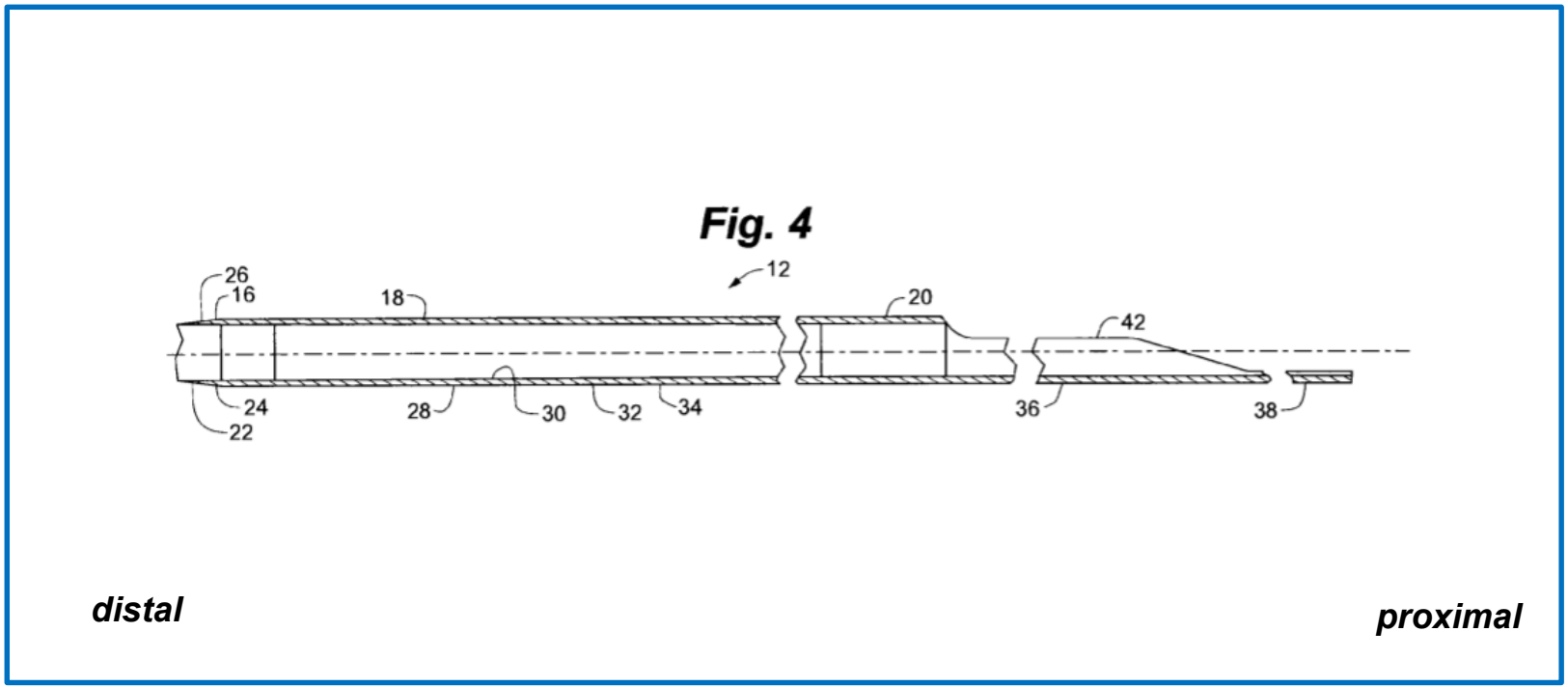
Itou: "inclined region that tapers into a non-inclined region"

Itou discloses that the partially cylindrical opening portion (231) is formed by obliquely cutting one end of a metal pipe. Ex-1007, 4:27-32, Fig 4. As shown in Figures 3 and 4 of Itou, the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region (arrow) that tapers into a non-inclined region.



IPR2020-00135, Ex-1005 (Brecker Decl.), ¶ 171

“inclined region that tapers into a non-inclined region”



IPR2020-00135, Ex-1001

RE47,379

38. A method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predefined length, the method comprising:

providing a flexible tip segment having a lumen therethrough;

providing a reinforced segment including one or more metallic elements covered with a polymer and having a lumen for coaxial alignment with the lumen of the flexible tip segment;

providing a substantially rigid segment extending from a proximal end portion to a distal end portion, wherein the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment;

defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape, the side opening portion extending for a distance along a longitudinal axis of the device such that the side

44. The method of claim 38, wherein defining the side opening portion includes forming a first inclined sidewall, forming a second inclined sidewall, and separating the first inclined sidewall and the second inclined sidewall by a non-inclined region.

IPR2020-00137, Ex-1001

RESSEMANN

IPR2020-00134, -00138

- Obvious to Achieve 1 Fr (IPR2020-00134, -00138)
- Ressemann Discloses “coaxial” lumen (IPR2020-00134)

IPR2020-00138

RE47,379 claims	Instituted Ground	References
25-26, 29-31, 36, 38-40, 42-45	1	Ressemann
25-26, 29-32, 35-40, 42-44	2	Ressemann and knowledge of a POSITA
33, 34	3	Ressemann, Takahashi and knowledge of a POSITA
44	4	Ressemann, Kataishi
44	5	Ressemann, Enger

Claims addressed in Patent Owner's Response

- 33, 34, 42, 44

Unrebutted claims: 25-26, 29-32, 35-40, 43, 45

- Obvious to Achieve 1 Fr
  - IPR2020-00134 (independent claims)
  - IPR2020-00138 (claims 33, 34)

- Ressemann Discloses “coaxial” lumen (IPR2020-00134)

IPR2020-00134, -00138: Representative 1 French Claim

US00RE47379E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number:** **US RE47,379 E**
(45) **Date of Reissued Patent:** ***May 7, 2019**

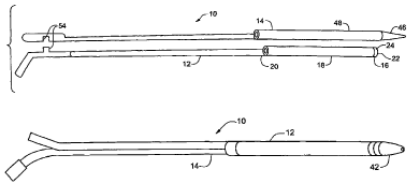
(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **Teleflex Innovations S.à.R.L.**, Grand Duchy (LU)

(58) **Field of Classification Search**
CPC A61M 25/01; A61M 25/0102; A61M 25/0067–25/0069; A61M 2025/0681;
(Continued)

