Surgical Technique

Fortilink®-SC

with TiPlus Technology

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1. Introduction

1.1. Device description

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 Catalogue 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 BAAT Medical Products BV.

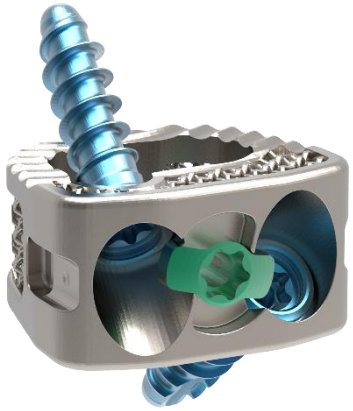

Figure 1. Fortilink®-SC with TiPlus Technology

1.2. 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.

1.3. 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

1.4. 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

1.5. 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

1.6. 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.

1.7. 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).

1.8. 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 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.
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.
EXPLANTATION 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.
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).      <u>RF Heating</u> 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. <u>Artifact</u> 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.
DISPOSAL The products must be disposed according local regulations.

1.9. 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

2. Surgical technique

2.1. 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.

2.2. Level confirmation

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

2.3. 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.

2.4. Discectomy and endplate preparation

Perform a complete discectomy using appropriate instrumentation. The 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.

2.5. 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 2*). For an overview of the available trial spacers, see 'Catalogue instruments'.

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.

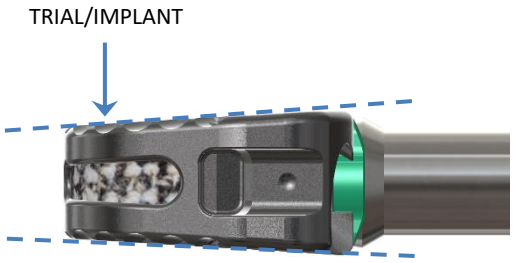

Figure 2

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.

2.6. 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 (64-INSERTGUIDE-X, see Catalogue instruments) together and insert into the implant inserter handle (64-INSERT-HANDLE, see Catalogue instruments) until the posts insert into the window (*Figure 3*). The fully assembled instrument is the guided implant inserter.

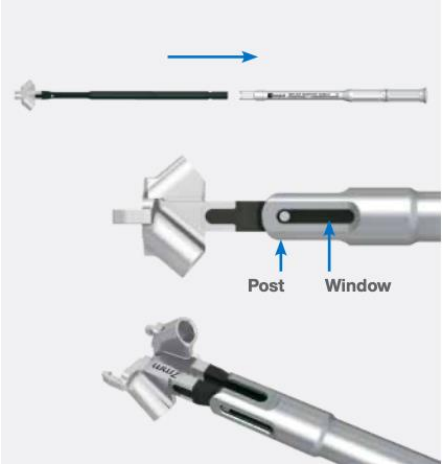

Figure 3

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.

2.7. 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 4*).

Figure 4

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

While maintaining downward pressure on the interbody fusion device, turn the silver knob on the implant inserter clockwise until it is fully tightened (*Figure 5*). Check to make sure the interbody fusion device is securely locked onto the implant inserter.

Figure 5

2.8. Implant preparation

With the interbody fusion device secured to the implant inserter, place the interbody fusion device into the corresponding footprint in the graft packing block (*Figure 6*). 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 using the graft packer.

Figure 5

2.9. 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 7*). Verify proper implant positioning using direct visualization and lateral fluoroscopy.

Figure 7

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.

2.10. 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) may be used. For an overview of the available instruments, see 'Catalogue instruments'.

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.

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 8*). Continue to advance the awl or drill until the positive internal stop is felt.

Figure 8

The non-guided awl and non-guided drill are not designed to be used within the guided implant inserter. The procedure for the non-guided instruments is described further in the Non-Guided Technique (Optional) section.

2.11. 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 9*).

Figure 9

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 10*). To release, press the button on the angled instrument stabilization handle to detach from the angled instrument.

