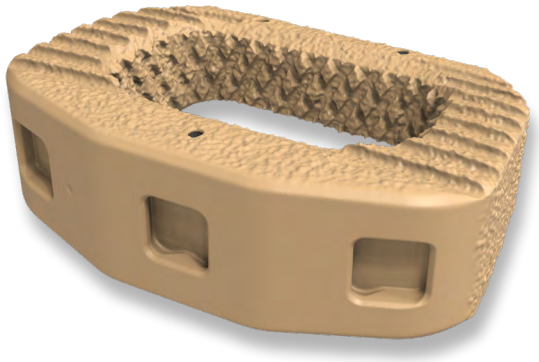
Fortilink®-A

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. K192718

INDICATIONS FOR USE:

When the Fortilink-A is used as a lumbar interbody fusion (IBF) implant, it is indicated for intervertebral body fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This IBF device is used to facilitate interbody fusion in the lumbar spine from L1-L2 to L5-S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF device is intended to be used with supplemental fixation cleared for the implanted level. Patients should have at least six (6) months of non-operative treatment prior to treatment with an interbody fusion device. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

INTRODUCTION

SURGICAL TECHNIQUE

ORDERING GUIDE

This document is intended exclusively for experts in the field, particularly physicians, and is not intended for laypersons.

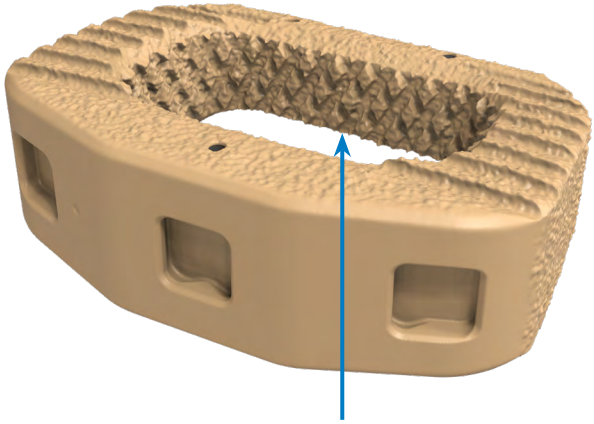
Information on the products and procedures contained in this document is general in nature and does not represent medical advice or recommendations. As with any technical guide, this information does not constitute any diagnostic or therapeutic statement with regard to a given medical case. An evaluation, examination, and advising of the patient are absolutely necessary for the physician to determine the specific requirements of the patient, and any appropriate adjustments needed, and the foregoing are not to be replaced by this document in whole or in part.

Information contained in this document was gathered and compiled by experts in the field and company employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. The company does not assume any liability, however, for the accuracy and/or completeness of the quality of the information, and is not liable for any losses whatsoever of any kind or any nature that may be caused by the use and/or reliance of said information.

INTRODUCTION

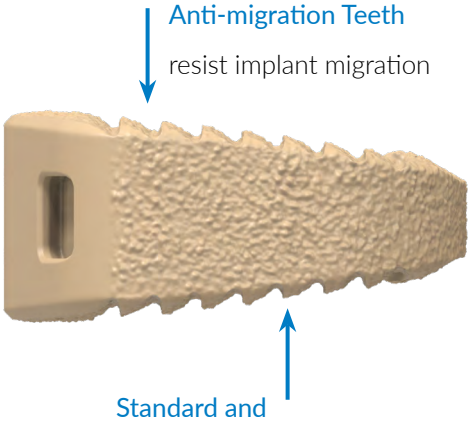
System Overview

- Made with 3D printed Tetrafuse® 3D Technology
- Designed for a direct anterior or anterolateral approach
- 20° and 30° hyperlordotic sizing available
- Implants available in 3 footprints (small, medium, large) in 2mm height increments
- Highly visible tantalum markers



Large Patterned Graft Window

increased surface area to aid in bone-to-implant osseointegration and increase potential for fusion



