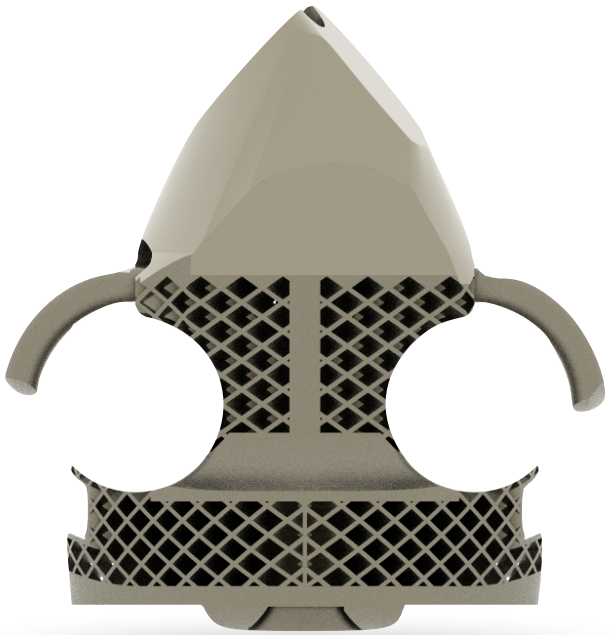
TSUNAMI MEDICAL

b-OK BONEINGROW®

GIGLIO

Interspinous Fusion System



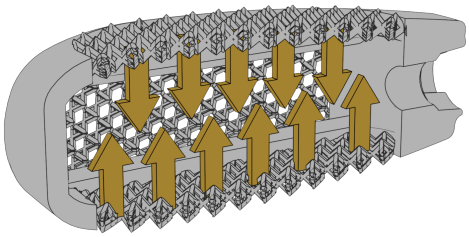
Surgical Technique

Percutaneous approach

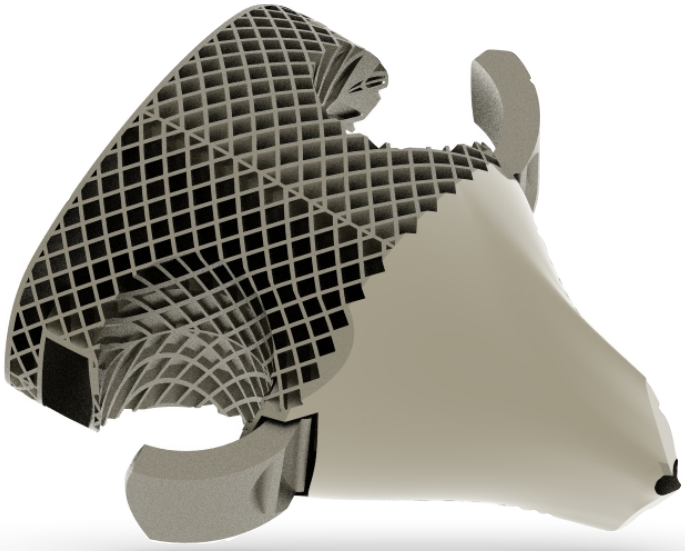
System Description

b-OK BoneInGrow™ Giglio Interspinous Fusion devices has been designed in order to promote highest quality fusion. Novel concept of titanium processing developed by Tsunami Medical provides an excellent environment for bone fusion due to followings factors:

- osseo integration of titanium particle
- benefits of fusion process due to Wolf's Law.
- open implants structure allows free flow of bone cells
- high porous surface supports settlement and growth of new osteogenic cells formations.



b-OK GIGLIO Interspinous Fusion System is intended to be used as interspinous spacer to promote fusion. Please see Product IFU for indications and contraindication. The b-OK system must be used by professionals with appropriate trainings accomplished.



GICLIO : Intended Use

It is intended to be used at levels L1 : S1 only.
Additional indications may include Baastrup Syndrome (kissing spine), adjunction to a micro-discectomy and unloading of disc adjacent to lumbar fusion. The GIGLIO IFS system is also indicated for those patients with impaired physical function and with leg, buttock, or growing pain which is relieved during flexion.

GIGLIO: Indications

Lumbar pathologies with indicated segmental spondylodesis, e.g.:

– Degenerative disk disease and spinal instabilitie
– Revision procedures for post-diskectomy syndrome
– Pseudoarthrosis or failed spondylodesis
– Degenerative spondylolisthesis
– Adult deformity

GIGLIO : Contraindications

- Vertebral body fractures
- Intersinous proces fracture
- Spinal tumor
- Infection
- Obesity

