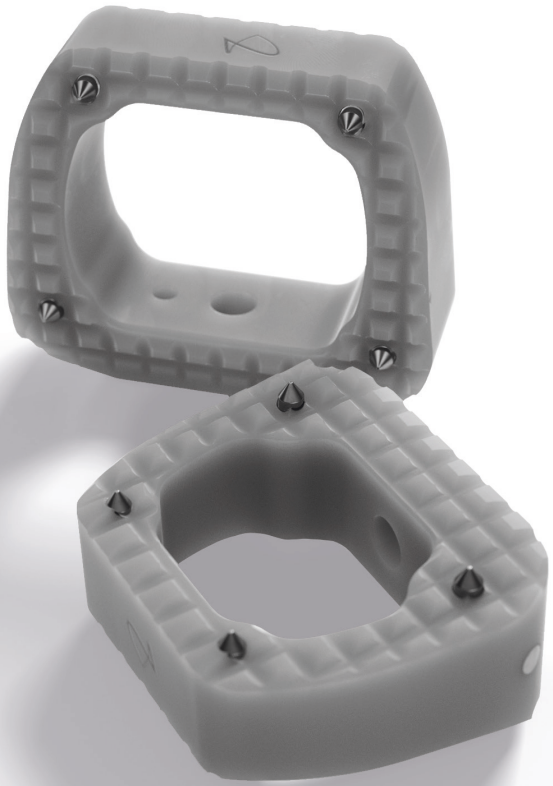
silony® MEDICAL

ROCCIA® ACIF ANTERIOR CERVICAL INTERBODY FUSION

INSTRUMENTATION GUIDE



MADE IN GERMANY

TABLE OF CONTENTS

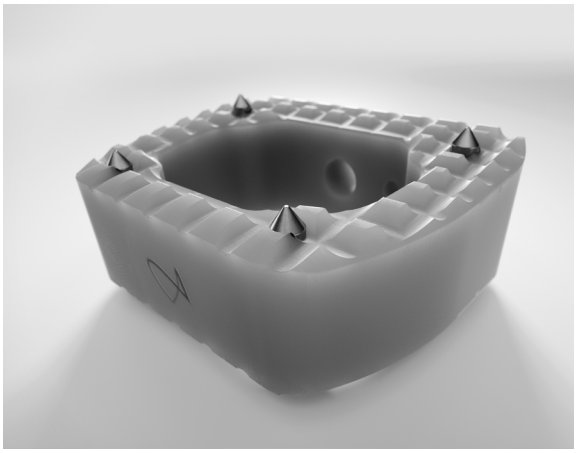
NOTE: This Guide describes the use of ROCCIA® ACIF for anterior cervical instrumentation – it does not replace briefing by a surgeon experienced in surgical instrumentation of the spinal column.

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 stabilisation and restoration of the physiological lordosis in the cervical spine. The cage is designed for anterior approaches.



The chamber system in the cage improves intercorporal 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.

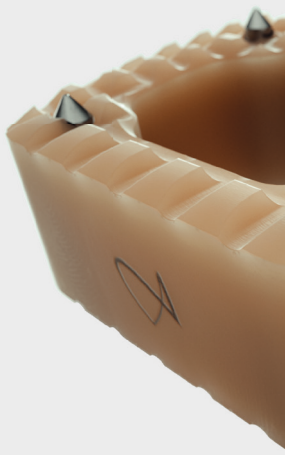
Pins anchored in the cage allow good visualisation of the correct position of the implant in the image converter and aid with the primary stability.

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.

ROCCIA® ACIF

PROVEN SYSTEM – COMBINED AND OPTIMISED

ROCCIA ACIF –
The reliable cage for individual treatment

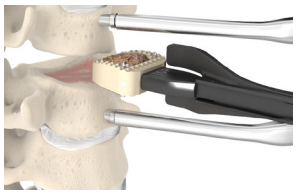


Preparing the fusion:

There is plenty of room in the generously proportioned ROCCIA ACIF chamber system for autologous or homologous bone and/or bone graft material for subsequent fusion.

Save time:

The delicate two-part ROCCIA ACIF Inserter is particularly easy to clean and integrates optimally into the lean instrument set. The black coating allows the inserter to be used under the microscope without producing reflections.