Anti-migration Teeth

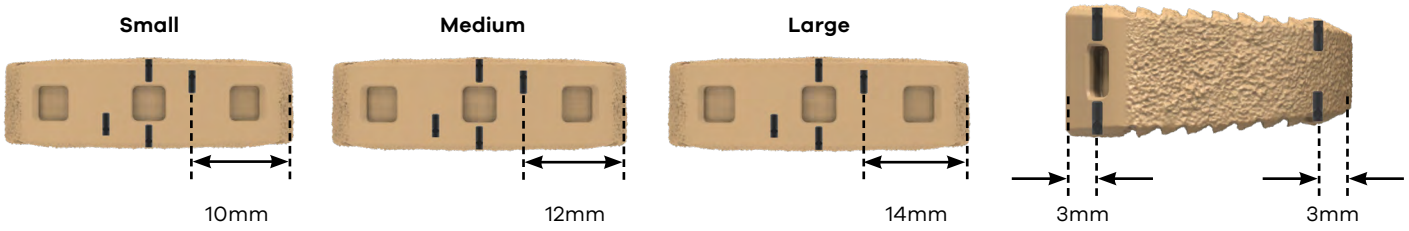
resist implant migration

Standard and Hyperlordotic Options

8° and 14° Standard Lordosis, 20° and 30° Hyperlordosis

Pin Locations & Configurations

- Posterior lateral marker pins indicate the distance from the posterior surface and the lateral surface
- Center marker pin indicates center of the IBF device
- See dimension measurements for each footprint below



SURGICAL TECHNIQUE

Step 1: Patient Positioning

- Patient should be placed in a supine position appropriate for an anterior approach. For anterior approach to the lower lumbar levels, position the patient in a slight Trendelenburg position.

Step 2: Exposure at Disc Level

- Locate the correct operative disc level and make an incision location by taking a lateral X-ray (fluoroscopic view) while holding a straight metal instrument at the side of the patient (Figure 1). This insures that the incision and exposure will allow direct visualization into the disc space. Expose the operative disc level and retract tissues using preferred instruments. Retract and protect the great vessels to allow complete exposure and visualization of the operative site.

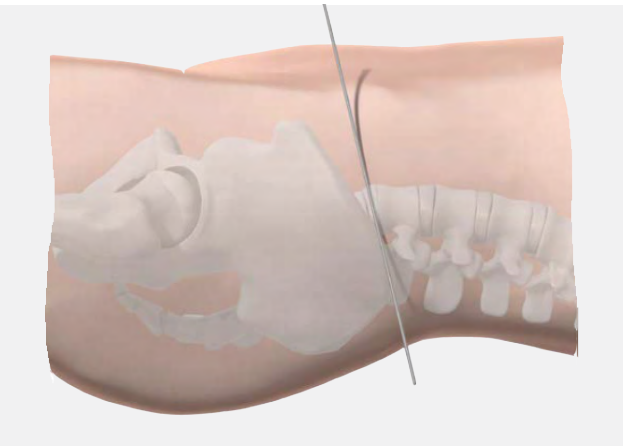


Figure 1

Step 3: Disectomy and Endplate Preparation

- Perform a complete discectomy using preferred surgical instruments.

Step 4: Distraction

- Spreaders may be used to distract the disc space. A smaller width of the spreader may be inserted first to aid in distraction of the disc space. After initial distraction, turn the spreader 90 degrees to the full spreader height to distract the disc space.

Step 5: Sizing/Trialing

- The Fortilink®-A instrument set includes detachable trial spacers to provide guidance prior to implant selection. There are trial spacers available for all corresponding implant sizes. Select an appropriate size detachable trial head and assemble it to the trial shaft handle by threading the trial handle clockwise until the positive stop is reached (Figure 2). Trial markings indicate footprint size, height and angle of lordosis. The trial spacer should require minimum force to insert yet fit snugly within the disc space (Figure 3). Sequentially increase the trial spacer size until the appropriate fit is determined. Using the trial spacer as a guide, verify that appropriate height restoration is achieved with direct visualization and lateral fluoroscopy.

  Insert the trial into the annulotomy window. Check fit and positioning with anterior/posterior and lateral fluoroscopy. Repeat until the desired fit is achieved to identify the optimal trial profile.