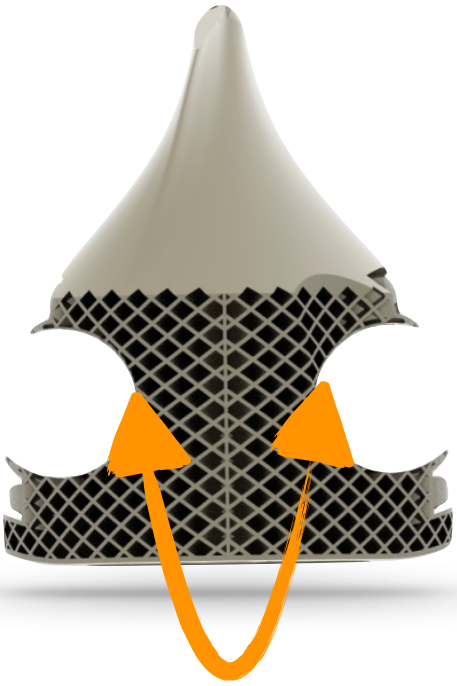
GIGLIO : overview

GIGLIO is a 3D printed Titanium Interspinous Fusion System, studied to maximize the fusion between interspinous process.
GIGLIO structure allows the bone tissue to grow rapidly inside the Implant. The contact with the bleeding interspinous process with the net structure of the Implant create a “bone grow” effect and a fast fusion.
The primary mechanic stabilization is guaranteed by the net, and by the two wings that penetrate the interspinous process
GIGLIO is designed with 2 Wings that create primary stability and promote bone growth; this will allow a solid fixation of the spinous processes

Fixing wings promoting bone growth

GIGLIO : implants dimensions

– GIGLIO is available with six different dimensions:
6mm; 8mm; 10mm; 12mm; 14mm; 16mm



Dimension measuring

GIGLIO : available dimensions

Codice	Descrizion
IFS 06	Implant dimension at interspinous space 6mm
IFS 08	Implant dimension at interspinous space 8mm
IFS 10	Implant dimension at interspinous space 10mm
IFS 12	Implant dimension at interspinous space 12mm
IFS 14	Implant dimension at interspinous space 14mm
IFS 16	Implant dimension at interspinous space 16mm

Surgical Techniques, percutaneous approche:

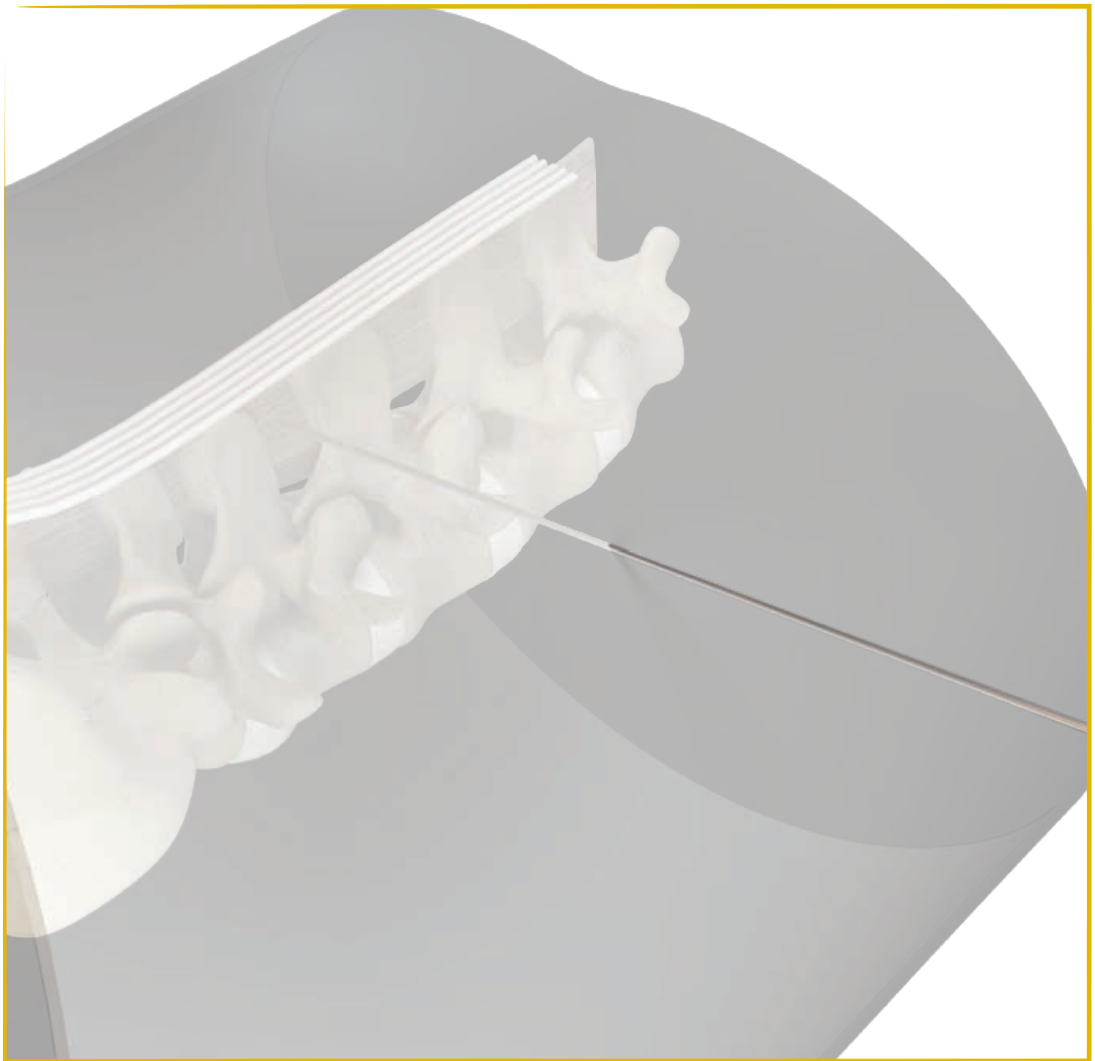
Patient is placed in prone position with legs slightly flexed on a radiolucent frame with foam padding. To optimize the effect of the implant, it is important to have the patient in a physiological lumbar lordosis.
The position of the vertebral levels must be confirmed using fluoroscopy.