Rely on safety:

The ROCCIA ACIF Depth Stop guarantees you safe and targeted insertion of the cage and provides a good option to control the position of the cage.

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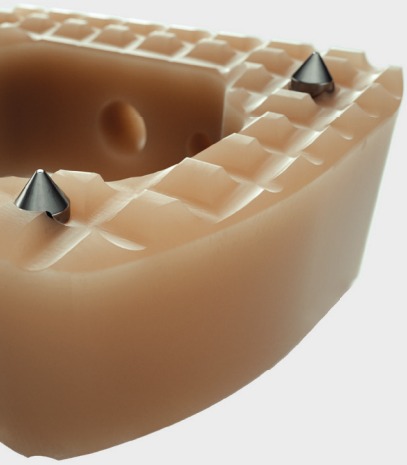
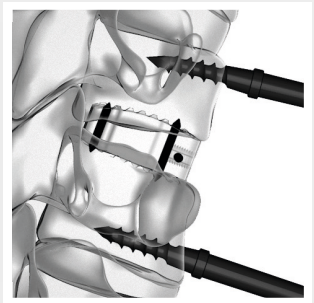


For firm anchorage:

Symmetrical tapered pyramidal teeth on the surface of the PEEK implant along with radiographic markers ensure good primary anchoring of the cage to the base and cover plates.



Keep control:

Radiographic markers facilitate imaging of the ACIF implant during insertion as well as for the postoperative follow-up examination.

For individual treatment:

The implant portfolio offers a wide range of sizes and shapes (5°, wedge-shaped & anatomic), enabling you to provide individual treatment depending on the patient's anatomy.

Indications

The ROCCIA ACIF system can be used for the following indications on the cervical spine (C2–T1):

- Symptomatic cervical discopathy
- Cervical spinal canal stenosis
- Clinical signs and symptoms of radiculopathy, myelopathy or symptoms of myelo-radiculopathy

Contraindications

The most important contraindications include:

- Anticipated or documented allergy or intolerance to the materials used (e.g. titanium, PEEK)
- Missing bone structures that render good anchoring of the implant impossible (e.g. in fractures, tumours, osteoporosis or infections)

NOTE: ROCCIA ACIF can be combined with additional stabilisation depending on the stability and the sagittal profile.

NOTE: Please also note the advice about indications and contraindications from 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 necessary steps when using the ROCCIA ACIF for anterior cervical interbody fusion. Using ROCCIA ACIF, both monosegmental and multisegmental treatments can be carried out in accordance with this instrumentation guide.

Instrumentation of ACIF – Position and approach; distraction

The patient is placed in a supine position. The head should be stably positioned in a slightly reclined position. When positioning the patient, care should be taken to ensure that the target segment can be depicted well in the fluroscopy 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 (Figs. 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

