

Cervical IBFD System

Surgical Technique Manual

Step by Step
Guide

Tray Description

Product Sizes

Step 1 : Patient Positioning

Place the patient in the supine position, with the head in slight extension. Expose the anterior cervical spine.

Step 2 : Perform Discectomy

Perform a discectomy or partial corpectomy to decompress the anterior aspect of the spinal cord.

Figure 1, 2, 3, 4

NOTE: "Use a pituitary to remove the anterior osteophyte in order to open the orifice of the disc space. It will allow the "nose of the implant to insert and self distract easier."

Figure 4

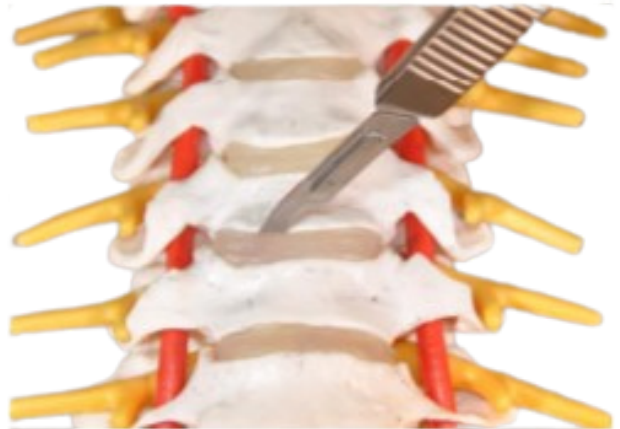


Figure 1



Figure 2



Figure 4



Figure 3

Step 3 : Trial Sizer

Insert the trial sizer into the vertebral disc space. Neutral & 6 degrees of lordosis trials are available. They are available with and without safety stops. The safety stop prevents the spacer from going too far posterior. The appropriately sized trial should fit securely between the endplates.

NOTE: Confirm proper sizing with fluoroscopy.

Figure 5, 6



Figure 5



Figure 6

Step 4 : Cervical Rasp

Rasp the disc space. The rasps are .5mm smaller than the true implant. This allows for a press fit of the final implant.

Figure 7, 8



Figure 7



Figure 8

Step 5 : Choose Implant

Select the appropriate size determined by the trial or rasp. Then assemble the implant onto the inserter. PEEK-OPTIMA, titanium, and 3D printed titanium implants are available.

Figure 9



While holding the interbody on the inserter, rotate the inserter knob clockwise to securely attach the interbody.

Step 6 : Pack the Implant

Place the implant into the cervical packing block and impact the bone into the implant.

Figure 10

NOTE: Profile of the instrument and implant match the packing block for secure fit.



Figure 10

Step 7 : Implant Insertion

Insert the interbody cage into the disc space. The bullet nose of the cage will allow for easier insertion, and the implant will have a tendency to self distract the disc space. The interbody cage should be flush with the anterior portion of the vertebral bodies. Disengage the inserter from the interbody cage by rotating the inserter knob counterclockwise until it is free from the interbody cage.

Figure 11, 12, 13

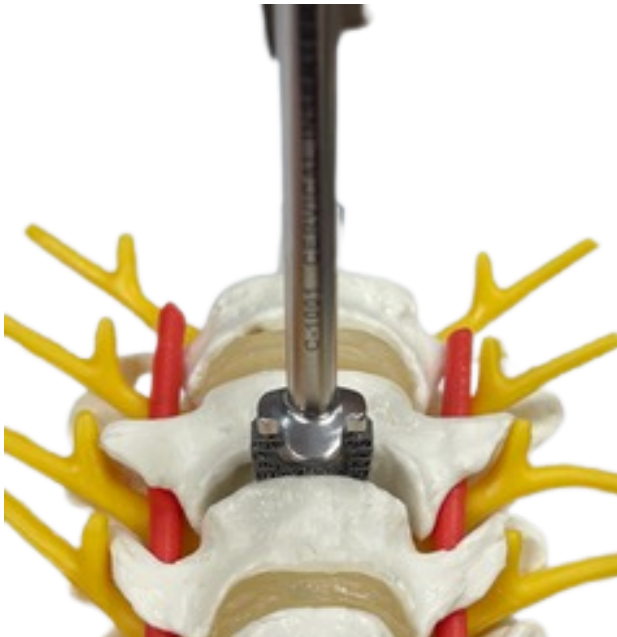


Figure 11



Figure 12



Figure 13

Step 8 : Implant Position

The implant tamp may be used to adjust the position of the implant if needed.

