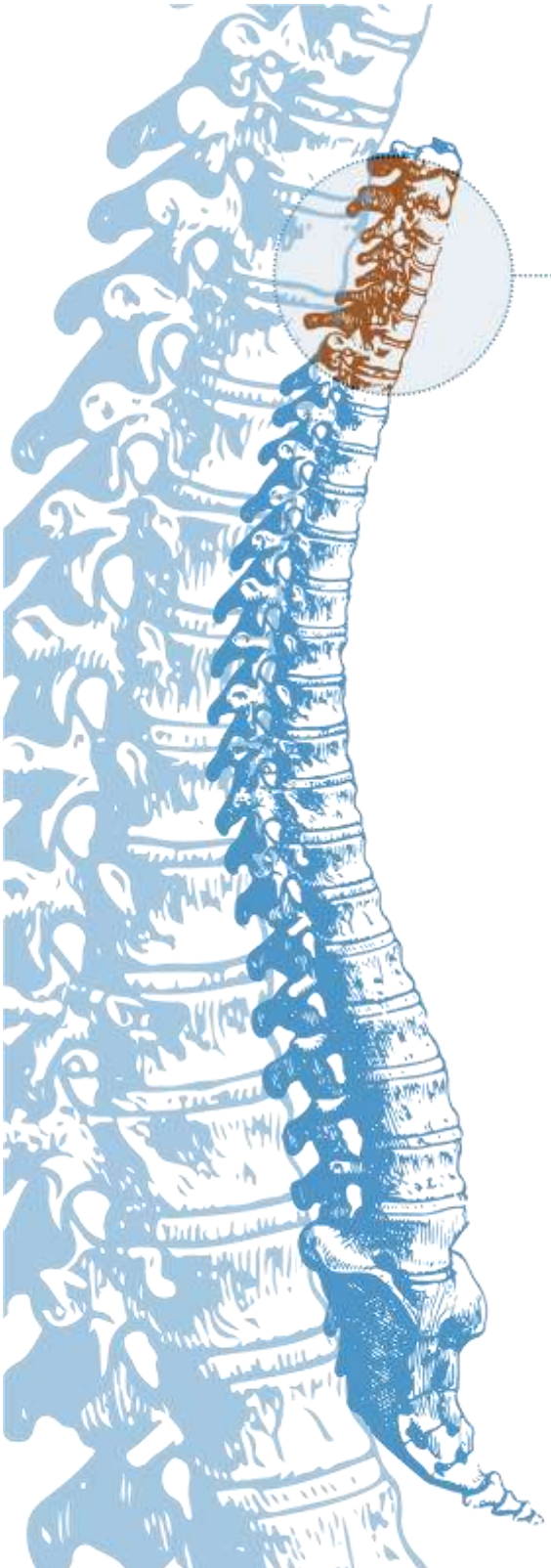


TSC ACIF Cage

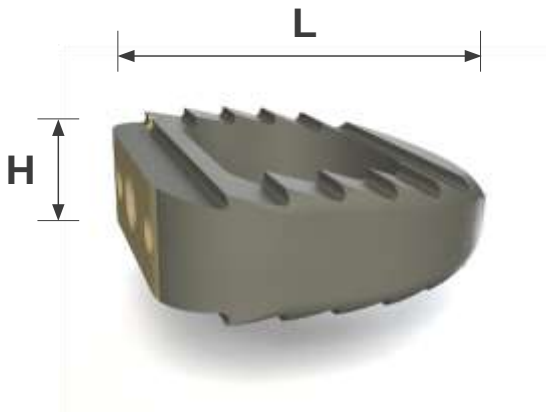
Surgical Technique Manual

Orthobion
PERFORMANCE IN ORTHOPEDICS

VIEWS & SIZES

To accommodate the various anatomical ranges, the TSC

ACIF cage is available in a wide variety of heights and endplate footprints also domed and lordotic shape.



Small

Length (mm): 13
Width (mm): 14,5
Height (mm): 4 • 5 • 6 • 7 • 8 9 10
Lordosis: Domed / 0° / 4°

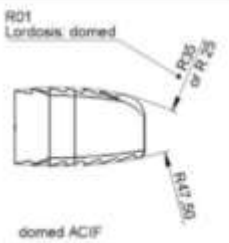
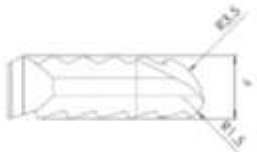
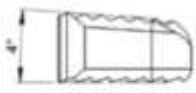
Medium

Length (mm): 15
Width (mm): 17
Height (mm): 4 • 5 • 6 • 7 • 8 9 10
Lordosis: Domed / 0° / 4°