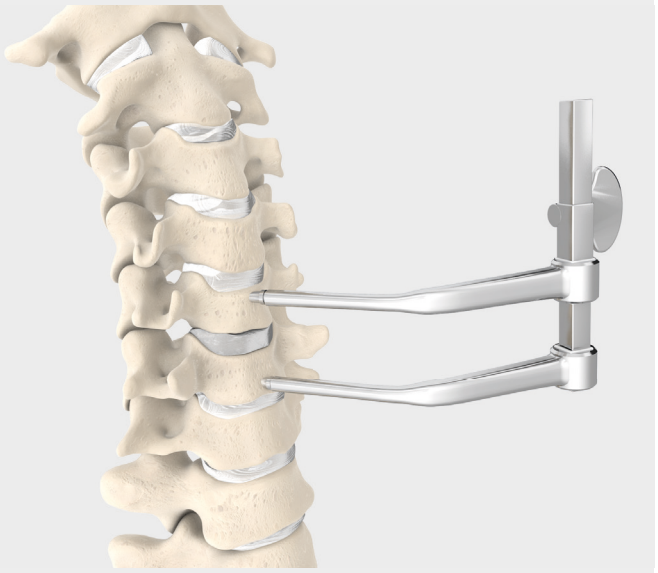


Fig. 1 Exposure of the target segment using standard retractors

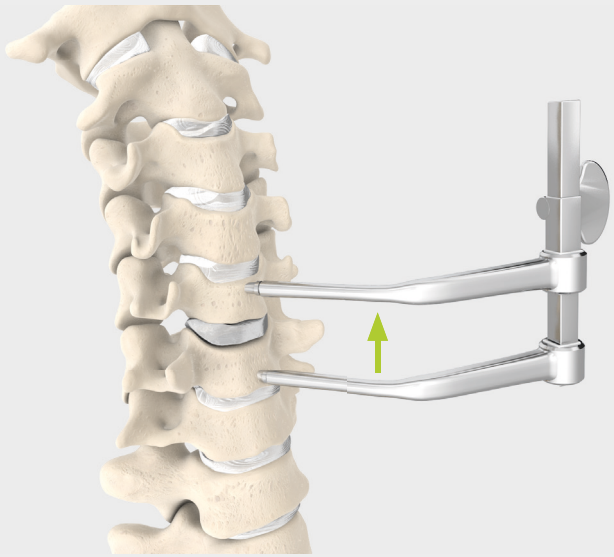


Fig. 2 Exposure of the target segment by spreading the retractor

Discectomy and decompression

The cervical intervertebral disc must be removed completely (Fig. 3). Therefor, box-shaped resection of the anterior longitudinal ligament is necessary first. Discectomy is performed as usual.
The cartilages on the end plates should be removed thoroughly until the end plates start to bleed slightly. When doing this, care should be taken to ensure that the end plates are not weakened in order to ensure sufficient supporting surface and stability for the 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 the implantation, anterior osteophytes or other bony changes must also be removed if necessary.

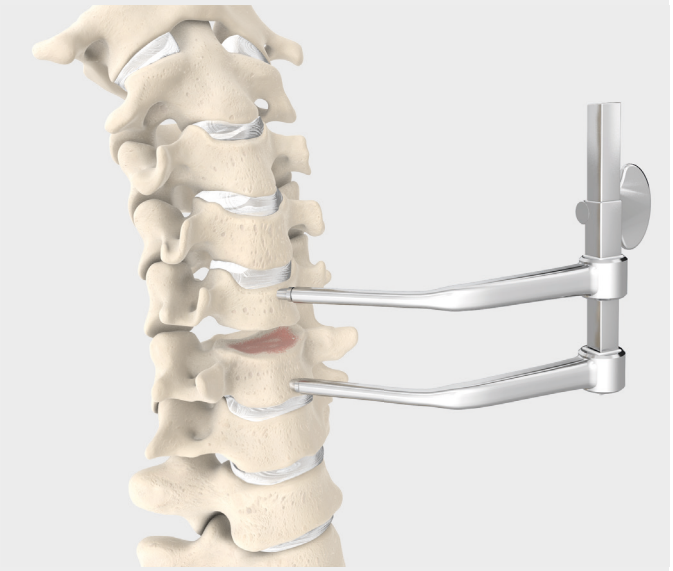


Fig. 3 Complete removal of the cervical intervertebral disc

NOTE: Careful preparation of the disc space, especially extensive cleaning of the end plates, provides the basis for better vascularisation and successful bony fusion. Damage of the bony base and cover plate can lead to sinking of the implant 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 customisation 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 this, the shaft is inserted completely into the sleeve 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
** Representative for other trial implant sizes see ROCCIA Trial Implants

