TSUNAMI MEDICAL

THE WAVE OF INNOVATION

Surgical Technique

GIANNUTRI

DLIF 3D Printed Titanium Cage

Expandable

Bone InGrowth Technology®

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Stromboli-J Overview

Giannutri expandable DLIF 3D printed Interbody Fusion Cage, presents the following main characteristics:

- **Excellent Stability**

The unique "net" structure obtained through additive manufacturing technology, provides strong primary fixation and elimination of implant migration risk.

- **Wide Variety of Footprints, Heights & Lordosis Angles**

One system matching patients' natural anatomy and surgeons' preferences.

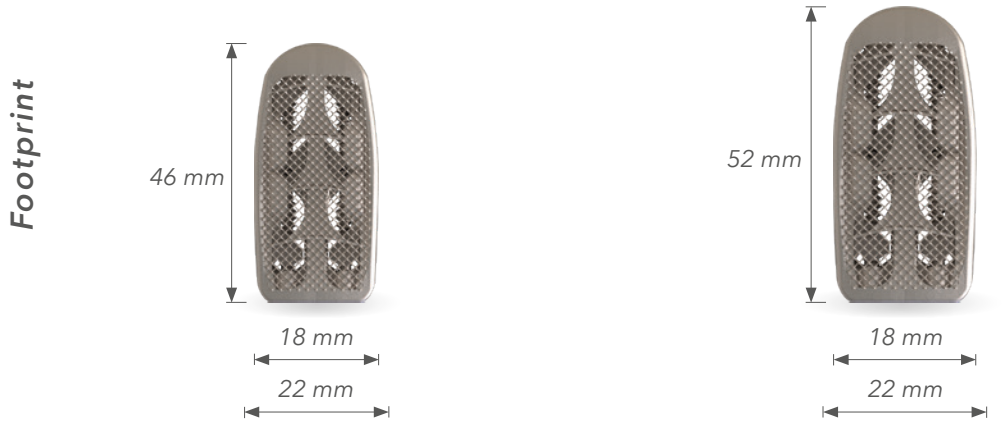
- **Bone InGrowth Technology**

Pore size of the net structure and the surface roughness of the implant edges facilitate fast and effective osteo-integration.
The elasticity modulus of the implant, similar to PEEK, is close to natural bone characteristics and is a key success factor.

- **Additional Expansion Feature**

Giannutri has a unique multi-direction extension mechanism: it allows cranial-caudal height extension and amendment to the required lordosis angle by individual and gradual extension in anterior and posterior direction. With this unique feature surgeons are able to make the implant perfectly fit the natural anatomy or achieve the required restoration of balance at one or more affected levels.
Both implantation and the individual expansion features are being performed with one and the same implant introducer, no additional instruments are required. Apart from ease of use for the surgeon and time saving, patient's safety and comfort are being secured because of this.
For Giannutri, Tsunami Medical offers four footprints and a range 8-13 mm heights, with possible lordosis angles ranging from 0° to 14°, thanks to its innovative expansion feature, as outlined below.

Stromboli-J Overview



Product Reference Codes

Ref. Code	Dimensions
ACXH46180800	Footprint Size **46x18mm** - Angles **0°-14°** Heights [mm] **08-13**
ACXH52180800	Footprint Size **52x18mm** - Angles **0°-14°** Heights [mm] **08-13**
ACXH46220800	Footprint Size **46x22mm** - Angles **0°-14°** Heights [mm] **08-13**
ACXH52220800	Footprint Size **52x22mm** - Angles **0°-14°** Heights [mm] **08-13**

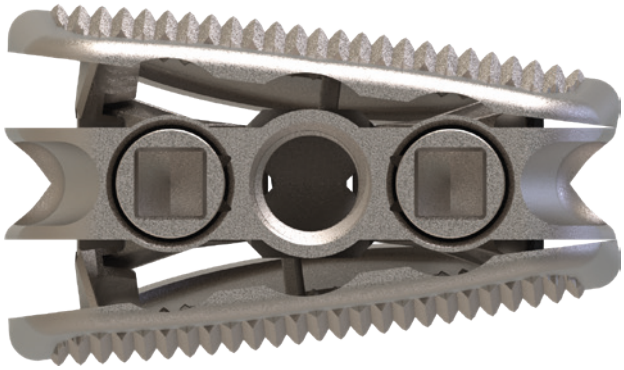
CE 0051

GIANNUTRI

Giannutri Intended Use

Giannutri is intended to recreate and maintain distance between vertebras to support biologic fusion in the thoracic, lumbar or lumbar-sacral spine zone.
When surgeons deem necessary to add an additional bone growth accelerator, Tsunami Medical's Universal Filling System supports the bone substitute filling procedure, either at pre-implantation or post-implantation stage of the surgical procedure, in an effective way.

Giannutri is intended to be used in combination with supplemental fixation, such as:



- Posterior stabilisation with pedicle screw systems
- Lateral fixation
- Interlaminar stabilisation devices

Interbody fusion cages are intended to be used exclusively by professionals with appropriate trainings accomplished.
The Instructions For Use (IFU) should be respected at all times.

Indications

Giannutri is intended for Thoracic and Lumbar interbody fixation for the following indications:

(1) Degenerative disc disease.
(2) Spondylolisthesis.
(3) Spinal stenosis.
(4) Trauma.
(5) Tumour.
(6) Pseudo-arthrosis.
(7) 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 which 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 a must be carefully evaluated prior surgery.
(8) Implants size, shape or anchorage functionality might be not enough to achieve expected clinical results.
(9) Combination with implants from other manufacturers.
(10) Potential risk of unexpected patient's 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.

Caution: in case of reuse there is a danger of cross contamination; any reuse is therefore not permitted.

Patient Positioning

Place the patient in supine position for lateral approach to lower lumbar levels of the spine. Approach the required level following the known surgical technique hereto. This patient position facilitates additional posterior fusion options without the need for turning the patient, with all related benefits. A pillow below the belly is recommended to flatten the lumbar lordosis, which facilitates an easier and safer entrance into the intervertebral disc space.

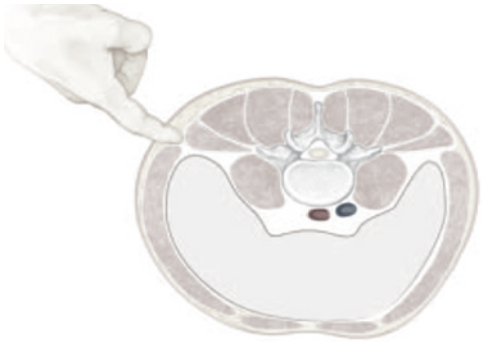
Patient in prone position.

When the surgeon prefers a lateral patient position, surgical steps are similar as described below; only with fluoroscopic imaging this 90 degrees deviation of position needs to be respected.

Surgical Incision Preparation

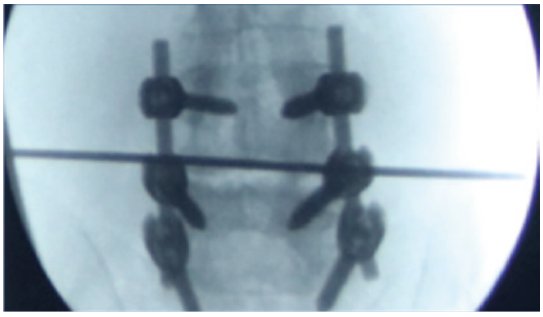
Map out through one abdominal pre-surgery MRI in prone position (like the surgical position) a safe corridor through the psoas muscle to the lumbar spine. Fluoroscopy is recommended, to ensure targeting the anterior two-third of the affected disc.

The anterior third of the psoas muscle is the most likely safe zone for avoiding the neural elements of the lumbar plexus.



Safe corridor through psoas muscle to the lumbar spine.

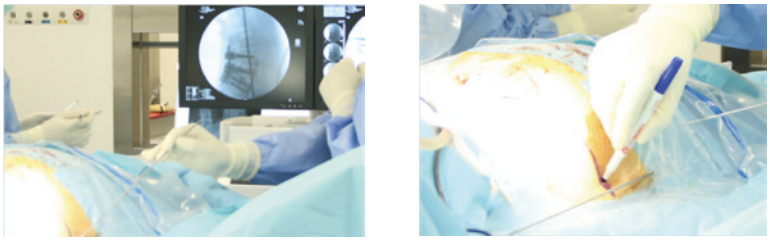
Note
Use a longitudinal incision if multiple levels will be fused.



X-ray of skin incision

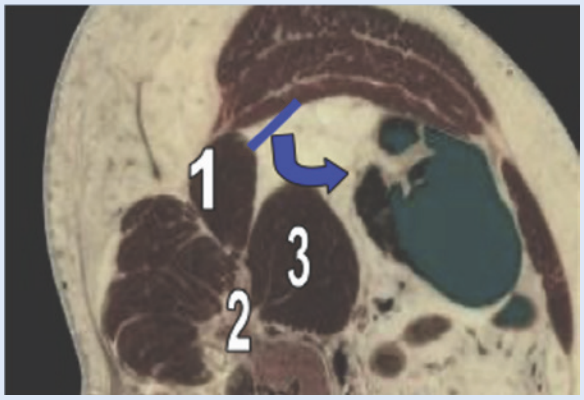
Skin Incision

Locate the correct level and incision with fluoroscopic views. Make a skin incision targeting the anterior third of the intervertebral disc space.



Two moments of the skin incision procedure during surgery.

First Steps' Summary



- Direct Observation of Muscle Layers
- Follow Internal Abdominal Wall
- Posterior to Anterior Abdominal Wall Finger Sweep

  Feel for:

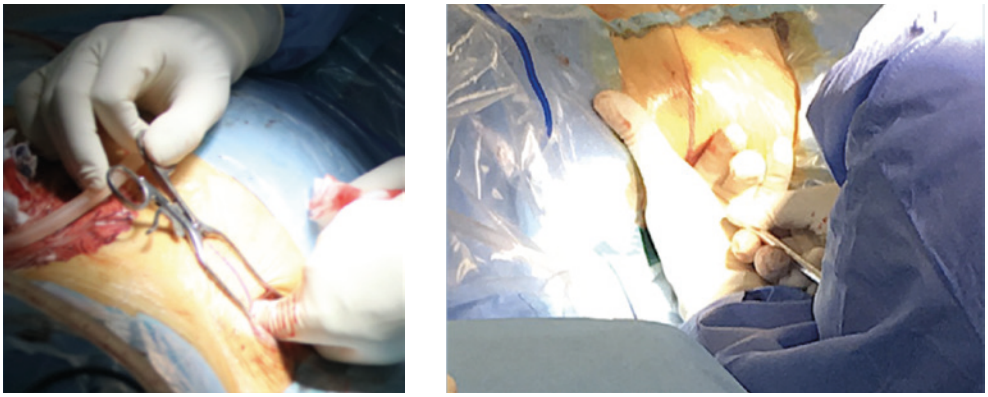
  - Quadratus Muscle
  - Transverse Process
  - Surface of the Psoas Muscle

Vertebral Disc Entering Procedure

Once the skin incision is made and the subcutaneous tissue is released, the oblique muscles of the abdomen should be visible. Separate the muscle fibers with blunt dissection and enter the retroperitoneal space. Move the peritoneum anterior with forefinger and continue blunt dissection to palpate down to the transverse process. Slide forward to the psoas muscle. After reaching the psoas muscle using the finger, it is time to enter with the first access instrument (assemble **BOK-LD-14-1/2**); it is possible to connect the instrument to a neuro monitoring system. The initial instrument has to be fixed in the disc space, using the hammer if necessary.

