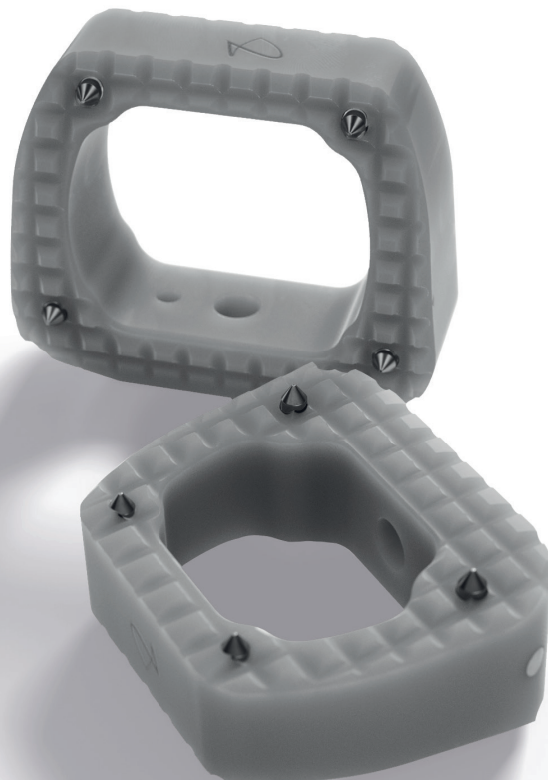


ROCCIA[®] ACIF ANTERIOR CERVICAL INTERBODY FUSION

INSTRUMENTATION GUIDE



MADE IN GERMANY

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NOTE: This guide describes the use of ROCCIA® ACIF for anterior cervical instrumentation. It does not replace briefing by a surgeon 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[®] ACIF – ANTERIOR CERVICAL INTERBODY FUSION

ROCCIA ACIF was developed for primary stabilization and restoration of the physiological lordosis in the cervical spine. The cage is designed for anterior approaches.

The chamber system in the cage improves interbody fusion, as its generously proportioned design allows for the insertion of either bone or bone graft materials. At the same time, the cage has a broad supporting surface that largely prevents sinking when implanted correctly.

The broad portfolio, with different heights, supporting surfaces, and shapes, allows individual selection of the implant based on the patient's anatomy.

Pins anchored in the cage allow good visualization of the correct position of the implant in the image intensifier and aid primary stability.

An intuitive instrument set with only a few surgical steps enables easy and efficient insertion of the cage. The cage is supplied sterile, which offers you additional user comfort.





Indications

The ROCCIA ACIF is indicated for intervertebral body fusion of the spine in skeletally mature patients. The ROCCIA ACIF is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) at up to two contiguous levels from C2 -T1. The System is intended to be used with supplemental fixation; the ROCCIA ACIF device is required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

Contraindications

Contraindications include but are not limited to:

- infection, local on the operative site
- Signs of local inflammation
- anticipated or documented allergy or intolerance to composite materials
- Patients who are unwilling to limit their activity or follow medical advice
- Patients with inadequate bone structure or bone quality
- Patients with physical or medical conditions that would prohibit a beneficial surgical outcome
- Patient for whom the use of the implant would be in conflict with anatomical structures
- Any case in which the chosen implants would be too large or too small to achieve a successful result
- Use with components from other systems
- Reusable or multiple uses
- Resterilization of the implants

NOTE: Please also note the indications and contraindications in the instructions for use for ROCCIA ACIF. The instructions also contain other important information that might lead to exclusion of the patient.

ROCCIA® ACIF INSTRUMENTATION

The following section describes each of the steps required when using the ROCCIA ACIF for anterior cervical interbody fusion. Using ROCCIA ACIF, both monosegmental and bisegmental treatments can be carried out in accordance with this instrumentation guide.

Instrumentation of ACIF – Position, Approach and Distraction

The patient is placed in a supine position. The head should be positioned in a stable fashion and in a slightly reclined position. When positioning the patient, care should be taken to ensure that the target segment can be clearly depicted during fluoroscopy, both laterally and in A-P projection.

The approach is carried out with the customary procedure used in anterior cervical surgery. Standard retractors (e.g. Caspar retractor) support the direct and complete exposure of the target segment (Fig. 1 and 2).

In order to facilitate the implantation of the ROCCIA ACIF Cage, good exposure and distraction is recommended. To accomplish this, superior and inferior distraction pins should be set in parallel to the corresponding end plates of the target segment. The distractor can then be mounted.

