

ROCCIA® TLIF CAGE FOR LUMBAR SPINAL FUSION

INSTRUMENTATION GUIDE



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NOTE: This Guide describes the use of the instrumentation for ROCCIA TLIF – it does not replace briefing by a physician experienced in the 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

ROCCIATLIF® - FOR LUMBAR SPINAL FUSION

The ROCCIA TLIF Cage is an implant for primary stabilization and restoration of physiological lordosis in the lumbar and thoracic spine. The cage is designed for posterior approaches.

The aim is to eliminate discogenic back pain, correct deformities, remedy instabilities, restore intervertebral height, restore physiological lordosis, and provide biomechanical support for bone fusion in the disc space.

The cage must be used with additional stabilization. For posterior lumbar stabilization, Silony Medical recommends the use of a posterior spinal fixator (e.g., the VERTICALE 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 a single instrument. This not only helps to speed up the surgical procedure but also decreases the need for instrument sets which then have to be cleaned and stored in the hospital.





Indications

Implants of the ROCCIA TLIF System are intended for use on the lumbar and thoracolumbar spine for the following indications:

- Degenerative disc diseases
- Deformities
- Segmental dysfunctions of the lumbar or possibly also thoracolumbar spine
- Spondylolisthesis
- Segmental instability
- Stenosis

Contraindications

The most important contraindications include:

- Anticipated or documented allergy or intolerance to the materials (e.g., titanium)
- Any case in which the chosen implants would be too large or too small to achieve a successful result
- Any patient for whom use of the implant would be in conflict with the anatomical structures
- Missing bone structures, which would render stable fixation of the implant impossible (e.g., associated with fractures, tumors, osteoporosis, or infections)

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

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

ACCESS FOR THE ROCCIA® TLIF CAGE

The access for the TLIF Cage is described below

Position and approach

RI-1410* ROCCIA Chisel 10 mm, Width reinforced

The patient is positioned in the prone position, as is common for the posterior approach. Exposing the abdomen helps decrease the load on the abdominal vessels. Corresponding bearing frames or padding underneath the pelvis and thorax can be used for this purpose. The main incision is usually performed medially above the spinous processes depending on the spinal segments being treated. The spinal erector muscles are then displaced strictly subperiosteally and dissected until the anatomical structures of the spinal column are clearly exposed.

The transforaminal approach to the disc space is usually achieved by unilateral resection of the facet joint on the approach side (Fig. 1). The 6, 8, or 10 mm ROCCIA Chisels can be used for this as well as standard instruments such as Luer forceps and rongeurs.

* Representative of other chisels see ROCCIA Instruments

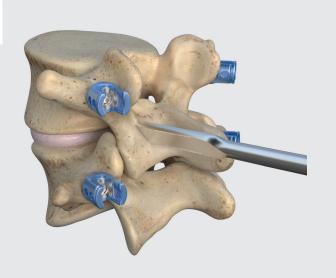


Fig 1 Resection of a facet joint with the chisel in the TLIF approach

ROCCIA® TLIF CAGE INSTRUMENTATION

The ROCCIA TLIF has been designed for transforaminal approaches, therefore the following instrumentation steps apply to both the preparation of the implant bed and the implantation of the intervertebral disc space of the aforementioned approache and surgical technique.

Discectomy

T-Handle

RI-1020* ROCCIA Ring Endplate Scraper Straight RI-1040** ROCCIA Curette Straight RI-1107*** ROCCIA Shaver, 7 mm GI-3101****

To begin with, the disc is incised with a standard scalpel. The disc material is loosened with the aid of shavers and then removed with the aid of various grippers, curettes and sharp spoons (Figs. 2 and 3). The fibrous ring is opened up in the process, and the nucleus and the inner fibrous ring are then removed and the surfaces of the endplates are roughened in order to prepare a spacious cage bed.

