

Fortilink®-TS

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.

INDICATIONS FOR USE:

When Fortilink®-TS is used as a lumbar interbody fusion (IBF) implant, these devices are 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. These IBF devices are 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 devices are 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.

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

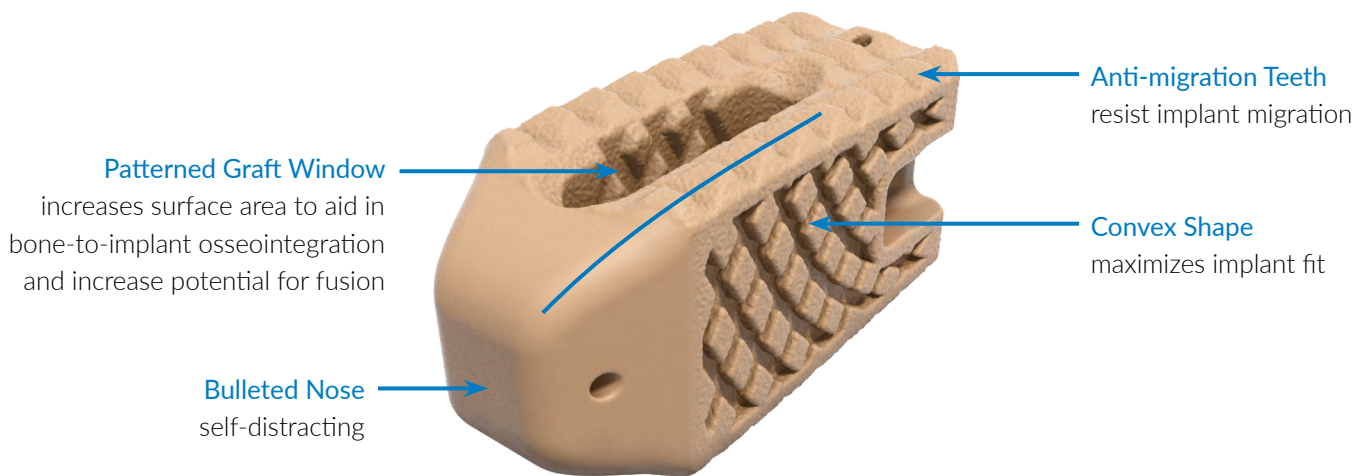
Information on the products and procedures contained in this document is general in nature and does not represent medical advice or recommendations. As with any technical guide, this information does not constitute any diagnostic or therapeutic statement with regard to a given medical case. An evaluation, 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.

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INTRODUCTION

> System Overview

- Made with 3D printed Tetrafuse® 3D Technology
- Designed for a unilateral or bilateral approach
- Implants available in heights from 8 to 17mm, in 1mm increments
- Highly visible tantalum markers
- Intended to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft



> Pin Locations & Configurations



SURGICAL TECHNIQUE

Step 1: Exposure of Disc Level

- Access the operative site and retract tissues to allow for complete exposure and visualization of the target disc space.

Step 2: Laminectomy/Laminotomy, Facetectomy and Discectomy

- Perform a conventional laminotomy, decompressing the thecal sac and nerve roots above and below the target disc space. Complete a direct decompression with unilateral or bilateral near-total facetectomy and foraminotomies, depending on the approach.

Perform an annulotomy and remove disc material from the disc space.

Step 3: Distraction

- Use pedicle screws implanted above and below the disc space (Figure 1) for distraction. Streamline® TL and Streamline® MIS Spinal Fixation Systems are options for pedicle screw distraction. Please refer to the Streamline TL or Streamline MIS Surgical Technique for additional information.

Alternatively, paddle distractors (included in the MIS Fusion™ Instrument Set) (Figure 2) may be used to initially distract the work space. This facilitates disc removal and placement of larger paddle distractors and/or shavers.

Using the paddle distractors, the resected space is sequentially distracted until the optimal height is achieved, indirectly decompressing nerve roots by restoring foraminal height.



Figure 1



Figure 2

Step 4: Disc Space Preparation

- For the bilateral approach, a paddle distractor may be in place. Insert the corresponding shaver on the contralateral side. Shavers are included in the MIS Fusion Instrument Set in sizes 7-15mm (in 1mm increments).

Rotate the shaver clockwise and counterclockwise to further remove disc material and cartilaginous endplate. Care should be taken to avoid pushing the shaver too far in the interspace and cutting through the anterior or lateral annulus. Remove loose tissue with pituitary rongeurs. Care should be taken when first rotating the shavers to not force them into the bony endplates, increasing the risk of subsidence. If the shaver catches, drop down one size and proceed.

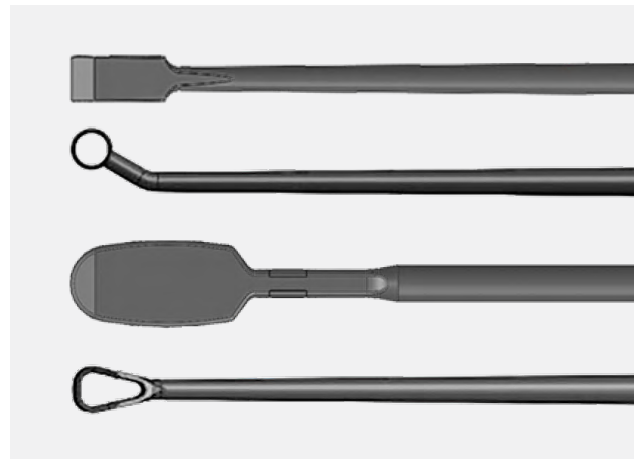


Figure 3

Step 5: Endplate Preparation

- Prepare the endplates following preferred technique. The MIS Fusion Instrument Set (Figure 3) offers various instruments to aid with endplate preparation. Rotating cutters should be used to safely remove as much of the lateral disc as possible. Straight and angled curettes and rasps are used to finish removing the cartilaginous endplates and perforate the bony endplates to expose bleeding bone. Instruments should be moved up and down in a repetitive fashion and angled obliquely toward the midline to prepare as much endplate as possible. For a bilateral approach, repeat on the contralateral side.