Anatomical Landmark identification and incision :

Determine by fluoroscopy the level decided using radiopaque marker.
AP view is suggested.
Once the desired level is determined, draw a line to guide during the device positioning.

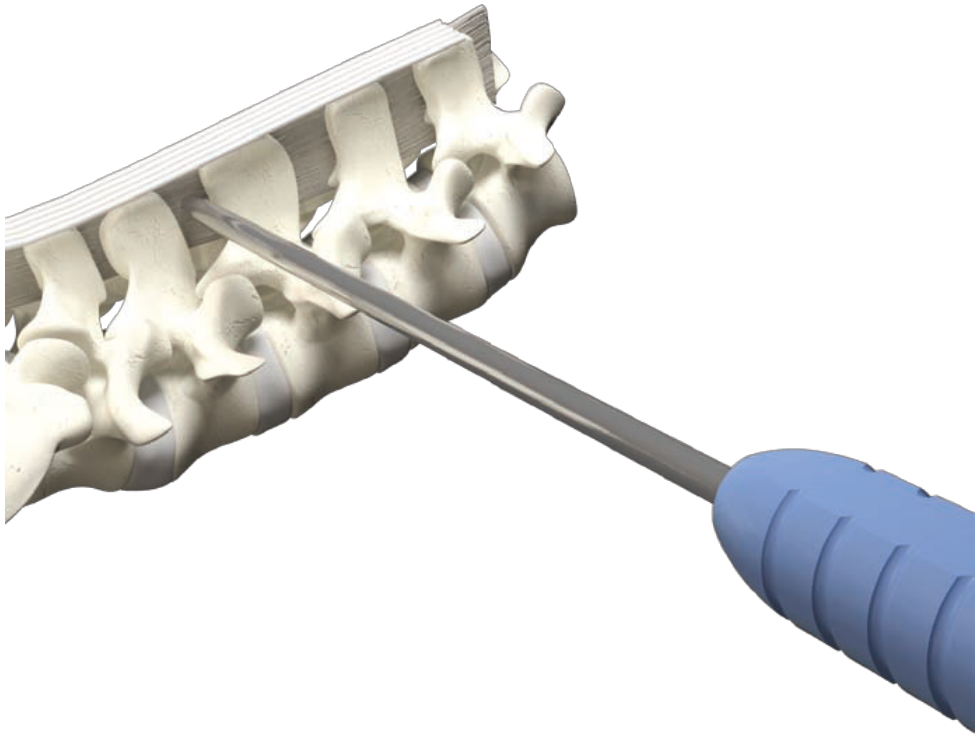
Using approximately three finger breadths (7 - 10 cm), measure off the midline along the marked location.

Once the position is targeted, make a 2-3 cm incision.



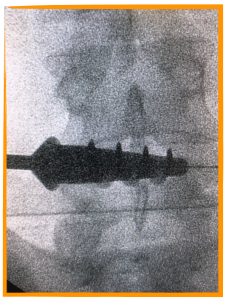
Targeting :

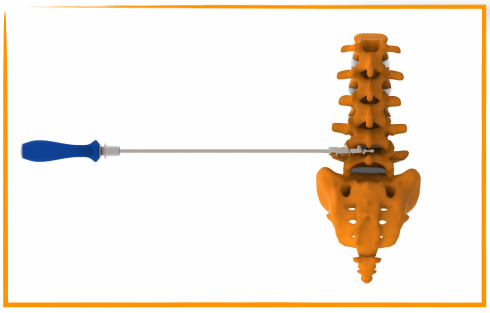
Insert the guidewire through the incision under LL fluoroscopy to reach the interspinous space and confirm depth.
Advance the Guidewire on the AP fluoroscopy view for a precise placement between the spinous processes at the determine level.
Place the Ligament Splitter over the Guidewire and dilate through the interspinous ligament.
Take an AP and lateral fluoroscopic image to verify positioning between the spinous processes.
Remove the Ligament Splitter while retaining guidewire in place.

