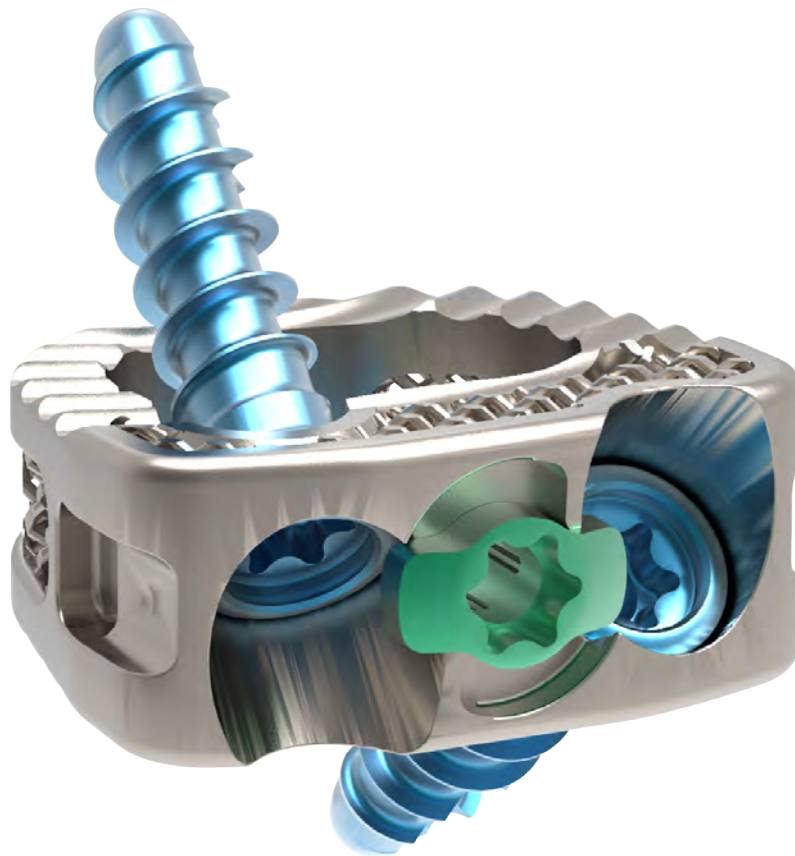




PARADIGM SPINE

AN XTANT MEDICAL COMPANY



**Fortilink[®]-SC
IBF Device
with TiPlus Technology**

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DEVICE DESCRIPTION

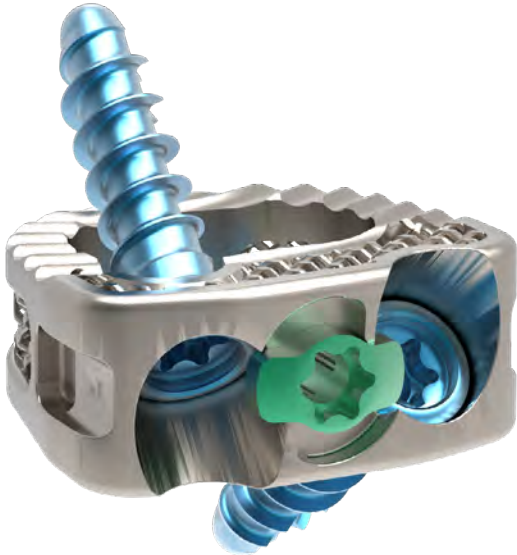


Figure 1
Fortilink®-SC with TiPlus Technology

The Fortilink-SC Ti (Figure 1) is a stand-alone interbody fusion device intended for the cervical spine (C2-T1) in patients with degenerative disc diseases. The Fortilink-SC Ti is composed out of a cage/wedge, two screws and a retainer. The Fortilink-SC Ti interbody fusion devices are manufactured with SLM (selective laser melting) and are built up from implant grade titanium alloy (Ti6Al4V). The Fortilink-SC Ti has an open mesh structure and a bone window both designed to allow bone ingrowth and facilitate fusion. The box-shaped design is intended to provide primary stability and increase the intervertebral height and lordosis. The screws provide primary stability to facilitate fusion and supplemental fixation is therefore not required. The retainer locks the screws. Both the screws and the retainer are made from titanium alloy.

The Fortilink-SC Ti will be used in combination with:

- Dedicated instrument set (see surgical technique for Catalog Instruments)
- General instruments typically used in spinal surgery (including rongeurs, forceps)

Further copies of the surgical technique and instructions for use can be requested at Paradigm Spine GmbH.

INTENDED PURPOSE

The Fortilink-SC Ti is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two levels from C2 to T1. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and is implanted via an anterior approach. Implants must be used with two of the provided bone screws. This system is to be used in patients who have had six weeks of non-operative treatment.

CLINICAL BENEFITS

The following benefits to the patient are intended to be achieved with the Fortilink-SC Ti:

- Decrease neck pain, as assessed using the Visual Analogue Scale (VAS)
- Clinical improvement, as assessed using the Neck Disability Index (NDI) and the Japanese Orthopaedic Association (JOA)
- Facilitate fusion, assessed by fusion rates in radiological follow-up images
- Increase in intervertebral height, as measured by increase in post-operative disc height on radiological imaging
- Increase in lordosis, as measured by increase in post-operative lordosis on radiological imaging

INDICATIONS

- Degenerative disc disease. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Stenosis

CONTRAINDICATIONS

- Active systemic infection or an active infection at the operative site
- A demonstrated allergy or sensitivity to any of the implant materials
- Severe osteoporosis
- Primary or metastatic tumors affecting the spine
- Conditions that may place excessive stresses on bones and the implants, including but not limited to morbid obesity, or other degenerative diseases
- Patients whose ability to follow postoperative restrictions, precautions and rehabilitation programs is limited

- Fractures, severe deformities or a severe instability in the area of surgery
- A medical or surgical situation that would preclude the benefit of surgery
- Pregnancy

STERILITY

The implant is delivered sterile packed. The devices are sterilized by irradiation. Do not re-use or re-sterilize the implants in this system, as adequate mechanical performance, biocompatibility and sterility cannot be guaranteed.

MATERIAL SPECIFICATION

The implants are manufactured from implant grade titanium alloy Ti6Al4V ELI (ASTM F3001).

The screws and retainers are made of implant grade titanium alloy Ti6Al4V ELI (ASTM F136).

SYSTEM OVERVIEW

Interbody fusion devices

The Fortilink-SC Ti interbody fusion devices come in a broad range of heights (6 - 10mm) and are available in three footprints (anterior width x depth).



Figure 2

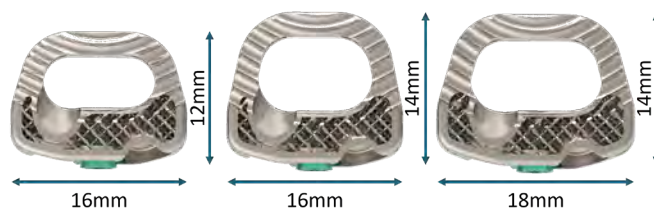


Figure 3

Screws

Self-drilling and self-tapping screws are available.

Diameters:

- 3.4mm self-drilling
- 3.4mm self-tapping
- 3.9mm self-tapping rescue

Lengths:

- 12, 14, and 16mm

Design:

- Screw thread designed for optimal bone purchase and tactile feedback from insertion to final seating
- Aggressive tip designs provide for rapid bone purchase
- Screw lengths correspond to posterior edge of implant when fully seated



Figure 4

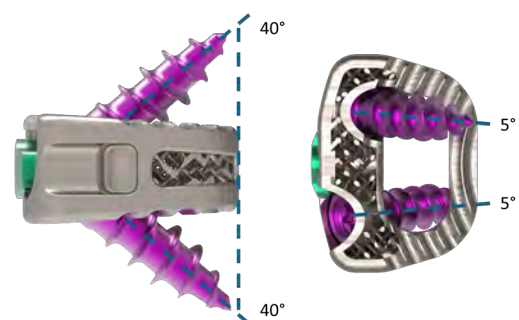


Figure 5

Screw angulation

- Cephalad/caudal: 40°
- Medial: 5°

1 SURGICAL EXPOSURE

Perform the standard ACDF approach and retract the tissues using appropriate instrumentation. Retract the trachea, esophagus and carotid artery in order to clearly see the vertebral bodies and discs.