Step 6: Implant Selection

- Trial spacers are available for all corresponding implants to provide guidance prior to implant selection. The trials (Figure 4) are used in conjunction with the Hudson T-handle.

Select the trial spacer 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. Sequentially increase the trial spacer size until the appropriate height is determined. Using the trial spacer as a guide, verify that appropriate height restoration is achieved with lateral fluoroscopy. Select the appropriate implant size.



Figure 4

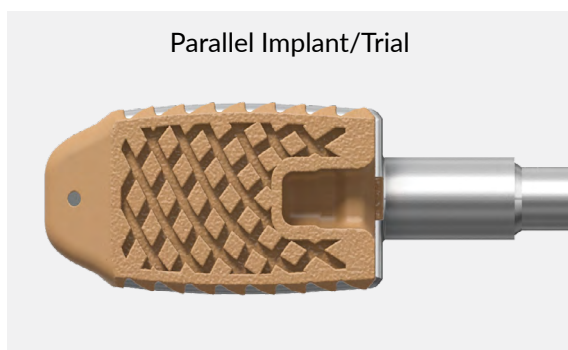


Figure 5

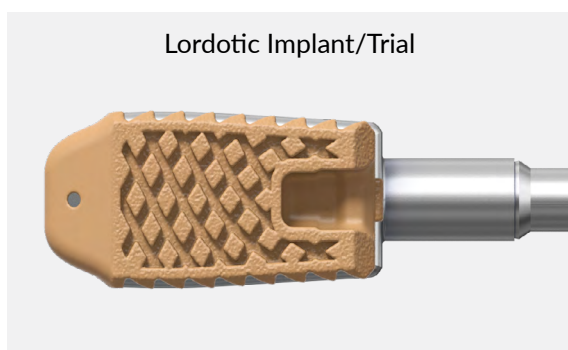


Figure 6

Note: The height of the trial spacer matches the height of the corresponding implant.

Warning: Using an implant larger than the size trialed could lead to implant failure.

Step 7: Implant Preparation and Insertion

- Pack the implant with autogenous bone graft and/or allogenic bone graft. If necessary, the thecal sac and inferior nerve root may be gently retracted medially with the nerve root retractor. Nerve root retractors are offered in the MIS Fusion Instrument Set.

Attach the inserter to the implant by pulling back on the release collar (Figure 7A), opening the jaws of the inserter. Place the implant in the open jaws of the inserter (Figure 7B) and release the collar. Lock the inserter by twisting the locking knob clockwise (Figure 8).

With the implant attached to the inserter, tap the implant to the final desired depth. Figure 9 shows the implant placement for the unilateral approach. The etch markings on the side of the inserter align with the opening arm of the inserter.

Caution: The Fortilink-TS implants should not be rotated during insertion. Attempting to rotate these implants during insertion may lead to implant failure.

Note: Maximize graft area by packing bone graft lateral and anterior in the interspace prior to the initial implant placement.

Detach the inserter from the implant by first twisting the locking knob counterclockwise to unlock. Then pull back on the release collar, opening the jaws of the inserter to release the implant.

Once released, remove the inserter from the disc space.

Pack bone graft into the disc space surrounding the implants. If performing a bilateral surgery, leave enough space beneath the annulotomy to allow for placement of the contralateral implant. When the disc space is distracted by an instrument, insert the second implant using the same technique. Figure 10 shows the implant placement for a bilateral approach.



Figure 7A

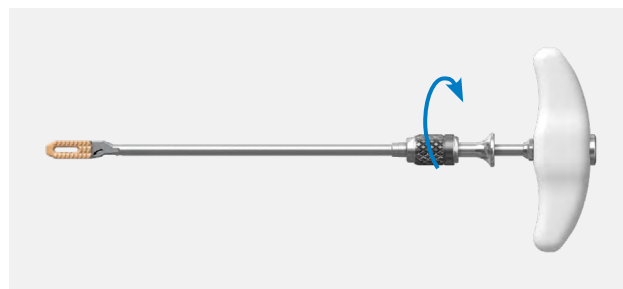


Figure 8

With the implant attached to the inserter, tap the implant to the final desired depth. Figure 9 shows the implant placement for the unilateral approach. The etch markings on the side of the inserter align with the opening arm of the inserter.

Note: Maximize graft area by packing bone graft lateral and anterior in the interspace prior to the initial implant placement.

Detach the inserter from the implant by first twisting the locking knob counterclockwise to unlock. Then pull back on the release collar, opening the jaws of the inserter to release the implant.

Once released, remove the inserter from the disc space.

Pack bone graft into the disc space surrounding the implants. If performing a bilateral surgery, leave enough space beneath the annulotomy to allow for placement of the contralateral implant. When the disc space is distracted by an instrument, insert the second implant using the same technique. Figure 10 shows the implant placement for a bilateral approach.