Various angled and curved 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

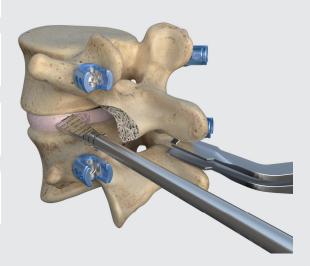


Fig. 2 Loosening of the disc material with a shaver

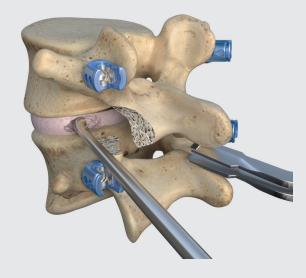
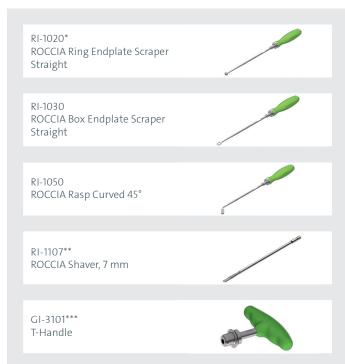


Abb. 3 Discectomy using a curette

NOTE: ROCCIA Shavers are only suitable for mobilizing the disc and preparing the superior endplates. They must not be used for distraction.

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

Preparing the disc space



For more extensive curettage, the ROCCIA Box Endplate Scraper is also provided (Fig. 4). The surface of the remaining cartilaginous layer of the inferior and superior endplates can be roughened with bone rasps, curettes, and shavers (Fig. 5).

The curved endplate scrapers in particular also facilitate the preparation of the opposite side when using the transforaminal approach.

- * 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

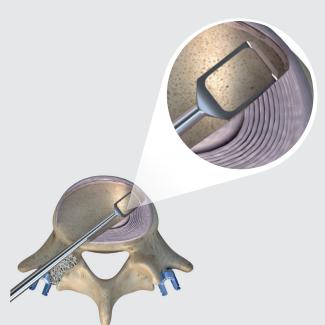


Fig. 4 Box endplate scraper for extensive removal of disc material

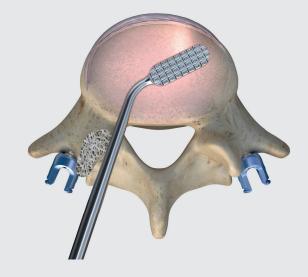


Fig. 5: Rasp for roughening the superior endplate

NOTE: Careful preparation of the disc space, especially extensive roughening of the endplates, provides the basis for better vascularization and successful bone fusion. Damage to the bony inferior and superior endplate 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 Paddle Sizers are available for distraction. They start at a height of 7 mm and increase in 1-mm increments up to a height of 13 mm; after that, the height increases in steps of 2 mm. At the distal end of the paddle sizers, there are depth markings between 20 and 60 mm in 5-mm increments (Fig. 7).

The distractors are connected to a T-handle via the quick-release coupling. For better orientation, the handle ends are aligned in the same way as the end of the paddle shavers. Two T-handles are available in the set to enable rapid instrumentation.

To perform the distraction, a blunt paddle sizer adjusted to the size of the disc space is first inserted into the disc space flat and then positioned by rotating by 90° (Fig. 7). The next paddle sizers are inserted in ascending order using the same movement until the desired height is achieved. The appropriate distraction height is reached when the distractor is under tension and conveys a stable feeling. Standard lamina spreader forceps can additionally be used for distrac-

- Representative of other distractor sizes see ROCCIA Instruments
- Representative of other T-handles see General instruments



Fig. 6 Depth marking on the paddle sizer

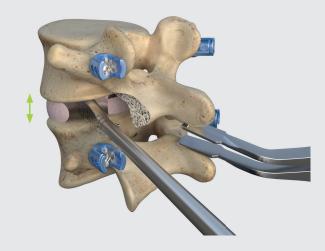


Fig. 7 Spreading the disc space with the paddle sizer

NOTE: Overdistraction should be avoided. This increases the risk of damage to the inferior and superior endplates and subsequent sinking of the implant and jeopardizes the restoration of physiological lordosis.

Selecting the trial implant



Blunt paddle sizers with depth markings between 20 and 60 mm in 5-mm increments are available to determine the size of the disc space. With heights of 7–13 mm (1-mm increments) as well as 15 mm and 17 mm, they correspond to the size of the later implant. Trial implants can be selected on the basis of these measurements and under image converter control (Fig. 8).

An appropriate trial implant with 5° or 15° lordosis is available for each definitive cage size. The trial implants are colormarked analogously to the implants to be implanted later on. The color marking additionally facilitates the identification of the matching inserter, which has correspondingly colored rings on the instrument stem.