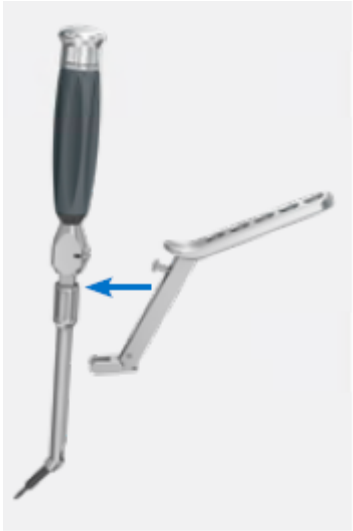

Figure 10

Figure 11

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 11*).

2.12. Screw insertion

The Fortilink-SC System offers the following instruments for screw insertion: stab-and-grab screw driver, 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 'Catalogue instruments'. Select the desired screw driver, screw type and length.

Figure 12

A screw final tightener is also available for making minor screw adjustments prior to final locking the interbody fusion device, see 'Catalogue 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.

Stab-and-Grab Screw Driver
Fully insert the tip of the stab-and-grab screw driver into the drive pocket of the screw. There may be tactile/audible feedback once the screw is secured to the stab-and-grab screw driver (*Figure 12*).

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.

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 13*).

Figure 13

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 14*). 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 15*). 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 14

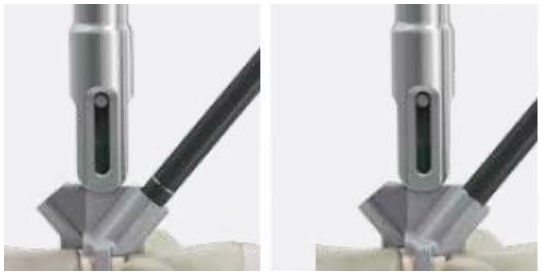

Figure 15

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 stab-and-grab screw driver from the screw by applying downward pressure to the guided implant inserter while simultaneously pulling the screw driver up.

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 fusion 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.

2.13. 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 16*).

Figure 16

SCREW SEATING
Confirm screw is securely connected to angled screw driver by gently pulling on the screw once extracted from the caddy. Push screw back on so it is fully seated and co-axial with the angled 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 17*).

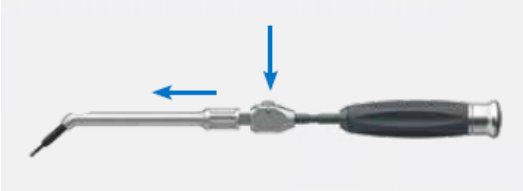

Figure 17

2. Remove the angled drill bit from the external shaft of the angled driver (*Figure 18*).

Figure 18

3. Insert additional angled screw driver bit from screw caddy into external shaft of the angled driver until positive stop is felt (*Figure 19*).

Figure 19

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 20*).

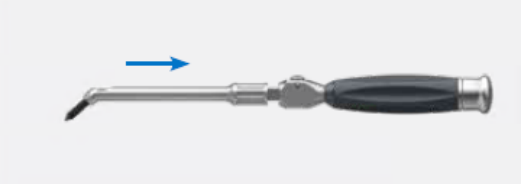

Figure 20

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.

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 21*). 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 22*). 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.

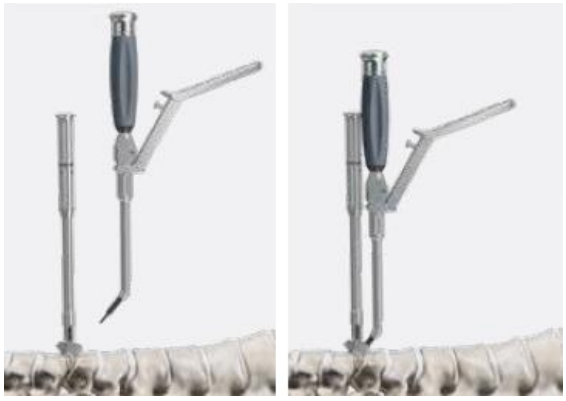

Figure 21

Figure 22

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.