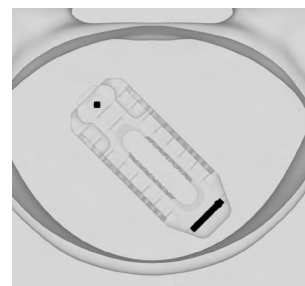


Figure 9
Implant Placement:
Unilateral Approach

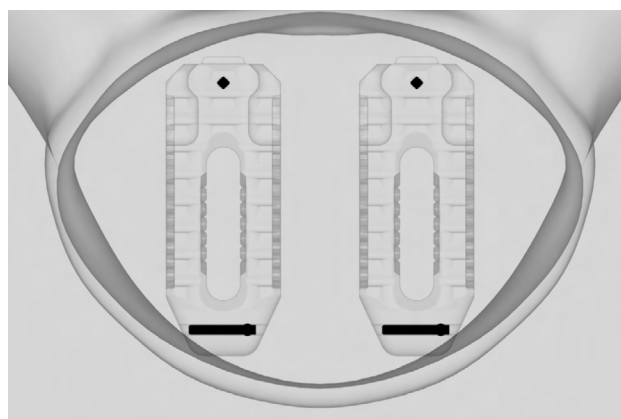


Figure 10
Implant Placement:
Bilateral Approach

Step 8: Radiographic Verification

- Verify the final implant placement with anterior/posterior (A/P) and lateral fluoroscopic images.

Bilateral Approach: An A/P view should show a “cross-hair” (per implant): two (2) vertical pins at the superior and inferior implant surfaces with one (1) horizontal pin centered between them (Figure 11A).

A lateral view should show one (1) dot (per implant) at the anterior face of the implant and two (2) vertical pins at the posterior face of the implant (at the superior and inferior implant surfaces) (Figure 11B).

Unilateral Approach: The A/P view should show one (1) horizontal pin at the anterior face of the implant and two (2) vertical pins at the posterior face of the implant (at the superior and inferior implant surfaces). The horizontal pin indicates the distal position of the implant nose, which should be near or slightly across the midline (Figure 11C).

The lateral view should show one (1) horizontal pin at the anterior face of the implant and two (2) vertical pins at the posterior face of the implant (at the superior and inferior implant surfaces) (Figure 11D).

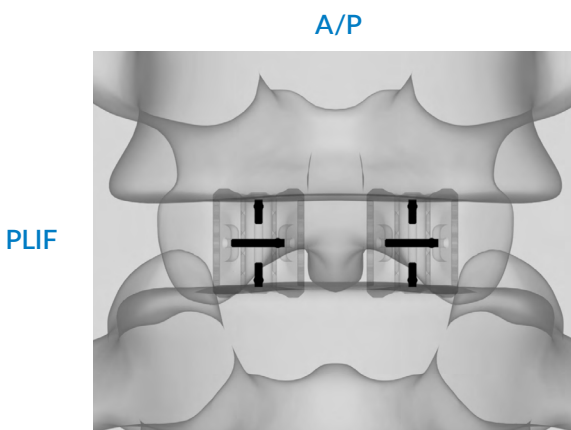


Figure 11A

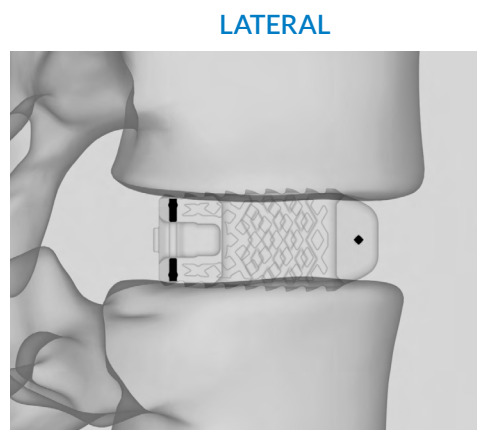


Figure 11B

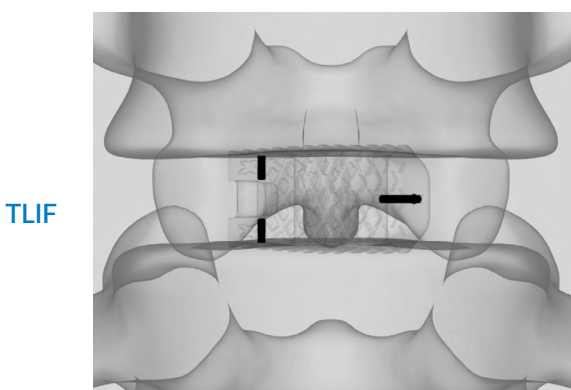


Figure 11C

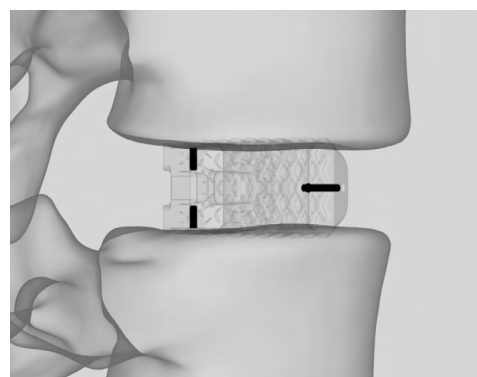


Figure 11D

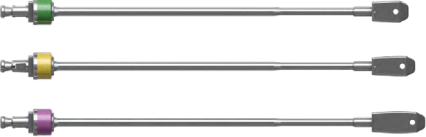
Note: Tetrafuse 3D Technology is radiolucent. The ghosted image depicted above is for reference purposes only and would not be seen under fluoroscopy.

Removal (If Necessary)

- For removal of the implant, slide the jaws into the slots of the implant and fully tighten the locking knob of the inserter. Attach the slap hammer adapter and slap hammer to the end of the inserter.

Using the slap hammer, carefully back slap the implant from the disc space.