Figure 14



Figure 14

Step 9 : Final Implant Positioning

Obtain AP & Lateral X-rays to verify implant position.

Figure 15, 16



Figure 15

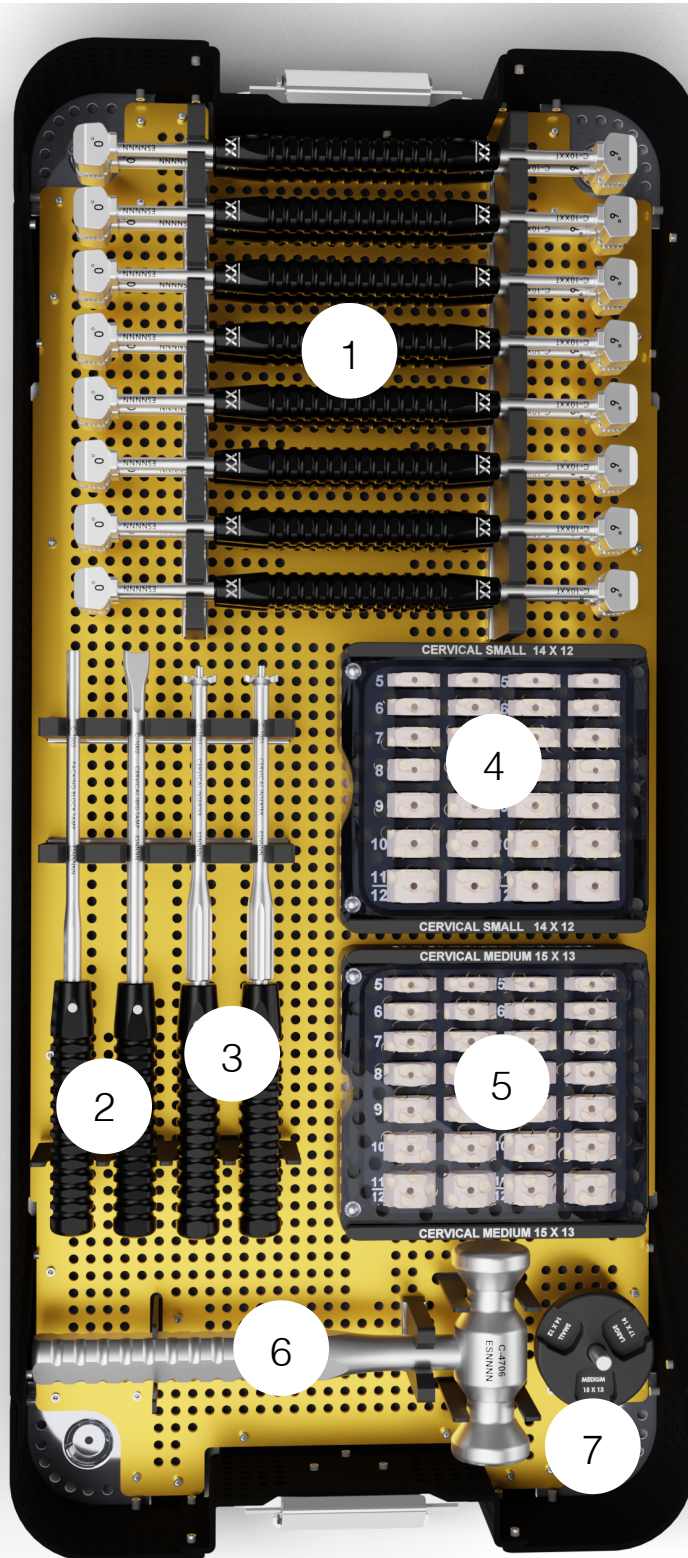


Figure 16

Step 10 : Implant Removal

Turn the inserter shaft clockwise to engage the implant, then pull up and remove the implant.

