

# Exhibit 4

# EXHIBIT DTX-5134-R

Request for Individual Custom Device  
(As required by Section 520 (b)  
of the Food, Drug & Cosmetic Act)

I have determined that a special device will be necessary to provide most effective relief of a patient condition described below. Available standard production devices are not completely suitable for this purpose. I agree that the custom device will be used only by me for use for the patient named below.

Please type or print:

Patient Name:

ELENA [REDACTED]

Patient Condition:

Elena had PCIF + plates L4-S1 with failure at L4-5. Had revision using cages at L4-5. Now ETO bone is dissolving at L5-S1. Cage fusion solid. Needs repair of failed PCIF at L5-S1 using

Description of Custom Device:

anterior cage device

Request anterior oval cages described in drawing

Small -12 33 mm x 22 mm x 12 mm high

Small -10 33 x 22 x 10

Surgery scheduled 11/21/90

John M. Brantigan MD 10/30/90  
Surgeon Date

BRANTIGAN

Print Name

2709 Franklin Blvd 6th Floor

Street Address

Cleveland OH 44113

City

State

Zip

(216) 363-2264

Telephone Number

Defendant's Exhibit

DTX-5134

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(As required by Section 520 (b)  
of the Food, Drug & Cosmetic Act)

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Please type or print:

Patient Name: [REDACTED]

KAREN

Patient Condition:

Karen had PLIF and VSP plate procedure for Grade III Spondyloarthrosis. She now has one broken S1 screw and one bent S1 screw and is having increasing pain and instability. Surgery scheduled 11/14/90

Description of Custom Device:

Request anterior cages described in drawings as:

Medium - 14      36mm x 24mm x 14 mm high

Medium - 12      36mm x 24mm x 12 mm high

Small - 14      33mm x 22mm x 14 mm high

John Brantigan MD      10/30/90  
Surgeon      Date

BRANTIGAN

Print Name

2709 Franklin Blvd 6<sup>th</sup> Floor  
Street Address

Cleveland OH      44113  
City      State      Zip

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Request for Individual Custom Device  
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Please type or print:

Patient Name:

David

Patient Condition:

Spinal instability L4-S1. Disc resorption L5-S1  
with large lateral osteophytes. Retrolisthesis L4-5

Well muscled overweight power lifter weighs 305 lbs.

Requires the strongest anterior and posterior support

Description of Custom Device:

we can provide to avoid  
broken screws.

4 carbon cages

13 mm x 13 mm x 25 mm

Surgery scheduled for 11/16/90

John M Brantigan MD 10/30/90  
Surgeon Date

BRANTIGAN

Print Name

2709 Franklin Blvd. 6th Floor

Street Address

Cleveland, OH 44113

City

State

Zip

(216) 363-2264

Telephone Number

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