

Surgical Technique

ALICUDI-J

ALIF 3D Printed Titanium Cage

Built-in Fixation

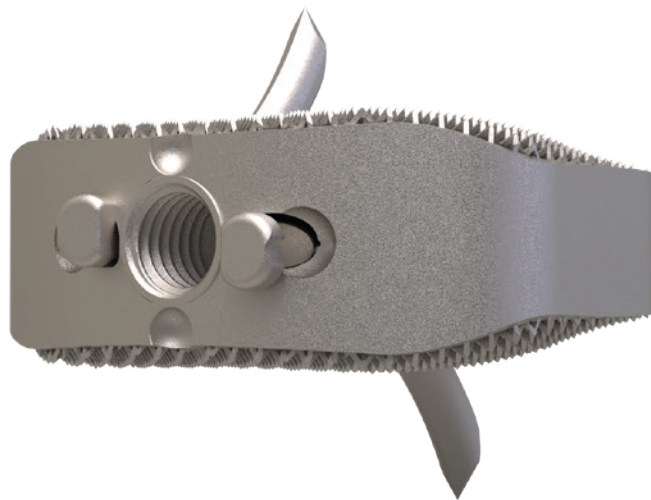
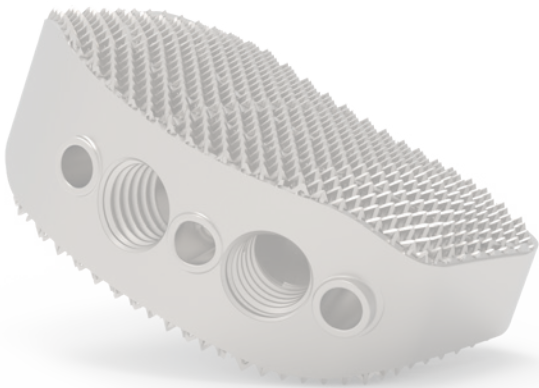


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Alicudi-J Overview

Alicudi, ALIF 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 Built-in Fixation**

Built-in pins contribute to further enhance primary fixation, as already guaranteed by the excellent stability provided by the “net” structure.

By using pins instead of screws as an additional fixation feature, there is no extra material on the implant required to secure the fixation mechanism. Thus, the elasticity features of the implant are not compromised, allowing for bone in-growth. The diagonal position of the pins secures rotation stability. Alicudi-J is manufactured in one production step, thanks to the additive manufacturing technology used. No additional instruments are required for implantation: the pins are extracted and locked into the implant by a feature on the amended original Alicudi implant inserter. It is possible to retract the pins, when needed.

For Alicudi-J, Tsunami Medical offers two footprints and seven heights, with three possible lordosis angles, as outlined below.

Footprint

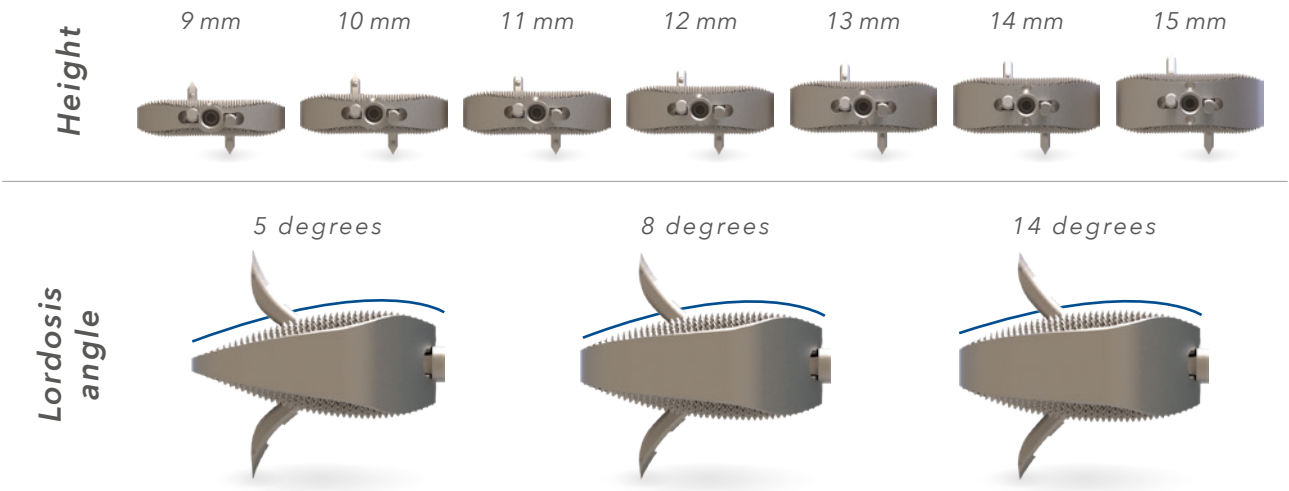
32x22 mm



38x28 mm



Alicudi-J Overview



Product Reference Codes

Ref. Code	Dimensions
ACAJ3222**05	Footprint Size 32x22mm - Angle 5° Range of Heights [mm] 09, 10, 11, 12, 13, 14, 15
ACAJ3222**08	Footprint Size 32x22mm - Angle 8° Range of Heights [mm] 09, 10, 11, 12, 13, 14, 15
ACAJ3222**14	Footprint Size 32x22mm - Angle 14° Range of Heights [mm] 09, 10, 11, 12, 13, 14, 15
ACAJ3828**05	Footprint Size 38x28mm - Angle 5° Range of Heights [mm] 09, 10, 11, 12, 13, 14, 15
ACAJ3828**08	Footprint Size 38x28mm - Angle 8° Range of Heights [mm] 09, 10, 11, 12, 13, 14, 15
ACAJ3828**14	Footprint Size 38x28mm - Angle 14° Range of Heights [mm] 09, 10, 11, 12, 13, 14, 15

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



ALICUDI-J

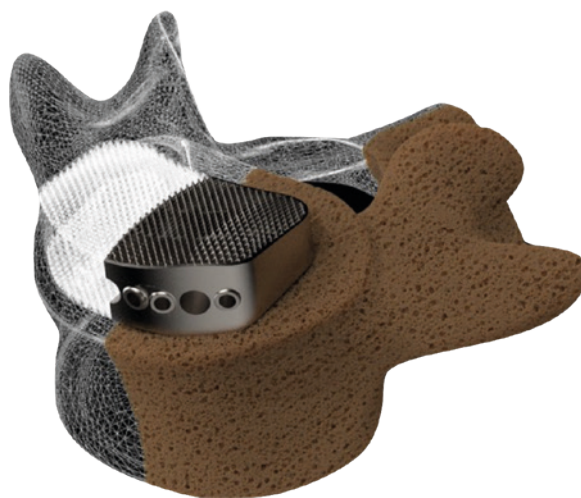
Alicudi-J Intended Use

Alicudi-J is intended to recreate and maintain distance between vertebrae to support biologic fusion in 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.

