TSUNAMI MEDICAL

THE WAVE OF INNOVATION

Surgical Technique

USTICA

TLIF 3D Printed Titanium Cage

Expandable

Bone InGrowth Technology®

Table of Contents

Ustica Overview

Ustica, expandable TLIF 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**

Ustica has a unique multi-direction expansion mechanism: it allows active cranial-caudal height expansion and amendment to the required lordosis angle by a passive adjustment of the implant's cranial and caudal contact surfaces to the natural anatomy of the patient. 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 Ustica, Tsunami Medical offers two footprints and a range 8-13 mm heights, with possible lordosis angles ranging from 2° to 14°, thanks to its innovative expansion feature, as outlined below.

	29x9 mm	*32x9 mm*	*40x9 mm*
Footprint			

Ustica Overview

Height

from 8 to 13 mm

Lordosis angle

from 2 to 8 degrees

from 6 to 14 degrees

Product Reference Codes

Ref. Code	Dimensions
ACTH29090805	Footprint Size **29x9mm** - Angles **2°-8°** Heights [mm] **08-13**
ACTH29090808	Footprint Size **29x9mm** - Angles **6°-14°** Heights [mm] **09-13**
ACTH32090805	Footprint Size **32x9mm** - Angles **2°-8°** Heights [mm] **08-13**
ACTH32090808	Footprint Size **32x9mm** - Angles **6°-14°** Heights [mm] **09-13**
ACTH40090805	Footprint Size **40x9mm** - Angles **2°-8°** Heights [mm] **08-13**
ACTH40090808	Footprint Size **40x9mm** - Angles **6°-14°** Heights [mm] **09-13**

CE 0051

USTICA

Ustica Intended Use

Ustica 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.

Ustica 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

Ustica 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

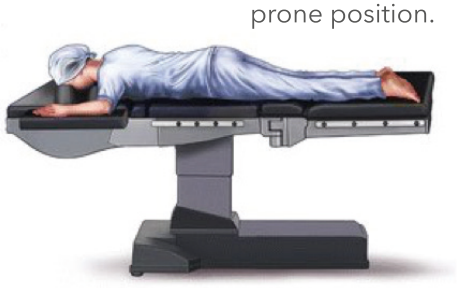
Contraindications include, but are not limited to:

(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.

Patient Positioning

Patient in prone position.



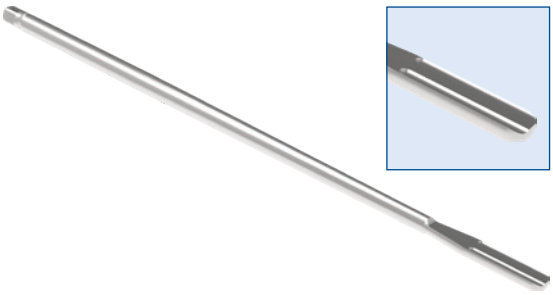
Patient position should expose the spine level which is going to be operated on.
Surgeons should evaluate the most appropriate position considering the surgical approach technique, decompression procedure and fusion technique.
For this surgical procedure place the patient in prone position for Posterior Transforaminal approach to lower lumbar levels of the spine. Approach the required level following the known surgical technique hereto.

Skin Incision

By using fluoroscopy the appropriate level of the lumbar spine must be verified.
Skin incision should allow adequate approach to reach the targeted spine segment(s).
Additional instruments like a vertebral distractor and soft tissue retractors are subject of consideration to allow easier access to the required vertebral segment.

To maintain proper vision on the surgical field a tissue retractor system is highly recommended. It is up to surgeon's experience to define and perform the soft tissue approach and bone decompression procedure. In some cases, specific patient's positioning may be required.

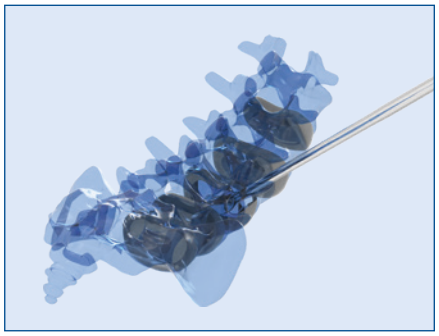
Disc Removal and Edplate Preparation

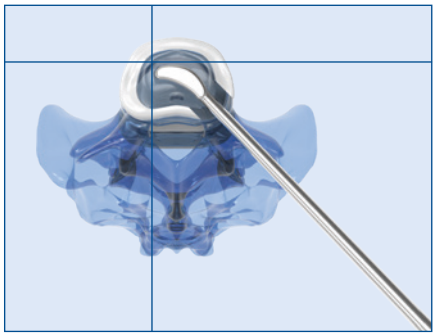


The discectomy procedure should be performed using standard disc cleaning instruments. The choice of appropriate instruments depends on approach, surgeons' preferences and projected results. Using rasps (BOK-LC-250-07 to 13 with 1 mm increments) and curettes is recommended while cleaning the disc (removal of nucleus material) and when preparing the vertebral endplate in order to create efficient bone contact (removal of superficial layers of the cartilage on the endplates). Adequate cleaning of the endplates is important to enable the provision of a blood supply to the implant. However, excessive cleaning may weaken the vertebral endplate and result in subsidence of the implant.

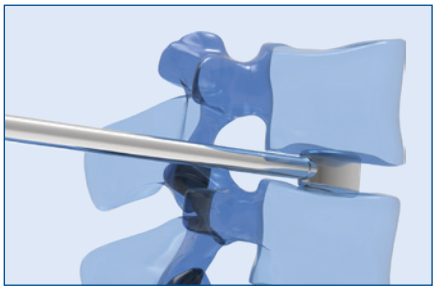
Implant Dimension Choice

Implant dimension choice procedure.



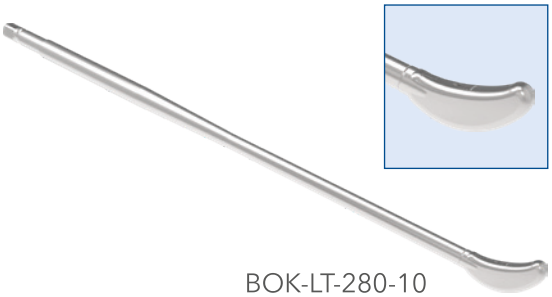


To select the appropriate implant size for “fixed” cages (cages with fixed dimensions in lengh, height, width and lordosis angle), implant trials should be used.



For Ustica however, only the projected lenght and lordosis angle are important, because of the expansion feature.

Lenght can be determined, either based on pre-operative planning or by using the TLIF expandable Footprint sizer with handle:
BOK-LT-280-3207 for lenght x height 32x7 mm
or TLIF expandable Footprint sizer with handle:
BOK-LT-280-4007 for lenght x height 40 x7 mm.



BOK-LT-280-10

The Lordosis angle of the implant is establised by an amendment of the endplates with netstructure of the implant to the patient’s natural anotomy after expansion.

Hereto pre-operative planning should give information about if this would be in the 2-8 degrees or 6-14 degrees lordosis angle margins. The final implant size is chosen accordingly. (see overview on page 5)

Implant Inserter Assembly

Implants Reference Codes

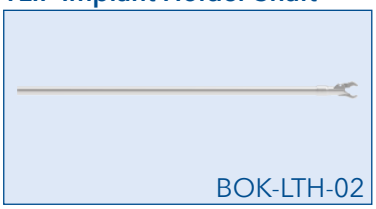
The correct implant size corresponds only to the length of the trial implant (either 32 mm or 40 mm); the trial implant (**BOK-LT-280-3207** or **BOK-LT-280-4007**) has no lordosis angle. The projected lordosis angle for the implant is determined after evaluation of the (pre-op) fluoroscopic images.

Components:

TLIF Implant Holder

BOK-LTH-01

TLIF Implant Holder Shaft



BOK-LTH-02

TLIF Implant Expander

BOK-LTH-03

TLIF Implant Holder

BOK-LTH-04

TLIF Implant Holder

TRQ-01

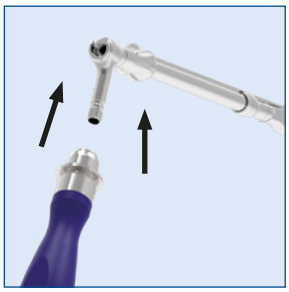
TLIF Implant Holder

BOK-LC-55

Attach the straight handle (**BOK-LC-55**) to the implant holder (**BOK-LTH-01**) and insert the implant holder shaft (**BOK-LTH-02**) into the implant holder (**BOK-LTH-01**).

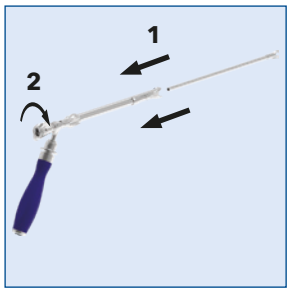
Please note there is only one way to properly insert the implant holder shaft: the "clamp" on the distal part should allow the implant to get attached. Once in the correct position, attach the implant holder shaft to the implant fixation knob (**BOK-LTH-04**) by tuning the knob clockwise after an initial first fixation of the thread of the implant holder shaft into the knob.

Usage Scheme:

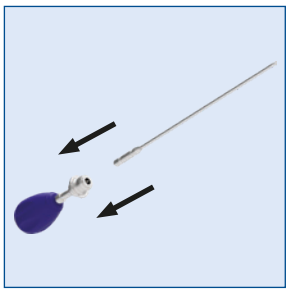


1. Attach the Straight Handle to the Implant Holder.

2. Attach the Implant Fixation Knob to the Implant Holder.



3. Use your index finger to drive the implant holder shaft from distal to proximal into the Implant Holder and fix into the Implant Fixation Knob.

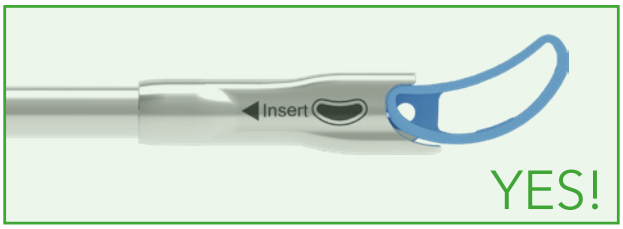


4. Insert the Implant Expander in the Torque Limiter. **PLEASE NOTE:** these assembled parts need to be put into the implant Holder **ONLY AFTER THE IMPLANT** reached its final position into the disc space.

• Stainless Steel INOX 304/17-4 ph • Silicone

**Dimensional tolerance ± 2 mm

Implant Inserter Assembly



WARNING!

DO NOT ASSEMBLE THE CAGE IN THE WRONG POSITION

Follow the directions as indicated in the picture next to this text: align as indicated on the Implant Holder.

Fix the implant with the inner line in the display of the Implant Holder shaft in the "release position" and turn the implant fixation knob clockwise until the line reaches the "locked position".