Distractors of this type have supportive functions:

- Distraction of the target segment
- Stability of the target segment throughout the entire surgical procedure
- Parallel alignment of the vertebrae

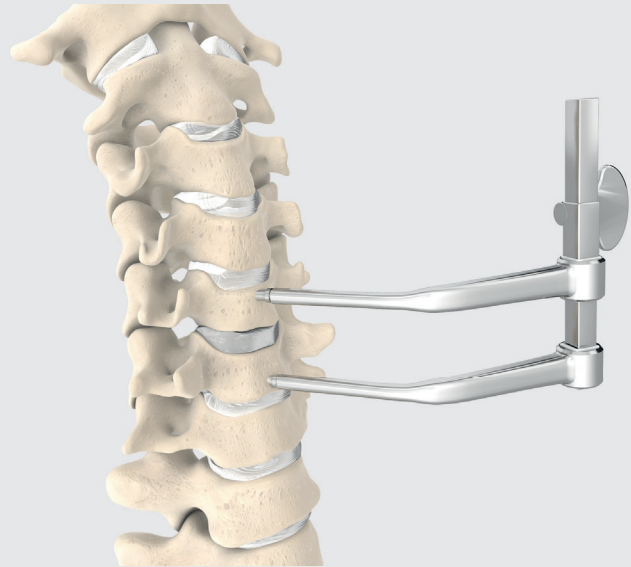


Fig. 1 Exposure of the target segment using standard retractors

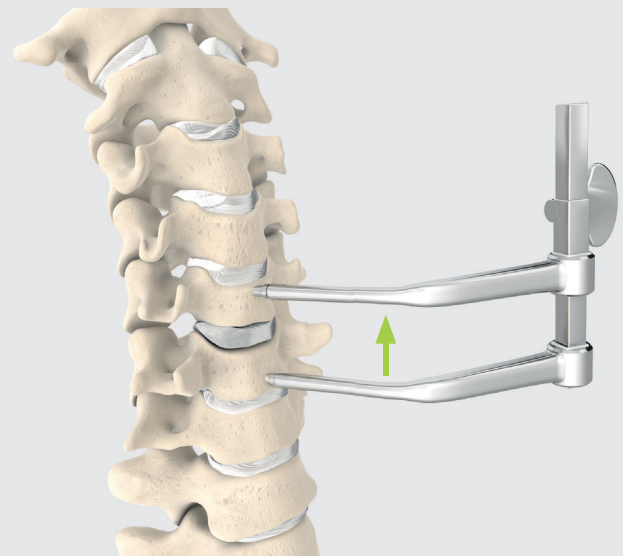


Fig. 2 Exposure of the target segment by spreading the retractor

Discectomy and Decompression

The cervical intervertebral disc must be removed completely (Fig. 3). Box-shaped resection of the anterior longitudinal ligament must therefore be undertaken first. Discectomy is performed as usual.

The cartilage on the end plates should be removed thoroughly until the end plates start to bleed slightly. When doing so, care should be taken to ensure that the end plates are not weakened. This ensures a sufficient supporting surface and stability for implantation of the ROCCIA ACIF Cage.

The neural structures are decompressed using punches or high-speed milling cutters. In order to achieve good access to the target segment for implantation, anterior osteophytes or other bone changes must also be removed if necessary.

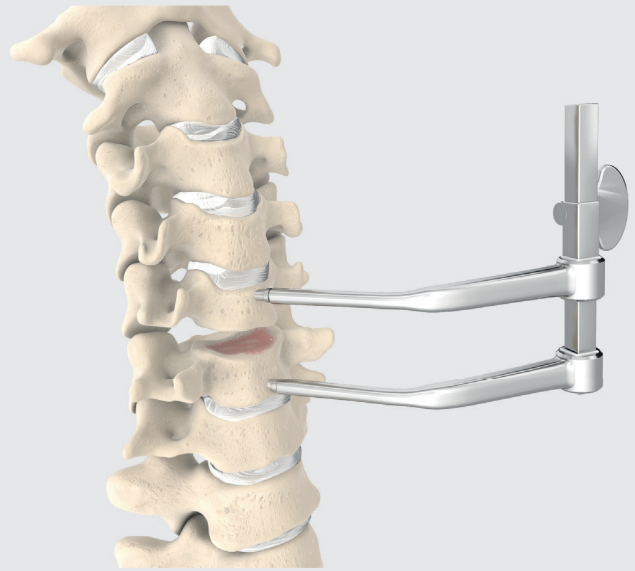


Fig. 3 Complete removal of the cervical intervertebral disc

NOTE: Careful preparation of the disc space, in particular extensive cleaning of the end plates, provides the basis for better vascularization and successful bony fusion. Damage to the bony base and cover plate can cause the implant to sink into the vertebral body.

Selecting the Trial Implant

RI-8010*
ROCCIA ACIF Inserter, dismountable



RI-8050
ROCCIA ACIF Depth Stop, lat. large



RI-T06161351**
ROCCIA ACIF Trial 6×16×13 mm, anatomic



The ROCCIA ACIF Cage System offers a broad selection of different lengths, widths, angles and anatomic shapes, each with 5° lordosis. This extensive portfolio enables individual customization to different patient anatomies and intra-operative requirements.

With the ROCCIA ACIF Trial implant, you can determine the implant to be used according to the individual anatomic situation. With the aid of the trial implant, you define the length, width and height, and at the same time check which anatomic shape is suitable for the situation.