This instrument has to be positioned with maximum accuracy, in the middle of the disc space, and will guide the positioning of the retractor system in the next steps.

The first access instrument is composed by one internal mandrel (**BOK-LD-14-2**), with round tip, and a smooth cannula (**BOK-LD-14-1**); this allows the surgeon to reach the disc through the psoas muscle without risk of possible damage to muscle and nerve systems.

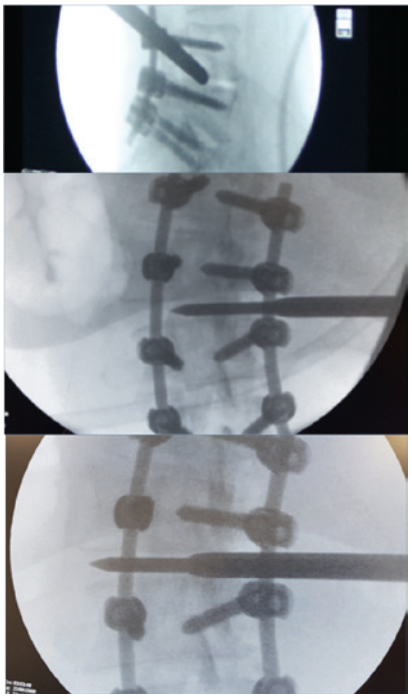


Two moments of the vertebral disc entering procedure during surgery.

Once the psoas muscle has been crossed and the disc has been reached in the optimal central position in lateral view, the central round mandrel must be removed and the conic mandrel inserted (**BOK-LD-14-3**), facilitating easy penetration of the annulus of the disc and fixation of the cannula for the next steps.

Is very useful to also push the cannula inside the disc space to assure a strong and reliable fixation, which is very important for the next steps of the surgical procedure.

To support easy entry of the disc space, a special cannulated instrument (**BOK-LD-14-4**) is available to push the cannula into the disc space.

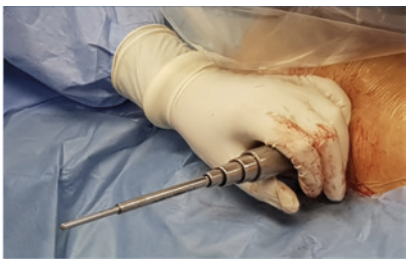


X-rays portraying three moments of the vertebral disc entering procedure with Stromboli First Access Guide (BOK-LD-14-1,2,3,4).

BOK-LD-14

Dissection Cannulas

Three additional cannulas (**BOK-LD-13-02/03/04**), each with an increased diameter, need to be placed on the initial cannula (**BOK-LD-13-1**) to gently enlarge the psoas muscle fibers, creating the space to position the GHOST retractor (**BOK-LD-04-22**).



Enlargement of psoas muscle fibers during surgery.

BOK-LD-13-*

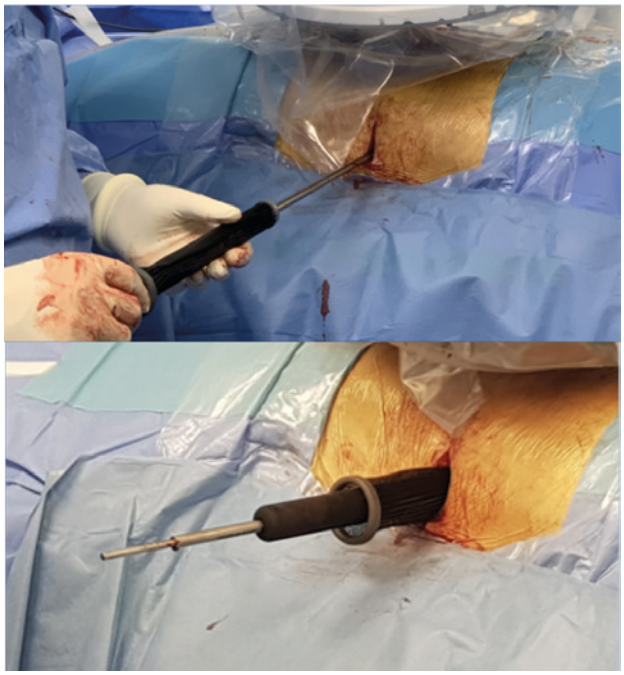
Retractor Assembling

Slide the retractor holder (**BOK-LD-05-22**) inside the Ghost retractor (**BOK-LD-04-22**) and push the square end of the holder into the metallic ring of the retractor till it stops (there is a hard stop on the holder).

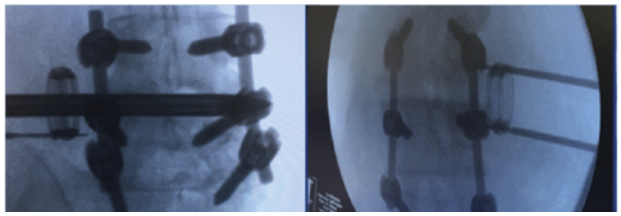
Retractor Positioning

Remove all the dissection cannulas, leaving only the initial instrument well fixed into the disc space.
Once all the dissection cannulas have been introduced, reaching the disc wall, position the assembled GHOST retractor.
Gently push the GHOST retractor on the cannulas inside the patient, till reaching the vertebral body, gently rotating the retractor helps to cross the soft tissues.

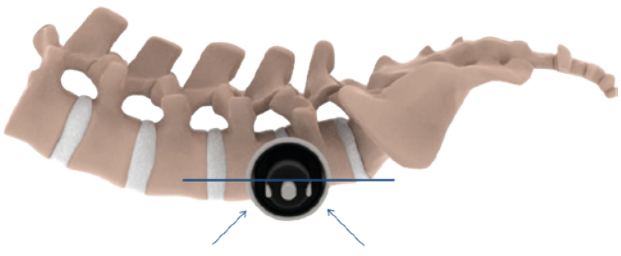
Use fluoroscopic control when reaching the vertebras.
After reaching the vertebral body, crossing the psoas muscle, fix the GHOST on the vertebral body, using the pin wires (**BOK-LD-06**).
Gently hammer (using **TH002**) the pin wires into the vertebral body to support fixation of the metallic ring of the GHOST retractor on the lateral part of the vertebral body.
For correct positioning of the fixation wires, use the two channels on the retractor holder, and slide the wires inside. The channels are designed to guide the wires through the fixing holes on the GHOST metallic ring, and enter the vertebral body. Control the position of the GHOST retractor: the wire channels have to be in cranio/caudal position.



Positioning of the assembled Ghost retractor during surgery.



X-rays of two moments of the Ghost retractor positioning during surgery.



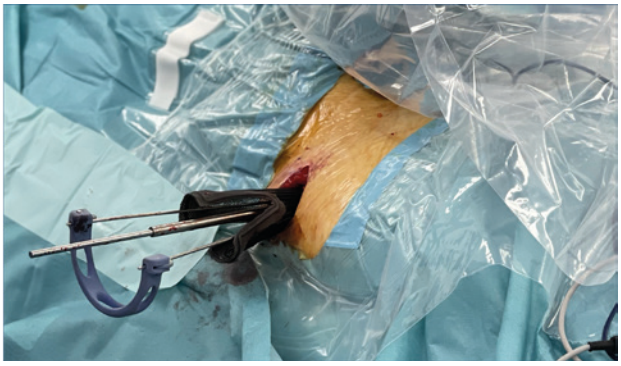
Correct positioning of the Ghost retractor.

Fixation Wires Spreading

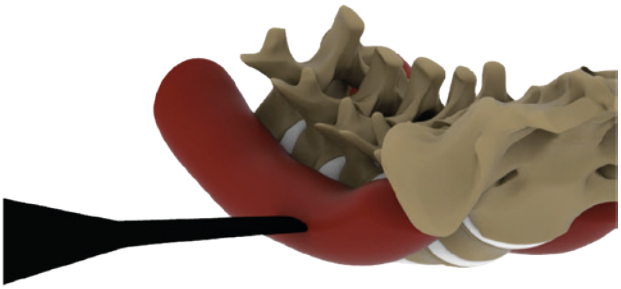
After fixing the Ghost metallic ring on the vertebral body, the retractor inserter and the initial metallic tube should be removed. The retractor is safely and strongly fixed on the vertebral bodies.

Attach the fixing wire spreader (**BOK-LD-15**) onto the fixing wires (**BOK-LD-06-1/2/3/4**).

Once the retractor inserter has been removed, the Ghost retractor will collapse under the pressure of the soft tissues and psoas muscle, leaving all the organs, muscles and nerves in natural position, without any stress on the respective tissues.



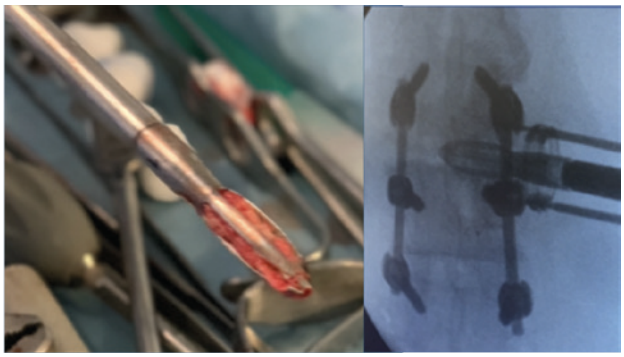
Fixing wire spreader attached onto the fixing wires during surgery.



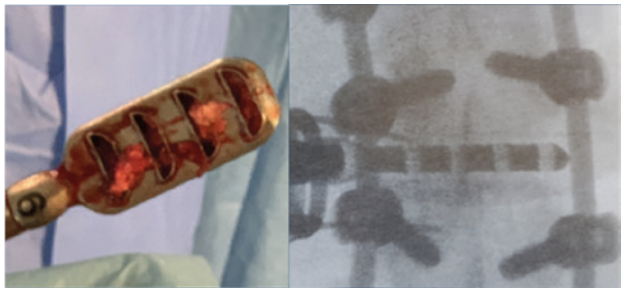
Position of Ghost retractor through the psoas muscle.

Discectomy

Two different shavers are available in the instrument set. First use the round shavers (**BOK-LD 1007/1009/1011/1013-FC**) to prepare the space for the parabolic ones. The parabolic shavers (**BOK-LD-1107/1109/1111/1113-FC**) are particularly indicated to prepare the vertebral endplate. Proceed progressively from the smaller to the bigger size to prepare the disc space for the implant. The anatomic patient structure needs to be verified and respected to use the most suitable one as last one: once the cartilage on the endplates has been removed, the right size (in height) has been reached. Adequate cleaning of the endplates is important to enable the provision of a blood supply to the implant. However, excessive cleaning or use of a rasp may weaken the endplate and result in subsidence of the implant.