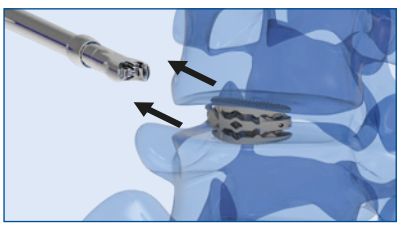
Control of Cage-Rotation

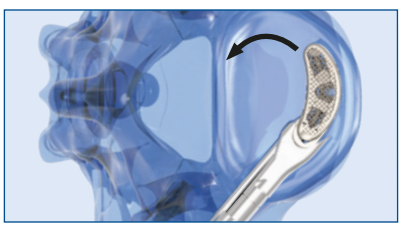
There is a window in the Implant Holder shaft to recognise the cage fixation situation in 3 different positions.

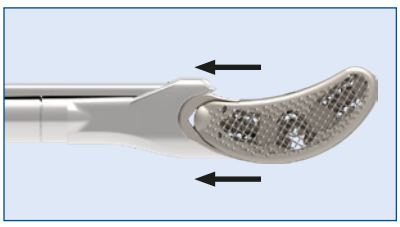
"RELEASE" Position
The cage is locked to the Implant Inserter and cannot rotate

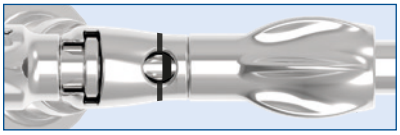
"CENTRAL" Position
The cage can be rotated freely, but is still attached to the Implant Inserter to enable manipulation and rotation of the implant.
Rotation is possible anywhere in between the Locked and Central position, but the Central position should never be surpassed.

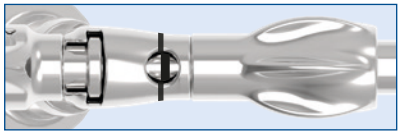
"LOCK" Position
The cage is locked to the Implant Inserter and cannot rotate

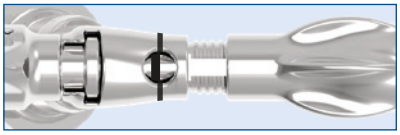






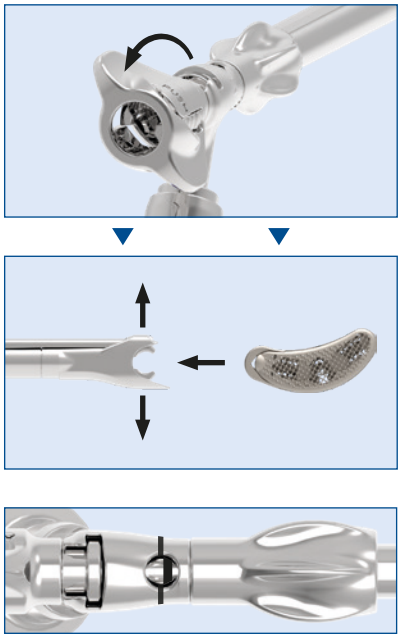






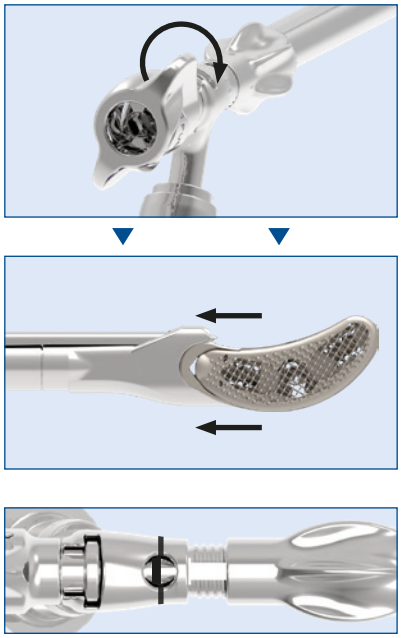
USTICA, TLIF

• Position 1



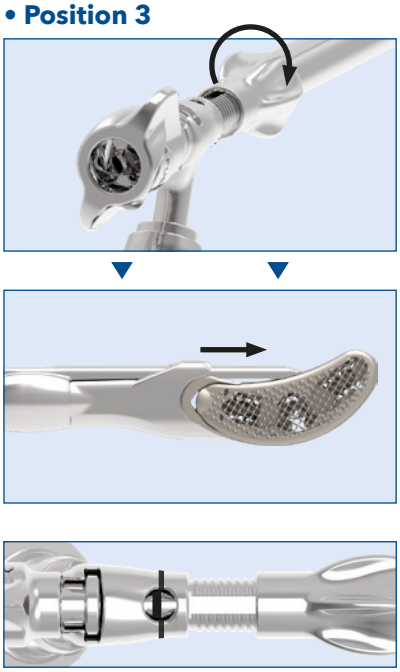
Turn the Implant Fixation Knob to the left to expand the clamp and attach the implant.

• Position 2



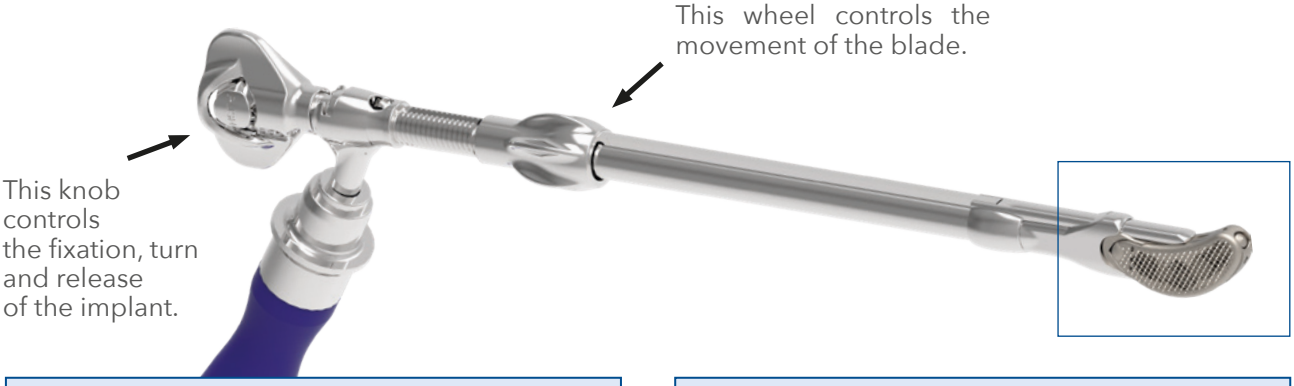
Turn the Implant Fixation Knob to the right to lock the implant on the Implant Holder, until the cage is fixed.

• Position 3



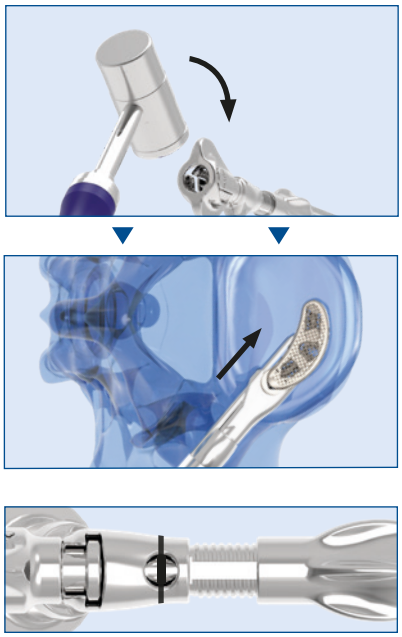
Turn the Implant Holder wheel to the right until the blade is all the way out to prevent the cage from turning.

Final position of the wheel



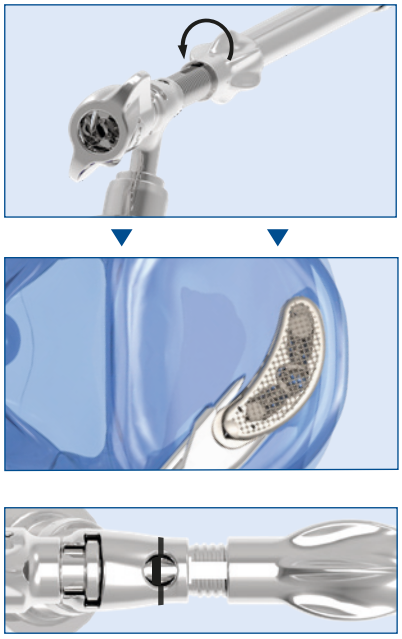
Once pulled out, the blade will keep the cage in fixed position onto the implant holder to prevent from turning during insertion.

• Position 4



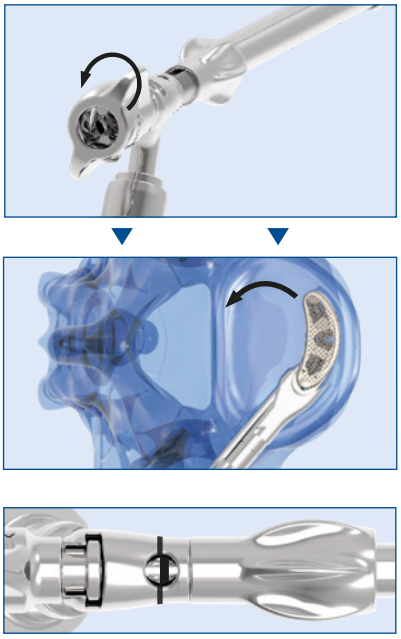
Now begin to Tap with the hammer on the Knob for cage insertion.

• Position 5



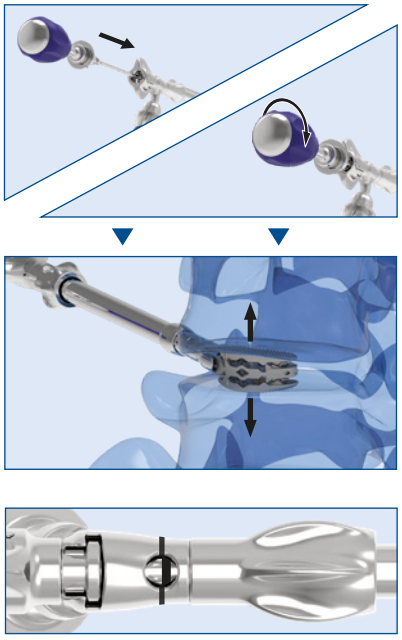
When the cage is positioned against the anterior wall, turn the wheel to the left, all the way up: this will retract the blade into the implant inserter. **PLEASE NOTE:** when not completly retracted, the blade will block turning of the cage.