Cervical IBFD Tray Layout



1. Trial & Rasp Sizers
2. Tamps
3. Inserters
4. Small Implant Caddy
5. Medium Implant Caddy
6. Mallet
7. Graft Packing Block

Available in Peek, Titanium & 3D Printed Titanium

C4105	Cervical PEEK IBFD, 14mm x 12mm, Small, Neutral, 5mm
C4106	Cervical PEEK IBFD, 14mm x 12mm, Small, Neutral, 6mm
C4107	Cervical PEEK IBFD, 14mm x 12mm, Small, Neutral, 7mm
C4108	Cervical PEEK IBFD, 14mm x 12mm, Small, Neutral, 8mm
C4109	Cervical PEEK IBFD, 14mm x 12mm, Small, Neutral, 9mm
C4110	Cervical PEEK IBFD, 14mm x 12mm, Small, Neutral, 10mm
C4111	Cervical PEEK IBFD, 14mm x 12mm, Small, Neutral, 11mm
C4112	Cervical PEEK IBFD, 14mm x 12mm, Small, Neutral, 12mm

C4005	Cervical PEEK IBFD, 14mm x 12mm, Small, 6°, 5mm
C4006	Cervical PEEK IBFD, 14mm x 12mm, Small, 6°, 6mm
C4007	Cervical PEEK IBFD, 14mm x 12mm, Small, 6°, 7mm
C4008	Cervical PEEK IBFD, 14mm x 12mm, Small, 6°, 8mm
C4009	Cervical PEEK IBFD, 14mm x 12mm, Small, 6°, 9mm
C4010	Cervical PEEK IBFD, 14mm x 12mm, Small, 6°, 10mm
C4011	Cervical PEEK IBFD, 14mm x 12mm, Small, 6°, 11mm
C4012	Cervical PEEK IBFD, 14mm x 12mm, Small, 6°, 12mm

C3105	Cervical PEEK IBFD, 15mm x 13mm, Medium, Neutral, 5mm
C3106	Cervical PEEK IBFD, 15mm x 13mm, Medium, Neutral, 6mm
C3107	Cervical PEEK IBFD, 15mm x 13mm, Medium, Neutral, 7mm
C3108	Cervical PEEK IBFD, 15mm x 13mm, Medium, Neutral, 8mm
C3109	Cervical PEEK IBFD, 15mm x 13mm, Medium, Neutral, 9mm
C3110	Cervical PEEK IBFD, 15mm x 13mm, Medium, Neutral, 10mm
C3111	Cervical PEEK IBFD, 15mm x 13mm, Medium, Neutral, 11mm
C3112	Cervical PEEK IBFD, 15mm x 13mm, Medium, Neutral, 12mm

C3005	Cervical PEEK IBFD, 15mm x 13mm, Medium, 6°, 5mm
C3006	Cervical PEEK IBFD, 15mm x 13mm, Medium, 6°, 6mm
C3007	Cervical PEEK IBFD, 15mm x 13mm, Medium, 6°, 7mm
C3008	Cervical PEEK IBFD, 15mm x 13mm, Medium, 6°, 8mm
C3009	Cervical PEEK IBFD, 15mm x 13mm, Medium, 6°, 9mm
C3010	Cervical PEEK IBFD, 15mm x 13mm, Medium, 6°, 10mm
C3011	Cervical PEEK IBFD, 15mm x 13mm, Medium, 6°, 11mm
C3012	Cervical PEEK IBFD, 15mm x 13mm, Medium, 6°, 12mm

Available in Peek, Titanium & 3D Printed Titanium

C5105	Cervical PEEK IBFD, 17mm x 14mm, Large, Neutral, 5mm
C5106	Cervical PEEK IBFD, 17mm x 14mm, Large, Neutral, 6mm
C5107	Cervical PEEK IBFD, 17mm x 14mm, Large, Neutral, 7mm
C5108	Cervical PEEK IBFD, 17mm x 14mm, Large, Neutral, 8mm
C5109	Cervical PEEK IBFD, 17mm x 14mm, Large, Neutral, 9mm
C5110	Cervical PEEK IBFD, 17mm x 14mm, Large, Neutral, 10mm
C5111	Cervical PEEK IBFD, 17mm x 14mm, Large, Neutral, 11mm
C5112	Cervical PEEK IBFD, 17mm x 14mm, Large, Neutral, 12mm