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.

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 23*).

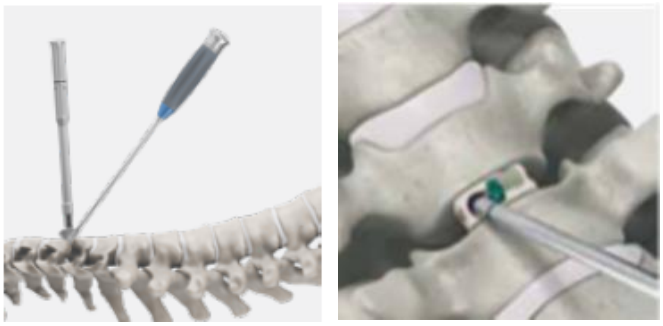

Figure 23

2.14. 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 24*).

Figure 24

Using a three-finger technique, rotate the final locker 90 degrees clockwise until the positive stop is felt (*Figure 25*).

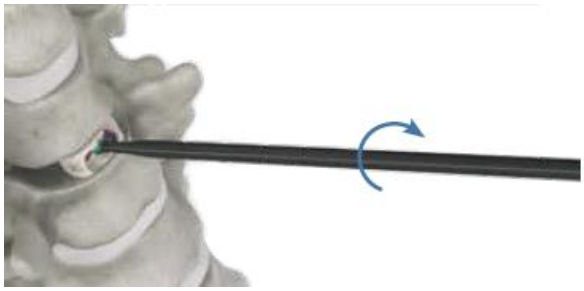

Figure 25

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.

2.15. Confirm final locking

CONFIRM FINAL LOCKING
Visually confirm that screws are covered by the locking mechanism on the interbody fusion device (*Figure 26*).

Figure 26

2.16. 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.

2.17. 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 27*).

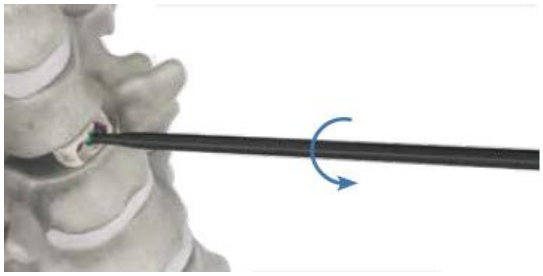

Figure 27

Rotate the final locker handle 90 degrees counterclockwise until the positive stop is felt. The screws are now uncovered. Remove the final locker (*Figure 28*).

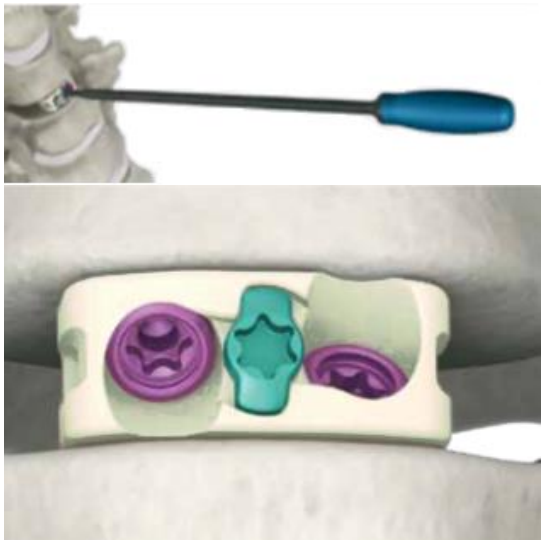

Figure 28

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

2.18. Implant removal (if necessary)

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

Open implant remover handles by disengaging the ratcheting feature. Insert each distal tip of the implant remover within each of the screw holes of the interbody fusion device. Squeeze the implant remover handles together, engaging the ratcheting feature to secure to the interbody fusion device (*Figure 29*).