• Position 6



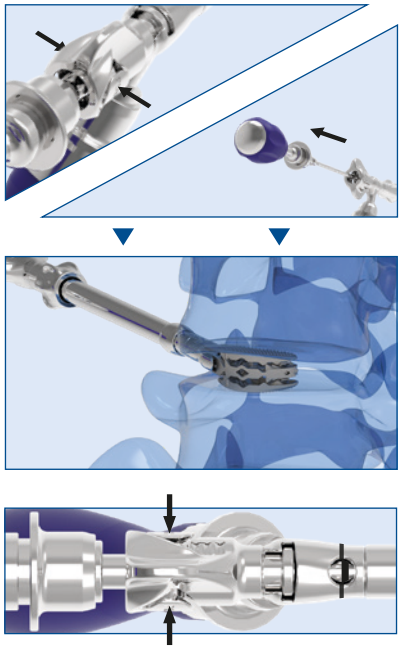
Partially unscrew the Holder Knob (turn left; one full turn) to allow the implant to turn. Tap onto the Knob to position it in the correct position.

• Position 7



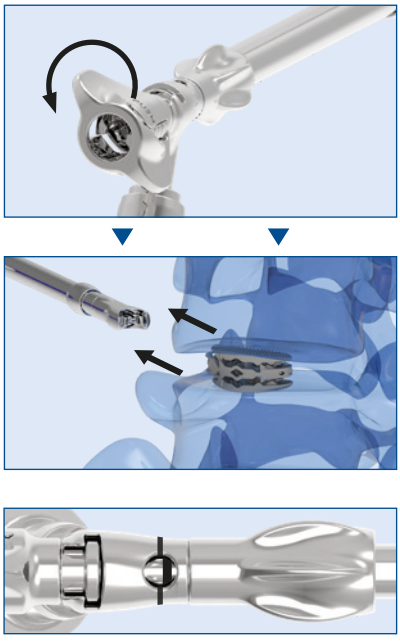
Insert the Expansion Shaft and turn to the right to the desired expansion. The torque Knob will prevent the contact surfaces (net structure) of the implant to damage the vertebral endplates.

• Position 8



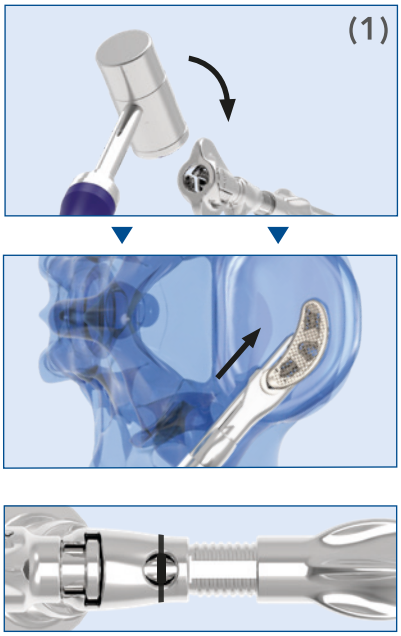
Press simultaneously the two buttons on the knob to remove the expansion shaft.

• Position 9



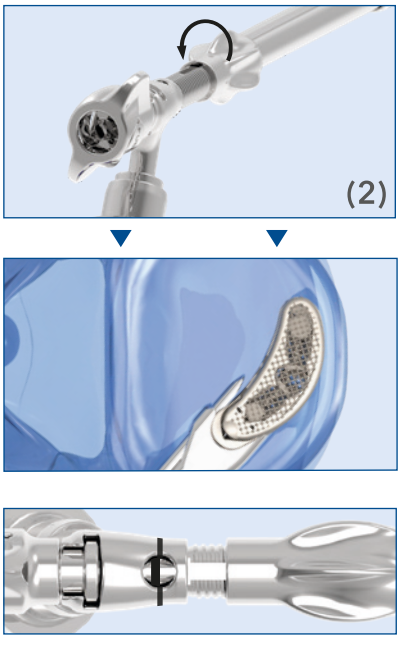
Turn the Implant Fixation Knob to the left to release the implant. Gently remove the implant inserter, NO force should be applied.

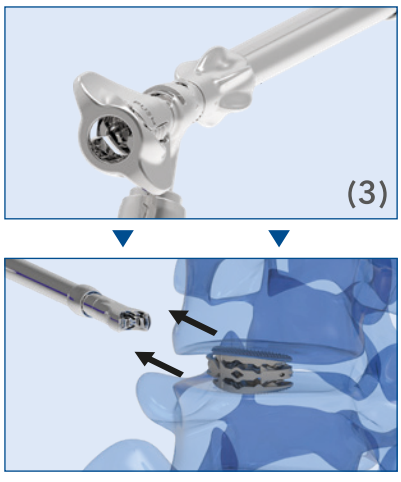
Implantation and Expansion



(1) If necessary increase distraction to facilitate implant insertion. Insert the cage by gently hammering. Keep appropriate space for insertion. Guiding the procedure, Lateral X-rays are highly recommended during the implantation procedure.

(2) After passing the posterior wall of the vertebral body, release the brackets that fix/hold the implant on the Implant Inserter into a multi axial position by slightly turning the fixation knob counterclockwise until the line in the window on the Implant inserter shaft moves to the middle till approximately fully aligned; do not surpass this Central/aligned position. the brackets holding the implant move into a Semi-Open position, anywhere in between the fully "Locked" and Central Position. When surpassing the Central/aligned position in the direction of the "Release" position, there is a serious chance to release the implant from the Implant Holder, which at this stage of the procedure would create serious challenges. Change the sagittal angulation of the Implant Holder by continuing gentle hammer blows to rotate the TLIF implant into the required position. Changing the angulation of the Implant Holder increases turning forces and facilitates the implant rotation procedure.





(3) After final positioning has been reached, release the brackets fully by turning the knob counterclockwise until the display line arrives at the end of the display window in the direction of "Release" or disappears. Detach the Implant Holder. Remove the Implant Holder and check the implant position, both in AP and Lateral X-rays.

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.