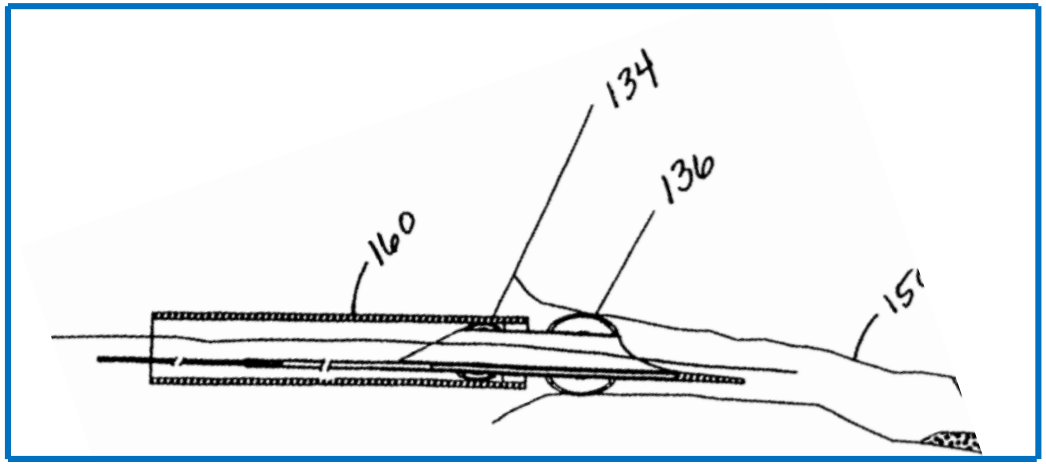
(56) **References Cited**
U.S. PATENT DOCUMENTS

33. The method of claim 25, wherein providing the reinforced segment includes forming or obtaining a reinforced segment including a lumen having a uniform inner diameter that is about one French smaller than an inner diameter of the continuous lumen of the guide catheter.

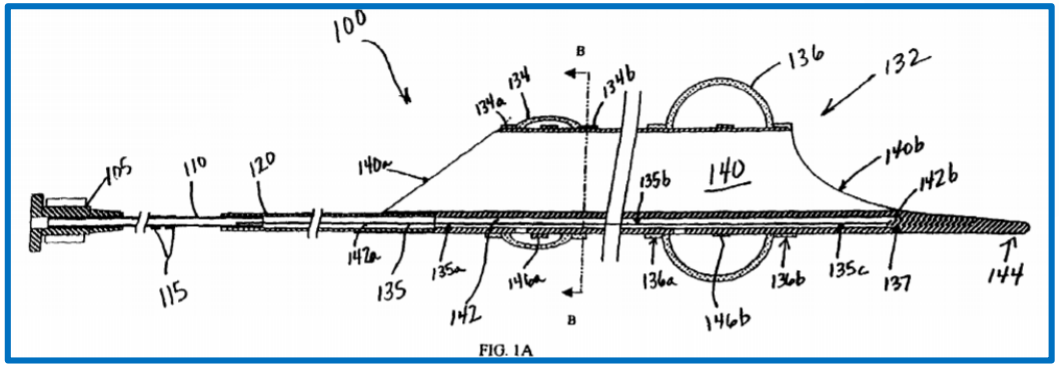


IPR2020-00138, Ex-1001

1 French



Ex-1608, Fig. 6C
IPR2020-00134



Ex-1608, Fig. 1 A

1 French

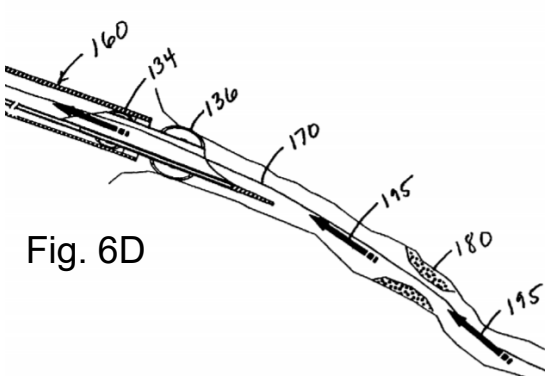


Fig. 6D

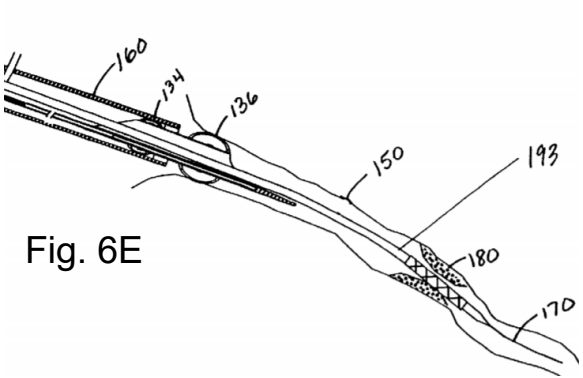


Fig. 6E

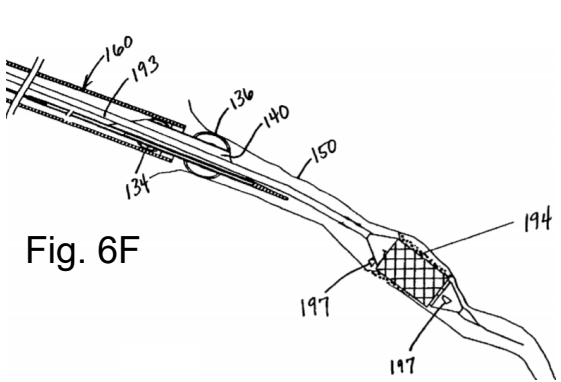


Fig. 6F

IPR2020-00134, Ex-1608

Takahashi

Basic Science Review

New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter

Saeko Takahashi,[1*] MD, Shigeru Saito,[1] MD, Shinji Tanaka,[1] MD, Yusuke Miyashita,[1] MD, Takaaki Shiono,[1] MD, Fumio Arai,[1] MD, Hiroshi Domae,[1] MD, Shutaro Satake,[1] MD, and Takenari Itoh,[2] PhD

A 6 Fr guiding catheter is commonly used in the percutaneous coronary intervention (PCI). However, one of the limitations of the 6 Fr guiding catheter is its weak backup support compared to a 7 or an 8 Fr guiding catheter. In this article, we present a new system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

Key words: five-in-six system; backup support; 6 Fr guiding catheter; chronic total occlusion

INTRODUCTION

Currently, a 6 Fr guiding catheter is commonly used in percutaneous coronary intervention (PCI), since its use can decrease access site complication, enable early ambulation, and reduce the consumption of the contrast dye [1–4]. Major limitations of a 6 Fr guiding catheter are the inner lumen is not big enough to accommodate bulky atherectomy devices, and its backup support is not strong compared to a 7 or an 8 Fr catheter. In this report, we demonstrate a new technique for PCI called the five-in-six system, which increases a backup support of a 6 Fr guiding catheter.

MATERIALS AND METHODS

The Five-in-Six System

The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A).

This 5 Fr Heartrail straight guiding catheter is 120 cm in length, whereas the 6 Fr guiding catheter is 100 cm. The 5 Fr Heartrail catheter has a very soft 13 cm end portion. This soft end portion can easily negotiate the tortuous coronary artery with the minimal damage and then it can be inserted more deeply into the artery. The inner lumen of the 5 Fr Heartrail catheter is 0.059″ in diameter; it can accept normal balloons or stent delivery systems less than 4.0 mm in diameter. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071″ in diameter to accommodate the 5 Fr Heartrail catheter; Launcher (Medtronic), Heartrail, and Radiguide (Terumo) guiding catheters can meet this inner lumen diameter.

