Surgical Technique

Fortilink®-SA

with TiPlus Technology

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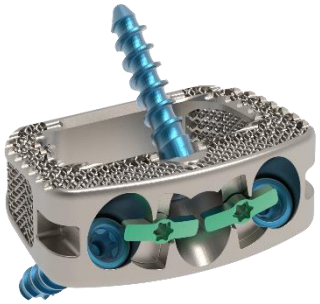

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1. Introduction

1.1. Device description

The Fortilink-SA Ti (*Figure 1*) is a stand-alone interbody fusion device intended for the lumbar spine (L1-S1) in patients with degenerative disc diseases. The Fortilink-SA Ti is composed out of a cage/wedge, three screws and two retainers. The Fortilink-SA Ti interbody fusion devices are manufactured with SLM (selective laser melting) and are built up from implant grade titanium alloy (Ti6Al4V). The Fortilink-SA Ti has an open mesh structure and a bone window both designed to allow bone ingrowth and facilitate fusion. The disc-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 only required for Fortilink-SA Ti with lordotic angles greater than or equal to 20 degrees. The retainer locks the screws. Both the screws and the retainer are made from titanium alloy.

The Fortilink-SA 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.

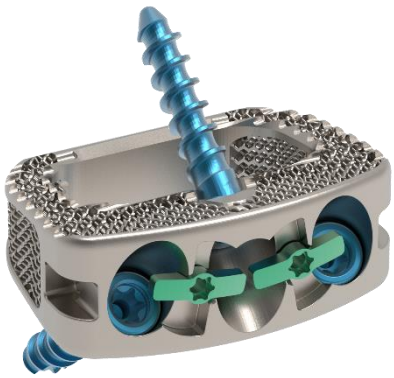

Figure 1. Fortilink®-SA with TiPlus Technology

1.2. Intended purpose

The Fortilink-SA Ti is indicated for stand-alone anterior lumbar interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L1 to S1. DDD is defined as back 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 three of the provided bone screws. This system is to be used in patients who have had six months of non-operative treatment. The Fortilink-SA Ti with lordotic angles greater than or equal to 20 degrees are required to be used with supplemental fixation for use in the lumbar spine.

1.3. Clinical benefits

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

- Decrease back pain, as assessed using the Visual Analogue Scale (VAS)
- Clinical improvement, as assessed using the Oswestry Disability Index (ODI)
- 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

1.4. Indications

Degenerative disc disease (DDD) of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

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
- Spondylolisthesis

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.

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

For the screws to remain within device footprint, follow the screw length table below.

Maximum screw length (mm) to remain within footprint

Fortilink-SA Ti footprint	Lateral screws	Central screw
32x25	20	25
36x27	25	30
40x29	30	30

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.
SCREW HOLE PREPARATION Due to a positive internal stop, (guided) awls and drills penetrate bone to a depth equal to shortest screw length. 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.
SUPPLEMENTAL FIXATION Interbody fusion devices are designed to withstand full load-bearing until bony union of the spinal segment(s) normally occurs. To ensure load-bearing capability, supplemental fixation is required for use with hyperlordotic devices (>20° lordosis).
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 to 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
- Visceral injury
- Retrograde ejaculation
- Infection
- Allergic reaction
- Pulmonary embolism
- Pneumonia
- Adjacent segment disease
- Heterotrophic ossification
- Bone erosion
- Epidural scarring
- Ureter damage

2. Surgical technique

2.1. Patient positioning

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

2.2. Exposure of disc level

Locate the correct operative disc level and make an incision location by taking a lateral X-ray (fluoroscopic view) while holding a straight metal instrument at the side of the patient (*Figure 2*). This insures that the incision and exposure will allow direct visualization into the disc space. Expose the operative disc level and retract tissues using appropriate instrumentation. Retract and protect the great vessels to allow complete exposure and visualization of the operative site.

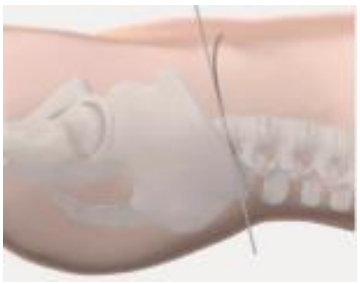

Figure 2

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.