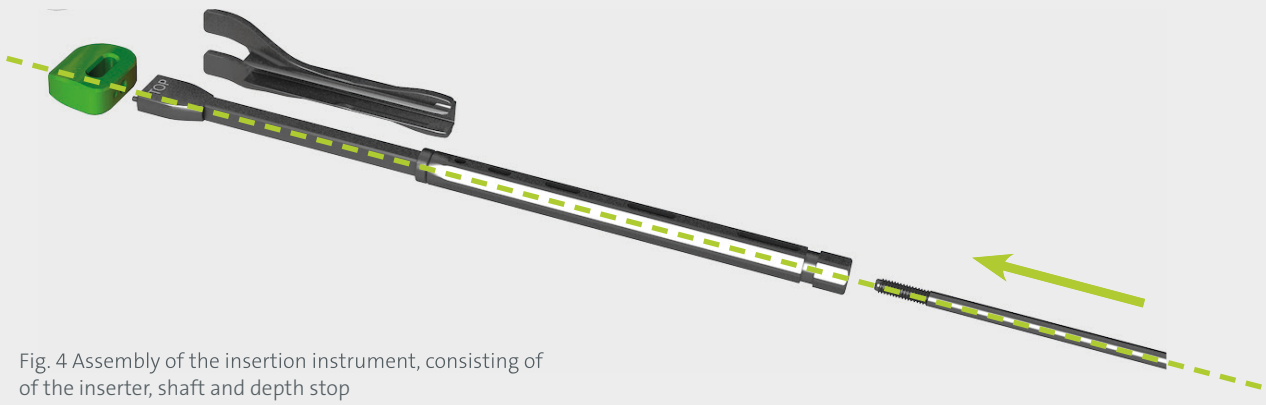


Fig. 4 Assembly of the insertion instrument, consisting of of the inserter, shaft and depth stop

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

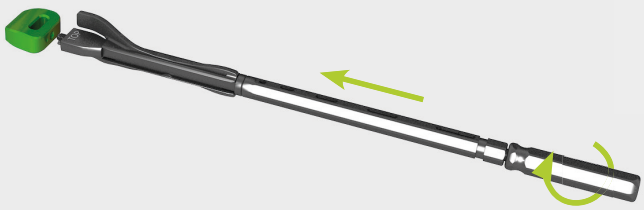


Fig. 5 Fixing the trial implant onto the inserter

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

Silony Medical recommends using an implant that is as wide as possible to achieve a large contact surface area 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 trial implant is neither too tight nor too loose. Accordingly, try out a smaller or larger version until the trial implant is seated stably in the intersegmental space. When doing this, you should, if necessary, undo the distractor if you are using one, in order to get a tactile feel for the primary stability of the implant.

* Representative for other inserters
** Representative for other trial implant sizes see ROCCIA Trial Implants

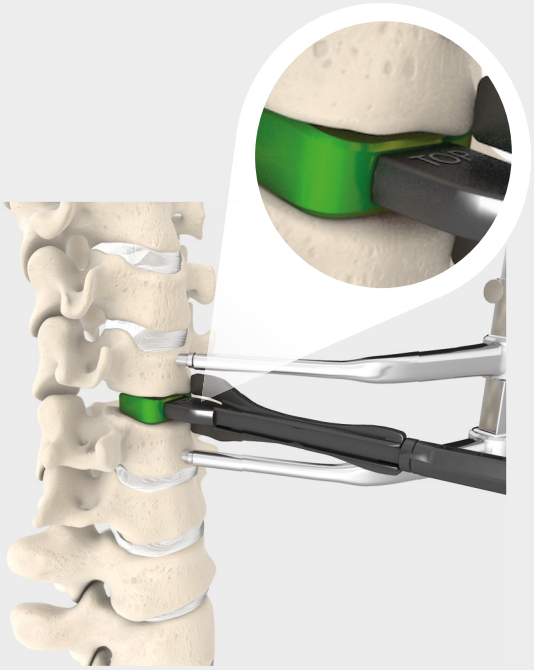


Fig. 6 Introducing the trial implant

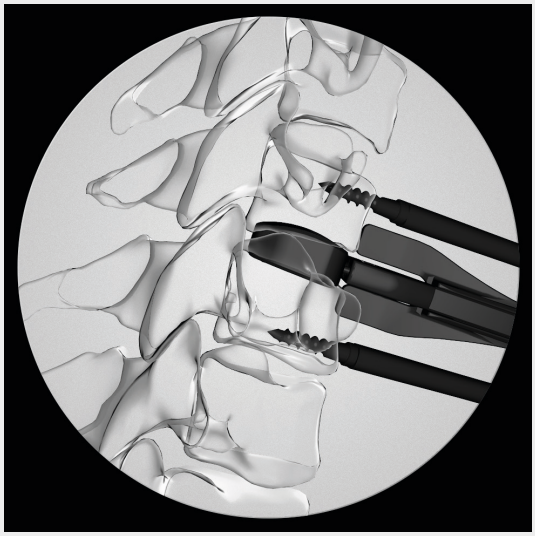


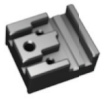
Fig. 7 X-ray control during insertion of the trial implant

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 also serves to simulate the insertion of the implant into its final position. If the trial implant cannot be brought into its desired end position, then renewed preparation of the intervertebral disc space may be necessary.