INSTRUMENTS

Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome. Surgeons must verify that the instruments are in good condition and in operating order prior to use during surgery.



CLEANING AND 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 the distributor.

2 LEVEL CONFIRMATION



LEVEL CONFIRMATION

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

3 DISTRACTOR PINS

If desired, insert distractor pins into the superior and inferior vertebral bodies surrounding the surgical level.

Distractor pins should be placed in the midline of the vertebral bodies so that interbody fusion device insertion remains unobstructed.

DISCECTOMY AND ENDPLATE PREPARATION

Perform a complete discectomy using appropriate instrumentation. A rasp can be used 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.



DISC SPACE PREPARATION

Care should be taken to avoid pushing the shaver too far in the interspace and cutting through the annulus.

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.



ENDPLATE PREPARATION

Appropriate removal of the cartilaginous layers of the endplates is important for the vascularization of the bone graft. However, make sure to clean the endplates carefully and maintain the integrity of the underlying bony endplate, as damage of the endplate can lead to implant subsidence.

5 IMPLANT SELECTION

Trial spacers are available to provide guidance prior to implant selection. Trials are sized line to line (footprint, height and lordosis) with the corresponding interbody fusion device (Figure 6). For an overview of the available trial spacers, see 'Catalog instruments'.

The trials do not have a positive stop to contact the anterior face of the vertebral bodies so fluoroscopy should be used to verify proper depth position.



SIZE SELECTION

Select the trial spacer that adequately fills the disc space and provides restoration of disc height. The trial should require minimal force to insert, yet fit snugly within the disc space. Trials have a metal cap that may be used for light tapping with a mallet so it is flush with the anterior surface of the adjacent vertebral bodies and fits appropriately. Sequentially increase the trial spacer size until the appropriate height is determined. Using the trial as a guide, verify that appropriate height restoration is achieved with lateral fluoroscopy.

Using an implant smaller or larger than the size trialed could lead to implant failure.

Preoperative planning and patient anatomy should be considered when selecting implant size and supplemental internal fixation. The physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the device.

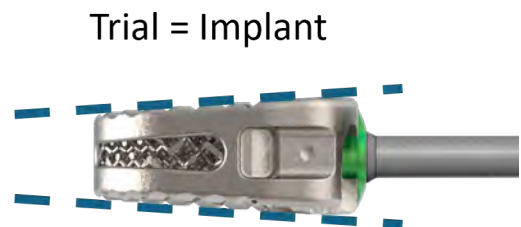


Figure 6

6

IMPLANT INSERTER ASSEMBLY

The Fortilink-SC System has two implant inserter options: a guided option with integrated guide tubes described below and a non-guided option without guide tubes described in the Non-Guided Technique (Optional) section.

The inserter guide shafts correspond to the interbody fusion device heights. Choose the appropriate inserter guide shaft that corresponds to the height of the implant selected.

Squeeze the tips of the inserter guide shaft (78-INSERTGUIDE-X, see Catalog instruments) together and insert into the implant inserter handle (78-INSERT-HANDLE, see Catalog instruments) until the posts insert into the window (Figure 7). The fully assembled instrument is the guided implant inserter.

The inserter guide shaft can be assembled to the implant inserter handle in a cephalad or caudal orientation.

Do not thread the inserter guide shaft into implant inserter handle until the interbody fusion device is ready to be attached.

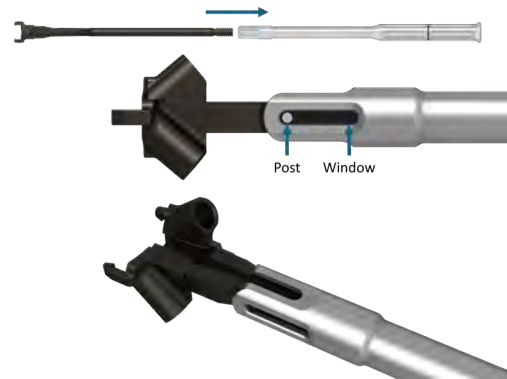


Figure 7

7 IMPLANT ATTACHMENT

Before assembling the implant to the inserter, confirm that the matching height inserter guide shaft is assembled to the implant inserter handle. The inserter guide shaft height is visibly etched near the distal tip adjacent to the guide tube. Attach the interbody fusion device to the implant inserter by aligning the implant inserter prongs with the interbody fusion device's lateral recesses and advance the interbody fusion device towards the implant inserter until fully seated (Figure 8).

The interbody fusion device can be attached to the implant inserter in a cephalad or caudal orientation.

While maintaining pressure on the interbody fusion device, turn the silver knob on the implant inserter clockwise until it is fully tightened (Figure 9). Check to make sure the interbody fusion device is securely locked onto the implant inserter.

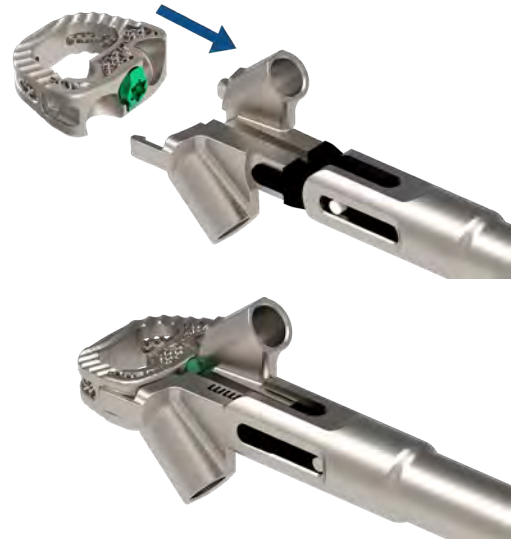


Figure 8



Figure 9

8 IMPLANT PREPARATION

The Fortilink-SC implant is to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Load the bone graft material within interbody fusion device graft window.

9 IMPLANT INSERTION

Insert the interbody fusion device into the prepared level by lightly tapping on the end of the implant inserter with a mallet until the implant inserter makes contact with the anterior surface of the vertebral body/bodies (Figure 10). Verify proper implant positioning using direct visualization and lateral fluoroscopy.

The guided implant inserter should remain attached until screw insertion is complete.



IMPLANT PLACEMENT

The cage has teeth to maximize primary stability, however make sure the soft tissue and dura are adequately retracted when inserting the implant to avoid damage from contact with the cage (in particular the teeth). Adequate implant positioning is critical; an improperly placed implant can adversely affect device performance or surgical outcome.



REMOVE DISTRACTOR PINS

Once the interbody fusion device is inserted to final position, remove distractor pins to ensure that pins do not interfere with implant screws during screw insertion.

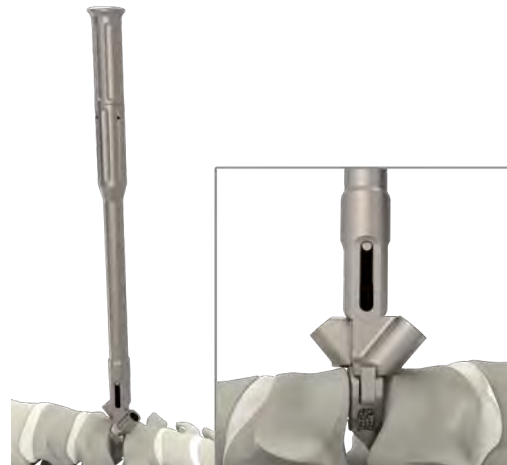


Figure 10

10

SCREW HOLE PREPARATION

The Fortilink-SC System offers the following screw hole preparation instruments: a guided awl or guided drill. When access is challenging, the angled awl and angled drill (Step 11, “Angled screw hole preparation (optional)”) may be used. For an overview of the available instruments, see ‘Catalog instruments’.