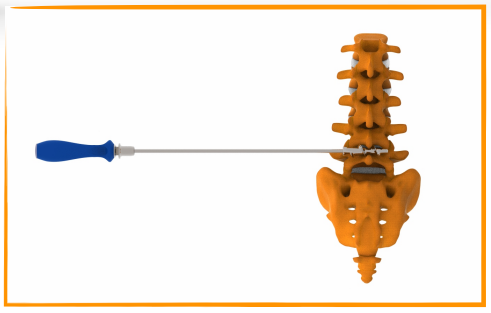


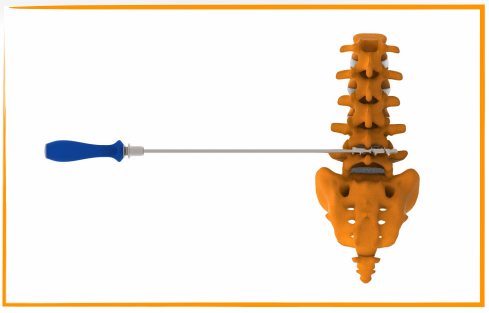
Insert Dilator Trial all in one:

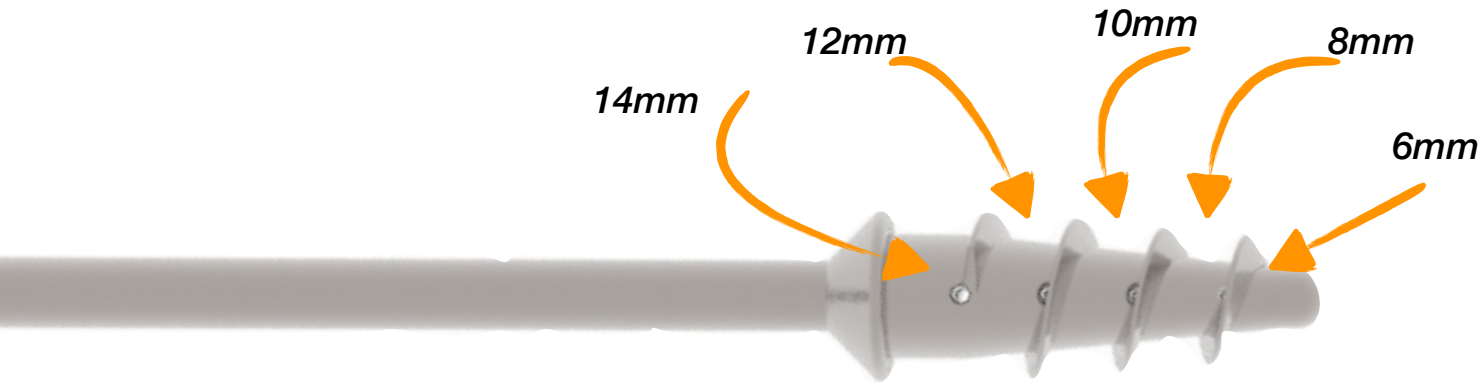
Starting with the Dilator/Trial, position the Dilator/Trial onto the guidewire.
Insert the assembly through the incision and down the path created by the Ligament Splitter.
Once the tip of the Dilator/Trial reach the interspinous space, begin rotating the blue Inserter handle clockwise to thread between the superior and inferior spinous processes. LL and AP views are use to confirm depth and positioning between the spinous processes.
The Dilator/Trial barrel should be positioned within the interspinous space.
To confirm proper Dilator/Trial positioning and size, rotate clockwise for a fluoroscopic feedback.
When proper dilation is reached verify with LL view the foramen opening.
Remove the Trial assembly by turning the blue Inserter handle counterclockwise, and pulling outward.





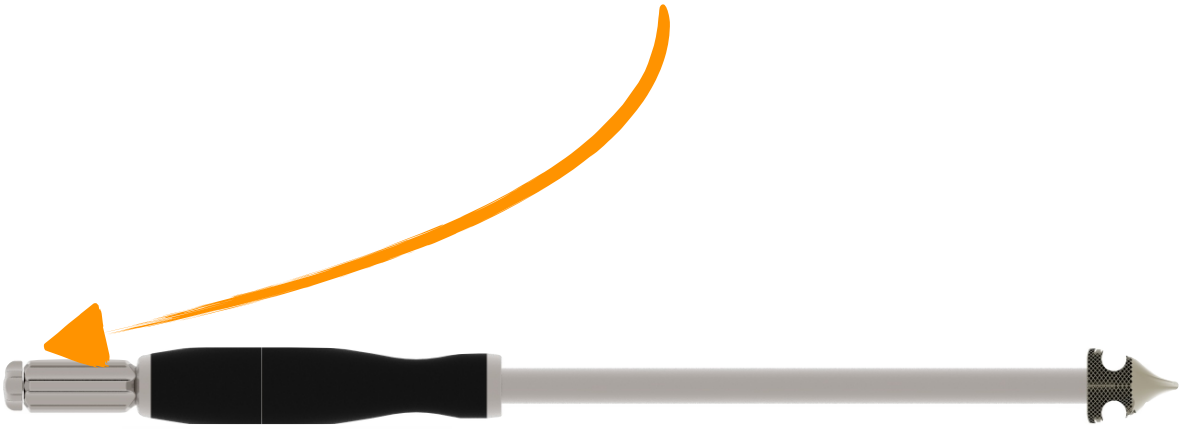






Implant Assembli :

