

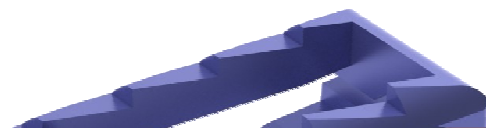


IFC Evolution

Intervertebral Fusion Cages



SURGICAL TECHNIQUE

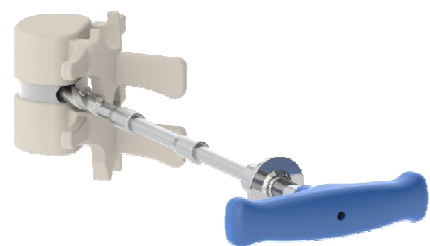


IFC Evolution

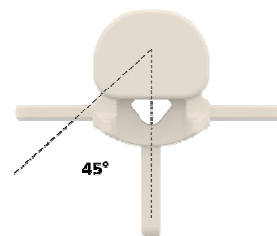
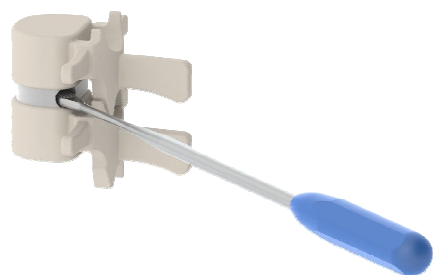
Intervertebral Fusion Cages

SURGICAL TECHNIQUE

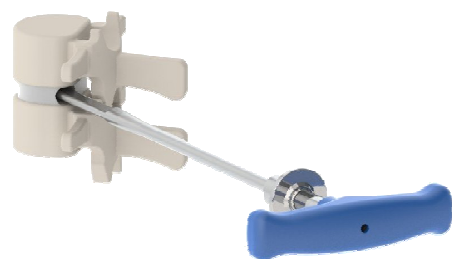
STEP 01 - PATIENT POSITIONING AND DISCECTOMY



The patient is placed in a prone position on the operating table. Access the distal place with a 45° approach to sagittal plane. To allow disc removal perform discectomy using the reamers and clean the intervertebral space by using the scraper. In case of miniminvasive approach the tissue dilators must be used to protect the surrounding tissues.



STEP 02 - IMPLANT SIZE SELECTION



If the intervertebral space is very tight, use the starter to spread it. Choose the starter with the appropriate size and insert it completely between the two vertebral bodies; keep the flat sides pointed towards the vertebral bodies and then turn it 90° to obtain the maximum distraction, Proceed with x-ray control to verify that the device is inserted in the desired direction and that the procedure has been correctly performed.

INDICATIONS

Appropriately used, Sinteia Plustek IFC Evolution Intervertebral Fusion Cages are indicated to promote the development of a solid intervertebral fusion of the lumbo-sacral segment of the spine. It is recommended in case of degenerative discopathy, pseudoarthrosis and spondylolisthesis.

STEP 03 - IMPLANT-INSTRUMENT CONNECTION



Once the proper size is chosen, connect the implant to the implant holder, by screwing it.

STEP 04 - IMPLANT INSERTION



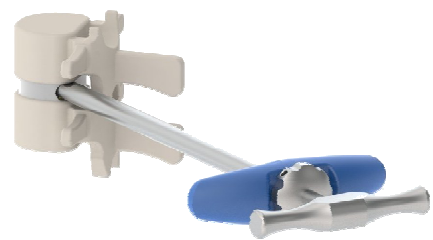
Insert the device, firmly connected to the implant holder, in the intervertebral space. Since the visual field could be limited, during implant insertion pay attention to keep the ratchet and the craniocaudal fenestration facing the vertebral endplates: so doing the expansion can be correctly performed. If necessary, once the device on the implant holder is positioned between the two vertebral bodies, impact the holder until it is properly positioned.

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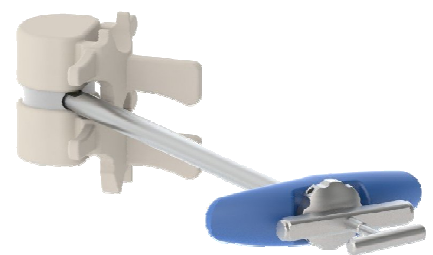
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SURGICAL TECHNIQUE

STEP 05 - EXPANSION / DE-EXPANSION

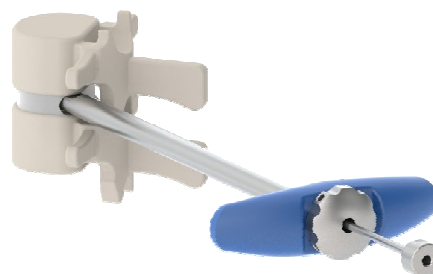


Proceed with X-ray control to verify correct positioning and expand with the appropriate instrument.



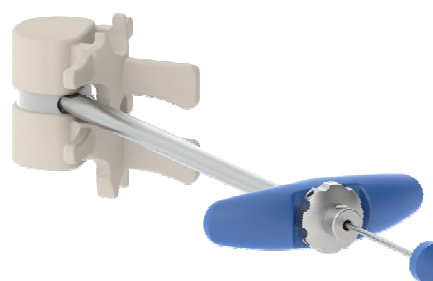
If it is necessary cage reposition, de-expand it with the appropriate tool.