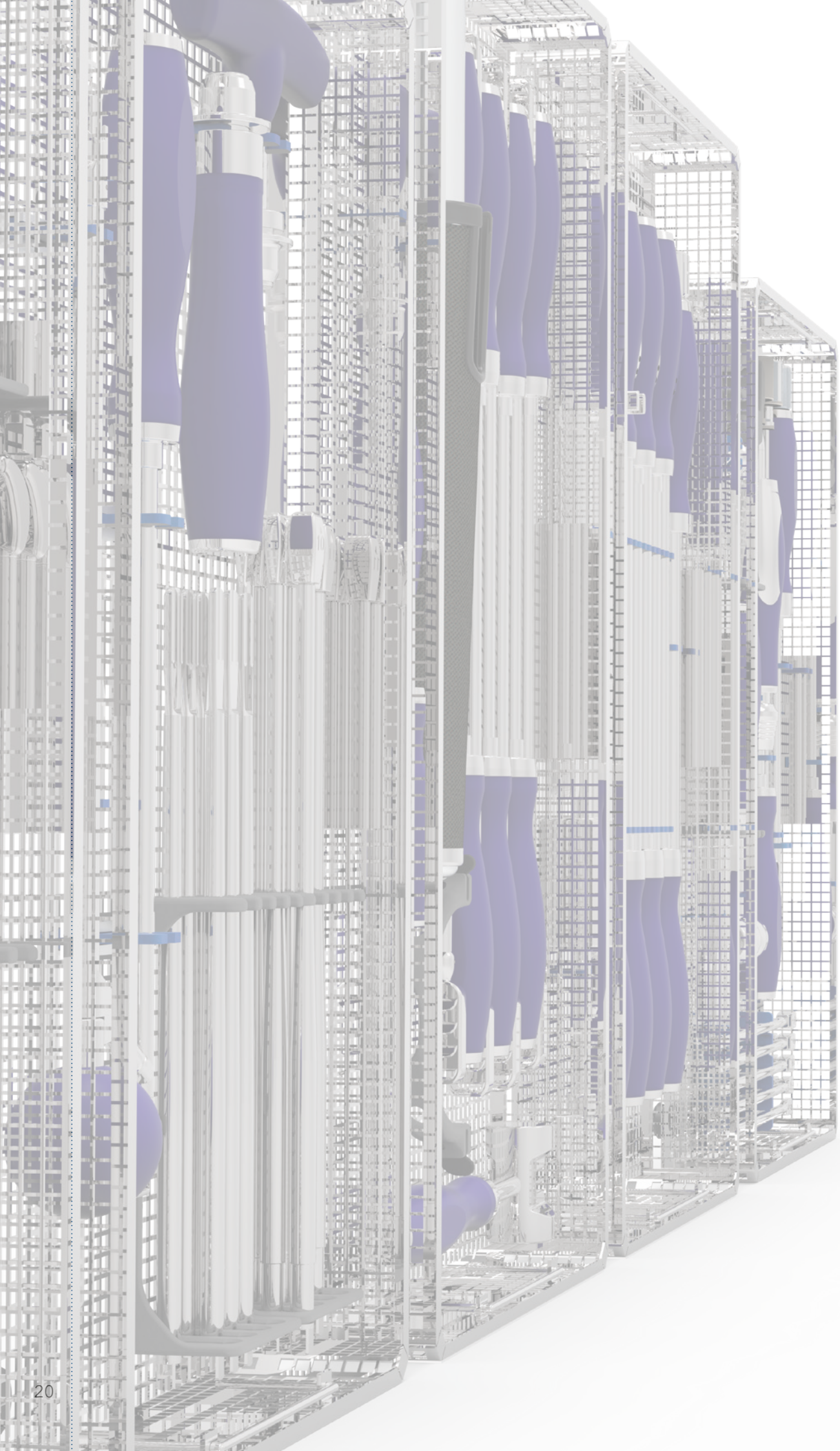
WARRANTY AND PRODUCT COMPLAINTS

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

TLIF
Surgery Set

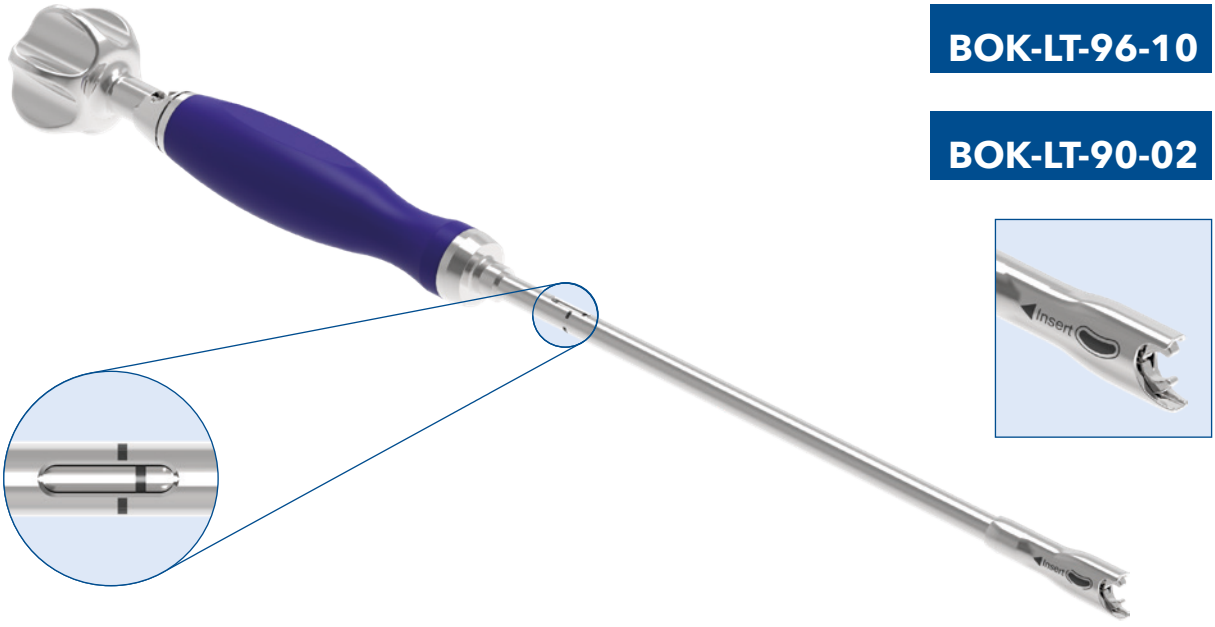
TLIF
Surgery Set

• *First Generation*

***TLIF** Implant Holder* Instrument Ref. Code: **BOK-LT-96**

BOK-LT-96-10

BOK-LT-90-02

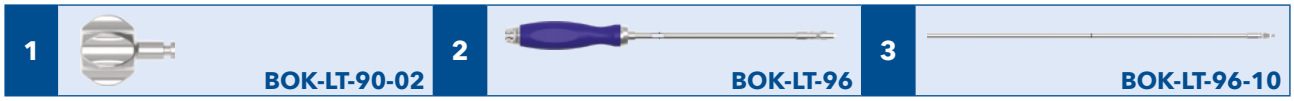


BOK-LT-90-02 TLIF Implant Holder Knob

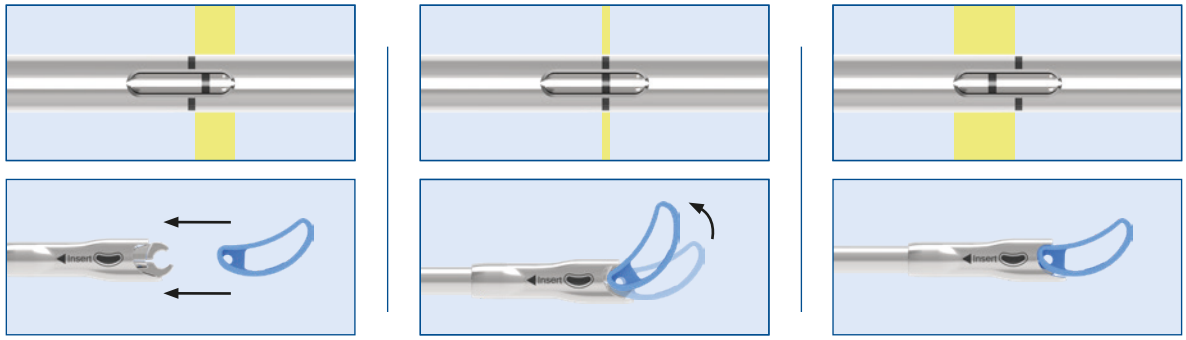
BOK-LT-96 TLIF Implant Holder

BOK-LT-96-10 TLIF Implant Holder Shaft

Components:



Usage Scheme:



1. Cage docking area.

2. Space where the cage can be moved, in the straight and turned position, while keeping it docked.

3. Area where the cage remains fixed in the straight position only.

***TLIF** Implant Holder*	
BOK-LT-96	TLIF Implant Holder
BOK-LT-96-10	TLIF Implant Holder Shaft
BOK-LT-90-02	TLIF Implant Holder Knob

**Dimensional tolerance ± 2 mm

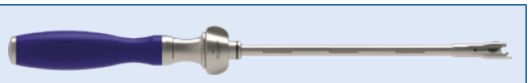
CE

TLIF
Surgery Set

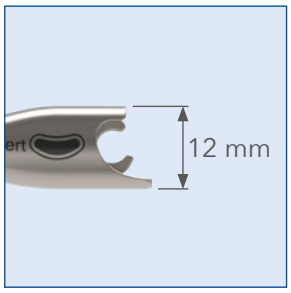
• *First Generation*

TLIF *Implant Holder* Instrument Ref. Code: **BOK-LT-100**

Components:

1	

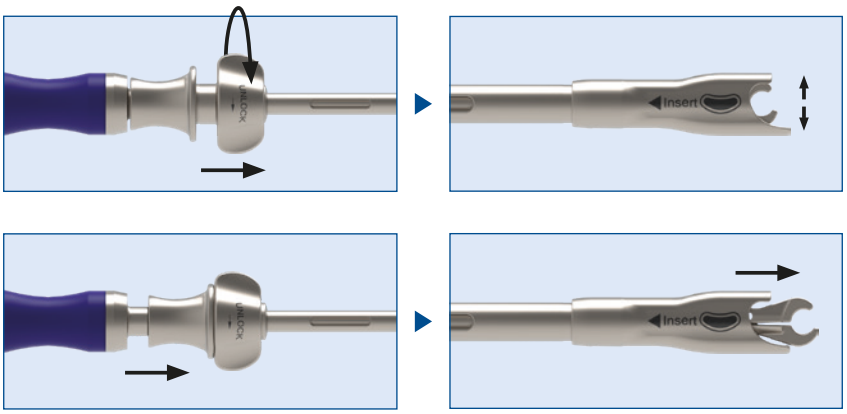
Dimensions:



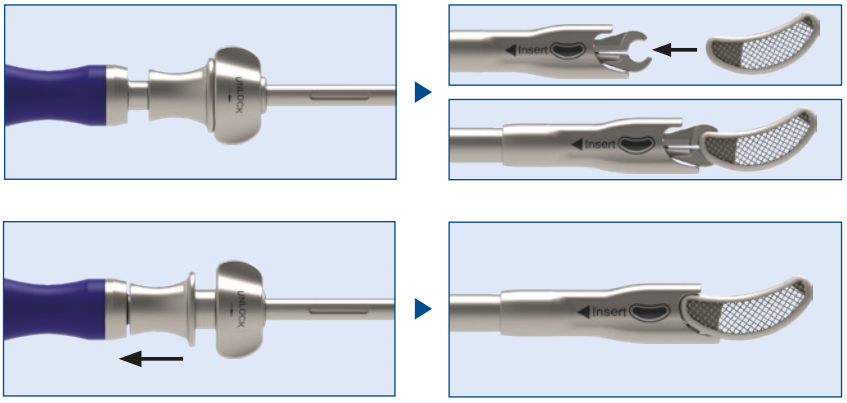
TLIF *Implant Holder*
BOK-LT-100

**Dimensional tolerance ± 2 mm

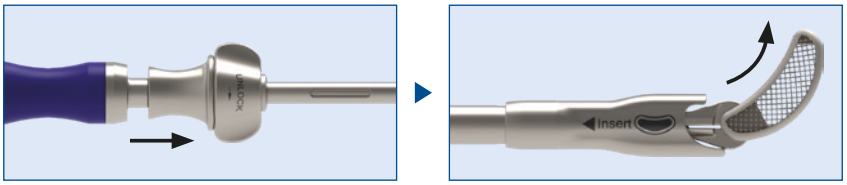
INSTRUNCTIONS FOR USE



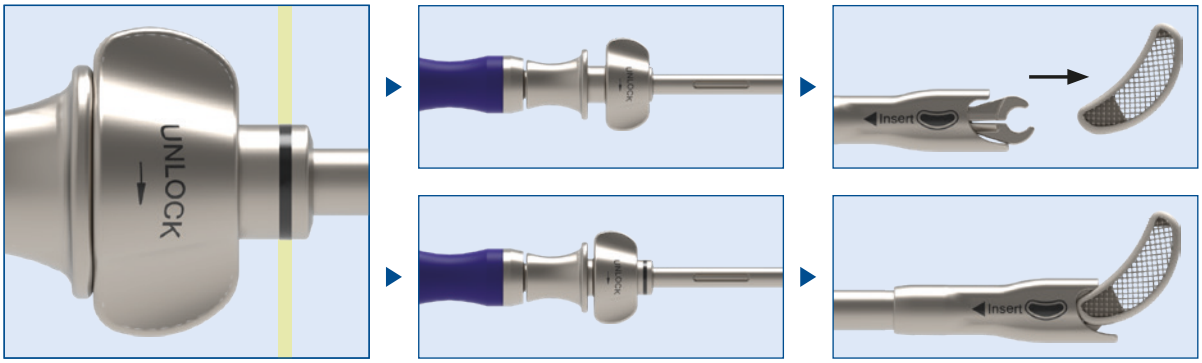
1. Turn the knob to the right to loosen the clamp. Push the cylinder forward to pull the clamp out.



2. Approach cage and insert into clamp. Release cylinder to keep cage fixed.



3. To turn cage, push cylinder forward again.



Note.
To turn the cage while keeping it attached to the holder, hold the knob at or before the margin line. Beyond the margin line the cage will be allowed to detach from the holder.

TLIF
Surgery Set

• *Expandable*

TLIF *Exp. Implant Holder* Instrument Ref. Code: **BOK-LTH-01**

BOK-LTH-02

BOK-LTH-03

BOK-LTH-04

BOK-LC-55

TRQ-01

Components:

TLIF *Exp. Implant Holder*

BOK-LTH-01

TLIF *Exp. Implant Holder Shaft*

BOK-LTH-02

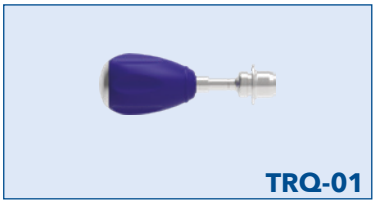
TLIF *Exp. Implant Holder Expansion Shaft*

BOK-LTH-03

TLIF *Exp. Implant Holder Fixation Knob*

BOK-LTH-04

Handle with Torque Limiter 2 NM Fast Connection

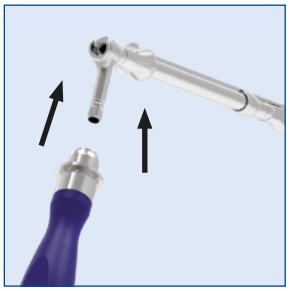


TRQ-01

Straight Handle Fast Connection

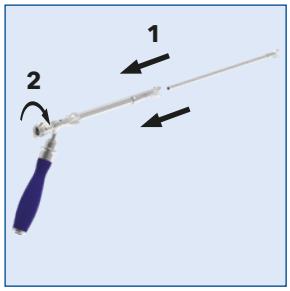
BOK-LC-55

Usage Scheme:

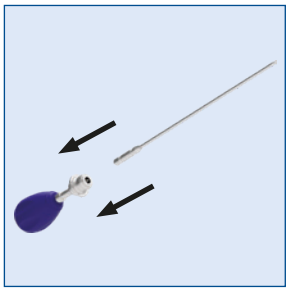


1. Attach the Straight Handle to the Implant Holder.

2. Attach the Implant Fixation Knob to the Implant Holder.



3. Use your index finger to drive the implant holder shaft from distal to proximal into the Implant Holder and fix into the Implant Fixation Knob.