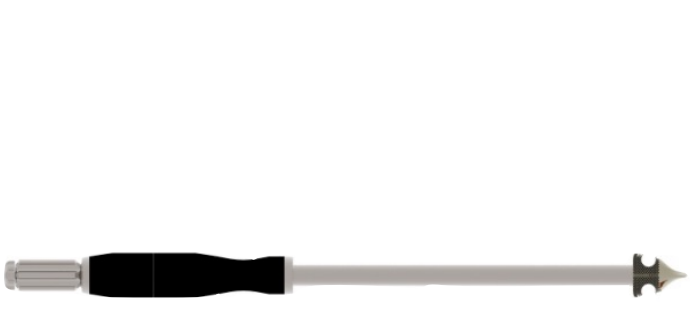
Connect the GIGLIO implant on the implant holder connecting on the top and fixing by rotating the small fixing wheel on the implant

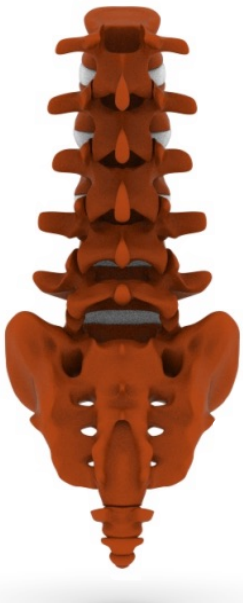


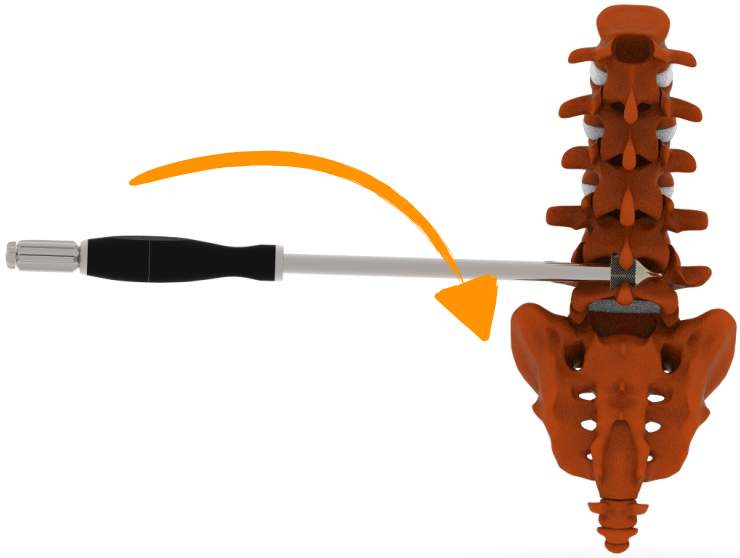
Implant Positioning :

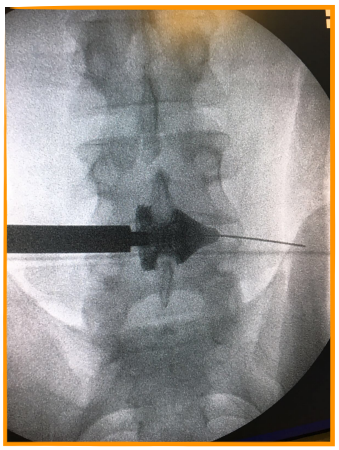
Under Fluoroscopy control, insert the assembly through the incision and down the targeted pathway. Once the Implant tip reach the interspinous space, start rotating the black Inserter handle clockwise to thread between the superior and inferior spinous processes.
Keep Inserter attached to Implant until placement is verified.

Note: Simultaneously push the Implant into the interspinous space while rotating the Inserter handle to easy GIGLIO positioning.