In Vitro Experiments

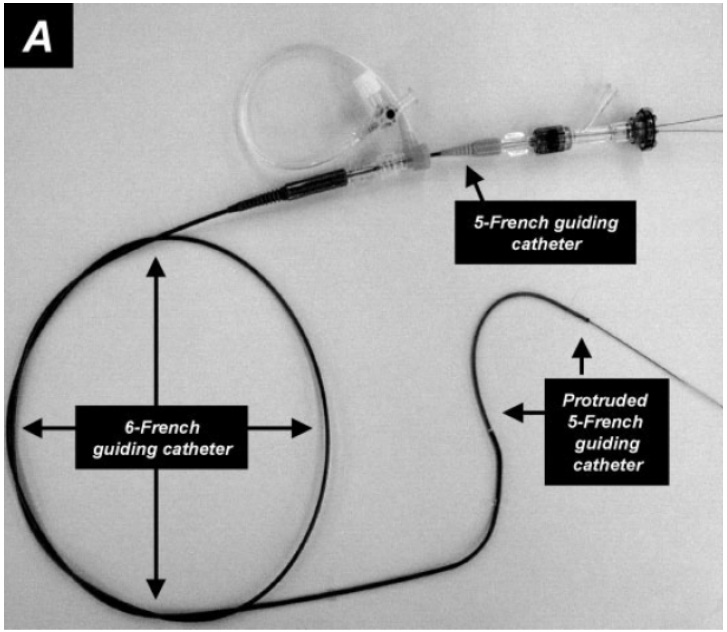
We measured the backup support of this five-in-six system in vitro using an experimental system. The artery model had three curves simulating tortuous coronary arteries. It was filled with water that was kept at 37°C (Fig. 1B). A guiding catheter was engaged into the ostium of the artery model. Then a rapid-exchange balloon catheter (Ryujin 2.5 × 20 mm; Terumo) was pushed into

[1]Division of Cardiology and Catheterization Laboratories, Heart Center of ShonanKamakura General Hospital, Kamakura City, Japan [2]Research and tory, Terumo Corpora

*Correspondence to: Dr Catheterization Laborat eral Hospital, 1202-1 E-mail: saekot@wa2.so

Received 8 October 20

DOI 10.1002/ccd.2022 Published online in Wile



system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

IPR2020-00126, Ex-1010

1 French

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UNITED STATES PA

BEFORE THE PAT

MEDTRONIC, INC., A

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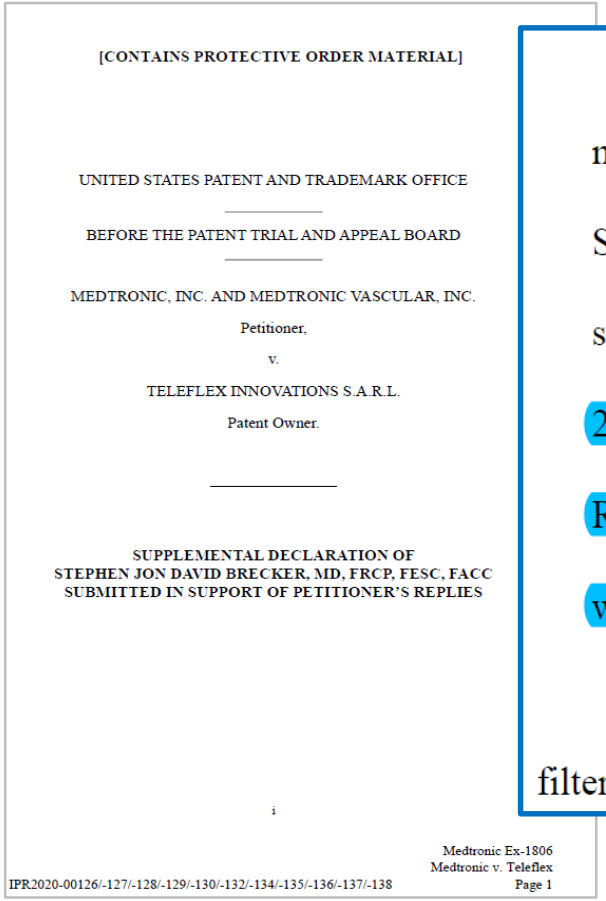
SUBMITTED IN SUP

112. I am aware that the Ressemann reference is entitled "Embolic Protection Devices and Related Methods of Use," and that the proposed modification of eliminating the sealing balloons from Ressemann would eliminate the ability of assembly 100 to be used to suction emboli. This modification, however, would have no impact on the ability of assembly 100 to be used to deliver a stent or balloon catheter, which is a second function disclosed by Ressemann. Ex-1008, 6:29-32, 13:55-14:27.

Medtronic Ex-1807
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

IPR2020-00134, Ex-1807 (Jones Decl.)

1 French



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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.

Petitioner,

v.

TELEFLEX INNOVATIONS S.A.R.L.

Patent Owner.

SUPPLEMENTAL DECLARATION OF
STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

i

Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

109. Additionally, before the Teleflex patents, a POSITA was aware of mechanisms different than Ressemann for providing embolic protection. Specifically, an article by Gorog describes several filter-based embolic protection systems. Ex-1811, 1. I am familiar with, and have used some of these systems. By 2005, filter-based systems were preferable to occlusive-based systems like Ressemann because it was known that some patients did not tolerate occlusion well.

110. Assembly 100, modified as proposed, could be used both to deliver a filter-based embolic protection system and to deliver a balloon or stent.

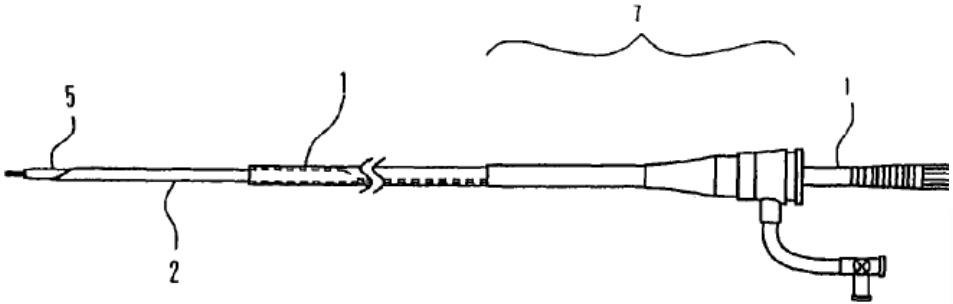
IPR2020-00134, Ex-1806 (Supplemental Brecker Decl.)