Filling the ROCCIA ACIF Cage

RI-2060
ROCCIA ACIF Loading Block



RI-2061
ROCCIA ACIF Bone Graft Pusher

RI-8010*
ROCCIA ACIF Inserter, dismountable

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 this, the depth stop can be left on the instrument.
Filling the cage with autologous bone material (or homologous bone or bone graft material) is an important precondition for reliable fusion. A loading block and a pusher are provided for this (Fig. 9). The colour rings on the pusher correspond to the colour 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 and on the loading block must be noted for this purpose (Fig. 9 zoom). The graduation marking indicates the posterior side of the cage.

* Representative for other inserters see ROCCIA instruments

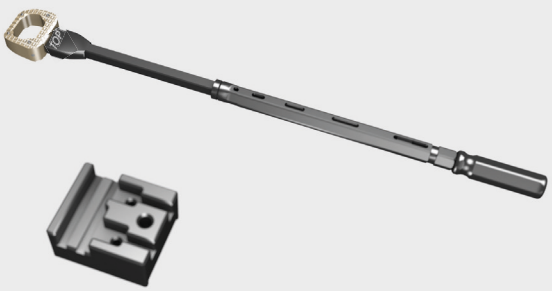


Fig. 8 Fixing the cage onto the inserter

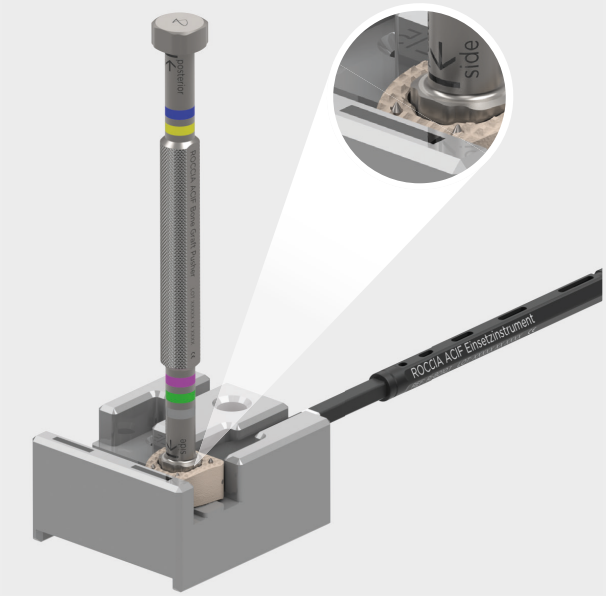


Fig. 9 Filling the cage with bone material in the loading block with pusher

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 the superior direction. The label 'TOP' on the inserter must face 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 being inserted too deeply.
A small driving mallet is available to make insertion of the cage easier.

* Representative for other inserters see ROCCIA instruments

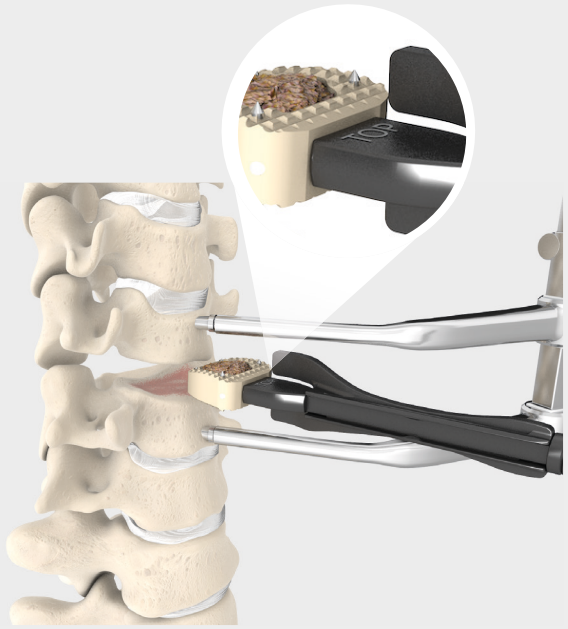


Fig. 10 Inserting the cage

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 the 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 for inserting 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 fluoroscopy (lateral and anterior-posterior view). When doing this, X-ray markers in the implant show the position of the cage.
After the final position has been confirmed in the fluoroscopy, the inserter is unscrewed completely from the implant and removed (Fig. 12 and 13). No force needs to be exerted to withdraw the inserter from the implant. Should resistance nevertheless be felt, it must be checked 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.