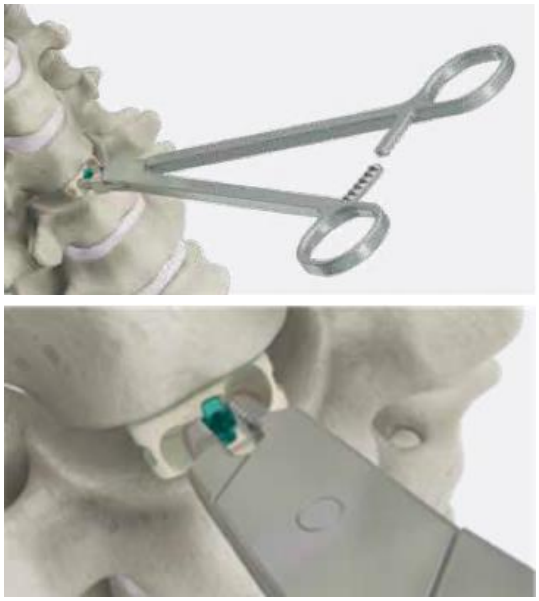

Figure 29

Once the implant remover is rigidly attached, carefully extract the interbody fusion device anteriorly.

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

The implant remover may not be used to insert an interbody fusion device.

⚠

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.

2.19. 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 'Catalogue 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 (64-INSERT-SHAFT) together and insert into the implant inserter handle (64-

INSERT-HANDLE) until the posts insert into the window (*Figure 30*). The fully assembled instrument is the non-guided implant inserter (*Figure 31*).

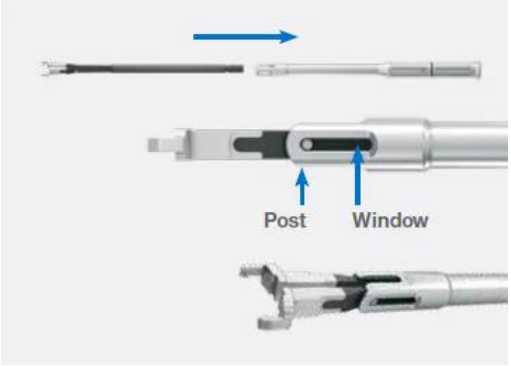

Figure 30

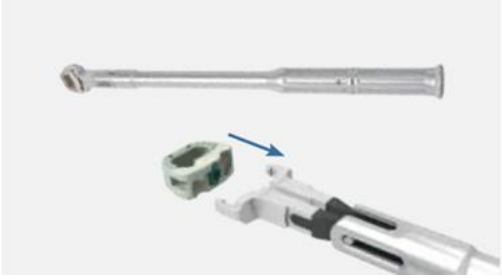

Figure 31

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”.

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 32*). Verify proper implant positioning using direct visualization and lateral fluoroscopy.

Figure 32

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. Countersinking 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.

If necessary, the implant tamp may be used to reposition the interbody fusion device. Insert the implant tamp by aligning its prongs with the interbody fusion device recesses and advance until fully seated with no gap (*Figure 33*). Advance the interbody fusion device by lightly tapping the end of the implant tamp with a mallet until desired interbody fusion device position is achieved and confirmed with fluoroscopy.

Figure 33

The implant tamp does not contain a positive stop and countersinking the interbody fusion device beyond the anterior surfaces of the vertebral bodies is not recommended.

Non-Guided Screw Hole Preparation
The awl and drill are designed to be used without the implant inserter. Insert the awl or 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 awl or drill until the positive internal stop is felt (*Figure 34*).

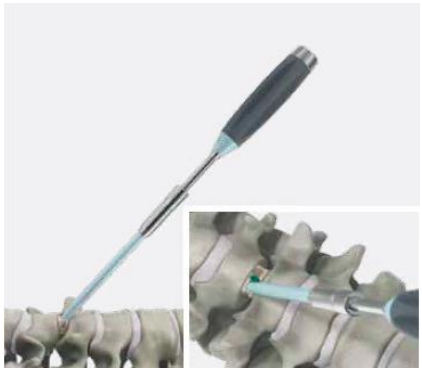

Figure 34

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

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 35*). 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 36*). Confirm proper placement using fluoroscopy.

