TSUNAMI MEDICAL

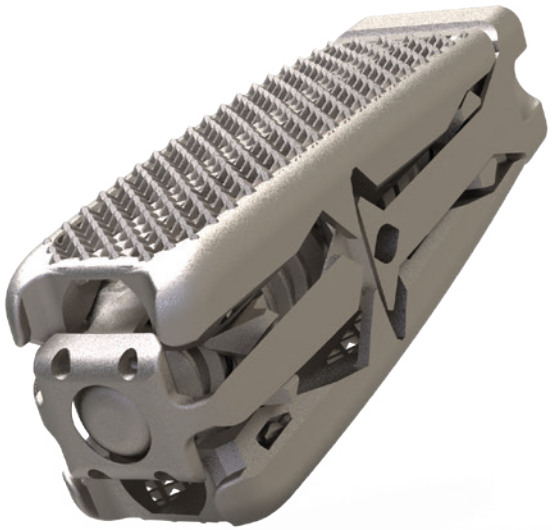
THE WAVE OF INNOVATION

Surgical Technique

PROCIDA

PLIF 3D Printed Titanium Cage

Expandable



Bone InGrowth Technology®

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Procida Overview

Procida, expandable PLIF 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

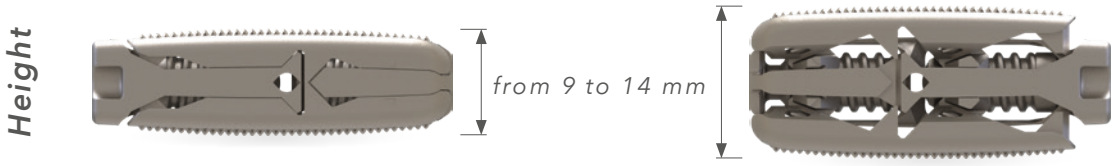
Procida has a unique multi-direction expansion mechanism: it allows cranial-caudal height expansion and amendment to the required lordosis angle by individual and gradual expansion in anterior and posterior direction. With this unique feature surgeons are able to make the implant perfectly fit the natural 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 Procida, Tsunami Medical offers two footprints and a range 9-14 mm heights, with possible lordosis angles ranging from 0° to 14°, thanks to its innovative expansion feature, as outlined below.

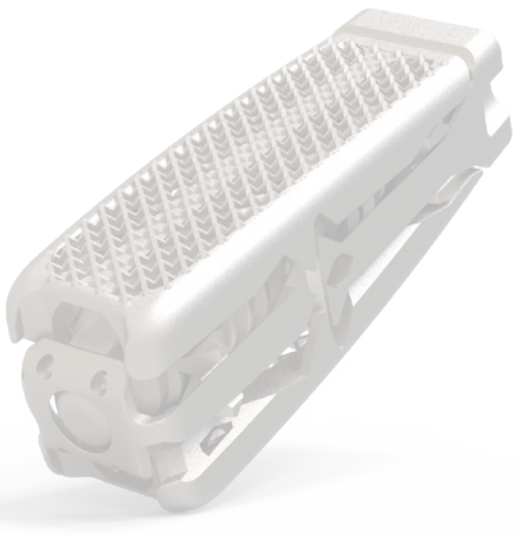
	29x9 mm	*32x9 mm*
Footprint		

Procida Overview



Product Reference Codes

Ref. Code	Dimensions
ACPH29090900	Footprint Size **29x9mm** - Angles **0°-14°** Heights [mm] **09-14**
ACPH32090900	Footprint Size **32x9mm** - Angles **0°-14°** Heights [mm] **09-14**



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PROCIDA

Procida Intended Use

Procida 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.

Procida 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

Procida is intended for thoracic, lumbar or lumbar-sacral 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

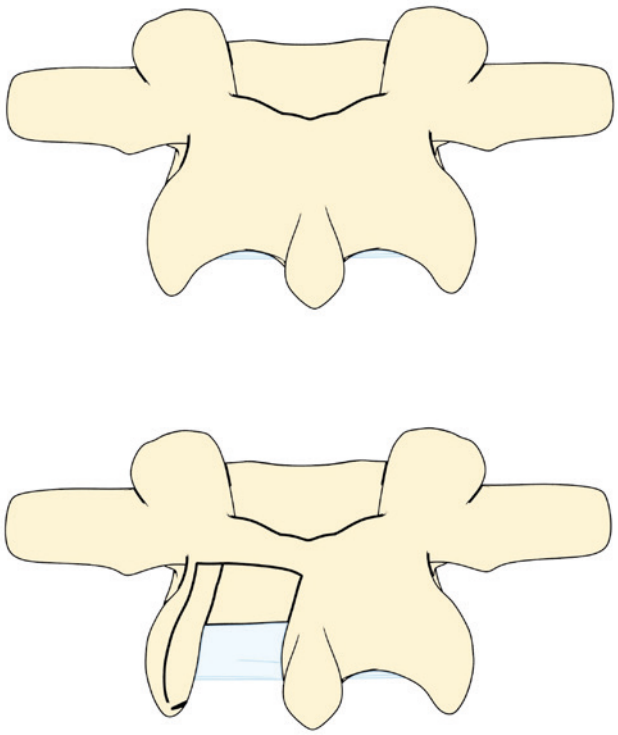
Patient position should expose the spine level, which is going to be operated on.
Surgeons should evaluate the most appropriate position considering the surgical approach technique, decompression procedure and fusion technique.
For this surgical procedure, place the patient in prone position for Direct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

Patient in prone position.

Skin Incision

By using fluoroscopy the appropriate level of the 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.

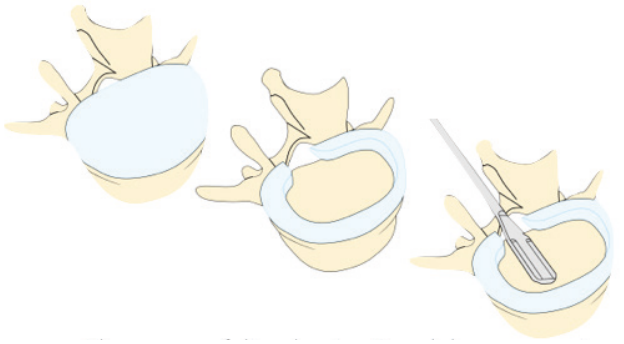
To maintain proper vision on the surgical field a tissue retractor system is highly recommended.
It is up to surgeon's experience to define and perform the soft tissue approach and bone decompression procedure. In some cases, specific patient's positioning may be required.



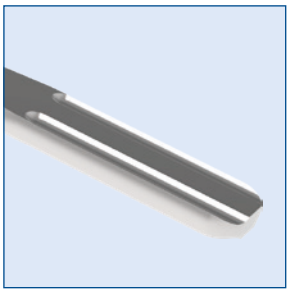
Skin incision procedure.

Disc Removal and Endplate Preparation

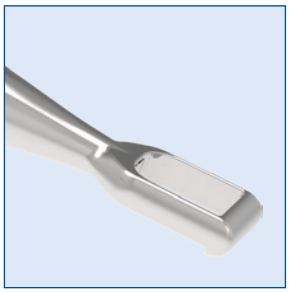
The discectomy procedure should be performed using standard disc cleaning instruments. The choice of appropriate instruments depends on approach, surgeons' preferences and projected results. Using rasps (standard in the set: **BOK-LC-240-07** to 13, with 1 mm increments) and curettes (**BOK-LC-70**) 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.



Three steps of disc cleaning & endplate preparation.



BOK-LC-250-**



BOK-LC-70

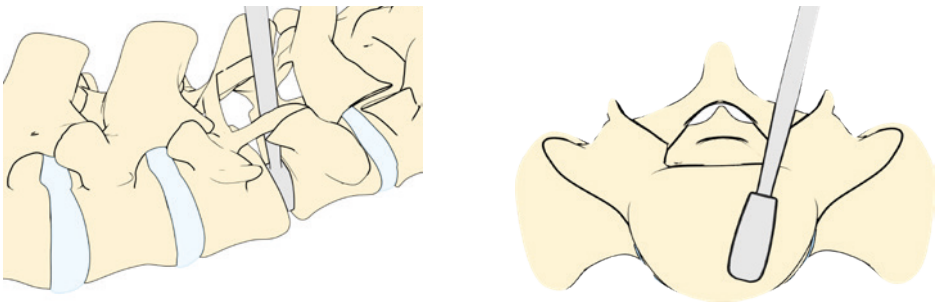
BOK-LC-70

Implant Dimension Choice

To select the appropriate cage size implants trials (**BOK-LC-245R-****) should be used. 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: The trial Implant must fit firmly with a tight press-fit between the endplates

As shown in the instruments overview: there is a wide variety of implant trials available; all with fixed shaft, either long or short. Also implant trials with a built-in rasp are available. There is an example of these shown in the picture next to this text (**BOK-LC-245R****)..
Keep the same trajectory and angulation as intended for implant insertion.