C5005	Cervical PEEK IBFD, 17mm x 14mm, Large, 6°, 5mm
C5006	Cervical PEEK IBFD, 17mm x 14mm, Large, 6°, 6mm
C5007	Cervical PEEK IBFD, 17mm x 14mm, Large, 6°, 7mm
C5008	Cervical PEEK IBFD, 17mm x 14mm, Large, 6°, 8mm
C5009	Cervical PEEK IBFD, 17mm x 14mm, Large, 6°, 9mm
C5010	Cervical PEEK IBFD, 17mm x 14mm, Large, 6°, 10mm
C5011	Cervical PEEK IBFD, 17mm x 14mm, Large, 6°, 11mm
C5012	Cervical PEEK IBFD, 17mm x 14mm, Large, 6°, 12mm

C6105	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, Neutral, 5mm
C6106	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, Neutral, 6mm
C6107	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, Neutral, 7mm
C6108	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, Neutral, 8mm
C6109	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, Neutral, 9mm
C6110	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, Neutral, 10mm
C6111	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, Neutral, 11mm
C6112	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, Neutral, 12mm

C6005	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, 6°, 5mm
C6006	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, 6°, 6mm
C6007	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, 6°, 7mm
C6008	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, 6°, 8mm
C6009	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, 6°, 9mm
C6010	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, 6°, 10mm
C6011	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, 6°, 11mm
C6012	Cervical PEEK IBFD, 17mm x 12mm, X-Wide, 6°, 12mm

Available in Peek, Titanium & 3D Printed Titanium

C7105	Cervical PEEK IBFD, 19mm x 16mm, X-Large, Neutral, 5mm
C7106	Cervical PEEK IBFD, 19mm x 16mm, X-Large, Neutral, 6mm
C7107	Cervical PEEK IBFD, 19mm x 16mm, X-Large, Neutral, 7mm
C7108	Cervical PEEK IBFD, 19mm x 16mm, X-Large, Neutral, 8mm
C7109	Cervical PEEK IBFD, 19mm x 16mm, X-Large, Neutral, 9mm
C7110	Cervical PEEK IBFD, 19mm x 16mm, X-Large, Neutral, 10mm
C7111	Cervical PEEK IBFD, 19mm x 16mm, X-Large, Neutral, 11mm
C7112	Cervical PEEK IBFD, 19mm x 16mm, X-Large, Neutral, 12mm

C7005	Cervical PEEK IBFD, 19mm x 16mm, X-Large, 6°, 5mm
C7006	Cervical PEEK IBFD, 19mm x 16mm, X-Large, 6°, 6mm
C7007	Cervical PEEK IBFD, 19mm x 16mm, X-Large, 6°, 7mm
C7008	Cervical PEEK IBFD, 19mm x 16mm, X-Large, 6°, 8mm
C7009	Cervical PEEK IBFD, 19mm x 16mm, X-Large, 6°, 9mm
C7010	Cervical PEEK IBFD, 19mm x 16mm, X-Large, 6°, 10mm
C7011	Cervical PEEK IBFD, 19mm x 16mm, X-Large, 6°, 11mm
C7012	Cervical PEEK IBFD, 19mm x 16mm, X-Large, 6°, 12mm

C4605	Cervical Titanium IBFD, 14mm x 12mm, Small, Neutral, 5mm
C4606	Cervical Titanium IBFD, 14mm x 12mm, Small, Neutral, 6mm
C4607	Cervical Titanium IBFD, 14mm x 12mm, Small, Neutral, 7mm
C4608	Cervical Titanium IBFD, 14mm x 12mm, Small, Neutral, 8mm
C4609	Cervical Titanium IBFD, 14mm x 12mm, Small, Neutral, 9mm
C4610	Cervical Titanium IBFD, 14mm x 12mm, Small, Neutral, 10mm
C4611	Cervical Titanium IBFD, 14mm x 12mm, Small, Neutral, 11mm
C4612	Cervical Titanium IBFD, 14mm x 12mm, Small, Neutral, 12mm