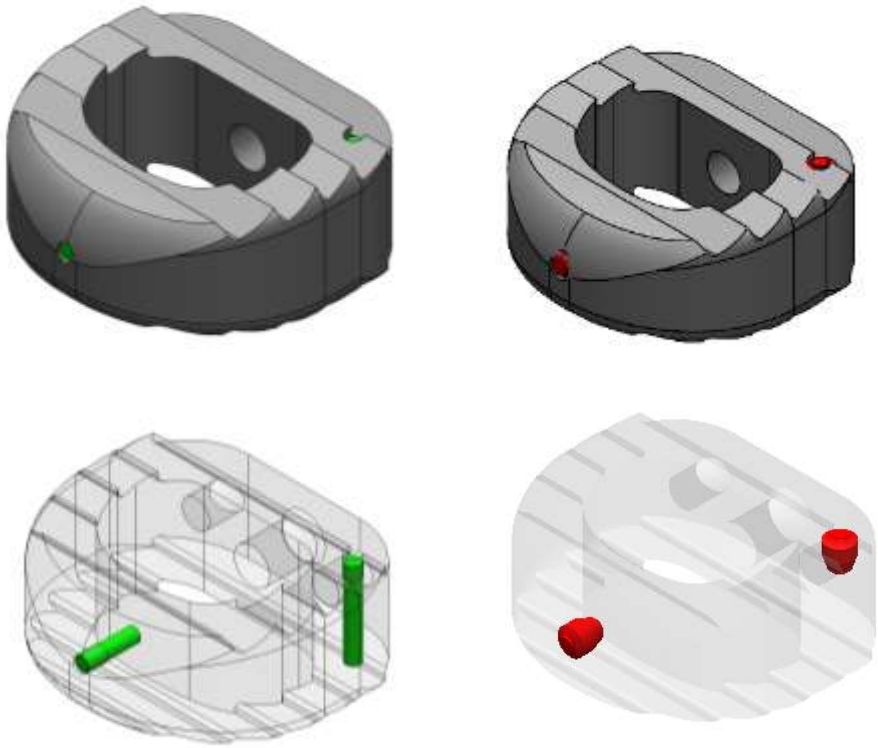
Large

Length (mm): 15
Width (mm): 19
Height (mm): 5 • 6 • 7 • 8 9 10
Lordosis: Domed / 0° / 4°

The structure of the three types of TSC ACIF Cages is showed in below table,

Angle	Domed	0°	4°
Image			
Description	The superior and inferior endplates of the cage is domed to each side.	The superior and inferior endplates of the cage is parallel to each other (0°).	The superior enplate of the cage has a slope of 4° angle to the inferior endplate.

TSC ACIF Cage is available with two Marker Sytems. With a Tantalum and a Titanium Marker.