Insert the guided awl or guided drill through the guided implant inserter and advance the awl or drill so that it penetrates the cortex of the vertebral body (Figure 11). Continue to advance the awl or drill until the positive internal stop is felt.



SCREW HOLE PREPARATION

The guided awl, guided drill, angled awl and angled drill must be used with the guided implant inserter.

The guided awl has a metal cap for light tapping with a mallet.

The guided awl and guided drill have a positive internal stop that corresponds to the 12mm screw length when used with the guided implant inserter.

Be careful not to over impact the screw hole as this could displace the interbody fusion device.

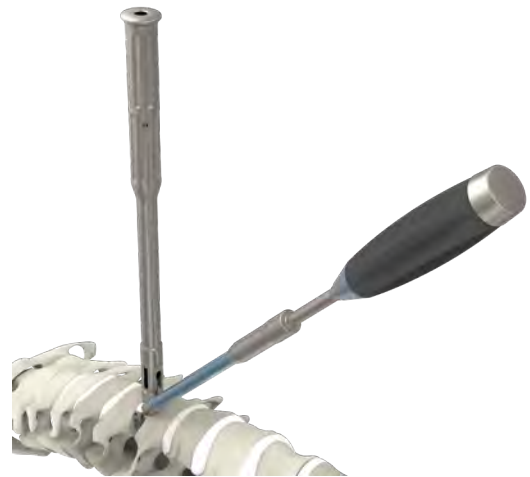


Figure 11

11 ANGLED SCREW HOLE PREPARATION (OPTIONAL)

Insert the angled awl or angled drill through the guided implant inserter and advance the awl or drill so that it penetrates the cortex of the vertebral body. Continue to advance the awl or drill until the positive internal stop is felt and indicated on the instruments (Figure 12).

The angled awl has a metal cap for light tapping with a mallet.

The angled awl and angled drill have a positive stop that corresponds to the 12mm screw length when used with the guided implant inserter.

If desired, the angled instrument stabilization handle can be attached to the angled awl, angled drill or angled screw driver to better control the tip of the instruments for screw hole preparation and screw insertion. The handle can be attached at a 0, 90, 180 or 270-degree angle. To attach, press the button on the angled instrument stabilization handle and insert the fork of the stabilization handle into the shaft of the angled instrument near the recess on the distal end of the handle (Figure 13). To release, press the button on the angled instrument stabilization handle to detach from the angled instrument.

Angled instrument stabilization handle should be assembled to angled awl, angled drill, and/or angled screw driver prior to being introduced into the guided implant inserter.

The angled instrument stabilization handle optimally attaches to angled instruments in 180-degree orientation away from angled instrument tip (Figure 14).



Figure 12

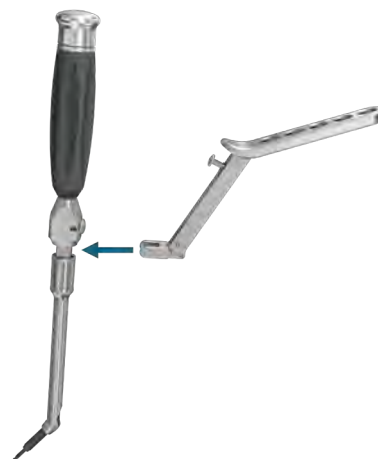


Figure 13



Figure 14

12 SCREW INSERTION

The Fortilink-SC System offers the following instruments for screw insertion: locking screw driver and angled (stab-and-grab) screw driver (Step 13, “Screw insertion with angled screw driver (optional)”). For an overview of the available instruments, see ‘Catalog instruments’. Select the desired screw driver, screw type and length.

A screw final tightener is also available for making minor screw adjustments prior to final locking the interbody fusion device, see ‘Catalog instruments’.

The screw final tightener does not have a screw retention feature and is not recommended for screw insertion.



SCREW SIZE

Screw lengths have been designed to correspond with the equivalent interbody implant depth so that the screws do not go beyond the posterior edge of the interbody fusion device.

Locking Screw Driver

Turn the locking screw driver knob counterclockwise until it no longer turns and is capable of engaging the screw drive pocket. Insert the tip of the locking screw driver into the screw drive pocket until it is fully seated and then rotate the knob clockwise until fully tightened and the screw is secured to the locking screw driver (Figure 16).

If use of the angled screw driver is desired, please refer to Step 13, “Screw insertion with angled screw driver (optional)” for the next steps.

Insert the screw driver with screw through the guided implant inserter until the screw tip engages the pilot hole (Figure 17). Using a three-finger technique, turn the screw driver clockwise to advance the screw along the path of the pilot hole. The screw is near the fully seated position once the silver line on the screw driver reaches the proximal end of the guide tube (Figure 18).



Figure 15



Figure 16



Figure 17

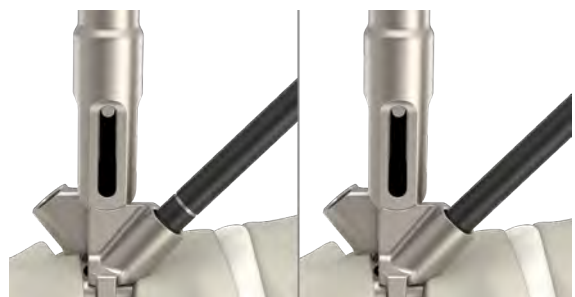


Figure 18

- 12 Fully seat the screw until you feel the bottom of the screw head contact the base of the screw hole pocket, being careful not to use excessive force. Confirm proper placement using fluoroscopy.



SCREW TIGHTENING

Do not overtighten the screws as it may strip in the bone. Should the screw strip, remove and replace it with the larger diameter rescue screw.

If using the locking screw driver, rotate the locking screw driver knob counterclockwise until the knob no longer turns and is able to be freely removed from the screw.

For the other screw hole, repeat the screw hole preparation steps as described in Step 10, "Screw hole preparation".

After the pilot hole is created, repeat the screw insertion steps listed above.

After both screws have been inserted into the interbody Wusion device, remove the guided implant inserter by rotating the knob counterclockwise until it spins freely and can detach from the interbody fusion device.

If difficulties exist in removing the guided implant inserter from the interbody fusion device, a circular motion can be applied to the proximal end of the inserter handle to aid in removal of the instrument from interbody fusion device.

13 SCREW INSERTION WITH ANGLED SCREW DRIVER (OPTIONAL)

Select the desired screw type and proper length. Screw lengths have been designed to correspond with the equivalent interbody implant depth so that the screws do not go beyond the posterior edge of the interbody fusion device.

Fully insert the tip of the angled screw driver into the drive pocket of the screw. There may be tactile/audible feedback once the screw is secured to the screw driver (Figure 19).



SCREW SEATING

Confirm screw is securely connected to screw driver by gently pulling on the screw. Push screw back on so it is fully seated and co axial with the screw driver.

If a second angled screw driver is desired, follow the steps below.

1. Disassemble the angled drill by pressing release button and sliding the external shaft of the angled driver away from the handle far enough for the angled drill bit to be removed (Figure 20).
2. Remove the angled drill bit from the external shaft of the angled driver (Figure 21).
3. Insert additional angled screw driver bit into external shaft of the angled driver until positive stop is felt (Figure 22).
4. Slide external shaft of the angled driver towards handle until positive stop is felt. There may be tactile/audible feedback as the release button re-engages the shaft (Figure 23).
5. Test that the external shaft is secured to the internal shaft by pulling it away from the handle, ensuring that it remains in place. At the same time, turn the handle clockwise to test that the angled screw driver bit turns with the handle.