C4505	Cervical Titanium IBFD, 14mm x 12mm, Small, 6°, 5mm
C4506	Cervical Titanium IBFD, 14mm x 12mm, Small, 6°, 6mm
C4507	Cervical Titanium IBFD, 14mm x 12mm, Small, 6°, 7mm
C4508	Cervical Titanium IBFD, 14mm x 12mm, Small, 6°, 8mm
C4509	Cervical Titanium IBFD, 14mm x 12mm, Small, 6°, 9mm
C4510	Cervical Titanium IBFD, 14mm x 12mm, Small, 6°, 10mm
C4511	Cervical Titanium IBFD, 14mm x 12mm, Small, 6°, 11mm
C4512	Cervical Titanium IBFD, 14mm x 12mm, Small, 6°, 12mm

Available in Peek, Titanium & 3D Printed Titanium

C3605	Cervical Titanium IBFD, 15mm x 13mm, Medium, Neutral, 5mm
C3606	Cervical Titanium IBFD, 15mm x 13mm, Medium, Neutral, 6mm
C3607	Cervical Titanium IBFD, 15mm x 13mm, Medium, Neutral, 7mm
C3608	Cervical Titanium IBFD, 15mm x 13mm, Medium, Neutral, 8mm
C3609	Cervical Titanium IBFD, 15mm x 13mm, Medium, Neutral, 9mm
C3610	Cervical Titanium IBFD, 15mm x 13mm, Medium, Neutral, 10mm
C3611	Cervical Titanium IBFD, 15mm x 13mm, Medium, Neutral, 11mm
C3612	Cervical Titanium IBFD, 15mm x 13mm, Medium, Neutral, 12mm
C3505	Cervical Titanium IBFD, 15mm x 13mm, Medium, 6°, 5mm
C3506	Cervical Titanium IBFD, 15mm x 13mm, Medium, 6°, 6mm
C3507	Cervical Titanium IBFD, 15mm x 13mm, Medium, 6°, 7mm
C3508	Cervical Titanium IBFD, 15mm x 13mm, Medium, 6°, 8mm
C3509	Cervical Titanium IBFD, 15mm x 13mm, Medium, 6°, 9mm
C3510	Cervical Titanium IBFD, 15mm x 13mm, Medium, 6°, 10mm
C3511	Cervical Titanium IBFD, 15mm x 13mm, Medium, 6°, 11mm
C3512	Cervical Titanium IBFD, 15mm x 13mm, Medium, 6°, 12mm
C5605	Cervical Titanium IBFD, 17mm x 14mm, Large, Neutral, 5mm
C5606	Cervical Titanium IBFD, 17mm x 14mm, Large, Neutral, 6mm
C5607	Cervical Titanium IBFD, 17mm x 14mm, Large, Neutral, 7mm
C5608	Cervical Titanium IBFD, 17mm x 14mm, Large, Neutral, 8mm
C5609	Cervical Titanium IBFD, 17mm x 14mm, Large, Neutral, 9mm
C5610	Cervical Titanium IBFD, 17mm x 14mm, Large, Neutral, 10mm
C5611	Cervical Titanium IBFD, 17mm x 14mm, Large, Neutral, 11mm
C5612	Cervical Titanium IBFD, 17mm x 14mm, Large, Neutral, 12mm
C5505	Cervical Titanium IBFD, 17mm x 14mm, Large, 6°, 5mm
C5506	Cervical Titanium IBFD, 17mm x 14mm, Large, 6°, 6mm
C5507	Cervical Titanium IBFD, 17mm x 14mm, Large, 6°, 7mm
C5508	Cervical Titanium IBFD, 17mm x 14mm, Large, 6°, 8mm
C5509	Cervical Titanium IBFD, 17mm x 14mm, Large, 6°, 9mm
C5510	Cervical Titanium IBFD, 17mm x 14mm, Large, 6°, 10mm
C5511	Cervical Titanium IBFD, 17mm x 14mm, Large, 6°, 11mm
C5512	Cervical Titanium IBFD, 17mm x 14mm, Large, 6°, 12mm

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C6605	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 5mm
C6606	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 6mm
C6607	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 7mm
C6608	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 8mm
C6609	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 9mm
C6610	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 10mm
C6611	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 11mm
C6612	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 12mm

