Fortilink®-C

IBF System
with **Tetrafuse® 3D** Technology

SURGICAL TECHNIQUE

DESCRIPTION

The Fortilink® interbody fusion (IBF) devices are designed to be inserted into the intervertebral body space of the spine and are intended for intervertebral body fusion. These implants are manufactured from a radiolucent polymer (PolyEtherKetoneKetone (PEKK)) (ASTM F2820) which should support radiographic imaging inside the implant to evaluate fusion status and are assembled with radiographic markers composed of tantalum (ASTM F560) to facilitate proper implant position. The implant is provided sterile by gamma irradiation and is intended to be used with supplemental fixation cleared for the implanted level. The implant is supplied with instrumentation necessary to facilitate the insertion and removal of the implant, as well as general manual surgical instruments.

The implant is provided in different footprints and varying heights to provide implant options best suited to an individual's pathology and anatomical condition.

INDICATIONS FOR USE:

When Fortilink-C is used as cervical interbody fusion (IBF) implants, these devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the cervical spine and are placed via an anterior approach from C2-C3 to C7-T1 using autogenous bone graft and/ or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The IBF devices are intended to be used with supplemental fixation cleared for the implanted level.

Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an interbody fusion device.

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INTRODUCTION

System Overview

The Fortilink®-C IBF System includes designs intended for use as cervical IBFs from C2-C3 disc space to C7-T1 disc space.

- Webless graft window incorporates 3D-printed TETRAfuse pattern to aid in bone-implant osseointegration
- Three radiographic markers facilitate visual confirmation of anterior/posterior (A/P) position and lateral edges of implant
- Made with TETRAfuse 3D Technology
- Intended to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft
- For use in one (1) or two (2) contiguous levels as an IBF device

Built-In Lordosis of 6° may allow for anatomic restoration of patient's curvature

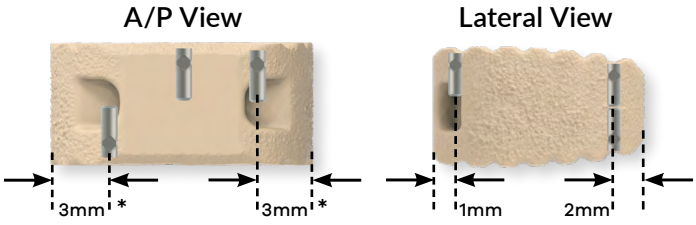
Convex Inferior and Superior Surfaces optimizes anatomic fit/apposition of the implant with the concave endplates

Anti-migration Teeth resist implant migration

Multiple Footprints allow for optimized sizing to the patient

Webless Implant offers ease of placement and continuity of bone graft material

Pin Locations & Configurations



Note: *14.5 x 17mm footprint pins are 4mm from lateral walls.*

SURGICAL TECHNIQUE

Step 1: Surgical Exposure

- Access the operative site and retract the tissues using appropriate instrumentation. Retract the trachea, esophagus, and coronary artery in order to clearly see the vertebral bodies and discs.

Step 2: Level Confirmation

- Insert a marker into the disc(s) and confirm the correct operative level(s) utilizing a lateral radiograph.

Step 3: Discectomy and Endplate Preparation

- Perform a complete discectomy using appropriate instrumentation. A ring curette and rasp are included in the instrument set for endplate preparation. Remove the posterior longitudinal ligament to access and remove any disc material that is pressing on the spinal cord and/or nerve roots. Remove any osteophytes that are contacting the neural elements. Remove the cartilaginous endplates to achieve exposure to the subchondral bone.

Step 4: Implant Selection with Trial Spacers

- Trial spacers are available for all corresponding implant footprints to provide guidance prior to graft selection (Figure 2A). Select the trial spacer size that adequately fills the disc space and provides restoration of disc height. The trial spacer should require minimal force to insert, yet fit snugly within the disc space.

  Using the trial spacer as a guide, verify that appropriate height restoration is achieved with direct visualization and lateral fluoroscopy. Select the implant size that matches the chosen trial spacer. All implants have a built-in 6-degree lordosis. Using an implant larger than the size trialed could lead to implant failure.