ORDERING GUIDE

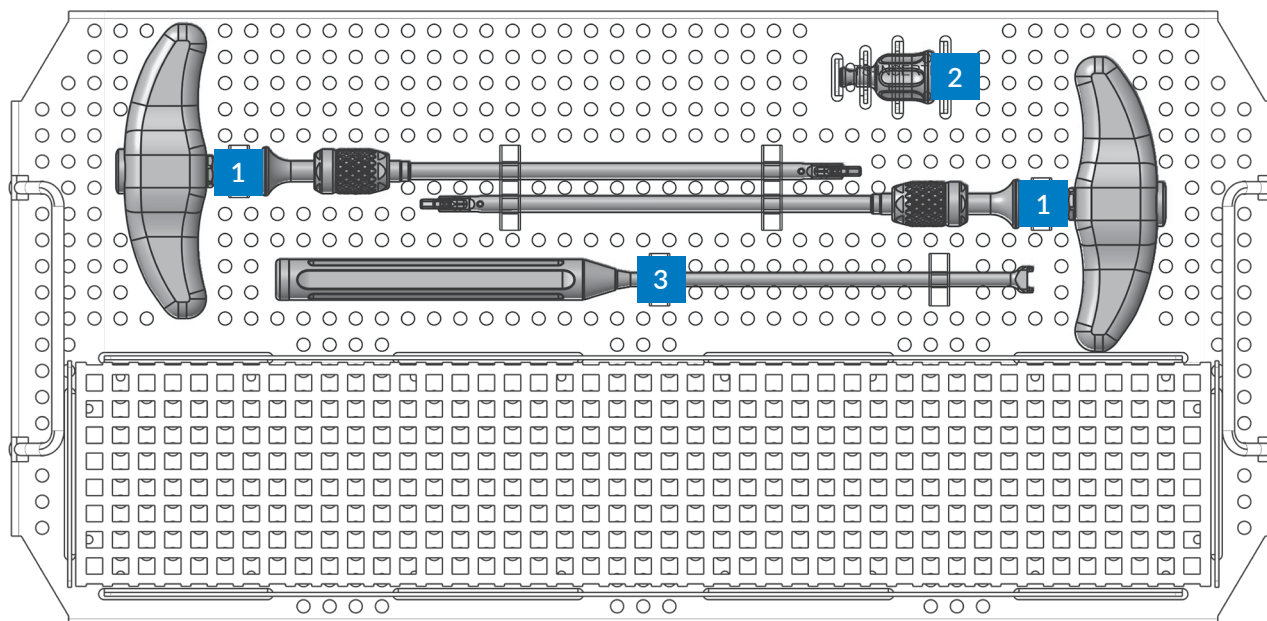
Part Number	Instrument	Description	
65-TS-INSERTER	Fortilink-TS Inserter	For insertion of Fortilink-TS interbody implants	
65-TS-TAMP	Fortilink-TS Tamp	For making minor adjustments to implant position	
38-SLAPADAPT	Slap Hammer Adaptor	For use with slaphammer and Fortilink-TS inserter to remove a Fortilink-TS implant if necessary	
38-THANDLE	Modular T-Handle	For attaching to implant trials	
38-SLAPHAMMER	Slap Hammer	For removal of implant trials; for use with slaphammer adaptor and Fortilink-TS inserter to remove a Fortilink-TS implant if necessary	
65-TS-TRLX-Y	Fortilink-TS Parallel Trial Spacer	For providing guidance on implant height selection; X= length, Y=height	
65-TS-TRLX-Y-6L	Fortilink-TS Lordotic Trial Spacer		