– = Tantalum Marker

O = Titanium Marker

INSTRUMENTS

Impactor

Rectangular Curette

Inserter TSC ACIF

Trial Inserter TSC ACIF

Hammer

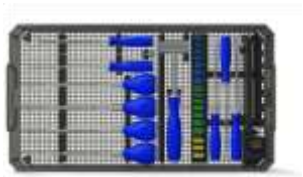
EPS TSC ACIF
5-13• 5-15 • 7-13 • 7-15

TSC ACIF Inserter Thread

Trial- Cage TSC ACIF

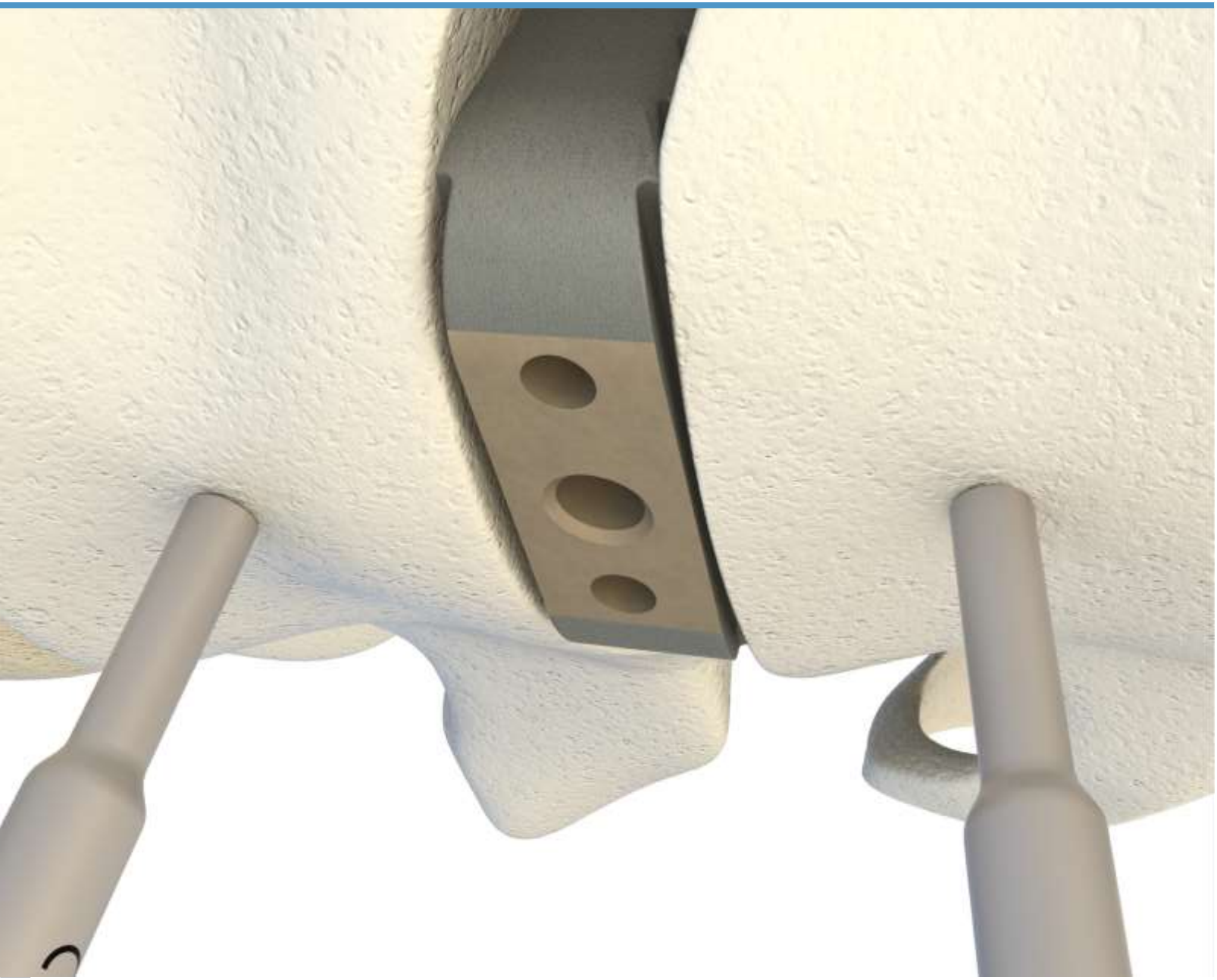
Bone Packing Lock

Bone Packing
Lock Plate TSC ACIF



TSC ACIF Tray

I. INDICATIONS AND CONTRA-INDICATIONS FOR CERVICAL INTER-BODY FUSION



Indications

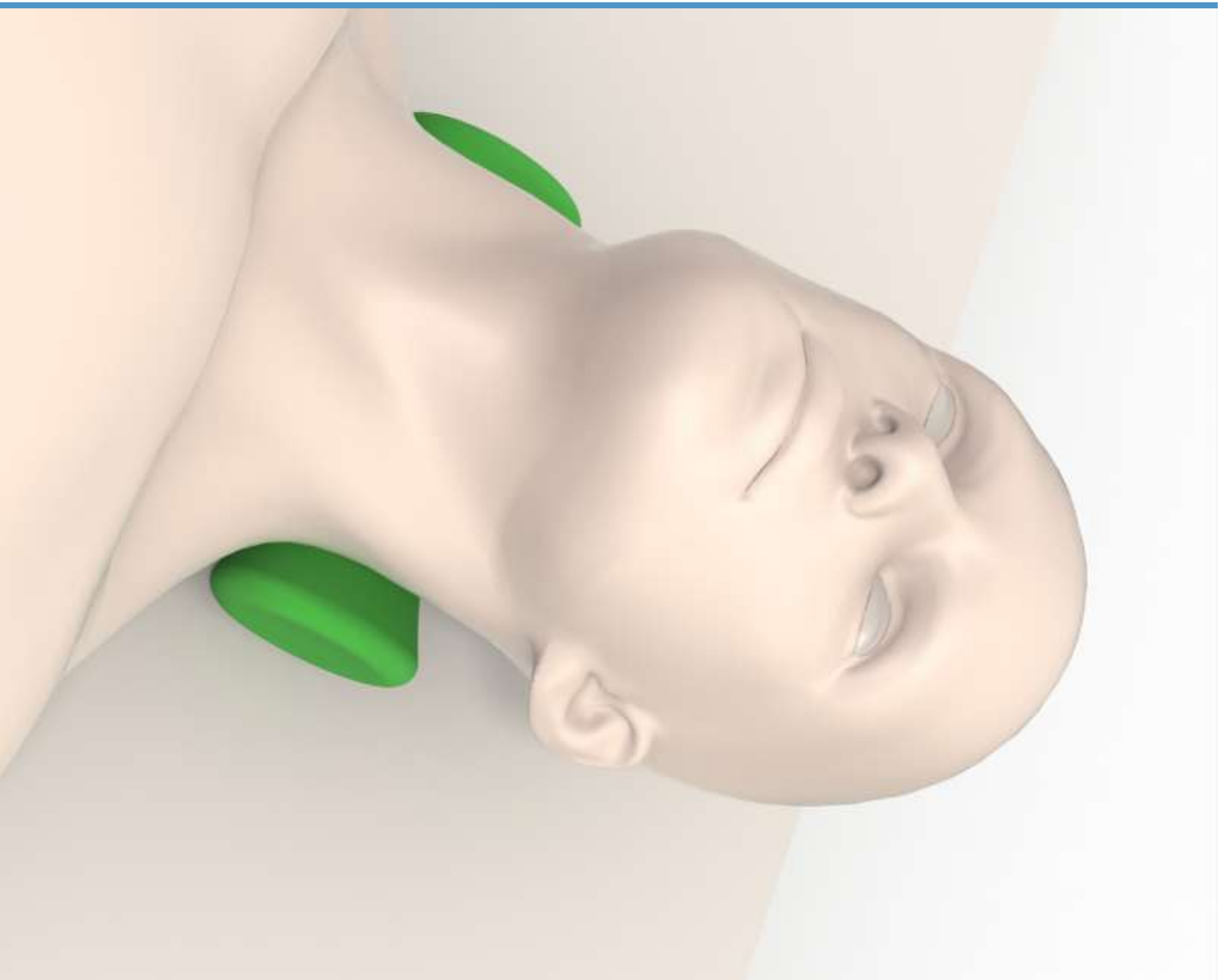
The Orthobion cervical interbody cage is intended for use, in skeletally mature patients, with degenerative disc diseases (DDD) or instabilities.