Figure 2A
Trial Spacers

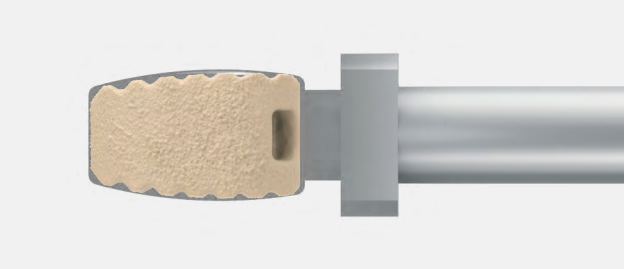


Figure 2B
Trial spacer height is line-to-line compared to implant

Step 5: Implant Insertion

- Pack the implant with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Make sure to fill the entire graft cavity.

  Two inserter forks are provided, one for the 10 x 12mm footprint and one for the 12 x 14mm and 14.5 x 17mm footprints. Select the appropriate inserter fork and attach to inserter housing. While threading, ensure the tabs on the fork align with slots in the inserter housing (Figure 3). Slide the fork into the housing base and then thread the housing handle onto the threads of the fork.

  Do not tighten completely to allow for implant attachment.

  Attach the inserter to the implant by aligning the tabs of the inserter with the slots of the implant (Figure 4A). Tighten the inserter by turning the back of the inserter handle clockwise (Figure 4B).

  Align the implant with the prepared disc space and gently tap the inserter until the implant is seated in the desired location. Confirm implant position with A/P and lateral radiographs.

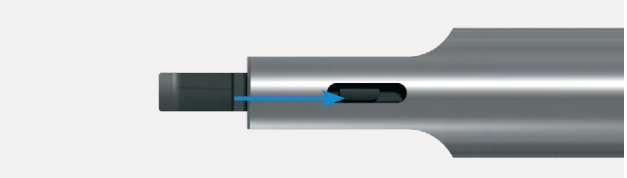


Figure 3

Figure 4A

Figure 4B

Note: *A tamp is provided if adjusting the implant position is desired. When using the tamp, ensure the posts on the tamp face align with the inserter slots on the implant.*

Warning: *For implant insertion, use only the instruments provided. Using other instruments to insert the implant could result in implant damage.*

Step 6: Radiographic Verification

- Prior to removing retractors and closing the incision, utilize a radiograph to verify proper placement and sizing of the implant.

  Verify the final interbody implant placement with A/P and lateral x-ray images. Figures 5A and 5B show marker pin location as seen on A/P x-ray images while Figures 5C and 5D show marker pin location on lateral x-ray images.

  Note: *Marker pin location will vary on A/P and lateral views depending whether anterior pin orientation is cephalad (left) or caudal (right).*

Anterior Pin Cephalad

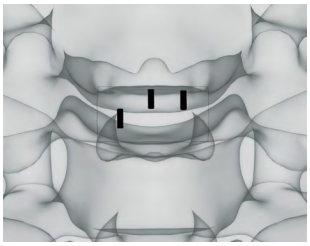


Figure 5A

Anterior Pin Caudal

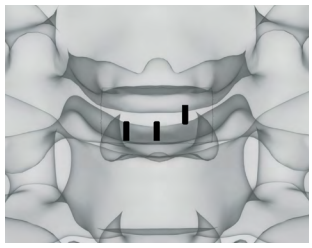


Figure 5B
A/P Views

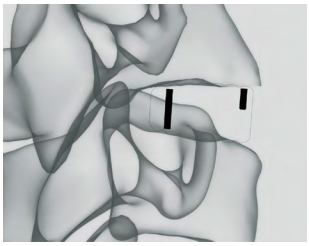


Figure 5C

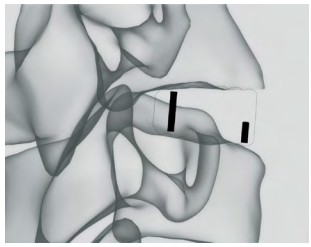


Figure 5D
Lateral Views

Removal (If Necessary)

- If removal of the implant is necessary, a caspar style retractor (or similar device) should be used to distract the disc space.

