

MEDICAL DIVISION



3092 DIRECTORS ACM MEMPINS IN 36131 (201) 396-5123 WATS: (200) 376-3123 FAX: (901) 322-1920

G. Karlin Michelson, M.D. 8610 Sepulveda Blvd. Suite 101 Los Angeles, California 90045 FAX (310) 821 - 5115

Dear Dr. Michelson,

It was good to talk with you today. I am very enthusiastic about moving forward with the many fusion device concepts. As we had discussed, we would like to begin working on the various implant and instrumentation designs. We covered a great deal of information in our discussions, so I have listed some of the things we discussed. Please let me know if I missed anything or have misunderstood anything. In order to move forward with the project we discussed the following:

- 1.) You will send me (via Fed Ex) today several implants and information on the design. This information will include prior modeling and analysis information on the implant, as well as regulatory filing information on the 510(k) application by KTI on a non-spine application of the threaded fusion device technology.
- 2.) You will contact your machinist about manufacturing several sets of implant and instrumentation systems. The machinist will measure the current instruments, photograph the instruments and forward these to us to allow us to begin modeling the complete system. We specifically talked about the following
- A. Primary PLIF Instrumentation 1 set of instruments sent after measurement by machinist, to allow us to get started. 3 additional sets of primary instruments to be manufactured. (Please have your machinist send a cost and timing estimate first)
- 8. Lordotic Distractors and Trephine (size 18 mm only) forward these at your earliest convenience. I don't recall if we discussed manufacture of these, but we should probably make 2 sets (for a total of 3 sets).
- C. Other PLIF Alternative Instrumentation We discussed making 2 sets of any other alternatives in a single size only (20 mm?). We should probably discuss anything not already covered by items A and B above.
- D. ALIF Instrumentation (20 mm size only) Manufacture 2 full sets (for 3 full sets total), this would include the lordotic wedge distractors, double-barrel outer sleeve and appropriate length reamer, driver, etc.

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PLAINTIFF'S EXHIBIT CASE NO. 08CV 01512 MNUV0278500

PX0193-0001

EXHIBIT NO. **PX0193**



Approx \$3,500

- E. Anterior Lateral Implant and Instruments (24D x 42L size only) complete the current set (e.g., manufacture slap hammer) and manufacture one duplicate set (for a total of 2 complete sets).
- F. Cervical Implant and Instrument Set (Size 16 mm only) please send this set for our review at your earliest convenience.
- G. Non-Threaded Concepts (Push-in Designs, Truncated Designs, and Cervical Fusion Device with Front Slot) - Please send me some samples of these for our review and records at your earliest convenience.

Dr. Michelson, I think this covers all the devices we discussed. Please call me if I have missed anything. I will look forward to receiving the implants and additional information tomorrow. I will stay in touch with you as we move forward to this project and will look forward to hearing from your machinist regarding the manufacture of the additional implant/instrument sets. Also, please do not hesitate to call me at any time. Due to the time difference and our schedules, you will probably need to call me at home at times. My home phone number is (901) 681-0243. Please do not hesitate to call me. I will talk with you soon. Take care.

Sincerely,

awrence M/Boyd

Manager Product Development

CC: Ron Pickard-John Pafford

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BC: David Brumfield Brad Estes

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DANEK GROUP, INC. January 14, 1994 MEDICAL DIVISION

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G. Karlin Michelson, M.D. 8610 Sepulveda Blvd. Suite 101 Los Angeles, Catifomia 90045 FAX 310 821-5115

Dear Dr. Michelson,

In follow-up to our discussion today about manufacture of the various instrument sets, here are the various items we discussed:

PUF Set 3 sets of 65 insts per set at \$3,000 per set
 (Timing approximately 3 weeks)

Total \$9,000

2. Lordotic Distractors Size 16 mm

 Lordotic distractors
 \$100 @

 inner Sleeve
 \$35 @

 Trephine
 \$ 150 @

 Cap Daiver
 \$ 150 @

 Rotary Knife
 \$ 200 @

3 sets total at \$600 per set

Total \$1,800

3. ALIF instrumentation (Size 18 mm and 20 mm)

	18 mm Se i	20 mm Set
\$125	6 🛭	69
\$250	1 😘	10
\$150	10	1@
\$125	19	109
\$225	197	
\$250	1 💇	
\$30	20	28
\$150	10	10
\$250	10	
Per Set	\$2210	\$1485
	\$250 \$150 \$125 \$225 \$250 \$30 \$150 \$250	\$125 6 9 \$250 1 9 \$150 1 9 \$125 1 9 \$225 1 9 \$250 1 9 \$30 2 9 \$150 1 9 \$250 1 9

Need three complete sets at \$3,695 per

Total \$11,085

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4. Anterior Lateral Instrumentation (24D x 42L)

Distractor 6, 8, 10, 12, 14 mm	\$1800 total
Slap Hammer	\$275 🕏
Driver Cap	\$225 @
Implant Oriver	\$275 @
Other	\$175 @

Total per set is \$2750 and we can use some components from the existing set

Total approx. \$4,500

Overall, it looks like it adds up as follows:

1. PLIF Instrumentation (3 Sets Manufactured)	\$9,000
2. Lordotto Distractors and Trephine (3 Sets)	\$1,800
3. ALiF Instruments (3 Sets Size 18 and 20 mm)	\$11,085
4. Anterior Lateral Insts. (2 Sets Total)	\$4,500

Dr. Michelson, please let me know if this agrees with your notes from our conversation. Please have your machinist send me a written quotation for these items and I will cut a purchase order. Call me if you have any items to discuss. Talk with you soon.

Sincerely,

Lawrence M. Boyd

Manager, Product Development

CC: John Pafford David Brumfield Brad Estes

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