Parallel and Lordotic Instrument Top Tray Layout

1 Fortilink-TS Inserters

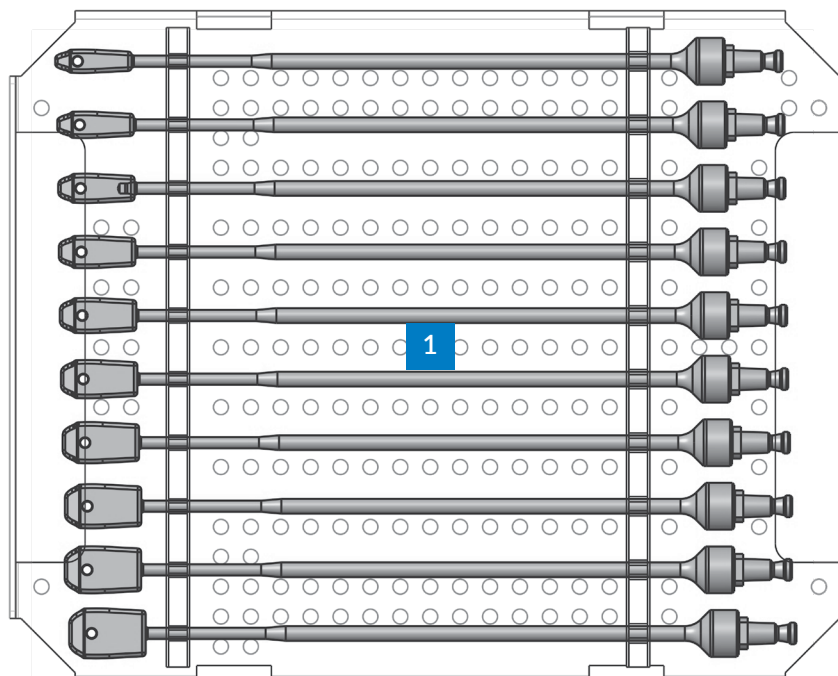
2 Slap Hammer Adapter

3 Tamp



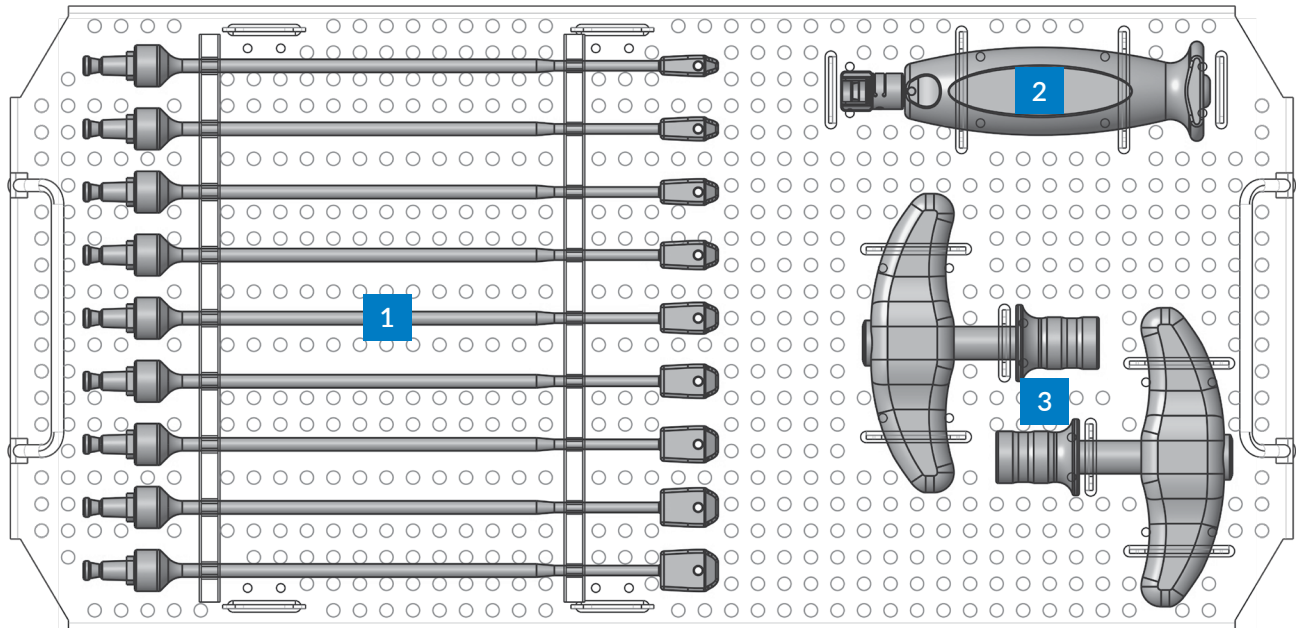
Parallel and Lordotic Instrument Middle Tray Layout

1 Trial Spacers



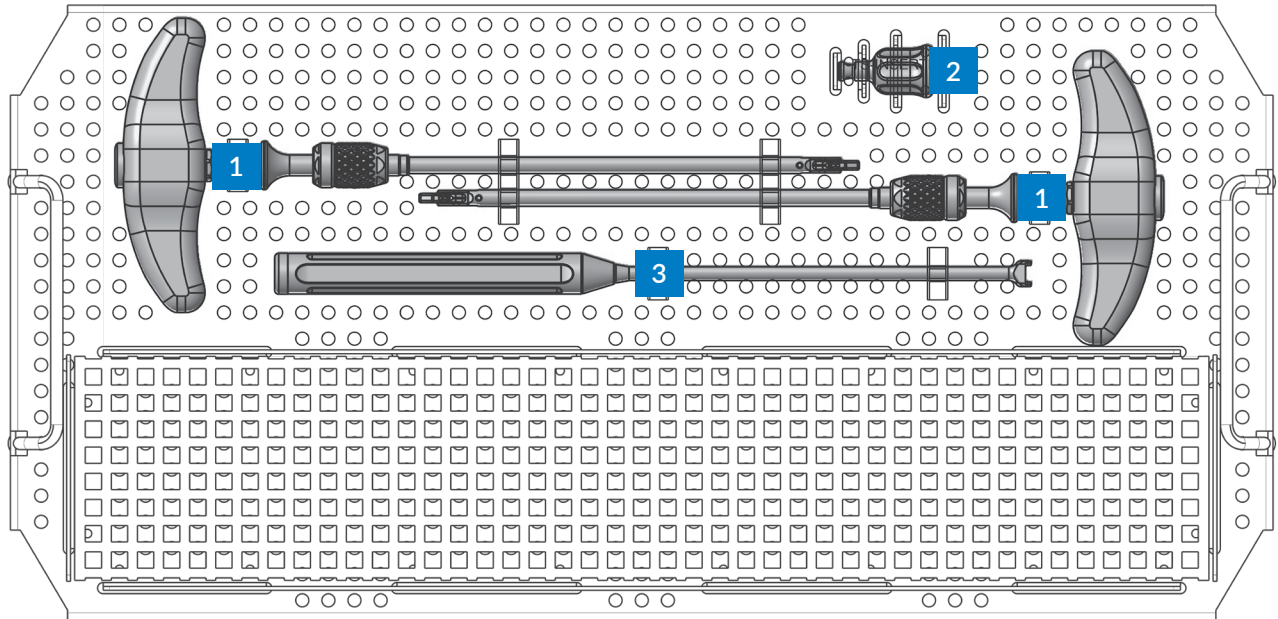
Parallel and Lordotic Instrument Bottom Tray Layout

