Instructions for use

Fortilink-SC Instruments

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Device description

The Fortilink-SC Instruments are used for the implantation of the Fortilink-SC Ti stand-alone anterior cervical interbody fusion cages. The dedicated instruments are to be used for the preparation and placement of the cage and screws. The instruments are delivered non-sterile to the end-user and will be reprocessed by the hospital or user.

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 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.

Intended purpose

The instruments dedicated for the Fortilink-SC Ti are intended for implantation of the Fortilink-SC Ti interbody fusion devices.

Indications for use

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

Contraindications

- Active systemic infection or an active infection at the operative site.
- A demonstrated allergy or sensitivity to any of the implant materials.
- Severe osteoporosis.
- Primary or metastatic tumors affecting the spine.
- Conditions that may place excessive stresses on bones and the implants, including but not limited to morbid obesity, or other degenerative diseases.
- Patients whose ability to follow postoperative restrictions, precautions and rehabilitation programs is limited.
- Fractures, severe deformities or a severe instability in the area of surgery.
- A medical or surgical situation that would preclude the benefit of surgery.
- Pregnancy.

Instructions for use

The operating procedure is described step by step in the surgical technique for the Fortilink-SC available at BAAT Medical Products.

⚠ 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.
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.
INSTRUMENTS Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome. Surgeons must verify that the instruments are in good condition and in operating order prior to use during surgery.
CLEANING 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.
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.
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.
DISPOSAL The products must be disposed according local regulations.

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:

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

Material specification

The Fortilink-SC Instruments contacting components are manufactured from medical grade stainless steel. Non-contacting components are manufactured from medical grade titanium alloy, aluminum alloy, silicone, rubber, and PPSU.

Packaging

Packages for each of the components should be intact upon receipt. Damaged or unintentionally opened packages and products should not be used and should be returned to BAAT Medical Products.

Recommended storage and handling conditions

The products shall be stored and handled with care. The products shall be stored and handled in an environment that is:

- dry and clean

Disposal

The disposal of this medical product requires no special measures. Be sure to observe all national/local regulations and guidelines when disposing of the packaging material and potentially infectious/sharp items.

Sterilization

The Fortilink-SC Instruments are delivered non-sterile and are to be sterilized by the user.

Recommended reprocessing procedure

LIMITATIONS ON REPROCESSING

Repeated processing has minimal effect on the products. End of life is normally determined by wear and damage due to use.

CLEANING AND DISINFECTION

Preparation at point of use

It is recommended that products are reprocessed as soon as is reasonably practical following use.

- Remove excess soil at point of use

Disassembly instructions

Disassemble for cleaning:

- Implant Inserter,
- Guided Awl,
- Guided Drill,
- Angled Drill/Screw Driver,
- Screw Driver, Locking.

Step-by-step instructions for disassembly are provided in the Surgical Technique.

Manual pre-cleaning

- Rinse under cold tap water (approx. 18 °C) for 10 s
- Sonicate in cleaning solution 0.5% Neodisher MediClean Forte (Dr. Weigert) at 40 °C for 5 min

- Treat the outer surface under cold tap water with a nylon brush until visibly clean
- Treat the inner surface/lumina under cold tap water with a bottle brush until visibly clean
- Rinse with cold desalinated water for 10 s

Automated cleaning and disinfection

Use a washer-disinfector according ISO 15883-1/2. Load products so that cannulations and holes can drain. Connect cannulated products to an MIS-rack. Load products so that cannulations and holes can drain. The trays must not be overloaded to guarantee optimal rinsing. Use the following program:

- 2 min pre-cleaning with cold tap water
- Draining
- 5 min cleaning with 55 °C tap water and 0.5% Neodisher MediClean Forte
- Draining
- 3 min rinsing with cold desalinated water
- Draining
- 2 min rinsing with cold desalinated water
- Draining
- 5 min thermal disinfection with 90 °C desalinated water (A_0-value > 3000). Other parameters are acceptable when an A_0-value of 3000 is achieved.
- Draining
- Drying, do not exceed 120 °C

MAINTENANCE AND INSPECTION

- The product must be examined for visible damage such as cracks, deformations, wear and corrosion. Cutting edges should be free of nicks and present a continuous edge. Discard blunt or damaged instruments.
- Apply a small quantity of surgical grade lubrication oil to hinges and threaded sections.
- Hinged instruments: Check for smooth movement of hinge without excessive "play". Locking (ratchet) mechanisms should be checked for action.
- Check instruments with long slender features (particularly rotating instruments) for distortion. Where instruments form part of a larger assembly, check assembly with mating components.

STERILIZATION

Assembly instructions

Assemble for sterilization:

- Implant Inserter,
- Guided Awl,
- Guided Drill,
- Angled Drill/Screw Driver,
- Screw Driver, Locking.

Step-by-step instructions for assembly are provided in the Surgical Technique.

Packaging

- Products may be loaded into the dedicated tray or a general-purpose sterilization tray
- Double wrap in sterilization paper according to ISO 11607-1, EN 868-2

Steam sterilization

When sterilizing multiple products in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded.

- Method: Pre-vacuum dynamic-air-removal according EN 13060 / EN 285 / ISO 17665
- Temperature: 132 °C
- Exposure time: 4 minutes

or

- Method: Pre-vacuum dynamic-air-removal according EN 13060 / EN 285 / ISO 17665
- Temperature: 134 °C
- Exposure time: 3 minutes

Drying

The integrity of packaging and containers should be visually checked after removal from the sterilizer. Damaged packaging and containers should be treated as non-conforming products. Drying should be carried out in an environment in which particles and microbial contamination are controlled.

- Drying time: 20 minutes

STORAGE

Products must be stored in a controlled environment.

DISPOSAL
The disposal of this medical product requires no special measures. Be sure to observe all national/local regulations and guidelines when disposing of packaging material and potentially infectious items.

Product complaints

If the implant ever "malfunctioned" and/or may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone or written correspondence. When filing a complaint, please provide the component(s) name and UDI(s), your name and address, the nature of the complaint and notification of whether a written report from the manufacturer is requested. Any serious incident that has occurred in relation to the device should also be reported to the competent authority of the Member State in which the user and/or patient is established.

End-user information

Instructions for use

Further copies of the Instruction for use can be requested at BAAT Medical Products.

Surgical techniques

Copies of the surgical technique can be requested at BAAT Medical Products.

Explanation symbols used in end-user information

The purpose of the used symbols is described below.

	Manufacturer		Date of manufacture		Consult instructions for use
	Catalogue Number		Batch code		Unique Device Identifier
	Keep dry		Caution		Non-sterile
	Do not use if package is damaged		Medical device		Distributor