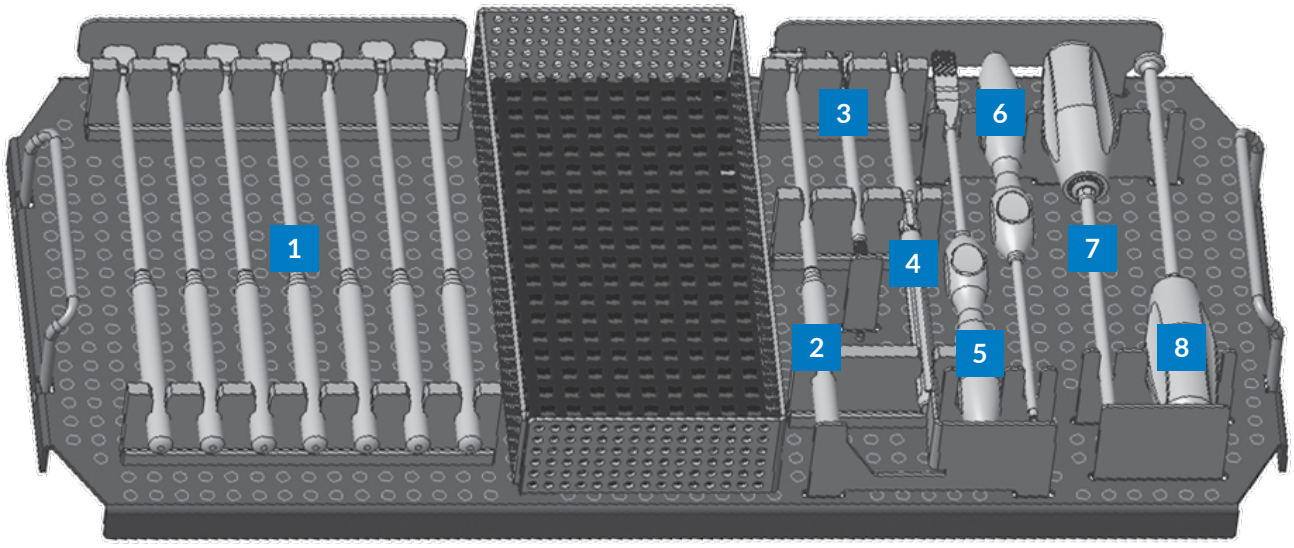
  Once the disc space is distracted, attach the appropriately sized inserter to the implant by placing the forks of the inserter into the slots of the implant. Tighten the inserter by turning the handle clockwise until snug.

  Remove the implant from the disc space.

