MORE THAN POSSIBLE.™

Instructions For Use

Fortilink – C TiPlus Inserter

Fortilink – TS TiPlus Inserter

Fortilink – TC TiPlus Inserter

Reprocessing Instructions

Disassembly Instructions

Surgalign Spine Technologies |
520 Lake Cook Rd Ste 315
Deerfield, IL 60015 United States
Phone: +1 844 894 7752 | www.surgalign.com

MORE THAN POSSIBLE.™

Instructions For Use

Description

The instruments in this system are intended for use in surgical procedures. These include dedicated instruments such as Fortilink-C, Fortilink-TS, Fortilink-TC Inserters which are provided specific to each implant footprint to allow for implant insertion and removal. These device specific accessories are included in system specific steam sterilization cases with other general instruments for the Fortilink with TiPlus Technology system.

Indications for Use

The Fortilink-C with TiPlus Technology is intended for spinal fusion procedures at one or more levels (C2-T1) in skeletally mature patients with cervical disc disease (defined as discogenic back pain with degeneration of the disc and/or myelopathy with herniated disc and/or osteophyte formation on posterior endplates confirmed by patient history and radiographic studies), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion at one or more levels of the cervical spine with accompanying radicular symptoms. Implants are to be packed with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. This device is intended to be used with an FDA-cleared supplemental fixation system appropriate for use in the cervical spine. This device is intended to be used in patients who have had six weeks of non-operative treatment.

The Fortilink-TS with TiPlus Technology is indicated for transforaminal and posterior interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with FDA-cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

The Fortilink-TC with TiPlus Technology is indicated for transforaminal interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with FDA-cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

Contraindications

The devices are contraindicated and should not be used including but not limited to, patients with the following:

- 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 stress 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 or surgery
- Pregnancy

Potential adverse effects

- Pain, discomfort, or abnormal sensations
- Dural leak
- Bone fracture
- Allergic reaction
- Cutting of skin or gloves of operating staff
- Vascular or visceral injury
- Neurological injury
- Infection
- Hemorrhage
- Death

Warnings

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.

The safety, effectiveness and performance of the devices have been established for conditions in which the devices are used as intended and when used as identified in the Indications for Use. The performance of the devices has not been evaluated for use that is contrary to the Intended Use, Indications for Use or for use that is contraindicated. Failure to use the devices as indicated could detrimentally affect the performance of their components.

Breakage, slippage, misuse, unintended disassembly of multi-component instruments or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel and/ or increased operating time.

Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose or even dangerous to the patient or surgical staff. These instruments should be carefully placed on trays, cleaned after each use, and stored in a dry environment.

It is important the surgeon exercises extreme caution when working near vital organs, nerves, or vessels and the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient.

MORE THAN POSSIBLE.™

Instructions For Use

Safety precautions

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.

- Prior to use, thoroughly read these instructions for use.
- Keep the instructions for use accessible to the staff.
- Placement and positional adjustment of implants must only be performed with system specific instruments. They must not be used with other instrumentation unless specifically recommended by Surgalign or BAAT Medical because the combination may be incompatible.
- The implants should not be rotated during insertion. Attempting to rotate these implants during insertion may lead to implant failure.
- The condition of all instruments should be checked prior to use. Damaged or worn instruments may present significant risks to safety and/or inability to function as intended and should not be used. Surgalign customer service should be contacted for instrument replacement.
- 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.
- Preoperative and operating procedures, including knowledge of surgical techniques, are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results.
- The surgeon's experience and training in surgical procedures affect the performance of this system and the use of instruments. A successful result is not always achieved in every surgical case where patient conditions may compromise the results.
- Proper patient selection and operative care are critical to the success of the surgery and avoidance of injury during surgery. Read and follow all other product information supplied by the manufacturer of the implants or the instruments.
- The surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the device.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
- If this device is used in a patient with, or suspected with, Creutzfeldt-Jakob disease (CJD), variant CJD or other transmissible spongiform encephalopathy (TSE) and related infections, safely dispose of all the contaminated devices in accordance with local procedures and guidelines.
- The use of a surgical instrument for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
- Follow the general guidelines and aseptic principles when handling items to be sterilized or sterile items.
- Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.
- Caution should be used while handling delicate instruments or instruments with sharp tips.
- The personnel entrusted with the processing must have the requisite knowledge and qualifications.
- Please ensure that only appropriate equipment is used for cleaning, disinfection, and sterilization of the reusable surgical devices and that performance requalification, periodic routine tests are carried out on the equipment in accordance with local procedures, guidelines, and standards.
- Caution: Federal (USA) law restricts the device to sale by or on the order of a physician.