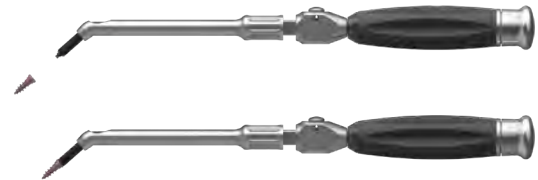


Figure 19

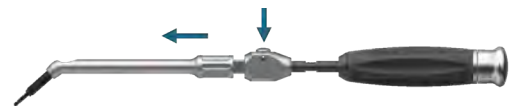


Figure 20



Figure 21



Figure 22



Figure 23

- 13** Insert the angled screw driver with screw through the guided implant inserter until the screw tip engages the pilot hole. Using a three-finger technique, turn the angled screw driver clockwise to advance the screw along the path of the pilot hole (Figure 24). As shown below, the screw is near the fully seated position when the angled screw driver external shaft nears the proximal end of the guide tube (Figure 25). Fully seat the screw until you feel the bottom of the screw head contact the base of the screw hole pocket, being careful not to use excessive force. Confirm proper placement using fluoroscopy.



Figure 24



SCREW TIGHTENING

Do not overtighten the screws as it may strip in the bone. Should the screw strip, remove and replace it with the larger diameter rescue screw.

Release the angled screw driver from the screw by applying downward pressure to the guided implant inserter while simultaneously pulling the angled screw driver up.

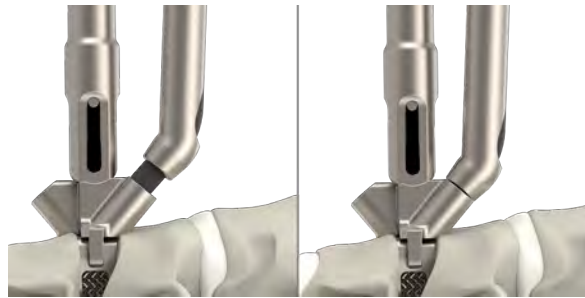


Figure 25

For the other screw hole, repeat the screw hole preparation steps as described in Step 10, “Screw hole preparation”.

After the pilot hole is created, repeat the screw insertion steps listed above.

After both screws have been inserted into the interbody fusion device, remove the guided implant inserter by rotating the knob counterclockwise until it spins freely and can detach from the interbody fusion device.



Figure 26

If difficulties exist in removing the guided implant inserter from the interbody fusion device, a circular motion can be applied to the proximal end of the inserter handle to aid in removal of the instrument from interbody fusion device.

If screws appear to not be fully seated, any of the screw drivers may be used to fully seat the screws, however, the screw final tightener is preferred as it has a non-retention feature for quick engagement into the screw drive pocket. The screw final tightener can be used with or without the guided implant inserter (Figure 26).

14 FINAL LOCK INTERBODY FUSION DEVICE

Engage the tip of the final locker until the hexalobe engages and seats into the locking mechanism of the interbody fusion device. Tactile feedback should occur once the final locker is completely engaged (Figure 27).

Using a three-finger technique, rotate the final locker 90 degrees counterclockwise until the positive stop is felt (Figure 28).



Figure 27



FINAL LOCKING

Do not overtighten locking mechanism beyond the positive stop as it will damage the interbody fusion device. If you do, remove the screws and interbody from the patient and discard. Replace with a new interbody fusion device and screws.

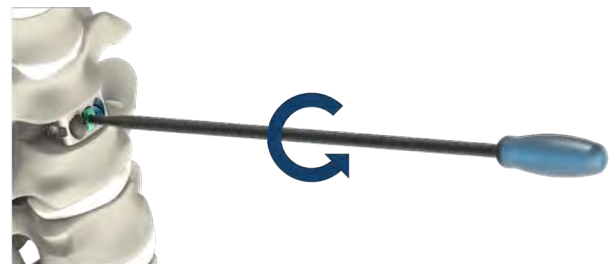


Figure 28

15 CONFIRM FINAL LOCKING



CONFIRM FINAL LOCKING

Visually confirm that screws are covered by the locking mechanism on the interbody fusion device (Figure 29).

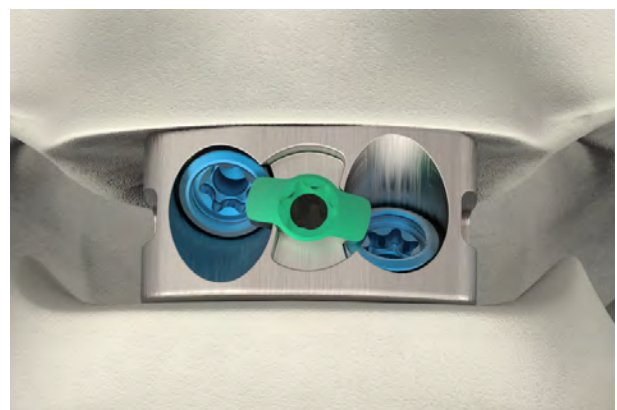


Figure 29

16 RADIOGRAPHIC VERIFICATION AND CLOSURE



RADIOGRAPHIC VERIFICATION

Verify the final implant placement with anterior/posterior and lateral fluoroscopy images.



CLOSING

Verify all instruments and any extra implants not intended to be implanted are removed from the patient before closing the surgical site.

17 SCREW REMOVAL (IF NECESSARY)

If it is necessary to remove a screw, engage the tip of the final locker until the hexalobe engages and seats into the locking mechanism of the interbody fusion device. Tactile feedback should occur once the final locker is completely engaged (Figure 30).

Rotate the final locker handle 90 degrees clockwise until the positive stop is felt. The screws are now uncovered. Remove the final locker (Figure 31).

The angled or locking screw driver can be used to remove the screw. If using the angled screw driver, fully insert the tip of the angled screw driver into the drive pocket of the screw. There may be tactile/audible feedback once the screw is secured to the angled screw driver.

If using the locking screw driver, turn the locking screw driver knob counterclockwise until it no longer turns and is capable of engaging the screw driver pocket. Insert the tip of the locking screw driver into the screw drive pocket until it is fully seated and rotate the knob clockwise until fully tightened and the screw is secured to the locking screw driver.

Once the desired screw driver has fully engaged the screw, rotate the handle counterclockwise and remove the screw. Replace the screw with the larger diameter rescue screw following the procedure described in Step 12, "Screw insertion" for guided screw insertion or following the screw insertion procedure described in Step 19, "Non-Guided Technique (Optional)" section. If removing the interbody fusion device, proceed with removing the second screw and then the interbody fusion device. The procedure for removing the interbody fusion device is described next.

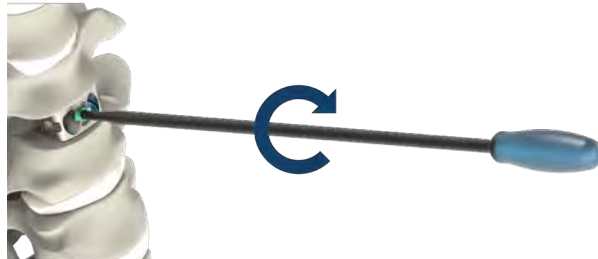


Figure 30



Figure 31

18 IMPLANT REMOVAL (IF NECESSARY)

The interbody fusion device may be removed once the screws are removed.

Discard the removed interbody fusion device and screws. If a new interbody fusion device is to be inserted, please follow the previous instructions.



