

ROCCIA[®] ALIF CAGE FOR ANTERIOR LUMBAR SPINAL FUSION

ALIF INSTRUMENTATION GUIDE



MADE IN GERMANY

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NOTE: This Guide describes the instrumentation for the ROCCIA ALIF Cage – it does not replace briefing by a physician experienced in surgical instrumentation of the spinal column.

We would be happy to assist you in finding a hospital that provides an opportunity to observe surgical procedures.

PREFACE

ROCCIA[®] ALIF – FOR ANTERIOR LUMBAR SPINAL FUSION

The ROCCIA ALIF Cage is an implant for primary stabilization and restoration of physiological lordosis in the lumbar spine. The cage is designed for anterior approach.

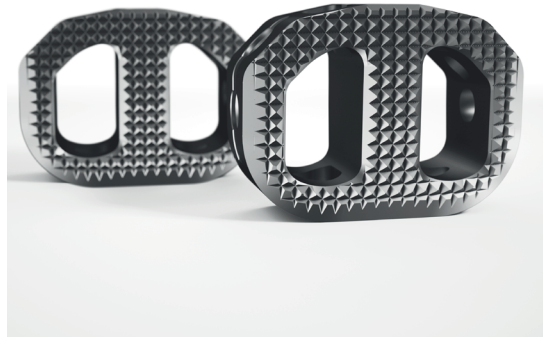
The aim is to eliminate the discogenic back pain, to correct deformities, to correct instabilities, to restore the intervertebral height, to achieve a physiological re-lordosis and to biomechanically support a bony fusion in the disc space.

The ROCCIA ALIF Cage is inserted into the disc space via the anterior approach to the spinal column, either anteromedial or anterolateral (anterior to the psoas).

The five threaded holes of the ROCCIA ALIF allow for accordingly correct placement of the cage.

The system is designed for use with supplemental internal spinal fixation. We recommend additional posterior spondylodesis with instrumentation such as our VERTICALE posterior spinal fixation system.

The ROCCIA instrumentation system, like all Silony Medical products, can be used in a modular manner and is ergonomically designed. Thus, the ROCCIA inserter enables the user to perform various instrumentation steps with just one single instrument. This not only helps to speed up the surgical procedure but also decreases the need for inventory, which then has to be cleaned and stored in the clinic.





Indications

The ROCCIA ALIF Cage is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The device is to be used in patients who have had at least six months of non-operative treatment.

The ROCCIA ALIF Cage implants are intended for use at one or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The ROCCIA ALIF Cage implants can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

NOTE: The ROCCIA ALIF Cage must be combined with additional stabilization. For dorsal lumbar intersegmental fusion procedures, Silony Medical recommends the use of a posterior spinal fixator (e.g. with the VERTICALE system).

Contraindications

- Expected or documented allergy or intolerance to the materials (e.g. titanium)
- Any case in which the selected implants would be too large or too small to achieve a successful result
- Any patient for whom the use of the implant would be in conflict with the anatomical structures
- Missing bone structures make impossible a good anchoring of the implants (e.g. fractures, tumors, osteoporosis or infections, among others)

NOTE: Please note the advice about indications and contraindications in the instructions for use of ROCCIA ALIF. The instructions for use also contains other important information, that might lead to exclusion of the patient.

POSITION AND APPROACH FOR THE ROCCIA[®] ALIF CAGE

Position and Approach

To optimize the treatment of the patient a wide range of ROCCIA ALIF sizes is available.

When implanting the ROCCIA ALIF Cage for anterior lumbar interbody fusion (ALIF), there are two main positioning options. On the other hand the standard supine position with closed legs and arms abducted at 90°, in which the surgeon usually stands to the left of the patient, on the other hand the da Vinci position in which the surgeon can stand between the patient's legs.

The direct anterior approach may require the retraction of the large vessels to provide sufficient space for the implantation of the cage. The anterior longitudinal ligament is resected. In anterolateral access from L5 upwards, the longitudinal ligament remains largely intact. The retraction of the large vessels is avoided.

ROCCIA® ALIF INSTRUMENTATION

The following instrumentation steps apply to the anterior approach.