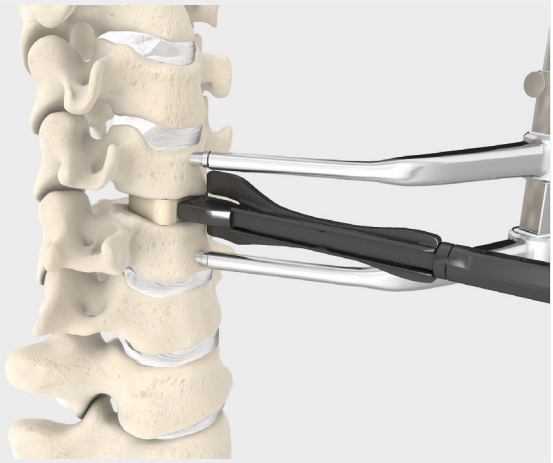


Fig. 11 Final position of the cage

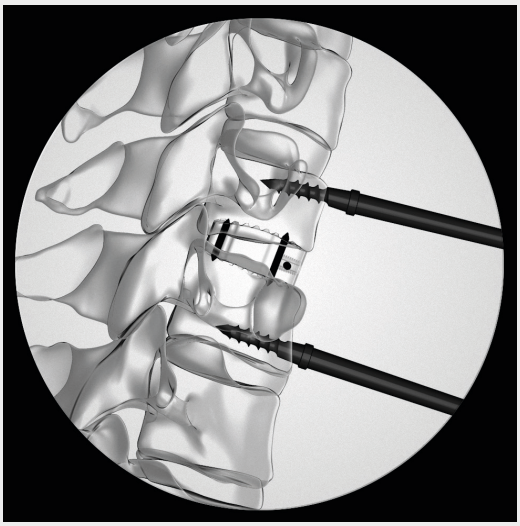


Fig. 12 X-ray control, lateral

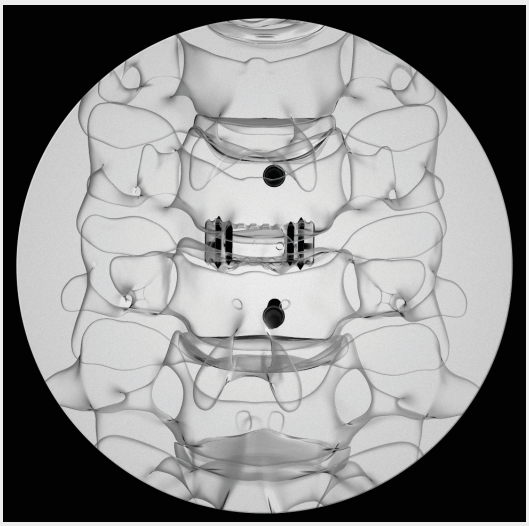


Fig. 13 X-ray control, anterior–posterior

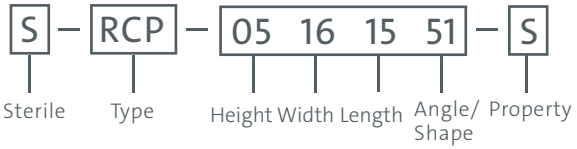
NOTE: Depending on the patient's individual pathology, additional stabilisation of the ROCCIA ACIF Cage with an anterior plate or a posterior screw-rod system may be required.