Because of the built-in fixation with pins feature Alicudi-J doesn't require supplemental fixation. However, based on surgeons' preference Alicudi-J can be used in combination with supplemental fixation, such as:

- Posterior stabilisation with pedicle screw systems
- Lateral fixation
- Interlaminar stabilisation devices, such as Tsunami Medical's Ischia.



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

Alicudi-J 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-arthritis.
- (7) Instability of motion segments.

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 Anterior surgical approach to the lower lumbar levels, the patient is placed in a supine position (Trendelenburg).

Approach the required level following the known surgical technique hereto.

Level Exposure

For anterior insertion, the intervertebral disc is exposed, such that there is a clear space on both sides of the vertebral midline.

If the vessels and/or other soft tissues cannot be retracted sufficiently, insertion from an anterolateral direction may be indicated.

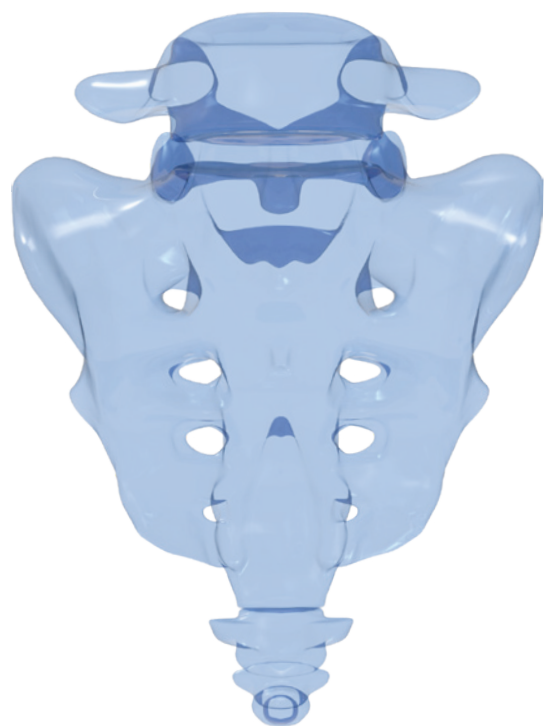


Patient in supine position.

Anterior Window Cut

A rectangular opening in the anterior longitudinal ligament and the disc's annulus fibrosus is performed. A trial implant may be used as a template to indicate the width of the annular window required (for assembly of the trial implant on the implant holder, see page 10).

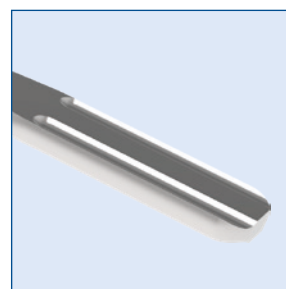
Care needs to be taken to retain as much anatomical structures as possible, because these are important for the stability of the instrumented segment.



Disc Removal and Endplate Preparation

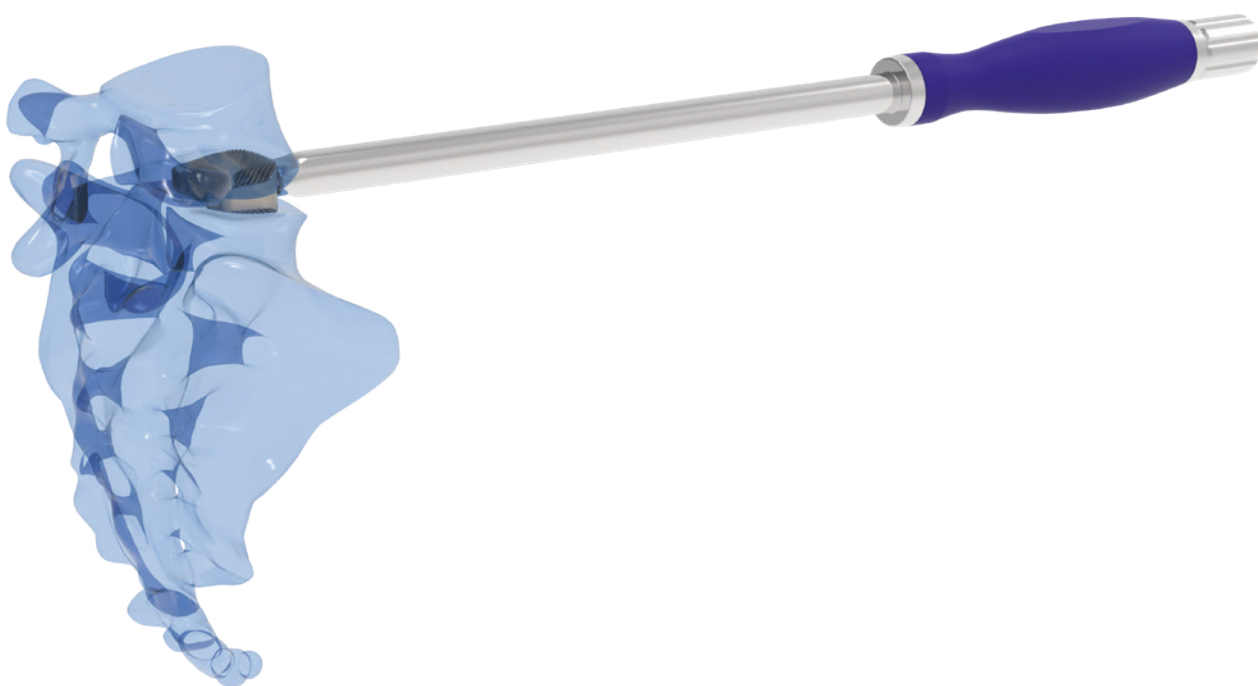
The discectomy procedure should be performed using standard disc cleaning instruments through the window in the anterior longitudinal ligament and annulus fibrosus.

The choice of appropriate instruments depends on approach, surgeons' preferences and projected results. Using rasps (standard in the set: **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 both the superior and inferior vertebral endplates in order to create efficient bone contact (removal of superficial layers of cartilage on the endplates).



BOK-LC-250-07

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.



Note

Adequate nucleus pulposus material removal is mandatory to promote bone in-growth. This also prevents displacement of residual disc material into the spinal canal and potential misplacement of the implant.

Implant Dimension Choice

Assemble the implant holder shaft (**BOK-ACAJ-02**) into the implant holder (**BOK-ACAJ-01**) and attach the implant trial that fits the intervertebral disc space best.

Connect the implant trial to the assembled implant holder by turning the knob clockwise on the silicone handle till a solid fixed position has been reached in order to avoid any problems during final trial implant positioning.

If a tight fit is not achieved, repeat the process using incrementally larger sizes of implant trials. Conversely, if the implant trial cannot be inserted, repeat using incrementally smaller sizes of implant trials.

The trial Implant must fit firmly with a tight press-fit between the endplates. Use fluoroscopy to check the trial implant position.



BOK-ACAJ-01 &
BOK-ACAJ-02



Implant trial example.