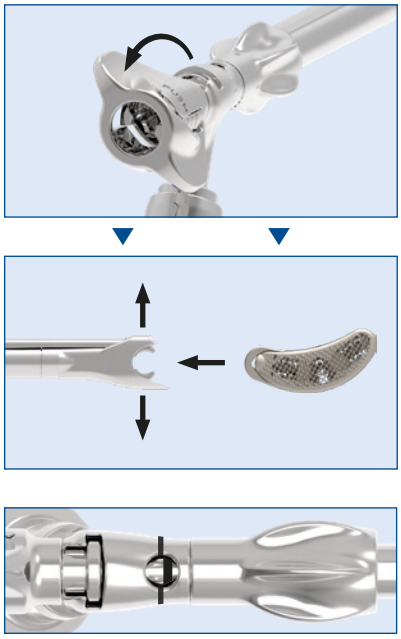
4. Insert the Implant Expander in the Torque Limiter. **PLEASE NOTE:** these assembled parts need to be put into the implant Holder **ONLY AFTER THE IMPLANT** reached its final position into the disc space.

CE

**Dimensional tolerance ± 2 mm

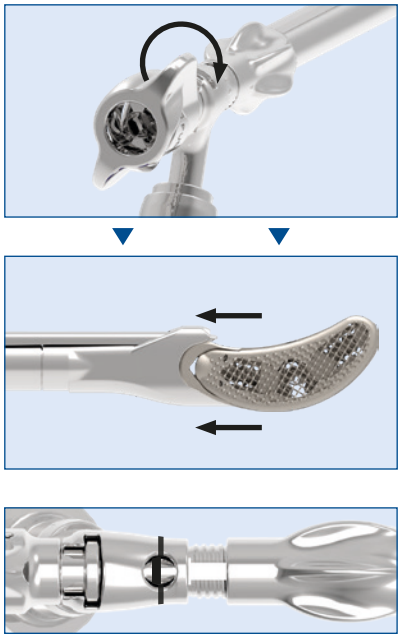
INSTRUNCTIONS FOR EXPANSION

• Position 1



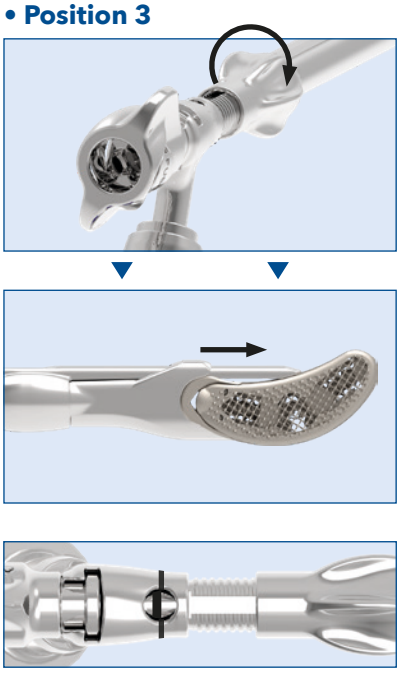
Turn the Implant Fixation Knob to the left to expand the clamp and attach the implant.

• Position 2



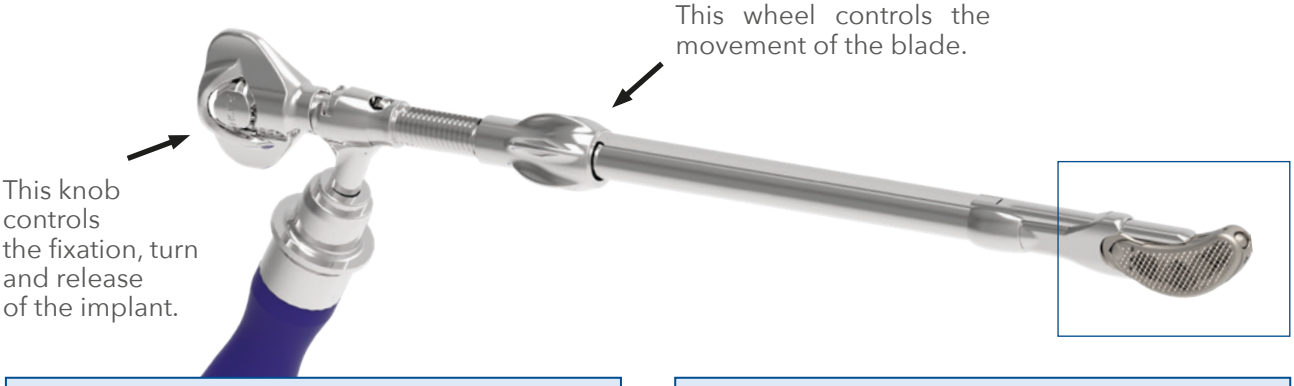
Turn the Implant Fixation Knob to the right to lock the implant on the Implant Holder, until the cage is fixed.

• Position 3



Turn the Implant Holder wheel to the right until the blade is all the way out to prevent the cage from turning.

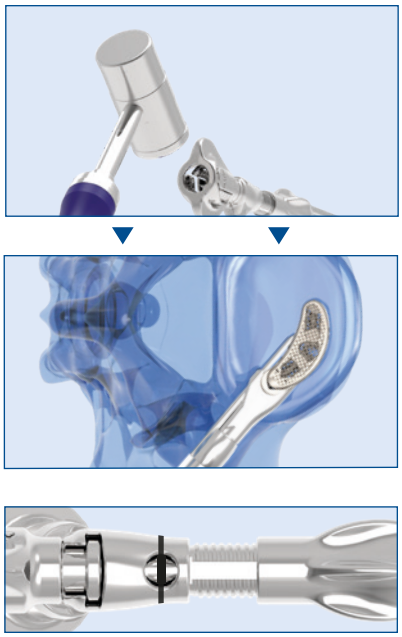
Final position of the wheel



Once pulled out, the blade will keep the cage in fixed position onto the implant holder to prevent from turning during insertion.

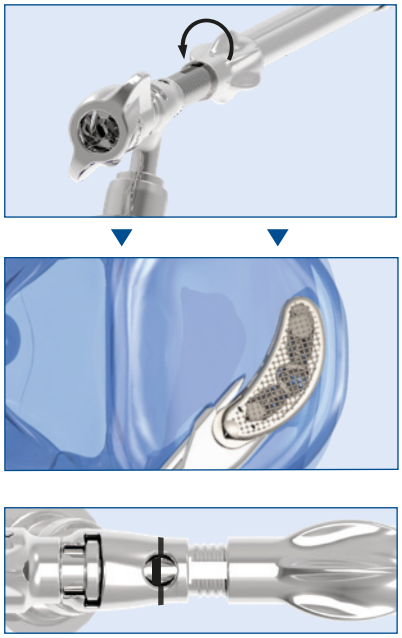
INSTRUNCTIONS FOR EXPANSION

• Position 4



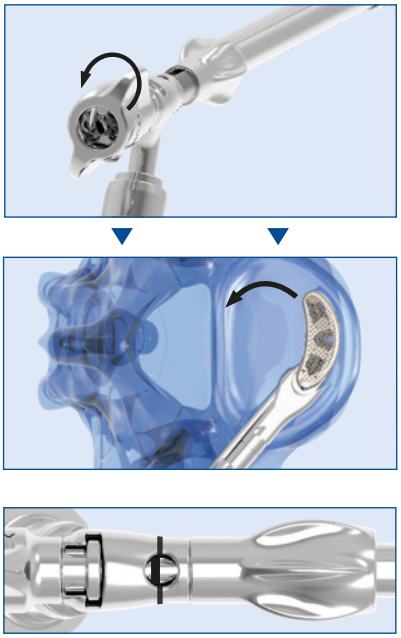
Now begin to Tap with the hammer on the Knob for cage insertion.

• Position 5



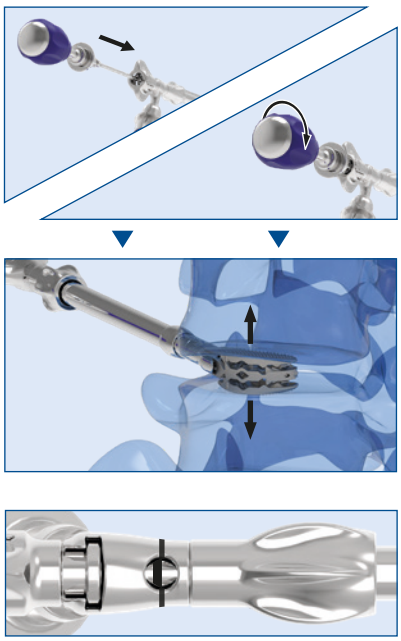
When the cage is positioned against the anterior wall, turn the wheel to the left, all the way up: this will retract the blade into the implant inserter. **PLEASE NOTE:** when not completly retracted, the blade will block turning of the cage.

• Position 6



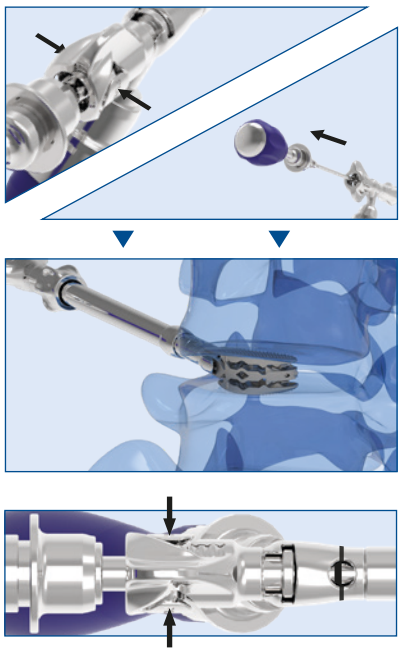
Partially unscrew the Holder Knob (turn left; one full turn) to allow the implant to turn. Tap onto the Knob to position it in the correct position.

• Position 7



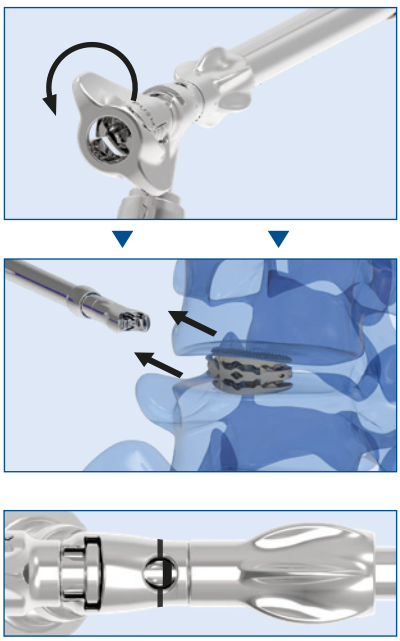
Insert the Expansion Shaft and turn to the right to the desired expansion. The torque Knob will prevent the contact surfaces (net structure) of the implant to damage the vertebral endplates.