- *DDD defined by:*
- *Radiculopathy and/or*
- *Myelopathy and/or*
- *Disc herniation and/or*
- *Osteophytes*
- *Root or spinal cord compression*

Contra-Indications

- *The Orthobion cervical interbody cage is contra-indicated for any posterior (dorsal) surgical implantation.*
- *Contra-indications include:*
- *Any case not described in the above indications*
- *Presence of Spinal Tumors*
- *Congenital abnormalities*
- *Elevation of sedimentation rate unexplained by other diseases*
- *Elevation of white blood count*
- *Patients with inadequate tissue coverage over the operative site*
- *Patients having inadequate bone stock, bone quality, or anatomical definition*
- *Patients unwilling to follow postoperative instructions.*
- *Fever or leukocytosis.*
- *Local, Spinal Infections at index level*
- *Patients suffering from mental illness*
- *Morbid obesity.*
- *Pregnancy*
- Cancer
- Smoking
- Alcoholism or drug abuse
- Spinal fractures
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Signs of local inflammation.
- Suspected or documented metal allergy or intolerance.
- Pediatric patients, where the patient has limited to no skeletal growth
-
- See also the WARNING, PRECAUTIONS and POSSIBLE ADVERSE AFFECTS sections of this IFU.
-
- The following are specific warning, precautions and adverse effects, which should be understood by the surgeon and explained to the patient. General surgical risks should be explained to the patient, prior to surgery.
-

II. PATIENT POSITIONING



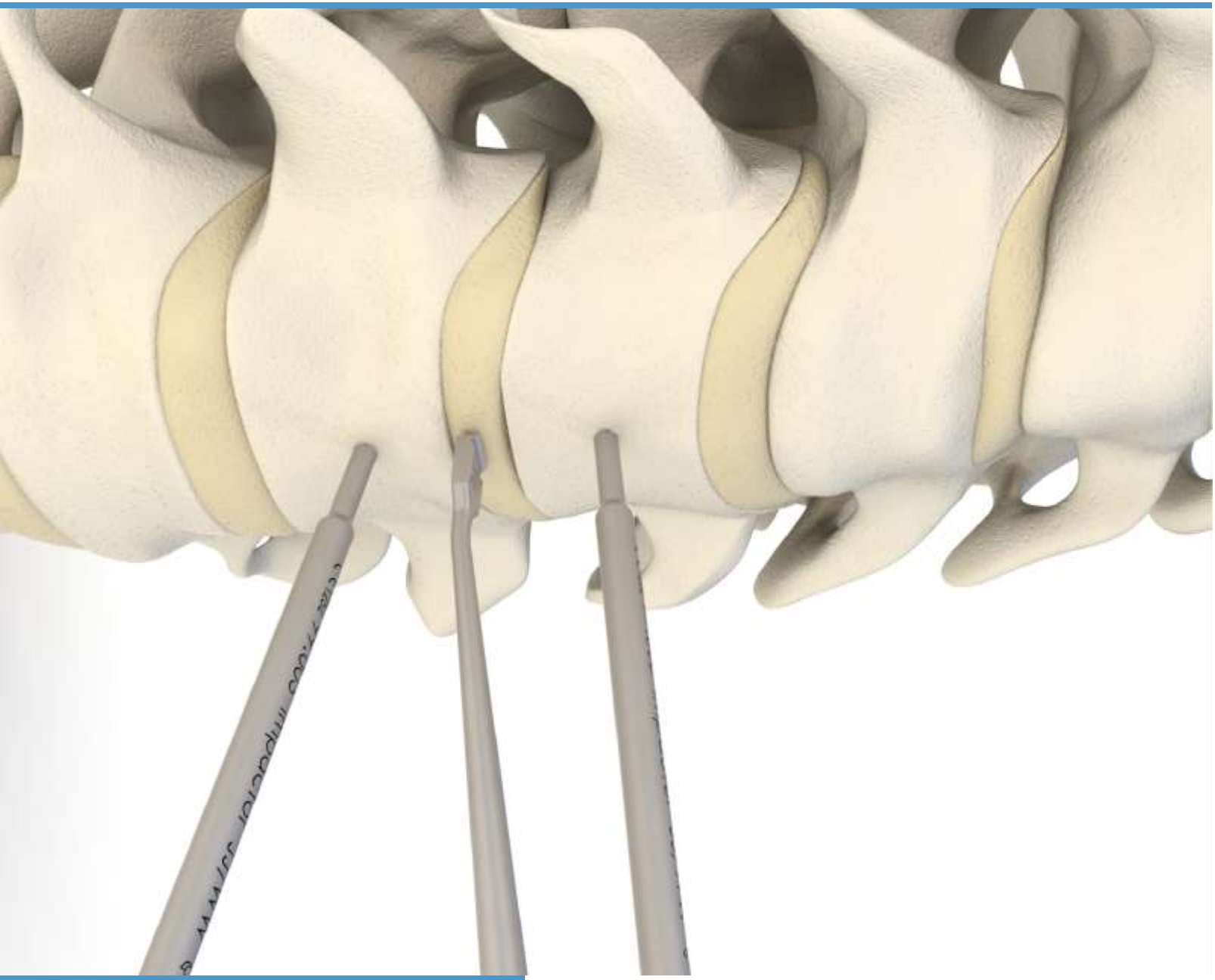
Place the patient in the Supine position with the head in slight extension. The posterior part of the neck is supported, by a soft neck-roll, to establish and maintain proper lordosis.
Based on surgeon preference, a right- or left-sided approach to the cervical spine is selected.