Components:

1		BOK-ACAJ-02	2		BOK-ACAJ-01
	Implant Holder Shaft			Implant Holder	

Implant Reference Codes

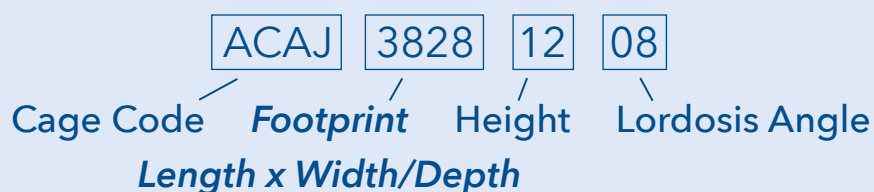
The correct implant size is the one that corresponds with the footprint, height and the lordosis angle of the implant trial.

Example

Cage Height > Trial height: 12 mm

Cage Footprint > Trial footprint: 38x28 mm (Length x Width/Depth in mm)

Cage Angle > Trial lordosis angle: 8°



Implant Packaging

The implant is supplied in a double rigid blister pack.

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, and takes out the implant.

Always ensure that the sterility of the implant, which is located in the inner blister, is maintained.

Cage Implantation

Firmly connect the right size implant to the assembled Implant Inserter (**BOK-ACAJ-02** + **BOK-ACAJ-01**).

Make sure the hammer surfaces on the lateral side of the Implant Holder are fully "up", which allows the pins of the implant to fully retract and be positioned into the Implant Holder for a secure fixation on the Implant Inserter; before implantation the superior and inferior surfaces of the implant don't show any of the pins sticking out, to allow a smooth insertion of the implant.

Place the implant into its final position.

Introduction may require gentle hammering on the backside of the Implant Inserter. The

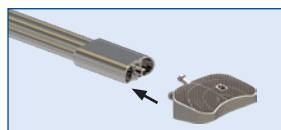
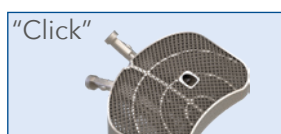
implant Inserter may be used to manipulate the cage within the disc space, if required.

Use the hammer (**TH002**) to extend the pins by tapping on the hammer surfaces on the lateral side of the implant Holder to final, which securely locks the pins into the implant.

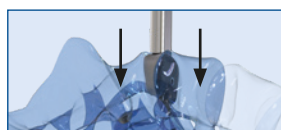
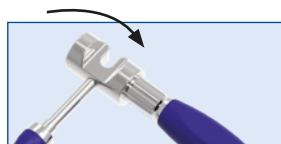
Once the cage is in the correct position and the pins are fully extended, the Implant Inserter should be removed: The Implant is released by turning the knob of **BOK-ACAJ-02** counterclockwise, leaving the implant in its optimal and securely fixed position.

Only when needed, the pins can be retracted by using the pin extractor (**BOK-J-EX01**).

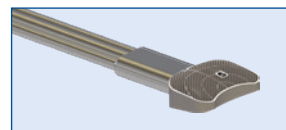
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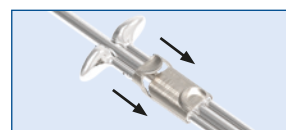
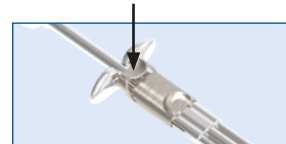
1. Extend the pins and insert in the Holder.



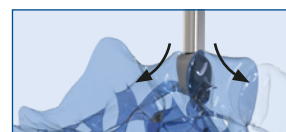
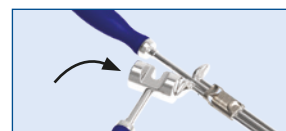
3. Use TH002 to facilitate cage entry.