2.3. Discectomy and endplate preparation

Perform a complete discectomy using appropriate instrumentation.

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.

2.4. Distraction

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

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.

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.

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 (*Figure 3*). 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.

Figure 3

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

2.6. Implant inserter assembly

To assemble, insert the shaft into the housing *(Figure 4)* and push shaft within housing until a positive stop is felt. Fixate by attaching and rotating the cage inserter knob clockwise until the shaft is fully seated. The fully assembled instrument is the implant inserter.

Figure 4

Rotate inserter knob counterclockwise until positive stop is felt, visually confirm distal end is fully open.

2.7. Implant attachment

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 5).*

Figure 5

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 knob on the implant inserter clockwise until it is fully tightened. Check to make sure the interbody fusion device is securely locked onto the implant inserter.

2.8. Implant preparation

Pack the implant with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

2.9. Implant insertion

Insert the interbody fusion device into the prepared level *(Figure 6).* Lightly tap on the end of the implant inserter with a mallet until the interbody fusion device is inserted to desired placement. Verify proper implant positioning using direct visualization and lateral fluoroscopy.

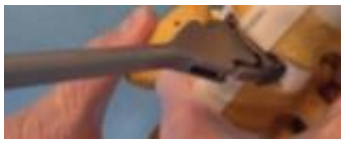

Figure 6

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 the implant inserter by rotating the knob counterclockwise until it freely spins and is able to detach from the 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. 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.

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.

2.10. Screw hole preparation

The Fortilink-SA System offers guided, freehand and angled screw hole preparation.
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
Due to a positive internal stop, (guided) awls and drills penetrate bone to a depth equal to shortest screw length.
Be careful not to over impact the screw hole as this could displace the interbody fusion device.

Guided Screw Hole Preparation
Insert the awl with guided front end or drill with guided front end through one of the implant holes 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.

Freehand Screw Hole Preparation
Insert the awl with freehand front end or drill with freehand front end through one of the implant holes 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.

Angled Screw Hole Preparation
Insert the angled awl and the awl guide in tandem or the angled drill through one of the implant holes 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.

Figure 7 and *Figure 8* show the Angled Awl and Awl Guide in tandem to create pilot hole and the Angled Drill to create pilot hole respectively.

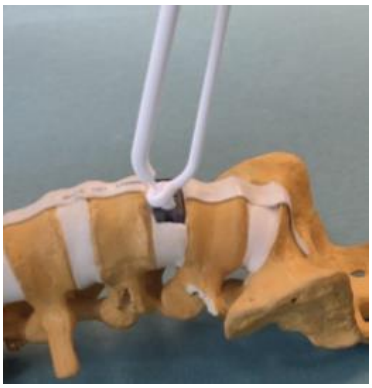

Figure 7

Figure 8

If desired, the angled 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 *(Figure 9)*. The angled handle should be assembled to angled awl, angled drill, and/or angled screw driver prior to being introduced into the implant holes. 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. To release, press the button on the angled instrument stabilization handle to detach from the angled instrument.

Figure 9

2.11. Screw insertion

The Fortilink-SA System offers the following instruments for screw insertion: stab-and-grab screw driver, locking screw driver, and angled (stab-and-grab) screw driver (See Catalogue instruments). Select the desired screw driver, screw type and length *(Table 1).*

SCREW SIZE
For the screws to remain within device footprint, follow the screw length table below.

Fortilink-SA *Ti footprint*	*Maximum screw length (mm) to remain within footprint*	
	Lateral screws	***Central screw***
32x25	*20*	*25*
36x27	*25*	*30*
40x29	*30*	*30*

Table 1

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.

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.

Insert the screw driver with screw directly into the interbody fusion device screw hole until the screw tip engages the pilot hole. 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. 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 two screw holes, repeat the screw hole preparation steps as described in Step 10, “Screw hole preparation”.

2.12. Screw insertion with angled screw driver (optional)

Select the desired screw type and proper length as prescribed in *Table 1* in Step 11, “Screw insertion”.

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 10).*

Figure 10

Confirm screw is securely connected to angled screw driver by gently pulling on the screw. 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 11)*

2. Remove the angled drill bit from the external shaft of the angled driver. *(*Figure *12)*

3. Insert additional angled screw driver bit into external shaft of the angled driver until positive stop is felt. *(*Figure *13)*

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 *14)*

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.