An oblique/ transverse incision is used, followed by a blunt dissection of the muscles (muscle-splitting technique) through an avascular dissection plane.
The strap muscle, trachea and esophagus are medially retracted, and the carotid sheath is retracted laterally.
By way of hand-held retractors, initial exposure of the anterior vertebral column and the Longus-Coli muscles is done. After the A.L.L. (Anterior Longitudinal Ligament), disc spaces and vertebral bodies are exposed, the Longus-Coli muscles are subperiosteally elevated, and self-retaining retractor blades are placed underneath them, keeping all tissue spread to access the operated segment.
Longitudinal self-retaining retractors are used to provide visualization of the index segment. An intervertebral distractor (Caspar-like distractor) can be used, following proper pin-placement.

Side Note

1. *Intervertebral distractors generate high force that could result in over-distraction if not used properly. Make reference to pre-operative planning and patient-specific spinal measurements in order to avoid over-distraction.*
2. *If properly placed, the intervertebral distractor can provide a visual reference for midline and cage insertion trajectory.*
3. *Do not allow the distractor pins to progress beyond the posterior vertebral cortical rim. Allowing the pins to progress beyond the posterior border of the vertebrae can result in patient injury.*

III. DISCECTOMY AND ENDPLATE PREPARATION

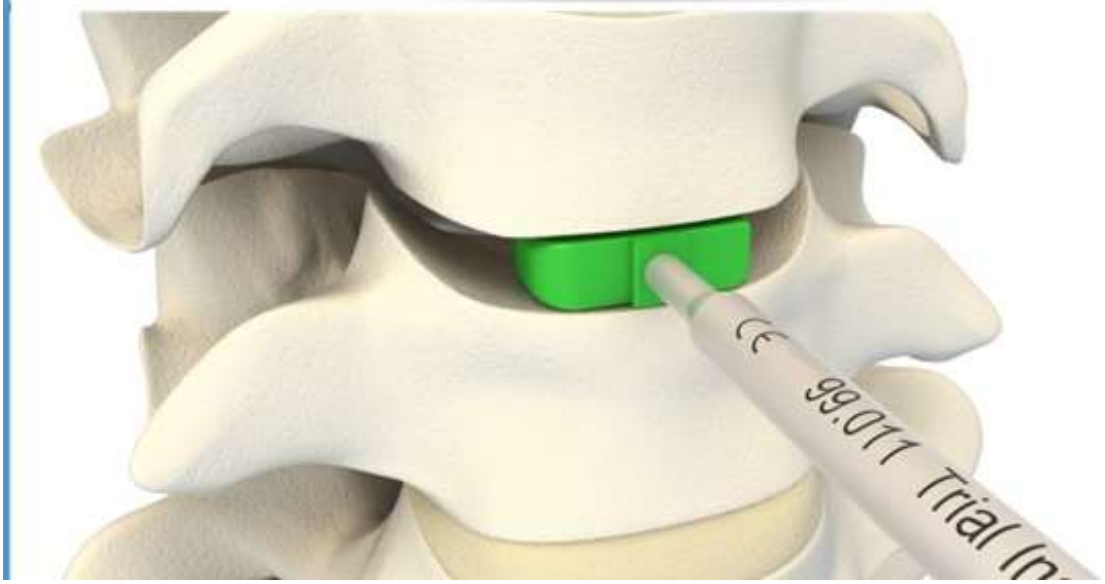


Rongeurs, Curettes, Pituitaries and other similar instruments may be used to remove the intervertebral disc material and cartilage to the posterior disc space, the lateral annulus and the Uncovertebral joints.
Osteophytes can be removed by way of Rasps, Shavers, high-speed drill or other needed instruments to remove any bony malformation to achieve a total symmetrical neural decompression. Upon desire a removal of the P.L.L. (Posterior Longitudinal Ligament) can be done.