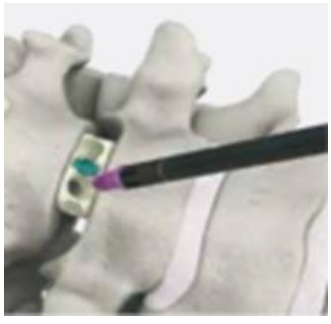

Figure 35

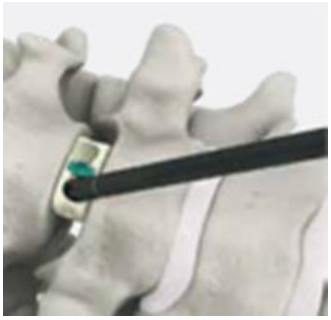

Figure 36

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.

3. Catalogue implants

Table 1. Cage implants

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
78-C-1612-06-0L	Fortilink-SC Ti 16x12x06-0L	16	12	06	0	1
78-C-1612-07-0L	Fortilink-SC Ti 16x12x07-0L	16	12	07	0	1
78-C-1612-08-0L	Fortilink-SC Ti 16x12x08-0L	16	12	08	0	1
78-C-1612-09-0L	Fortilink-SC Ti 16x12x09-0L	16	12	09	0	1
78-C-1612-10-0L	Fortilink-SC Ti 16x12x10-0L	16	12	10	0	1
78-C-1612-11-0L	Fortilink-SC Ti 16x12x11-0L	16	12	11	0	1
78-C-1612-12-0L	Fortilink-SC Ti 16x12x12-0L	16	12	12	0	1
78-C-1612-06-7L	Fortilink-SC Ti 16x12x06-7L	16	12	06	7	1
78-C-1612-07-7L	Fortilink-SC Ti 16x12x07-7L	16	12	07	7	1
78-C-1612-08-7L	Fortilink-SC Ti 16x12x08-7L	16	12	08	7	1
78-C-1612-09-7L	Fortilink-SC Ti 16x12x09-7L	16	12	09	7	1
78-C-1612-10-7L	Fortilink-SC Ti 16x12x10-7L	16	12	10	7	1
78-C-1612-11-7L	Fortilink-SC Ti 16x12x11-7L	16	12	11	7	1
78-C-1612-12-7L	Fortilink-SC Ti 16x12x12-7L	16	12	12	7	1
78-C-1614-06-0L	Fortilink-SC Ti 16x14x06-0L	16	14	06	0	1
78-C-1614-07-0L	Fortilink-SC Ti 16x14x07-0L	16	14	07	0	1
78-C-1614-08-0L	Fortilink-SC Ti 16x14x08-0L	16	14	08	0	1
78-C-1614-09-0L	Fortilink-SC Ti 16x14x09-0L	16	14	09	0	1
78-C-1614-10-0L	Fortilink-SC Ti 16x14x10-0L	16	14	10	0	1
78-C-1614-11-0L	Fortilink-SC Ti 16x14x11-0L	16	14	11	0	1
78-C-1614-12-0L	Fortilink-SC Ti 16x14x12-0L	16	14	12	0	1
78-C-1614-06-7L	Fortilink-SC Ti 16x14x06-7L	16	14	06	7	1
78-C-1614-07-7L	Fortilink-SC Ti 16x14x07-7L	16	14	07	7	1
78-C-1614-08-7L	Fortilink-SC Ti 16x14x08-7L	16	14	08	7	1
78-C-1614-09-7L	Fortilink-SC Ti 16x14x09-7L	16	14	09	7	1
78-C-1614-10-7L	Fortilink-SC Ti 16x14x10-7L	16	14	10	7	1
78-C-1614-11-7L	Fortilink-SC Ti 16x14x11-7L	16	14	11	7	1
78-C-1614-12-7L	Fortilink-SC Ti 16x14x12-7L	16	14	12	7	1
78-C-1814-06-0L	Fortilink-SC Ti 18x14x06-0L	18	14	06	0	1
78-C-1814-07-0L	Fortilink-SC Ti 18x14x07-0L	18	14	07	0	1
78-C-1814-08-0L	Fortilink-SC Ti 18x14x08-0L	18	14	08	0	1
78-C-1814-09-0L	Fortilink-SC Ti 18x14x09-0L	18	14	09	0	1
78-C-1814-10-0L	Fortilink-SC Ti 18x14x10-0L	18	14	10	0	1
78-C-1814-11-0L	Fortilink-SC Ti 18x14x11-0L	18	14	11	0	1
78-C-1814-12-0L	Fortilink-SC Ti 18x14x12-0L	18	14	12	0	1
78-C-1814-06-7L	Fortilink-SC Ti 18x14x06-7L	18	14	06	7	1