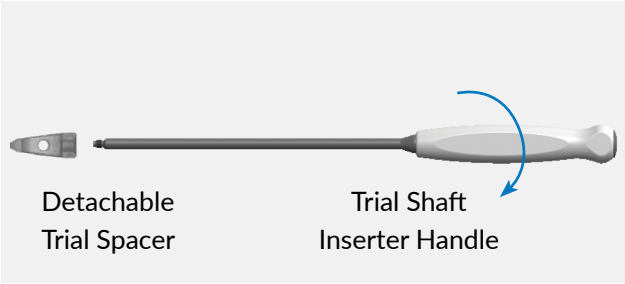


Figure 2

Figure 3

Step 6: Implant Prep

- Select the implant based upon the trial sizing. The Fortilink®-A trials are sized line-to-line to the implant. Pack the Fortilink-A implant with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Straight Inserter

Anterolateral Inserter

Step 7: Inserter Prep

- Both anterolateral and straight inserters are available to aid with insertion for specific approaches (Figure 4). Each inserter type has their specific inner shaft and external housing.

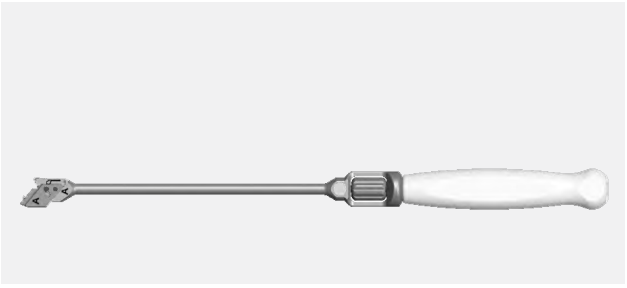


Figure 4

Step 8: Inserter Assembly

- To assemble, insert the inner shaft into the housing (Figure 5A), depress the button (Figure 5B) and push shaft within housing until a positive stop is felt. With the jaws facing you, align the inner shaft jaw flat and housing jaw flat (Figure 6), rotate the knob clockwise until the shaft is fully seated (Figure 5C).

  Note: *Verify the labeling on the inner shaft is the same when assembling to the housing ("S" indicates straight inserter and "A" indicates the anterolateral inserter).*

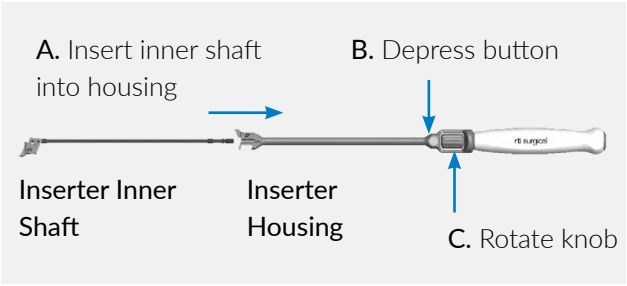


Figure 5

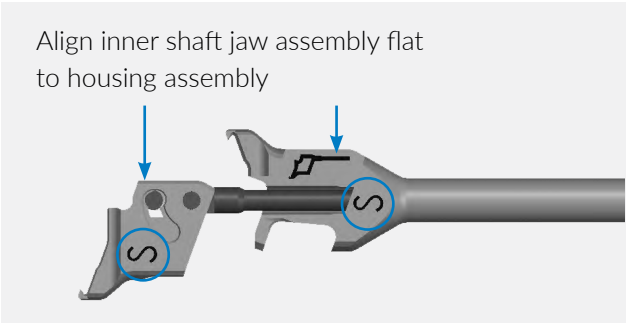


Figure 6

Step 9: Inserter and Implant Loading

- Rotate inserter knob counterclockwise until positive stop is felt, visually confirm distal end is fully open (Figure 7).

  Attach the selected implant to the inserter by placing the inserter jaw into the recessed implant pocket (Figure 8). Rotate the knob clockwise until a positive stop is reached. Verify the implant is fully attached to inserter before inserting into the disc space (Figure 9). Insert the implant into the desired position as determined by direct visualized and lateral fluoroscopy.

  If fine adjustments are needed for final placement of the implant, the tamp may be used to aid in final positioning of the implant (Figure 10). When using the tamp, always ensure that it is docked within the inserter geometry for direct tamping and if corner tamping is required, ensure that the cup portion of the tamp is at the corner of the implant. Always use gentle force when tamping.