2. Screw the knob to lock the cage.



4. Press the top button to release the clip.

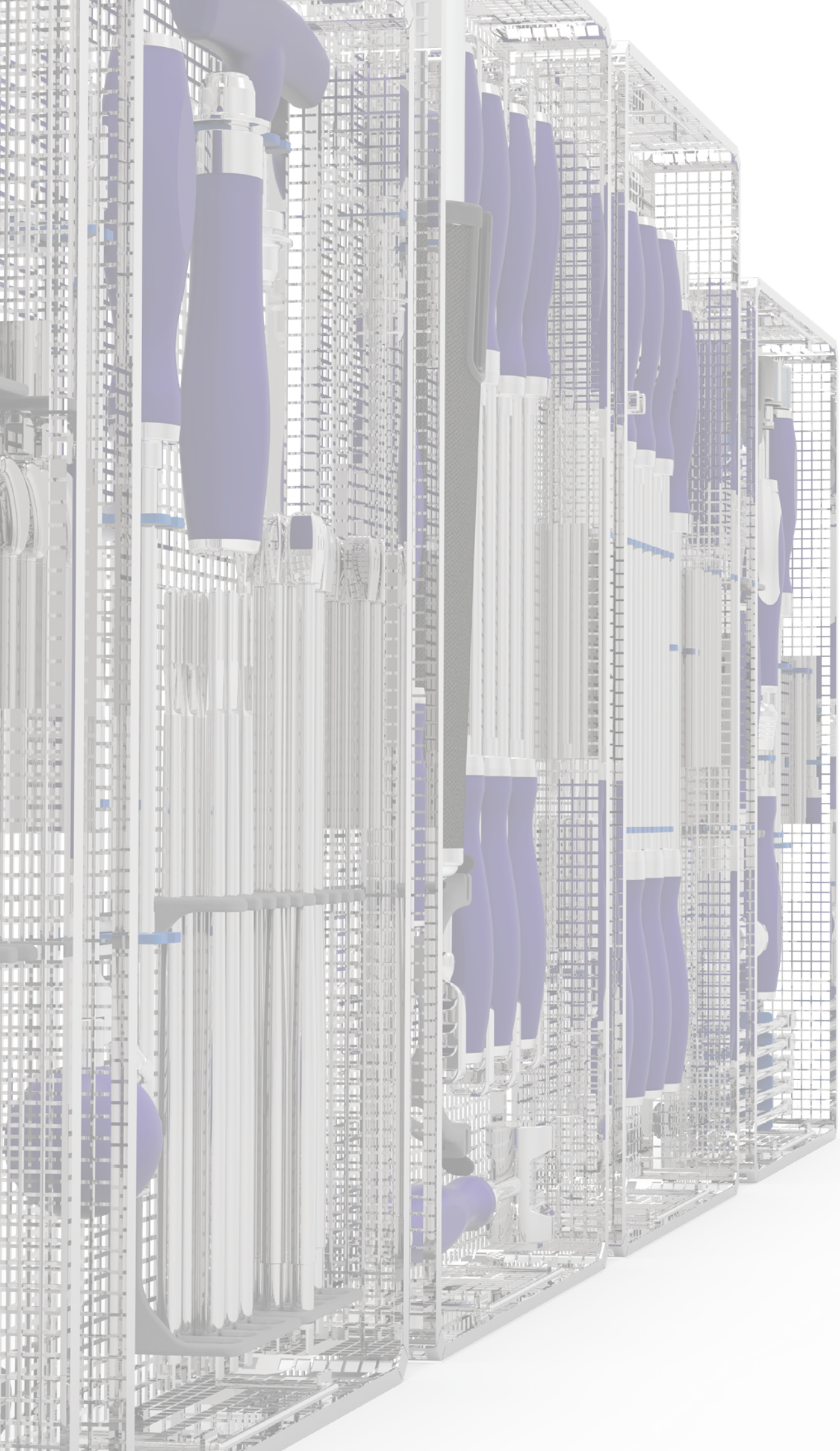


5. Hammering on the surfaces to extend the pins.

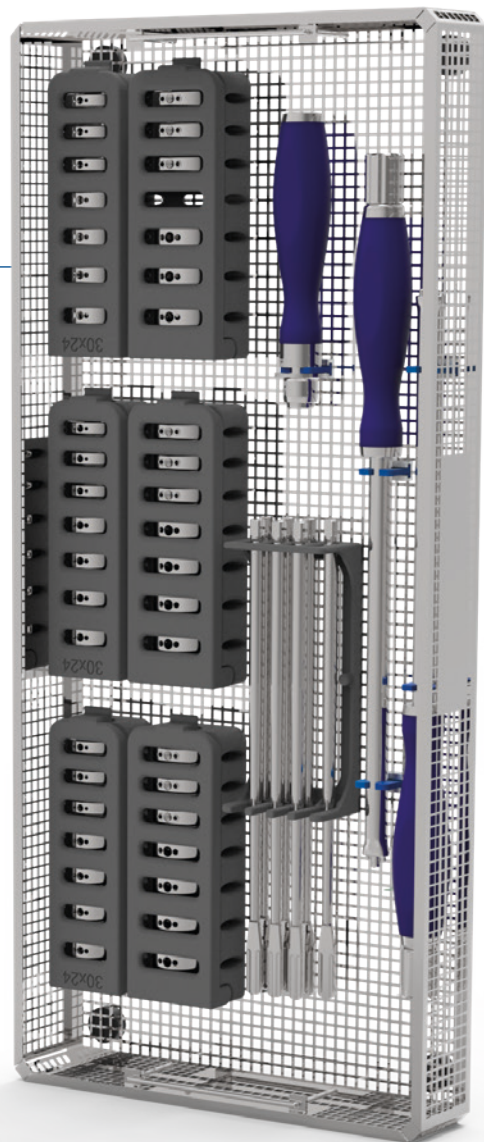




**For more informations
on our products**



ALIF Surgery Set



ALIF Surgery Set

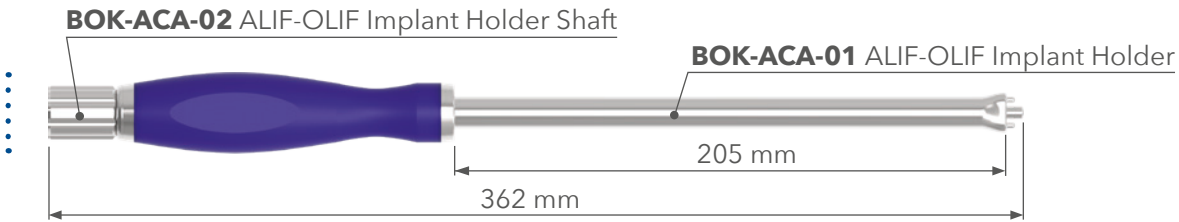
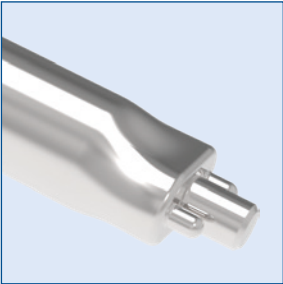
• *First Generation*

ALIF-OLIF Implant Holder

Instrument Ref. Code: **BOK-ACA-01**



BOK-ACA-02



Components:

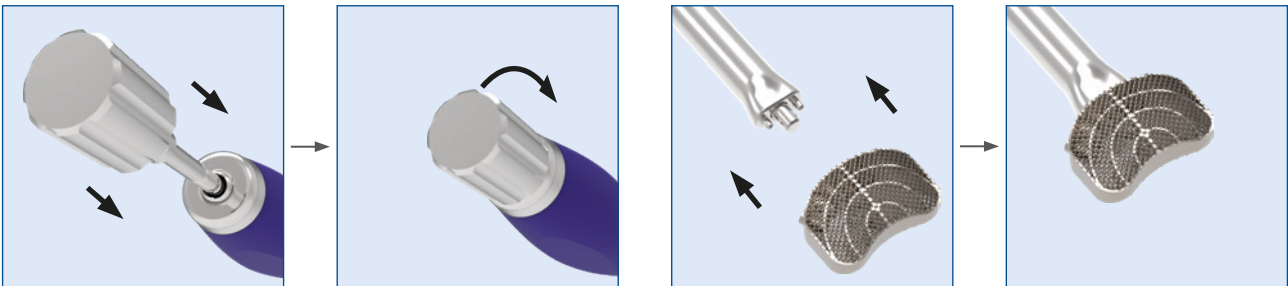
1

BOK-ACA-02

2

BOK-ACA-01

Assembly Scheme:



Insert the Shaft in the Holder and screw the knob.

Connect the Cage to the coupling.

ALIF-OLIF Implant Holder Shaft	
BOK-ACA-01	ALIF-OLIF Implant Holder
BOK-ACA-02	ALIF-OLIF Implant Holder Shaft