First, the insertion instrument must be assembled (Fig. 4). To do so, the shaft is inserted into the sleeve completely and screwed on tightly. The depth stop is then attached onto the instrument (Fig. 4). The depth stop can be removed and re-attached without removing the trial implant.

* Representative for other inserters, see ROCCIA instruments

** Representative for other trial implant sizes, see ROCCIA ACIF Trial implants

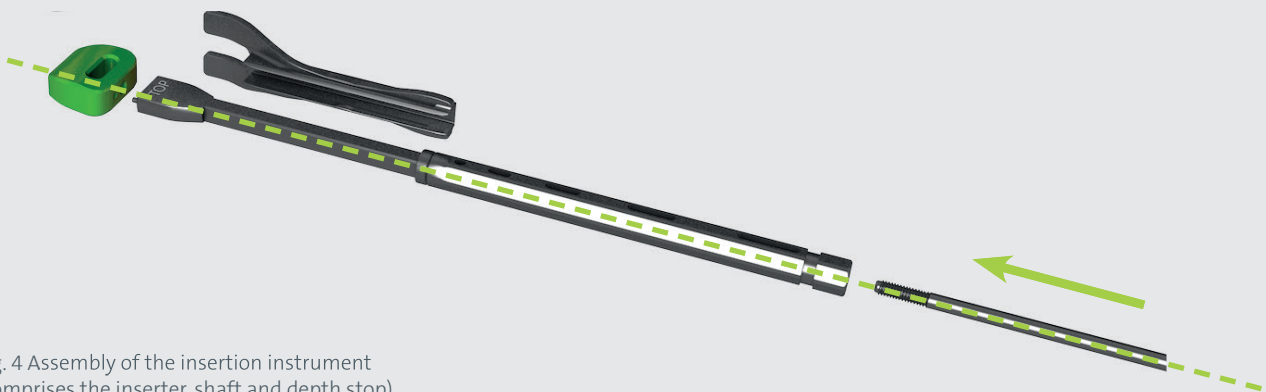


Fig. 4 Assembly of the insertion instrument (comprises the inserter, shaft and depth stop)

Selecting the Trial Implant

RI-8010*
ROCCIA ACIF Inserter, dismountable



RI-8050
ROCCIA ACIF Depth Stop, lat. large



RI-T06161351**
ROCCIA ACIF Trial 6×16×13 mm, anatomic



The required trial implant is screwed onto the inserter (Fig. 5) and inserted into the intervertebral space under lateral X-ray control (Fig. 6 and 7). If anatomically shaped trials are used, the convex end plate must always face in the superior direction. The label "TOP" on the inserter must face in the superior direction when inserting the trial (Fig. 6, inset).

Silony Medical recommends using an implant that is as wide as possible to achieve a large contact surface and to ensure support on the anterior and posterior cortical region of the end plates.

To determine the height, it is important to make sure that the implant is neither too tight nor too loose. Accordingly, try out a smaller or larger version until the trial implant is seated in a stable fashion in the intersegmental space. When doing so, you should, if necessary, undo the distractor if you are using one, in order to get a feel for the primary stability of the implant.

* Representative for other inserters, see ROCCIA instruments

** Representative for other trial implant sizes, see ROCCIA ACIF Trial implants

NOTE: The external dimension of the trial implant corresponds to the core dimension of the implant without the interlock or the X-ray marker.

NOTE: The trial implant is also used to simulate insertion of the implant into its final position. If the trial implant cannot be brought into the required end position, then it may be necessary to prepare the intervertebral disc space again.