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
78-C-1814-07-7L	Fortilink-SC Ti 18x14x07-7L	18	14	07	7	1
78-C-1814-08-7L	Fortilink-SC Ti 18x14x08-7L	18	14	08	7	1
78-C-1814-09-7L	Fortilink-SC Ti 18x14x09-7L	18	14	09	7	1
78-C-1814-10-7L	Fortilink-SC Ti 18x14x10-7L	18	14	10	7	1
78-C-1814-11-7L	Fortilink-SC Ti 18x14x11-7L	18	14	11	7	1
78-C-1814-12-7L	Fortilink-SC Ti 18x14x12-7L	18	14	12	7	1
78-C-2016-06-0L	Fortilink-SC Ti 20x16x06-0L	20	16	06	0	1
78-C-2016-07-0L	Fortilink-SC Ti 20x16x07-0L	20	16	07	0	1
78-C-2016-08-0L	Fortilink-SC Ti 20x16x08-0L	20	16	08	0	1
78-C-2016-09-0L	Fortilink-SC Ti 20x16x09-0L	20	16	09	0	1
78-C-2016-10-0L	Fortilink-SC Ti 20x16x10-0L	20	16	10	0	1
78-C-2016-11-0L	Fortilink-SC Ti 20x16x11-0L	20	16	11	0	1
78-C-2016-12-0L	Fortilink-SC Ti 20x16x12-0L	20	16	12	0	1
78-C-2016-06-7L	Fortilink-SC Ti 20x16x06-7L	20	16	06	7	1
78-C-2016-07-7L	Fortilink-SC Ti 20x16x07-7L	20	16	07	7	1
78-C-2016-08-7L	Fortilink-SC Ti 20x16x08-7L	20	16	08	7	1
78-C-2016-09-7L	Fortilink-SC Ti 20x16x09-7L	20	16	09	7	1
78-C-2016-10-7L	Fortilink-SC Ti 20x16x10-7L	20	16	10	7	1
78-C-2016-11-7L	Fortilink-SC Ti 20x16x11-7L	20	16	11	7	1
78-C-2016-12-7L	Fortilink-SC Ti 20x16x12-7L	20	16	12	7	1

Table 2. Sterile Screw Implants

Product number	Product name	Diameter (mm)	Length (mm)	Quantity
78-34-SD-12	Fortilink-SC Ti Self-Drilling Screw 3,4x12	3.4	12	2
78-34-SD-14	Fortilink-SC Ti Self-Drilling Screw 3,4x14	3.4	14	2
78-34-SD-16	Fortilink-SC Ti Self-Drilling Screw 3,4x16	3.4	16	2
78-34-ST-12	Fortilink-SC Ti Self-Tapping Screw 3,4x12	3.4	12	2
78-34-ST-14	Fortilink-SC Ti Self-Tapping Screw 3,4x14	3.4	14	2
78-34-ST-16	Fortilink-SC Ti Self-Tapping Screw 3,4x16	3.4	16	2
78-39-ST-12	Fortilink-SC Ti Self-Tapping Rescue Screw 3,9x12	3.9	12	2
78-39-ST-14	Fortilink-SC Ti Self-Tapping Rescue Screw 3,9x14	3.9	14	2
78-39-ST-16	Fortilink-SC Ti Self-Tapping Rescue Screw 3,9x16	3.9	16	2

4. Catalogue instruments

Instruments are manufactured by Pioneer Surgical Technology Inc. and distributed by Surgalign Spine Technologies, Inc.