• Position 8



Press simultaneously the two buttons on the knob to remove the expansion shaft.

• Position 9

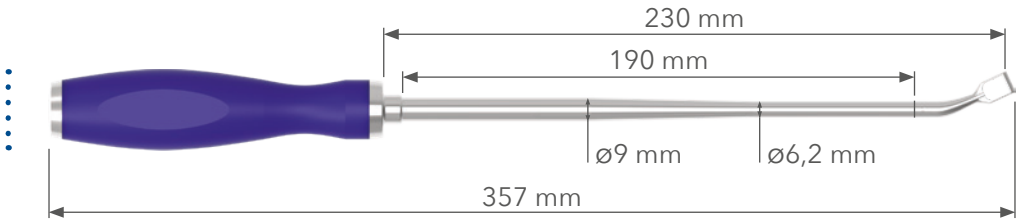


Turn the Implant Fixation Knob to the left to release the implant. Gently remove the implant inserter, NO force should be applied.

TLIF
Surgery Set

- *First Generation*
- *Expandable*

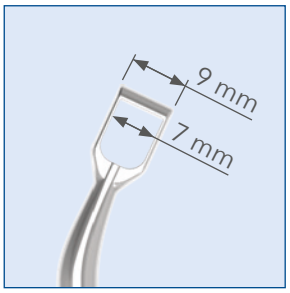
One Side Curved Squared Curette Instrument Ref. Code: **BOK-LT-70**

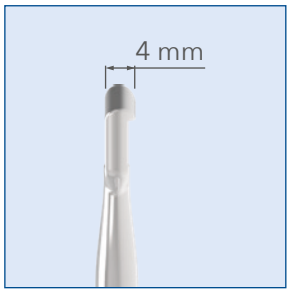


Components:

1	

Dimensions:





One Side Curved Squared Curette
BOK-LT-70

**Dimensional tolerance ± 2 mm

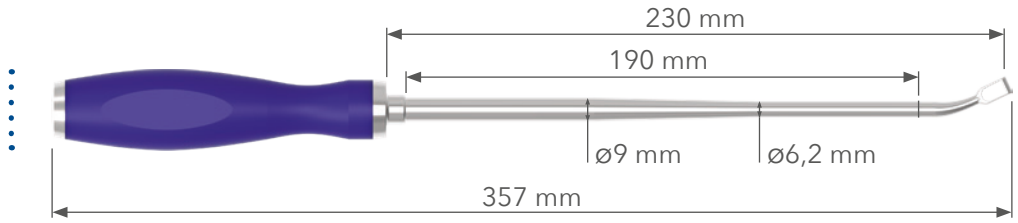
CE

TLIF
Surgery Set

- *First Generation*
- *Expandable*

One Side Curved Squared Curette Small

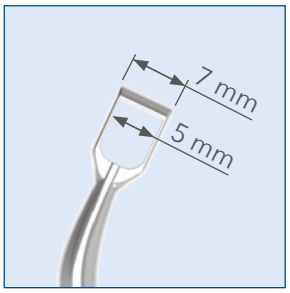
Instrument Ref. Code: **BOK-LT-70S**

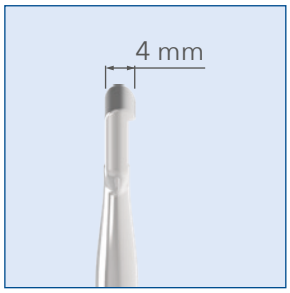


Components:

1	

Dimensions:





One Side Curved Squared Curette Small
BOK-LT-70S

**Dimensional tolerance ± 2 mm

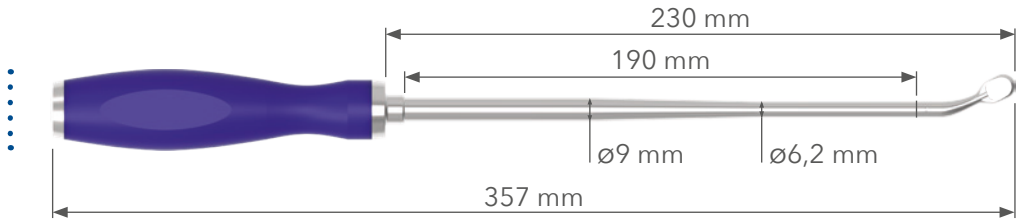
CE

TLIF
Surgery Set

- *First Generation*
- *Expandable*

Double Side Curved Rounded Curette

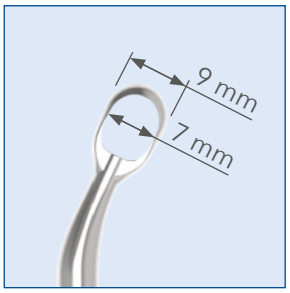
Instrument Ref. Code: **BOK-LT-71**

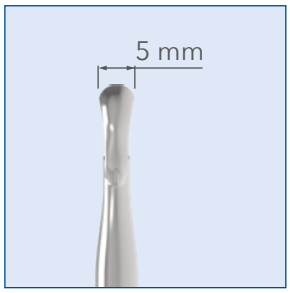


Components:

1

Dimensions:





Double Side Curved Rounded Curette
BOK-LT-71

**Dimensional tolerance ± 2 mm

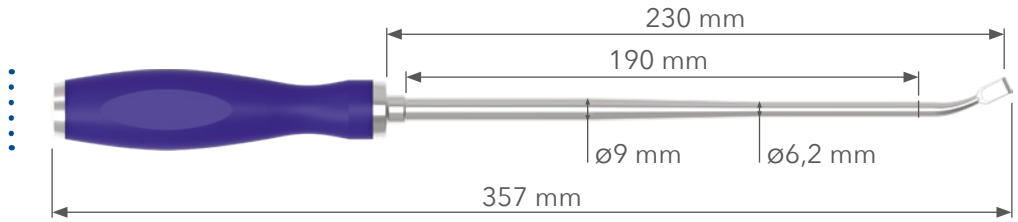
CE

TLIF
Surgery Set

- *First Generation*
- *Expandable*

Double Side Curved Squared Curette

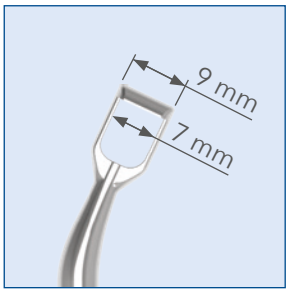
Instrument Ref. Code: **BOK-LT-72**

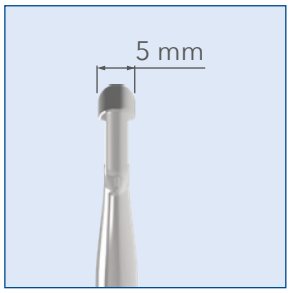


Components:

1

Dimensions:





Double Side Curved Squared Curette
BOK-LT-72

**Dimensional tolerance ± 2 mm

CE

TLIF
Surgery Set

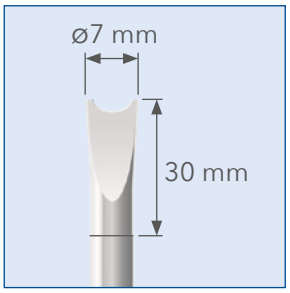
- *First Generation*
- *Expandable*

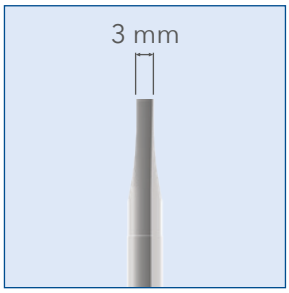
Implant Impactor Instrument Ref. Code: **BOK-LT-73L**

Components:

1

Dimensions:





Implant Impactor
BOK-LT-73L

**Dimensional tolerance ± 2 mm

CE

TLIF
Surgery Set

- *First Generation*
- *Expandable*

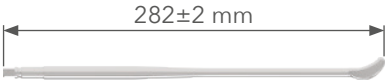
***TLIF** Implant Trial*
Fast Connection

Instrument Ref. Code: **BOK-LT-280-****

CE

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

Details



Description	Code
*TLIF Implant Trial 26mmx**7mm** Fast Connection*	**BOK-LT-280-07**
*TLIF Implant Trial 26mmx**8mm** Fast Connection*	**BOK-LT-280-08**
*TLIF Implant Trial 26mmx**9mm** Fast Connection*	**BOK-LT-280-09**
*TLIF Implant Trial 26mmx**10mm** Fast Connection*	**BOK-LT-280-10**
*TLIF Implant Trial 26mmx**11mm** Fast Connection*	**BOK-LT-280-11**
*TLIF Implant Trial 26mmx**12mm** Fast Connection*	**BOK-LT-280-12**
*TLIF Implant Trial 26mmx**13mm** Fast Connection*	**BOK-LT-280-13**

TLIF
Surgery Set

• *Expandable*

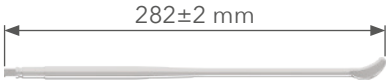
***TLIF** Implant Trial*
Fast Connection

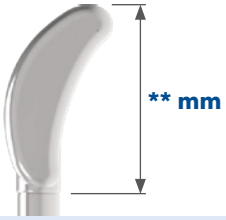
Instrument Ref. Code: **BOK-LT-280-**07**

CE

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

Details





Description	Code
*TLIF Implant Trial **32mm**x**7mm** Fast Connection*	**BOK-LT-280-3207**
*TLIF Implant Trial **40mm**x**7mm** Fast Connection*	**BOK-LT-280-4007**

TLIF
Surgery Set

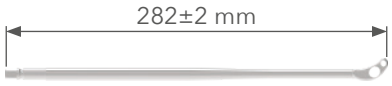
- *First Generation*
- *Expandable*

TLIF** Implant Trial Rasp* Instrument Ref. Code: **BOK-LT-280R-*

CE

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

Details



Description	Code
*TLIF Implant Trial Rasp 26mmx**5mm***	**BOK-LT-280R-05**
*TLIF Implant Trial Rasp 26mmx**6mm***	**BOK-LT-280R-06**
*TLIF Implant Trial Rasp 26mmx**7mm***	**BOK-LT-280R-07**
*TLIF Implant Trial Rasp 26mmx**8mm***	**BOK-LT-280R-08**
*TLIF Implant Trial Rasp 26mmx**9mm***	**BOK-LT-280R-09**
*TLIF Implant Trial Rasp 26mmx**10mm***	**BOK-LT-280R-10**
*TLIF Implant Trial Rasp 26mmx**11mm***	**BOK-LT-280R-11**
*TLIF Implant Trial Rasp 26mmx**12mm***	**BOK-LT-280R-12**
*TLIF Implant Trial Rasp 26mmx**13mm***	**BOK-LT-280R-13**