1	Trial Spacers	2	Slap Hammer	3	T-Handles
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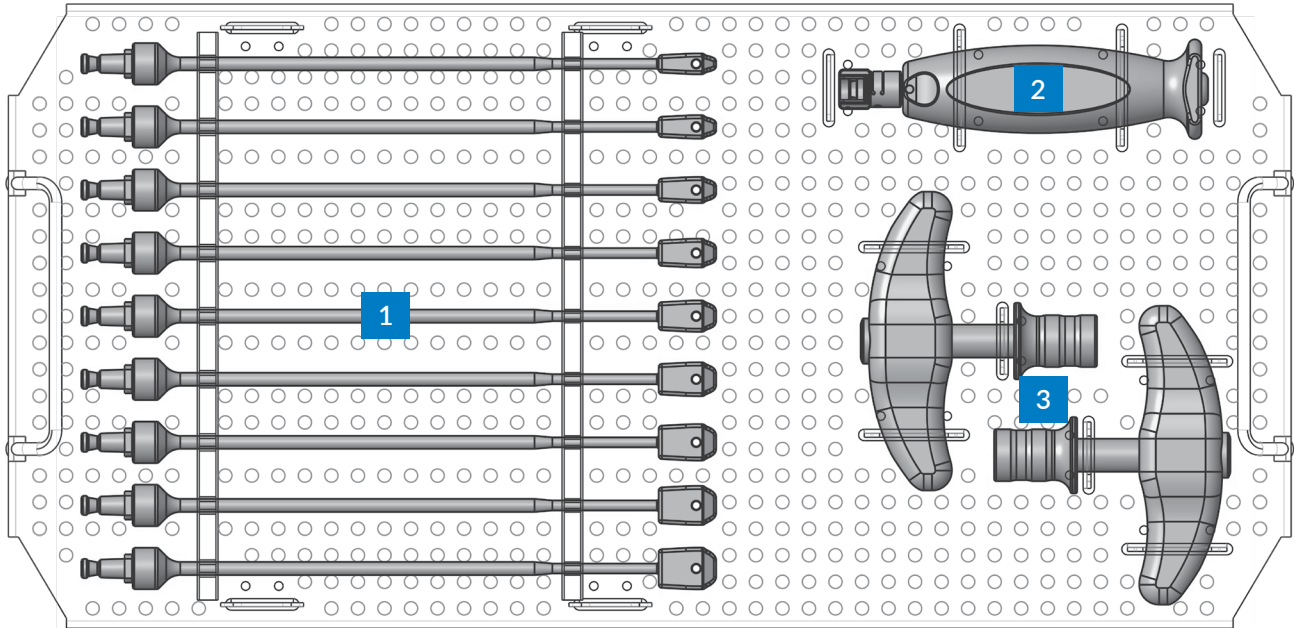
Optional 32mm Instrument Top Tray Layout

1	Fortilink-TS Inserters	2	Slap Hammer Adapter	3	Tamp
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Optional 32mm Instrument Bottom Tray Layout

1	Trial Spacers	2	Slap Hammer	3	T-Handles
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Standard Loaner Parallel Implant Set (65-LS-TS-IMP)

22mm Parallel Implants

Part Number	Description	Length	Width	Max. Height	A/P Height	Graft Vol.	Lordosis	Qty.
65-TS-8-22	8 x 22mm Parallel Fortilink-TS	22mm	10mm	8mm	7mm	0.26 cc	0°	4
65-TS-9-22	9 x 22mm Parallel Fortilink-TS	22mm	10mm	9mm	8mm	0.30 cc	0°	4
65-TS-10-22	10 x 22mm Parallel Fortilink-TS	22mm	10mm	10mm	9mm	0.34 cc	0°	4
65-TS-11-22	11 x 22mm Parallel Fortilink-TS	22mm	10mm	11mm	10mm	0.38 cc	0°	4
65-TS-12-22	12 x 22mm Parallel Fortilink-TS	22mm	10mm	12mm	11mm	0.42 cc	0°	4
65-TS-13-22	13 x 22mm Parallel Fortilink-TS	22mm	10mm	13mm	12mm	0.47 cc	0°	4
65-TS-14-22	14 x 22mm Parallel Fortilink-TS	22mm	10mm	14mm	13mm	0.51 cc	0°	4
65-TS-15-22	15 x 22mm Parallel Fortilink-TS	22mm	10mm	15mm	14mm	0.55 cc	0°	4
65-TS-16-22	16 x 22mm Parallel Fortilink-TS	22mm	10mm	16mm	15mm	0.59 cc	0°	2

26mm Parallel Implants

Part Number	Description	Length	Width	Max. Height	A/P Height	Graft Vol.	Lordosis	Qty.
65-TS-8-26	8 x 26mm Parallel Fortilink-TS	26mm	10mm	8mm	7mm	0.36 cc	0°	2
65-TS-9-26	9 x 26mm Parallel Fortilink-TS	26mm	10mm	9mm	8mm	0.42 cc	0°	2
65-TS-10-26	10 x 26mm Parallel Fortilink-TS	26mm	10mm	10mm	9mm	0.48 cc	0°	2
65-TS-11-26	11 x 26mm Parallel Fortilink-TS	26mm	10mm	11mm	10mm	0.53 cc	0°	2
65-TS-12-26	12 x 26mm Parallel Fortilink-TS	26mm	10mm	12mm	11mm	0.59 cc	0°	2
65-TS-13-26	13 x 26mm Parallel Fortilink-TS	26mm	10mm	13mm	12mm	0.65 cc	0°	2
65-TS-14-26	14 x 26mm Parallel Fortilink-TS	26mm	10mm	14mm	13mm	0.71 cc	0°	2
65-TS-15-26	15 x 26mm Parallel Fortilink-TS	26mm	10mm	15mm	14mm	0.77 cc	0°	2
65-TS-16-26	16 x 26mm Parallel Fortilink-TS	26mm	10mm	16mm	15mm	0.83 cc	0°	2
65-TS-17-26	17 x 26mm Parallel Fortilink-TS	26mm	10mm	17mm	16mm	0.89 cc	0°	2

Optional 32mm Parallel Implant Set (65-LS-TS-IMP-32)

Part Number	Description	Length	Width	Max. Height	A/P Height	Graft Vol.	Lordosis	Qty.
65-TS-10-32	10 x 32mm Parallel Fortilink-TS	32mm	10mm	10mm	9mm	0.68 cc	0°	2
65-TS-11-32	11 x 32mm Parallel Fortilink-TS	32mm	10mm	11mm	10mm	0.76 cc	0°	2
65-TS-12-32	12 x 32mm Parallel Fortilink-TS	32mm	10mm	12mm	11mm	0.85 cc	0°	2
65-TS-13-32	13 x 32mm Parallel Fortilink-TS	32mm	10mm	13mm	12mm	0.93 cc	0°	2
65-TS-14-32	14 x 32mm Parallel Fortilink-TS	32mm	10mm	14mm	13mm	1.02 cc	0°	2
65-TS-15-32	15 x 32mm Parallel Fortilink-TS	32mm	10mm	15mm	14mm	1.11 cc	0°	2
65-TS-16-32	16 x 32mm Parallel Fortilink-TS	32mm	10mm	16mm	15mm	1.19 cc	0°	2
65-TS-17-32	17 x 32mm Parallel Fortilink-TS	32mm	10mm	17mm	16mm	1.28 cc	0°	2