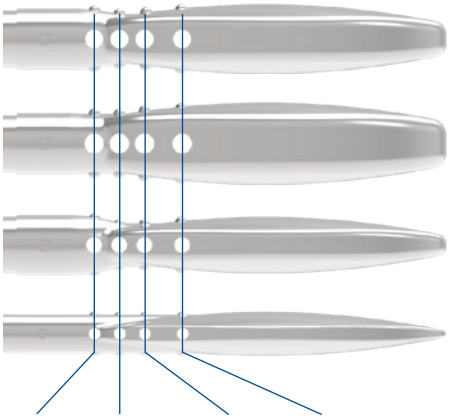


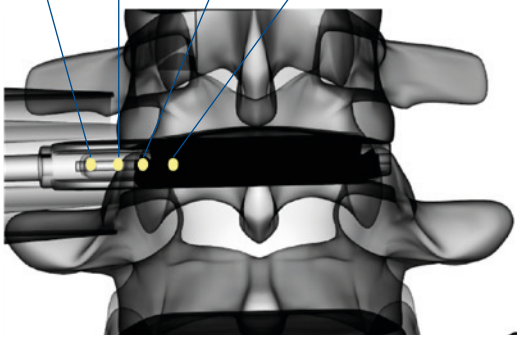
Round shaver during surgery, live picture and X-rays.



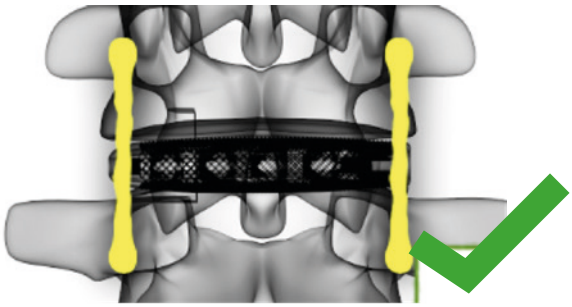
Parabolic shaver during surgery, live picture and X-rays.

Implant Dimension Choice





Practical example on length definition through probe usage.



Correct implant length choice.

Height

After completing disc cleaning, position the implant probe (**BOK-LD1207/1209/1211/1213-FC**) on the silicone handle (**BOK-LC-55X**) and gently enter into the disc space.

Gentle and controlled blows with the hammer (**TH002**) can support entering the disc space, when needed.

Probes are available in four heights dimensions (7, 9, 11, 13 mm) and they are flat (0 degrees lordosis angle).

Lordosis Angle

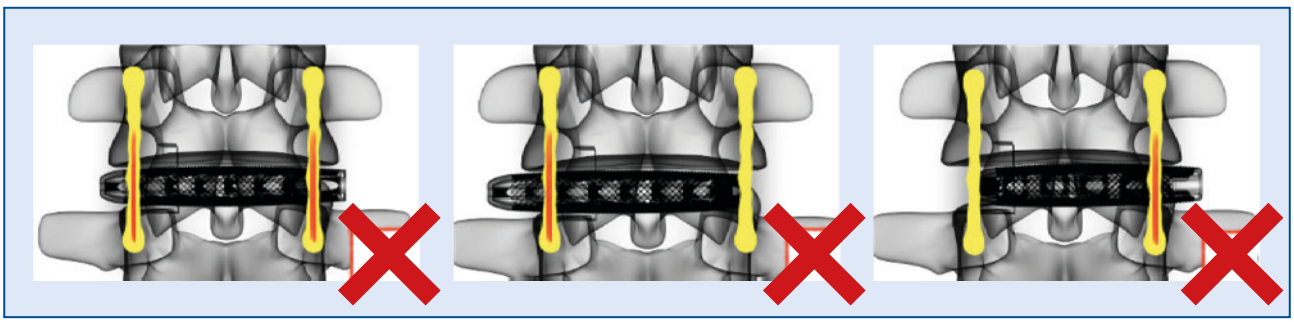
Pre-operative radiological imaging is strongly recommended to decide on the lordosis angulation of the implant.

Length

After defining the required height, the required length of the implant is defined based on the holes in the instrument which should be examined through fluoroscopic control (AP):

The tip of the probe should hit the contralateral wall of the vertebral bodies, whereas the holes in the instrument indicate the length of the implant: the hole that shows on the wall at the entry point represents the required length: see also images below.

A lateral cage should cover as much of the vertebral bodies' endplates as possible, and thus should be placed from cortex to the contralateral cortex, but it should never exceed the lateral cortex wall.



Three examples of not correct implant length choice.

Implant Reference Codes

The correct implant size is the one that corresponds with the the length, indicated by the holes in the probe. Height and Lordosis Angle are controlled by expansion mechanism: determined after evaluation of (pre-OP) fluoroscopy imaging. Width (either 18 or 22 mm) is following surgeon's preference.

Example

Cage Height > Ranges from 8 mm-13 mm; * minimal height (8mm) is shown in the reference code

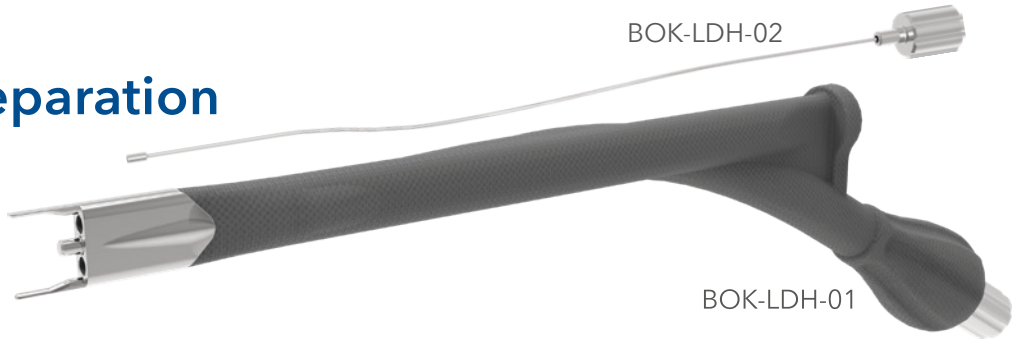
Cage Length > Probe length hole: 52 mm

Cage Width > 22 mm

Cage Angle > Lordosis angle: Ranges from 0° -14°; ** minimal lordosis angle (0° mm) is shown in the reference code

ACXH	5222	08	00
Cage Code	***Footprint*** ***Length x Width***	Height*	Lordosis Angle**

Implant Preparation

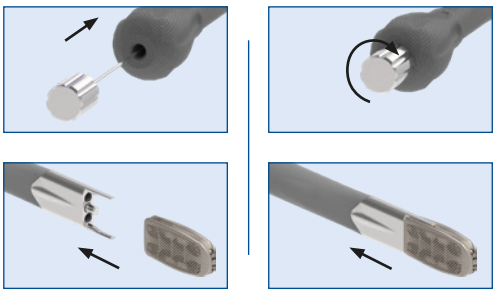


The implant is delivered in a double rigid blister packaging.

Remove the blister in the unsterile field (rotation nurse), always carefully paying attention on the preservation of the sterility of the implant, which is in the internal blister. Drop the internal blister into the sterile field for further processing by the scrub technician.

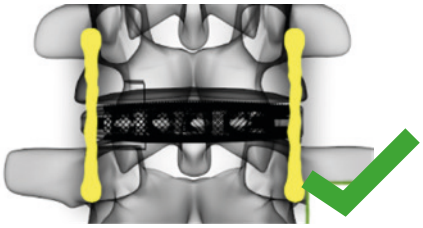
Assemble the implant holder by sticking the (flexible) implant holder shaft (**BOK-LDH-02**) into the hand piece of the implant holder (**BOK-LDH-01**).

Connect the implant to the assembled implant holder by screwing till reaching a solid fixed position in order to avoid any problems during final implant positioning.



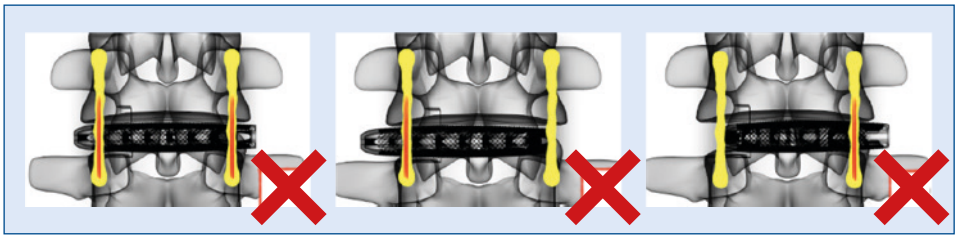
1. Insert the Holder Shaft.
2. Screw the knob to lock the cage.

Implant positioning



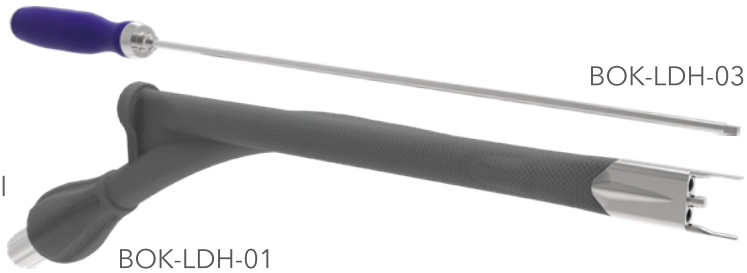
Correct implant positioning.

Gently push the implant through the Ghost retractor till reaching the intervertebral space.
The shape of the nose of the implant will help a smooth entry into the disc space.



Three examples of **not correct** implant length choice.

Place the implant into its final position.
Introduction may require gentle hammering on the backside of the Implant Inserter. The implant Inserter may be used to manipulate the cage within the disc space, if required.

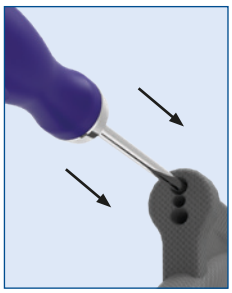


BOK-LDH-03

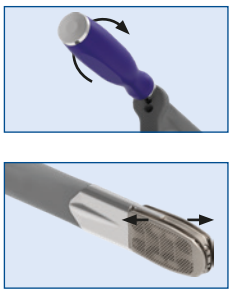
BOK-LDH-01

Important Note
The implant should never exceed the lateral walls of the vertebral bodies.

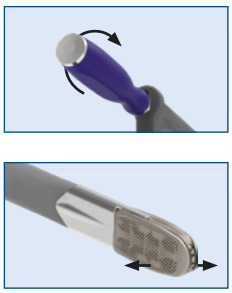
Use the implant expansion shaft (**BOK-LDH-03**) to expand the implant: hold the implant holder in one hand and with the other hand turn the expansion shaft clockwise in the "upper hole" of the implant holder: this expands the connecting ("upper) part of the implant: when the patient is in prone position and the handle of the implant inserter is facing to the floor the posterior part of the implant will be expanded; turning the expansion shaft clockwise in the "lower hole" of the implant holder expands the connecting "lower part" of the implant: when the implant holder is in above described position the implant expands on the anterior side; turning the expansion shaft counterclockwise in either hole lowers the endplates of the implants on either the posterior or anterior side.
Expand and/or lower both the endplates of the implant anterior and posterior till a firm fit has been established in the intervertebral space, such to be guided and evaluated under fluoroscopic control: both AP and Lateral view.
Once the cage is in the correct position and expanded to the surgeon's satisfaction, showing the right height and lordosis angle the Implant Inserter should be removed:
The Implant is released by turning the knob of **BOK-LDH-02** counterclockwise, leaving the implant in its optimal and securely fixed position.