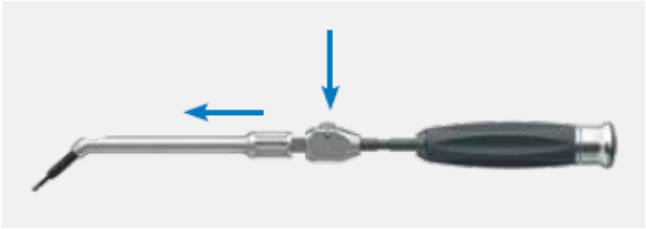

Figure 11

Figure 12

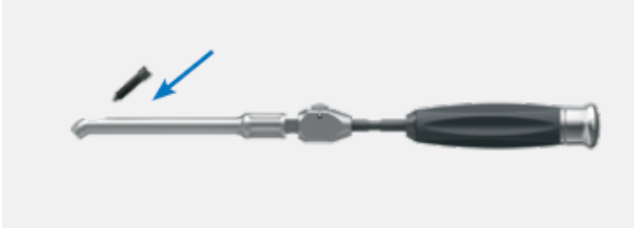

Figure 13

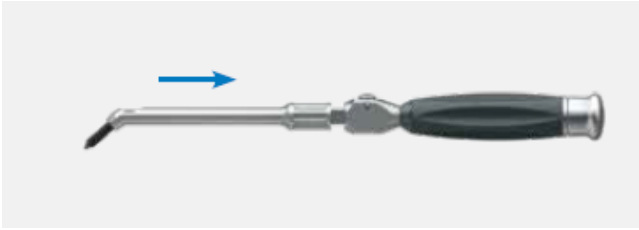

Figure 14

Insert the angled screw driver with screw through the implant hole 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 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.

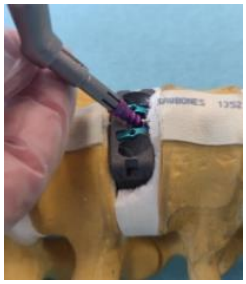

Figure 15

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.

For the other screw holes, 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.

If screws appear to not be fully seated, any of the screw drivers may be used to fully seat the screws.

2.13. Final lock interbody fusion device

Engage the tip of the locking bolt driver until the hexalobe engages and seats into the locking mechanism of the interbody fusion device *(Figure 16).* Tactile feedback should occur once the final locker is completely engaged.

Figure 16

Using a three-finger technique, rotate the locking bolt driver until the positive stop is felt and the screws are blocked.

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.

2.14. Confirm final locking

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

2.15. 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.

2.16. Screw removal (if necessary)

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

Rotate the locking bolt driver until the positive stop is felt and the screws are uncovered. Remove the final locker.

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 11, “Screw insertion”. If removing the interbody fusion device, proceed with removing the second and the third screw and then the interbody fusion device. The procedure for removing the interbody fusion device is described next.

2.17. Implant removal (if necessary)

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

Assemble the inserter. After assembly (see previous steps), re-engage inserter to the implant. Rotate knob of inserter clockwise for reattachment until it is fully tightened. Attach slap hammer adapter to proximal end of the inserter. Assemble slap hammer to the slap hammer attachment. Carefully back slap the hammer and remove the implant from the disc space.

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.