Side Note

1. *Removing the Cartilaginous layers to exposing bleeding bone might promote improved fusion results*
2. *Proper irrigation, suction and cleaning of the endplates is important although excessive cleaning can result in removal of bone underlying the cartilaginous layers and can lead to weakening of the endplates*
3. *Take care to preserve cortical bone and maintain endplate angle*
4. *Excessive removal of endplate cortical bone may result in sub-optimal outcomes*
5. *Slight symmetrical resection of the Medial borders of the Uncinate Processes may need to be performed to allow a more correct fit.*
6. *The marked height and length are only for your information and not for measurement. The Curette or Endplate Shaver (EPS) are designed in typical Cage measurements. The vertebrae of the Patient can be smaller. Please make sure that you will not harm the Spine canal or other patient tissues during the surgery.*
7. *Implants and Instruments must be used by qualified professionals*

IV. IMPLANT SIZING & TRIAL IMPLANTATION



After decompression and endplate preparation have been completed, the correct TSC ACIF cage size needs to be selected.

Choose the trial implant by way of patient's anatomy and estimated implant height. The trial implants have various colorcoding that is based on the various footprint-sizes (Small, Medium, Large), allow for decent coverage of the endplate.

Once the appropriate trial implant is chosen, attach the trial implant onto the universal handle by rotating the handle in a clockwise direction.
Under fluoroscopic guidance, insert the trial implant into the disc space by using light tapping with a mallet onto the universal handle.

Side Note

1. *External distraction applied when the trial implant is inserted, may result in an over estimation of the actual disc height.*
2. *The trial implant should be positioned in such way that it rests on the cortical bone.*

Warning

Fluoroscopic visualization must be maintained during the trial implant insertion. Don't let the trial implant go past the posterior borders of the vertebra. Failure to visualize the trial implant during this step can result in patient injury.

Relieve all external distraction, off of the Caspar distractor, so that the vertebral endplates and the trial implant are in firm contact.
Continue advancing the trial implant while observing the progress on lateral fluoroscopy, until the posterior edge of the trial implant is within an estimate of 1-2 mm of the posterior vertebral border.

With the trial implant in the desired position, observe the treatment level disc space height, facet joints and spinous process and compare to the adjacent levels.
Good correlation of adjacent level height with the index level, and no over-distraction of the disc space should be visual.

If additional height is desired, repeat the above steps by using higher trial implant sizes.