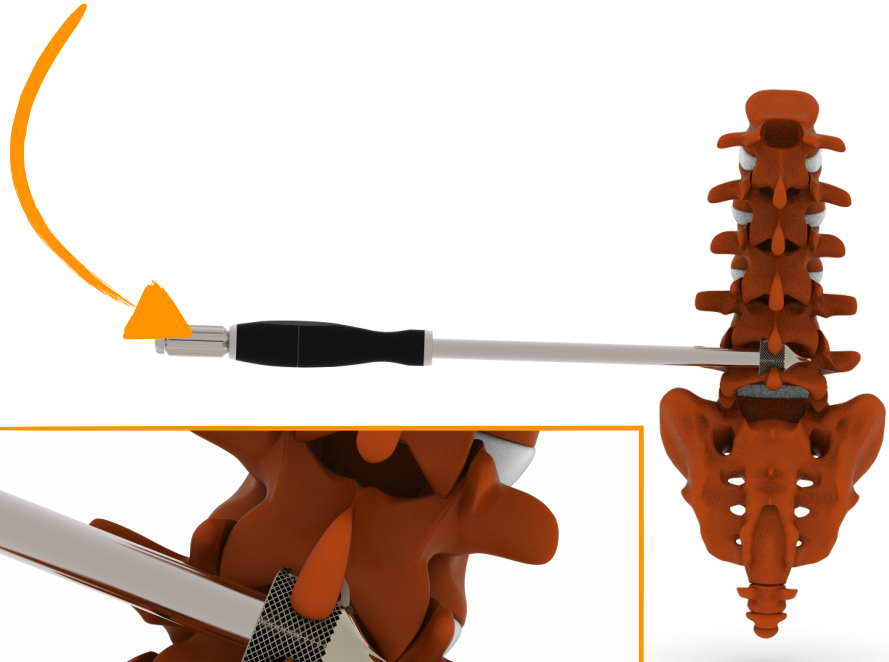


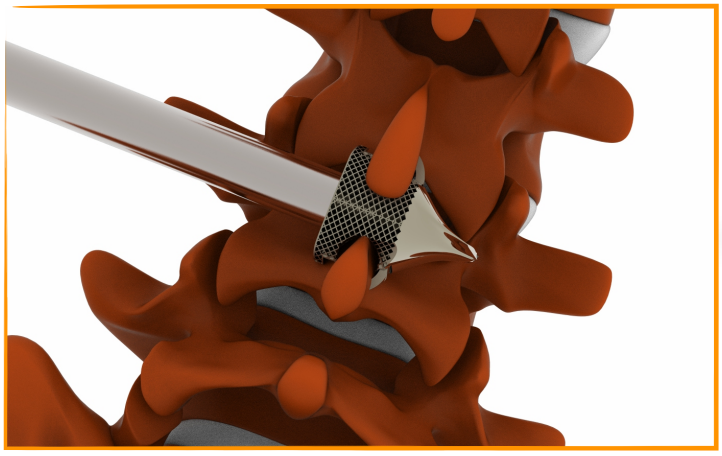




Implant Fixation :

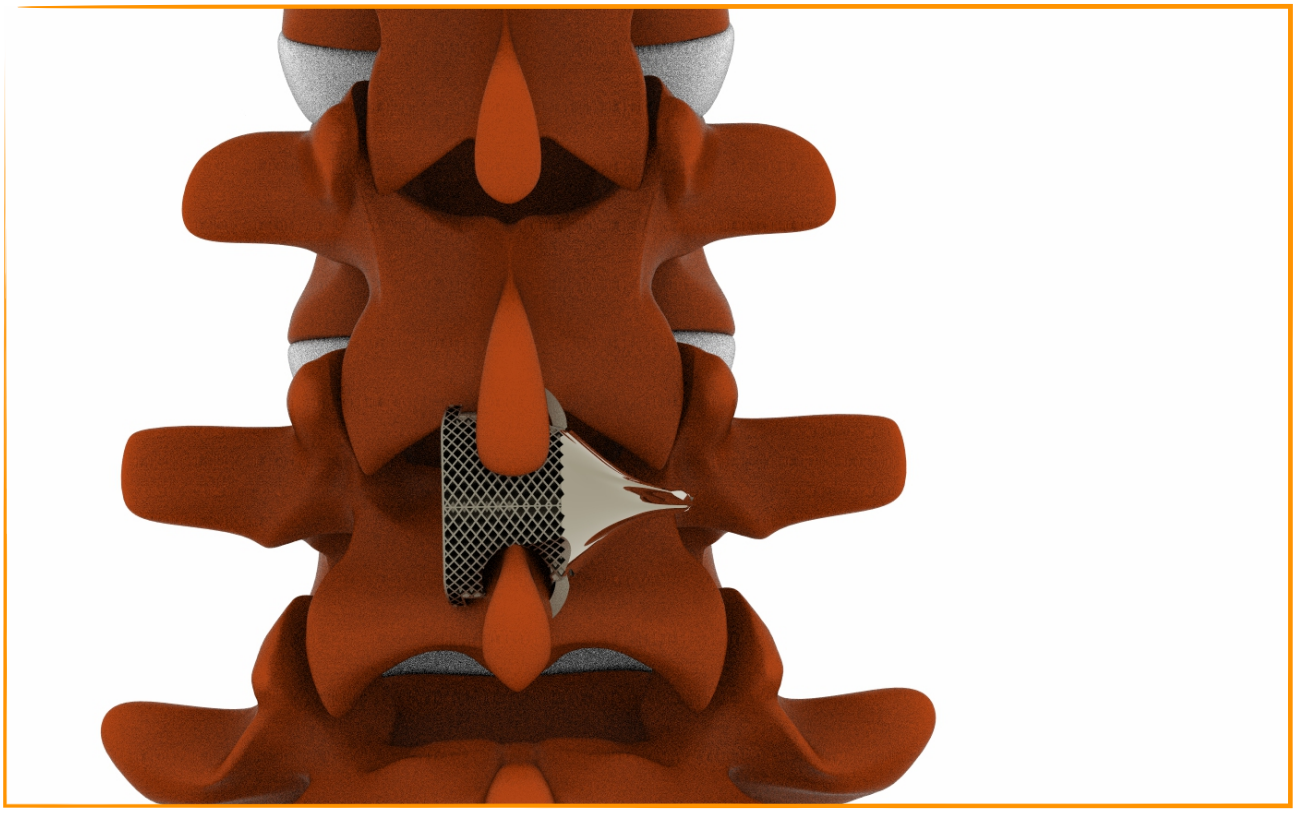
Ones the position between the interspinous process is reached, and verified by fluoroscopy, proceed with the implant fixation by rotating clockwise the leverage on the implant holder