C6505	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 5mm
C6506	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 6mm
C6507	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 7mm
C6508	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 8mm
C6509	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 9mm
C6510	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 10mm
C6511	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 11mm
C6512	Cervical Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 12mm

C7605	Cervical Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 5mm
C7606	Cervical Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 6mm
C7607	Cervical Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 7mm
C7608	Cervical Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 8mm
C7609	Cervical Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 9mm
C7610	Cervical Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 10mm
C7611	Cervical Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 11mm
C7612	Cervical Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 12mm

C7505	Cervical Titanium IBFD, 19mm x 16mm, X-Large, 6°, 5mm
C7506	Cervical Titanium IBFD, 19mm x 16mm, X-Large, 6°, 6mm
C7507	Cervical Titanium IBFD, 19mm x 16mm, X-Large, 6°, 7mm
C7508	Cervical Titanium IBFD, 19mm x 16mm, X-Large, 6°, 8mm
C7509	Cervical Titanium IBFD, 19mm x 16mm, X-Large, 6°, 9mm
C7510	Cervical Titanium IBFD, 19mm x 16mm, X-Large, 6°, 10mm
C7511	Cervical Titanium IBFD, 19mm x 16mm, X-Large, 6°, 11mm
C7512	Cervical Titanium IBFD, 19mm x 16mm, X-Large, 6°, 12mm

Available in Peek, Titanium & 3D Printed Titanium

C3141205	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, Neutral, 5mm
C3141206	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, Neutral, 6mm
C3141207	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, Neutral, 7mm
C3141208	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, Neutral, 8mm
C3141209	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, Neutral, 9mm
C3141210	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, Neutral, 10mm
C3141211	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, Neutral, 11mm
C3141212	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, Neutral, 12mm

C3L141205	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, 6°, 5mm
C3L141206	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, 6°, 6mm
C3L141207	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, 6°, 7mm
C3L141208	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, 6°, 8mm
C3L141209	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, 6°, 9mm
C3L141210	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, 6°, 10mm
C3L141211	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, 6°, 11mm
C3L141212	Cervical 3D Titanium IBFD, 14mm x 12mm, Small, 6°, 12mm

C3151305	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, Neutral, 5mm
C3151306	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, Neutral, 6mm
C3151307	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, Neutral, 7mm
C3151308	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, Neutral, 8mm
C3151309	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, Neutral, 9mm
C3151310	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, Neutral, 10mm
C3151311	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, Neutral, 11mm
C3151312	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, Neutral, 12mm

C3L151305	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, 6°, 5mm
C3L151306	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, 6°, 6mm
C3L151307	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, 6°, 7mm
C3L151308	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, 6°, 8mm
C3L151309	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, 6°, 9mm
C3L151310	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, 6°, 10mm
C3L151311	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, 6°, 11mm
C3L151312	Cervical 3D Titanium IBFD, 15mm x 13mm, Medium, 6°, 12mm

Available in Peek, Titanium & 3D Printed Titanium

C3171405	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, Neutral, 5mm
C3171406	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, Neutral, 6mm
C3171407	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, Neutral, 7mm
C3171408	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, Neutral, 8mm
C3171409	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, Neutral, 9mm
C3171410	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, Neutral, 10mm
C3171411	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, Neutral, 11mm
C3171412	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, Neutral, 12mm

C3L171405	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, 6°, 5mm
C3L171406	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, 6°, 6mm
C3L171407	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, 6°, 7mm
C3L171408	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, 6°, 8mm
C3L171409	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, 6°, 9mm
C3L171410	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, 6°, 10mm
C3L171411	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, 6°, 11mm
C3L171412	Cervical 3D Titanium IBFD, 17mm x 14mm, Large, 6°, 12mm

C3171305	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 5mm
C3171306	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 6mm
C3171307	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 7mm
C3171308	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 8mm
C3171309	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 9mm
C3171310	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 10mm
C3171311	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 11mm
C3171312	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, Neutral, 12mm

C3L171305	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 5mm
C3L171306	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 6mm
C3L171307	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 7mm
C3L171308	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 8mm
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C3L171310	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 10mm
C3L171311	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 11mm
C3L171312	Cervical 3D Titanium IBFD, 17mm x 12mm, X-Wide, 6°, 12mm