3. Insert the Cage Expander to expand the cage.



4. Expander in upper hole expands upper part of implant.



5. Expander in bottom hole expands lower part of implant.

Retractor Removal

Once the final implant position is reached, remove the implant holder and after a last fluoroscopy control, the Ghost retractor can be removed; To this, the following procedure \ MUST BE RESPECTED:

Detach and remove the Fixing wire spreader (**BOK-LD-15**).
Re-insert the retractor holder (**BOK-LD-05-22**) inside the Ghost retractor (**BOK-LD-04-22**), making sure the fixing wires fit the grooves in the the retractor holder and push the end of the holder into the metallic ring of the retractor till it stops (there is a hard stop on the holder). Use the Fixing wire Screwdriver (**BOK-LD-07**) to remove the fixing wires first. Then remove the retractor holder (**BOK-LD-05-22**) and the Ghost retractor (**BOK-LD-04-22**) WHILE STILL ASSEMBLED (so together in one piece).

INSTRUCTIONS FOR USE

LUMBAR TITANIUM INTERBODY FUSION CAGE IMPORTANT INFORMATION ABOUT THE LUMBAR TITANIUM INTERBODY FUSION CAGE SYSTEM

The LUMBAR TITANIUM INTERBODY FUSION CAGE is intended to recreate and maintain distance between vertebras to support biologic fusion in the thoracic, lumbar or lumbar-sacral spine zone. As complementary device, it should NOT be used as stand-alone. The device must always be within the limits of the vertebral cortices. If this indication is not followed, the device can be crushed because it protrudes from the spinal column and may not withstand the forces involved in such conditions.

DESCRIPTION

The LUMBAR TITANIUM INTERBODY FUSION CAGE consists of cages in variable sizes and shapes. The dimensions of implants are designed based on anatomical conditions and decisions hereto are made by physicians.

LUMBAR TITANIUM INTERBODY FUSION CAGE components should be used in combination with other spinal systems or other fixation systems in order to obtain stabilization.

All components of LUMBAR TITANIUM INTERBODY FUSION CAGE cannot be re-used under any circumstances.

LUMBAR TITANIUM INTERBODY FUSION CAGE is designed to be applied for posterior, posterior-lateral, anterior and lateral approach.

In particular, this instruction for use is applicable for codes:

ACT Cage for transforaminal arthrodesis "TLIF"

ACA "ALIF" anterior arthrodesis cage

ACP Cage for posterior arthrodesis "ACIF"

ACX Cage for lateral arthrodesis "XLIF"

ACL Cage for posterolateral oblique arthrodesis "OLIF"

ACO Anterior Cage for Lumbar Arthrodesis

ACTH Expandable lumbar cage

ACXH Expandable extra-lateral cage and variable lordosis for lumbar arthrodesis

ACPH Variable lordosis expandable cage for posterolateral arthrodesis

MM Expandable anterior cage for lumbar arthrodesis

CT Expandable anterolateral cage for lumbar arthrodesis

MMJ Self-locking expandable anterior cage for lumbar arthrodesis

ACXJ Self-locking extra-lateral cage for lumbar arthrodesis

ACAJ Self-locking anterior cage for lumbar arthrodesis

ACOJ Self-locking anterior cage for lumbar arthrodesis

ACTZ Lumbar Cage

MATERIALS

The entire system is made of medical grade titanium described by ISO 5832-3 or 10993-5 or ASTM F2026 or ASTM F136 standards. Tsunami Medical warrants that all devices are manufactured from one of the foregoing material specifications.

INDICATIONS

LUMBAR TITANIUM INTERBODY FUSION CAGE is intended for lumbar interbody fixation for the following indications:

(1) Degenerative disc disease.
(2) Spondylolisthesis.
(3) Spinal stenosis.
(4) Trauma.
(5) Tumour.
(6) Pseudo-arthrosis.
(7) 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 which 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 a must be carefully evaluated prior surgery.
(8) Implants size, shape or anchorage functionality might be not enough to achieve expected clinical results.
(9) Combination with implants from other manufacturers.
(10) Potential risk of unexpected patient's 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.

Caution: in case of reuse there is a danger of cross contamination; any reuse is therefore not permitted.

POTENTIAL ADVERSE EVENTS

Possible adverse events which might occur after spinal surgery with or without instrumentation including, but are not limited to:

(1) Disassembly, bending, and/or breakage of any or all of the system's components.
(2) Migration of any of the system's 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 improper use of instruments.
(5) Dura leakage, distortion or damage.
(6) Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, radiculopathy, paralysis, hypertension, or any others related to surgery in general 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) Pseudo-arthrosis 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) Change 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 cases, additional surgery or surgeries might be necessary to correct or change potential adverse events.

WARNINGS

The effectiveness and safety of interbody fixation is only applicable for certain conditions with which require the fusion supported by medical device. The device might be supportive for such mechanical instability like deformity, fracture, listhesis, dislocation, tumour, pseudo-arthrosis. The effectiveness and safety for any other conditions are unknown.

PRECAUTIONS

The LUMBAR TITANIUM INTERBODY FUSION CAGE are complementary implants to posterior fixation systems. The applications of pedicle screw and/or interbody cages should be performed by

experienced surgeons with specific training in use of LUMBAR TITANIUM INTERBODY FUSION CAGE. The spinal screw fixation system and/or interbody 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 result is 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 and alcoholics are at risk for non-fusion. Also, patients with weak muscle or bone conditions and/or 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 patient's anatomy or any other patient or implant correction, X-ray or CT or any other diagnostic examinations may be necessary. The proper, patient's individual implant 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 cutting edges, reversed bending, scratching or notching may generate internal stress, which may weak the implants or construct.

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

PRE-OPERATIVE:

(1) Patients that meet the criteria described in the indications should only be selected.

(2) Patients' conditions should be checked prior to 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 in sterile packaging must be checked on sterility and expiration date of sterility prior surgery.

(5) Implants and instruments should be stored in certain conditions to warrant the sterility and protection from any contamination or corrosive environment.

(6) It's highly recommended that all personnel interacting with any mechanical components of the spinal system should be familiar with all components before use.

INTRA-OPERATIVE:

(1) Extreme caution should be taken when working close to or around the spinal cord and nerve roots.

(2) Whenever possible or required, intra-operative diagnostic systems 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 the surgical technique carefully. 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 maneuvers for all screws, nuts or other fixing parts have been performed. Image diagnostics is highly recommended at this stage.

POST-OPERATIVE:

The physician's post-operative directions and warnings to the patient, and the corresponding patient's compliance, are extremely important.

(1) Detailed instructions about the use and limitations of the device should be communicated

with the patient.

(2) The patient should be warned to avoid falls or sudden jolts in spinal position.

(3) The patient should be warned for this possibility and instructed to limit and restrict physical activities, especially lifting and twisting movements and any type of sports participation. The patient should be advised not to smoke, or to consume alcohol or non-steroids or use anti-inflammatory medications such as aspirin during the bone graft healing.

(4) As a precaution, before patients with implants receive any subsequent surgery (such as surgical dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.

(5) Any retrieved implants should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the LUMBAR TITANIUM INTERBODY FUSION CAGE components should never be reused under any circumstances.

PACKAGING

LUMBAR TITANIUM INTERBODY FUSION CAGE is sterile packaged; in order to control the correct sterilization, make sure that the package arrives properly closed. Do not use if the blister is open or damaged.

STORAGE

The components of the LUMBAR TITANIUM INTERBODY FUSION CAGE must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapours and extreme changes in temperature and humidity. Sterile parts must be stored in original packages as a precaution for prevented to any damages.

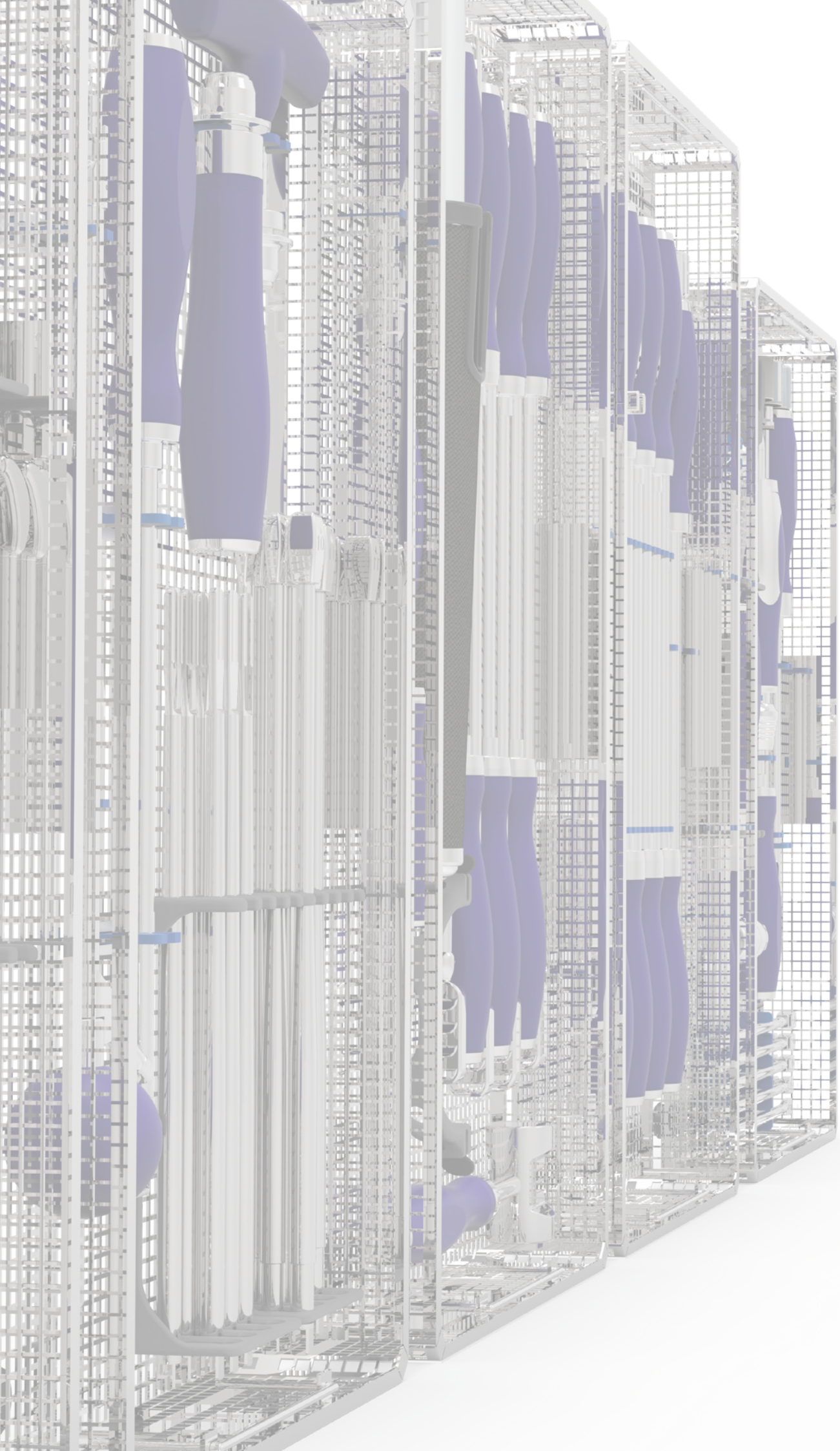
WARRANTY AND PRODUCT COMPLAINTS

Every spinal product from Tsunami Medical is guaranteed to be free of defects in handling and materials when used properly for its intended purpose. Any implant or instrument delivered from Tsunami Medical proving to be defective after proper use following the instructions provided and used for its intended purpose will be replaced or repaired, at Tsunami discretion, without charge. Any customer or user, who has any complaint or who has experienced any dissatisfaction in the product quality, durability, safety or reliability should inform Tsunami Medical or its dedicated Distributor in the customer's territory. When filing a complaint, please provide the component(s) name, part number, lot number(s), your name and address and a detailed description of the complaint. Please provide the report directly to Tsunami Medical or to its dedicated Distributor.