STEP 06 - BONE GRAFT INSERTION



It is now possible to fill-in the expanded device with bone substitute using the bone substitute injector

Once the cage is in situ, complete the surgery with an additional posterior stabilization and posterolateral graft.

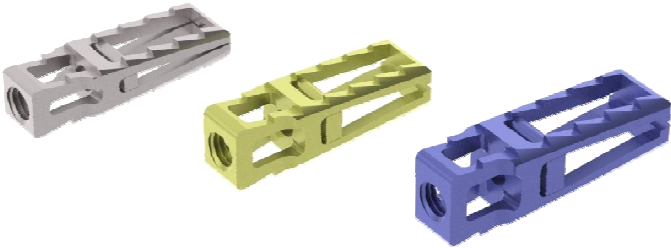




IMPLANTS

Intervertebral Fusion Cages

IFC - 15T5XA

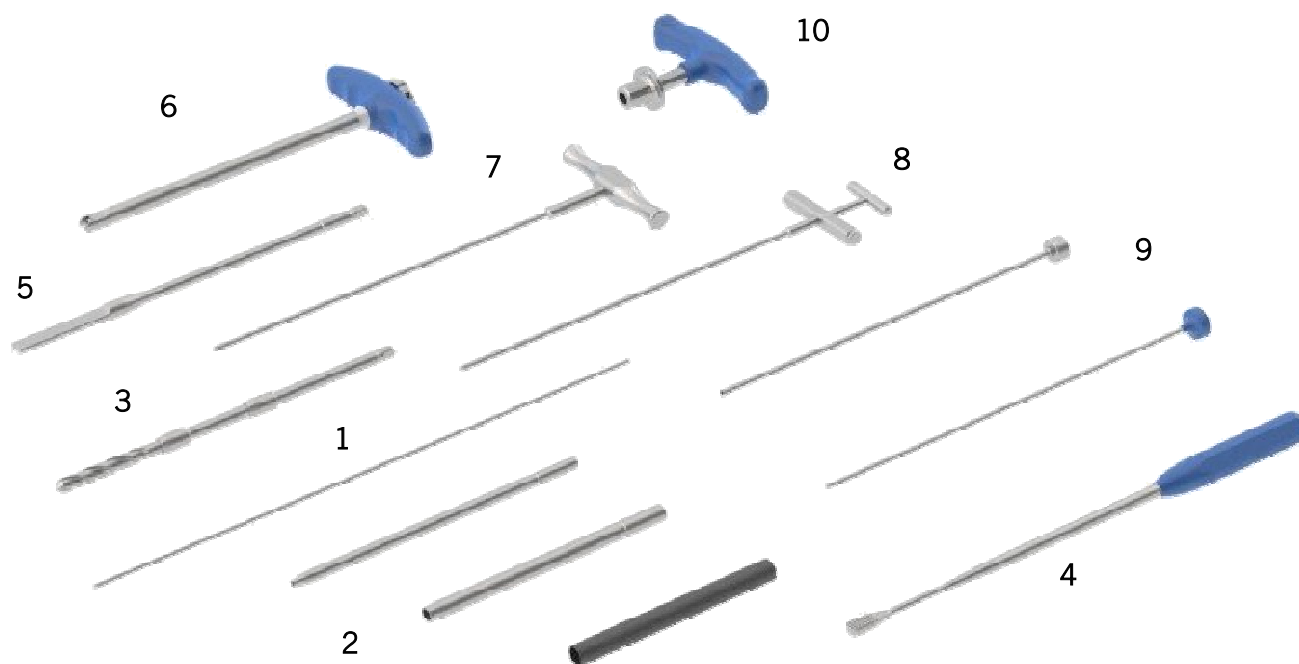


IFC Evolution

Intervertebral Fusion Cages

INSTRUMENTS

Guide Wire	IFC - 002ST2540S	1
Tissue Dilators	IFC - 001ST4XS	2
Reamer	IFC - 005ST00XXS	3
Scraper	IFC - 004ST0000S	4
Starter	IFC - 003ST04XXS	5
Long Module Holder	IFC - 007ST0000S	6
Long Module Expander	IFC - 007ST0001S	7
Long Module Extractor	IFC - 007ST0002S	8
Bone Substitute Injector	IFC - 008ST000XS	9
Universal Handle	IFC - 010ST00005	10





CONTRAINDICATIONS

The contro-indications to the implant of Sintea Plustek IFC Evolution Intervertebral fusion cages are analougous to those of similar products currently available on the market and include but are not limited to the following:

ABSOLUTE

- Active infections
- Allergy to the metal components
- Patients who are either unwilling or unable to follow prescriptions

RELATIVE:

- Metastasis
- Several muscular, neurological or vascular diseases
- Fever or leukocystosis
- Pregnancy, with the exception of unstable vertebral fractures
- Signs of phlogosis of the implant area
- Inadequate coverage of soft tissues at the implant site
- Severe osteoporosis

If Sintea Plustek IFC Evolution intervertebral fusion cages are considered the best solution for the patient and if the latter presents one or more of the above contraindications, it is absolutely necessary to inform him/her about any possible adverse effect which may influence the success of the procedure

Sintea Plustek S.r.l.

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