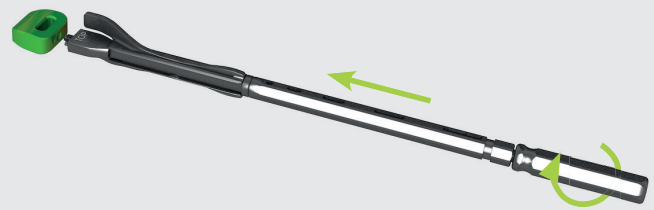


Fig. 5 Mounting the trial implant on the inserter

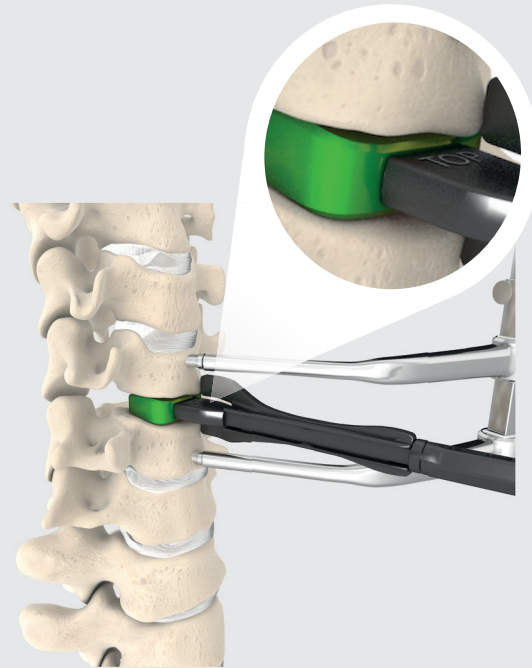


Fig. 6 Introducing the trial implant

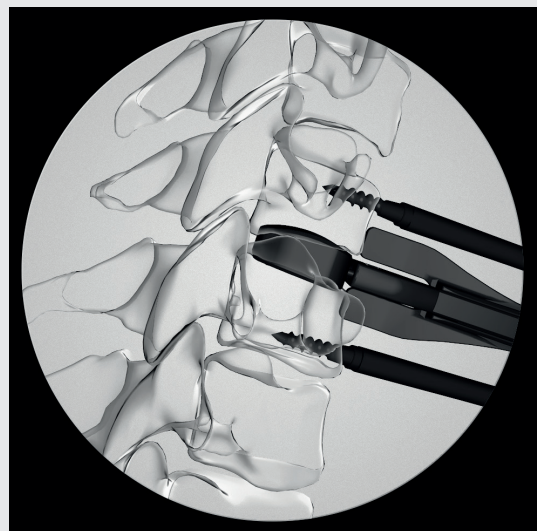


Fig. 7 X-ray control during insertion of the trial implant

Filling the ROCCIA ACIF Cage

RI-2060
ROCCIA ACIF Loading Block



RI-2061
ROCCIA ACIF Bone Graft Pusher



RI-8010*
ROCCIA ACIF Inserter, dismountable

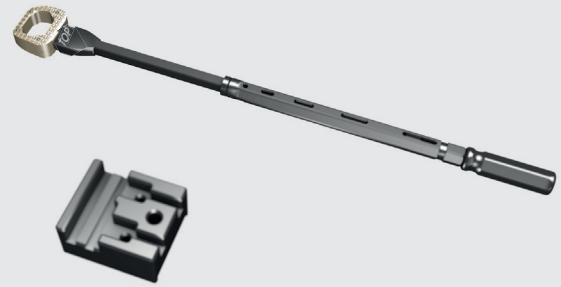


Fig. 8 Mounting the cage on the inserter

The selected ROCCIA ACIF Cage is screwed onto the previously assembled ROCCIA Inserter (Fig. 8). The inserter must not be screwed too tightly onto the cage. When doing so, the depth stop can be left on the instrument.

Cage filling with autologous and/or allogeneic bone graft is an important precondition for reliable fusion. A loading block and a pusher are provided for this purpose (Fig. 9). The color rings on the pusher correspond to the color of the previously used trial implant. The pusher surface is adjusted to the corresponding cage footprint. The alignment of the pusher corresponding to the graduation markings on the pusher must be noted on the loading block for this purpose (Fig. 9, zoom). The graduation marking indicates the posterior side of the cage.

* Representative for other inserters, see ROCCIA instruments

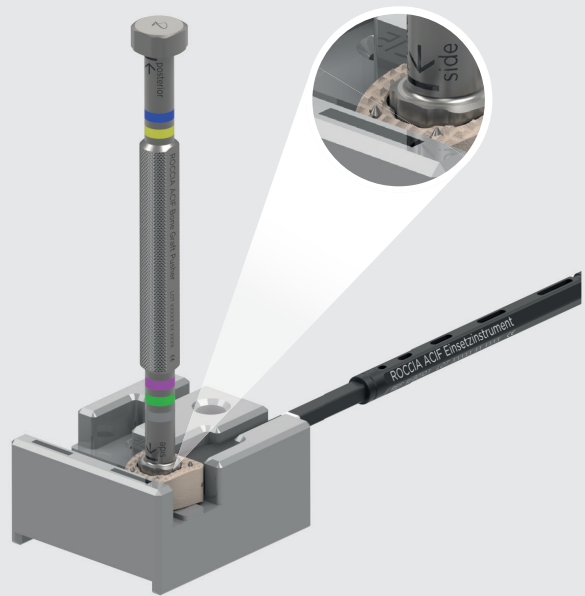


Fig. 9 Filling the cage with bone material in the loading block with a pusher

Inserting the ROCCIA ACIF Cage

RI-8010*
ROCCIA ACIF Inserter, dismountable



RI-8050
ROCCIA ACIF Depth Stop, lat. large



RI-8060
ROCCIA Driving Mallet, small



Check the superior and inferior alignment of the cage. If anatomically shaped cages are used, the convex end plate must always face in the superior direction. The label "TOP" on the inserter must face in the superior direction when inserting the cage (Fig. 10, zoom).

The cage is inserted into the disc space under X-ray control (Fig. 10).

The depth stop on the inserter prevents the implant from being inserted too deeply.

A small driving mallet is available to make insertion of the cage easier.