- Obvious to Achieve 1 Fr (IPR2020-00134, -00138)
- Ressemann Discloses “coaxial” lumen (IPR2020-00134) (independent claims)

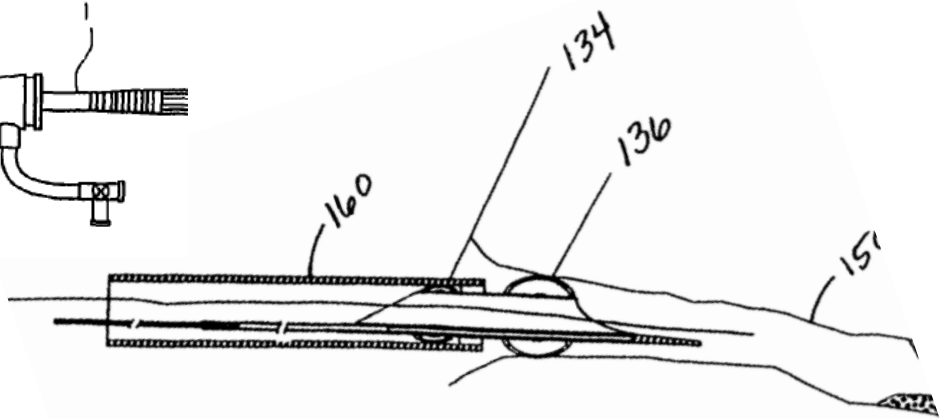
"coaxial"

Medtronic Proposal	Teleflex Proposal
"the axis of the lumen of the guide extension catheter is aligned in the same direction as the axis of the lumen of the guide catheter"	"plain and ordinary meaning"
IPR2020-00134, Paper 80 (Reply),9; Ex-1806 (Supplemental Brecker Decl.), ¶ 26	IPR2020-00134, Paper 99 (Surreply); Paper 41 (POR)

“coaxial”



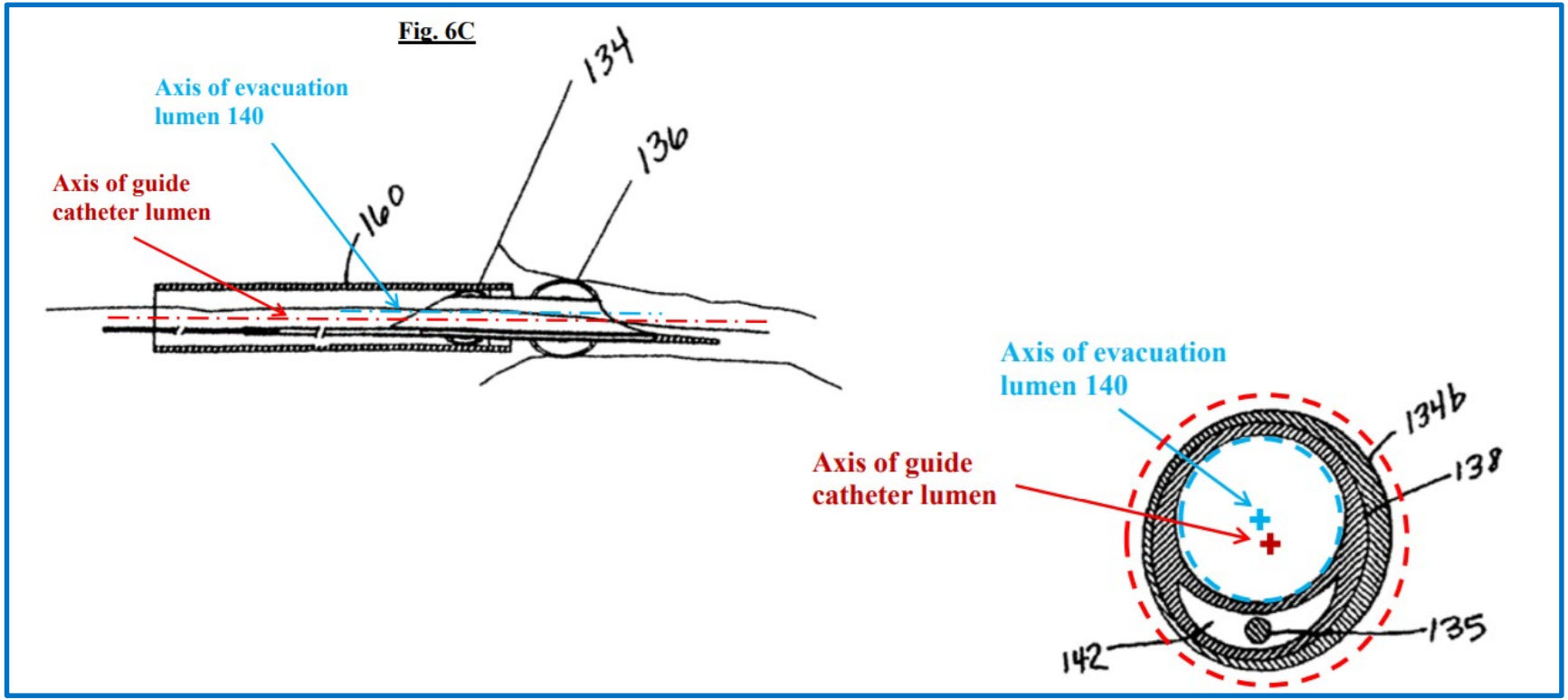
Ex-1607, Fig. 5



Ex-1608, Fig. 6C

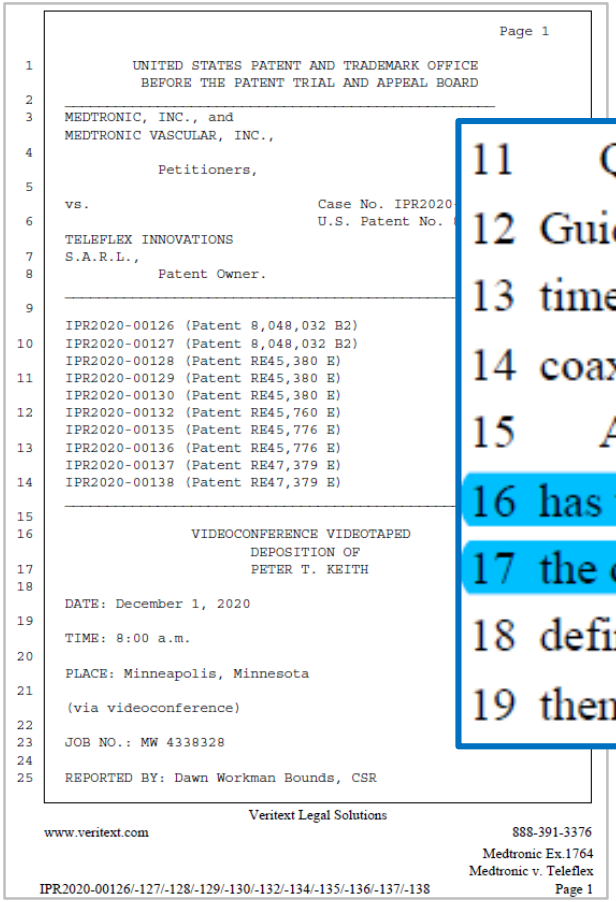
IPR2020-00134, Petition, 29, 62

“coaxial”



IPR2020-00134, Paper 41 (POR), 12

“coaxial”



Page 1

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

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020
U.S. Patent No.