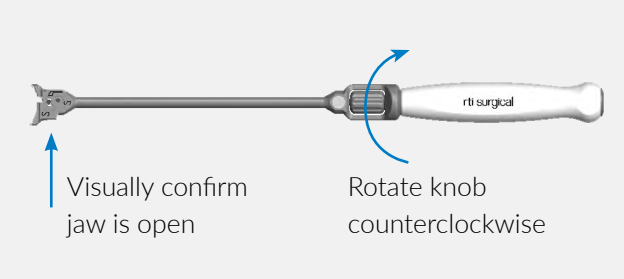


Figure 7

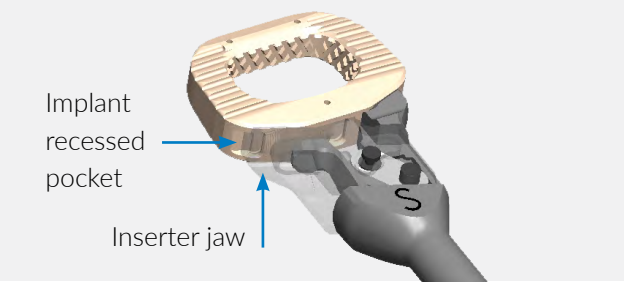


Figure 8

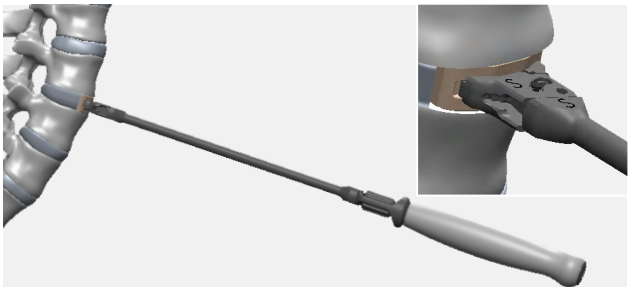


Figure 9

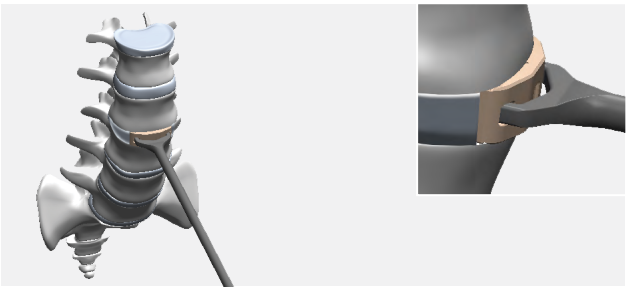


Figure 10

Step 10: Radiographic Verification

- Verify final implant placement with A/P and lateral fluoroscopic images (Figures 11A and B).

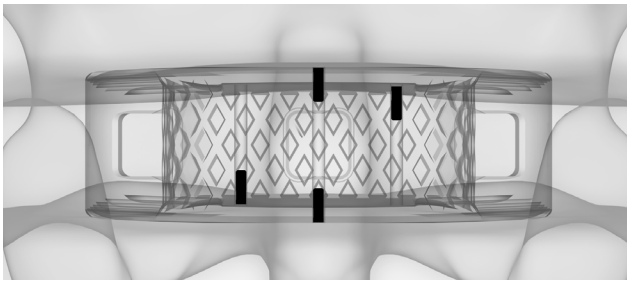


Figure 11A

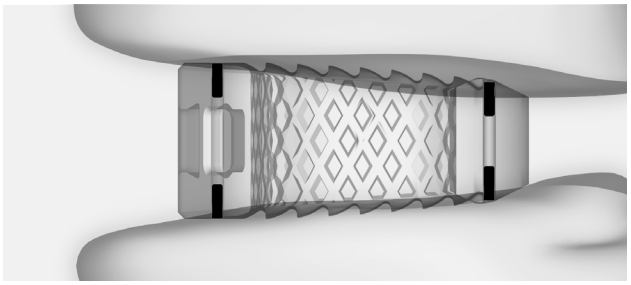


Figure 11B

Step 11: Fixation

- Supplemental posterior pedicle fixation may be achieved with the Streamline® TL* (Figure 13) or Streamline MIS Spinal Fixation System (Figure 14).*

**Please see labeling for these specific products for the complete list of clinical applications, warnings, precautions and other important information.*