* Representative for other inserters, see ROCCIA instruments

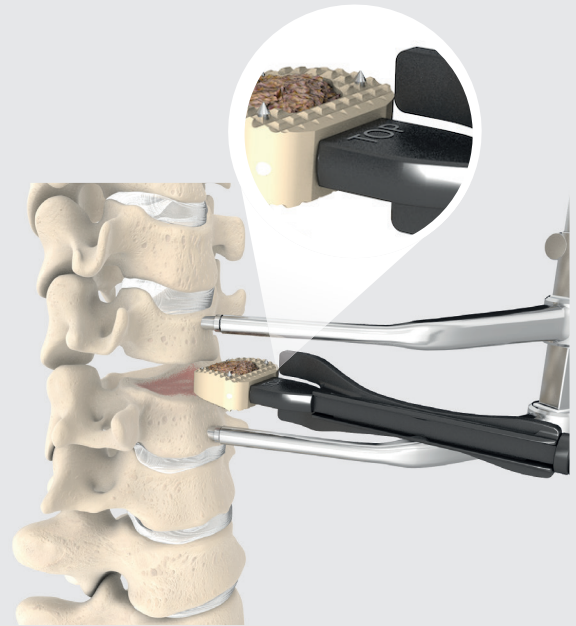


Fig. 10 Inserting the cage

NOTE: The trial implant has a smooth surface. Because of the serration used for anchorage, the cage has a rough surface. This means that greater force may be required to insert the cage. If surgical intervention is carried out with the aid of a distractor, then it is advisable to slightly increase the distraction in order to reduce the forces required to insert the cage. After complete implantation, this distraction should immediately be loosened again.

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

Removing the Instrument Set

The final position of the implant (Fig. 11) should be checked using the image intensifier (lateral and anterior-posterior view). When doing so, X-ray markers in the implant show the position of the cage.

After the final position has been confirmed using the image intensifier, the inserter is unscrewed completely from the implant and removed (Fig. 12 and 13). No force must be exerted to withdraw the inserter from the implant. Should resistance nevertheless be felt, check whether the inserter has been unscrewed completely. If necessary, this process must be repeated. Make sure that the final position of the implant is not altered when the inserter is removed.

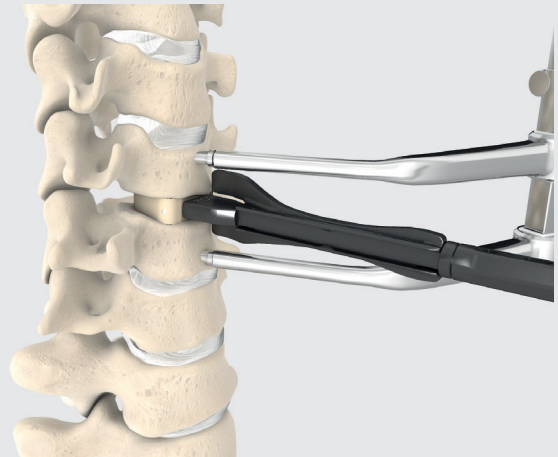


Fig. 11 Final position of the cage

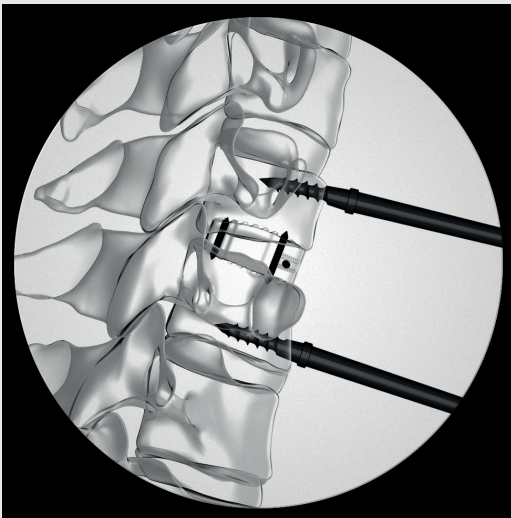


Fig. 12 X-ray examination, lateral

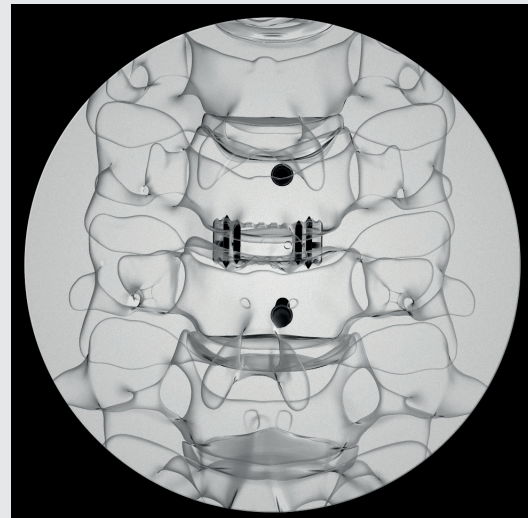


Fig. 13 X-ray examination, anterior-posterior

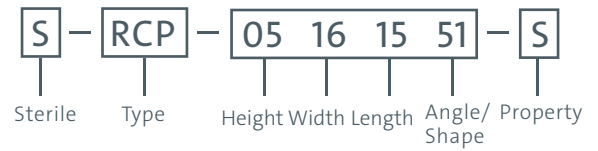
ROCCIA® ACIF IMPLANTS PRODUCT INFORMATION