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
PETER T. KEITH

DATE: December 1, 2020

TIME: 8:00 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338328

REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex.1764
Medtronic v. Teleflex

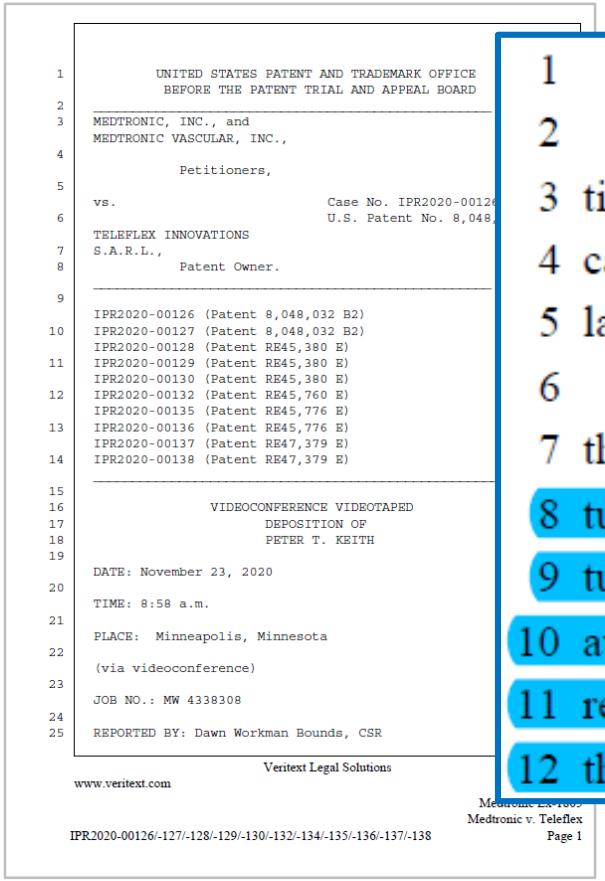
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

Q. Would you say that if a device such as GuideLiner was perfectly coaxial at least some of the time in a standard guide catheter, that would constitute coaxial guide catheter?

A. Well, I've already opined that I don't think it has to be perfectly coaxial at any point to meet the -- the ordinary meaning of coaxial. So I think by definition if it also happened to be perfectly coaxial, then that would still be coaxial.

IPR2020-00134, Ex-1764 (Keith Tr), 94:10-19

“coaxial”



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

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020-00126
U.S. Patent No. 8,048,

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
PETER T. KEITH

DATE: November 23, 2020

TIME: 8:58 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338308

REPORTED BY: Dawn Workman Bounds, CSR

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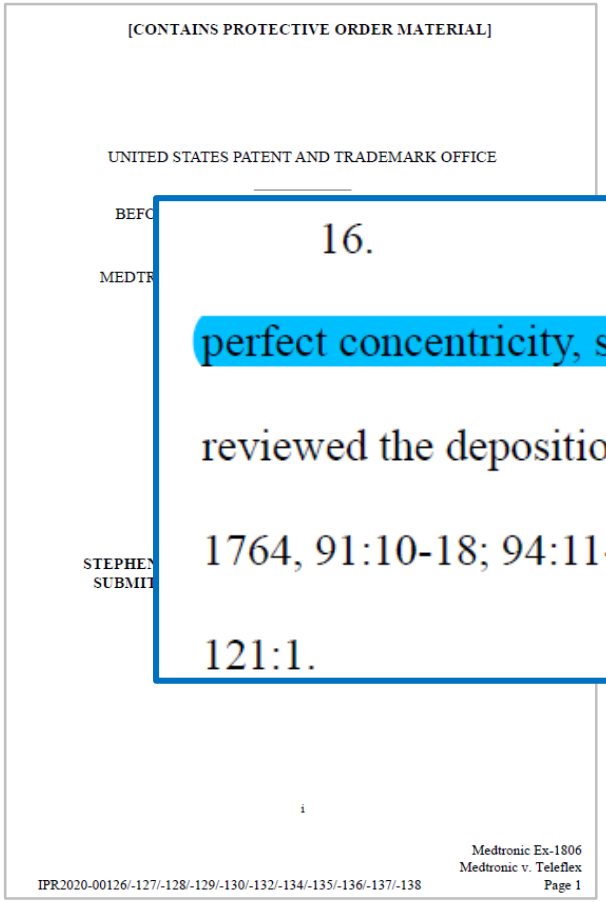
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

A. Well, let's -- let me be clear about one thing. Even in a catheter where there's just a tiny bit of space, the one catheter inside the other catheter isn't perfectly always in the same axis as the larger catheter. It's close, but it's not exactly there. And catheter engineers and designers know this; that, you know, structures of catheters that are tubes inside tubes or catheter arrangements that are tubes inside tubes are, you know, not magically automatically in line be their axis, but they still are referred to as coaxial structures and arrangements if they're relatively close.

IPR2020-00134, Ex-1805 (Keith Tr), 120:1-12

“coaxial”



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UNITED STATES PATENT AND TRADEMARK OFFICE

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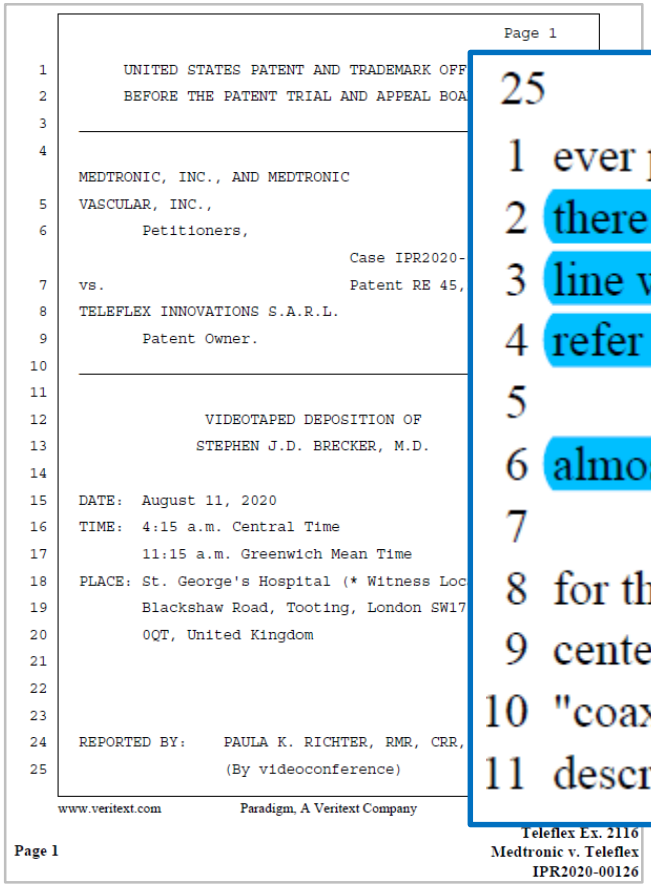
Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

16. A POSITA does not understand “coaxial” to refer to perfect concentricity, so that the catheters share exactly the same center line. I have reviewed the deposition testimony of Mr. Keith, who, now, agrees with this. Ex-1764, 91:10-18; 94:11-19; Ex-1800, 23:19-24:1; Ex-1805, 107:19-109:6; 117:14-121:1.