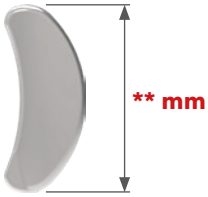
TLIF
Surgery Set

- *First Generation*
- *Expandable*

TLIF** Titanium Trial* Instrument Ref. Code: **BOK-LT-T***

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

Details

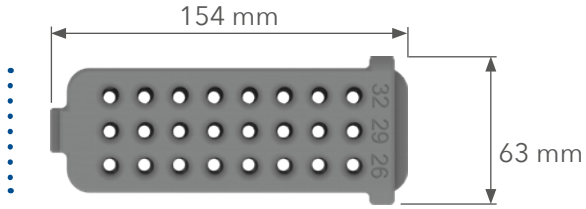


Description	Code	Description	Code
TLIF Titanium Trial ***26x7mm***	**BOK-LT-T2607**	*TLIF Titanium Trial* ***29x11mm***	**BOK-LT-T2911**
TLIF Titanium Trial ***26x8mm***	**BOK-LT-T2608**	*TLIF Titanium Trial* ***29x12mm***	**BOK-LT-T2912**
TLIF Titanium Trial ***26x9mm***	**BOK-LT-T2609**	*TLIF Titanium Trial* ***29x13mm***	**BOK-LT-T2913**
TLIF Titanium Trial ***26x10mm***	**BOK-LT-T2610**	*TLIF Titanium Trial* ***29x14mm***	**BOK-LT-T2914**
TLIF Titanium Trial ***26x11mm***	**BOK-LT-T2611**	*TLIF Titanium Trial* ***32x7mm***	**BOK-LT-T3207**
TLIF Titanium Trial ***26x12mm***	**BOK-LT-T2612**	*TLIF Titanium Trial* ***32x8mm***	**BOK-LT-T3208**
TLIF Titanium Trial ***26x13mm***	**BOK-LT-T2613**	*TLIF Titanium Trial* ***32x9mm***	**BOK-LT-T3209**
TLIF Titanium Trial ***26x14mm***	**BOK-LT-T2614**	*TLIF Titanium Trial* ***32x10mm***	**BOK-LT-T3210**
TLIF Titanium Trial ***29x7mm***	**BOK-LT-T2907**	*TLIF Titanium Trial* ***32x11mm***	**BOK-LT-T3211**
TLIF Titanium Trial ***29x8mm***	**BOK-LT-T2908**	*TLIF Titanium Trial* ***32x12mm***	**BOK-LT-T3212**
TLIF Titanium Trial ***29x9mm***	**BOK-LT-T2909**	*TLIF Titanium Trial* ***32x13mm***	**BOK-LT-T3213**
TLIF Titanium Trial ***29x10mm***	**BOK-LT-T2910**	*TLIF Titanium Trial* ***32x14mm***	**BOK-LT-T3214**

TLIF
Surgery Set

- *First Generation*
- *Expandable*

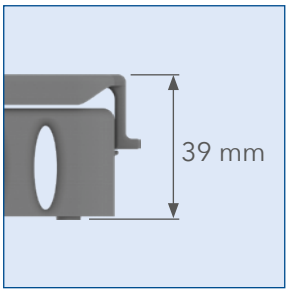
TLIF *Trial Tray Complete* Instrument Ref. Code: **BOK-LT-TB01**



Components:

1	

Dimensions:



For N°24 Trials.

TLIF Trial Tray Complete
BOK-LT-TB01

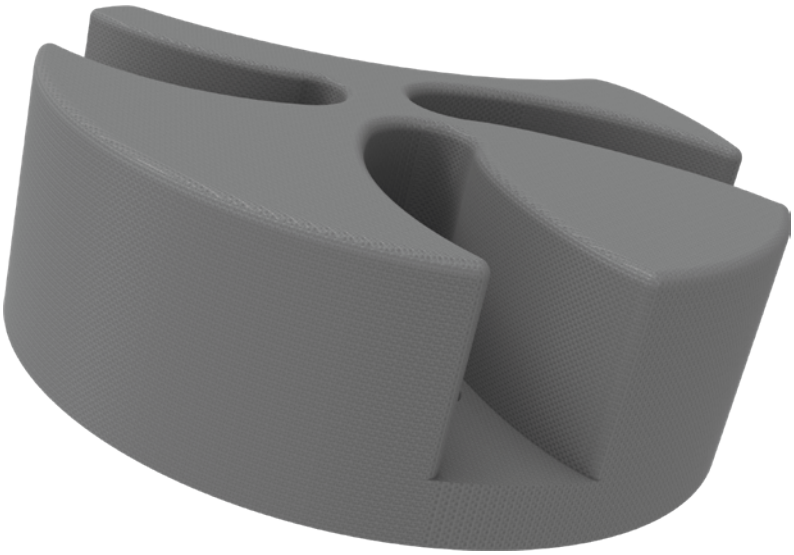
**Dimensional tolerance ± 2 mm

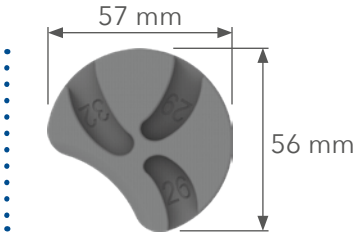
CE

TLIF
Surgery Set

- *First Generation*
- *Expandable*

***TLIF** Implant Filling Support* Instrument Ref. Code: **BOK-LT-62**

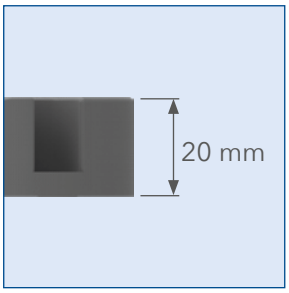




Components:

1	

Dimensions:



TLIF Implant Filling Support
BOK-LT-62

**Dimensional tolerance ± 2 mm

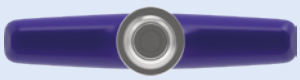
CE

GENERAL
INSTRUMENTS

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

T Handle Fast Connection Instrument Ref. Code: **BOK-LC-52**

Components:

1	

Dimensions:

T Handle Fast Connection
BOK-LC-52

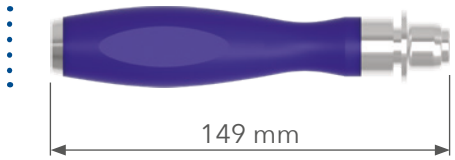
**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

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

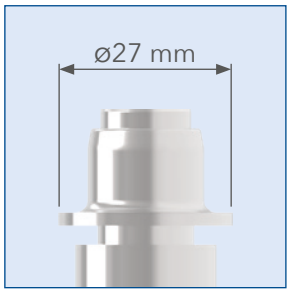
Straight Handle Fast Connection Instrument Ref. Code: **BOK-LC-55**

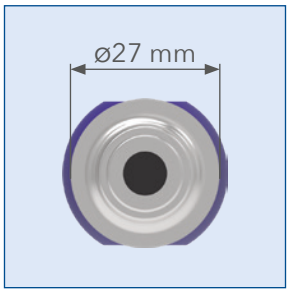


Components:

1	

Dimensions:





Straight Handle Fast Connection
BOK-LC-55

**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

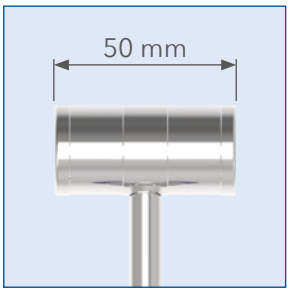
- *First Generation*
- *Built-In Fixation*
- *Expandable*

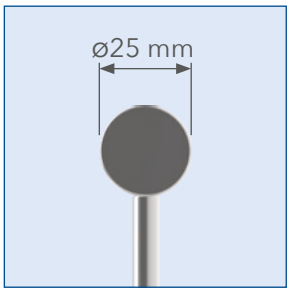
Hammer Instrument Ref. Code: **BOK-LC-59**

Components:

1

Dimensions:





Hammer
BOK-LC-59

**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

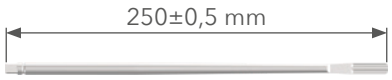
- *First Generation*
- *Built-In Fixation*
- *Expandable*

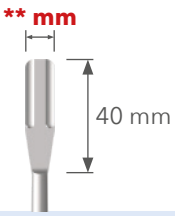
Shavers Instrument Ref. Code: **BOK-LC-250-****

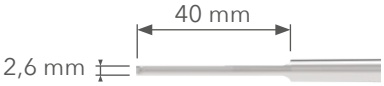
CE

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

Details





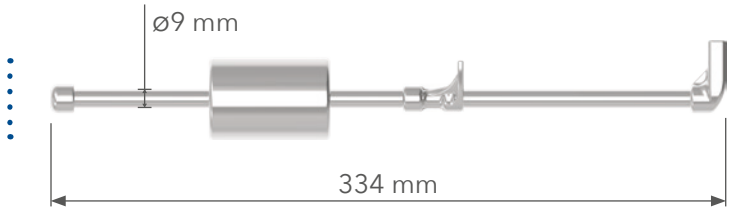


Description	Code
*Shaver **7mm***	**BOK-LC-250-07**
*Shaver **8mm***	**BOK-LC-250-08**
*Shaver **9mm***	**BOK-LC-250-09**
*Shaver **10mm***	**BOK-LC-250-10**
*Shaver **11mm***	**BOK-LC-250-11**
*Shaver **12mm***	**BOK-LC-250-12**
*Shaver **13mm***	**BOK-LC-250-13**

GENERAL
INSTRUMENTS

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

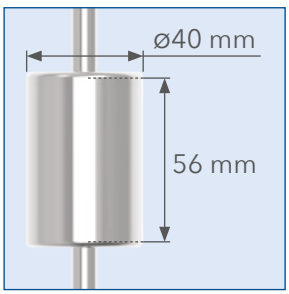
Universal Slide Hammer Instrument Ref. Code: **BOK-LT-80**



Components:

1	

Dimensions:



Universal Slide Hammer
BOK-LT-80

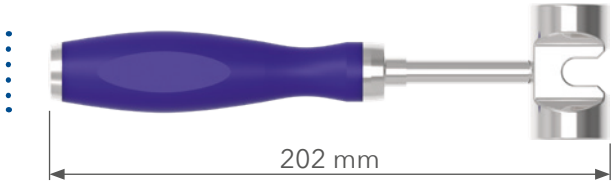
**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

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

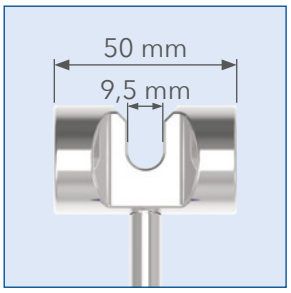
Hammer 250g Instrument Ref. Code: **TH002**