ROCCIA® ACIF IMPLANTS PRODUCT INFORMATION

ROCCIA® ACIF Implants

Article number explanation for the

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

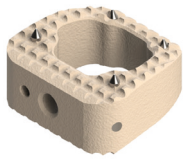


System:
ROCCIA

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	
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S-RCP-07141351-S	ROCCIA ACIF Cage, 7×14×13 mm, anatomic	
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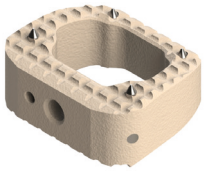
S-RCP-04161351-S	ROCCIA ACIF Cage, 4×16×13 mm, anatomic	
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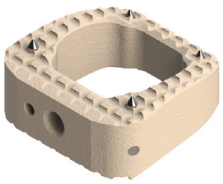
S-RCP-04161551-S	ROCCIA ACIF Cage, 4×16×15 mm, anatomic	
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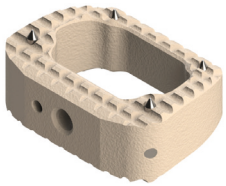
S-RCP-04181351-S	ROCCIA ACIF Cage, 4×18×13 mm, anatomic	
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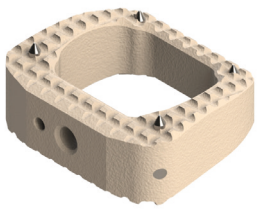
S-RCP-04181551-S	ROCCIA ACIF Cage, 4×18×15 mm, anatomic	
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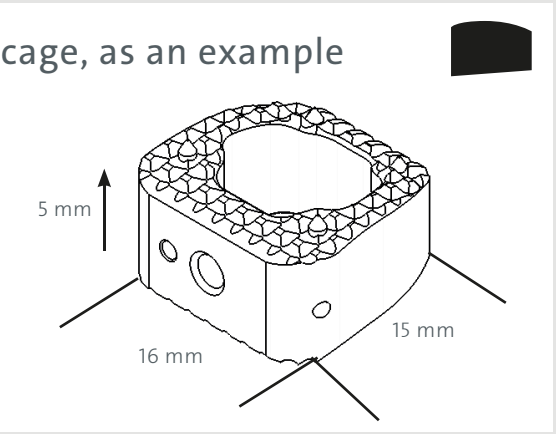

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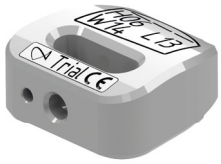	ROCCIA ACIF Trial 4×14×13 mm, anatomic	RI-T04141351
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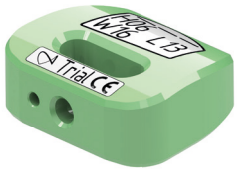
	ROCCIA ACIF Trial 7×14×13 mm, anatomic	RI-T07141351
	ROCCIA ACIF Trial 8×14×13 mm, anatomic	RI-T08141351
	ROCCIA ACIF Trial 4×16×13 mm, anatomic	RI-T04161351
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	ROCCIA ACIF Trial 7×18×13 mm, anatomic	RI-T07181351
	ROCCIA ACIF Trial 8×18×13 mm, anatomic	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

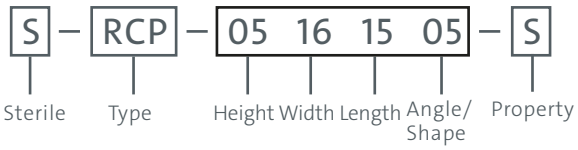
Configuration:
anatomic

Material:
Ti6Al4V ELI

ROCCIA® ACIF Implants

Article number explanation for the

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

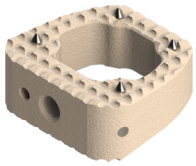
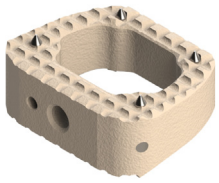
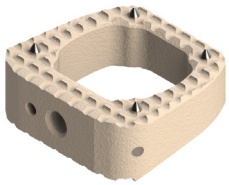
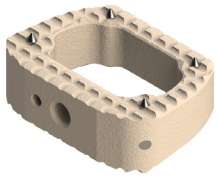
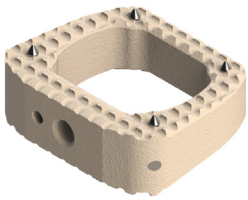


System:
ROCCIA

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	
S-RCP-08161505-S	ROCCIA ACIF Cage, 8×16×15 mm, wedge-shaped	
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	

cage, as an example

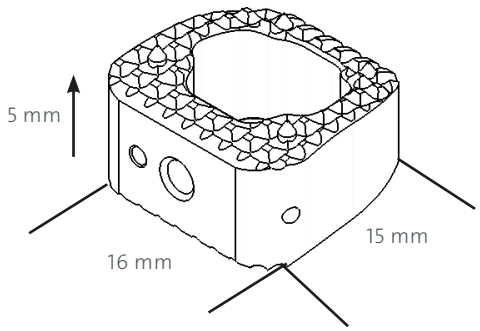
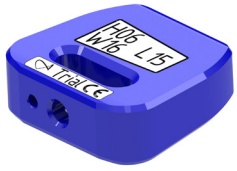
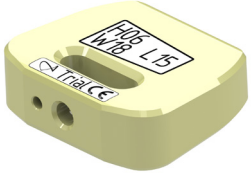