- Representative of other distractor sizes, see ROCCIA Instruments
- ** Representative of other T-handles see General instruments



Fig. 8 Image converter control with paddle sizer for selection of the trial implant

Determining the cage sizes with the trial implants

RI-1324 ROCCIA Inserter M4, dismountable



RI-T11341205* ROCCIA TLIF Trial 11 x 34 x 12 mm 5°



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 completely onto the respective ROCCIA Inserter and then, applying gentle pressure, carefully inserted through the transforaminal window into the intervertebral space (Fig. 9). At the surgeon's discretion a mallet can also be used to insert the trial. After that, the position and size of the trial implant is verified in the image converter.

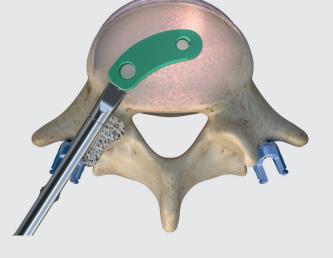


Fig. 9 Introducing the trial implant

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 in 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 smaller size has to be used or the segment has to be distracted further using the aforementioned instruments. Once the correct size has been determined, the distraction can be temporarily loosened.

Representative of other trial implant sizes see ROCCIA Trial Implants

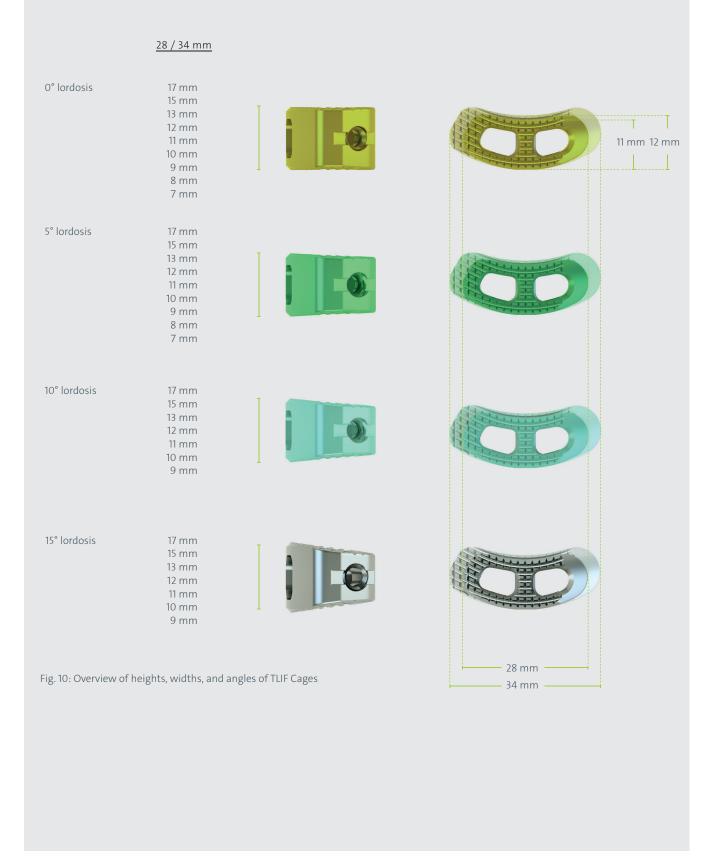
NOTE: Correctly selecting the cage size has a decisive impact on the success of the instrumentation and fusion.

NOTE: The height of the trial implant matches the height of the final ROCCIA TLIF Implant including the

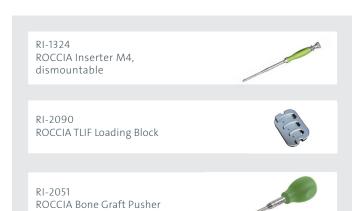
Multitude of cage sizes

To optimize the treatment of the patient in terms of anatomy and pathology, a wide range of ROCCIA TLIF sizes is available (Fig. 10). The portfolio comprises nine anterior heights (from 7 to 13 mm, in 1 mm increments, and heights of 15 mm and 17 mm) and two widths (28 and 34 mm). In addition to the regular lordotic angles of 0°, 5°, and 10°, hyperlordotic cages with an angle of 15° are also available.

The inserter with the particular color code corresponds to the respective cage.