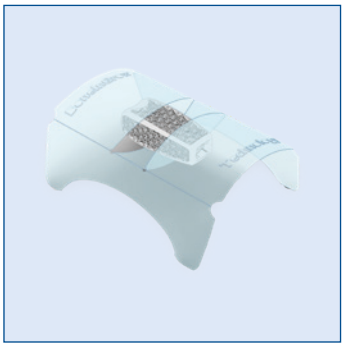
When trialing is performed, PLEASE NOTE the implant trials/(rasps) are 24 mm long, whereas the actual implant is either 29 mm or 32 mm long. Please also note that implant trials are designed "flat" (0 degrees of lordosis). Pre-operative radiological imaging is strongly recommended.

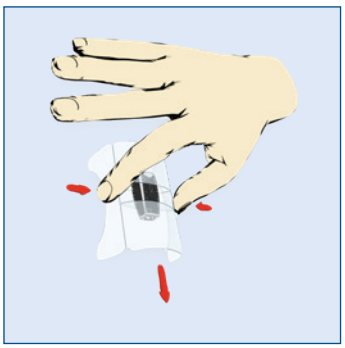


Graphic representation of implant trialing.

Implant Packaging

The implant is supplied in a double rigid blister pack with a special internal holder.
The rotation nurse opens the outer (non-sterile) blister of the implant and hands the implant to the sterile OR nurse or scrub technician. The sterile OR nurse removes the inner (sterile) blister, opens it, takes out the holder and presses as indicated next to this text to release the implant. Always ensure that the sterility of the implant, which is located in the inner blister, is maintained.





Implant Preparation

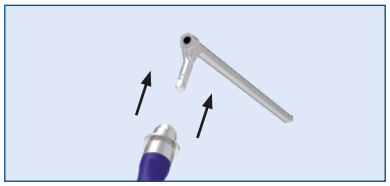
Insert the implant holder shaft (**BOK-LCH-02**) into the implant holder (**BOK-LCH-01**) and attach the straight Silicone handle (**BOK-LC-55**), which has a quick coupler for the attachment, on the 90 degrees angled attachment on the implant holder;
To avoid confusion or even cause damages on implants or instruments:

Connect the implant to the assembled implant holder by turning the knob of the the implant holder shaft (**BOK-LCH-02**) clockwise till a solid fixed position has been reached in order to avoid any problems during final implant positioning.

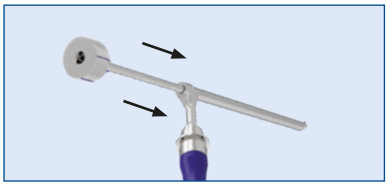
The straight Silicone handle (**BOK-LC-55**) is attached before implant implantation; the Torque limiter (**TRQ-01**) is assembled after implant implantation.

PROCIDA, PLIF

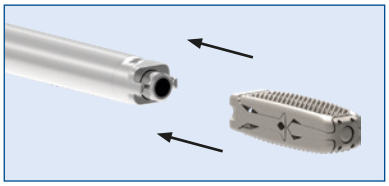
Usage Scheme:



1. Connect the Straight Handle to the Holder.



2. Insert the Holder Shaft.



3. Connect the cage to the coupling.

Components:

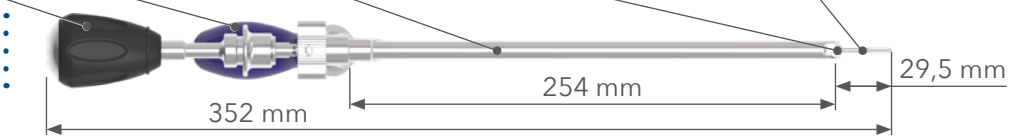
TRQ-01
Handle with Torque Limiter 2 NM Fast Connection

BOK-LC-55
Straight Handle Fast Connection

BOK-LCH-01
PLIF Exp. Implant Holder

BOK-LCH-02
PPLIF Exp. Implant Holder Shaft

BOK-LCH-03
PLIF Exp. Implant Holder Expansion Shaft



Components:

Implant Reference Codes

Height and Lordosis Angle are controlled by the implant's expansion mechanism: determined after evaluation of (pre-OP) fluoroscopy imaging. Length (either 32 or 29 mm) is also following (pre-OP) fluoroscopy imaging and surgeon's preference.

ACPH | 3209 | 09 | 00

Cage Code — ***Footprint*** — Height* — Lordosis Angle**

Length x Width/Depth

Example

*Cage Length > Ranges from 9-14 mm; minimal height (9mm) is shown in the reference code.

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

Cage Implantation

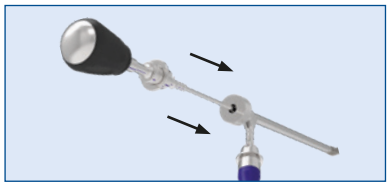
If necessary, increase the distraction of the vertebral segment to facilitate implant insertion.
Insert the cage, giving gentle hammer blows on the back side (which is facing you) of the implant holder shaft (**BOK-LCH-02**), using the hammer (**BOK-LC-59** or **TH002**) till final positioning has been reached.

Expansion Preparation

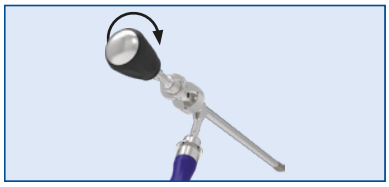
Once the implant is in its final correct position, complete the implant inserter assembly, by assembling the Torque limiter (**TRQ-01**) to the the ACPH expansion shaft (**BOK-LCH-03**).

Gently insert the combined ACPH expansion shaft + the Torque limiter into the implant holder shaft till it “clicks” into “position A” (See also expansion of the implant on page 14).

4. We have so the clean Holder.

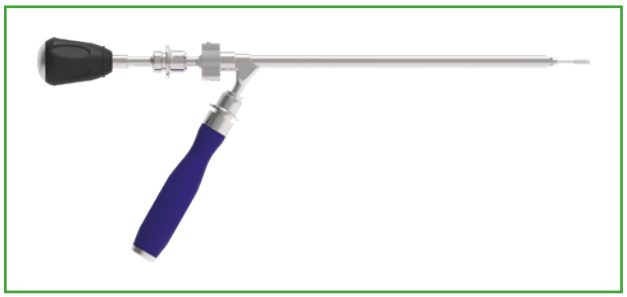


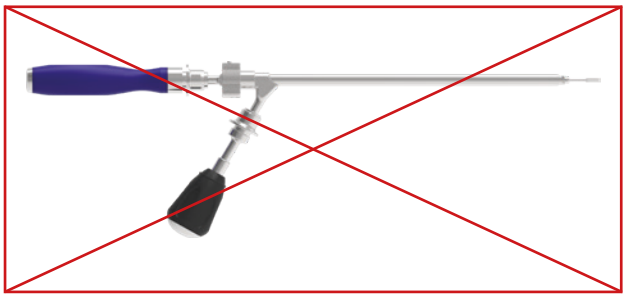
5. Insert the Torque Limiter with the Expansion Shaft.



6. Screw the Torq Limiter to expand the cage.

Straight Silicone handle and Torque Limiter attachment

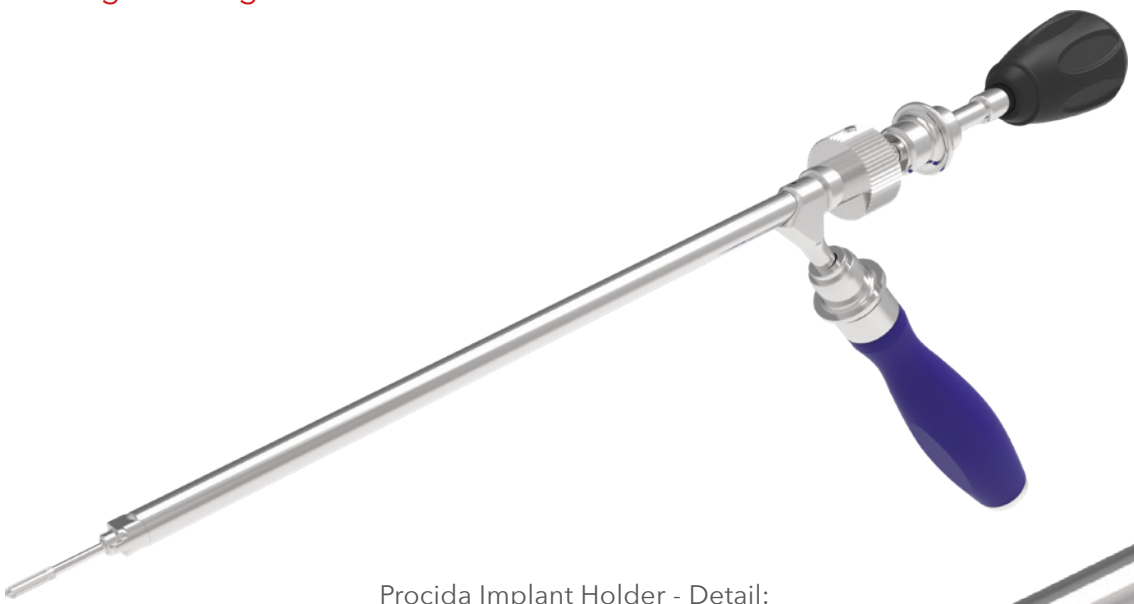




Caution:

ALWAYS make sure to attach the straight Silicone handle (**BOK-LC-55**) on the 90 degrees angled attachment of the implant holder (**BOK-LCH-01**) and the Torque limiter (**TRQ-01**) on the ACPH expansion shaft (**BOK-LCH-03**) and NEVER the other way around;

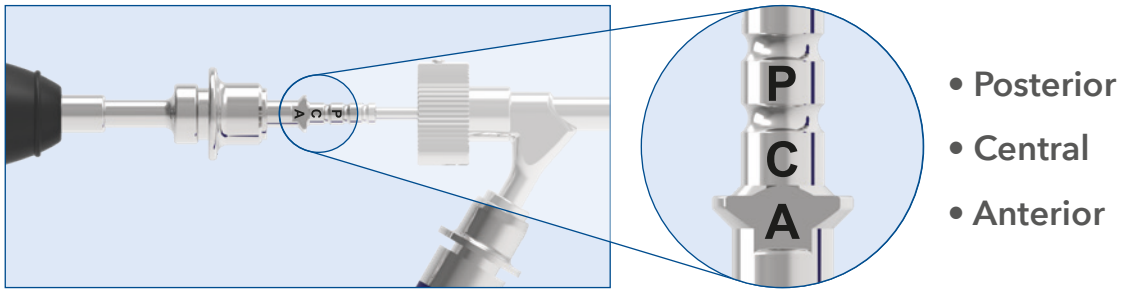
If you'd use the straight Silicone handle on the ACPH expansion shaft: during the expansion process the implant may damage the vertebral endplates or the expansion shaft might damage the cage or even break.



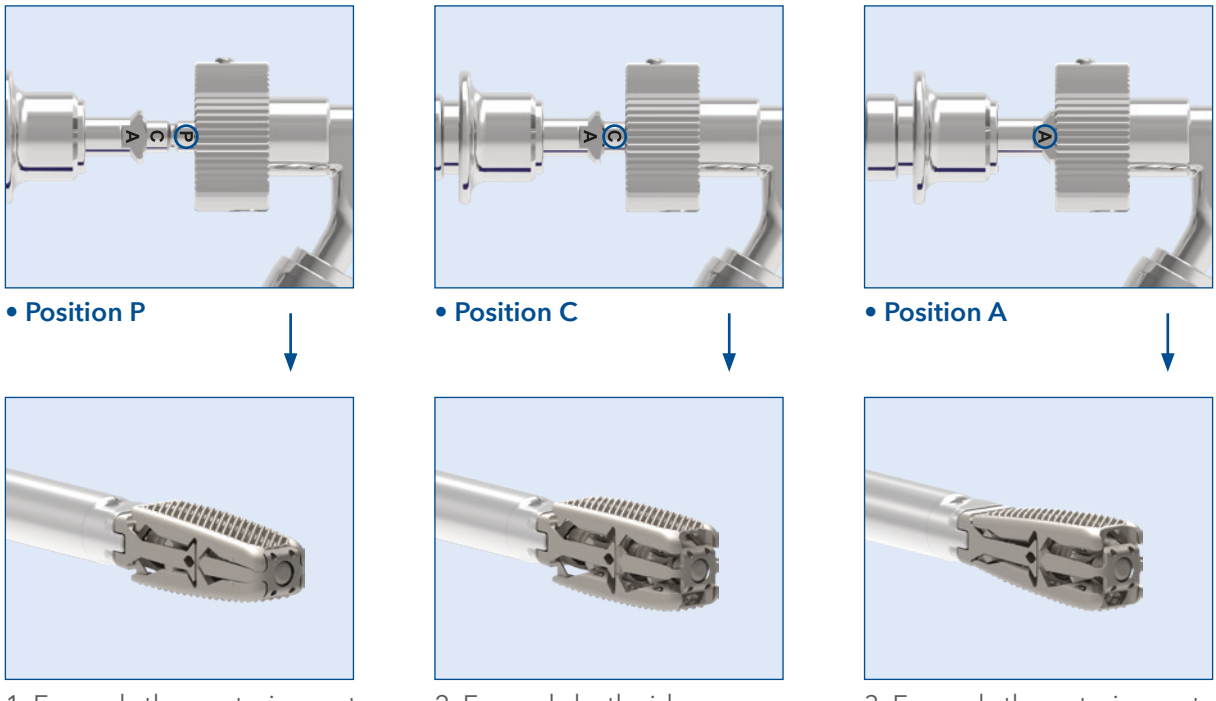
Procida Implant Holder - Detail:
ACPH expansion shaft (**BOK-LCH-03**)

Expansion of the Implant

Expand the implant by turning the Torque limiter clockwise , starting in position “A” till an initial lock in the intervertebral disc space has been reached , after which amendments can be made adjusting the height of either the posterior, parallel or anterior part of the implant individually; to this, follow the scheme in the different positions of the expansion nodes at the proximal part of the ACPH expansion shaft. Turning clockwise means expanding the implant, turning anti-clockwise lowers the endplates of the implant in the respective directions. The Torque limiter prevents “over-expansion” and thus potentially damaging the vertebral endplates and/or the implant’s expansion mechanism.



Position of the expansion nodes



Positions

Position "A" - expands the anterior part of the implant.
Position "C" - expands both sides (Parallel expansion).
Position "P" - expands the posterior part of the implant.

After Cage Implantation and expansion

Detach the implant inserter once a firm fixation in the intervertebral space has been achieved: remove the assembled Torque limiter (**TRQ-01**) and ACPH expansion shaft (**BOK-LCH-03**) first by gently toggling the ACPH expansion shaft out ;
then turn the knob of the the implant holder shaft (**BOK-LCH-02**) counterclockwise to release the implant from the inserter.

Lateral fluoroscopic imaging control during both the implantation and expansion procedure is strongly recommended.

Prior to placement of the second implant, autologous bone or bone substitutes could be inserted into the intervertebral disc space close to the implant, leaving enough space for the second implant.
Repeat the assembly and implantation procedure for the insertion of the second cage on the contralateral side.

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

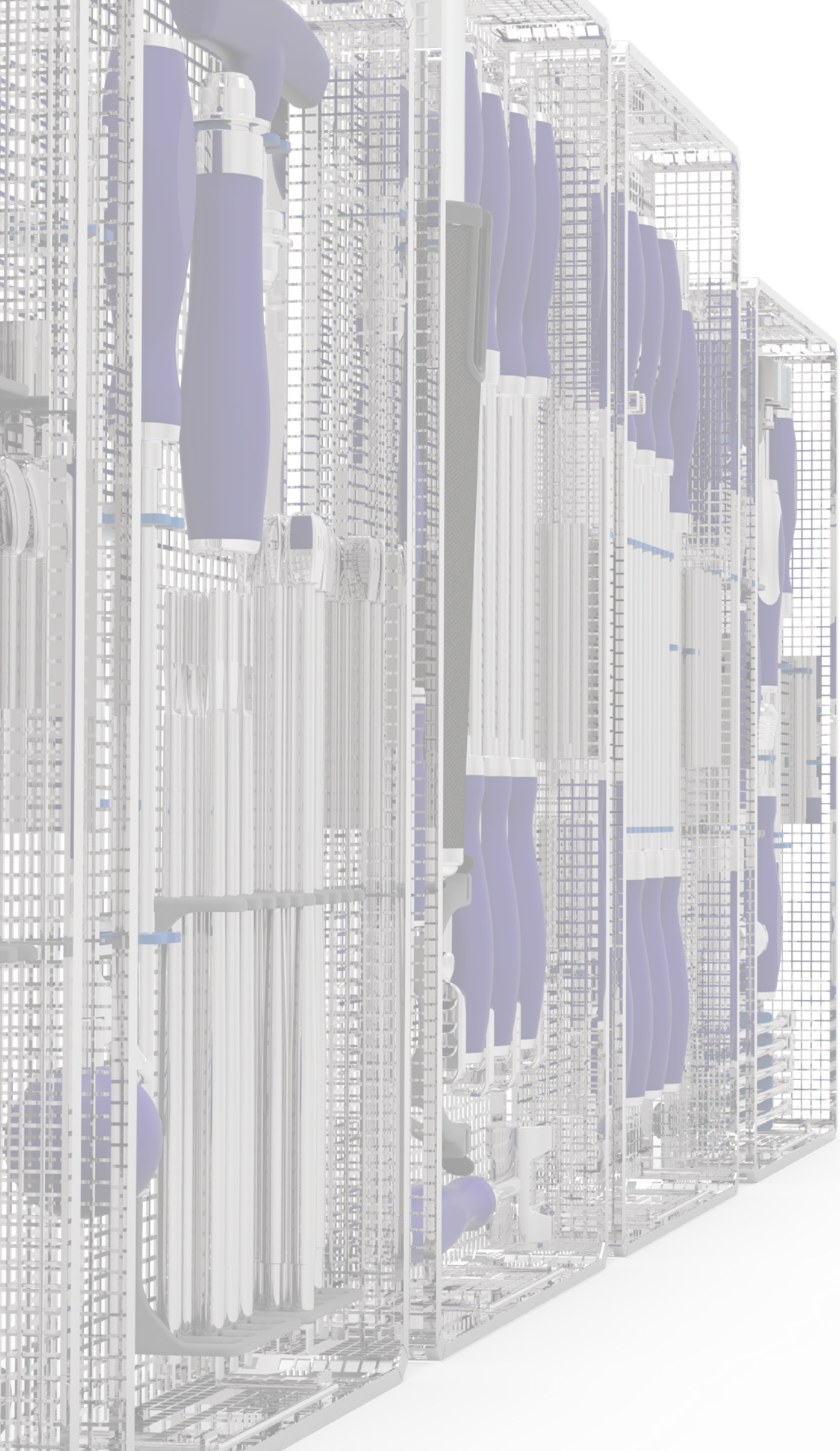
The components of the LUMBAR TITANIUM INTERBODY FUSION CAGE must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapours and extreme changes in temperature and humidity. Sterile parts must be stored in original packages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