Standard Loaner Parallel Instrument Set (65-LS-TS-INS)

Part Number	Description	Qty.
65-TS-INSERTER	Fortilink-TS Inserter	2
65-TS-TAMP	Fortilink-TS Tamp	1
38-SLAPADAPT	Hudson Slap Hammer Adaptor	1
38-THANDLE	Hudson T-Handle	2
38-SLAPHAMMER	Hudson Slap Hammer	1
65-TS-TRL22-8	8 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL22-9	9 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL22-10	10 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL22-11	11 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL22-12	12 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL22-13	13 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL22-14	14 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL22-15	15 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL22-16	16 x 22mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-8	8 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-9	9 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-10	10 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-11	11 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-12	12 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-13	13 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-14	14 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-15	15 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-16	16 x 26mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL26-17	17 x 26mm Fortilink-TS Parallel Trial Spacer	1

Optional Loaner 32mm Parallel Instrument Set (65-LS-TS-INS-32)

Part Number	Description	Qty.
65-TS-INSERTER	Fortilink-TS Inserter	2
65-TS-TAMP	Fortilink-TS Tamp	1
38-SLAPADAPT	Hudson Slap Hammer Adaptor	1
38-THANDLE	Hudson T-Handle	2
38-SLAPHAMMER	Hudson Slap Hammer	1
65-TS-TRL32-10	10 x 32mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL32-11	11 x 32mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL32-12	12 x 32mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL32-13	13 x 32mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL32-14	14 x 32mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL32-15	15 x 32mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL32-16	16 x 32mm Fortilink-TS Parallel Trial Spacer	1
65-TS-TRL32-17	17 x 32mm Fortilink-TS Parallel Trial Spacer	1

Standard Loaner Lordotic Implant Set (65-LS-TS-IMP-6L)

22mm Lordotic Implants

Part Number	Description	Length	Width	Anterior Height	Posterior Height	Graft Vol.	Lordosis	Qty.
65-TS-8-22-6L	8 x 22mm Lordotic Fortilink-TS	22mm	10mm	8mm	6.6mm	0.26 cc	6°	4
65-TS-9-22-6L	9 x 22mm Lordotic Fortilink-TS	22mm	10mm	9mm	7.6mm	0.29 cc	6°	4
65-TS-10-22-6L	10 x 22mm Lordotic Fortilink-TS	22mm	10mm	10mm	8.6mm	0.34 cc	6°	4
65-TS-11-22-6L	11 x 22mm Lordotic Fortilink-TS	22mm	10mm	11mm	9.6mm	0.38 cc	6°	4
65-TS-12-22-6L	12 x 22mm Lordotic Fortilink-TS	22mm	10mm	12mm	10.6mm	0.42 cc	6°	4
65-TS-13-22-6L	13 x 22mm Lordotic Fortilink-TS	22mm	10mm	13mm	11.6mm	0.46 cc	6°	4
65-TS-14-22-6L	14 x 22mm Lordotic Fortilink-TS	22mm	10mm	14mm	12.6mm	0.51 cc	6°	4
65-TS-15-22-6L	15 x 22mm Lordotic Fortilink-TS	22mm	10mm	15mm	13.6mm	0.55 cc	6°	4
65-TS-16-22-6L	16 x 22mm Lordotic Fortilink-TS	22mm	10mm	16mm	14.6mm	0.59 cc	6°	2

26mm Lordotic Implants

Part Number	Description	Length	Width	Anterior Height	Posterior Height	Graft Vol.	Lordosis	Qty.
65-TS-8-26-6L	8 x 26mm Lordotic Fortilink-TS	26mm	10mm	8mm	6.6mm	0.37 cc	6°	2
65-TS-9-26-6L	9 x 26mm Lordotic Fortilink-TS	26mm	10mm	9mm	7.6mm	0.42 cc	6°	2
65-TS-10-26-6L	10 x 26mm Lordotic Fortilink-TS	26mm	10mm	10mm	8.6mm	0.48 cc	6°	2
65-TS-11-26-6L	11 x 26mm Lordotic Fortilink-TS	26mm	10mm	11mm	9.6mm	0.54 cc	6°	2
65-TS-12-26-6L	12 x 26mm Lordotic Fortilink-TS	26mm	10mm	12mm	10.6mm	0.60 cc	6°	2
65-TS-13-26-6L	13 x 26mm Lordotic Fortilink-TS	26mm	10mm	13mm	11.6mm	0.66 cc	6°	2
65-TS-14-26-6L	14 x 26mm Lordotic Fortilink-TS	26mm	10mm	14mm	12.6mm	0.72 cc	6°	2
65-TS-15-26-6L	15 x 26mm Lordotic Fortilink-TS	26mm	10mm	15mm	13.6mm	0.78 cc	6°	2
65-TS-16-26-6L	16 x 26mm Lordotic Fortilink-TS	26mm	10mm	16mm	14.6mm	0.83 cc	6°	2
65-TS-17-26-6L	17 x 26mm Lordotic Fortilink-TS	26mm	10mm	17mm	15.6mm	0.89 cc	6°	2

Standard Loaner Lordotic Instrument Set (65-LS-TS-INS-6L)