CUSTOMER SERVICE

Additional information about the LUMBAR TITANIUM INTERBODY FUSION CAGE or any other Tsunami Medical's Spinal System is available from Tsunami Medical. You may also want to contact your local Tsunami Medical Sales Representative.

For more informations on our products



TSUNAMI MEDICAL

THE WAVE OF INNOVATION

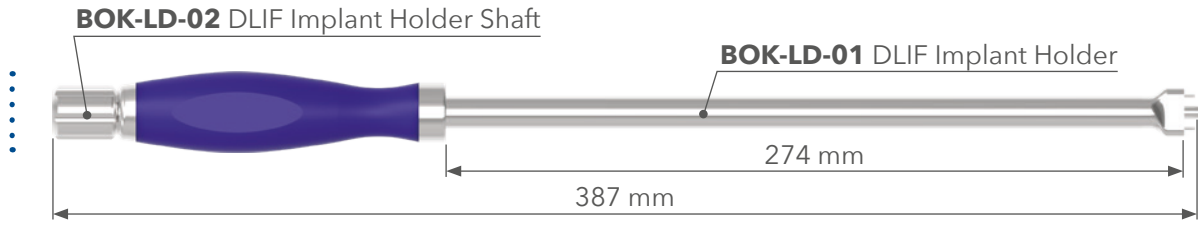
DLIF
Surgery Set

DLIF
Surgery Set

• *First Generation*

***DLIF** Implant Holder* Instrument Ref. Code: **BOK-LD-01**

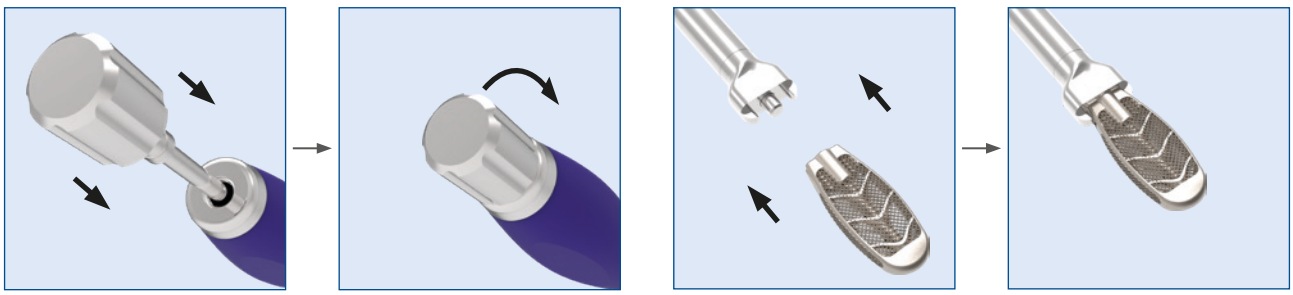
BOK-LD-02



Components:

1	 **BOK-LD-02**	**2**	 **BOK-LD-01**

Assembly Scheme:



Insert the Shaft in the Holder and screw the knob.

Connect the Cage to the coupling.

***DLIF** Implant Holder*	
BOK-LD-01	DLIF Implant Holder
BOK-LD-02	DLIF Implant Holder Shaft

**Dimensional tolerance ± 2 mm

CE

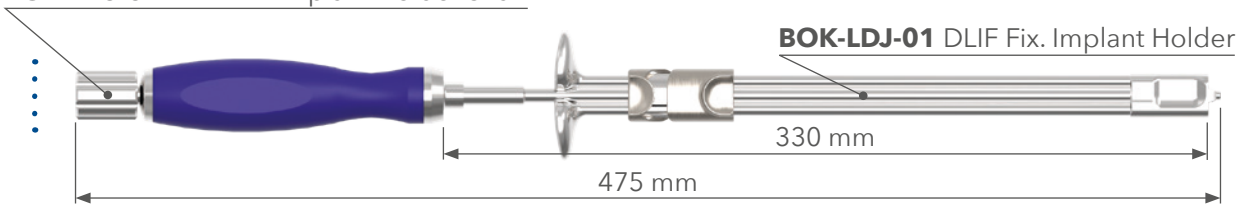
DLIF
Surgery Set

• *Built-In Fixation*

***DLIF** Fix. Implant Holder* Instrument Ref. Code: **BOK-LDJ-01**

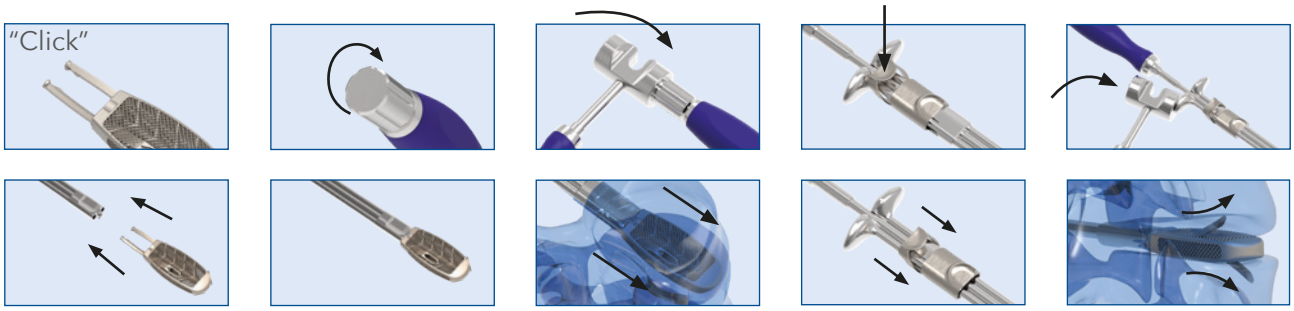
BOK-LDJ-02

BOK-LDJ-02 DLIF Fix. Implant Holder Shaft



Components:

Usage Scheme:



1. Extend the pins and insert in the Holder.

2. Screw the knob to lock the cage.

3. Use TH002 to facilitate cage entry.

4. Press the top button to release the clip.

5. Hammering on the surfaces to extend the pins

DLIF Fix. Implant Holder	
BOK-LDJ-01	Implant Holder
BOK-LDJ-02	Implant Holder Shaft

**Dimensional tolerance ± 2 mm

CE

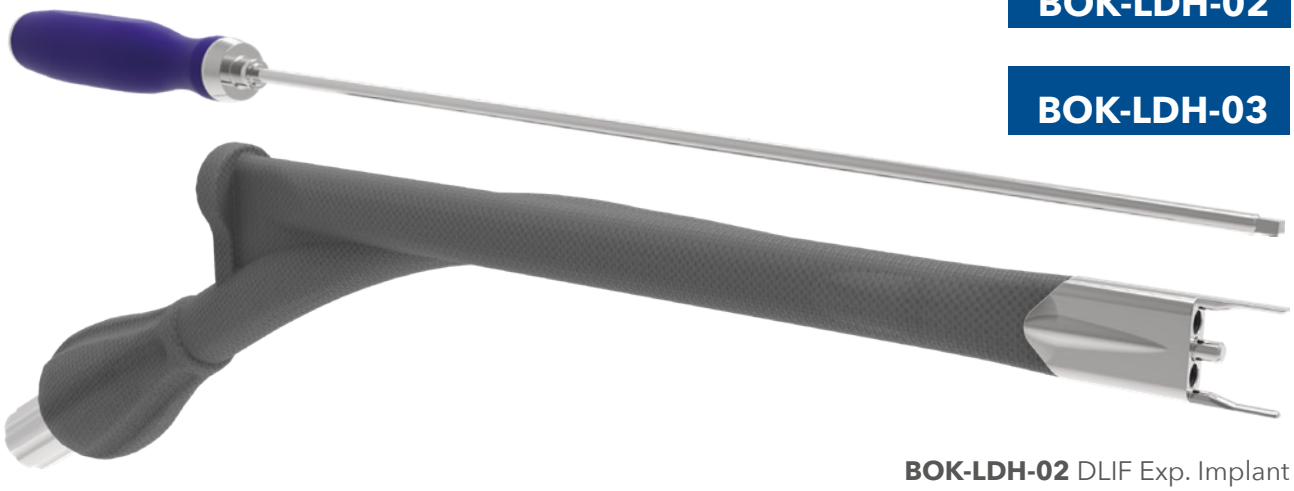
DLIF
Surgery Set

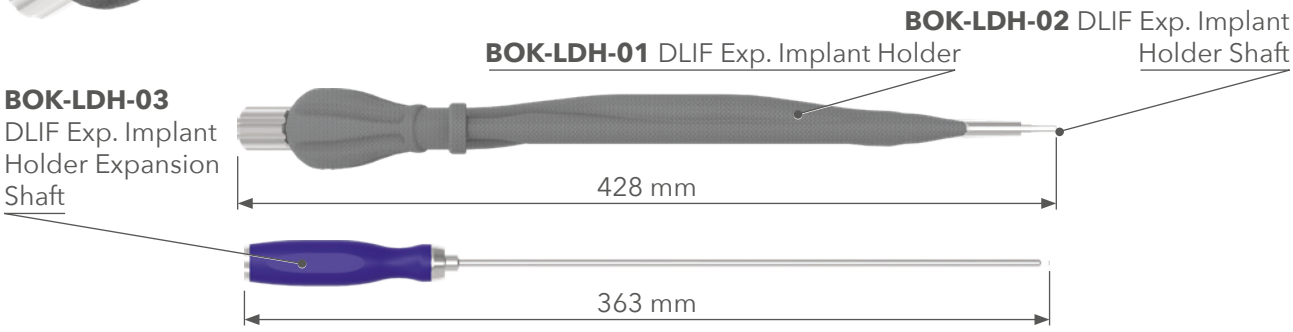
• *Expandable*

DLIF *Exp. Implant Holder* Instrument Ref. Code: **BOK-LDH-01**

BOK-LDH-02

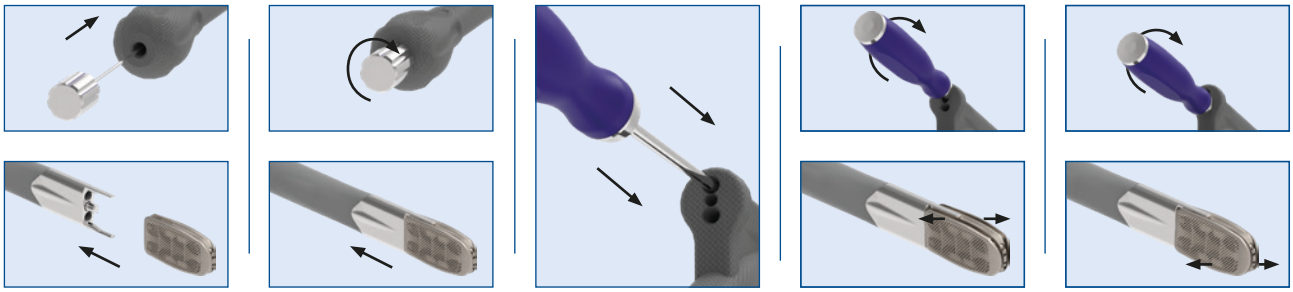
BOK-LDH-03





Components:

Usage Scheme:



1. Insert the Holder Shaft.

2. Screw the knob to lock the cage.

3. Insert the Cage Expander to expand the cage.

4. Expander in upper hole expands upper part of implant.

5. Expander in bottom hole expands lower part of implant.

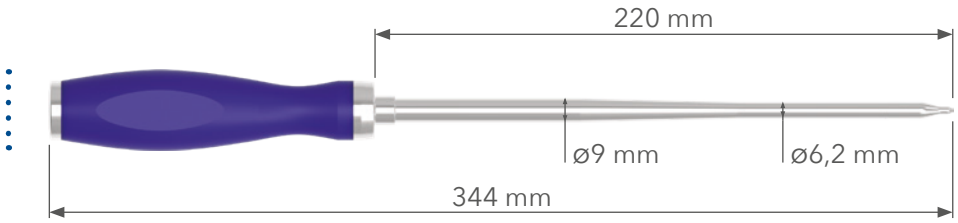
DLIF *Exp. Implant Holder*	
BOK-LDH-01	DLIF Exp. Implant Holder
BOK-LDH-02	DLIF Exp. Implant Holder Shaft
BOK-LDH-03	DLIF Exp. Implant Holder Expansion Shaft

**Dimensional tolerance ± 2 mm

DLIF
Surgery Set

• *Built-In Fixation*

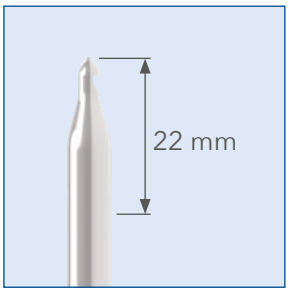
Pin Extractor Instrument Ref. Code: **BOK-J-EX01**



Components:

1	

Dimensions:



Pin Extractor
BOK-J-EX01

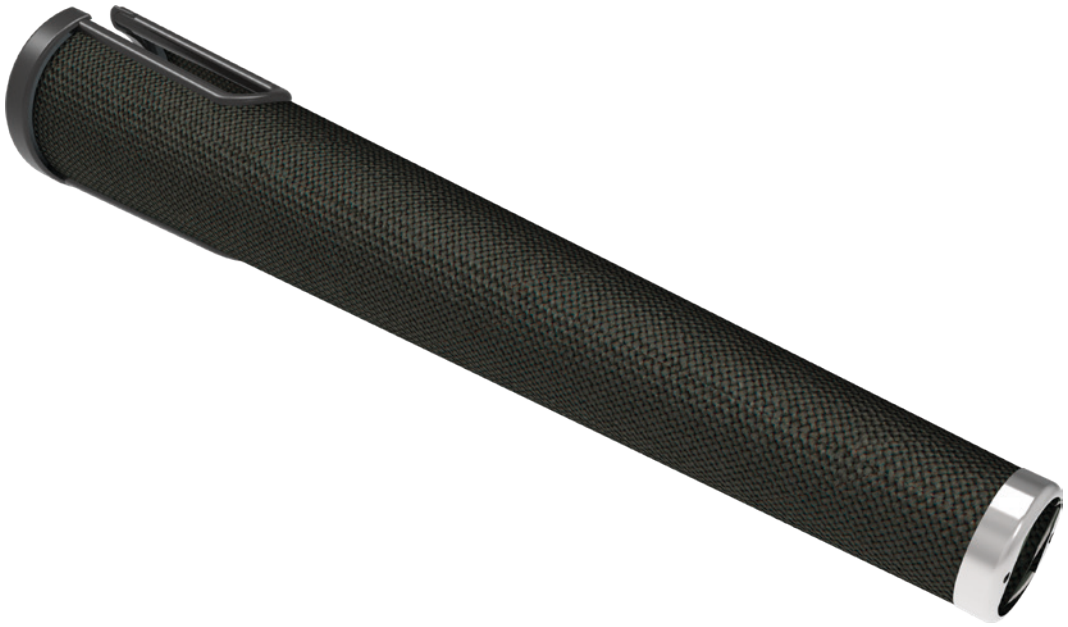
**Dimensional tolerance ± 2 mm

CE

DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

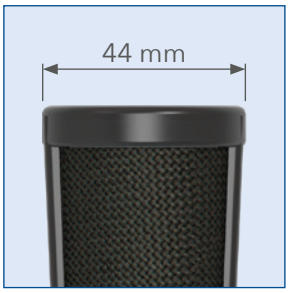
***DLIF** Ghost Retractor* Instrument Ref. Code: **BOK-LD-04-22**

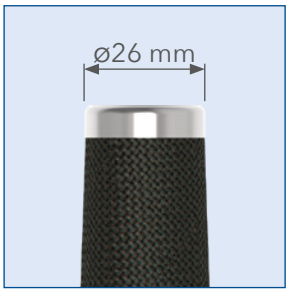


Components:

1	

Dimensions:





DLIF Ghost Retractor
BOK-LD-04-22

**Dimensional tolerance ± 2 mm

CE

DLIF
Surgery Set

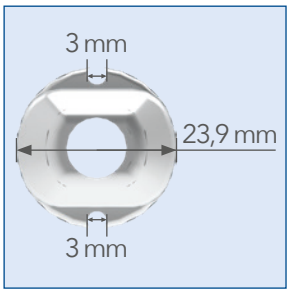
- *First Generation*
- *Built-In Fixation*
- *Expandable*

Ghost Retractor Shaft Instrument Ref. Code: **BOK-LD-05-22**

Components:

1

Dimensions:



Ghost Retractor Shaft
BOK-LD-05-22

**Dimensional tolerance ± 2 mm

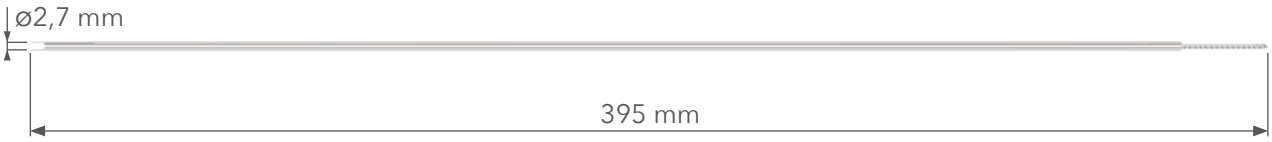
CE

DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

Ghost Retractor Fixing Wire four pieces

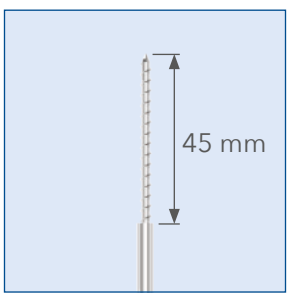
Instrument Ref. Code: **BOK-LD-06**



Components:

1

Dimensions:



Ghost Retractor Fixing Wire four pieces
BOK-LD-06

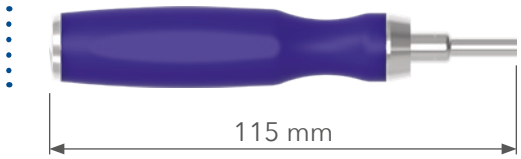
**Dimensional tolerance ± 2 mm

CE

DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

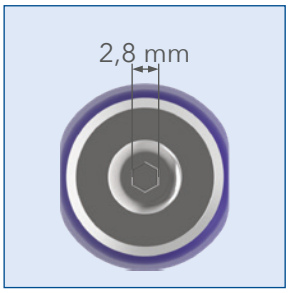
***DLIF** Fixing Wire Screwdriver* Instrument Ref. Code: **BOK-LD-07**



Components:

1

Dimensions:



DLIF Fixing Wire Screwdriver
BOK-LD-07

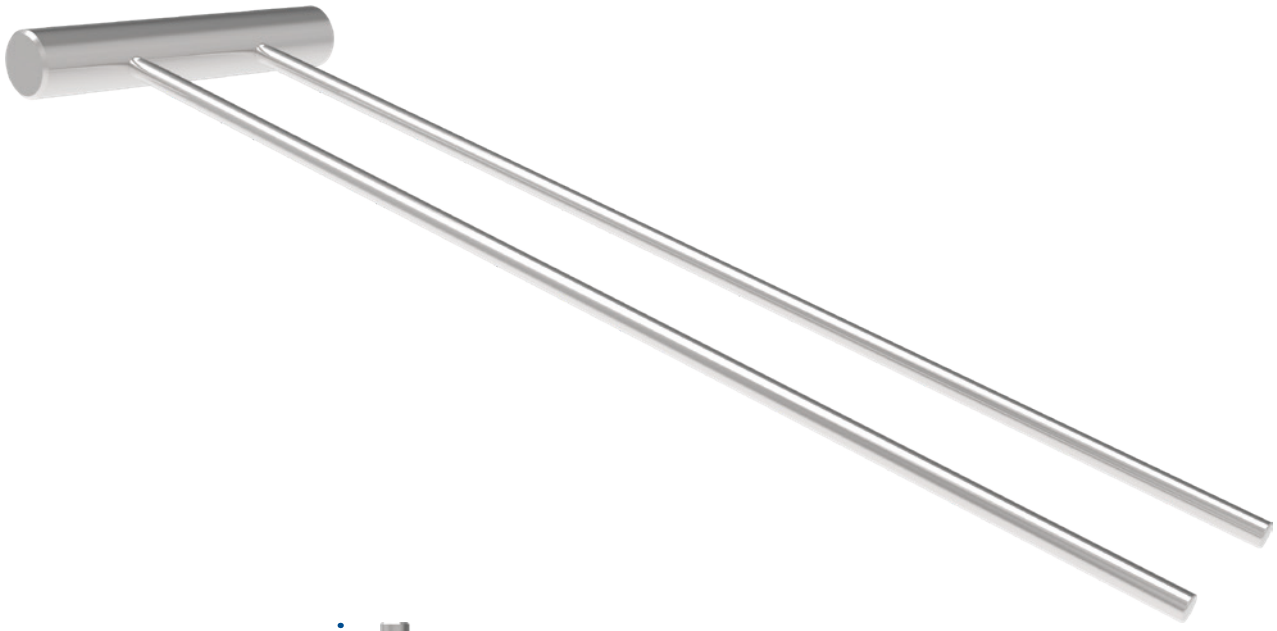
**Dimensional tolerance ± 2 mm

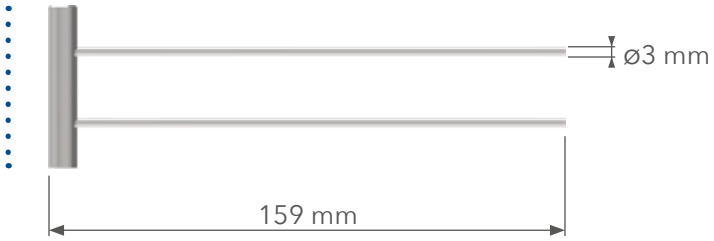
CE

DLIF
Surgery Set

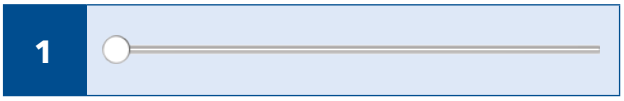
- *First Generation*
- *Built-In Fixation*
- *Expandable*