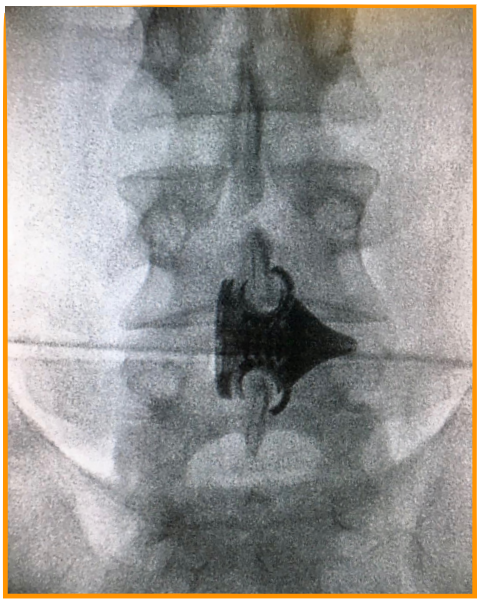




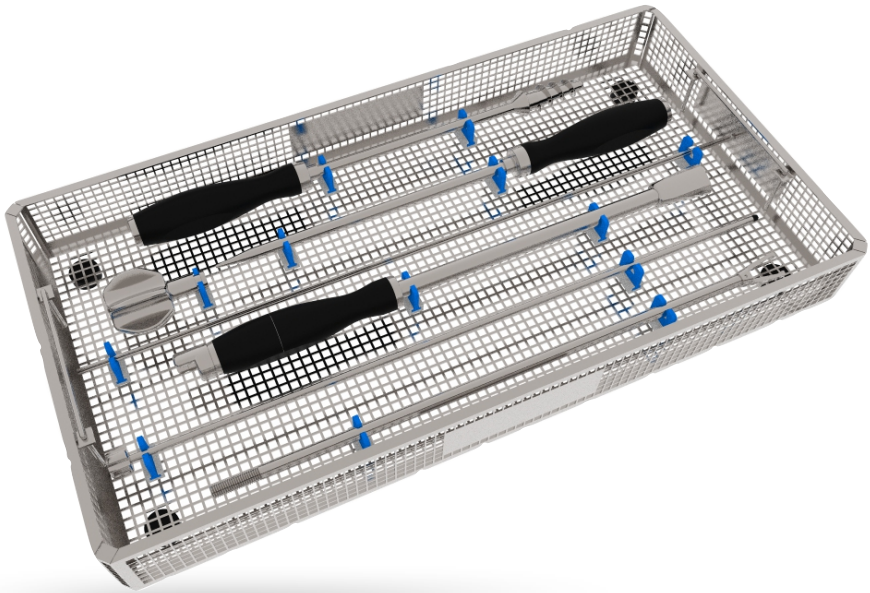
Implant Leave in place :

After the opening of the wings and the fluoroscope control, proceed to release the implant by rotating counterclockwise the fixing wheel on the implant holder, and gently pull back all the implant holder, leaving in place the implant.





Instrument Set:



CODE : G01 First Access

CODE: G02 Implant trial

IMPLANT HOLDER:

CODE: G03 Implant holder body

CODE: G04 Implant holder fork

CODE: G05 Implant holder Block

CODE: G06 wings spreader

CODE: G07 Guide wires

General Information

IMPORTANT INFORMATION ON THE B-OK LUMBAR TITANIUM INTERSPINOUS PROCES FUSION SYSTEM GIGLIO

The B-OK Lumbar Spinal System is intended recreate and maintain distance between vertebras to support biologic fusion in the thoracic, lumbar or sacral spine. As complementary device it should NOT be used as standalone.

DESCRIPTION:

The B-OK Lumbar Spinal System consists of the GIGLIO IFS in variable sizes and shapes. The composition of implants may be vary depends on anatomical conditions and physician decision.
All components of B-OK Spinal System should be never reused under any circumstances.
Lumbar Titanium IFS is designed to be applied to lateral approaches.
In particular these instructions for use apply to the following codes:

IFS Interspinous Lateral fusion Implant for Lumbar Interspinous process Arthrodesis (IFS) GIGLIO

MATERIALS:

The entire system is be made out of medical grade titanium or titanium alloy described by ISO 5832-3 or 10993-5 or ASTM F2026 or ASTM F136 standards. Tsunami Medical sorely warrants that all devices are manufacture from one of the foregoing material specifications. No other warranties, express or implied, are made. Please see the Tsunami product brochure for further information.