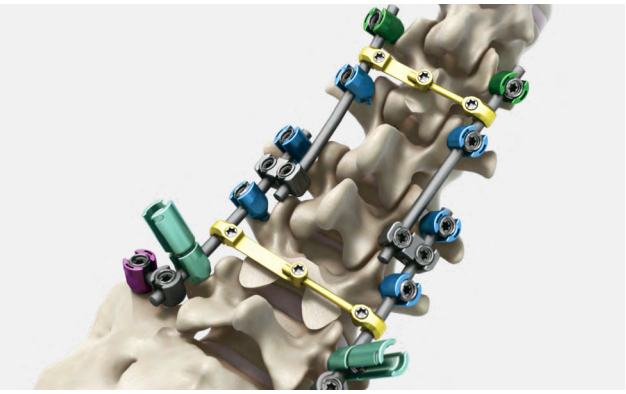


Figure 13

Removal (If Necessary)

- Assemble the inner jaw to the housing. After assembled (see previous steps), re-engage inserter to the implant. Rotate knob of inserter clockwise for reattachment until positive stop is felt. Attach slap hammer adapter to proximal end of the inserter. Assemble slap hammer to the slap hammer attachment. Carefully back slap the hammer and remove the implant from the disc space.

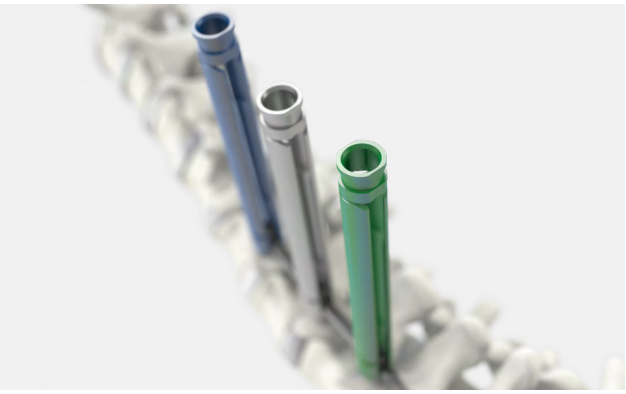


Figure 14

ORDERING GUIDE

Standard Sets

- 65-LS-A-INSERTER
- 65-LS-A-TRIALS
- 65-LS-A-IMP

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

8° and 14° Implants

Part Number	Footprint	Anterior Height	Posterior Height	Lordosis	Graft Vol.*	Quantity
65-A-S08-8L	S	8mm	5.65mm	8°	1.63cc	2
65-A-S10-8L	S	10mm	7.65mm	8°	2.10cc	2
65-A-S12-8L	S	12mm	9.65mm	8°	2.56cc	2
65-A-S14-8L	S	14mm	11.65mm	8°	3.03cc	2
65-A-S16-8L	S	16mm	13.65mm	8°	3.49cc	2
65-A-S18-8L	S	18mm	15.65mm	8°	3.96cc	1
65-A-M08-8L	M	8mm	5.38mm	8°	2.27cc	2
65-A-M10-8L	M	10mm	7.38mm	8°	2.92cc	2
65-A-M12-8L	M	12mm	9.38mm	8°	3.57cc	2
65-A-M14-8L	M	14mm	11.38mm	8°	4.22cc	2
65-A-M16-8L	M	16mm	13.38mm	8°	4.87cc	2
65-A-M18-8L	M	18mm	15.38mm	8°	5.52cc	1
65-A-L08-8L	L	8mm	5.15mm	8°	3.00cc	2
65-A-L10-8L	L	10mm	7.15mm	8°	3.86cc	2
65-A-L12-8L	L	12mm	9.15mm	8°	4.72cc	2
65-A-L14-8L	L	14mm	8.15mm	8°	5.58cc	2
65-A-L16-8L	L	16mm	10.15mm	8°	6.44cc	2
65-A-L18-8L	L	18mm	9.15mm	8°	7.31cc	1
65-A-S10-14L	S	10mm	5.38mm	14°	1.82cc	2
65-A-S12-14L	S	12mm	7.38mm	14°	2.28cc	2
65-A-S14-14L	S	14mm	9.38mm	14°	2.75cc	2
65-A-S16-14L	S	16mm	11.38mm	14°	3.22cc	2
65-A-S18-14L	S	18mm	13.38mm	14°	3.68cc	1
65-A-M10-14L	M	10mm	4.94mm	14°	2.50cc	2
65-A-M12-14L	M	12mm	6.94mm	14°	3.15cc	2
65-A-M14-14L	M	14mm	8.94mm	14°	3.80cc	2
65-A-M16-14L	M	16mm	10.94mm	14°	4.45cc	2
65-A-M18-14L	M	18mm	12.94mm	14°	5.10cc	1
65-A-L12-14L	L	12mm	6.50mm	14°	4.12cc	2
65-A-L14-14L	L	14mm	8.50mm	14°	4.98cc	2
65-A-L16-14L	L	16mm	10.50mm	14°	5.84cc	2
65-A-L18-14L	L	18mm	12.50mm	14°	6.70cc	1