TSUNAMI MEDICAL

THE WAVE OF INNOVATION

PLIF
Surgery Set

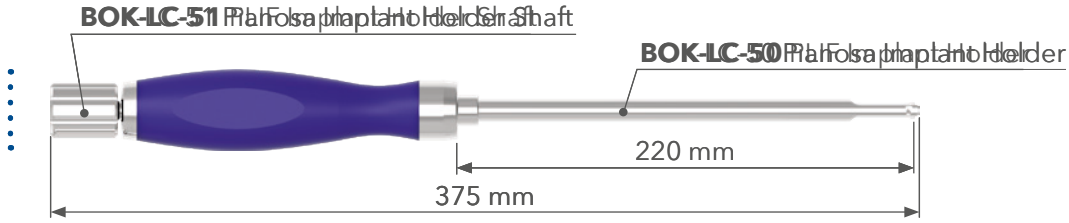
PLIF
Surgery Set

• *First Generation*

Pianosa Implant Holder
PLIF Implant Holder (Dismantable)

Instrument Ref. Code: **BOK-LC-50**

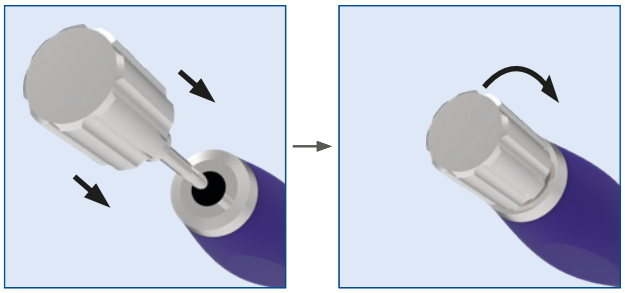
BOK-LC-51



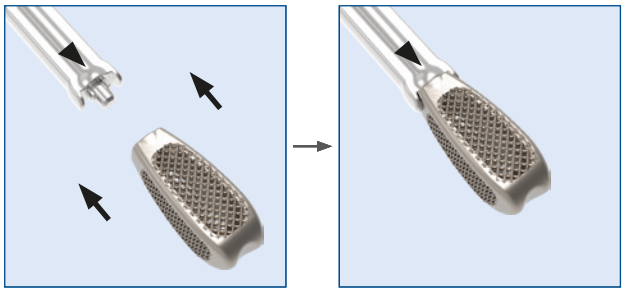
Components:

1	 BOK-LC-51	2	 BOK-LC-50

Assembly Scheme:



Insert the Shaft in the Holder and screw the knob.



Connect the Cage to the coupling.

PLIF Implant Holder	
Pianosa Implant Holder (Dismantable)	
BOK-LC-50	PLIF Implant Holder Implant Holder body with soft silicone handle
BOK-LC-51	PLIF Implant Holder Shaft Implant Holder shaft

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

**Dimensional tolerance ± 2 mm

CE

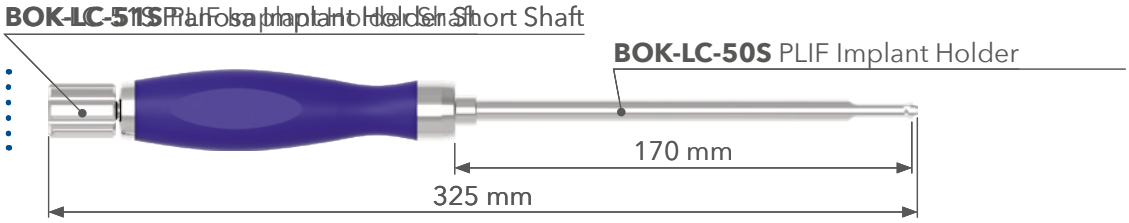
PLIF
Surgery Set

• *First Generation*

Pianosa Implant Holder Short
(Dismantable)

Instrument Ref. Code: **BOK-LC-50S**

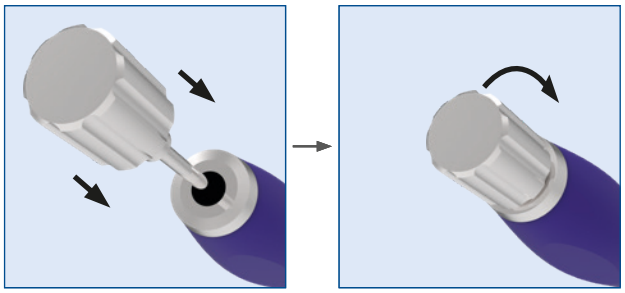
BOK-LC-51S



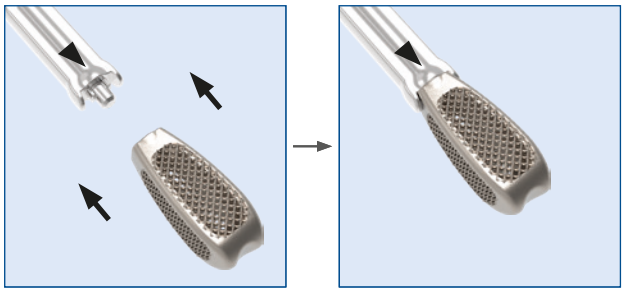
Components:

1	 BOK-LC-51S	2	 BOK-LC-50S

Assembly Scheme:



Insert the Shaft in the Holder and screw the knob.



Connect the Cage to the coupling.

PLIF Implant Holder	
Pianosa Implant Holder Short (Dismantable)	
BOK-LC-50S	PLIF Implant Holder
BOK-LC-50S	Implant Holder body with soft silicone handle
BOK-LC-51S	PLIF Implant Holder Shaft
BOK-LC-51S	Implant Holder shaft

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

**Dimensional tolerance ± 2 mm

CE

PLIF
Surgery Set

• *Expandable*

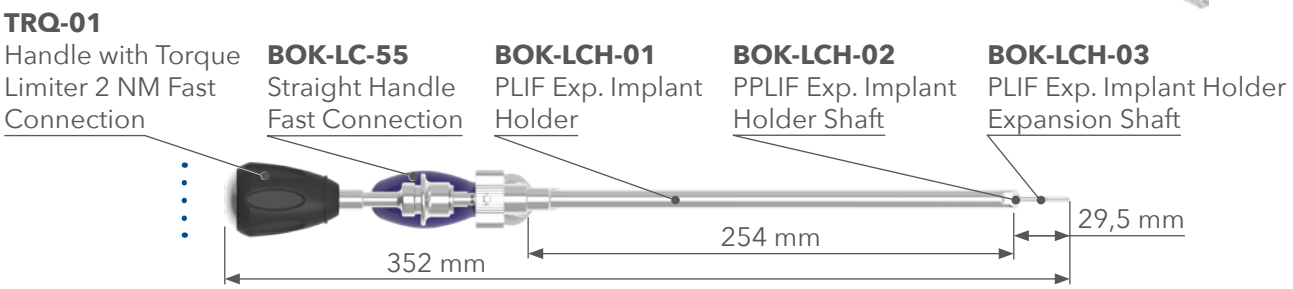
***PLIF** Exp. Implant Holder* Instrument Ref. Code: **BOK-LCH-01**

BOK-LCH-02

BOK-LCH-03

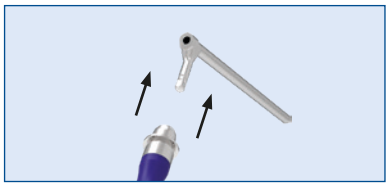
TRQ-01

BOK-LC-55

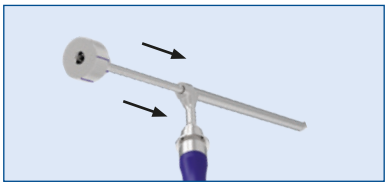


Components:

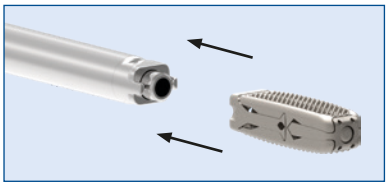
Usage Scheme:



1. Connect the Straight Handle to the Holder.

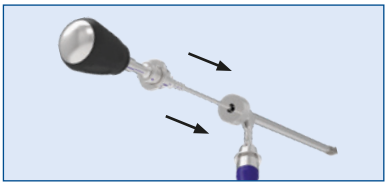


2. Insert the Holder Shaft.

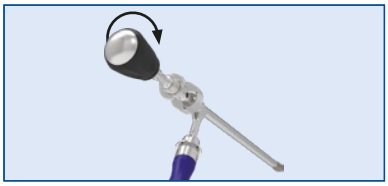


3. Connect the cage to the coupling.

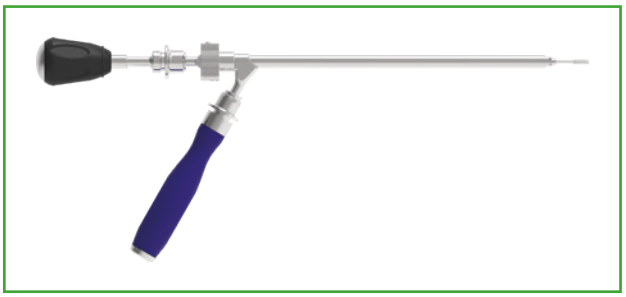
4. We have so the clean Holder.

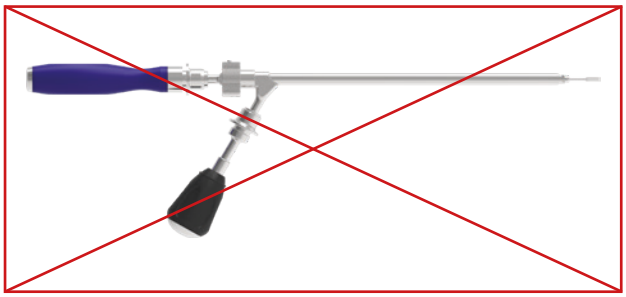


5. Insert the Torque Limiter with the Expansion Shaft.



6. Screw the Torq Limiter to expand the cage.



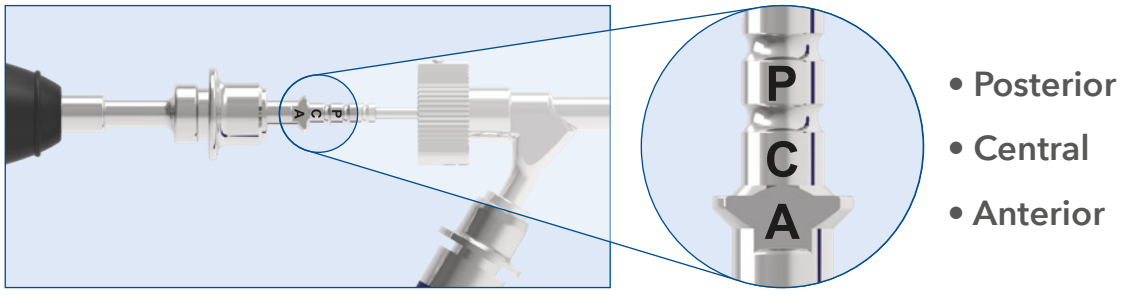


PLIF *Exp. Implant Holder*		
BOK-LCH-01	**BOK-LCH-02**	**BOK-LCH-03**
TRQ-01	**BOK-LC-55**	

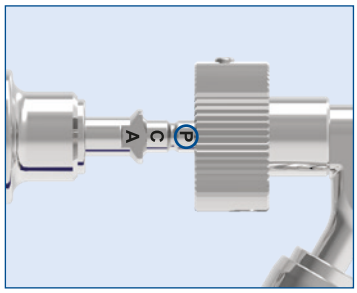
**Dimensional tolerance ± 2 mm

CE

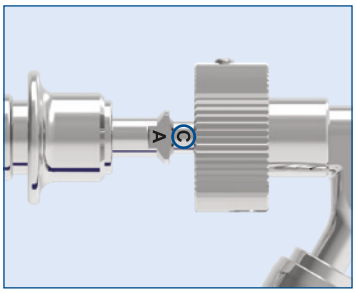
EXTENSION NODES



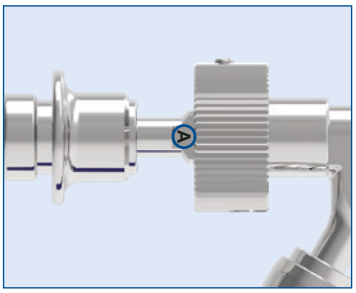
Position of the expansion nodes



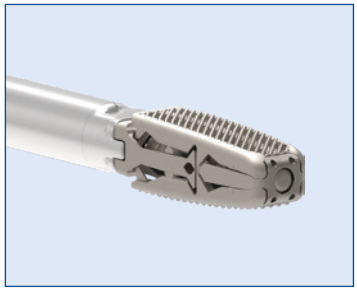
• **Position P**



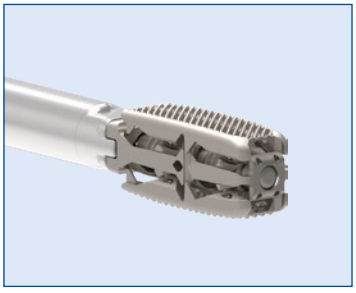
• **Position C**



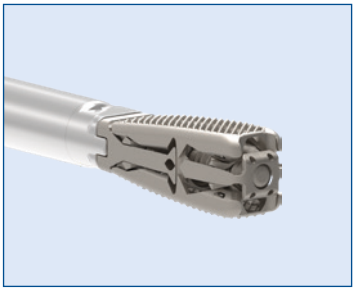
• **Position A**



1. Expands the posterior part.



2. Expands both sides.

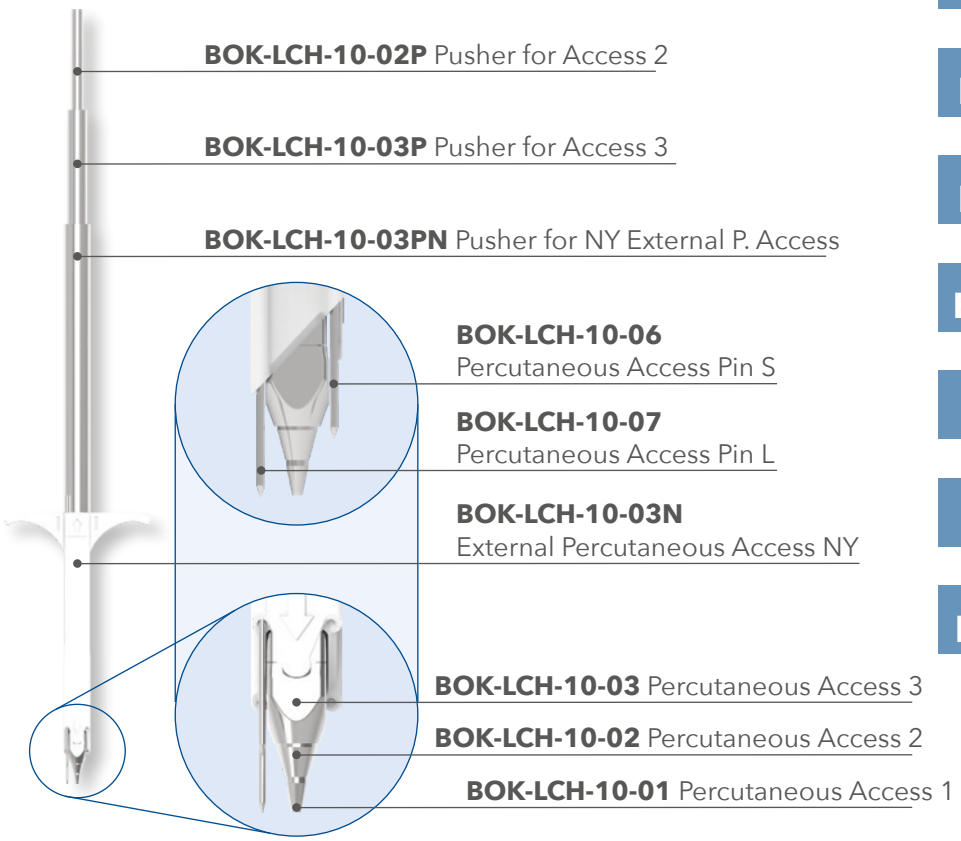


3. Expands the anterior part.

PLIF
Surgery Set

• *Expandable*

PLIF** Exp. Percutaneous Access 1* Instrument Ref. Code: **BOK-LCH-10-0*



BOK-LCH-10-01

BOK-LCH-10-02

BOK-LCH-10-03

BOK-LCH-10-02P

BOK-LCH-10-03P

BOK-LCH-10-03PN

BOK-LCH-10-06

BOK-LCH-10-07

BOK-LCH-10-03N

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

CE

Components:

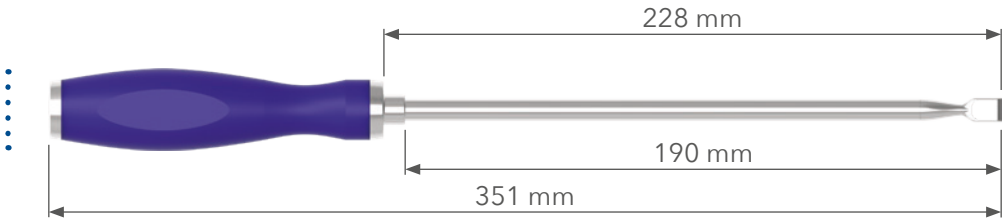
**Dimensional tolerance ± 2 mm

1	BOK-LCH-10-01	2	BOK-LCH-10-02	3	BOK-LCH-10-03
4	BOK-LCH-10-02P	5	BOK-LCH-10-03P	6	BOK-LCH-10-03PN
7	BOK-LCH-10-03N	8	BOK-LCH-10-06	9	BOK-LCH-10-07

PLIF
Surgery Set

- *First Generation*
- *Expandable*

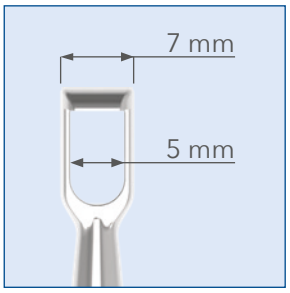
One Side Squared Curette Instrument Ref. Code: **BOK-LC-70**

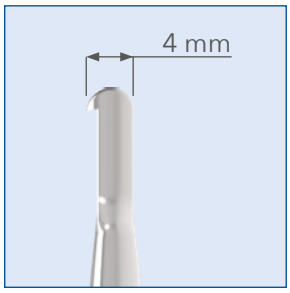


Components:

1

Dimensions:





One Side Squared Curette
BOK-LC-70

**Dimensional tolerance ± 2 mm

CE

PLIF
Surgery Set

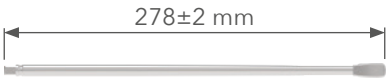
- *First Generation*
- *Expandable*

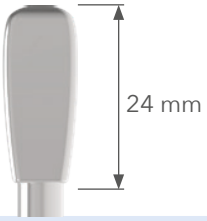
PLIF** Implant Trial* Instrument Ref. Code: **BOK-LC-280-*

CE

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

Details





Description	Code
*PLIF Implant Trial 24mmx**7mm***	**BOK-LC-280-07**
*PLIF Implant Trial 24mmx**8mm***	**BOK-LC-280-08**
*PLIF Implant Trial 24mmx**9mm***	**BOK-LC-280-09**
*PLIF Implant Trial 24mmx**10mm***	**BOK-LC-280-10**
*PLIF Implant Trial 24mmx**11mm***	**BOK-LC-280-11**
*PLIF Implant Trial 24mmx**12mm***	**BOK-LC-280-12**
*PLIF Implant Trial 24mmx**13mm***	**BOK-LC-280-13**

PLIF
Surgery Set

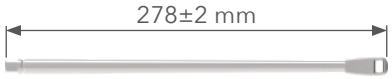
- *First Generation*
- *Expandable*

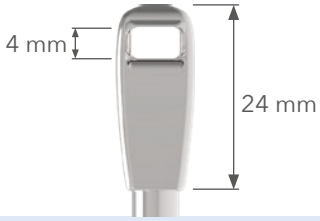
PLIF** Implant Trial Rasp* Instrument Ref. Code: **BOK-LC-280R-*

CE

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

Details





Description	Code
*PLIF Implant Trial Rasp 24mmx**5mm***	**BOK-LC-280R-05**
*PLIF Implant Trial Rasp 24mmx**6mm***	**BOK-LC-280R-06**
*PLIF Implant Trial Rasp 24mmx**7mm***	**BOK-LC-280R-07**
*PLIF Implant Trial Rasp 24mmx**8mm***	**BOK-LC-280R-08**
*PLIF Implant Trial Rasp 24mmx**9mm***	**BOK-LC-280R-09**
*PLIF Implant Trial Rasp 24mmx**10mm***	**BOK-LC-280R-10**
*PLIF Implant Trial Rasp 24mmx**11mm***	**BOK-LC-280R-11**
*PLIF Implant Trial Rasp 24mmx**12mm***	**BOK-LC-280R-12**
*PLIF Implant Trial Rasp 24mmx**13mm***	**BOK-LC-280R-13**

PLIF
Surgery Set

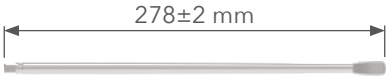
- *First Generation*
- *Expandable*

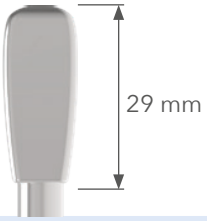
PLIF** Implant Trial* Instrument Ref. Code: **BOK-LC-280-29*

CE

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

Details





Description	Code
*PLIF Implant Trial 29mmx**5mm***	**BOK-LC-280-2905**
*PLIF Implant Trial 29mmx**6mm***	**BOK-LC-280-2906**
*PLIF Implant Trial 29mmx**7mm***	**BOK-LC-280-2907**
*PLIF Implant Trial 29mmx**8mm***	**BOK-LC-280-2908**
*PLIF Implant Trial 29mmx**9mm***	**BOK-LC-280-2909**
*PLIF Implant Trial 29mmx**10mm***	**BOK-LC-280-2910**
*PLIF Implant Trial 29mmx**11mm***	**BOK-LC-280-2911**
*PLIF Implant Trial 29mmx**12mm***	**BOK-LC-280-2912**
*PLIF Implant Trial 29mmx**13mm***	**BOK-LC-280-2913**

PLIF
Surgery Set

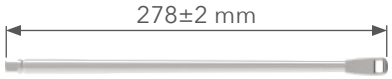
- *First Generation*
- *Expandable*

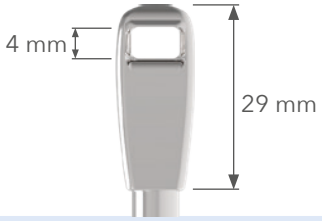
PLIF** Implant Trial Rasp* Instrument Ref. Code: **BOK-LC-280R-29*