Discectomy

RI-1020*
ROCCIA Ring Endplate Scraper
Straight



RI-1040**
ROCCIA Curette Straight



RI-1107***
ROCCIA Shaver 7 mm



GI-3101****
T-Handle



To begin with, the disc is incised with a standard scalpel. The disc material is loosened by means of shavers and then removed using various standard forceps and available endplate scrapers and curettes (Figs. 1 and 2). The ventral fibrous ring is opened up in the process, and the nucleus and the inner fibrous ring are then removed and the surfaces of the end plates are roughened in order to prepare a spacious cage bed.

Various angled endplate scrapers are available to facilitate the removal of the intervertebral disc tissue in the wide lateral disc space.

- * Representative of other ring endplate scrapers (angled and curved)
- ** Representative of other curettes (curved)
- *** Representative of other shaver sizes, see ROCCIA Instruments
- **** Representative of other T-Handles, see General Instruments

NOTE: ROCCIA shavers are only suitable for mobilizing the disc and preparing the cover plates. They must not be used for distraction.

NOTE: If possible, the outer fibrous ring should be preserved as support for the cage.

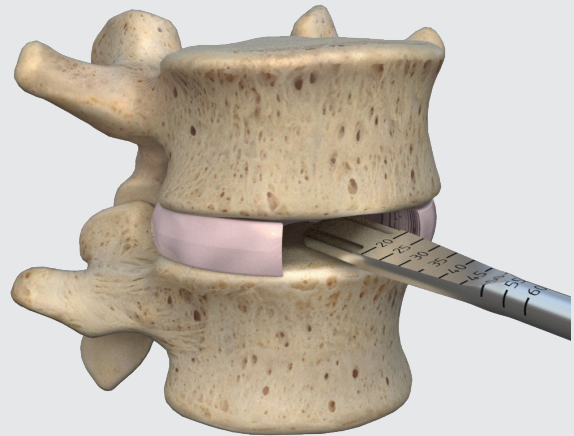


Fig. 1 Loosening of the disc material with a shaver

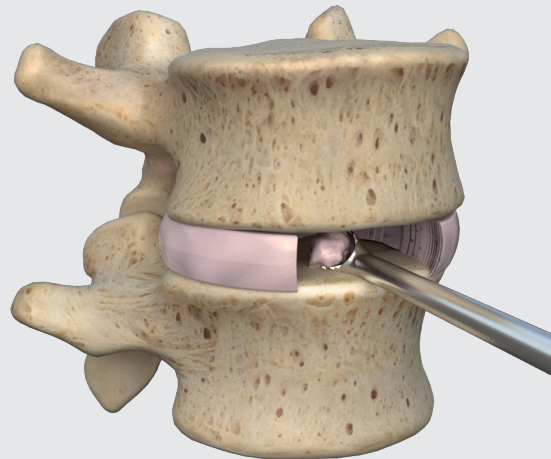


Fig. 2 Discectomy using a curette

Preparing the disc space

RI-1020*
ROCCIA Ring Endplate Scraper
Straight



RI-1030
ROCCIA Box Endplate Scraper
Straight



RI-1050
ROCCIA Rasp
Curved 45°



RI-1107**
ROCCIA Shaver 7 mm



GI-3101***
T-Handle



For more extensive curettage, the ROCCIA Box Endplate Scraper is also available (Fig. 3). The surface of the remaining cartilaginous layer of the base plate and cover plate can be roughened with bone rasps, curettes, and shavers (Fig. 4). The curved endplate scrapers, in particular, also facilitate the preparation of the opposite side.

- * Representative of other ring endplate scrapers (angled and curved)
- ** Representative of other shaver sizes, see ROCCIA Instruments
- *** Representative of other T-Handles, see General Instruments