IPR2020-00134, Ex-1806 (Supplemental Brecker Decl.)

“coaxial”



Page 1

UNITED STATES PATENT AND TRADEMARK OFF
BEFORE THE PATENT TRIAL AND APPEAL BOA

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,
Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-
Patent RE 45,

VIDEOTAPED DEPOSITION OF
STEPHEN J.D. BRECKER, M.D.

DATE: August 11, 2020
TIME: 4:15 a.m. Central Time
11:15 a.m. Greenwich Mean Time
PLACE: St. George's Hospital (* Witness Loc
Blackshaw Road, Tooting, London SW17
0QT, United Kingdom

REPORTED BY: PAULA K. RICHTER, RMR, CRR,
(By videoconference)

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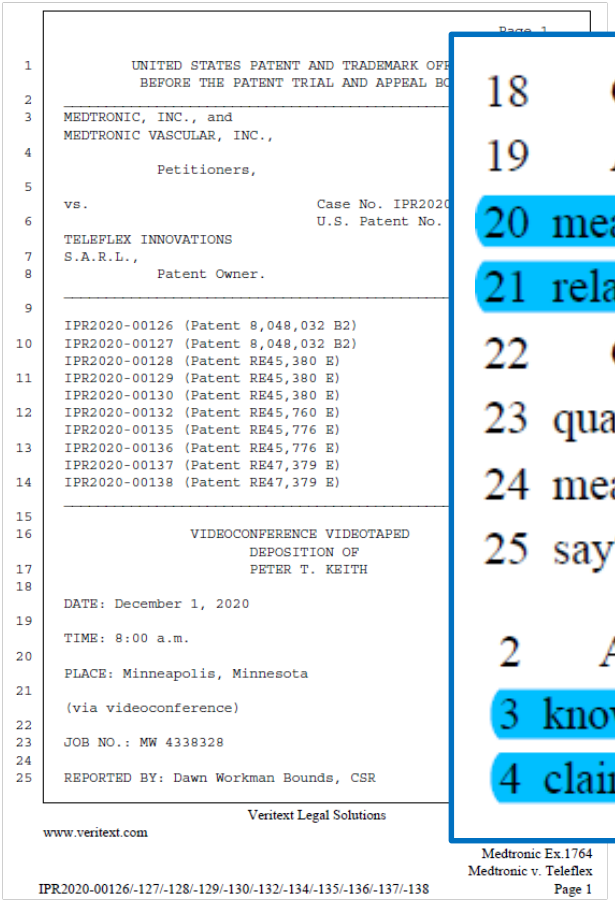
Page 1

Teleflex Ex. 2116
Medtronic v. Teleflex
IPR2020-00126

From the very first point that I ever put a guide catheter into a coronary artery, there is a need for the guide catheter to be in line with the coronary artery, and cardiologists refer to that as being coaxial. They do not need and, in fact, almost never will share a center line. So if my position become -- in order for things to be coaxial, they have to share a center line, I would have been misusing the term "coaxial" as a cardiologist would use it in describing guide catheters throughout.

IPR2020-00134, Ex-2116, (Brecker Tr.) 323:25-324:11

“coaxial”



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BEFORE THE PATENT TRIAL AND APPEAL BO

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020
U.S. Patent No.

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
PETER T. KEITH

DATE: December 1, 2020

TIME: 8:00 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338328

REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex.1764
Medtronic v. Teleflex
Page 1

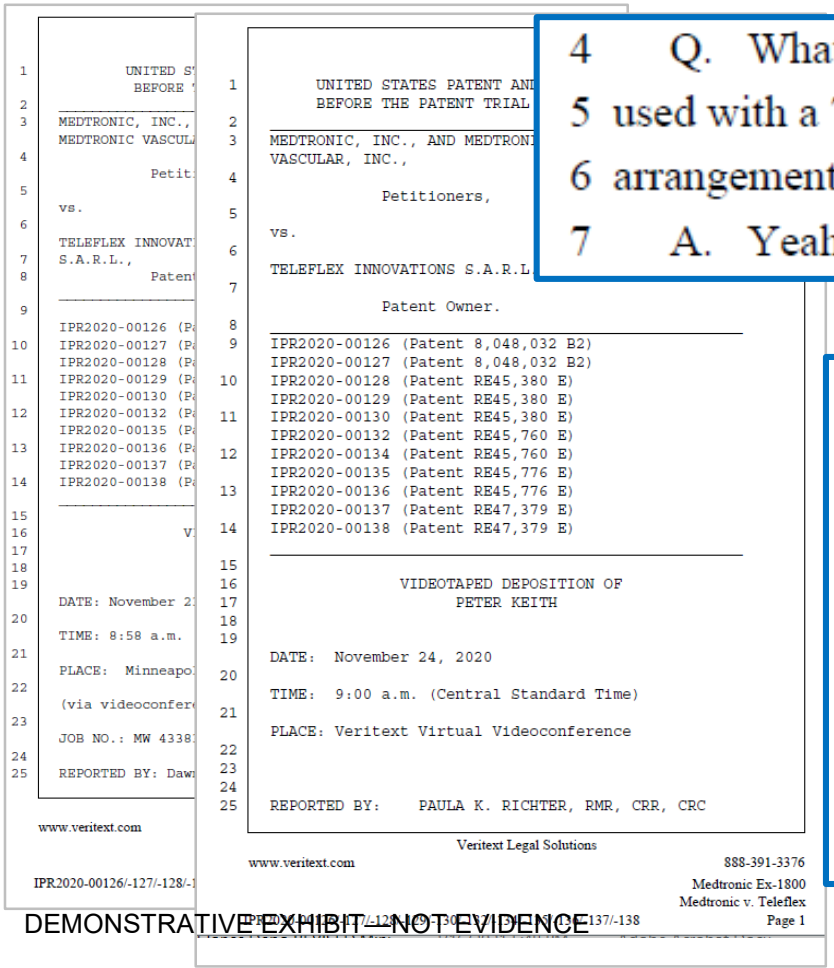
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

18 Q. Okay. So humor me. What is the definition?
19 A. In what I talked about before, I think coaxial
20 means essentially a tube-in-a-tube arrangement that is
21 relatively close-fitting.
22 Q. Okay. And you -- do you have an ability to
23 quantify what relatively close-fitting means to you -- or
24 means to a person of skill in the art in 2006, I should
25 say?