ROCCIA ACIF Anatomic Implants by Article Number	PI 02
ROCCIA ACIF Trial Implants, Anatomic by Article Number	PI 03
ROCCIA ACIF Wedge-shaped Implants by Article Number	PI 04
ROCCIA ACIF Trial Implants, Wedge-Shaped by Article Number	PI 05
ROCCIA ACIF Instruments by Article Number	PI 06
ROCCIA ACIF Index	PI 07

ROCCIA® ACIF Implants

Explanation of Cage Article Number

ROCCIA ACIF Cage, 5×16×15 mm, anatomic



System:
ROCCIA

Implant Type:
ACIF

Configuration:
anatomic

Material:
PEEK
Ti6Al4V ELI (X-ray marker)

Article Number	Description	Illustration
S-RCP-04141351-S	ROCCIA ACIF Cage, 4×14×13 mm, anatomic	
S-RCP-05141351-S	ROCCIA ACIF Cage, 5×14×13 mm, anatomic	
S-RCP-06141351-S	ROCCIA ACIF Cage, 6×14×13 mm, anatomic	
S-RCP-07141351-S	ROCCIA ACIF Cage, 7×14×13 mm, anatomic	
S-RCP-08141351-S	ROCCIA ACIF Cage, 8×14×13 mm, anatomic	
S-RCP-04161351-S	ROCCIA ACIF Cage, 4×16×13 mm, anatomic	
S-RCP-05161351-S	ROCCIA ACIF Cage, 5×16×13 mm, anatomic	
S-RCP-06161351-S	ROCCIA ACIF Cage, 6×16×13 mm, anatomic	
S-RCP-07161351-S	ROCCIA ACIF Cage, 7×16×13 mm, anatomic	
S-RCP-08161351-S	ROCCIA ACIF Cage, 8×16×13 mm, anatomic	
S-RCP-04161551-S	ROCCIA ACIF Cage, 4×16×15 mm, anatomic	
S-RCP-05161551-S	ROCCIA ACIF Cage, 5×16×15 mm, anatomic	
S-RCP-06161551-S	ROCCIA ACIF Cage, 6×16×15 mm, anatomic	
S-RCP-07161551-S	ROCCIA ACIF Cage, 7×16×15 mm, anatomic	
S-RCP-08161551-S	ROCCIA ACIF Cage, 8×16×15 mm, anatomic	
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S-RCP-06181351-S	ROCCIA ACIF Cage, 6×18×13 mm, anatomic	
S-RCP-07181351-S	ROCCIA ACIF Cage, 7×18×13 mm, anatomic	
S-RCP-08181351-S	ROCCIA ACIF Cage, 8×18×13 mm, anatomic	
S-RCP-04181551-S	ROCCIA ACIF Cage, 4×18×15 mm, anatomic	
S-RCP-05181551-S	ROCCIA ACIF Cage, 5×18×15 mm, anatomic	
S-RCP-06181551-S	ROCCIA ACIF Cage, 6×18×15 mm, anatomic	
S-RCP-07181551-S	ROCCIA ACIF Cage, 7×18×15 mm, anatomic	
S-RCP-08181551-S	ROCCIA ACIF Cage, 8×18×15 mm, anatomic	

ROCCIA® ACIF Trial Implants

rs (Example)