CE

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

Details



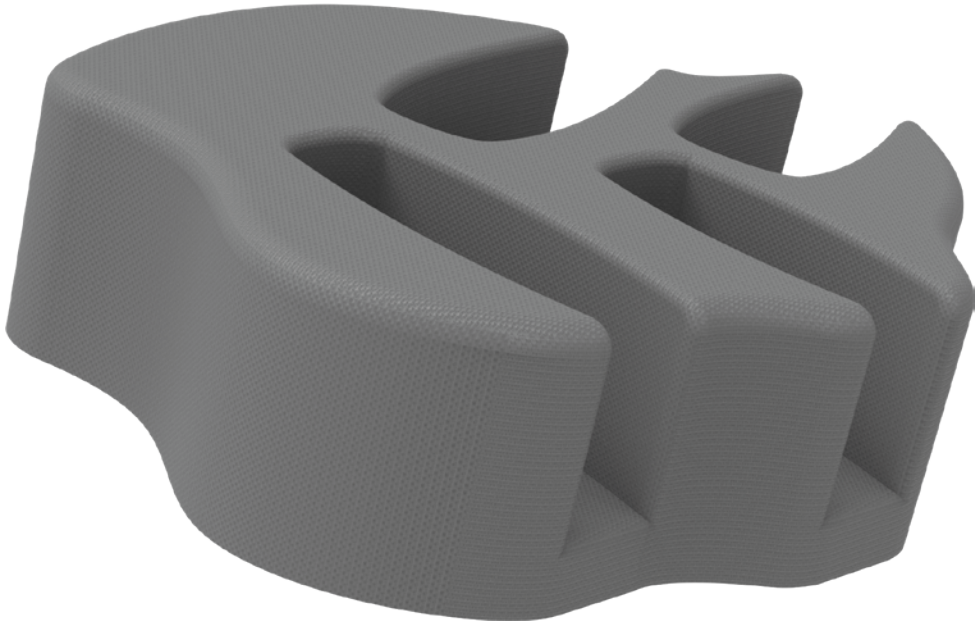


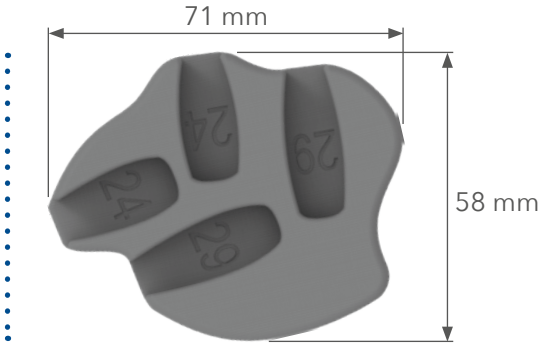
Description	Code
*PLIF Implant Trial Rasp 29mmx**5mm***	**BOK-LC-280R-2905**
*PLIF Implant Trial Rasp 29mmx**6mm***	**BOK-LC-280R-2906**
*PLIF Implant Trial Rasp 29mmx**7mm***	**BOK-LC-280R-2907**
*PLIF Implant Trial Rasp 29mmx**8mm***	**BOK-LC-280R-2908**
*PLIF Implant Trial Rasp 29mmx**9mm***	**BOK-LC-280R-2909**
*PLIF Implant Trial Rasp 29mmx**10mm***	**BOK-LC-280R-2910**
*PLIF Implant Trial Rasp 29mmx**11mm***	**BOK-LC-280R-2911**
*PLIF Implant Trial Rasp 29mmx**12mm***	**BOK-LC-280R-2912**
*PLIF Implant Trial Rasp 29mmx**13mm***	**BOK-LC-280R-2913**

PLIF
Surgery Set

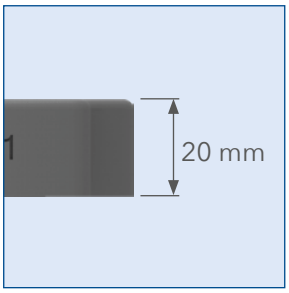
- *First Generation*
- *Expandable*

***PLIF** implant Filling Support* Instrument Ref. Code: **BOK-LC-61**





Dimensions:



***PLIF** implant Filling Support*
BOK-LC-61

**Dimensional tolerance ± 2 mm

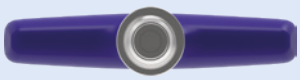
CE

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

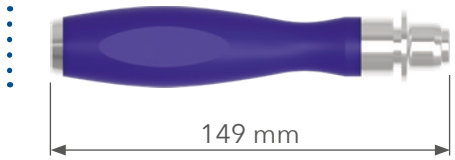
**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

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

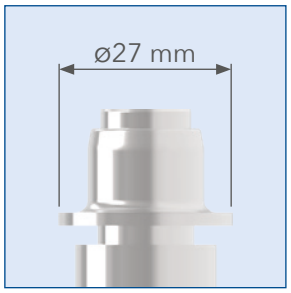
Straight Handle Fast Connection Instrument Ref. Code: **BOK-LC-55**

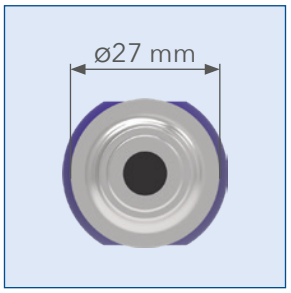


Components:

1	

Dimensions:





Straight Handle Fast Connection
BOK-LC-55

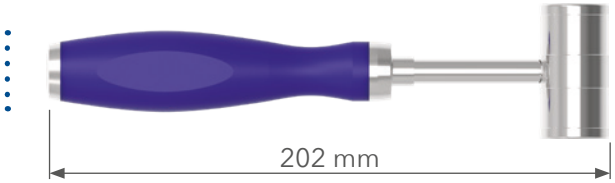
**Dimensional tolerance ± 2 mm

CE

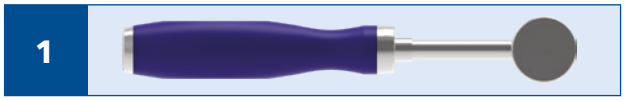
GENERAL
INSTRUMENTS

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

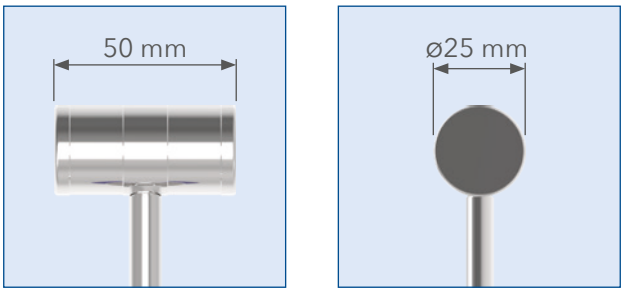
Hammer Instrument Ref. Code: **BOK-LC-59**



Components:



Dimensions:



Hammer
BOK-LC-59

**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

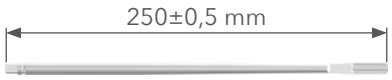
- *First Generation*
- *Built-In Fixation*
- *Expandable*

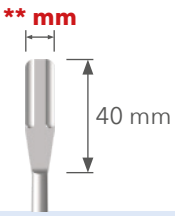
Shavers Instrument Ref. Code: **BOK-LC-250-****

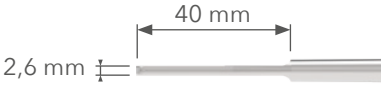
CE

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

Details





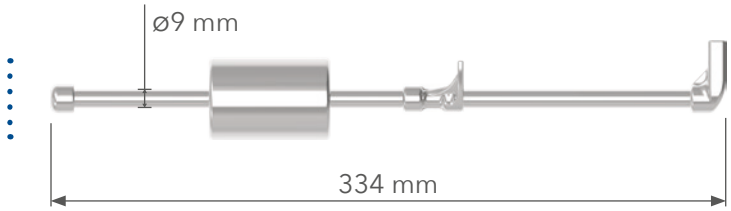


Description	Code
*Shaver **7mm***	**BOK-LC-250-07**
*Shaver **8mm***	**BOK-LC-250-08**
*Shaver **9mm***	**BOK-LC-250-09**
*Shaver **10mm***	**BOK-LC-250-10**
*Shaver **11mm***	**BOK-LC-250-11**
*Shaver **12mm***	**BOK-LC-250-12**
*Shaver **13mm***	**BOK-LC-250-13**

GENERAL
INSTRUMENTS

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

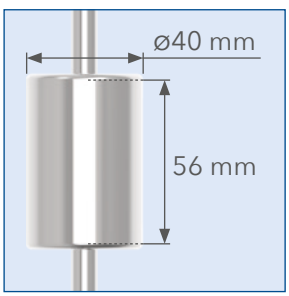
Universal Slide Hammer Instrument Ref. Code: **BOK-LT-80**



Components:

1	

Dimensions:



Universal Slide Hammer
BOK-LT-80

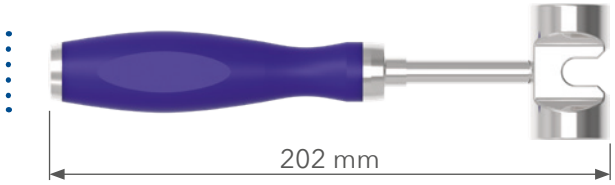
**Dimensional tolerance ± 2 mm

CE

GENERAL
INSTRUMENTS

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

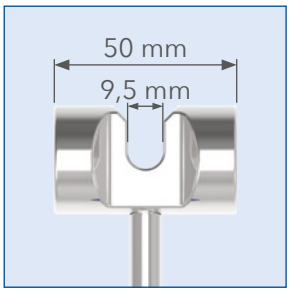
Hammer 250g Instrument Ref. Code: **TH002**

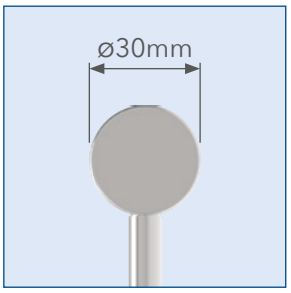


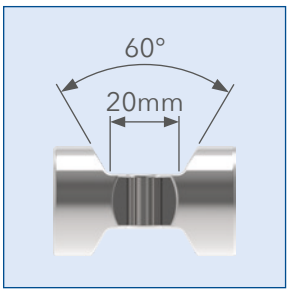
Components:

1

Dimensions:







Hammer 250g
TH002

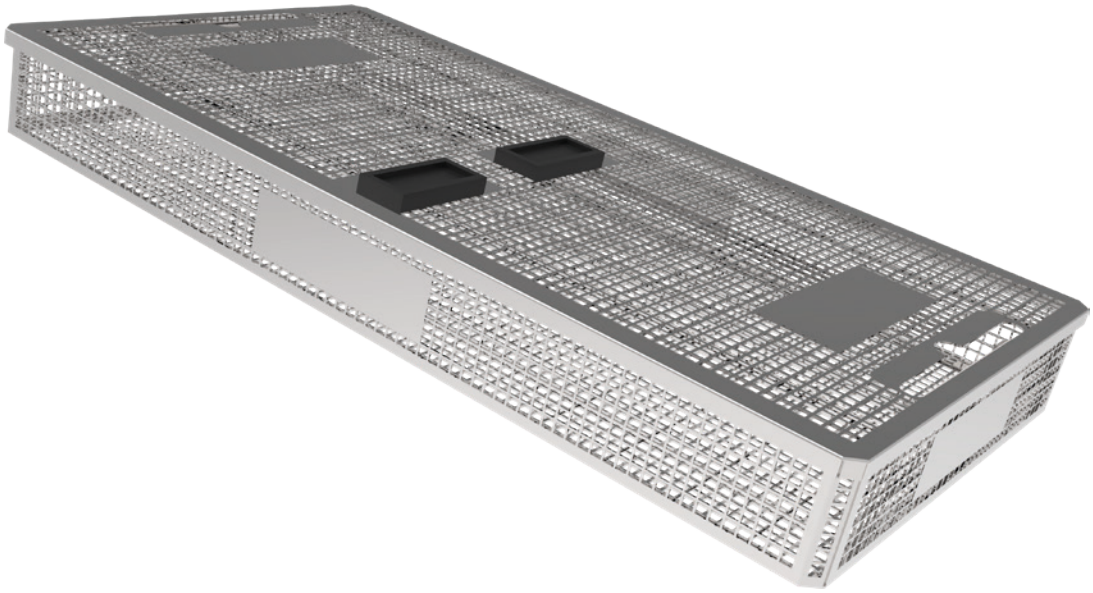
**Dimensional tolerance ± 2 mm

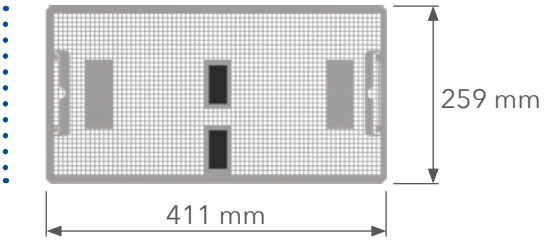
CE

GENERAL
INSTRUMENTS

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

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

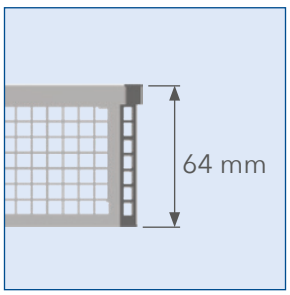




Components:

1	

Dimensions:



Small Tray
K3-729

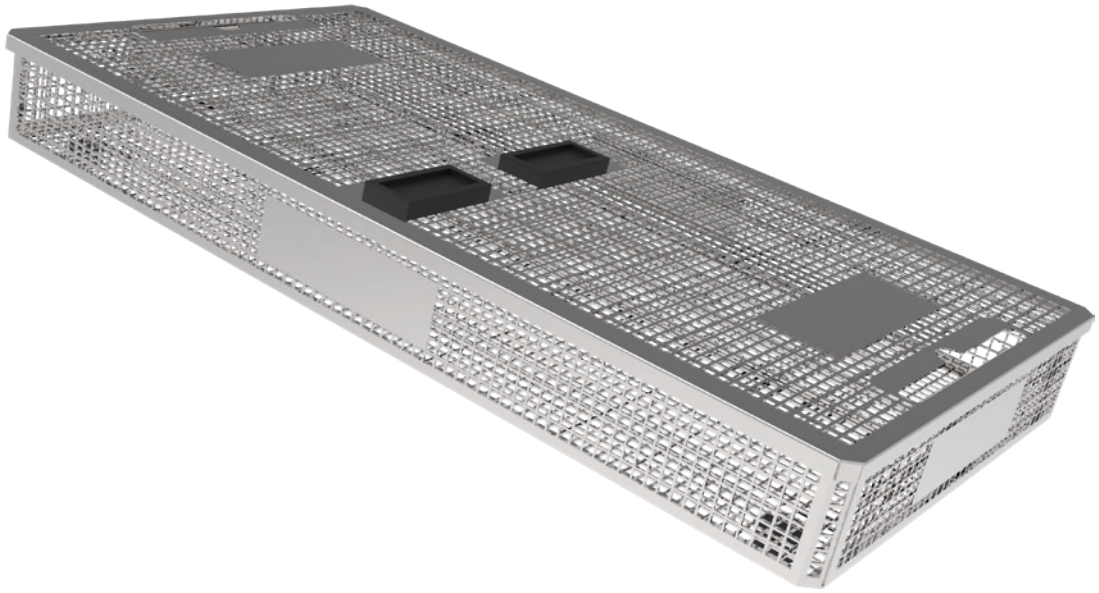
**Dimensional tolerance ± 2 mm

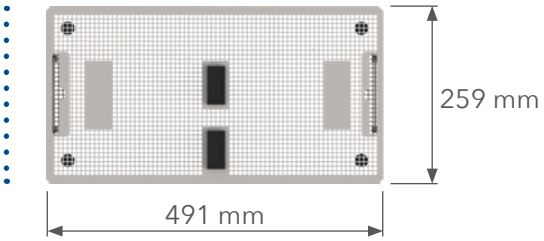
CE

GENERAL
INSTRUMENTS

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

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

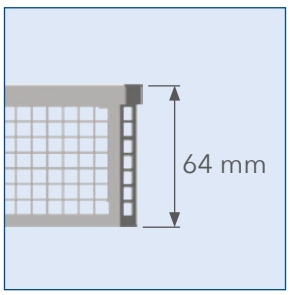




Components:

1

Dimensions:



Medium Tray
K3-725

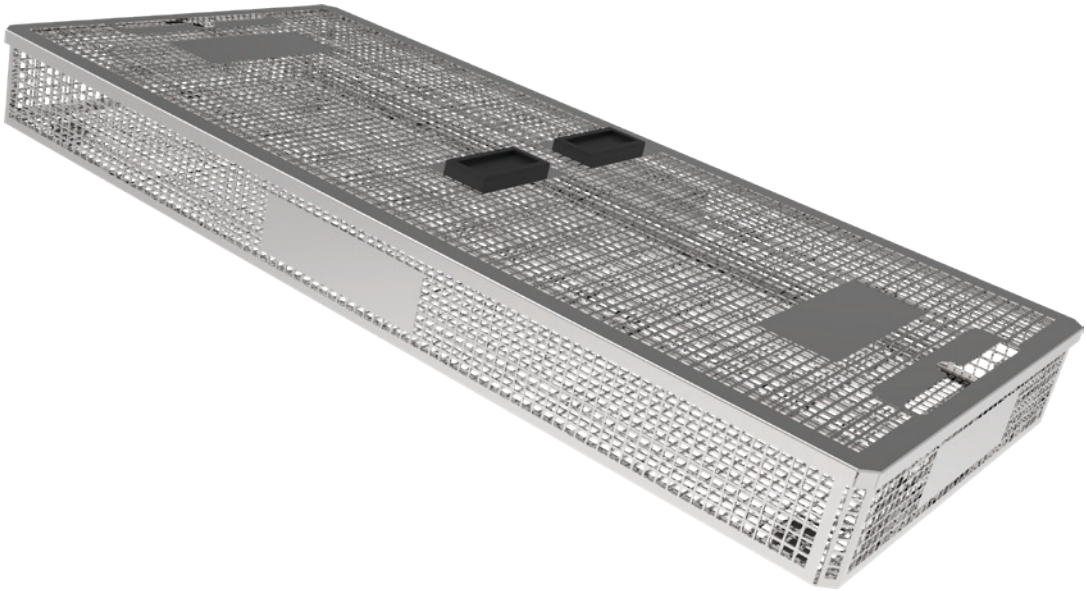
**Dimensional tolerance ± 2 mm

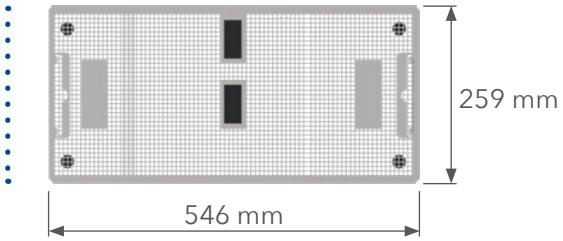
CE

GENERAL
INSTRUMENTS

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

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

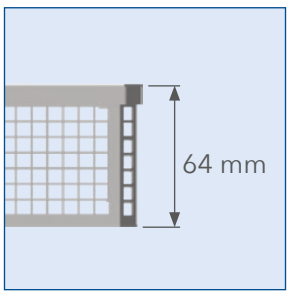




Components:

1

Dimensions:

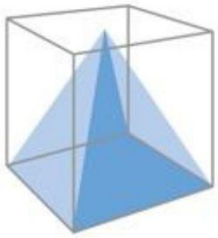


Large Tray
K3-721

**Dimensional tolerance ± 2 mm

CE

Distribuidor por:



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ST_PROCIDA_REV5_20250715

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