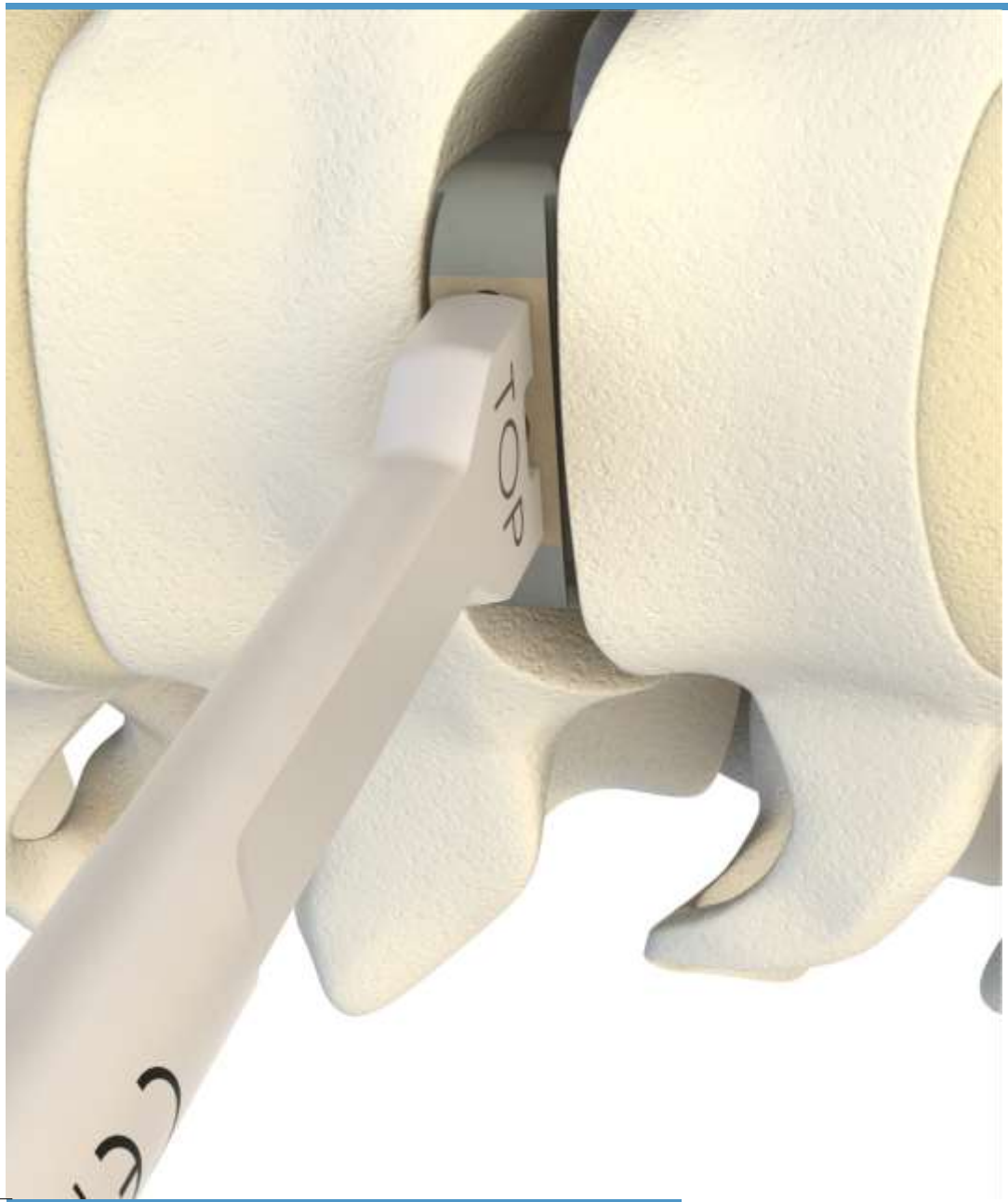
V. TSC ACIF CAGE FILLING

Select the appropriate size implant that matches the trial implant used in the previous step.

Use the implant inserter to attach the implant onto the threaded inserter. The curved surface of the implant must face cranial at all time.

Once the implant is threaded onto the handle, proceed with positioning the cage in the bone packing lock, where it can be filled with autograft, bonegraft or other similar materials.
Once the cage is filled with the bony material, use an impactor tool to compact the material inside creating a mono-block cage.

VI. TSC ACIF CAGE INSERTION



It is important that the implant will be positioned as close to midline as possible. This can be verified, upon correct midline placement of the distractor pins, in the vertebrae.

Apply slight distraction with the Caspar distractor in order for easy facilitation of the implant, into the disc space.

Verify that the curved surface is facing cranial, towards the patient's head.

Use the mallet to apply slight tapering onto the implant handle to insert the implant with light hammering force.
When the implant is within the dis space, use fluoroscopy to verify continues progression into the disc space. The posterior implant marker needs to be used as guidance, in order to achieve a final position of the implant up to 1-2mm off the posterior rim.
Perform a last control of the implant positioning by way of fluoroscopy.

When the cage positioning is successfully achieved, apply a press-fit compression with the Caspar distractor onto the implanted segment.

Releases the implant from the handle by turning the handle counter-clockwise until the handle is completely lose from the implant.

Side Note

1. *Slight distraction can be applied to re-align the implant in the most optimal position*
2. *The Caspar distractor pins can help as a midline reference in placing the implant in the correct midline position*

Warning

Fluoroscopic visualization must be maintained during the insertion of the implant. Do not the implant to go further beyond the posterior border of the vertebrae. Failure to visualize the implant during this step can result in patient injury.