SINGLE USE ONLY

Do not re-use or re-sterilize the implants in this system, as adequate mechanical performance, biocompatibility and sterility cannot be guaranteed.

19 NON-GUIDED TECHNIQUE (OPTIONAL)

The Fortilink-SC System offers instruments for a non-guided technique to allow for interbody fusion device insertion as well as screw hole preparation, see 'Catalog instruments'. Surgical technique Steps 1 - 5 remain the same regardless of using a guided or non-guided technique.

Implant Inserter Assembly

The inserter shaft (no guide tubes) is compatible with all implant heights. Squeeze the tips of the inserter shaft (78-INSERT-SHAFT) together and insert into the implant inserter handle (78-INSERT-HANDLE) until the posts insert into the window (Figure 32). The fully assembled instrument is the non-guided implant inserter (Figure 33).

The inserter shaft can be assembled to the implant inserter handle in a cephalad or caudal orientation.

Do not thread the inserter shaft into implant inserter handle until the interbody fusion device is ready to be attached.

Follow the standard instructions for Step 7, "Implant attachment", and Step 8, "Implant preparation".

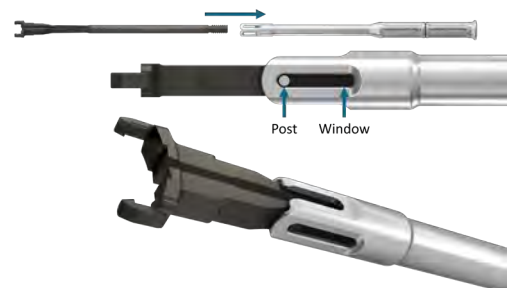


Figure 32

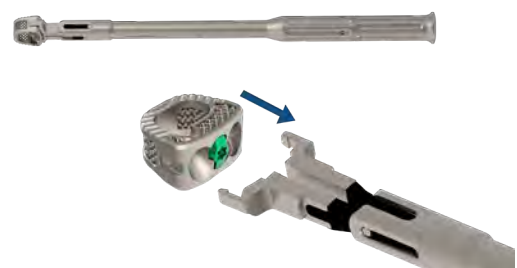


Figure 33

19 Interbody Fusion Device Insertion

Insert the interbody fusion device in the prepared level by lightly tapping on the end of the non-guided implant inserter with a mallet until the interbody fusion device is inserted to desired placement (Figure 34). Verify proper implant positioning using direct visualization and lateral fluoroscopy.

The non-guided implant inserter does not contain positive stops and should be monitored closely with direct visualization and lateral fluoroscopy during interbody fusion device insertion to ensure that it is not placed too posteriorly, resulting in difficulty to insert screws. Inserting the interbody fusion device beyond the anterior surfaces of the vertebral bodies is not recommended.

Remove the non-guided implant inserter by rotating the silver knob counterclockwise until it freely spins and is able to detach from the interbody fusion device.

If difficulties exist in removing the non-guided implant inserter from the interbody fusion device, a circular motion can be applied to the proximal end of the inserter handle to aid in removal of the instrument from interbody fusion device.

Non-Guided Screw Hole Preparation

The guided awl and guided drill can be used without the implant inserter. Insert the guided awl or guided drill directly into the interbody fusion device screw hole and advance so that the tip penetrates the cortex of the vertebral body. Continue to advance the guided awl or guided drill until the positive internal stop is felt (Figure 35).

The guided awl has a metal cap for light tapping with a mallet. Be careful not to over-impact the screw hole as this could displace the interbody fusion device during screw hole preparation.

The guided awl and guided drill each contain a positive internal stop that corresponds to the 12mm screw length.



Figure 34

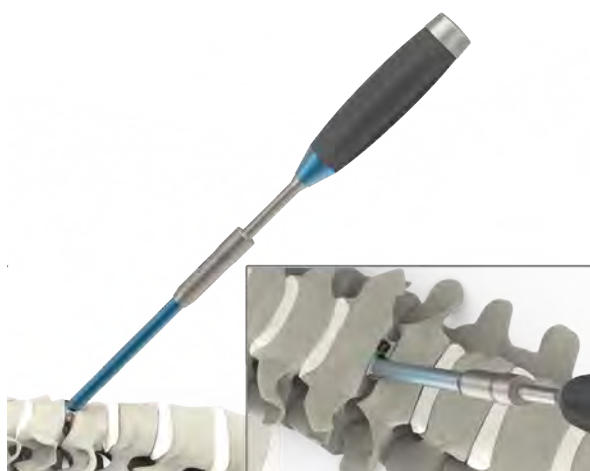


Figure 35

19 Screw Insertion

Select the desired screw driver and attach the screw as prescribed in Step 12, “Screw insertion”.

Screw lengths have been designed to correspond with the equivalent interbody implant depth so that the screws do not go beyond the posterior edge of the interbody fusion device.

Insert the screw driver with screw directly into the interbody fusion device screw hole until the screw tip engages the pilot hole (Figure 36). Turn the screw driver clockwise to advance the screw along the path of the pilot hole. Fully seat the screw until you feel the bottom of the screw head contact the base of the screw hole pocket, being careful not to use excessive force (Figure 37). Confirm proper placement using fluoroscopy.



SCREW TIGHTENING

Do not overtighten the screws as it may strip in the bone. Should the screw strip, remove and replace it with the larger diameter rescue screw.

Release the screw driver from the screw as prescribed in Step 12, “Screw insertion.” For the other screw hole, repeat the screw hole preparation steps as described above. After the pilot hole is created, repeat the screw insertion steps listed above.

Resume the standard surgical technique Steps 14 - 16 to complete the procedure.

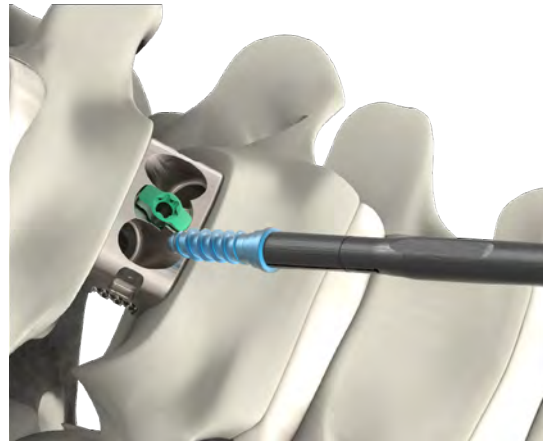


Figure 36

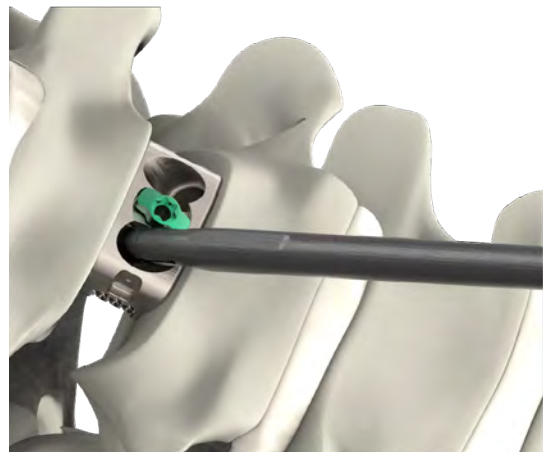


Figure 37

INSTRUMENT DISASSEMBLY/REASSEMBLY

There are some Fortilink-SC instruments which require disassembly prior to cleaning. Below, please find instructions on how to disassemble these instruments prior to cleaning. They should be reassembled prior to sterilization in the provided sterilization case.

Implant Inserter (78-INSERTGUIDE-X or 78-INSERT-SHAFT, 78-INSERT-HANDLE)

Note: X = 6 - 10mm, 1mm increments

- Disassembly: Turn the silver knob on the implant inserter counterclockwise until the inserter guide shaft or inserter shaft is able to fully disengage from the handle. Squeeze the inserter guide shaft or inserter shaft together adjacent to the posts so the posts can clear the opening/window on the inserter handle and be removed from the inserter handle (Figure 38).