Instrument list Fortilink-SC Ti (CIF SC)	
Part #	**Description**
64-CE-INSERTHANDLE	Inserter Handle
64-CE-INSRTGUID-6	Inserter Guide Shaft (6mm)
64-CE-INSRTGUID-7	Inserter Guide Shaft (7mm)
64-CE-INSRTGUID-8	Inserter Guide Shaft (8mm)
64-CE-INSRTGUID-9	Inserter Guide Shaft (9mm)
64-CE-INSRTGUID-10	Inserter Guide Shaft (10mm)
64-CE-INSERT-SHAFT	Inserter Shaft
64-CE-TAMP	Tamp
64-CE-ANG-SCRWDRVR	Angled Screw Driver Bit
64-CE-ANG-DRILL	Angled Drill Bit
64-CE-ANG-HANDLE	Angled Instrument Stabilization Handle
64-CE-ANG-AWL	Angled Awl
64-CE-ANG-DRIVER	Angled Screw Driver
64-CE-GUIDEDAWL	Guided Awl, 12mm
64-CE-GUIDEDDRILL	Guided Drill, 12mm
64-CE-AWL	Awl, 12mm
64-CE-DRILL	Drill, 12mm
64-CE-SCRWTIGHTNR	Screw Final Tightener
64-CE-SCRWDRVR-SG	Screw Driver, Stab-and-Grab
64-CE-SCRWDRVR-LKG	Screw Driver, Locking
64-CE-PACKERBLOCK	Graft Packing Block
64-CE-GRAFTPACKER	Graft Packer
64-CE-RASP	Rasp
64-CE-LOCKER	Final Locker
64-CE-IMP-REMOVER	Implant Remover
64-CETR-1612-6-7L	Trial, 16 W x 12 D x 6 H x 7 L
64-CETR-1612-7-7L	Trial, 16 W x 12 D x 7 H x 7 L
64-CETR-1612-8-7L	Trial, 16 W x 12 D x 8 H x 7 L
64-CETR-1612-9-7L	Trial, 16 W x 12 D x 9 H x 7 L
64-CETR-1612-10-7L	Trial, 16 W x 12 D x 10 H x 7 L
64-CETR-1614-6-7L	Trial, 16 W x 14 D x 6 H x 7 L
64-CETR-1614-7-7L	Trial, 16 W x 14 D x 7 H x 7 L
64-CETR-1614-8-7L	Trial, 16 W x 14 D x 8 H x 7 L
64-CETR-1614-9-7L	Trial, 16 W x 14 D x 9 H x 7 L
64-CETR-1614-10-7L	Trial, 16 W x 14 D x 10 H x 7 L
64-CETR-1814-6-7L	Trial, 18 W x 14 D x 6 H x 7 L

Instrument list Fortilink-SC Ti (CIF SC)	
Part #	**Description**
64-CETR-1814-7-7L	Trial, 18 W x 14 D x 7 H x 7 L
64-CETR-1814-8-7L	Trial, 18 W x 14 D x 8 H x 7 L
64-CETR-1814-9-7L	Trial, 18 W x 14 D x 9 H x 7 L
64-CETR-1814-10-7L	Trial, 18 W x 14 D x 10 H x 7 L
64-CETR-2016-6-7L	Trial, 20 W x 16 D x 6 H x 7 L
64-CETR-2016-7-7L	Trial, 20 W x 16 D x 7 H x 7 L
64-CETR-2016-8-7L	Trial, 20 W x 16 D x 8 H x 7 L
64-CETR-2016-9-7L	Trial, 20 W x 16 D x 9 H x 7 L
64-CETR-2016-10-7L	Trial, 20 W x 16 D x 10 H x 7 L