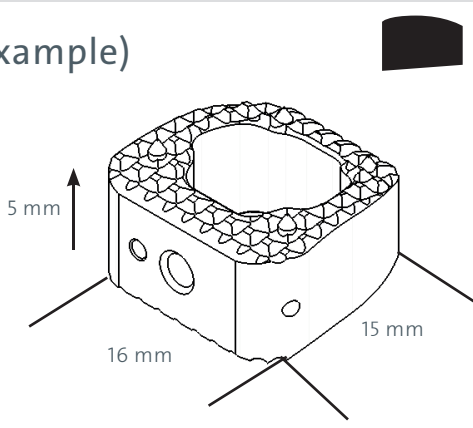


Illustration	Description	Article Number
	ROCCIA ACIF Trial 4×14×13 mm, anatomic	RI-T04141351
	ROCCIA ACIF Trial 5×14×13 mm, anatomic	RI-T05141351
	ROCCIA ACIF Trial 6×14×13 mm, anatomic	RI-T06141351
	ROCCIA ACIF Trial 7×14×13 mm, anatomic	RI-T07141351
	ROCCIA ACIF Trial 8×14×13 mm, anatomic	RI-T08141351
	ROCCIA ACIF Trial 4×16×13 mm, anatomic	RI-T04161351
	ROCCIA ACIF Trial 5×16×13 mm, anatomic	RI-T05161351
	ROCCIA ACIF Trial 6×16×13 mm, anatomic	RI-T06161351
	ROCCIA ACIF Trial 7×16×13 mm, anatomic	RI-T07161351
	ROCCIA ACIF Trial 8×16×13 mm, anatomic	RI-T08161351
	ROCCIA ACIF Trial 4×16×15 mm, anatomic	RI-T04161551
	ROCCIA ACIF Trial 5×16×15 mm, anatomic	RI-T05161551
	ROCCIA ACIF Trial 6×16×15 mm, anatomic	RI-T06161551
	ROCCIA ACIF Trial 7×16×15 mm, anatomic	RI-T07161551
	ROCCIA ACIF Trial 8×16×15 mm, anatomic	RI-T08161551
	ROCCIA ACIF Trial 4×18×13 mm, anatomic	RI-T04181351
	ROCCIA ACIF Trial 5×18×13 mm, anatomic	RI-T05181351
	ROCCIA ACIF Trial 6×18×13 mm, anatomic	RI-T06181351
	ROCCIA ACIF Trial 7×18×13 mm, anatomic	RI-T07181351
	ROCCIA ACIF Trial 8×18×13 mm, anatomic	RI-T08181351
	ROCCIA ACIF Trial 4×18×15 mm, anatomic	RI-T04181551
	ROCCIA ACIF Trial 5×18×15 mm, anatomic	RI-T05181551
	ROCCIA ACIF Trial 6×18×15 mm, anatomic	RI-T06181551
	ROCCIA ACIF Trial 7×18×15 mm, anatomic	RI-T07181551
	ROCCIA ACIF Trial 8×18×15 mm, anatomic	RI-T08181551

System:
ROCCIA

Instrument Type:
Trial implant

Configuration:
anatomic

Material:
Ti6Al4V ELI

ROCCIA® ACIF Implants

Explanation of Cage Article Number

ROCCIA ACIF Cage, 5×16×15 mm, wedge-shaped



System:
ROCCIA

Implant Type:
ACIF

Configuration:
wedge-shaped

Material:
PEEK
Ti6Al4V ELI (X-ray marker)

Article Number	Description	Illustration
S-RCP-04141305-S	ROCCIA ACIF Cage, 4×14×13 mm, wedge-shaped	
S-RCP-05141305-S	ROCCIA ACIF Cage, 5×14×13 mm, wedge-shaped	
S-RCP-06141305-S	ROCCIA ACIF Cage, 6×14×13 mm, wedge-shaped	
S-RCP-07141305-S	ROCCIA ACIF Cage, 7×14×13 mm, wedge-shaped	
S-RCP-08141305-S	ROCCIA ACIF Cage, 8×14×13 mm, wedge-shaped	
S-RCP-04161305-S	ROCCIA ACIF Cage, 4×16×13 mm, wedge-shaped	
S-RCP-05161305-S	ROCCIA ACIF Cage, 5×16×13 mm, wedge-shaped	
S-RCP-06161305-S	ROCCIA ACIF Cage, 6×16×13 mm, wedge-shaped	
S-RCP-07161305-S	ROCCIA ACIF Cage, 7×16×13 mm, wedge-shaped	
S-RCP-08161305-S	ROCCIA ACIF Cage, 8×16×13 mm, wedge-shaped	
S-RCP-04161505-S	ROCCIA ACIF Cage, 4×16×15 mm, wedge-shaped	
S-RCP-05161505-S	ROCCIA ACIF Cage, 5×16×15 mm, wedge-shaped	
S-RCP-06161505-S	ROCCIA ACIF Cage, 6×16×15 mm, wedge-shaped	
S-RCP-07161505-S	ROCCIA ACIF Cage, 7×16×15 mm, wedge-shaped	
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S-RCP-04181305-S	ROCCIA ACIF Cage, 4×18×13 mm, wedge-shaped	
S-RCP-05181305-S	ROCCIA ACIF Cage, 5×18×13 mm, wedge-shaped	
S-RCP-06181305-S	ROCCIA ACIF Cage, 6×18×13 mm, wedge-shaped	
S-RCP-07181305-S	ROCCIA ACIF Cage, 7×18×13 mm, wedge-shaped	
S-RCP-08181305-S	ROCCIA ACIF Cage, 8×18×13 mm, wedge-shaped	
S-RCP-04181505-S	ROCCIA ACIF Cage, 4×18×15 mm, wedge-shaped	
S-RCP-05181505-S	ROCCIA ACIF Cage, 5×18×15 mm, wedge-shaped	
S-RCP-06181505-S	ROCCIA ACIF Cage, 6×18×15 mm, wedge-shaped	
S-RCP-07181505-S	ROCCIA ACIF Cage, 7×18×15 mm, wedge-shaped	
S-RCP-08181505-S	ROCCIA ACIF Cage, 8×18×15 mm, wedge-shaped	

ROCCIA® ACIF Trial Implants

rs (Example)