Available in Peek, Titanium & 3D Printed Titanium

C3191605	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 5mm
C3191606	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 6mm
C3191607	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 7mm
C3191608	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 8mm
C3191609	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 9mm
C3191610	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 10mm
C3191611	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 11mm
C3191612	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, Neutral, 12mm

C3L191605	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, 6°, 5mm
C3L191606	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, 6°, 6mm
C3L191607	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, 6°, 7mm
C3L191608	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, 6°, 8mm
C3L191609	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, 6°, 9mm
C3L191610	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, 6°, 10mm
C3L191611	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, 6°, 11mm
C3L191612	Cervical 3D Titanium IBFD, 19mm x 16mm, X-Large, 6°, 12mm

Eminent Spine LLC Cervical Interbody Fusion System:



Eminent Spine LLC
2004 Ventura Drive STE 100
Plano, TX 75093

System Contents:



Non-Sterile Implants – Single Use Only
Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION and INTENDED USE:

The Cervical device is a rectangular shaped implant, which is available in a parallel or lordotic configuration of various heights. It is hollow to allow for the placement of allograft or autograft bone. There are teeth on the superior and inferior surface of the device to provide increased stability and inhibit movement of the implant.

INDICATIONS:

When used as an intervertebral body fusion device, the implant is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. When used as a vertebral body replacement device, the device is indicated to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma / fracture. It is intended to be used with autograft or allograft bone.

CONTRAINDICATIONS:

1. Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to PEEK or Titanium alloy 6Al-4V material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be noncompliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:

Cervical implants are manufactured from either PEEK (Optima LT1 or VESTAKEEP i4R) with Tantalum pins or entirely of Titanium alloy 6Al-4V with no pins. Surgical instruments provided with the implants are manufactured from stainless steel.

CLEANING of INSTRUMENTS and IMPLANTS:

1. Clean all instruments and implants prior to use, and as soon as possible after use. Do not allow blood or debris to dry on the instruments that were used in surgery. If cleaning must be delayed, place instruments that were used in surgery in a covered container with neutral pH detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts. Remove implants (in caddies) from set cases.
3. Immerse the instruments and implants in a neutral pH detergent or enzymatic solution prepared in accordance with the manufacturer's instructions and soak for 15 minutes.
4. Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard-to-clean areas) until all visible soil has been removed.
5. Rinse the instruments and implants in running water for at least 3 minutes. Thoroughly flush cannulations, holes, and other hard-to-clean areas.
6. After manual cleaning has been completed, load the parts into a suitable automated cleaner and follow the manufacturer's recommended practices. Use only neutral pH enzymatic cleaners and detergents. Avoid excessively acidic or alkaline solutions.

INSPECTION:

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Eminent Spine® representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Eminent Spine® representative for a replacement.

STERILIZATION:

All implants and instruments are supplied visually clean and nonsterile and must be sterilized prior to use. The following sterilization cycle has been validated:

Method: Steam

Cycle: Pre-Vacuum

Temperature: 270°F (132°C)

Exposure Time: 4 minutes

Number of pulses: 4

Dry time: 30 minutes

Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Cases (including instruments and implants) used in surgery should be cleaned and re-sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it should be cleaned and re-sterilized after surgery.

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: A42013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: A42013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

- For terminally sterilized devices, only FDA-cleared sterilization barriers (e.g., wraps, pouches, containers) should be used for packaging

POSTOPERATIVE MOBILIZATION:

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS:

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. **PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
 - a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
 - b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
 - c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.
 - d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
 - e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
 - f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS:

1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body else the risk of subsidence may increase.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be reimplanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.
6. MAGNETIC RESONANCE ENVIRONMENT. The Eminent Spine® Cervical Implant has not been evaluated for safety and compatibility in the MR environment. The implant has not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS:

1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.

8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
10. Paralysis.
11. Death.
12. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:

Eminent Spine LLC products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Eminent Spine LLC for current information.



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For product information or questions pertaining to sales and service, please contact your local sales representative or Eminent Spine LLC customer service.

Eminent Spine LLC 2021

Cervical IBFD System

Notes

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16