Note: The inserter guide shaft, inserter shaft and implant inserter handle are stored separately in the sterilization case.



Figure 38

GUIDED AWL (78-GUIDEDAWL)

- Disassembly: Rotate the outer sleeve (A) of the guided awl counterclockwise until it can be removed from handle. Slide outer housing (B – light green sleeve) off of preassembled shaft (Figure 39).
- Reassembly: Slide outer housing labeled “Guided Awl” (B – light green sleeve) over preassembled shaft until it reaches positive stop. Repeat action for outer sleeve (A) and rotate clockwise until tightened and handle becomes one piece.

GUIDED DRILL (78-GUIDEDDRILL)

- Disassembly: Rotate the outer sleeve (A) of the guided drill counterclockwise until it can be removed from handle. Slide outer housing (B – dark green sleeve) off of preassembled shaft (Figure 40).
- Reassembly: Slide outer housing labeled “Guided Drill” (B – dark green sleeve) over preassembled shaft until it reaches positive stop. Repeat action for outer sleeve (A) and rotate clockwise until tightened and handle becomes one piece.

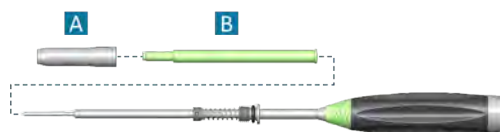


Figure 39

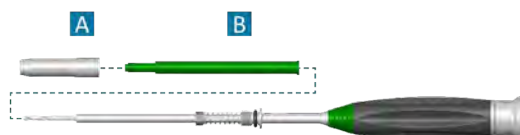


Figure 40

ANGLED DRILL/SCREW DRIVER (78-ANG-DRILL, 78-ANG-SCREWDRIVER, AND 78-ANG-DRIVER)

- Disassembly: With the release button (A) facing upward, press and hold the release button and slide the external shaft of the angled driver (B) away from the handle far enough for the angled drill or angled screw driver bits (C) to be removed proximally from the external shaft of the angled screw driver. Once the bit is removed, press and hold the release button and continue to slide the external shaft of the angled driver distally until it separates from the angled driver handle (D) (Figure 41).
- Reassembly: Connect the external shaft of the angled driver (B) to the distal end of the angled driver handle (D) with the release button (A) facing upward and slide towards the handle. Do not slide the external shaft of the angled driver completely back to the positive stop. Place the angled drill or angled screw driver bits (C) through the external shaft of the angled driver until it reaches the positive stop. Slide the external shaft of the angled driver all the way to the handle until it comes to a stop on the angled driver handle. There may be tactile/audible feedback as the release button re-engages the shaft. Test that the external shaft of the angled driver is locked to the angled driver handle by pulling it away from the handle, ensuring that it remains assembled as one piece. At the same time, turn the handle to test that the angled drill or angled screw driver bits turn with the handle.

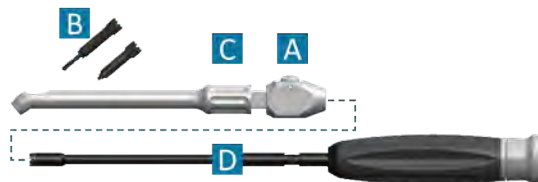


Figure 41

SCREW DRIVER, LOCKING (78-SCREWDRIVER-LKG)

- Disassembly: Stabilize the instrument by laying it on a flat surface with the recessed button (A) facing upward. Rotate the silver knob (B) counterclockwise until it stops. Using the screw final tightener (C), depress and hold the recessed button and continue rotating the silver knob counterclockwise until the draw rod (D) is sticking out of the handle approximately one-fourth of an inch. Release the button. Remove the draw rod proximally through the handle and remove the silver knob from the locking screw driver (Figure 42).

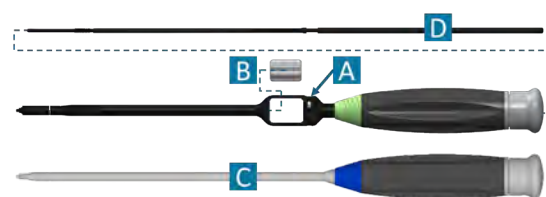


Figure 42

- **Reassembly:** Stabilize the instrument by laying it on a flat surface with the recessed button (A) facing upward. Place the silver knob (B) into the locking screw driver; it can be oriented in either direction. Insert the draw rod (D) into the handle, with the thread portion pointed distally ensuring that it passes through the silver knob. Using the screw final tightener (C), depress and hold the recessed button and advance the draw rod until it stops; it should stick out approximately one-fourth of an inch from the handle. Rotate the silver knob clockwise until the draw rod is near flush with the handle cap.

CAUTION: Do not fully tighten the silver knob during reassembly. Doing so without a screw attached can lead to damaging the instrument.






STERILE CAGE IMPLANTS










Part No.	Description	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)
78-C-1612-06-7L	Fortilink-SC Ti 16x12x06-7L	16	12	6	7
78-C-1612-07-7L	Fortilink-SC Ti 16x12x07-7L	16	12	7	7
78-C-1612-08-7L	Fortilink-SC Ti 16x12x08-7L	16	12	8	7
78-C-1612-09-7L	Fortilink-SC Ti 16x12x09-7L	16	12	9	7
78-C-1612-10-7L	Fortilink-SC Ti 16x12x10-7L	16	12	10	7
78-C-1614-06-7L	Fortilink-SC Ti 16x14x06-7L	16	14	6	7
78-C-1614-07-7L	Fortilink-SC Ti 16x14x07-7L	16	14	7	7
78-C-1614-08-7L	Fortilink-SC Ti 16x14x08-7L	16	14	8	7
78-C-1614-09-7L	Fortilink-SC Ti 16x14x09-7L	16	14	9	7
78-C-1614-10-7L	Fortilink-SC Ti 16x14x10-7L	16	14	10	7
78-C-1814-06-7L	Fortilink-SC Ti 18x14x06-7L	18	14	6	7
78-C-1814-07-7L	Fortilink-SC Ti 18x14x07-7L	18	14	7	7
78-C-1814-08-7L	Fortilink-SC Ti 18x14x08-7L	18	14	8	7
78-C-1814-09-7L	Fortilink-SC Ti 18x14x09-7L	18	14	9	7
78-C-1814-10-7L	Fortilink-SC Ti 18x14x10-7L	18	14	10	7

STERILE SCREW IMPLANTS

Part No.	Description	Diameter (mm)	Length (mm)
78-34-SD-12	Fortilink-SC Ti Self-Drilling Screw 3,4x12	3.4	12
78-34-SD-14	Fortilink-SC Ti Self-Drilling Screw 3,4x14	3.4	14
78-34-SD-16	Fortilink-SC Ti Self-Drilling Screw 3,4x16	3.4	16
78-34-ST-12	Fortilink-SC Ti Self-Tapping Screw 3,4x12	3.4	12
78-34-ST-14	Fortilink-SC Ti Self-Tapping Screw 3,4x14	3.4	14
78-34-ST-16	Fortilink-SC Ti Self-Tapping Screw 3,4x16	3.4	16
78-39-ST-12	Fortilink-SC Ti Self-Tapping Rescue Screw 3,9x12	3.9	12
78-39-ST-14	Fortilink-SC Ti Self-Tapping Rescue Screw 3,9x14	3.9	14
78-39-ST-16	Fortilink-SC Ti Self-Tapping Rescue Screw 3,9x16	3.9	16