Filling of the cage



Remaining areas of the intervertebral disc space can be filled with autologous bone (e.g., from the iliac crest), with homologous bone (foreign cancellous bone) or with bone graft material either before or after implantation of the cage in order to achieve the largest possible fusion surface area. The bone material must be inserted well compressed into the cage. 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. 11).

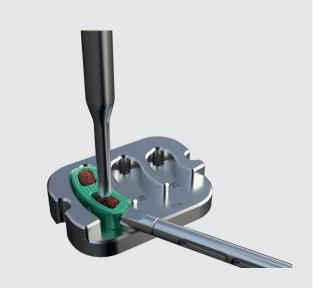


Fig. 11 Filling the cage with bone material in the loading block with pusher

Inserting the cage

RI-1324 ROCCIA Inserter M4, dismountable



RI-1355 ROCCIA Slotted Mallet, solid



The ROCCIA Inserter, which is used in the same way as previously for the trial implants, is screwed completely into the threaded holes of the cage, enabling the cage to be definitively inserted without requiring any further instrument change (Fig. 12).

The implant should be inserted promptly after removal of the trial to prevent subsequent sinking. The filled implant is carefully inserted into the disc space and the correct alignment of the implant is verified. Slight pressure or careful hammering with the ROCCIA Slotted Mallet on the inserter may be required.

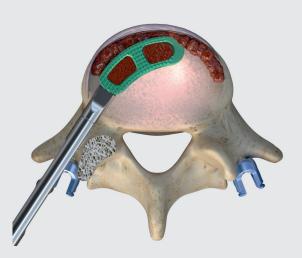


Fig. 12 Inserting the filled cage into the disc space

Correct position of the ROCCIA® TLIF Cage

If possible, when using the TLIF approach, the ROCCIA Inserter is left inside the cage until an AP image and a lateral image with the image converter confirm the correct position of the cage.

For biomechanical reasons, the optimal position of the implanted ROCCIA TLIF Cage should be in the anterior to central third of the disc space, centered as far as possible in the frontal projection (guided by the spinous processes or pedicles, Figs. 13 and 14).

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.

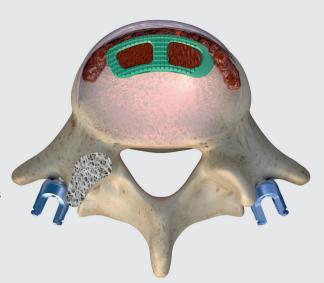


Fig. 13 Optimal position of the filled TLIF Cage

NOTE: Posterior tension band wiring with the VERTICALE Posterior Spinal Fixator is recommended. Tension band wiring supports the biomechanical stability of the motion segment and the stability of the TLIF 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.

NOTE: When implanting a TLIF Cage with 15° lordosis, it is also imperative to stabilize the segment using a fixation system or anterior plating.

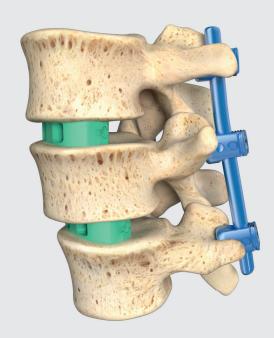
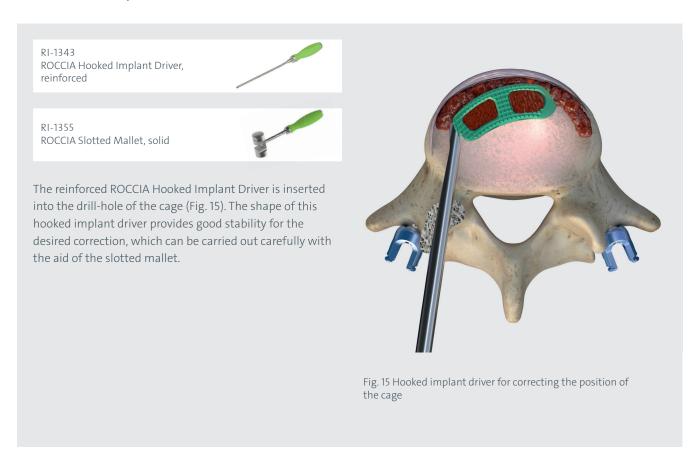