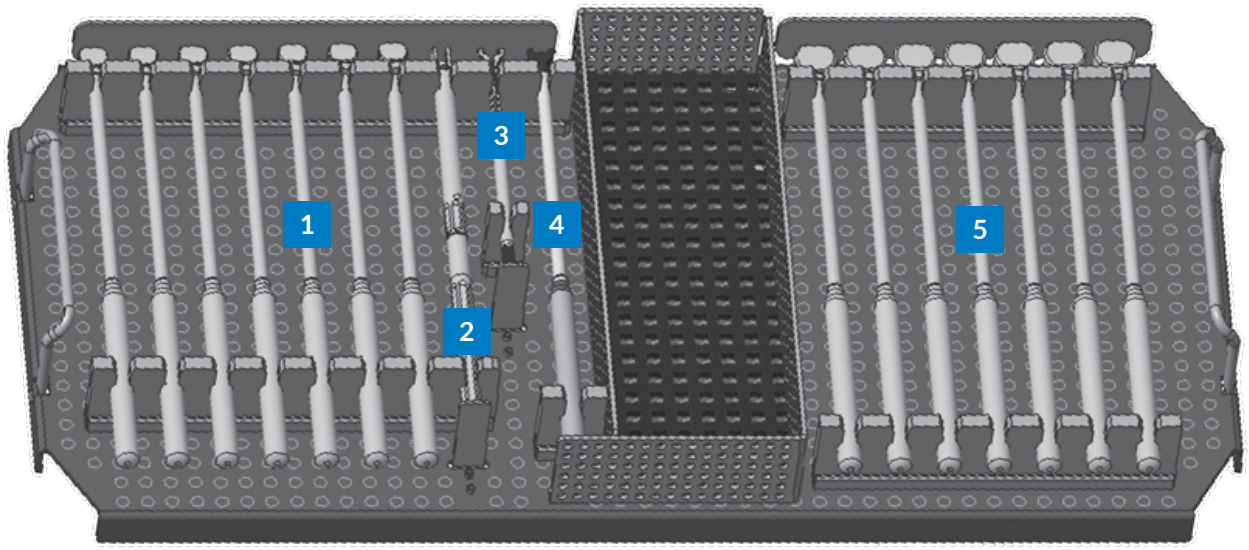
ORDERING GUIDE

Part Number	Instrument	Description	
30-C-RASP	Rasp	For endplate preparation	
30-C-RCURETTE	Ring Currette	For endplate preparation	
30-C-TRL1012-X	10 x 12mm Trial Spacers	For providing guidance for implant footprint and height selection X = 5 - 11mm height	
30-C-TRL1214-X	12 x 14mm Trial Spacers	For providing guidance for implant footprint and height selection X = 5 - 11mm height	
30-C-TRL1517-X	14.5 x 17mm Trial Spacers	For providing guidance for implant footprint and height selection X = 5 - 11mm height	
65-C-TAMP-SM	Fortilink-C 10 x 12mm Tamp	Used to make minor adjustments to 10 x 12mm implant position	
65-C-TAMP-LG	Fortilink-C 12 x 14mm and 14.5 x 17mm Tamp	Used to make minor adjustments to 12 x 14mm and 14.5 x 17mm implant position	
65-C-INSERTER	Fortilink-C Inserter Housing	In conjunction with Inserter Fork, only used to implant Fortilink-C interbody devices	
65-C-FORK-SM	Fortilink-C Inserter Fork, Small	In conjunction with Inserter Housing, only used to implant Fortilink-C interbody devices	
65-C-FORK-LG	Fortilink-C Inserter Fork, Large	In conjunction with Inserter Housing, only used to implant Fortilink-C interbody devices	
30-C-INSERTER	C-Plus™ Inserter	Only used to implant C-Plus interbody devices	
30-C-INSERTER-S	C-Plus Inserter with Stop	Only used to implant C-Plus interbody devices	

Top Tray Layout					
1	Trial Spacers, 12 x 14mm	4	Fortilink-C Inserter Housing	7	C-Plus Inserter
2	Fortilink-C 12 x 14mm & 14.5 x 17mm Tamp	5	Rasp	8	C-Plus Inserter w/ Stop
3	Fortilink-C Inserter Fork, Large	6	Ring Curette		



Bottom Tray Layout					
1	Trial Spacers, 10 x 12mm	3	Fortilink-C Inserter Fork, Small	5	Trial Spacers, 14.5 x 17mm
2	Fortilink-C Inserter Housing	4	Fortilink-C 10 x 12mm Tamp		



Instrument Set (65-LS-CERVICAL-INS)

Part Number	Description	Qty
65-C-TAMP-SM	Fortilink-C 10 x 12mm Tamp	1
65-C-TAMP-LG	Fortilink-C 12 x 14mm & 14.5 x 17mm Tamp	1
65-C-INSERTER	Fortilink-C Inserter Housing	2
65-C-FORK-SM	Fortilink-C Inserter Fork, Small	1
65-C-FORK-LG	Fortilink-C Inserter Fork, Large	1
30-C-INSERTER	C-Plus Inserter	1
30-C-INSERTER-S	C-Plus Inserter With Stop	1
30-C-RASP	Rasp	1
30-C-RCURETTE	Ring Curette	1
30-C-TRL1012-5	Trial Spacer, 10 x 12 x 5mm	1
30-C-TRL1012-6	Trial Spacer, 10 x 12 x 6mm	1
30-C-TRL1012-7	Trial Spacer, 10 x 12 x 7mm	1
30-C-TRL1012-8	Trial Spacer, 10 x 12 x 8mm	1
30-C-TRL1012-9	Trial Spacer, 10 x 12 x 9mm	1
30-C-TRL1012-10	Trial Spacer, 10 x 12 x 10mm	1
30-C-TRL1012-11	Trial Spacer, 10 x 12 x 11mm	1
30-C-TRL1214-5	Trial Spacer, 12 x 14 x 5mm	1
30-C-TRL1214-6	Trial Spacer, 12 x 14 x 6mm	1
30-C-TRL1214-7	Trial Spacer, 12 x 14 x 7mm	1
30-C-TRL1214-8	Trial Spacer, 12 x 14 x 8mm	1
30-C-TRL1214-9	Trial Spacer, 12 x 14 x 9mm	1
30-C-TRL1214-10	Trial Spacer, 12 x 14 x 10mm	1
30-C-TRL1214-11	Trial Spacer, 12 x 14 x 11mm	1
30-C-TRL1517-5	Trial Spacer, 14.5 x 17 x 5mm	1
30-C-TRL1517-6	Trial Spacer, 14.5 x 17 x 6mm	1
30-C-TRL1517-7	Trial Spacer, 14.5 x 17 x 7mm	1
30-C-TRL1517-8	Trial Spacer, 14.5 x 17 x 8mm	1
30-C-TRL1517-9	Trial Spacer, 14.5 x 17 x 9mm	1
30-C-TRL1517-10	Trial Spacer, 14.5 x 17 x 10mm	1
30-C-TRL1517-11	Trial Spacer, 14.5 x 17 x 11mm	1