3. Catalogue implants

Table 2. Cage implants

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
78-A-3225-10-8L	Fortilink-SA Ti 32x25x10-8L	32	25	10	8	1
78-A-3225-12-8L	Fortilink-SA Ti 32x25x12-8L	32	25	12	8	1
78-A-3225-14-8L	Fortilink-SA Ti 32x25x14-8L	32	25	14	8	1
78-A-3225-16-8L	Fortilink-SA Ti 32x25x16-8L	32	25	16	8	1
78-A-3225-18-8L	Fortilink-SA Ti 32x25x18-8L	32	25	18	8	1
78-A-3225-10-14L	Fortilink-SA Ti 32x25x10-14L	32	25	10	14	1
78-A-3225-12-14L	Fortilink-SA Ti 32x25x12-14L	32	25	12	14	1
78-A-3225-14-14L	Fortilink-SA Ti 32x25x14-14L	32	25	14	14	1
78-A-3225-16-14L	Fortilink-SA Ti 32x25x16-14L	32	25	16	14	1
78-A-3225-18-14L	Fortilink-SA Ti 32x25x18-14L	32	25	18	14	1
78-A-3225-12-20L	Fortilink-SA Ti 32x25x12-20L	32	25	12	20	1
78-A-3225-14-20L	Fortilink-SA Ti 32x25x14-20L	32	25	14	20	1
78-A-3225-16-20L	Fortilink-SA Ti 32x25x16-20L	32	25	16	20	1
78-A-3225-18-20L	Fortilink-SA Ti 32x25x18-20L	32	25	18	20	1
78-A-3225-20-20L	Fortilink-SA Ti 32x25x20-20L	32	25	20	20	1
78-A-3225-16-30L	Fortilink-SA Ti 32x25x16-30L	32	25	16	30	1
78-A-3225-18-30L	Fortilink-SA Ti 32x25x18-30L	32	25	18	30	1
78-A-3225-20-30L	Fortilink-SA Ti 32x25x20-30L	32	25	20	30	1
78-A-3225-22-30L	Fortilink-SA Ti 32x25x22-30L	32	25	22	30	1
78-A-3627-10-8L	Fortilink-SA Ti 36x27x10-8L	36	27	10	8	1
78-A-3627-12-8L	Fortilink-SA Ti 36x27x12-8L	36	27	12	8	1
78-A-3627-14-8L	Fortilink-SA Ti 36x27x14-8L	36	27	14	8	1
78-A-3627-16-8L	Fortilink-SA Ti 36x27x16-8L	36	27	16	8	1
78-A-3627-18-8L	Fortilink-SA Ti 36x27x18-8L	36	27	18	8	1
78-A-3627-10-14L	Fortilink-SA Ti 36x27x10-14L	36	27	10	14	1
78-A-3627-12-14L	Fortilink-SA Ti 36x27x12-14L	36	27	12	14	1
78-A-3627-14-14L	Fortilink-SA Ti 36x27x14-14L	36	27	14	14	1
78-A-3627-16-14L	Fortilink-SA Ti 36x27x16-14L	36	27	16	14	1
78-A-3627-18-14L	Fortilink-SA Ti 36x27x18-14L	36	27	18	14	1
78-A-3627-12-20L	Fortilink-SA Ti 36x27x12-20L	36	27	12	20	1
78-A-3627-14-20L	Fortilink-SA Ti 36x27x14-20L	36	27	14	20	1
78-A-3627-16-20L	Fortilink-SA Ti 36x27x16-20L	36	27	16	20	1
78-A-3627-18-20L	Fortilink-SA Ti 36x27x18-20L	36	27	18	20	1
78-A-3627-20-20L	Fortilink-SA Ti 36x27x20-20L	36	27	20	20	1
78-A-3627-16-30L	Fortilink-SA Ti 36x27x16-30L	36	27	16	30	1
78-A-3627-18-30L	Fortilink-SA Ti 36x27x18-30L	36	27	18	30	1

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
78-A-3627-20-30L	Fortilink-SA Ti 36x27x20-30L	36	27	20	30	1
78-A-3627-22-30L	Fortilink-SA Ti 36x27x22-30L	36	27	22	30	1
78-A-4029-10-8L	Fortilink-SA Ti 40x29x10-8L	40	29	10	8	1
78-A-4029-12-8L	Fortilink-SA Ti 40x29x12-8L	40	29	12	8	1
78-A-4029-14-8L	Fortilink-SA Ti 40x29x14-8L	40	29	14	8	1
78-A-4029-16-8L	Fortilink-SA Ti 40x29x16-8L	40	29	16	8	1
78-A-4029-18-8L	Fortilink-SA Ti 40x29x18-8L	40	29	18	8	1
78-A-4029-10-14L	Fortilink-SA Ti 40x29x10-14L	40	29	10	14	1
78-A-4029-12-14L	Fortilink-SA Ti 40x29x12-14L	40	29	12	14	1
78-A-4029-14-14L	Fortilink-SA Ti 40x29x14-14L	40	29	14	14	1
78-A-4029-16-14L	Fortilink-SA Ti 40x29x16-14L	40	29	16	14	1
78-A-4029-18-14L	Fortilink-SA Ti 40x29x18-14L	40	29	18	14	1
78-A-4029-12-20L	Fortilink-SA Ti 40x29x12-20L	40	29	12	20	1
78-A-4029-14-20L	Fortilink-SA Ti 40x29x14-20L	40	29	14	20	1
78-A-4029-16-20L	Fortilink-SA Ti 40x29x16-20L	40	29	16	20	1
78-A-4029-18-20L	Fortilink-SA Ti 40x29x18-20L	40	29	18	20	1
78-A-4029-20-20L	Fortilink-SA Ti 40x29x20-20L	40	29	20	20	1
78-A-4029-18-30L	Fortilink-SA Ti 40x29x18-30L	40	29	18	30	1
78-A-4029-20-30L	Fortilink-SA Ti 40x29x20-30L	40	29	20	30	1
78-A-4029-22-30L	Fortilink-SA Ti 40x29x22-30L	40	29	22	30	1