Fig. 14 Optimal position of the filled TLIF Cage including posterior fixation

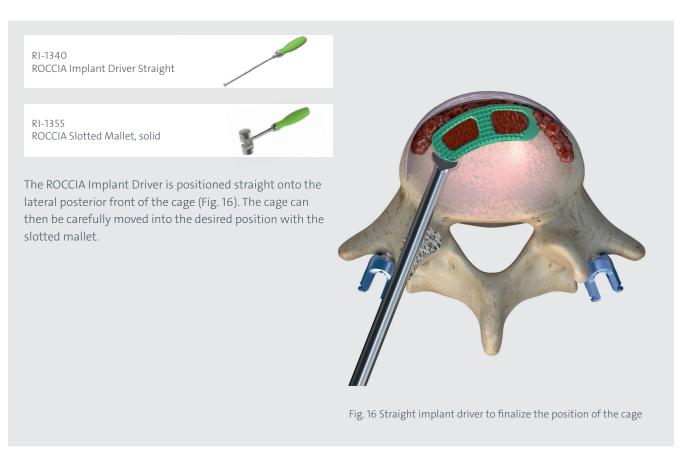
POSITION CORRECTION OF THE ROCCIA TLIF CAGE

A straight implant driver and a hooked implant driver are provided for definitive positioning of the ROCCIA TLIF Cage. The use of these instruments is outlined below.

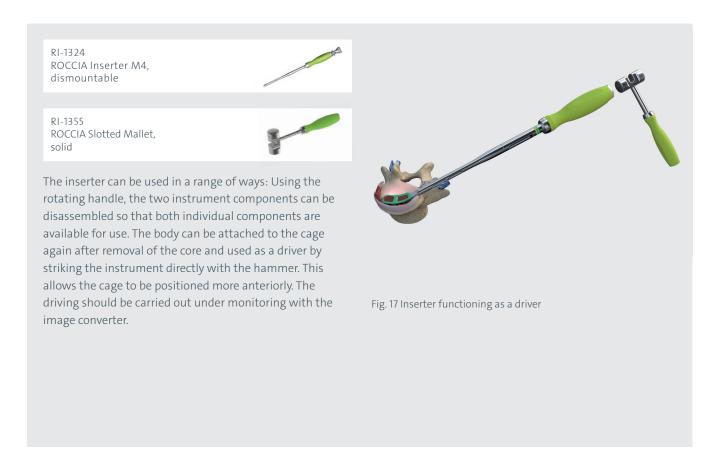
Hooked implant driver



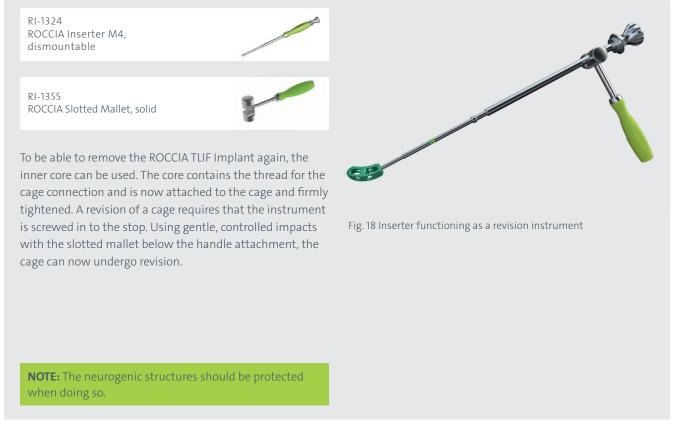
Implant Driver Straight



Inserter as a driver



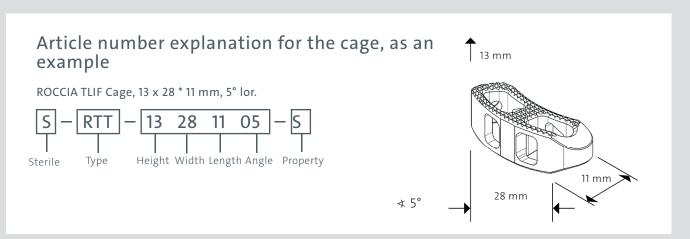
Inserter as a revision instrument



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ROCCIA® TLIF Implants





System: ROCCIA

Implant type:

Configuration: 28 mm

ROCCIA® TLIF Implants

System: ROCCIA

Implant type: TLIF

Configuration: 28 mm

Material: Ti6Al4V ELI

Article number	Description	Illustration
S-RTT09281115-S	ROCCIA TLIF Cage 9 x 28 x 11 mm, 15° lor.	
S-RTT10281115-S	ROCCIA TLIF Cage 10 x 28 x 11 mm, 15° lor.	
S-RTT11281115-S	ROCCIA TLIF Cage 11 x 28 x 11 mm, 15° lor.	
S-RTT12281115-S	ROCCIA TLIF Cage 12 x 28 x 11 mm, 15° lor.	
S-RTT13281115-S	ROCCIA TLIF Cage 13 x 28 x 11 mm, 15° lor.	
S-RTT15281115-S	ROCCIA TLIF Cage 15 x 28 x 11 mm, 15° lor.	
S-RTT17281115-S	ROCCIA TLIF Cage 17 x28 x 11 mm, 15° lor.	

System: ROCCIA

Implant type: TLIF

Configuration: 34 mm

Article number	Description	Illustration
S-RTT-08341200-S	ROCCIA TLIF Cage 8 x 34 x 12 mm, 0° lor.	
S-RTT-09341200-S	ROCCIA TLIF Cage 9 x 34 x 12 mm, 0° lor.	
S-RTT-10341200-S	ROCCIA TLIF Cage 10 x 34 x 12 mm, 0° lor.	The state of the s
S-RTT-11341200-S	ROCCIA TLIF Cage 11 x 34 x 12 mm, 0° lor.	
S-RTT-12341200-S	ROCCIA TLIF Cage 12 x 34 x 12 mm, 0° lor.	
S-RTT-13341200-S	ROCCIA TLIF Cage 13 x 34 x 12 mm, 0° lor.	
S-RTT-15341200-S	ROCCIA TLIF Cage 15 x 34 x 12 mm, 0° lor.	
S-RTT-17341200-S	ROCCIA TLIF Cage 17 x 34 x 12 mm, 0° lor.	
S-RTT-07341205-S	ROCCIA TLIF Cage 7 x 34 x 12 mm, 5° lor.	
S-RTT-08341205-S	ROCCIA TLIF Cage 8 x 34 x 12 mm, 5° lor.	
S-RTT-09341205-S	ROCCIA TLIF Cage 9 x 34 x 12 mm, 5° lor.	
S-RTT-10341205-S	ROCCIA TLIF Cage 10 x 34 x 12 mm, 5° lor.	
S-RTT-11341205-S	ROCCIA TLIF Cage 11 x 34 x 12 mm, 5° lor.	
S-RTT-12341205-S	ROCCIA TLIF Cage 12 x 34 x 12 mm, 5° lor.	
S-RTT-13341205-S	ROCCIA TLIF Cage 13 x 34 x 12 mm, 5° lor.	
S-RTT-15341205-S	ROCCIA TLIF Cage 15 x 34 x 12 mm, 5° lor.	
S-RTT-17341205-S	ROCCIA TLIF Cage 17 x 34 x 12 mm, 5° lor.	
S-RTT-09341210-S	ROCCIA TLIF Cage 9 x 34 x 12 mm, 10° lor.	
S-RTT-10341210-S	ROCCIA TLIF Cage 10 x 34 x 12 mm, 10° lor.	
S-RTT-11341210-S	ROCCIA TLIF Cage 11 x 34 x 12 mm, 10° lor.	
S-RTT-12341210-S	ROCCIA TLIF Cage 12 x 34 x 12 mm, 10° lor.	
S-RTT-13341210-S	ROCCIA TLIF Cage 13 x 34 x 12 mm, 10° lor.	
S-RTT-15341210-S	ROCCIA TLIF Cage 15 x 34 x 12 mm, 10° lor.	
S-RTT-17341210-S	ROCCIA TLIF Cage 17 x34 x 12 mm, 10° lor.	