Illustration	Description	Article number
	ROCCIA ACIF Trial, 4×14×13 mm, wedge-shaped	RI-T04141305
	ROCCIA ACIF Trial, 5×14×13 mm, wedge-shaped	RI-T05141305
	ROCCIA ACIF Trial, 6×14×13 mm, wedge-shaped	RI-T06141305
	ROCCIA ACIF Trial, 7×14×13 mm, wedge-shaped	RI-T07141305
	ROCCIA ACIF Trial, 8×14×13 mm, 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
	ROCCIA ACIF Trial, 7×18×13 mm, wedge-shaped	RI-T07181305
	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

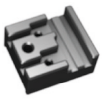
System:
ROCCIA

Instrument type:
Trial implant

Configuration:
wedge-shaped

Material:
Ti6Al4V ELI

ROCCIA® ACIF Instruments

Article number	Description	Illustration	Page
RI-2060	ROCCIA ACIF Loading Block		12
RI-2061	ROCCIA ACIF Bone Graft Pusher		12
RI-8010	ROCCIA ACIF Inserter, dismountable		10, 11, 12, 13
RI-8050	ROCCIA ACIF Depth Stop, lat. large		10, 11, 13
RI-8060	ROCCIA Driving Mallet, small		13
RI-8110	ROCCIA ACIF Inserter, long, dismountable		10, 11, 12, 13

ROCCIA® ACIF Alphabetical Index

A–Z	Description	Article number	Page
B	Bone Graft Pusher	RI-2061	12
D	Depth Stop, lat. large	RI-8050	10, 11, 13
	Driving Mallet, small	RI-8060	13
I	Inserter, dismountable	RI-8010	10, 11, 12, 13
	Inserter, long, dismountable	RI-8110	
L	Loading Block	RI-2060	12
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	
	Trial 8×18×13 mm, anatomic	RI-T08181351	
	Trial 4×18×15 mm, anatomic	RI-T04181551	
	Trial 5×18×15 mm, anatomic	RI-T05181551	
	Trial 6×18×15 mm, anatomic	RI-T06181551	
	Trial 7×18×15 mm, anatomic	RI-T07181551	
	Trial 8×18×15 mm, anatomic	RI-T08181551	

A–Z	Description	Article number	Page
T	Trial 4×14×13 mm, wedge-shaped	RI-T04141305	PI 05
	Trial 5×14×13 mm, wedge-shaped	RI-T05141305	
	Trial 6×14×13 mm, wedge-shaped	RI-T06141305	
	Trial 7×14×13 mm, wedge-shaped	RI-T07141305	
	Trial 8×14×13 mm, wedge-shaped	RI-T08141305	
	Trial 4×16×13 mm, wedge-shaped	RI-T04161305	
	Trial 5×16×13 mm, wedge-shaped	RI-T05161305	
	Trial 6×16×13 mm, wedge-shaped	RI-T06161305	
	Trial 7×16×13 mm, wedge-shaped	RI-T07161305	
	Trial 8×16×13 mm, wedge-shaped	RI-T08161305	
	Trial 4×16×15 mm, wedge-shaped	RI-T04161505	
	Trial 5×16×15 mm, wedge-shaped	RI-T05161505	
	Trial 6×16×15 mm, wedge-shaped	RI-T06161505	
	Trial 7×16×15 mm, wedge-shaped	RI-T07161505	
	Trial 8×16×15 mm, wedge-shaped	RI-T08161505	
	Trial 4×18×13 mm, wedge-shaped	RI-T04181305	
	Trial 5×18×13 mm, wedge-shaped	RI-T05181305	
	Trial 6×18×13 mm, wedge-shaped	RI-T06181305	
	Trial 7×18×13 mm, wedge-shaped	RI-T07181305	
	Trial 8×18×13 mm, wedge-shaped	RI-T08181305	
	Trial 4×18×15 mm, wedge-shaped	RI-T04181505	
	Trial 5×18×15 mm, wedge-shaped	RI-T05181505	
	Trial 6×18×15 mm, wedge-shaped	RI-T06181505	
	Trial 7×18×15 mm, wedge-shaped	RI-T07181505	
	Trial 8×18×15 mm, wedge-shaped	RI-T08181505	

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