Part Number	Description	Qty.
65-TS-INSERTER	Fortilink-TS Inserter	2
65-TS-TAMP	Fortilink-TS Tamp	1
38-SLAPADAPT	Hudson Slap Hammer Adaptor	1
38-THANDLE	Hudson T-Handle	2
38-SLAPHAMMER	Hudson Slap Hammer	1
65-TS-TRL22-8-6L	8 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL22-9-6L	9 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL22-10-6L	10 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL22-11-6L	11 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL22-12-6L	12 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL22-13-6L	13 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL22-14-6L	14 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL22-15-6L	15 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL22-16-6L	16 x 22mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-8-6L	8 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-9-6L	9 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-10-6L	10 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-11-6L	11 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-12-6L	12 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-13-6L	13 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-14-6L	14 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-15-6L	15 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-16-6L	16 x 26mm Fortilink-TS Lordotic Trial Spacer	1
65-TS-TRL26-17-6L	17 x 26mm Fortilink-TS Lordotic Trial Spacer	1

Standard Loaner MIS Fusion Instrument Set (29-LS-MISFUSION)

Part Number	Description	Qty.
29-NRETRACT-11	11mm Nerve Root Retractor	1
29-NRETRACT-7	7mm Nerve Root Retractor	1
29-SUCTION-7	7fr Suction Tip	1
29-SUCTION-11	11fr Suction Tip	1
29-SUCTION-9-NR	9FR Suction Nerve Root Ret. - 9mm	1
29-BIPOLAR-S-LG	Large Bipolar Forceps	1
29-BIPOLAR-S-SM	Small Bipolar Forceps	1
29-BIPOLAR-U-SM	Small Bipolar Forceps - Up	1
29-PENFIELD-4	#4 Penfield - Double End	1
29-WOODSON	Woodson Elevator	1
29-PUTTER	Putter	1
29-BALLPROBE	Ball Probe	1
29-NHOOK	Nerve Hook	1
29-BLADEHLDR-B	Blade Holder	1
29-9PIT-2-S	2mm Pituitary - Straight	1
29-9PIT-4-S	4mm Pituitary - Straight	1
29-9PIT-6-S	6mm Pituitary - Straight	1
29-9PIT-2-U	2mm Pituitary - Up	1
29-9PIT-4-U	4mm Pituitary - Up	1
29-9PIT-6-U	6mm Pituitary - Up	1
29-9KERR-2-B	2mm Kerrison	1
29-9KERR-3-B	3mm Kerrison	1
29-9KERR-4-B	4mm Kerrison	1
29-MPIT-2-S	2mm Micro Pituitary - Straight	1
29-MPIT-2-U	2mm Micro Pituitary - Up	1
29-MCUR-000-S	#3-0 Micro Curette - Straight	1
29-MCUR-0-S	#0 Micro Curette - Straight	1
29-MCUR-2-S	#2 Micro Curette - Straight	1
29-MCUR-000-FA	#3-0 Micro Curette - FA	1
29-MCUR-0-FA	#0 Micro Curette - FA	1
29-MCUR-2-FA	#2 Micro Curette - FA	1
29-MCUR-000-RA	#3-0 Micro Curette - RA	1
29-MCUR-0-RA	#0 Micro Curette - RA	1
29-MCUR-2-RA	#2 Micro Curette - RA	1

Part Number	Description	Qty.
29-CURETTE-2-S	#2 Cup Curette - Straight	1
29-CURETTE-2-FA	#2 Cup Curette - FA	1
29-CURETTE-2-RA	#2 Cup Curette - RA	1
29-CURETTE-2-LH	#2 Cup Curette - Left	1
29-CURETTE-2-RH	#2 Cup Curette - Right	1
29-CURETTE-4-S	#4 Cup Curette - Straight	1
29-CURETTE-4-FA	#4 Cup Curette - FA	1
29-CURETTE-4-RA	#4 Cup Curette - RA	1
29-RAKECUR-8-FA	8mm Rake Curette - FA	1
29-RINGCUR-2-LA	Angled Ring Curette	1
29-OSTEOTOM-8-S	8mm Osteotome	1
29-PADDLE-5	5mm Paddle	1
29-PADDLE-6	6mm Paddle	1
29-PADDLE-7	7mm Paddle	1
29-PADDLE-8	8mm Paddle	1
29-PADDLE-9	9mm Paddle	1
29-PADDLE-10	10mm Paddle	1
29-PADDLE-11	11mm Paddle	1
29-PADDLE-12	12mm Paddle	1
29-PADDLE-13	13mm Paddle	1
29-PADDLE-14	14mm Paddle	1
29-PADDLE-15	15mm Paddle	1
29-SHAVER-7	7mm Shaver	1
29-SHAVER-8	8mm Shaver	1
29-SHAVER-9	9mm Shaver	1
29-SHAVER-10	10mm Shaver	1
29-SHAVER-11	11mm Shaver	1
29-SHAVER-12	12mm Shaver	1
29-SHAVER-13	13mm Shaver	1
29-SHAVER-14	14mm Shaver	1
29-SHAVER-15	15mm Shaver	1
38-THANDLE	Hudson T-Handle	1
29-RASP-A	8mm Rasp - Angled	1
29-RASP-S	8mm Rasp - Straight	1

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®-TS Inserter Cleaning

1. Verify inserter is in **“UNLOCKED”** position by turning the locking knob counterclockwise until it stops.
2. Using the sliding posterior handle to articulate the distal clamp arm, verify there is no debris in distal hinge points (Figure 13). Flush distal end of inserter, using the flush ports to assist with areas not in direct line of sight.
3. Continue to actuate the posterior handle to articulate the moving areas while flushing the ports to expose all areas of the inserter.



Figure 13

NOTES

[illegible]



☎ 888-886-9354
✉ cs@xtantmedical.com
🌐 xtantmedical.com

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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