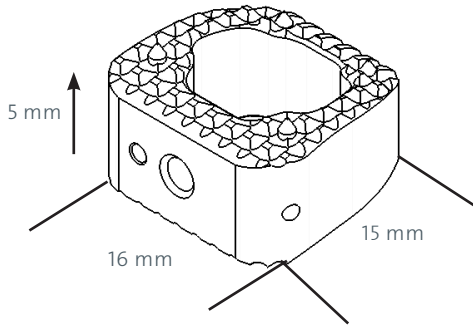


Illustration	Description	Article Number
	ROCCIA ACIF Trial, 4×14×13 mm, wedge-shaped	RI-T04141305
	ROCCIA ACIF Trial, 5×14×13 mm, wedge-shaped	RI-T05141305
	ROCCIA ACIF Trial, 6×14×13 mm, wedge-shaped	RI-T06141305
	ROCCIA ACIF Trial, 7×14×13 mm, wedge-shaped	RI-T07141305
	ROCCIA ACIF Trial, 8×14×13 mm, wedge-shaped	RI-T08141305
	ROCCIA ACIF Trial, 4×16×13 mm, wedge-shaped	RI-T04161305
	ROCCIA ACIF Trial, 5×16×13 mm, wedge-shaped	RI-T05161305
	ROCCIA ACIF Trial, 6×16×13 mm, wedge-shaped	RI-T06161305
	ROCCIA ACIF Trial, 7×16×13 mm, wedge-shaped	RI-T07161305
	ROCCIA ACIF Trial, 8×16×13 mm, wedge-shaped	RI-T08161305
	ROCCIA ACIF Trial, 4×16×15 mm, wedge-shaped	RI-T04161505
	ROCCIA ACIF Trial, 5×16×15 mm, wedge-shaped	RI-T05161505
	ROCCIA ACIF Trial, 6×16×15 mm, wedge-shaped	RI-T06161505
	ROCCIA ACIF Trial, 7×16×15 mm, wedge-shaped	RI-T07161505
	ROCCIA ACIF Trial, 8×16×15 mm, wedge-shaped	RI-T08161505
	ROCCIA ACIF Trial, 4×18×13 mm, wedge-shaped	RI-T04181305
	ROCCIA ACIF Trial, 5×18×13 mm, wedge-shaped	RI-T05181305
	ROCCIA ACIF Trial, 6×18×13 mm, wedge-shaped	RI-T06181305
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	ROCCIA ACIF Trial, 8×18×13 mm, wedge-shaped	RI-T08181305
	ROCCIA ACIF Trial, 4×18×15 mm, wedge-shaped	RI-T04181505
	ROCCIA ACIF Trial, 5×18×15 mm, wedge-shaped	RI-T05181505
	ROCCIA ACIF Trial, 6×18×15 mm, wedge-shaped	RI-T06181505
	ROCCIA ACIF Trial, 7×18×15 mm, wedge-shaped	RI-T07181505
	ROCCIA ACIF Trial, 8×18×15 mm, wedge-shaped	RI-T08181505

System:
ROCCIA

Instrument Type:
Trial implant

Configuration:
wedge-shaped

Material:
Ti6Al4V ELI

ROCCIA® ACIF Instruments

Article Number	Description	Illustration	Page
RI-2060	ROCCIA ACIF Loading Block		10
RI-2061	ROCCIA ACIF Bone Graft Pusher		10
RI-8010	ROCCIA ACIF Inserter, dismantable		8, 9, 10, 11,
RI-8050	ROCCIA ACIF Depth Stop, lat. large		8, 9, 11
RI-8060	ROCCIA Driving Mallet, small		11
RI-8110	ROCCIA ACIF Inserter, long, dismantable		8, 9, 10, 11

ROCCIA® ACIF Alphabetical Index

A-Z	Description	Article Number	Page
B	Bone Graft Pusher	RI-2061	10
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	Driving Mallet, small	RI-8060	11
I	Insertor, dismountable	RI-8010	8, 9, 10, 11
	Insertor, long, dismountable	RI-8110	
L	Loading Block	RI-2060	10
T	Trial 4×14×13 mm, anatomic	RI-T04141351	PI 03
	Trial 5×14×13 mm, anatomic	RI-T05141351	
	Trial 6×14×13 mm, anatomic	RI-T06141351	
	Trial 7×14×13 mm, anatomic	RI-T07141351	
	Trial 8×14×13 mm, anatomic	RI-T08141351	
	Trial 4×16×13 mm, anatomic	RI-T04161351	
	Trial 5×16×13 mm, anatomic	RI-T05161351	
	Trial 6×16×13 mm, anatomic	RI-T06161351	
	Trial 7×16×13 mm, anatomic	RI-T07161351	
	Trial 8×16×13 mm, anatomic	RI-T08161351	
	Trial 4×16×15 mm, anatomic	RI-T04161551	
	Trial 5×16×15 mm, anatomic	RI-T05161551	
	Trial 6×16×15 mm, anatomic	RI-T06161551	
	Trial 7×16×15 mm, anatomic	RI-T07161551	
	Trial 8×16×15 mm, anatomic	RI-T08161551	
	Trial 4×18×13 mm, anatomic	RI-T04181351	
	Trial 5×18×13 mm, anatomic	RI-T05181351	
	Trial 6×18×13 mm, anatomic	RI-T06181351	
	Trial 7×18×13 mm, anatomic	RI-T07181351	
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Notes

A series of horizontal dotted lines for writing notes.



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