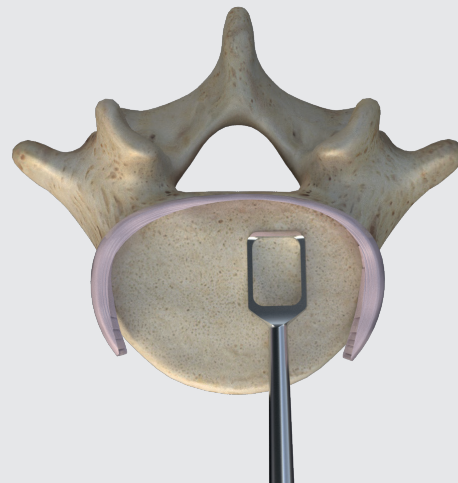


Fig. 3 Box endplate scraper for extensive removal of disc material

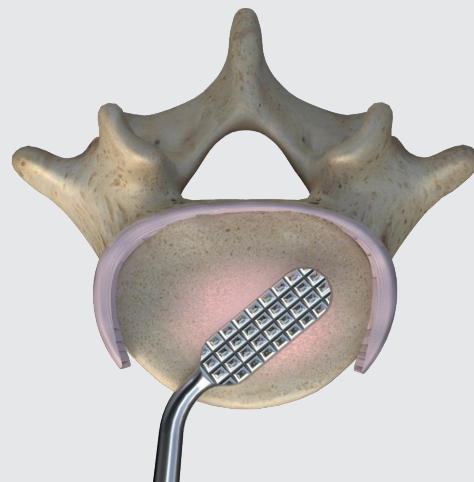


Fig. 4 Rasp for roughening the cover plates

NOTE: Careful preparation of the disc space, especially extensive roughening of the endplates, provides the basis for better vascularisation and successful bone fusion. Damage to the bony base and cover plate can lead to sinking of the implant into the vertebral body.

Distracting the Disc Space

RI-1207*
ROCCIA Paddle Sizer 7 mm



GI-3101**
T-Handle



Blunt ROCCIA distractors with depth marking are available for distraction.

The paddle shavers are connected to a T-Handle by means of a quick-release system. For better orientation, the handle ends are aligned in the same way as the end of the paddle shavers. Two T-Handles are available to enable rapid instrumentation.

For distraction, a blunt distractor corresponding to the disc height is first inserted into the disc space and erected by 90° rotation (Fig. 5). The next distractors are then inserted in steps of 1 mm with the same movement until the desired height is achieved. The appropriate distraction height is achieved when the paddle shaver is under tension and provides a feeling of stability.

* Representative of other paddle sizer sizes, see ROCCIA Instruments

** Representative of other T-Handles, see General Instruments

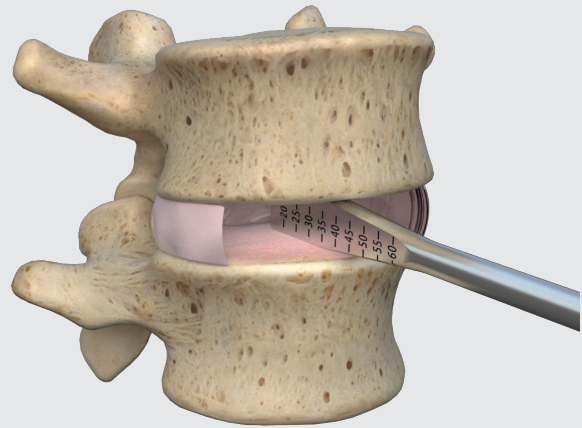


Fig. 5 Spreading the disc space with the distractor

NOTE: Overdistraction should be avoided. This increases the risk of damaging the base plates and cover plates and subsequent sinking of the implant and jeopardizes the restoration of physiological lordosis.

Selecting the Trial Implant

RI-1324
ROCCIA Inserter M4,
dismountable



RI-1325
ROCCIA Inserter M5,
dismountable



RI-1207*
ROCCIA Paddle Sizer 7 mm



GI-3101**
T-Handle

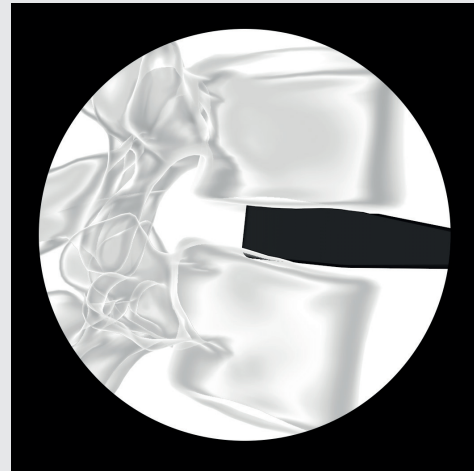


Fig.6 Image converter control with paddle sizer for selection of the trial implant

To determine the size of the disc space, the blunt distractors with depth markings are available. Trial implants can be selected on the basis of these measurements (Fig. 6).

An appropriate trial implant with 5° or 15° lordosis is available for each definitive cage size. Due to the tothing, the final implant is approx. 0.7 mm higher than the trial implant. The trial implants are marked analogously to the implants to be implanted later on.