**Dimensional tolerance ± 2 mm



ALIF Surgery Set

• *Built-In Fixation*

ALIF Fix. Implant Holder

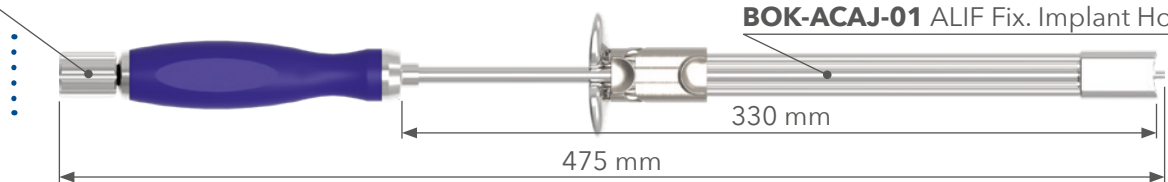
Instrument Ref. Code: **BOK-ACAJ-01**

BOK-ACAJ-02



BOK-ACAJ-02 ALIF Fix. Implant Holder Shaft

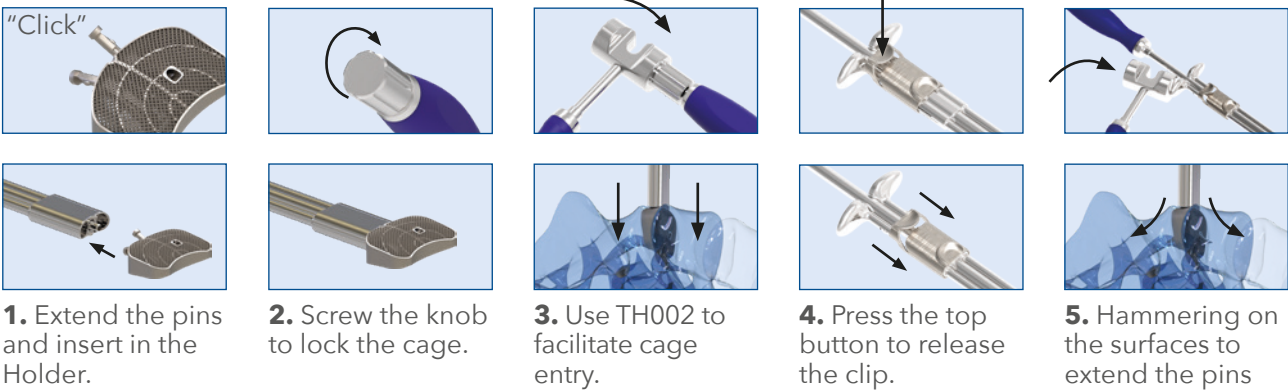
BOK-ACAJ-01 ALIF Fix. Implant Holder



Components:



Usage Scheme:



ALIF Fix. Implant Holder	
BOK-ACAJ-01	ALIF Fix. Implant Holder
BOK-ACAJ-02	ALIF Fix. Implant Holder Shaft

**Dimensional tolerance ± 2 mm

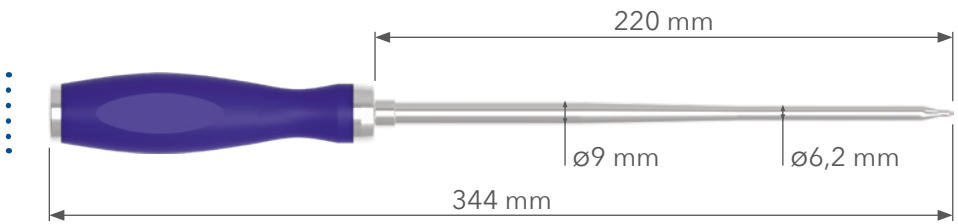
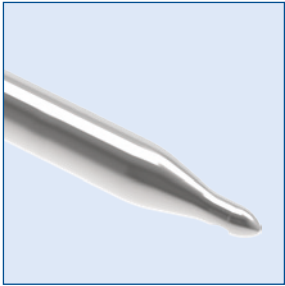


ALIF Surgery Set

• Built-In Fixation

Pin Extractor

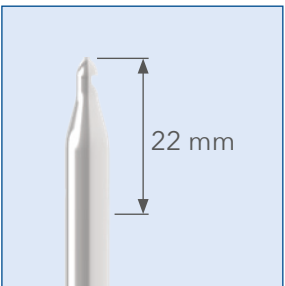
Instrument Ref. Code: **BOK-J-EX01**



Components:



Dimensions:



Pin Extractor

BOK-J-EX01

**Dimensional tolerance ± 2 mm



ALIF Surgery Set

- First Generation
- Built-In Fixation

ALIF Implant Trial

Instrument Ref. Code:

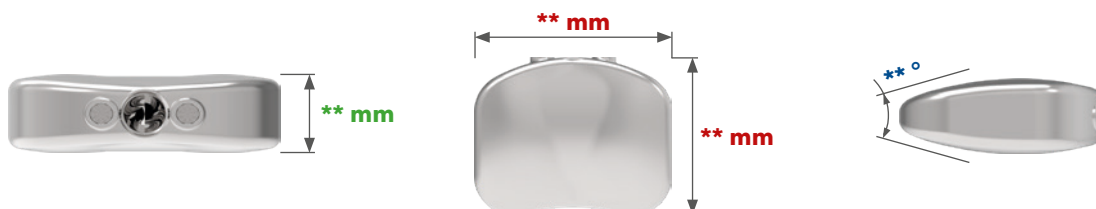
BOK-ACA-XS****



**Dimensional tolerance ± 2 mm

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

Details



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ALIF Implant Trial 30mmx24mmx9mm - 5°	BOK-ACA-XS0905	ALIF Implant Trial 30mmx24mmx13mm - 8°	BOK-ACA-XS1308
ALIF Implant Trial 30mmx24mmx10mm - 5°	BOK-ACA-XS1005	ALIF Implant Trial 30mmx24mmx14mm - 8°	BOK-ACA-XS1408
ALIF Implant Trial 30mmx24mmx11mm - 5°	BOK-ACA-XS1105	ALIF Implant Trial 30mmx24mmx15mm - 8°	BOK-ACA-XS1508
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ALIF Implant Trial 30mmx24mmx13mm - 5°	BOK-ACA-XS1305	ALIF Implant Trial 30mmx24mmx11mm - 14°	BOK-ACA-XS1114
ALIF Implant Trial 30mmx24mmx14mm - 5°	BOK-ACA-XS1405	ALIF Implant Trial 30mmx24mmx12mm - 14°	BOK-ACA-XS1214
ALIF Implant Trial 30mmx24mmx15mm - 5°	BOK-ACA-XS1505	ALIF Implant Trial 30mmx24mmx13mm - 14°	BOK-ACA-XS1314
ALIF Implant Trial 30mmx24mmx09mm - 8°	BOK-ACA-XS0908	ALIF Implant Trial 30mmx24mmx14mm - 14°	BOK-ACA-XS1414
ALIF Implant Trial 30mmx24mmx10mm - 8°	BOK-ACA-XS1008	ALIF Implant Trial 30mmx24mmx15mm - 14°	BOK-ACA-XS1514
ALIF Implant Trial 30mmx24mmx11mm - 8°	BOK-ACA-XS1108		

ALIF Surgery Set

- First Generation
- Built-In Fixation

ALIF Implant Trial

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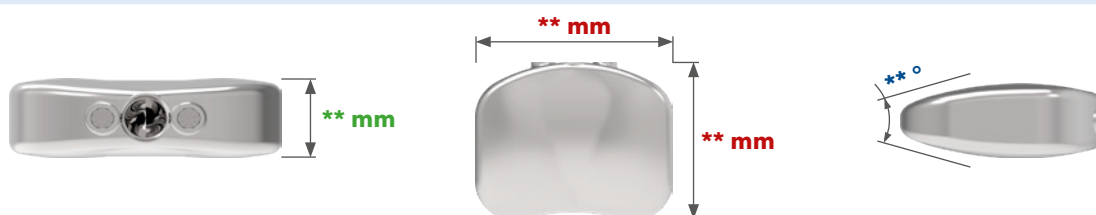
BOK-ACA-S****