2 A. Again, I haven't formed an opinion about, you
3 know, putting hard numbers on that. I don't think the
4 claim needs that level of specificity.

IPR2020-00134, Ex-1764 (Keith Tr), 98:18-99:1; 99:2-4

“coaxial”



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

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOTAPED DEPOSITION OF
PETER KEITH

DATE: November 24, 2020

TIME: 9:00 a.m. (Central Standard Time)

PLACE: Veritext Virtual Videoconference

REPORTED BY: PAULA K. RICHTER, RMR, CRR, CRC

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Medtronic Ex-1800
Medtronic v. Teleflex
Page 1

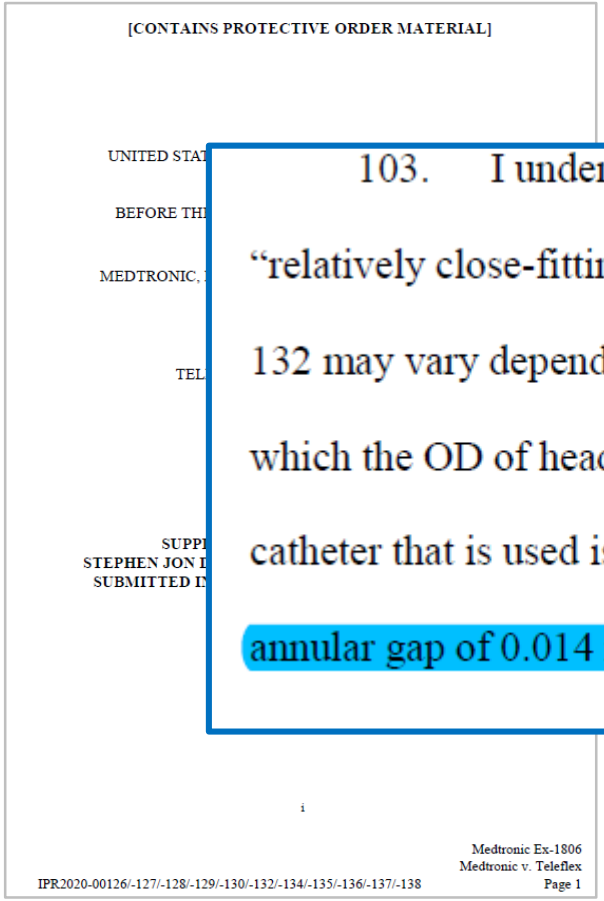
4 Q. What about if a 5 French extension catheter is
5 used with a 7 French catheter, is that a coaxial
6 arrangement?
7 A. Yeah, I think it probably is.

IPR2020-00134, Ex-1805 (Keith Tr), 119: 4-7

19 Q. Okay. This particular example is a 4 French
20 child catheter and a 6 French mother, correct?
21 A. Yes, that's what's shown.
22 Q. And I think we covered this yesterday, but
23 that is a coaxial arrangement, right?
24 A. I haven't made a specific opinion on that,
25 but I think that's -- it very well could be a
1 coaxial arrangement.

IPR2020-00134, Ex-1800 (Keith Tr), 23:19-24:1

“coaxial”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Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

103. I understand Teleflex’s position to be that the coaxial relationship be “relatively close-fitting.” Ressemann teaches that the diameter of evacuation head 132 may vary depending on intended application, and describes an embodiment in which the OD of head 132 is about 0.076 inches, and the ID of the 8 French guide catheter that is used is about 0.090 inches. Ex-1008, 10:9-29. This presents an annular gap of 0.014 inches.

IPR2020-00134, Ex-1806 (Supplemental Brecker Decl.)

“coaxial”

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104. An 0.014 annular gap is smaller than the 0.018 inch annular gap between the OD of a 4 French catheter and the ID of a 6 French catheter, which Keith admits is coaxial. *See* Ex-1840, 1 (describing using a 4 Fr angiographic catheter within a 6 Fr guide catheter in a coaxial fashion). Thus, even under Teleflex’s understanding, the relationship disclosed in Ressemann is “relatively close fitting.”

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Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

IPR2020-00134, Ex-1806 (Supplemental Brecker Decl.)

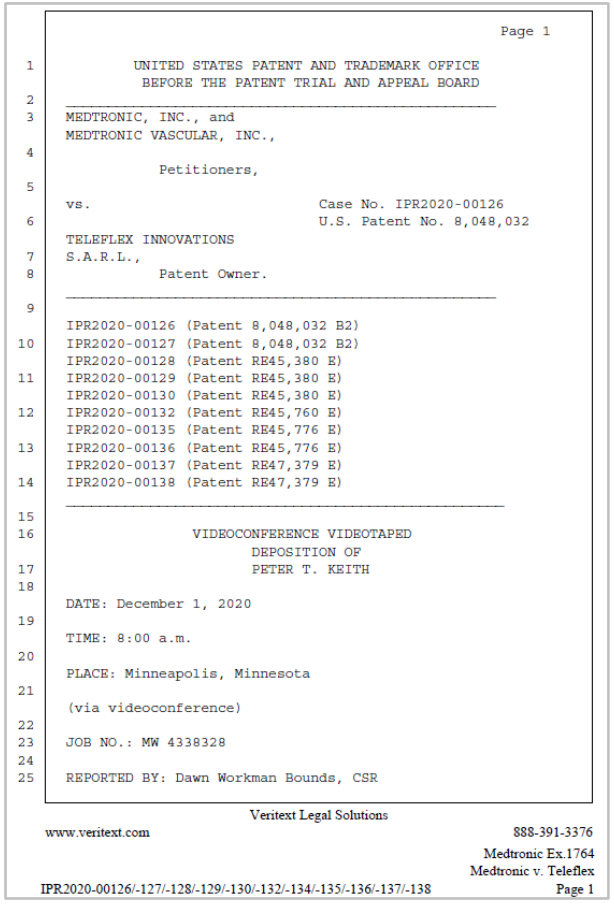
"coaxial"

To be clear, Teleflex is not saying that "coaxial" requires mathematical precision. Some clearance is required between the coaxial guide extension catheter and the surrounding guide catheter.

Indeed, the '760 specification uses "coaxial" consistent with its ordinary meaning. All examples of the "coaxial guide catheter" show a distal tubular portion with a lumen that it is disposed approximately coincident with the axis of the lumen of the guiding catheter.