General instructions for use

This package insert is designed to assist in using surgical instruments only and is not intended to provide information on surgical technique for specific Fortilink with TiPlus Technology devices. Contact Surgalign customer service for the specific product Surgical Technique Manual.

CLEANING & REPROCESSING

These reusable surgical instruments are delivered unsterile. Therefore, they are to be cleaned, disinfected, and sterilized prior to each application.

Non-Sterile Instruments:

- Instruments must be cleaned and sterilized per the below instructions prior to introduction into a sterile surgical field. or (if applicable) return of the product to the manufacturer.
- To minimize corrosion and prolong the usable life of instruments used during surgery, remove gross traces of blood and residues then thoroughly clean and dry immediately after use. Do not allow soils to dry.
- Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
- Prior to and during use, including reprocessing, inspect instruments for:
  - Damage such as but not limited to, wear, discoloration, corrosion, cracking, fracture, or unrecognizable markings.
  - Proper function including but not limited to, sharpness, movement of hinges and couplings, joint stability, and legible markings.
  - Instruments that show signs of damage or an inability to function should not be used and should be returned to the manufacturer.

MORE THAN POSSIBLE.™

Instructions For Use

Cleaning and Reprocessing of Non-Sterile Instruments

- Instruments must be cleaned separately from instrument trays and cases.
- Do not Instruments must be cleaned and sterilized per the below instructions prior to introduction into a sterile surgical field. or (if applicable) return of the product to the manufacturer.
- To minimize corrosion and prolong the usable life of instruments used during surgery, remove gross traces of blood and residues then thoroughly clean and dry immediately after use. Do not allow soils to dry.
- Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
- Prior to and during use, including reprocessing, inspect instruments for:
- Damage such as but not limited to, wear, discoloration, corrosion, cracking, fracture, or unrecognizable markings.
- Proper function including but not limited to, sharpness, movement of hinges and couplings, joint stability, and legible markings.
- Instruments that show signs of damage or an inability to function should not be used and should be returned to the manufacturer.

Procedure: Manual Cleaning

1. Disassemble the instruments, as applicable. See below for specific instructions.
2. Rinse soiled device under running, cold tap water for a minimum of two (2) minutes. Remove gross soil using a soft bristle brush or soft, lint-free cloth.
3. Prepare a neutral pH enzymatic solution per the manufacturer's recommended instructions in warm tap water (approximately 33-43°C (92-110°F)).
4. Soak devices in freshly prepared neutral pH enzymatic solution for a minimum of ten
5. (10) minutes.
6. Rinse device using cool running tap water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels and other hard to reach areas. Actuate joints, handles and other moveable device features under running water, in order to rinse thoroughly.
7. Prepare a neutral pH enzymatic solution in warm tap water (approximately 33-43°C (92- 110°F)), per the manufacturer's recommended instructions.
8. Manually clean devices for a minimum of five (5) minutes in freshly prepared neutral pH enzymatic solution. Use a syringe, pipette, or water jet to flush lumens and channels. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles, and other movable device features to expose all areas to enzymatic solutions. Clean device underwater to prevent aerosolization of contaminants.
9. Rinse device using deionized (DI) running water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other moveable device features under running water in order to rinse thoroughly.
10. Visually inspect device for residual soil. If present, repeat steps 1-8 above.
11. Gently dry the device components with a soft lint-free cloth. Ensure the device is completely dry. Visually inspect the device; it should be clean, dry and residue-free.
12. Reassemble instruments, if applicable, following instructions in the surgical technique manual.

Procedure: Automated (Mechanical) Cleaning

Pre-Cleaning

1. Disassemble instruments, as applicable. See surgical technique manual for specific instructions.
2. Rinse the device components under running lukewarm tap water (22-43°C (72-110°F)) for a minimum of one (1) minute. After rinsing, remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth.
3. Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
4. Fully immerse the device components in the fresh, newly prepared enzymatic cleaning solution for a minimum of five (5) minutes.
5. After soaking, manually clean the device components for a minimum of two (2) minutes using a soft-bristled brush to remove soil and debris from the device and device lumens. Brush the device while fully immersed to prevent aerosolization of contaminants. After cleaning, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 ml of the cleaning solution.
6. Remove the device components from the cleaning solution and place in a bath of lukewarm tap water (22-43°C (72-110°F)) for a minimum of one (1) minute. Ensure the device components are fully immersed. Once the rinse time has elapsed, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 ml of the water.