**Dimensional tolerance ± 2 mm

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

Details



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ALIF Implant Trial 32mmx22mmx9mm - 5°	BOK-ACA-S0905	ALIF Implant Trial 32mmx22mmx13mm - 8°	BOK-ACA-S1308
ALIF Implant Trial 32mmx22mmx10mm - 5°	BOK-ACA-S1005	ALIF Implant Trial 32mmx22mmx14mm - 8°	BOK-ACA-S1408
ALIF Implant Trial 32mmx22mmx11mm - 5°	BOK-ACA-S1105	ALIF Implant Trial 32mmx22mmx15mm - 8°	BOK-ACA-S1508
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ALIF Implant Trial 32mmx22mmx10mm - 8°	BOK-ACA-S1008	ALIF Implant Trial 32mmx22mmx14mm - 14°	BOK-ACA-S1414
ALIF Implant Trial 32mmx22mmx11mm - 8°	BOK-ACA-S1108	ALIF Implant Trial 32mmx22mmx15mm - 14°	BOK-ACA-S1514

ALIF Surgery Set

- First Generation
- Built-In Fixation

ALIF Implant Trial

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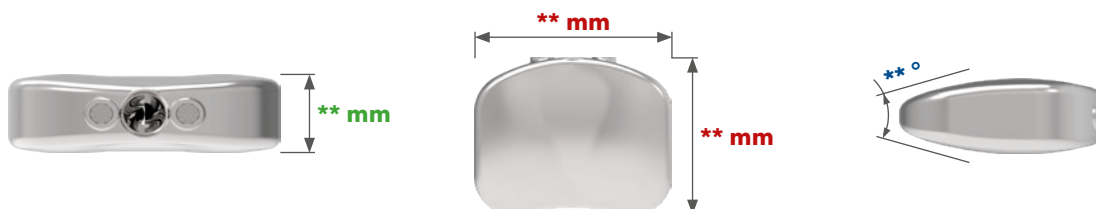
BOK-ACA-M****



**Dimensional tolerance ± 2 mm

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

Details



Description

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ALIF Implant Trial 36mm x24mm x10mm - 8°	BOK-ACA-M1008
ALIF Implant Trial 36mm x24mm x12mm - 8°	BOK-ACA-M1208
ALIF Implant Trial 36mm x24mm x14mm - 8°	BOK-ACA-M1408
ALIF Implant Trial 36mm x24mm x08mm - 14°	BOK-ACA-M0814
ALIF Implant Trial 36mm x24mm x10mm - 14°	BOK-ACA-M1014
ALIF Implant Trial 36mm x24mm x12mm - 14°	BOK-ACA-M1214
ALIF Implant Trial 36mm x24mm x14mm - 14°	BOK-ACA-M1414
ALIF Implant Trial 36mm x24mm x15mm - 14°	BOK-ACA-M1514

ALIF Surgery Set

- First Generation
- Built-In Fixation

ALIF Implant Trial

Instrument Ref. Code:

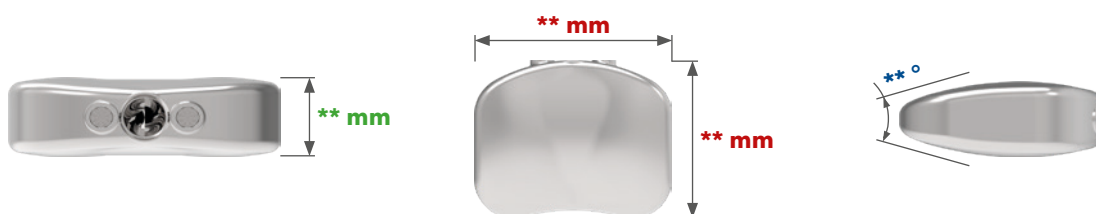
BOK-ACA-L****



**Dimensional tolerance ± 2 mm

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

Details



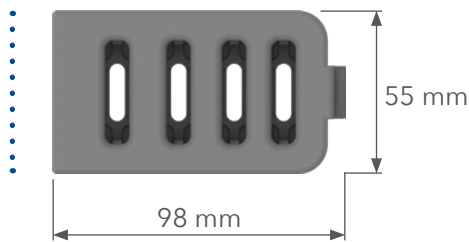
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ALIF Implant Trial 38mmx28mmx11mm - 5°	BOK-ACA-L1105	ALIF Implant Trial 38mmx28mmx15mm - 8°	BOK-ACA-L1508
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ALIF Implant Trial 38mmx28mmx10mm - 8°	BOK-ACA-L1008	ALIF Implant Trial 38mmx28mmx14mm - 14°	BOK-ACA-L1414
ALIF Implant Trial 38mmx28mmx11mm - 8°	BOK-ACA-L1108	ALIF Implant Trial 38mmx28mmx15mm - 14°	BOK-ACA-L1514
ALIF Implant Trial 38mmx28mmx12mm - 8°	BOK-ACA-L1208		

ALIF Surgery Set

- First Generation
- Built-In Fixation

ALIF Trial Box-XS
(4 Housing - Even/Odd)

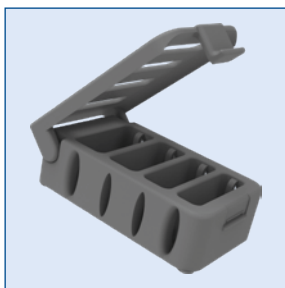
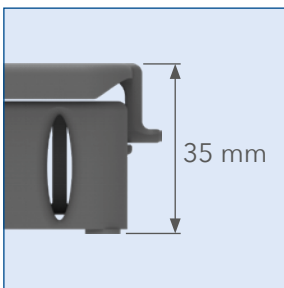
Instrument Ref. Code: **BOK-ACA-TBXS01**



Components:



Dimensions:



For N°4 XS and/or S Trials.

ALIF Trial Box-XS (4 Housing - Even/Odd)

BOK-ACA-TBXS01

**Dimensional tolerance ± 2 mm



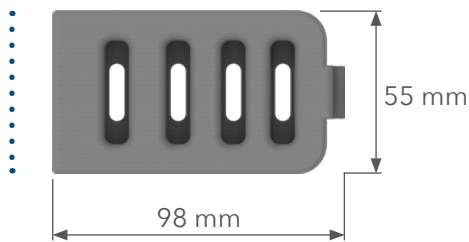
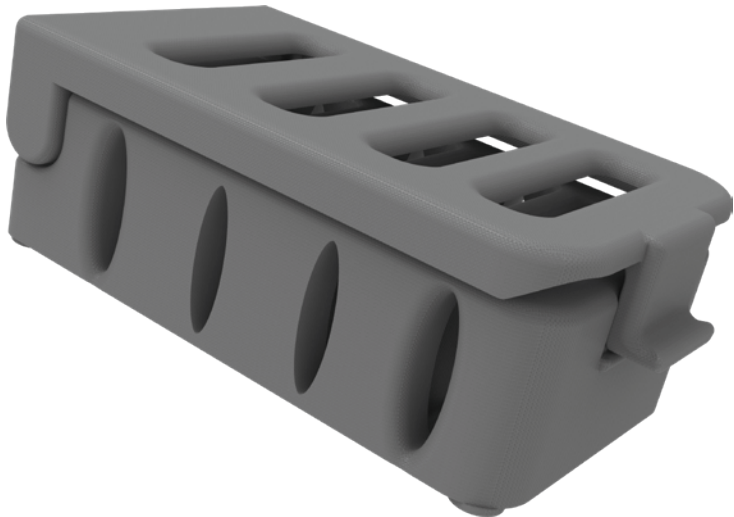
ALIF Surgery Set

- First Generation
- Built-In Fixation

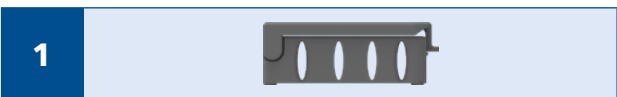
ALIF Trial Box L
(4 Housing - Even/Odd)

Instrument Ref. Code:

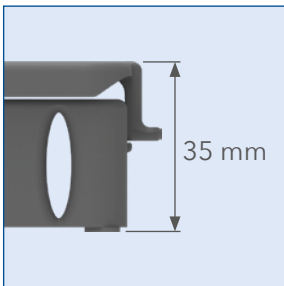
BOK-ACA-TBL-01



Components:



Dimensions:



For N°4 M and/or L Trials.