IPR2020-00134, Paper 99 (Surreply), 5

“coaxial”



Page 1

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

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020-00126
U.S. Patent No. 8,048,032

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
PETER T. KEITH

DATE: December 1, 2020

TIME: 8:00 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338328

REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex.1764
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

Q. Okay. Another portion of your testimony a couple of times when you were being asked about coaxial, you used the phrasing a tube within a tube. And I just want to make sure there's no lack of clarity of what you were thinking of when you were using that terminology.

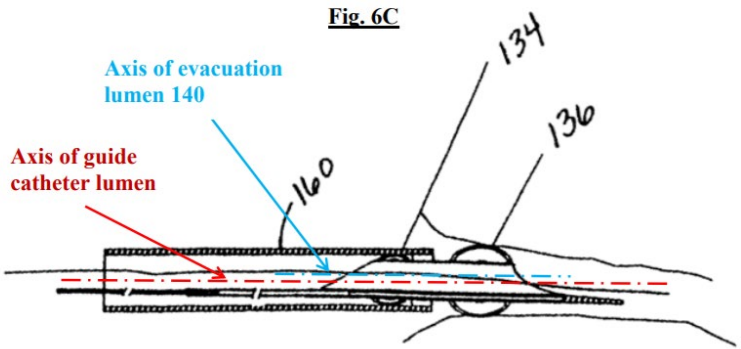
Can you just expand a little bit more about what you mean by tube within a tube?

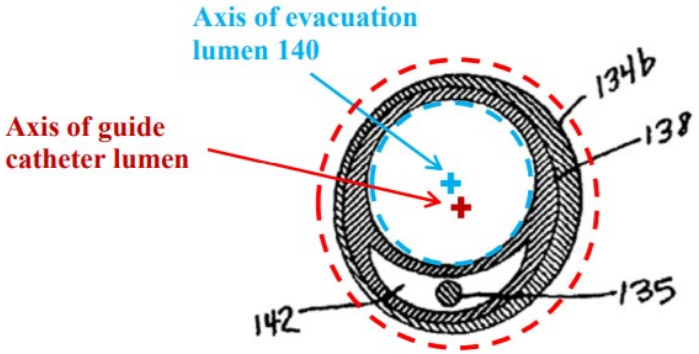
A. Sure. And I thought I was -- maybe I wasn't being as clear in some of the words that I was using in my prior answers on that. But what I'm getting at is that the tubes themselves essentially are -- have radial symmetry to them. So it's a -- you know, it's a tube that if you looked at that tube, it wouldn't have a different characteristic or quality in one direction versus another direction; i.e., it has radial symmetry.

IPR2020-00134, Ex-1764 (Keith Tr), 101:10-24

"coaxial"

In this regard, Petitioner wrongly accuses Teleflex of taking the position that the term "coaxial" required "lumens to be perfectly concentric." Reply, 2-3. Teleflex said nothing about perfect concentricity. POR, 11-13. Rather, Teleflex and its experts stated that Ressemann is not coaxial because it is configured to have an offset lumen. *Id.*; *see also* Ex-2138 (Mr. Keith), ¶¶104-05, 110; Ex-2145 (Dr.





IPR2020-00134, Paper 99 (Surreply), 6, 11

“coaxial”

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UNITED STATES PA

BEFORE THE PAT

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101. As illustrated below, lumen 140 is aligned in the same direction as the lumen of guiding catheter 160.

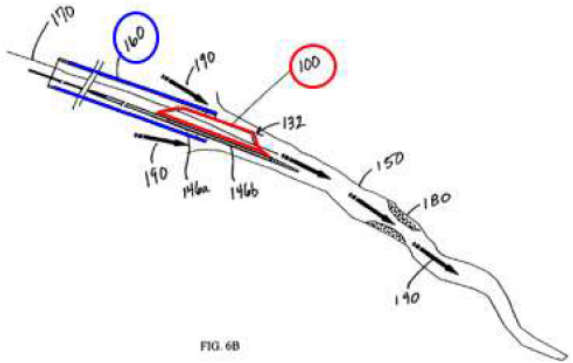

FIG. 6B

Ex-1008, Fig. 6B (annotation added); *and see* 12:9-14:39 (describing Figs. 6A-6I).

Medtronic Ex-1806
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

IPR2020-00134, Ex-1806 (Supplemental Brecker Decl.)

"coaxial"

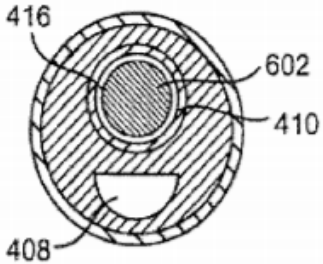

FIG. 7

FIG. **7** is an alternate embodiment of balloon catheter **100** taken along line B-B of FIG. **2**, and illustrates a non-coaxial arrangement of guidewire lumen **416** and inflation lumen **408** as discussed with reference to FIG. **4**. Guidewire **602** is shown within guidewire shaft **410**.

Ex-2224, Fig. 7; 7:26-30

16	Q. Now let's then just go briefly to Figure 7,	06:53:01
17	and if you would read the paragraph starting at	06:53:06
18	line 27.	06:53:09
19	A. (Reviews document.)	06:53:27
20	Q. And just to confirm what that paragraph says,	06:53:34
21	it indicates that Figure 7 illustrates a	06:53:41
22	non-coaxial arrangement of guidewire lumen 416 and	06:53:48
23	inflation lumen 408, correct?	06:53:54
24	A. Yes, that's what it says.	06:53:56

Ex-2238 (Brecker Tr.), 54:16-24

“coaxial”

1	Figure 4 shows side-by-side lumens, correct?	06:12:52
2	A. Yes.	06:13:00
3	Q. Would a person of ordinary skill in the art	06:13:00
4	consider those two lumens to be coaxial with each	06:13:07
5	other?	06:13:12
6	A. So typically, when one is thinking about	06:13:12
7	coaxial, you want one inside the other. However,	06:13:28
8	if those are both inside a larger catheter, then	06:13:36
9	it's fair to call them coaxial lumens to the	06:13:45
10	larger catheter.	06:13:52
11	Q. So if those -- if this device is put inside a	06:13:56
12	guide catheter, you would call them coaxial?	06:14:02
13	A. Oh, if you put this --	06:14:09
	***	
17	THE WITNESS: If you put that inside	06:14:17
18	a guide catheter, I think cardiologists would	06:14:19
19	understand that the lumens inside are coaxial.	06:14:25

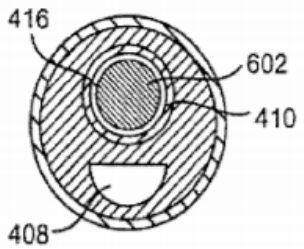

FIG. 7

IPR2020-00134, Ex-2224 (Fig. 7);
Ex-2238 (Brecker Tr), 44:1-19, Paper 114 at 6-7