ROCCIA® TLIF Implants

Article number	Description	Illustration
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S-RTT10341215-S	ROCCIA TLIF Cage 10 x 34 x 12 mm, 15° lor.	
S-RTT11341215-S	ROCCIA TLIF Cage 11 x 34 x 12 mm, 15° lor.	
S-RTT12341215-S	ROCCIA TLIF Cage 12 x 34 x 12 mm, 15° lor.	
S-RTT13341215-S	ROCCIA TLIF Cage 13 x 34 x 12 mm, 15° lor.	
S-RTT15341215-S	ROCCIA TLIF Cage 15 x 34 x 12 mm, 15° lor.	
S-RTT17341215-S	ROCCIA TLIF Cage 17 x 34 x 12 mm, 15° lor.	

System: ROCCIA

Implant type: TLIF

Configuration: 34 mm

ROCCIA® TLIF Trial Implants

System: ROCCIA

Instrument type: Trial implant

Configuration: 28 mm

Material: Ti6Al4V ELI

Article number	Description	Illustration
RI-T07281105	ROCCIA TLIF Trial 7 x 28 x 11 mm, 5° lor.	
RI-T08281105	ROCCIA TLIF Trial 8 x 28 x 11 mm, 5° lor.	
RI-T09281105	ROCCIA TLIF Trial 9 x 28 x 11 mm, 5° lor.	
RI-T10281105	ROCCIA TLIF Trial 10 x 28 x 11 mm, 5° lor.	
RI-T11281105	ROCCIA TLIF Trial 11 x 28 x 11 mm, 5° lor.	
RI-T12281105	ROCCIA TLIF Trial 12 x 28 x 11 mm, 5° lor.	
RI-T13281105	ROCCIA TLIF Trial 13 x 28 x 11 mm, 5° lor.	
RI-T15281105	ROCCIA TLIF Trial 15 x 28 x 11 mm, 5° lor.	
RI-T17281105	ROCCIA TLIF Trial 17 x 28 x 11 mm, 5° lor.	
RI-T09281115	ROCCIA TLIF Trial 9 x 28 x 11 mm, 15° lor.	
RI-T10281115	ROCCIA TLIF Trial 10 x 28 x 11 mm, 15° lor.	
RI-T11281115	ROCCIA TLIF Trial 11 x 28 x 11 mm, 15° lor.	0
RI-T12281115	ROCCIA TLIF Trial 12 x 28 x 11 mm, 15° lor.	
RI-T13281115	ROCCIA TLIF Trial 13 x 28 x 11 mm, 15° lor.	
RI-T15281115	ROCCIA TLIF Trial 15 x 28 x 11 mm, 15° lor.	
RI-T17281115	ROCCIA TLIF Trial 17 x 28 x 11 mm, 15° lor.	

System: ROCCIA

Instrument type: Trial implant

Configuration: 34 mm

Article number	Description	Illustration
RI-T07341205	ROCCIA TLIF Trial 7 x 34 x 12 mm, 5° lor.	
RI-T08341205	ROCCIA TLIF Trial 8 x 34 x 12 mm, 5° lor.	
RI-T09341205	ROCCIA TLIF Trial 9 x 34 x 12 mm, 5° lor.	
RI-T10341205	ROCCIA TLIF Trial $10 \times 34 \times 12$ mm, 5° lor.	
RI-T11341205	ROCCIA TLIF Trial 11 x 34 x 12 mm, 5° lor.	
RI-T12341205	ROCCIA TLIF Trial 12 x 34 x 12 mm, 5° lor.	
RI-T13341205	ROCCIA TLIF Trial 13 x 34 x 12 mm, 5° lor.	
RI-T15341205	ROCCIA TLIF Trial 15 x 34 x 12 mm, 5° lor.	
RI-T17341205	ROCCIA TLIF Trial 17 x 34 x 12 mm, 5° lor.	
RI-T09341215	ROCCIA TLIF Trial 9 x 34 x 12 mm, 15° lor.	
RI-T10341215	ROCCIA TLIF Trial 10 × 34 × 12 mm, 15° lor.	
RI-T11341215	ROCCIA TLIF Trial 11 x 34 x 12 mm, 15° lor.	
RI-T12341215	ROCCIA TLIF Trial 12 x 34 x 12 mm, 15° lor.	
RI-T13341215	ROCCIA TLIF Trial 13 x 34 x 12 mm, 15° lor.	
RI-T15341215	ROCCIA TLIF Trial 15 x 34 x 12 mm, 15° lor.	
RI-T17341215	ROCCIA TLIF Trial 17 x 34 x 12 mm, 15° lor.	

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General Instruments

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