The colour marking facilitates identification of the matching inserter, which has colored rings on the instrument stem.

* Representative of other paddle sizer sizes, see ROCCIA Instruments

** Representative of other T-Handles, see General Instruments

Determining the Cage Sizes with the Trial Implants

RI-1324
ROCCIA Inserter M4,
dismountable



RI-1325
ROCCIA Inserter M5,
dismountable



RI-15342515*
ROCCIA ALIF Trial
15 x 34 x 25 mm 15°

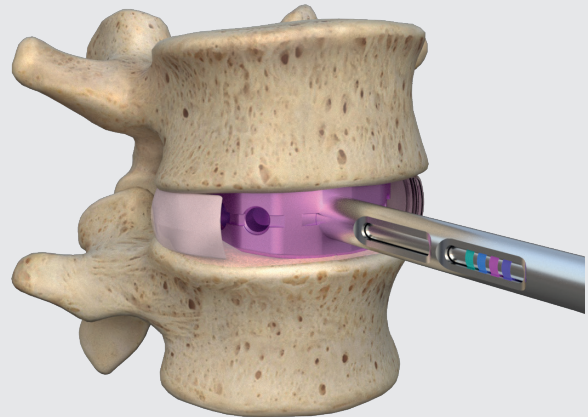


Fig. 7 Inserting the trial implant

ROCCIA inserters are required to insert the trial implants. The ROCCIA inserters fit onto both the trial implants and the definitive implants. The selected trial implant is screwed onto the respective ROCCIA inserter and then, applying mild pressure, carefully inserted into the intervertebral space (Fig. 7). At the surgeon's discretion, a mallet can also be used to insert the trial implant. After that the position and size of the trial implant is verified in the image converter.

To ensure that the height of the intervertebral disc is preserved after loosening the distraction, the implant must fit between the endplates after full distraction of the segment.

Using the largest possible implant for each individual patient maximizes the stability of the segment.

If the trial implant does not sufficiently fill the intervertebral disc space, the next larger implant must be used. If the trial implant cannot be inserted because the intervertebral disc space is too small, either the next smallest size has to be used or the segment has to be distracted further using the aforementioned instruments.

* Representative of other trial implant sizes, see ROCCIA Trial Implants

NOTE: Correctly selecting the cage size has a decisive impact on the success of the instrumentation and fusion.

Multitude of Cage Sizes

To optimize the treatment of the patient in terms of anatomy and pathology, a wide range of ROCCIA ALIF sizes is available (Fig. 8). The portfolio comprises five anterior heights (from 9 to 17 mm, in 2-mm increments) and two widths (34 and 40 mm). In addition to the regular lordotic angles of 5° and 10°, hyperlordotic cages with an angle of 15° and 20° are also available.