CATALOG INSTRUMENTS

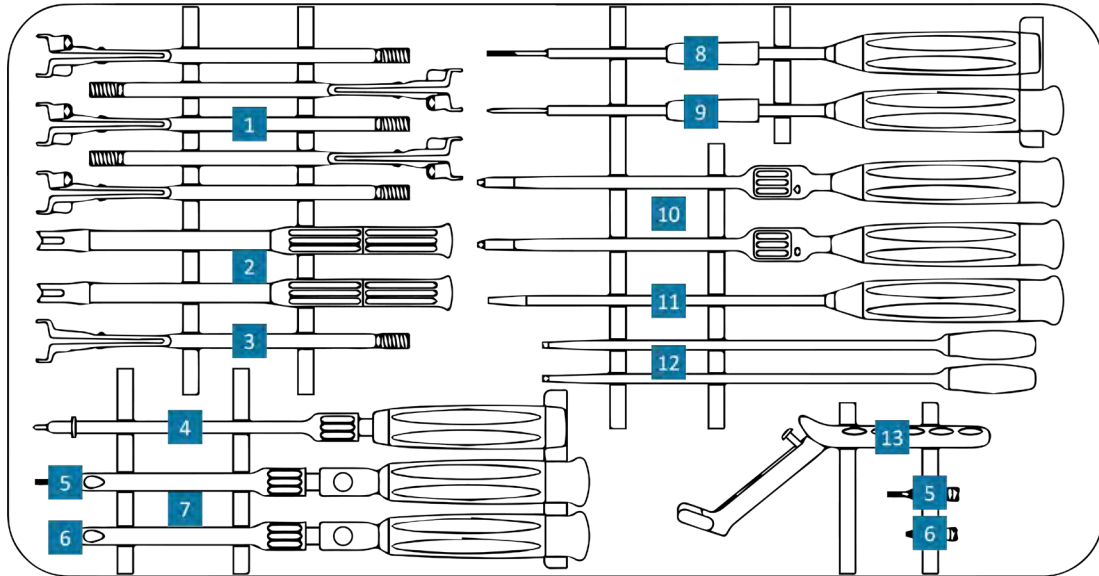
Part No.	Description	Image
78-TR-1612-6-7L	Trial, 16 W x 12 D x 6 H x 7 L	
78-TR-1612-7-7L	Trial, 16 W x 12 D x 7 H x 7 L	
78-TR-1612-8-7L	Trial, 16 W x 12 D x 8 H x 7 L	
78-TR-1612-9-7L	Trial, 16 W x 12 D x 9 H x 7 L	
78-TR-1612-10-7L	Trial, 16 W x 12 D x 10 H x 7 L	
78-TR-1614-6-7L	Trial, 16 W x 14 D x 6 H x 7 L	
78-TR-1614-7-7L	Trial, 16 W x 14 D x 7 H x 7 L	
78-TR-1614-8-7L	Trial, 16 W x 14 D x 8 H x 7 L	
78-TR-1614-9-7L	Trial, 16 W x 14 D x 9 H x 7 L	
78-TR-1614-10-7L	Trial, 16 W x 14 D x 10 H x 7 L	
78-TR-1814-6-7L	Trial, 18 W x 14 D x 6 H x 7 L	
78-TR-1814-7-7L	Trial, 18 W x 14 D x 7 H x 7 L	
78-TR-1814-8-7L	Trial, 18 W x 14 D x 8 H x 7 L	
78-TR-1814-9-7L	Trial, 18 W x 14 D x 9 H x 7 L	
78-TR-1814-10-7L	Trial, 18 W x 14 D x 10 H x 7 L	
78-INSERTGUIDE-6	Inserter Guide Shaft (6mm)	
78-INSERTGUIDE-7	Inserter Guide Shaft (7mm)	
78-INSERTGUIDE-8	Inserter Guide Shaft (8mm)	
78-INSERTGUIDE-9	Inserter Guide Shaft (9mm)	
78-INSERTGUIDE-10	Inserter Guide Shaft (10mm)	
78-INSERT-SHAFT	Implant Inserter Shaft	
78-INSERT-HANDLE	Implant Inserter Handle	
78-GUIDEDAWL	Guided Awl, 12mm	

Part No.	Description	Image
78-GUIDEDDRILL	Guided Drill, 12mm	
78-SCREWDRIVER-LKG	Screw Driver, Locking	
78-SCREWTIGHTENER	Screw Final Tightener	
78-ANG-AWL	Angled Awl, 12mm	
78-ANG-DRIVER	Angled Driver	
78-ANG-DRILL	Angled Drill Bit, 12mm	
78-ANG-SCREWDRIVER	Angled Screw Driver Bit	
78-ANG-HANDLE	Angled Instrument Stabilization Handle	
78-LOCKER	Final Locker	
78-TRAY	Tray	See images below

CATALOG INSTRUMENTS

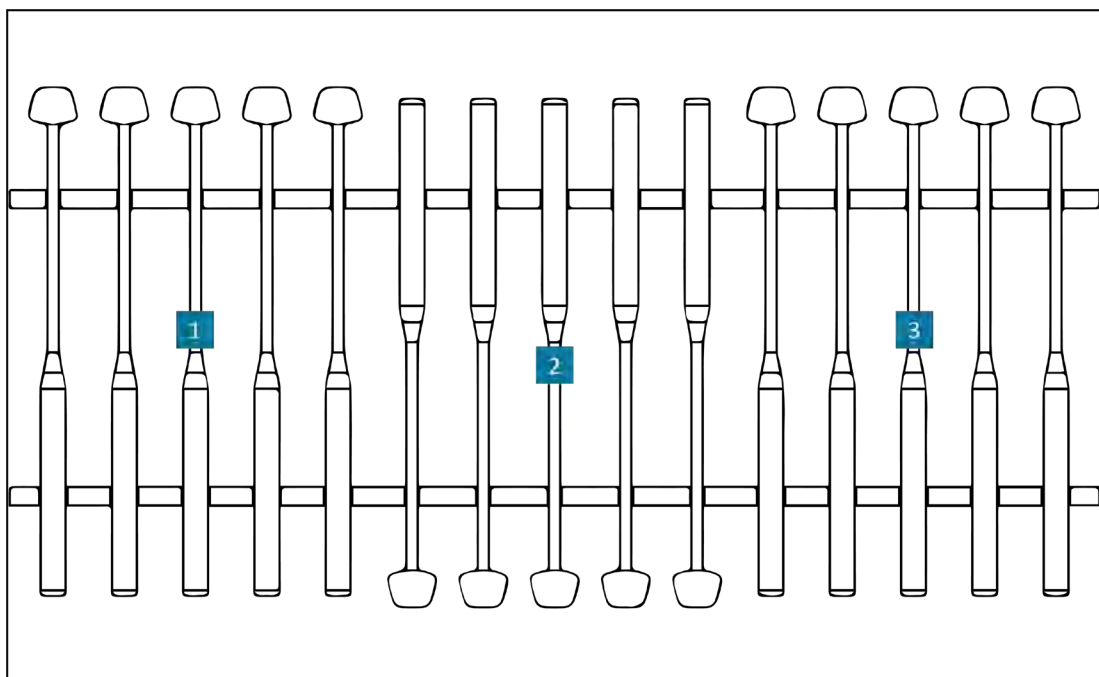
Bottom Tray Layout

1. Inserter Guide Shafts (6 – 10mm)	6. Angled Screw Driver Bit (2)	10. Screwdriver, locking (2)
2. Implant Inserter Handle (2)	7. Angled Driver	11. Screw Final Tightener
3. Implant Inserter Shaft	8. Guided Drill	12. Final Locker (2)
4. Angled Awl	9. Guided Awl	13. Angled Instrument Stabilization Handle
5. Angled Drill Bit (2)		



Top Tray Layout

1. 16 x 12mm Trials (5)	2. 16 x 14mm Trials (5)	3. 18 x 14mm Trials (5)
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WARNINGS AND PRECAUTIONS

INTENDED USERS

Prior to use the surgeon must become familiar with the device system and the surgical procedure. Use surgical instrumentation, accessories, and surgical technique guide provided with this device system. The implantation of the IBF device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

PATIENT EDUCATION

Preoperative

The patient should understand that stress on an implant could involve more than weight bearing. In the absence of solid bony union, patient weight alone, muscular forces associated with moving, or repeated stresses of apparent relatively small magnitude, can compromise the implant. Patients should be fully informed of these risks prior to and following surgery.