Table 3. Screw Implants

Product number	Product name	Diameter (mm)	Length (mm)	Quantity
78-45-SD-20	Fortilink-SA Ti Self-Drilling Screw 4,5x20	4.5	20	3
78-45-SD-25	Fortilink-SA Ti Self-Drilling Screw 4,5x25	4.5	25	3
78-45-SD-30	Fortilink-SA Ti Self-Drilling Screw 4,5x30	4.5	30	3
78-45-SD-35	Fortilink-SA Ti Self-Drilling Screw 4,5x35	4.5	35	3
78-45-ST-20	Fortilink-SA Ti Self-Tapping Screw 4,5x20	4.5	20	3
78-45-ST-25	Fortilink-SA Ti Self-Tapping Screw 4,5x25	4.5	25	3
78-45-ST-30	Fortilink-SA Ti Self-Tapping Screw 4,5x30	4.5	30	3
78-45-ST-35	Fortilink-SA Ti Self-Tapping Screw 4,5x35	4.5	35	3
78-55-ST-20	Fortilink-SA Ti Self-Tapping Rescue Screw 5,5x20	5.5	20	3
78-55-ST-25	Fortilink-SA Ti Self-Tapping Rescue Screw 5,5x25	5.5	25	3
78-55-ST-30	Fortilink-SA Ti Self-Tapping Rescue Screw 5,5x30	5.5	30	3
78-55-ST-35	Fortilink-SA Ti Self-Tapping Rescue Screw 5,5x35	5.5	35	3

4. Catalogue instruments

Instruments are manufactured by Paradigm Spine GmbH and distributed by Surgalign Spine Technologies, Inc.

Instrument list Fortilink-SA Ti (ALIF SA)	
Part #	**Description**
AAT01100	Fortilink-SA TiPlus Implant inserter
AAT01200	Fortilink-SA TiPlus Tamp
AAT01300	Fortilink-SA TiPlus Slaphammer adapter
AAT01400	Fortilink-SA TiPlus Slaphammer
AAT02300	Fortilink-SA TiPlus Angled Awl
AAT02400	Fortilink-SA TiPlus Angled Awl guide
AAT02130	Fortilink-SA TiPlus Awl shaft
AAT02530	Fortilink-SA TiPlus Drill shaft
AAT02120	Fortilink-SA TiPlus Awl/Drill outer sleeve
AAT02110	Fortilink-SA TiPlus Awl , guided front end
AAT02210	Fortilink-SA TiPlus Awl, unguided front end
AAT02510	Fortilink-SA TiPlus Drill, guided front end
AAT02610	Fortilink-SA TiPlus Drill, unguided front end
AAT02700	Fortilink-SA TiPlus Angled Driver
AAT02710	Fortilink-SA TiPlus Angled Drill, Bit T20
AAT02720	Fortilink-SA TiPlus Angled Driver, Bit 20mm
AAT03100	Fortilink-SA TiPlus Locking Driver
AAT03200	Fortilink-SA TiPlus Stab n Grab Driver
AAT03300	Fortilink-SA TiPlus Locking Driver, T10
AAT04100	Fortilink-SA TiPlus Angled Handle
AAT04200	Fortilink-SA TiPlus Straight Handle
AAT04300	Fortilink-SA TiPlus Straight Handle Ratchet, 1/4" coupling
AAT04400	Fortilink-SA TiPlus T-handle Ratchet, 1/4" coupling