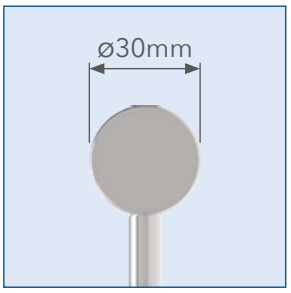


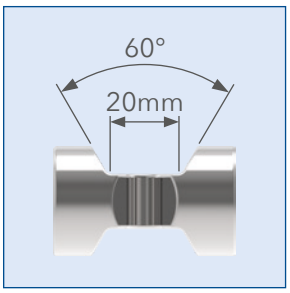
Components:

1

Dimensions:







Hammer 250g
TH002

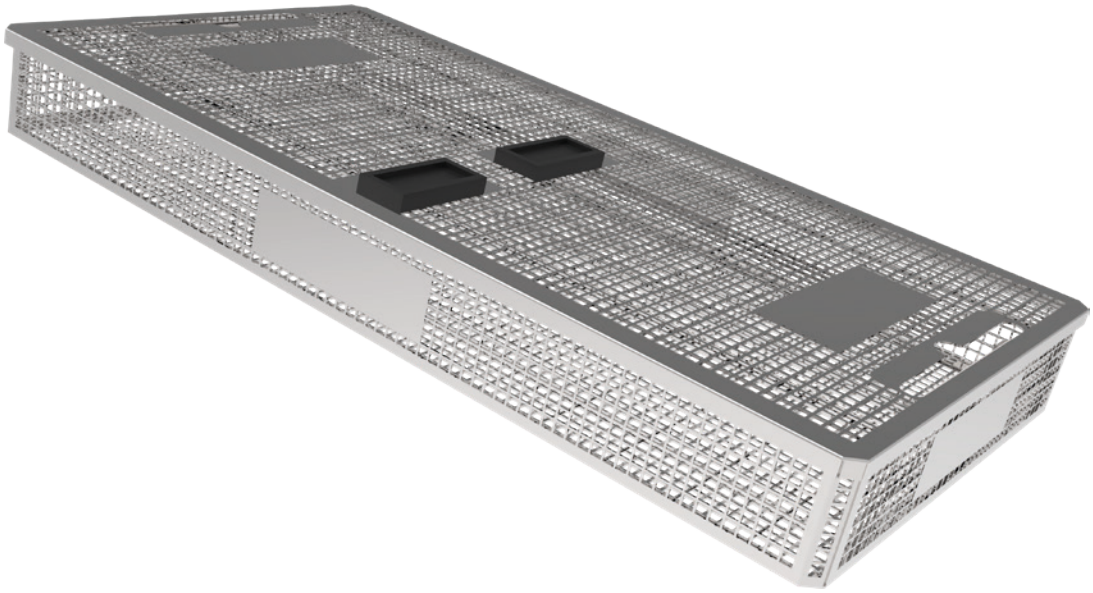
**Dimensional tolerance ± 2 mm

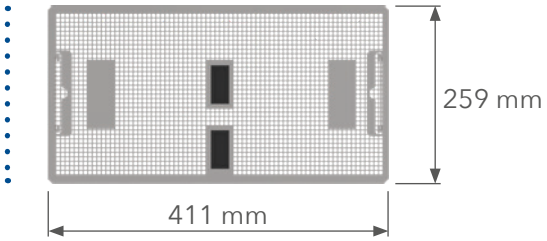
CE

GENERAL
INSTRUMENTS

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

Small Tray Instrument Ref. Code: **K3-729**

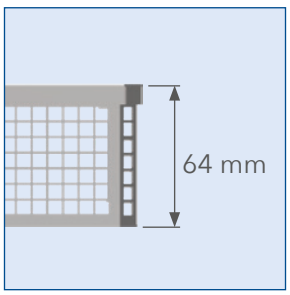




Components:

1	

Dimensions:



Small Tray
K3-729

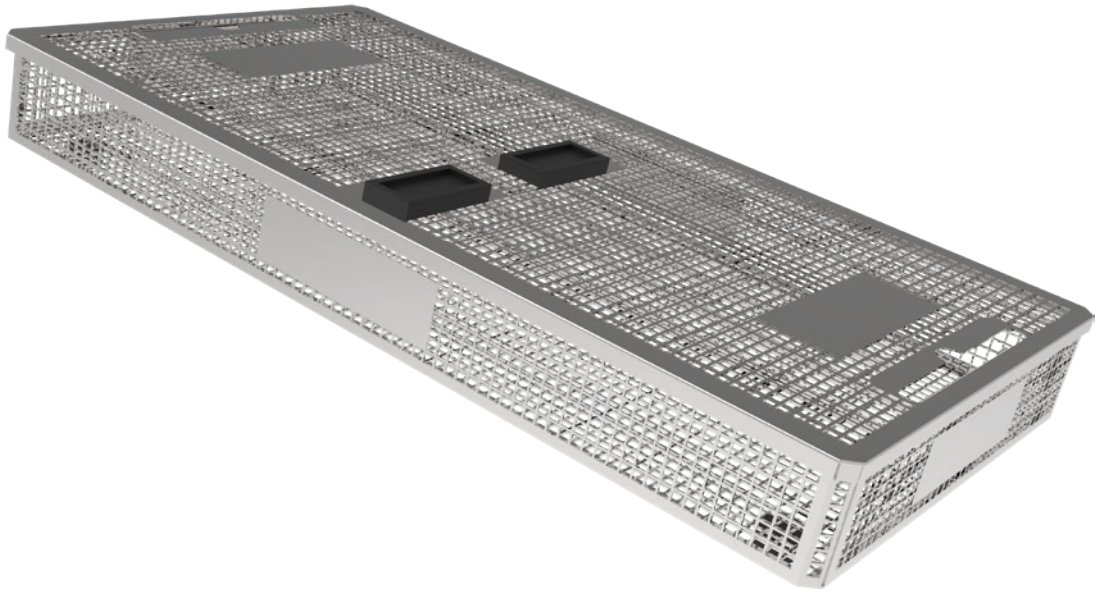
**Dimensional tolerance ± 2 mm

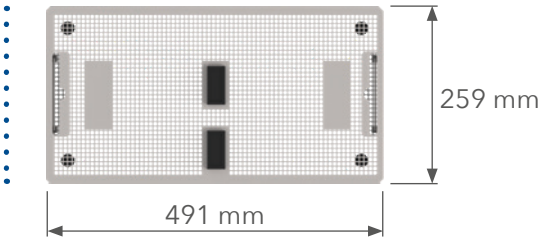
CE

GENERAL
INSTRUMENTS

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

Medium Tray Instrument Ref. Code: **K3-725**

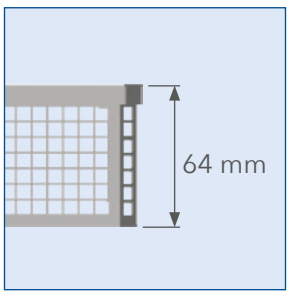




Components:

1

Dimensions:



Medium Tray
K3-725

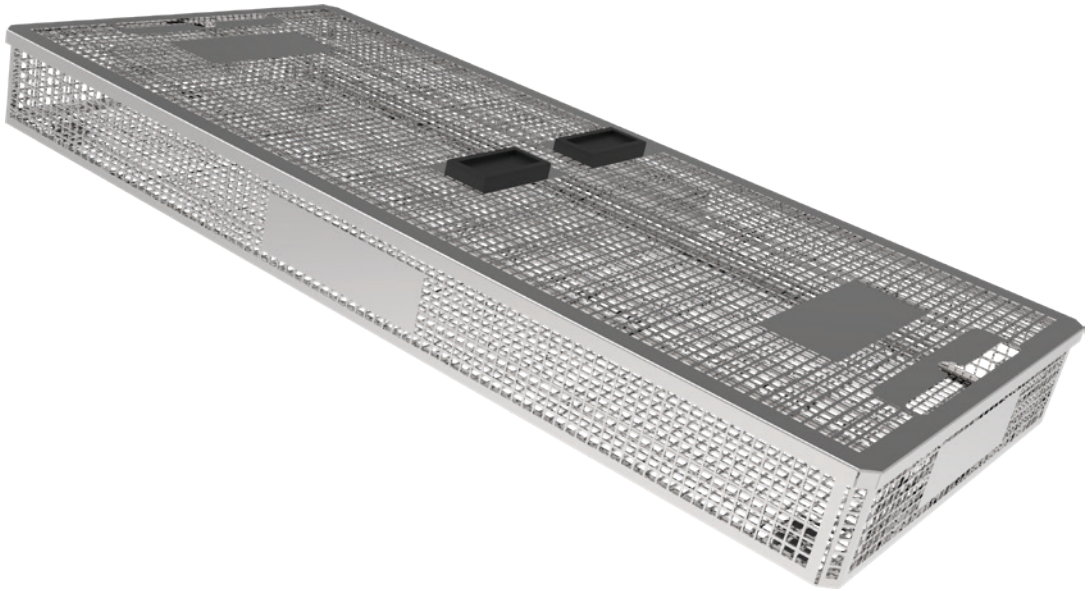
**Dimensional tolerance ± 2 mm

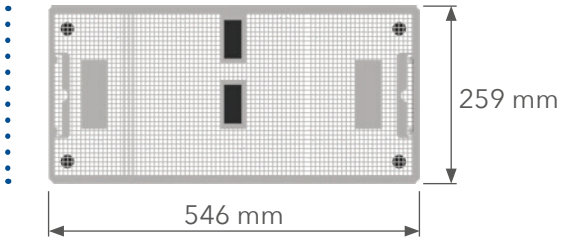
CE

GENERAL
INSTRUMENTS

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

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

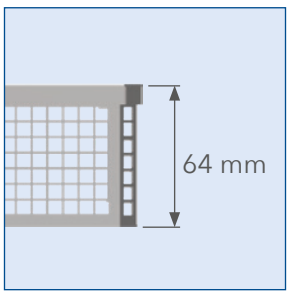




Components:

1

Dimensions:

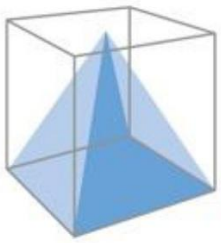


Large Tray
K3-721

**Dimensional tolerance ± 2 mm

CE

Distribuidor por:



BIOSpine. S.L.

Camino de los Cinamomos 283-5
33203 - Gijón (Asturias)
985195325
info@biospine.info

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Made in Italy

Tsunami Medical S.r.l.
Reg. Offices: via E. Giorgi n. 27 – 41124 Modena (MO) Italy
Production & Administrative Site: Via XXV Aprile n. 22 - 41037 Mirandola (MO) Italy
Tel. +39.0535.38397 - Fax. +39.0535.38399
www.tsunamimedical.com - info@tsunamimed.com

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