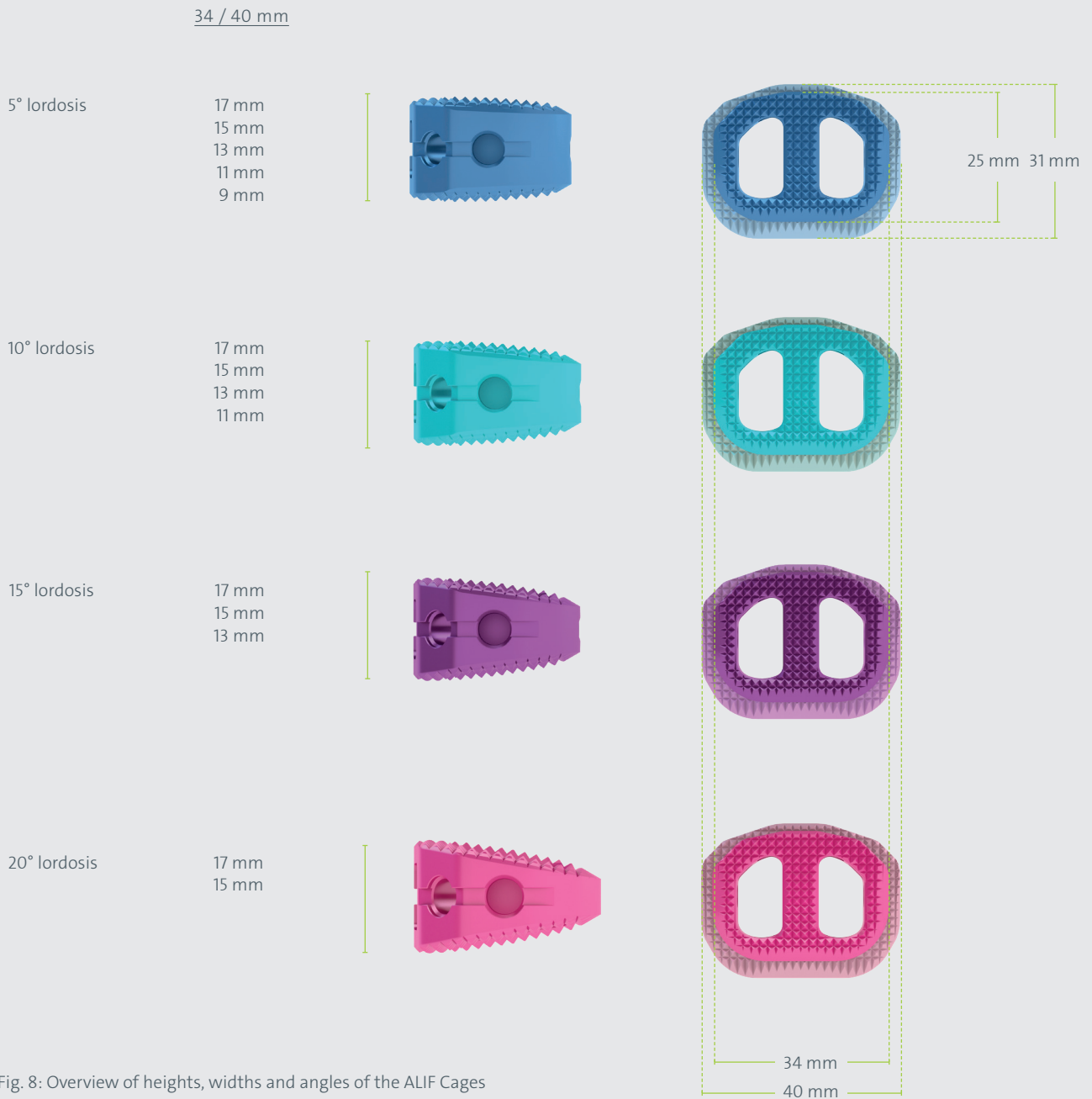


Fig. 8: Overview of heights, widths and angles of the ALIF Cages

Filling of the Cage

RI-1324
ROCCIA Inserter M4,
dismountable



RI-1325
ROCCIA Inserter M5,
dismountable



RI-2080
ROCCIA ALIF Loading Block



RI-2051
ROCCIA Bone Graft Pusher



Remaining areas of the intervertebral disc space can be filled with autogenous bone (e.g. from the iliac crest), either before or after implantation of the cage in order to achieve the largest possible fusion surface area. Filling of the disc space, but also filling of the implant, is an important prerequisite for secure fusion. A loading block and a pusher are provided for this (Fig. 9). The autogenous bone material must be introduced well compressed in the cage.

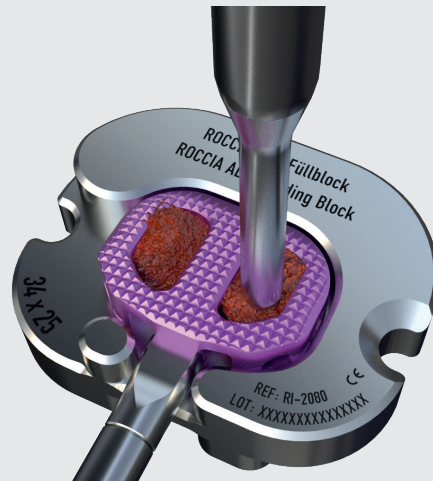


Fig. 9 Filling the cage with bone material in the loading block with pusher

Inserting the Cage

RI-1324
ROCCIA Inserter M4,
dismountable



RI-1325
ROCCIA Inserter M5,
dismountable



RI-1355
ROCCIA Slotted Mallet, solid



The trial cage is removed just shortly before definitively placing the implant in order to prevent subsequent sinking. To ensure comfortable insertion when using the ALIF approach, an anteromedial drill-hole in the implant is available. In addition, the cage has a drill-hole at 45° and a strictly lateral drill-hole at 90° for the anterolateral approach.