Automated Cleaning

1. Place the device components in the automated washer.
2. Perform the automated cycle per instructions in the table below.
3. Visually inspect the device. It should be clean, dry and residue-free.
4. Reassemble instruments, if applicable, following instructions in the surgical technique manual.

Automated (Mechanical) Cleaning Parameters

Cycle	Time (Minutes)	Minimum Temperature	Detergent
Enzyme Wash	4:00	Hot Water 60°C (140°F)	Enzymatic cleaner (neutral pH) prepared per manufacturer's instructions
Wash	2:00	Hot water	Neutral detergent prepared per manufacturer's instructions
Rinse	2:00	Heated deionized or high purity water 70°C (158°F)	N/A
Dry	15:00	80 °C (176°F)	N/A

MORE THAN POSSIBLE.™

Instructions For Use

Inspection, Maintenance and Functional check

Inspection

The cleaned and disinfected instruments are visually inspected for soil or detergent residues, damages and moisture. Worn-out, corroded, deformed or otherwise damaged instruments are not to be further reprocessed. Instruments that are still contaminated at this stage are sorted out and subjected once more to the cleaning and disinfection process. In cases of damages, the cleaned and disinfected instruments are sterilized and made available for repair.

⚠ *Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.*

If moisture is detected, manual drying should be performed.

Maintenance

No maintenance is carried out by the processing facility.

Functional check and lubrication

Functional check should be performed where possible. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used. The disassembled instruments should be reassembled for the functional check.

STERILIZATION

Independent testing has shown the following conditions to be effective:

Method	Steam
Cycle	Pre-vacuum (Wrapped)
Temperature	132°C (270°F)
Recommended Exposure Time	4 Minutes
Recommended Dry Time	40 Minutes

- Use of an FDA cleared wrap is recommended to ensure product sterility.
- Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted.
- The values specified here (duration/temperature) can achieve a sterility assurance level (SAL) of at least 10-6.

Limitations on reprocessing

Repeated processing cycles in compliance with these instructions for use have minimal effects on device life cycle and function. Instruments do not have an indefinite life cycle. Their end of life is determined by wear and damage due to surgical use and handling. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be further used.

Storage

After sterilization, the reusable instruments should be stored in dry and dust-free hospital environmental conditions.

Warranty

All warranty rights are lost if repairs or modifications are carried out by an unauthorized service center. The manufacturer does not take responsibility for any effects on safety, reliability or performance of the product if the product is not used in conformity with the instructions for use. Technical alterations reserved.

Product Complaints

Complaints or dissatisfaction with the device quality, safety, reliability, durability, effectiveness and/or performance, brought forth by a health care professional, whether via a customer or user of the product, should be immediately conveyed to Surgalign customer service via telephone at (844) 894-7752 or email at customerservice@surgalign.com. It is important to note that when filing a complaint, the following information must be included to properly respond to the complaint:

Name and address; nature of the complaint; the component(s) trade name and catalog number; applicable lot number(s); and notification of whether a written report is being solicited.

For further information

For product information including surgical technique manuals, brochures, or questions pertaining to sales and service, please contact Surgalign customer service via telephone at (844) 894-7752 or email at customerservice@surgalign.com.

Symbols

	Distributer
LOT	Lot number
REF	Catalog number
NON STERILE	Non-sterile
	Do not use if package is damaged
	Keep dry
https://ifu.surgalign.com	Consult instructions for use at this website.
	Caution
QTY	Content of usable units(s)
Rx only	Federal law restricts this device to sale by or on the order of a physician.

Surgalign Spine Technologies |
520 Lake Cook Rd Ste 315
Deerfield, IL 60015 United States
Phone: +1 844 894 7752 | www.surgalign.com

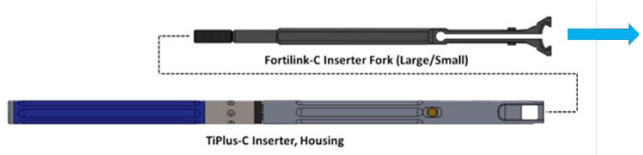
Disassembly Instructions

Do not use a tool with sharp ends.

Fortilink-C TiPlus Inserter
65-C-INS-TIPLUS

Step 1: Compress inserter fork distal tip and rotate proximal handle.

Step 2: Inserter fork will translate from the inserter housing until disassembly is complete.



Fortilink-TC Straight TiPlus Inserter
65-TC-INSERTER

Step 1: Hold handle and thumbwheel and pull slap hammer attachment from proximal end.

Step 2: Inner shaft will translate from inserter housing and thumbwheel until disassembly is complete.