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MEMORANDUM

TO: RON PICKARD
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FROM: LARRY BOYD

DATE: JANUARY 26, 1994

SUBJECT: MICHELSON DEVICES - INTERBODY FUSION DEVICES

Attached please find a report on interbody fusion devices. This report discusses some of the current interbody fusion device concepts, especially Dr. Michelson's technology, and the development, marketing and manufacturing issues associated with the commercialization of interbody fusion devices.

I hope this information is useful to you in beginning to plan our strategy in this important area. Please let me know if you have any questions, comments or concerns. I would appreciate any feedback you may have on this report. Please feel free to call me at any time.

Best Regards,

DEPOSITION EXHIBIT
Pafford-350

THE SPINE SPECIALIST℠

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MSD 1041682

Lukianov
EXHIBIT NO. 135
11/9/10
J. HOSTETLER

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PLAINTIFF'S EXHIBIT
CASE NO. 08CV 01512
EXHIBIT NO. PX0116

PX0116-0001

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CONFIDENTIAL

INTERBODY FUSION DEVICE CONCEPTS

January 1994

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Present Situation

Market Environment

On January 12, Sofamor Danek group acquired the interbody fusion device concepts of Dr. Gary Karlin Michelson via licensing and purchase agreements. The acquisition of these implant and instrumentation concepts puts Danek in a strong position to dominate the evolving market for interbody fusion devices. The Michelson technology complements our existing product line, as well as supporting and complementing various product development programs currently underway.

The spinal implant marketplace is undergoing rapid changes as new technologies for achieving interbody fusion appear on the horizon. Implants specifically designed for interbody fusion (Interbody Fusion Devices–IBFDs) are being developed by all major spinal implant manufacturers. Several designs are currently undergoing controlled clinical evaluation. Interest in the devices is growing, as these new devices begin to show the feasibility of developing implants that are superior to the use of allograft, or autograft bone grafting alone.

Sofamor Danek Group currently has under development an interbody fusion device (with Dr. Jeffrey Kozak of Houston) designed solely for anterior interbody fusion. Additionally, bone substitutes are under development by both Sofamor (HA/TCP Paste with Dr. Passuti in Nantes) and Danek (OPLA with bone proteins from Genetics Institute). These materials will likely require the use of a device to provide for load bearing due to their relatively poor mechanical properties. The purchase of the Michelson technology expands this product offering and gives the company access to a broad range of technology for anterior, posterior, lateral and laparoscopic surgery of the cervical, thoracic and lumbar spine. Sofamor Danek Group is now poised to become a major player in this new market segment–Interbody Fusion Devices.

Products and Services

The present stage of interbody fusion device product design and development varies. The Kozak IBFD is currently undergoing mechanical cadaveric testing, animal testing and finite element analysis. Initial results from mechanical testing show favorable stiffness of the IBFD vs. the Harms Cage and femoral ring allograft. Pilot animal studies appeared to show bone fusion, but histological processing will be required. The bone substitutes are in various stages, but initial data is encouraging for the OPLA with bone stimulating proteins and the HA/TCP paste. The Michelson technology has been initially developed by Zimmer. It appears that some testing and analysis has been performed, but additional testing will be required. We are currently evaluating the anticipated testing required for the Michelson threaded IBFD concept.

Product Life Cycle

Our current flagship product line is the Texas Scottish Rite (TSRH) Spinal System. As a forward-looking spinal implant manufacturer we recognize the potential for new technologies to both augment this existing technology and potentially supplant this technology, depending on the surgical application. Clearly, a strong market for the TSRH system and related systems will continue to exist in the near future and some clear indications for those rod-based and plate-based fixation devices will always exist (e.g, deformity, trauma, tumor...).

The market for interbody fusion devices will take time to develop. However, we are now beginning to see the initial penetration of this technology into the marketplace. Time factors influencing our ability to realize significant U.S. sales for this technology center around the potentially long process required to receive U.S. FDA clearance for the devices. Additionally, the process of finalizing the design, testing and manufacturing launch quantities is now being analyzed.

Pricing and Profitability

Current prices for interbody fusion devices appear high. The reported price for a single SpineTech BAK device is on the order of $2,000. Two devices are required per spinal level, so the cost per fused level is around $4,000. Dr. Gary Michelson has estimated that the manufacturing cost for these devices is in the $50 range for large quantities. Prior manufacturing quotes in the Zimmer files show costs of $100 to $200 for 100 pieces. This would lead one to conclude that the potential profitability of these products is quite significant. Reimbursement issues would appear to be addressable, if the apparent success of the SpineTech BAK implant and the Surgical Dynamics Ray Cage clinicals are an indicator.

Customers

It would appear that several of our current leading-edge customers are using the BAK or Ray Cage for posterior lumbar interbody fusions (PLIFs), anterior lumbar interbody fusions (ALIFs) and laparoscopic ALIFs. These are considered innovative devices and unique approaches to interbody fusions. These loyal Danek (or Sofamor) customers represent a potential source of design input and future clinicians as we develop our own innovative devices. Many of these users have requested that we develop such a threaded device to compete with the SpineTech and Surgical Dynamics technologies. They have recognized the potential for improvements to the current technology and we should make an effort to factor these comments into the design process, where possible.

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