***DLIF** Fixing Wire Pusher* Instrument Ref. Code: **BOK-LD-08**

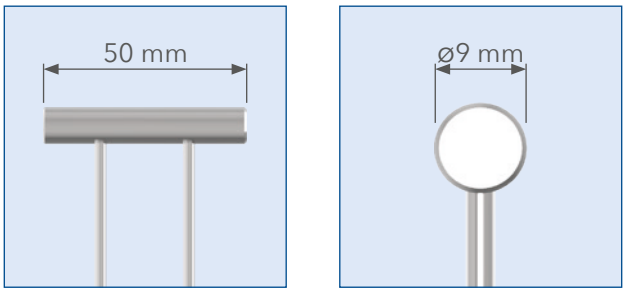




Components:



Dimensions:



***DLIF** Fixing Wire Pusher*
BOK-LD-08

**Dimensional tolerance ± 2 mm

CE

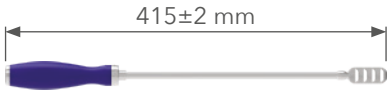
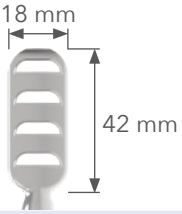
DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

DLIF** Flat Shaver* Instrument Ref. Code: **BOK-LD-10*

CE

** Choose preferred height and use it instead of the asterisks to get the final reference.

Details		
		

Description	Code
*DLIF Flat Shaver **6mm***	**BOK-LD-1006**
*DLIF Flat Shaver **7mm***	**BOK-LD-1007**
*DLIF Flat Shaver **8mm***	**BOK-LD-1008**
*DLIF Flat Shaver **9mm***	**BOK-LD-1009**
*DLIF Flat Shaver **10mm***	**BOK-LD-1010**
*DLIF Flat Shaver **11mm***	**BOK-LD-1011**
*DLIF Flat Shaver **12mm***	**BOK-LD-1012**
*DLIF Flat Shaver **13mm***	**BOK-LD-1013**

DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

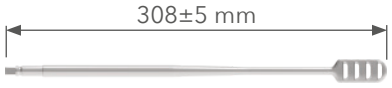
***DLIF** Flat Shaver*
Fast Connection

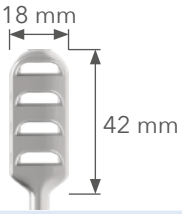
Instrument Ref. Code: **BOK-LD-10**-FC**

CE

** Choose preferred height and use it instead of the asterisks to get the final reference.

Details





Description	Code
*DLIF Flat Shaver **5mm** Fast Connection*	**BOK-LD-1005-FC**
*DLIF Flat Shaver **6mm** Fast Connection*	**BOK-LD-1006-FC**
*DLIF Flat Shaver **7mm** Fast Connection*	**BOK-LD-1007-FC**
*DLIF Flat Shaver **8mm** Fast Connection*	**BOK-LD-1008-FC**
*DLIF Flat Shaver **9mm** Fast Connection*	**BOK-LD-1009-FC**
*DLIF Flat Shaver **10mm** Fast Connection*	**BOK-LD-1010-FC**
*DLIF Flat Shaver **11mm** Fast Connection*	**BOK-LD-1011-FC**
*DLIF Flat Shaver **12mm** Fast Connection*	**BOK-LD-1012-FC**
*DLIF Flat Shaver **13mm** Fast Connection*	**BOK-LD-1013-FC**

DLIF
Surgery Set

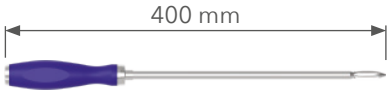
- *First Generation*
- *Built-In Fixation*
- *Expandable*

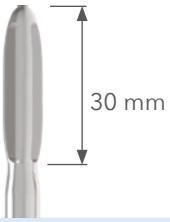
DLIF** Parabolic Shaver* Instrument Ref. Code: **BOK-LD-11*

CE

** Choose preferred height and use it instead of the asterisks to get the final reference.

Details





Description	Code
*DLIF Parabolic Shaver **7mm***	**BOK-LD-1107**
*DLIF Parabolic Shaver **8mm***	**BOK-LD-1108**
*DLIF Parabolic Shaver **9mm***	**BOK-LD-1109**
*DLIF Parabolic Shaver **10mm***	**BOK-LD-1110**
*DLIF Parabolic Shaver **11mm***	**BOK-LD-1111**
*DLIF Parabolic Shaver **12mm***	**BOK-LD-1112**
*DLIF Parabolic Shaver **13mm***	**BOK-LD-1113**

DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

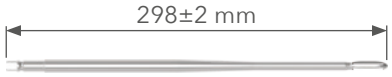
***DLIF** Parabolic Shaver*
Fast Connection

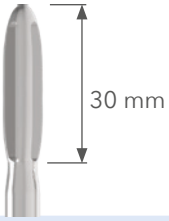
Instrument Ref. Code: **BOK-LD-11**-FC**

CE

** Choose preferred height and use it instead of the asterisks to get the final reference.

Details





Description	Code
*DLIF Parabolic Shaver **7mm** Fast Connection*	**BOK-LD-1107-FC**
*DLIF Parabolic Shaver **8mm** Fast Connection*	**BOK-LD-1108-FC**
*DLIF Parabolic Shaver **9mm** Fast Connection*	**BOK-LD-1109-FC**
*DLIF Parabolic Shaver **10mm** Fast Connection*	**BOK-LD-1110-FC**
*DLIF Parabolic Shaver **11mm** Fast Connection*	**BOK-LD-1111-FC**
*DLIF Parabolic Shaver **12mm** Fast Connection*	**BOK-LD-1112-FC**
*DLIF Parabolic Shaver **13mm** Fast Connection*	**BOK-LD-1113-FC**

DLIF
Surgery Set

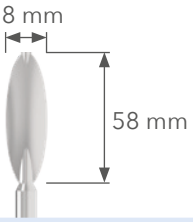
- *First Generation*
- *Built-In Fixation*
- *Expandable*

DLIF** Implant Trial* Instrument Ref. Code: **BOK-LD-12*

CE

** Choose preferred height and use it instead of the asterisks to get the final reference.

Details



Description	Code
DLIF Implant Trial ***7mm***	**BOK-LD-1207**
DLIF Implant Trial ***9mm***	**BOK-LD-1209**
DLIF Implant Trial ***11mm***	**BOK-LD-1211**
DLIF Implant Trial ***13mm***	**BOK-LD-1213**

DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

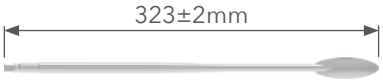
***DLIF** Implant Trial*
Fast Connection

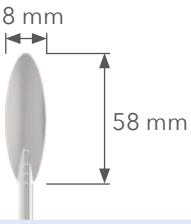
Instrument Ref. Code: **BOK-LD-12**-FC**

CE

** Choose preferred height and use it instead of the asterisks to get the final reference.

Details





Description	Code
*DLIF Implant Trial **7mm** Fast Connection*	**BOK-LD-1207-FC**
*DLIF Implant Trial **9mm** Fast Connection*	**BOK-LD-1209-FC**
*DLIF Implant Trial **11mm** Fast Connection*	**BOK-LD-1211-FC**
*DLIF Implant Trial **13mm** Fast Connection*	**BOK-LD-1213-FC**

DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

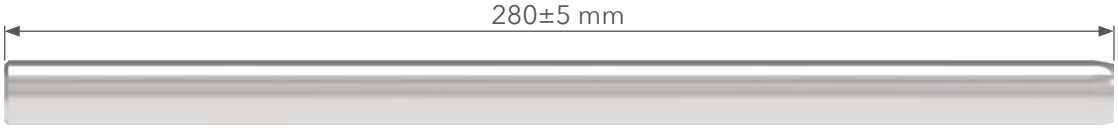
***DLIF** Tissue Dissector* Instrument Ref. Code: **BOK-LD-13-*B**

CE

** Choose preferred dimension and use it instead of the asterisks to get the final reference.

DLIF Tissue Dissector 1	**BOK-LD-13-1**

DLIF Tissue Dissector 2	**BOK-LD-13-2B**



DLIF Tissue Dissector 3	**BOK-LD-13-3B**

DLIF Tissue Dissector 4	**BOK-LD-13-4B**

DLIF
Surgery Set

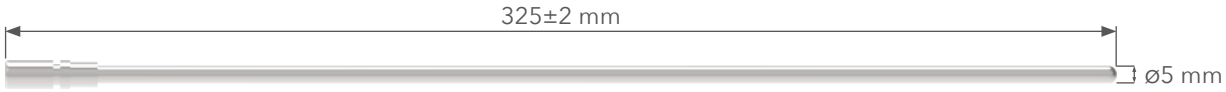
- *First Generation*
- *Built-In Fixation*
- *Expandable*

DLIF** Dissector First Access Guide* Instrument Ref. Code: **BOK-LD-14-

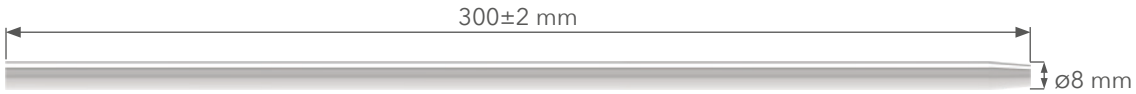
CE

** Choose preferred dimension and use it instead of the asterisks to get the final reference.

DLIF Dissector First Access Guide 1	**BOK-LD-14-1**

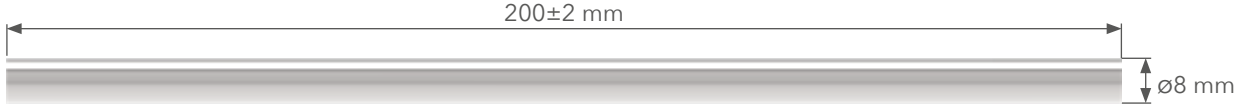


DLIF Dissector First Access Guide 2	**BOK-LD-14-2**



DLIF Dissector First Access Guide 3	**BOK-LD-14-3**

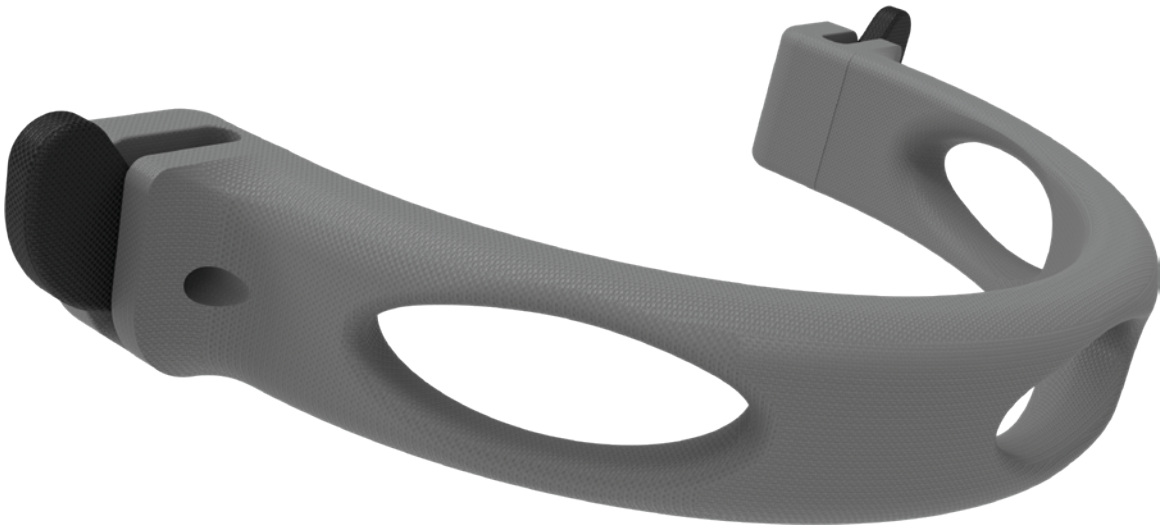
DLIF Dissector First Access Guide 4	**BOK-LD-14-4**