**Graft volumes are approximate.*

Optional Loaner Implant Set (65-LS-A-IMP20)

20° Implants

Part Number	Footprint	Anterior Height	Posterior Height	Lordosis	Graft Vol.*	Quantity
65-A-S12-20L	S	12mm	5.11mm	20°	2.01cc	1
65-A-S14-20L	S	14mm	7.11mm	20°	2.48cc	1
65-A-S16-20L	S	16mm	9.11mm	20°	2.94cc	1
65-A-S18-20L	S	18mm	11.11mm	20°	3.41cc	1
65-A-S20-20L	S	20mm	13.11mm	20°	3.87cc	1
65-A-M14-20L	M	14mm	6.46mm	20°	3.38cc	1
65-A-M16-20L	M	16mm	8.46mm	20°	4.03cc	1
65-A-M18-20L	M	18mm	10.46mm	20°	4.68cc	1
65-A-M20-20L	M	20mm	12.46mm	20°	5.33cc	1
65-A-L14-20L	L	14mm	5.80mm	20°	4.37cc	1
65-A-L16-20L	L	16mm	7.80mm	20°	5.23cc	1
65-A-L18-20L	L	18mm	9.80mm	20°	6.09cc	1
65-A-L20-20L	L	20mm	11.80mm	20°	6.95cc	1

**Graft volumes are approximate.*

Optional Loaner Implant Set (65-LS-A-IMP30)

30° Implants

Part Number	Footprint	Anterior Height	Posterior Height	Lordosis	Graft Vol.*	Quantity
65-A-S16-30L	S	16mm	5.18mm	30°	2.47cc	1
65-A-S18-30L	S	18mm	7.18mm	30°	2.94cc	1
65-A-S20-30L	S	20mm	9.18mm	30°	3.41cc	1
65-A-S22-30L	S	22mm	11.18mm	30°	3.88cc	1
65-A-M18-30L	M	18mm	6.19mm	30°	3.96cc	1
65-A-M20-30L	M	20mm	8.19mm	30°	4.61cc	1
65-A-M22-30L	M	22mm	10.19mm	30°	5.27cc	1
65-A-L18-30L	L	18mm	5.14mm	30°	5.06cc	1
65-A-L20-30L	L	20mm	7.20mm	30°	5.92cc	1
65-A-L22-30L	L	22mm	9.20mm	30°	6.78cc	1

**Graft volumes are approximate.*

Optional Hyperlordotic Sets

- 20°
  - 65-LS-A-TRIAL-20
  - 65-LS-A-IMP20
- 30°
  - 65-LS-A-TRIAL-30
  - 65-LS-A-IMP30

Standard Instrument Set (65-LS-A-INSERTER)

Part Number	Description
65-A-INSERTER	Fortilink-A, Straight Inserter
65-A-SHAFT	Fortilink-A, Straight Jaw Shaft
65-A-INSERTER-A	Fortilink-A, Anterolateral Inserter
65-A-SHAFT-A	Fortilink-A, Anterolateral Jaw Shaft
65-A-TAMP	Fortilink-A, Tamp
38-SLAPHAMMER	Slap Hammer
38-SLAPADAPT	Slap Hammer Adapter

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. See back page for contact information.

Fortilink®-A Inserter Disassembly

To disassemble, unscrew the inserter shaft from the housing by depressing the button (Figure 15A) and rotating the thumb knob (Figure 15B) counterclockwise until the knob spins freely. Pull the shaft out of the housing (Figure 15C).

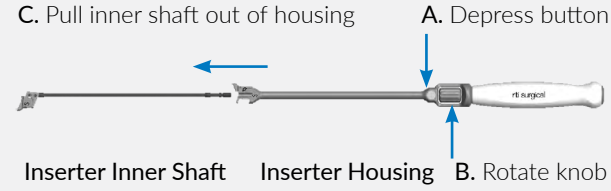


Figure 15

NOTES

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

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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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