ALIF Trial Box L (4 Housing - Even/Odd)	
BOK-ACA-TBL01	Implant Trial Box

**Dimensional tolerance ± 2 mm

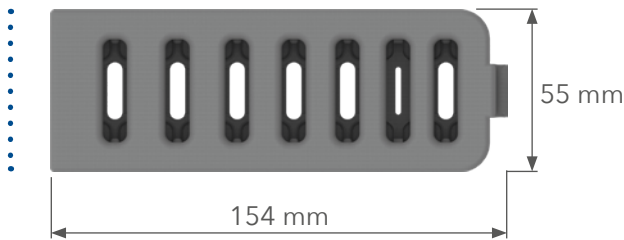


ALIF Surgery Set

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

ALIF Trial Tray XS/S
(7 Housing)

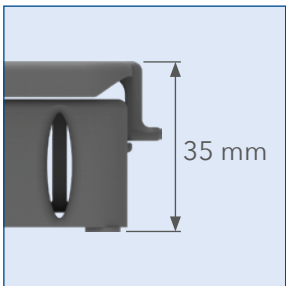
Instrument Ref. Code: **BOK-ACA-TBXS02**



Components:



Dimensions:



For N°7 XS and/or S Trials.

ALIF Trial Tray XS/S (7 Housing)	
BOK-ACA-TBXS02	Implant Trial Box

**Dimensional tolerance ± 2 mm



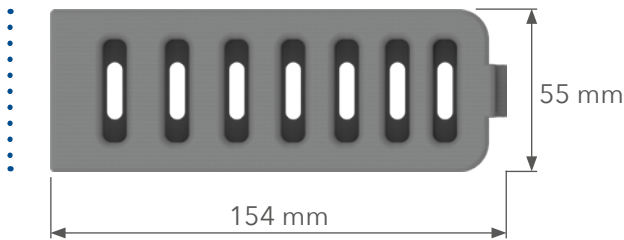
ALIF Surgery Set

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

ALIF Trial Tray L/M
(7 Housing)

Instrument Ref. Code:

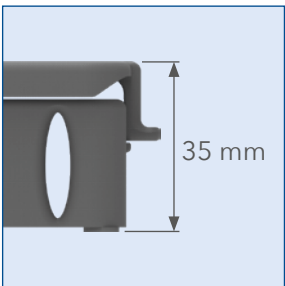
BOK-ACA-TBL02



Components:



Dimensions:



For N°7 M and/or L Trials.

ALIF Trial Tray L/M (7 Housing)	
BOK-ACA-TBL02	Implant Trial Box

**Dimensional tolerance ± 2 mm



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



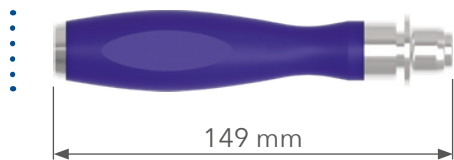
GENERAL INSTRUMENTS

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

Straight Handle Fast Connection

Instrument Ref. Code:

BOK-LC-55

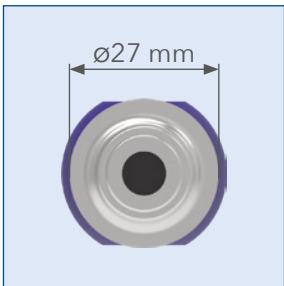
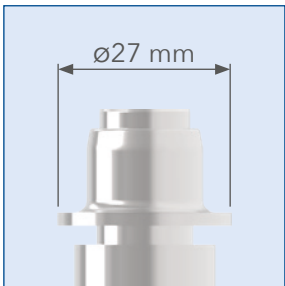


Components:

1



Dimensions:



Straight Handle Fast Connection

BOK-LC-55

**Dimensional tolerance ± 2 mm



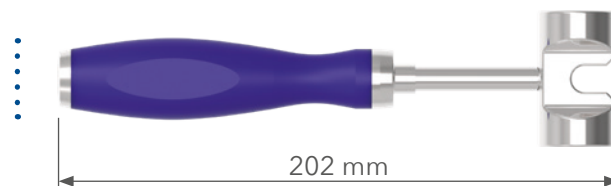
GENERAL INSTRUMENTS

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

Hammer 250g

Instrument Ref. Code:

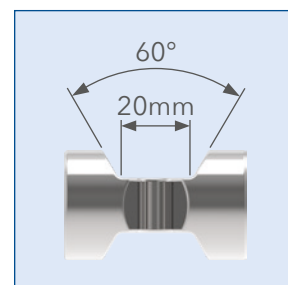
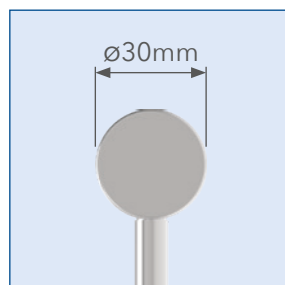
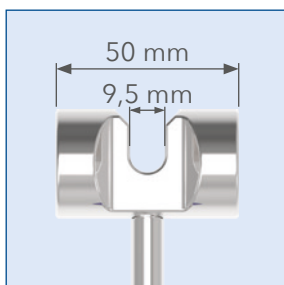
TH002



Components:



Dimensions:



Hammer 250g

TH002

**Dimensional tolerance ± 2 mm



GENERAL INSTRUMENTS

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

Shavers

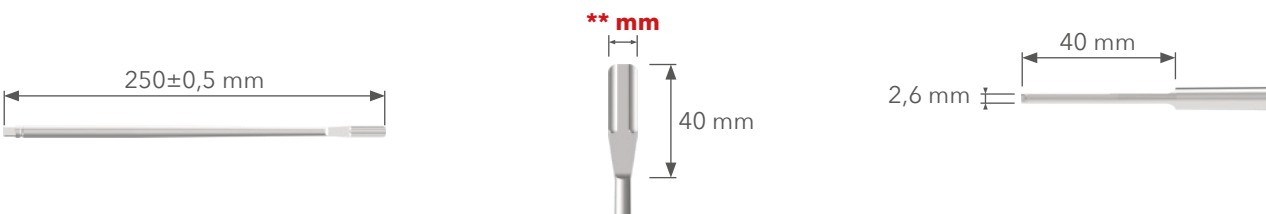
Instrument Ref. Code: **BOK-LC-250-****



**Dimensional tolerance ± 2 mm

** 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

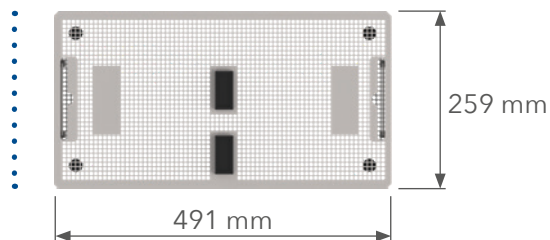
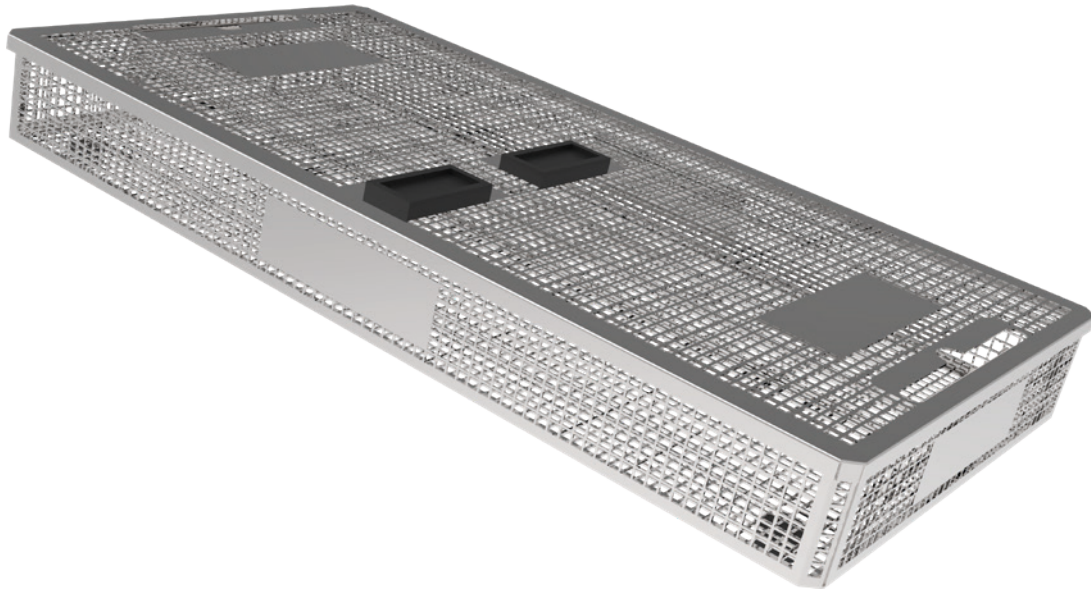
GENERAL INSTRUMENTS

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

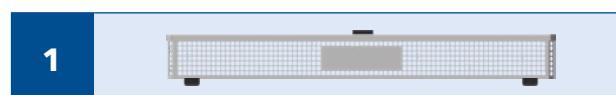
Medium Tray

Instrument Ref. Code:

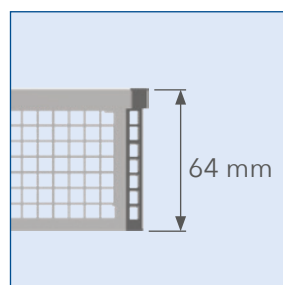
K3-725



Components:



Dimensions:



Medium Tray

K3-725

**Dimensional tolerance ± 2 mm



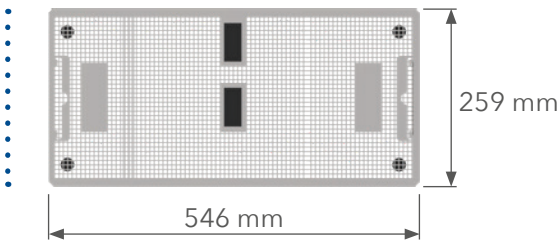
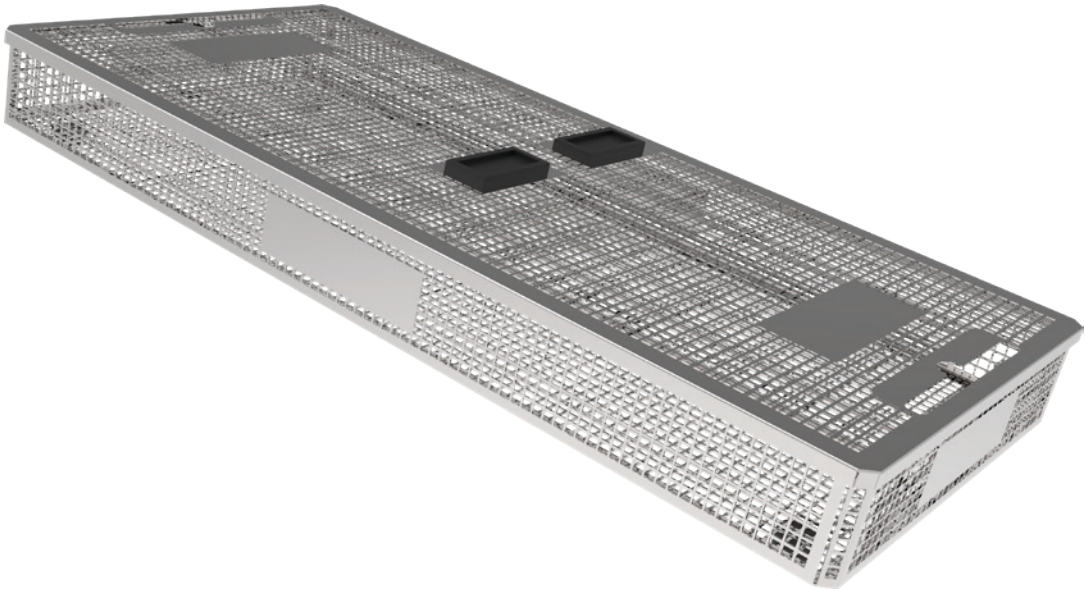
GENERAL INSTRUMENTS

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

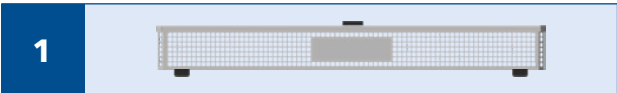
Large Tray

Instrument Ref. Code:

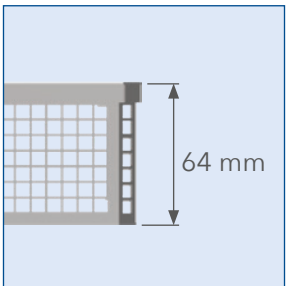
K3-721



Components:



Dimensions:



<i>Large Tray</i>
K3-721

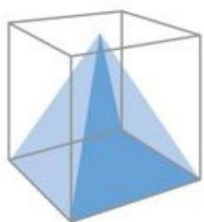
**Dimensional tolerance ± 2 mm





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on our products**

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