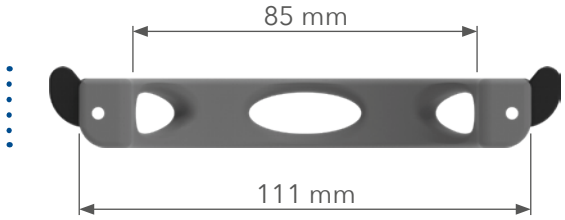


DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

***DLIF** Fixing Wire Spreader* Instrument Ref. Code: **BOK-LD-15**

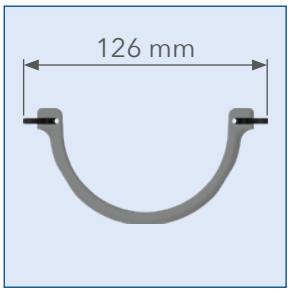


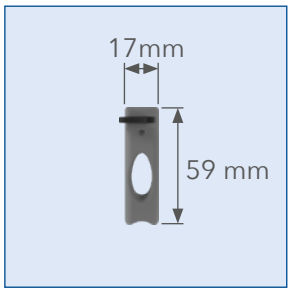


Components:

1	

Dimensions:





***DLIF** Fixing Wire Spreader*
BOK-LD-15

**Dimensional tolerance ± 2 mm

CE

DLIF
Surgery Set

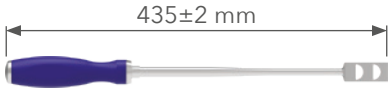
- *First Generation*
- *Built-In Fixation*
- *Expandable*

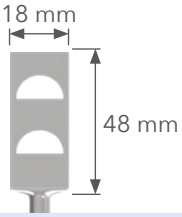
DLIF** Cutting Box* Instrument Ref. Code: **BOK-LD-17*

CE

** Choose preferred height and use it instead of the asterisks to get the final reference.

Details





Description	Code
DLIF Cutting Box ***6mm***	**BOK-LD-1706**
DLIF Cutting Box ***7mm***	**BOK-LD-1707**
DLIF Cutting Box ***8mm***	**BOK-LD-1708**
DLIF Cutting Box ***9mm***	**BOK-LD-1709**
DLIF Cutting Box ***10mm***	**BOK-LD-1710**
DLIF Cutting Box ***11mm***	**BOK-LD-1711**
DLIF Cutting Box ***12mm***	**BOK-LD-1712**

DLIF
Surgery Set

- *First Generation*
- *Built-In Fixation*
- *Expandable*

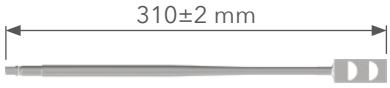
***DLIF** Cutting Box*
Fast Connection

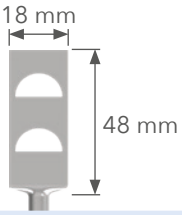
Instrument Ref. Code: **BOK-LD-17**-FC**

CE

** Choose preferred height and use it instead of the asterisks to get the final reference.

Details



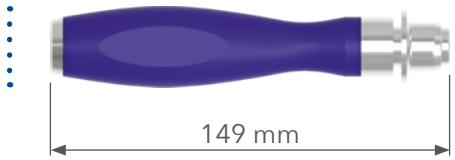


Description	Code
*DLIF Cutting Box **6mm** Fast Connection*	**BOK-LD-1706-FC**
*DLIF Cutting Box **7mm** Fast Connection*	**BOK-LD-1707-FC**
*DLIF Cutting Box **8mm** Fast Connection*	**BOK-LD-1708-FC**
*DLIF Cutting Box **9mm** Fast Connection*	**BOK-LD-1709-FC**
*DLIF Cutting Box **10mm** Fast Connection*	**BOK-LD-1710-FC**
*DLIF Cutting Box **11mm** Fast Connection*	**BOK-LD-1711-FC**
*DLIF Cutting Box **12mm** Fast Connection*	**BOK-LD-1712-FC**

GENERAL
INSTRUMENTS

- *First Generation*
- *Built-In Fixation*
- *Expandable*

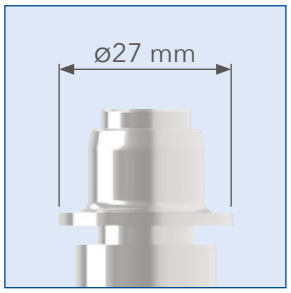
Straight Handle Fast Connection Instrument Ref. Code: **BOK-LC-55**

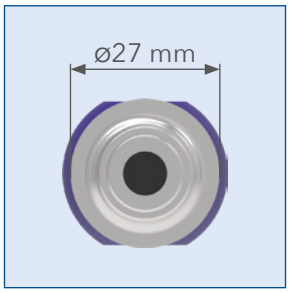


Components:

1	

Dimensions:





Straight Handle Fast Connection
BOK-LC-55

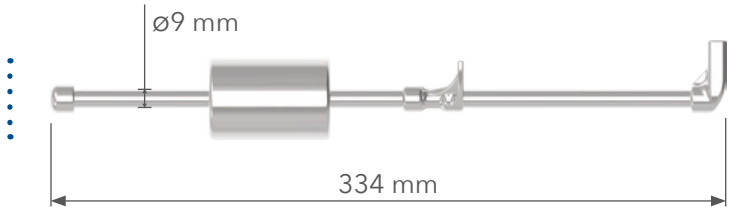
**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

- *First Generation*
- *Built-In Fixation*
- *Expandable*

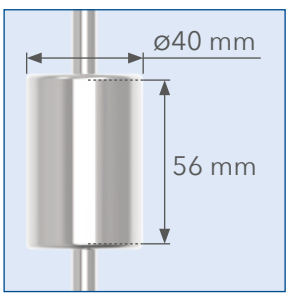
Universal Slide Hammer Instrument Ref. Code: **BOK-LT-80**



Components:

1	

Dimensions:



Universal Slide Hammer
BOK-LT-80

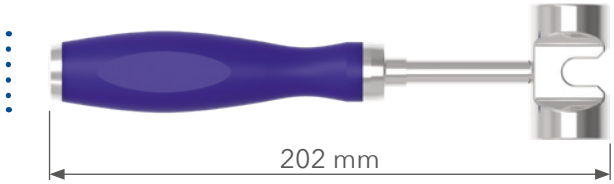
**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

- *First Generation*
- *Built-In Fixation*
- *Expandable*

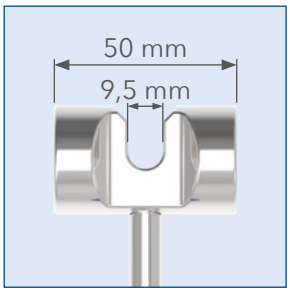
Hammer 250g Instrument Ref. Code: **TH002**

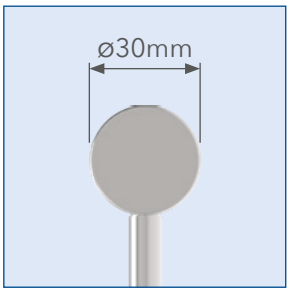


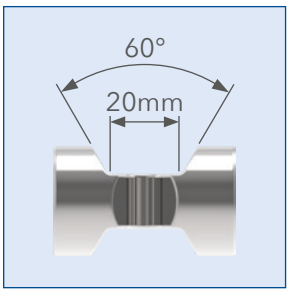
Components:

1

Dimensions:







Hammer 250g
TH002

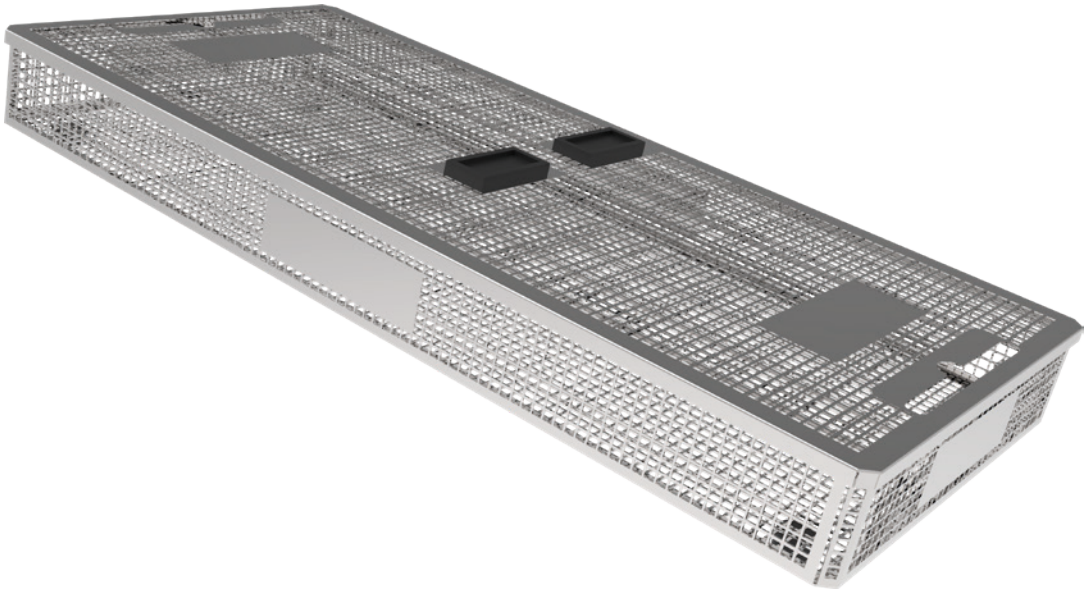
**Dimensional tolerance ± 2 mm

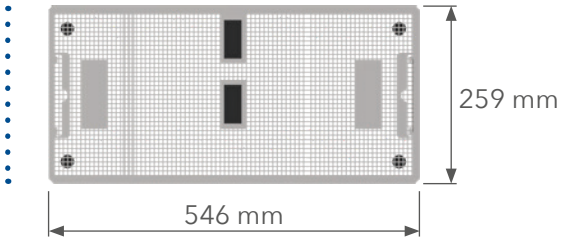
CE

GENERAL
INSTRUMENTS

- *First Generation*
- *Built-In Fixation*
- *Expandable*

Large Tray Instrument Ref. Code: **K3-721**

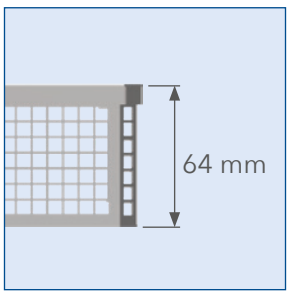




Components:

1	

Dimensions:

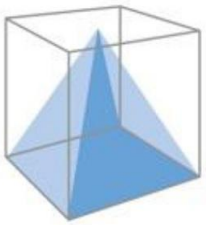


Large Tray
K3-721

**Dimensional tolerance ± 2 mm

CE

Distribuidor por:



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