Postoperative

The surgeon should provide clear directions, warnings and must obtain verification of patient understanding for patient post-operative compliance.

- Partial- or non-weight bearing may be recommended or required to achieve firm bone union.
- Warn patient against smoking, consuming alcohol, and/or taking steroids, non-steroidal anti-inflammatory agents and aspirin or other drugs not prescribed by the physician.
- Warn patient against sudden changes in position, strenuous activity or falls that may cause additional injury and advice that the patient seek medical opinion before entering environments in which this might occur.
- Warn patient to consult the surgeon in the event of malfunction of the device or changes in its performance that may affect safety.
- If appropriate, restrict patient's mobility to allow bony union.
- If nonunion occurs, the surgeon may revise or remove the system.

READ THE INSTRUCTIONS

All users are expected to read the instructions for use that accompany all devices being utilized with these implants.

PATIENT SELECTION

- Avoid patients not meeting the criteria described in the indications.
- Avoid patients with conditions that may predispose to a possible poor result or adverse effect.

LEVEL CONFIRMATION

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

IMPACT RISK

No implant system can withstand the forces of sudden dynamic loads such as falls or other accidents.

SINGLE USE ONLY

Do not re-use or re-sterilize the implants in this system, as adequate mechanical performance, biocompatibility and sterility cannot be guaranteed.

MIXING WITH OTHER DEVICES

Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

INSTRUMENTS

Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome. Surgeons must verify that the instruments are in good condition and in operating order prior to use during surgery.

INSERTION INSTRUMENTS

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

CLEANING AND 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 the distributor.

PACKAGING INTEGRITY

Inspect the product, including all packaging and labeling materials carefully:

- Do not use past expiration date specified on the product label.
- Do not use if the implant or packaging is damaged or unintentionally opened before use.
- Do not use if there are discrepancies in label information.

DISC SPACE PREPARATION

Care should be taken to avoid pushing the shaver too far in the interspace and cutting through the annulus.

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.

ENDPLATE PREPARATION

Appropriate removal of the cartilaginous layers of the endplates is important for the vascularization of the bone graft. However, make sure to clean the endplates carefully and maintain the integrity of the underlying bony endplate, as damage of the endplate can lead to implant subsidence.

DISTRACTION

Adequate distraction is one of the preconditions for the primary stability of the implant; it is critical to ensure that the segment is not over distracted to avoid damage of ligaments and/or endplates.

SCREW SIZE

Screw lengths have been designed to correspond with the equivalent interbody implant depth so that the screws do not go beyond the posterior edge of the interbody fusion device.

SIZE SELECTION

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.

Using an implant smaller or larger than the size trialed could lead to implant failure.

Preoperative planning and patient anatomy should be considered when selecting implant size and supplemental internal fixation. The physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the device.

SIZE CORRESPONDANCE

The relation of the size of the trial spacers to the size of the implants must be taken into account.

PRODUCT AVAILABILITY

It must be ascertained that the implant is available in all sizes in the range that is appropriate for the patient before starting the procedure in order to make sure that the optimal size, which is determined intraoperatively with the trial sizers, will be available.

IMPLANT PLACEMENT

The cage has teeth to maximize primary stability, however make sure the soft tissue and dura are adequately retracted when inserting the implant to avoid damage from contact with the cage (in particular the teeth). Adequate implant positioning is critical; an improperly placed implant can adversely affect device performance or surgical outcome.

REMOVE DISTRATOR PINS

Once the interbody fusion device is inserted to final position, remove distractor pins to ensure that pins do not interfere with implant screws during screw insertion.

SCREW HOLE PREPARATION

The guided awl, guided drill, angled awl and angled drill must be used with the guided implant inserter. The guided awl has a metal cap for light tapping with a mallet.

The guided awl and guided drill have a positive internal stop that corresponds to the 12mm screw length when used with the guided implant inserter. Be careful not to over impact the screw hole as this could displace the interbody fusion device.

SCREW SEATING

Confirm screw is securely connected to screw driver by gently pulling on the screw. Push screw back on so it is fully seated and co axial with the screw driver.

SCREW TIGHTENING

Do not overtighten the screws as it may strip in the bone. Should the screw strip, remove and replace it with the larger diameter rescue screw.

FINAL LOCKING

Do not overtighten locking mechanism beyond the positive stop as it will damage the interbody fusion device. If you do, remove the screws and interbody from the patient and discard. Replace with a new interbody fusion device and screws.

CONFIRM FINAL LOCKING

Visually confirm that screws are covered by the locking mechanism on the interbody fusion device.

CLOSING

Verify all instruments and any extra implants not intended to be implanted are removed from the patient before closing the surgical site.

LOAD-BEARING

While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone.

These implants can break when subjected to the increased loading associated with delayed union or nonunion. Typically, internal fixation devices are load-sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, an implant could eventually break due to fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant.

EXPLANATION

After implantation of an interbody fusion device and identification of the presence of fusion, only the supplemental fixation components should be removed.

COMORBIDITIES

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

PREVIOUS SURGERY

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

INSTRUMENT WEAR

Instruments are subject to damage during use as well as long-term potentially damaging effects such as wear. Damage may result in significant risks to safety and/or inability to function as intended.

INSTRUMENT FRAGMENTS

If instruments are damaged or broken during use, metal fragments can be viewed by radiographic assessment. It is the surgeon's responsibility to carefully consider the risks and benefits of retrieving the fragments.

If the fragment is retained in the patient, it is recommended that the surgeon advise the patient of specific information regarding the fragment material, including size and location and the potential risks associated with the retained fragment.

IMPLANT HANDLING

Correct handling of the implant is extremely important. Alterations will produce internal stresses which may lead to eventual breakage of the implant. An explanted implant should never be re-implanted. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

RADIOGRAPHIC VERIFICATION

Verify the final implant placement with anterior/posterior and lateral fluoroscopy images.

DISPOSAL

The products must be disposed according local regulations.



MRI SAFETY INFORMATION

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial gradient magnetic field of 720-Gauss/cm (a higher value for the spatial gradient magnetic field may apply if properly calculated).
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (per pulse sequence).

RF Heating

In non-clinical testing, the device can produce a temperature rise of less than or equal to 6.0 degrees C using an MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15-minutes (per pulse sequence) of scanning in a 3-Tesla MR system.

The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

Artifact

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device. In all cases, the healthcare professional is responsible for the MR conditions, MR imaging quality and patient safety. Any safety issues or major image artefacts should be reported.

POTENTIAL ADVERSE EFFECTS

The same medical/surgical conditions or complications that apply to any surgical procedure may also occur during or following implantation of this device system. The surgeon is responsible for informing the patient of the potential risks associated with treatment, including complications and adverse reactions. The surgeon may need to perform additional surgery to address any complications or adverse reactions, which may or may not be device related.

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery include:

- Implant component fracture
- Migration, dislocation, or subsidence of the implant
- Loss of fixation
- Pseudoarthrosis (i.e., non-union)
- Fracture of the vertebra
- Neurological injury
- Cardiovascular complications
- Infection
- Allergic reaction
- Pulmonary embolism
- Pneumonia
- Adjacent segment disease
- Dysphagia
- Esophageal perforation
- Horner’s syndrome
- Heterotrophic ossification
- Bone erosion
- Epidural scarring



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