The selected implant is screwed onto the respective ROCCIA Inserter. The filled implant is carefully inserted into the disc space and the correct alignment of the implant is verified (Fig. 10). Slight pressure or careful hammering with the ROCCIA Slotted Mallet on the implant holder may be required.

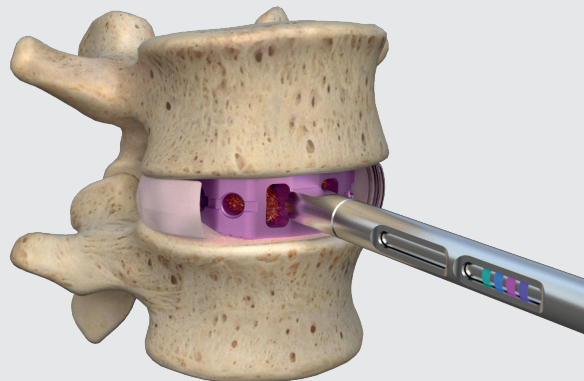


Fig. 10 Inserting the filled cage into the disc space

Correct Position of the ROCCIA® ALIF Cage

For biomechanical reasons, the optimum position of the implanted ROCCIA ALIF cage should be in the anterior to middle third of the disc space and centered as far as possible in the frontal projection (Figs. 11 and 12).

The more anterior the cage is positioned, the better lordosis can be achieved in the respective section of the spine.

Once it has been successfully implanted, the remaining disc space should be filled up to ensure secure fusion.

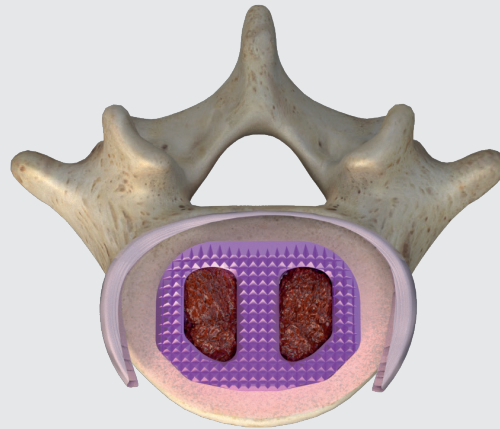


Fig. 11 Optimum position of the filled ALIF Cage

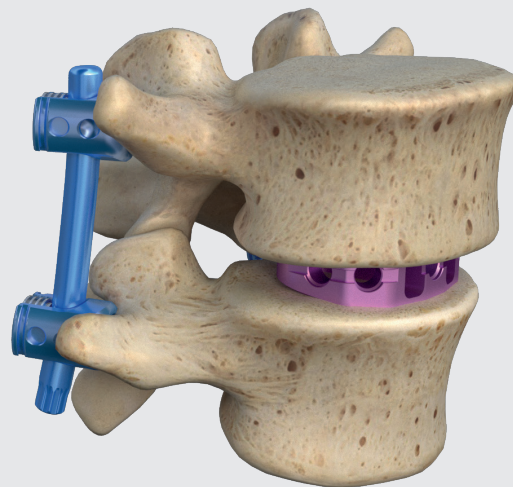


Fig. 12 Optimum position of the filled ALIF Cage including posterior fixation

NOTE: It is imperative to provide the segment with additional stabilization using a posterior fixation system or anterior plating. Tension band wiring supports the biomechanical stability of the motion segment of the spine and the stability of the ALIF Cage. The final steps of posterior fixation (e.g. insertion of the rod, compression and final tightening of the set screws) are completed after implantation of the cage.

CORRECTING THE POSITION OF THE ROCCIA[®] ALIF CAGE

A straight implant driver is available for definitive positioning of the ROCCIA ALIF Cage. The use of this instrument is outlined below.

Implant Driver Straight

RI-1340
ROCCIA Implant Driver Straight



RI-1355
ROCCIA Slotted Mallet, solid



The ROCCIA implant driver is positioned straight onto the anterior front of the cage (Fig. 14). The cage can then be carefully moved into the desired position with the slotted mallet.