Standard Implant Loaner Set (65-LS-CERVICAL-IMP)

Part Number	Width	Depth	Height	Graft Vol.*
65-C-1012-5-6L	12mm	10mm	5mm	0.15cc
65-C-1214-5-6L	14mm	12mm	5mm	0.20cc
65-C-1517-5-6L	17mm	14.5mm	5mm	0.32cc
65-C-1012-6-6L	12mm	10mm	6mm	0.18cc
65-C-1214-6-6L	14mm	12mm	6mm	0.24cc
65-C-1517-6-6L	17mm	14.5mm	6mm	0.39cc
65-C-1012-7-6L	12mm	10mm	7mm	0.22cc
65-C-1214-7-6L	14mm	12mm	7mm	0.28cc
65-C-1517-7-6L	17mm	14.5mm	7mm	0.47cc
65-C-1012-8-6L	12mm	10mm	8mm	0.25cc
65-C-1214-8-6L	14mm	12mm	8mm	0.32cc
65-C-1517-8-6L	17mm	14.5mm	8mm	0.55cc
65-C-1012-9-6L	12mm	10mm	9mm	0.28cc
65-C-1214-9-6L	14mm	12mm	9mm	0.36cc
65-C-1517-9-6L	17mm	14.5mm	9mm	0.62cc
65-C-1012-10-6L	12mm	10mm	10mm	0.31cc
65-C-1214-10-6L	14mm	12mm	10mm	0.40cc
65-C-1517-10-6L	17mm	14.5mm	10mm	0.70cc
65-C-1012-11-6L	12mm	10mm	11mm	0.35cc
65-C-1214-11-6L	14mm	12mm	11mm	0.45cc
65-C-1517-11-6L	17mm	14.5mm	11mm	0.77cc

**Graft volumes are approximate.*

CLEANING & STERILIZATION

Implants are provided sterile.

Reusable instruments are provided non-sterile.

For specific cleaning and sterilization instructions, refer to the instructions for use provided with the device or contact Xtant Medical Customer Service. See back page for contact information.

Fortilink®-C Inserter Disassembly

The Fortilink-C inserter (65-C-INSERTER) should be disassembled for cleaning.

1. To disassemble, unscrew the fork from the housing by rotating the back of the housing counterclockwise until you feel a stop (Figure 6).
2. Squeeze the tips of the forks together and continue to rotate the back of the housing counterclockwise until the forks can be removed from the housing (Figure 7).

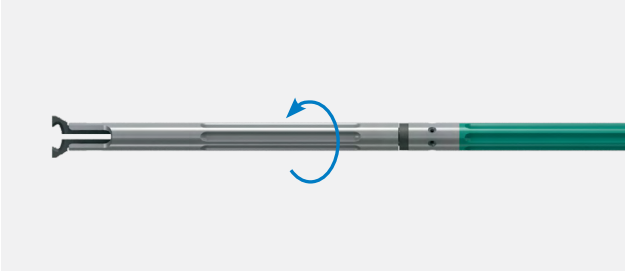


Figure 6

Figure 7

INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

LIMITED WARRANTY and DISCLAIMER: Xtant Medical products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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