INDICATIONS:

B-OK Lumbar Spinal System is intended for lumbar interspinous Process fusion fixation for the following indications:
1. Degenerative disk disease.
2. Spondylolisthesis.
3. Spinal stenosis.
4. Instability of motion segments.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:
(1) Risk of infection or infection in progress, or fever or inflammation.
(2) Obesity.
(3) Pregnancy.
(4) Mental illness.
(5) Allergy on any system components.
(6) Any anatomical, medical or surgical conditions witch may preclude potential or intentional benefits of spinal implants application.
(7) Bone, joints or ligaments conditions such but not limited as: osteopenia, bone absorption, osteomalacia. Osteoporosis is relative contraindications an must by carefully evaluated prior surgery.
(8) Implants size, shape or anchorage functionality might be not enough to achieve expected clinical results.
(9) Mixing of implants with other manufacturers or with other fixation systems.
(10) Potential risk of unexpected patients anatomy destruction, interference with neurological, functional or other deficits.
(11) Any risk of patient's unwillingness to follow postoperative instructions.
(12) Any other not described in indications.
(13) Any previous abdominal surgery.

POTENTIAL ADVERSE EVENTS

Possible adverse events which might occur after spinal surgery with or without instrumentation include, but are not limited to:
(1) Disassembly, bending, and/or breakage of any or all of the system components.
(2) Migrations any of system components.
(3) Pressure on the skin from component parts in patients with inadequate tissue coverage.
(4) Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
(5) Dura leakage, distortion or damage.
(6) Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, radiculopathy, paralysis, hypesthesia, or any others related to general surgery associated to anesthesia.
(7) Infections.
(8) Loss of urinary functions.
(9) Permanent or temporary or developing sexual dysfunctions.
(10) Postoperative change of body curvature, change of physiological range of movement.
(11) Pseudoarthrosis or non-fusion or delayed fusion.
(12) Bone loss or overgrowth, or any other bone malformations.
(13) Permanent or temporary limitation or inability to perform daily activities.
(14) Changing in mental behavior.
(15) Permanent or temporary or developing respiratory problems.
(16) Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
(17) Death.
In some of cases additional surgery or surgeries might be necessary to correct or change potential adverse events.

WARNINGS:

The effectiveness and safety of Interspinous fixation is only applicable for certain conditions with significant instability which require the posterior fusion supported by medical device. The device might be supportive for such mechanical instability like deformity, fracture, listhesis, dislocation, tumor, pseudoarthrosis. The effectiveness and safety for any other conditions are unknown.

b-OK GIGLIO IFS has been designed strictly for Interspinous Fusion lateral technique.

PRECAUTIONS

The Lumbar Titanium Interspinous Fusion Systems are complementary implants to Inter-body fixation systems and should be used as standalone. The applications of pedicle screw and/or inter-body cages should be performed by experienced surgeons with specific training in use of Lumbar Titanium Cage. The spinal screw fixation system and/or inter body cage system should not be considered as sole spinal support. No implants can withstand body loads without bone support. Therefore bends, breakages, loosening, disassembling may occur over the time. A successful results are not always achievable. The factors as proper preoperative and operative procedure, comprehensive knowledge of surgical techniques, proper selection of implant's size and type are considerably important in treatment process. Patients with obesity, smokers, alcohol abused are risk of non-fusion surgery.
Also patients in weak muscle or bone conditions, nervous system dysfunctions are poor candidates for spinal fusion. Prior or during or after the surgery in order to evaluate or check the positioning of the implants or patients anatomy or any other patients or implants correction X-ray or CT or any other invasive diagnostic examinations may be necessary to be performed.
The proper, patient's individual implants selection in terms of type, size, shape or design is vital to successful surgery performance. Proper implants and instruments handling is crucial. Extensive bending or contouring should be avoided. Sharp edges cutting, reversed bending, scratching or notching may generate internal stressing which may weak the implants or construct.

IMPORTANT: All necessary informations about surgery, potential risks, benefits and adverse effects should be conveyed to the patient prior to surgery.

PREOPERATIVE:

(1) Patients meet the criteria described in the indications should be only selected.
(2) Patients conditions should be checked prior surgery Any required diagnostics should be performed.
(3) The efficient and adequate implants and instruments inventory must be secured and be available during the surgery.
(4) All implants, instruments and any other components should be cleaned and sterilized before use. Any implants, instruments or components delivered as sterile must be checked due to sterility and expiration time prior surgery.
(5) Implants and instruments should be stored in certain conditions to warranty the sterility and protection from any contamination or corrosive environment.
(6) It's highly recommended that all personnel interacting with any mechanical components from the spinal system should be familiar with all components before using.

INTRAOPERATIVE:

(1) Extreme caution should be used when working close or around the spinal cord and nerve roots.
(2) Whenever possible or required intraoperative diagnostic system should be used to facilitate surgery.
(3) Breakage, bends, scratch slippage, part loosening or improper use of any implant or instrument during the surgery may cause injury to OR personal or patient.
(4) It's very important to follow carefully surgical technique. Proper application of any instrument or implant may facilitate surgery.
(5) Before closing of soft tissue double check of all implants positioning, geometrical relations, and fixing, tightening or mounting manoeuvres for all screws, nuts or other fixing parts should be performed. Image diagnostics is highly recommended at this stage.

POSTOPERATIVE:

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.
(1) Detailed instructions on the use and limitations of the device should be given to the patient.
(2) The patient should be warned to avoid falls or sudden jolts in spinal position.
(3) The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
(4) As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
(5) Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the B-OK Spinal System components should never be reused under any circumstances.