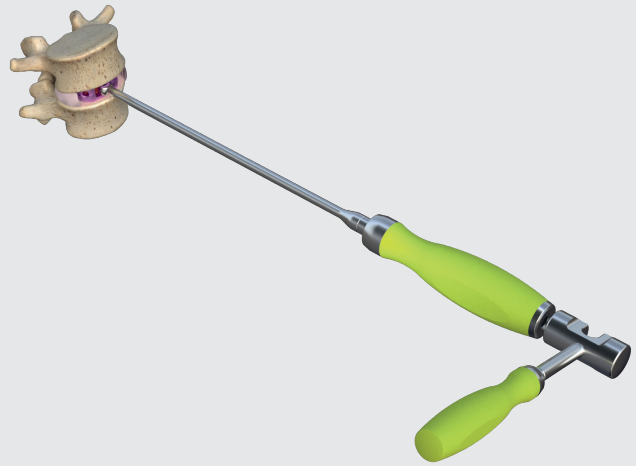


Fig. 14 Straight implant driver to finalize the cage position

Insertor as a Revision Instrument

RI-1324
ROCCIA Insertor M4,
dismountable



RI-1325
ROCCIA Insertor M5,
dismountable



RI-1355
ROCCIA Slotted Mallet, solid



To remove the ROCCIA ALIF implant, the inner core of the ROCCIA insertion instrument can be used. The core is attached to the cage and tightened. The removal of a cage requires that the instrument be screwed in until it stops. The cage can be removed by slight careful hammering under the handle (Fig. 15).



Fig. 15 Insertor functioning as a revision instrument

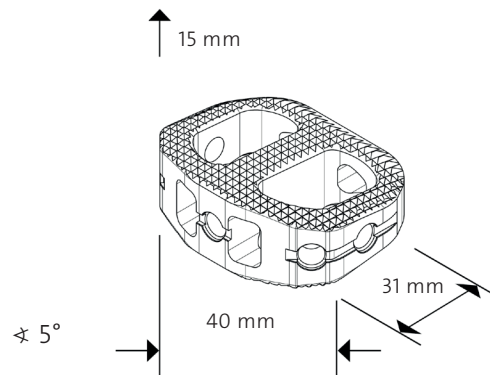
ROCCIA® ALIF PRODUCT INFORMATION

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ROCCIA® ALIF Implants

Article number explanation for the cage, as an example

ROCCIA ALIF Cage 15x40x31mm, 5° lor.



System:
ROCCIA

Implant type:
ALIF

Configuration:
34 mm

Material:
Ti6Al4V ELI

Article number	Description	Illustration
S-RAT-09342505-S	ROCCIA ALIF Cage 09 x 34 x 25mm, 5° lor.	
S-RAT-11342505-S	ROCCIA ALIF Cage 11 x 34 x 25mm, 5° lor.	
S-RAT-13342505-S	ROCCIA ALIF Cage 13 x 34 x 25mm, 5° lor.	
S-RAT-15342505-S	ROCCIA ALIF Cage 15 x 34 x 25mm, 5° lor.	
S-RAT-17342505-S	ROCCIA ALIF Cage 17 x 34 x 25mm, 5° lor.	
S-RAT-11342510-S	ROCCIA ALIF Cage 11 x 34 x 25mm, 10° lor.	
S-RAT-13342510-S	ROCCIA ALIF Cage 13 x 34 x 25mm, 10° lor.	
S-RAT-15342510-S	ROCCIA ALIF Cage 15 x 34 x 25mm, 10° lor.	
S-RAT-17342510-S	ROCCIA ALIF Cage 17 x 34 x 25mm, 10° lor.	
S-RAT-13342515-S	ROCCIA ALIF Cage 13 x 34 x 25mm, 15° lor.	
S-RAT-15342515-S	ROCCIA ALIF Cage 15 x 34 x 25mm, 15° lor.	
S-RAT-17342515-S	ROCCIA ALIF Cage 17 x 34 x 25mm, 15° lor.	
S-RAT-15342520-S	ROCCIA ALIF Cage 15 x 34 x 25mm, 20° lor.	
S-RAT-17342520-S	ROCCIA ALIF Cage 17 x 34 x 25mm, 20° lor.	