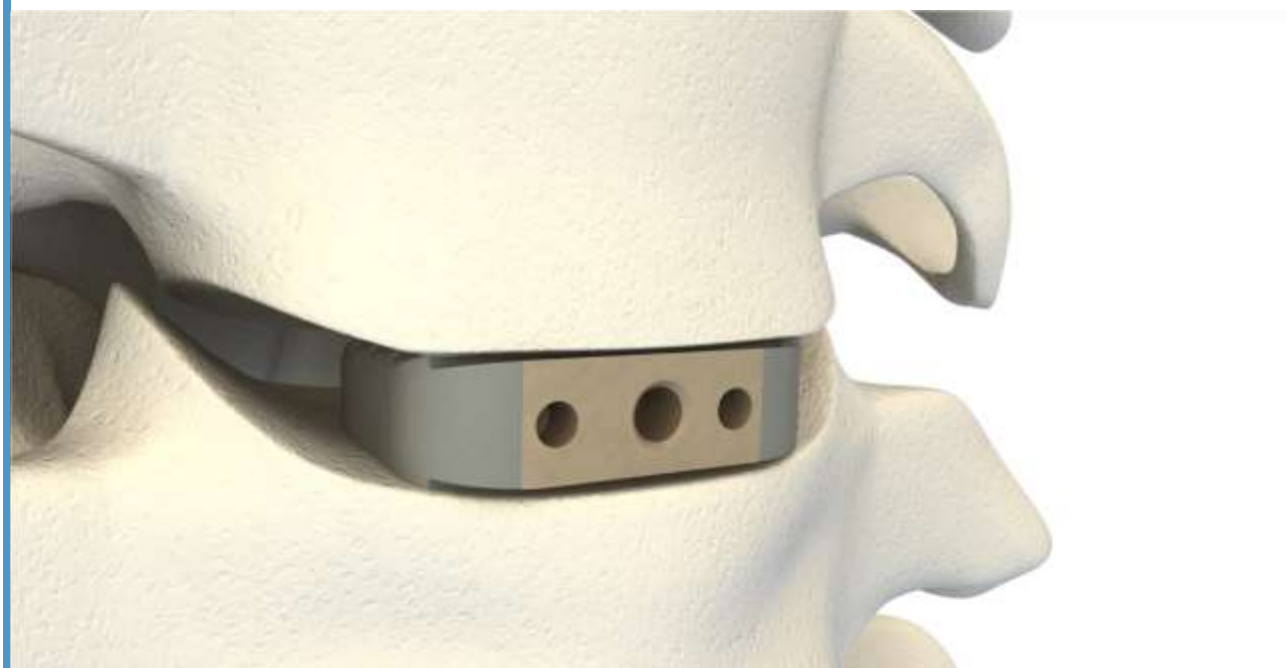
VII. FINALIZATION OF IMPLANTATION

Remove the Caspar distractor and unscrew the distractor pins, with the pin-driver in a counter clockwise movement.

Bone (filling) wax may be used to prevent excessive bleeding of the vertebral bodies when removing the Caspar pins.

Confirm proper implant positioning, both in lateral as well as in A/P fluoroscopy.

Close the wound following standard practices.



VIII. EXPLANTATION OF IMPLANT

Standard removal:

The threaded inserter handle can then be re-attached again onto the implant, by way of turning the handle in a clock-wise movement, after which the implant can be removed from the disc space.

Removal in the case of a bone fusion:

Explantation/ removal of the implant may be accomplished by using a high-speed burr to resect the implant.

The implant can be removed by exposing the anterior surface of the implant and by way of creating a clear plane around the implant by removing surrounding bone with an Osteotomes or High-Speed burr.

IX. PRODUCT ORDERING INFORMATION

Ref	Description
99.143	MEDIUM - Trial CAGE TSC ACIF 15mm x 17mm x 10mm
99.144	LARGE - Trial CAGE TSC ACIF 15mm x 19mm x 6mm
99.145	LARGE - Trial CAGE TSC ACIF 15mm x 19mm x 7mm
99.146	LARGE - Trial CAGE TSC ACIF 15mm x 19mm x 8mm
99.170	SMALL - Trial CAGE domed TSC ACIF 13mm x 14,5mm x 4mm
99.171	SMALL - Trial CAGE domed TSC ACIF 13mm x 14,5mm x 5mm
99.172	SMALL - Trial CAGE domed TSC ACIF 13mm x 14,5mm x 6mm
99.173	SMALL - Trial CAGE domed TSC ACIF 13mm x 14,5mm x 7mm
99.174	SMALL - Trial CAGE domed TSC ACIF 13mm x 14,5mm x 8mm
99.175	SMALL - Trial CAGE domed TSC ACIF 13mm x 14,5mm x 9mm
99.176	SMALL - Trial CAGE domed TSC ACIF 13mm x 14,5mm x 10mm
99.177	MEDIUM - Trial CAGE domed TSC ACIF 15mm x 17mm x 4mm
99.178	MEDIUM - Trial CAGE domed TSC ACIF 15mm x 17mm x 5mm
99.179	MEDIUM - Trial CAGE domed TSC ACIF 15mm x 17mm x 6mm
99.180	MEDIUM - Trial CAGE domed TSC ACIF 15mm x 17mm x 7mm
99.181	MEDIUM - Trial CAGE domed TSC ACIF 15mm x 17mm x 8mm
99.182	MEDIUM - Trial CAGE domed TSC ACIF 15mm x 17mm x 9mm
99.183	MEDIUM - Trial CAGE domed TSC ACIF 15mm x 17mm x 10mm
99.184	LARGE - Trial CAGE domed TSC ACIF 15mm x 19mm x 6mm
99.185	LARGE - Trial CAGE domed TSC ACIF 15mm x 19mm x 7mm
99.186	LARGE - Trial CAGE domed TSC ACIF 15mm x 19mm x 8mm
99.028	Curette 1
99.010	TSC ACIF Instrument Case
99.027	TSC ACIF Instrument Case Cover

Orthobion
PERFORMANCE IN ORTHOPEDICS

Gottlieb - Daimler - Strasse 5
D - 78467 Konstanz
T. +49 (0) 7531 12218 30
F. +49 (0) 7531 12218 59
E. andreas.ottenschlaeger@orthobion.com

www.orthobion.com

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