ROCCIA® ALIF Implants

Article number	Description	Illustration
S-RAT-09403105-S	ROCCIA ALIF Cage 09 x 40 x 31mm, 5° lor.	
S-RAT-11403105-S	ROCCIA ALIF Cage 11 x 40 x 31mm, 5° lor.	
S-RAT-13403105-S	ROCCIA ALIF Cage 13 x 40 x 31mm, 5° lor.	
S-RAT-15403105-S	ROCCIA ALIF Cage 15 x 40 x 31mm, 5° lor.	
S-RAT-17403105-S	ROCCIA ALIF Cage 17 x 40 x 31mm, 5° lor.	
S-RAT-11403110-S	ROCCIA ALIF Cage 11 x 40 x 31mm, 10° lor.	
S-RAT-13403110-S	ROCCIA ALIF Cage 13 x 40 x 31mm, 10° lor.	
S-RAT-15403110-S	ROCCIA ALIF Cage 15 x 40 x 31mm, 10° lor.	
S-RAT-17403110-S	ROCCIA ALIF Cage 17 x 40 x 31mm, 10° lor.	
S-RAT-13403115-S	ROCCIA ALIF Cage 13 x 40 x 31mm, 15° lor.	
S-RAT-15403115-S	ROCCIA ALIF Cage 15 x 40 x 31mm, 15° lor.	
S-RAT-17403115-S	ROCCIA ALIF Cage 17 x 40 x 31mm, 15° lor.	
S-RAT-15403120-S	ROCCIA ALIF Cage 15 x 40 x 31mm, 20° lor.	
S-RAT-17403120-S	ROCCIA ALIF Cage 17 x 40 x 31mm, 20° lor.	

System:
ROCCIA

Implant type:
ALIF

Configuration:
40 mm

Material:
Ti6Al4V ELI

ROCCIA® ALIF Trial Implants

System:
ROCCIA

Instrument type:
Trial implant

Configuration:
34 mm

Material:
Ti6Al4V ELI

Article number	Description	Illustration
RI-T09342505	ROCCIA ALIF Trial 9 x 34 x 25mm, 5° lor.	
RI-T11342505	ROCCIA ALIF Trial 11 x 34 x 25mm, 5° lor.	
RI-T13342505	ROCCIA ALIF Trial 13 x 34 x 25mm, 5° lor.	
RI-T15342505	ROCCIA ALIF Trial 15 x 34 x 25mm, 5° lor.	
RI-T17342505	ROCCIA ALIF Trial 17 x 34 x 25mm, 5° lor.	
RI-T13342515	ROCCIA ALIF Trial 13 x 34 x 25mm, 15° lor.	
RI-T15342515	ROCCIA ALIF Trial 15 x 34 x 25mm, 15° lor.	
RI-T17342515	ROCCIA ALIF Trial 17 x 34 x 25mm, 15° lor.	

System:
ROCCIA

Instrument type:
Trial implant


Configuration:
40 mm



Material:
Ti6Al4V ELI

Article number	Description	Illustration
RI-T09403105	ROCCIA ALIF Trial 09 x 40 x 31mm, 5° lor.	
RI-T11403105	ROCCIA ALIF Trial 11 x 40 x 31mm, 5° lor.	
RI-T13403105	ROCCIA ALIF Trial 13 x 40 x 31mm, 5° lor.	
RI-T15403105	ROCCIA ALIF Trial 15 x 40 x 31mm, 5° lor.	
RI-T17403105	ROCCIA ALIF Trial 17 x 40 x 31mm, 5° lor.	
RI-T13403115	ROCCIA ALIF Trial 13 x 40 x 31mm, 15° lor.	
RI-T15403115	ROCCIA ALIF Trial 15 x 40 x 31mm, 15° lor.	
RI-T17403115	ROCCIA ALIF Trial 17 x 40 x 31mm, 15° lor.	

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RI-1210	ROCCIA Paddle Sizer 10 mm		
RI-1211	ROCCIA Paddle Sizer 11 mm		
RI-1212	ROCCIA Paddle Sizer 12 mm		
RI-1213	ROCCIA Paddle Sizer 13 mm		
RI-1215	ROCCIA Paddle Sizer 15 mm		
RI-1217	ROCCIA Paddle Sizer 17 mm		
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ROCCIA® Instruments

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RI-1508	ROCCIA Chisel 8 mm, angled 25°		
RI-1510	ROCCIA Chisel 10 mm, angled 25°		
RI-1706	ROCCIA Chisel 6 mm Angle 25°, reinforced		No image
RI-1708	ROCCIA Chisel 8 mm Angle 25°, reinforced		
RI-1710	ROCCIA Chisel 10 mm Angle 25°, reinforced		
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General Instruments

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