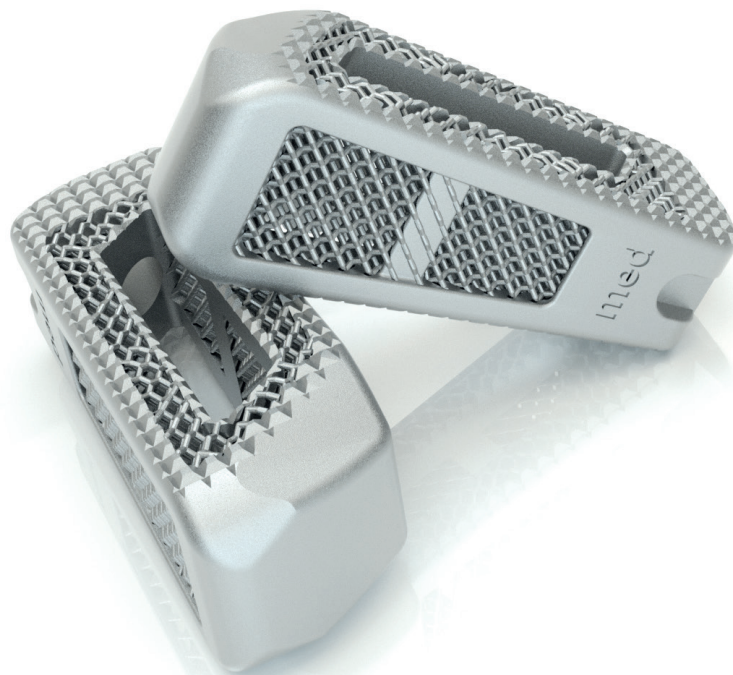


# FAVO<sup>®</sup> S-TLIF CAGE FOR LUMBAR SPINAL FUSION

INSTRUMENTATION GUIDE



MADE IN GERMANY

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**NOTE:** This Guide describes the FAVO S-TLIF Cage instrumentation – it does not replace briefing by a physician experienced in the surgical technique of the spinal column.

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

## PREFACE

# FAVO<sup>®</sup> S-TLIF CAGE – FOR LUMBAR SPINAL FUSION

The FAVO S-TLIF (straight transforaminal lumbar interbody fusion) Cage is an implant for primary stabilization and improvement of lordosis in the lumbar and thoracic spine. The cage is designed for transforaminal approaches.

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

Silony Medical recommends additional posterior fixation of the spinal segment being treated, for example, with the posterior screw-rod system for the thoracic and lumbar spine from the VERTICALE product family.



# Indications

The FAVO S-TLIF system can be used to manage the following indications of the lumbar and thoracic spine:

- Degenerative disc diseases
- Deformities
- Spondylolisthesis (up to Grade 1)
- Segmental instability
- Stenosis

# Contraindications

Contraindications include, but are not limited to:

- 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, that render good anchoring of the implants impossible (e.g., associated with fractures, tumors, osteoporosis, or infections)

**NOTE:** Silony Medical recommends additional posterior fixation of the spinal segment being treated, for example, with the posterior screw-rod system for the thoracic and lumbar spine from the VERTICALE product family.

**NOTE:** Please note the advice on indications and contraindications in the IFU of FAVO S-TLIF. The Instruction for use also contains other important information that might lead to exclusion of the patient

# ACCESS FOR THE FAVO<sup>®</sup> S-TLIF CAGE

The access for the FAVO S-TLIF Cage is described below.

# Position and approach

RI-1410\*  
ROCCIA Chisel 10 mm,  
reinforced



The patient is positioned in the prone position as is common for the posterior approach. Exposing the abdomen decreases the load on the abdominal vessels. Corresponding bearing frames or padding underneath the pelvis and thorax can be used for this. 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 on both sides and prepared until the anatomical structures of the spinal column are clearly exposed.

The transforaminal approach to the disc space is usually achieved by means of 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 swages.

\* Representative of other chisels  
see ROCCIA Instruments

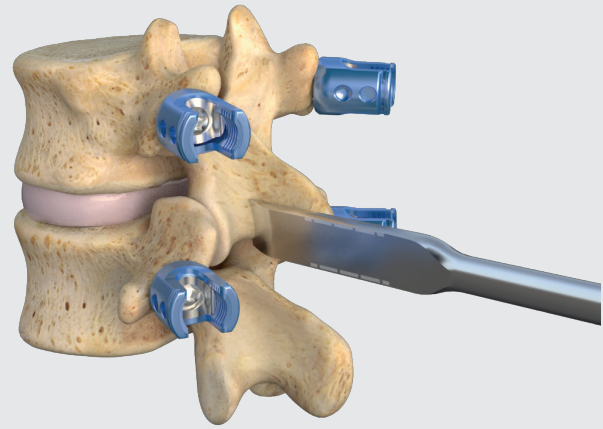


Fig 1 Resection of a facet joint with the chisel for a TLIF approach

**NOTE:** The FAVO S-TLIF System is compatible with the ROCCIA Instruments as described below.

# FAVO<sup>®</sup> S-TLIF CAGE INSTRUMENTATION

# Discectomy

RI-1020\*  
ROCCIA Ring Endplate Scraper  
Straight



RI-1040\*\*  
ROCCIA Curette Straight



FI-4107  
FAVO Shaver, 7 mm, parallel



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 is then removed using various standard forceps and available endplate scrapers and curettes (Fig. 2, Fig. 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 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 for other ring endplate scrapers (angled and curved)
- \*\* Representative for other curettes (curved)
- \*\*\* Representative for other shaver sizes see ROCCIA and FAVO Instruments
- \*\*\*\* Representative for other T-handles see General instruments

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

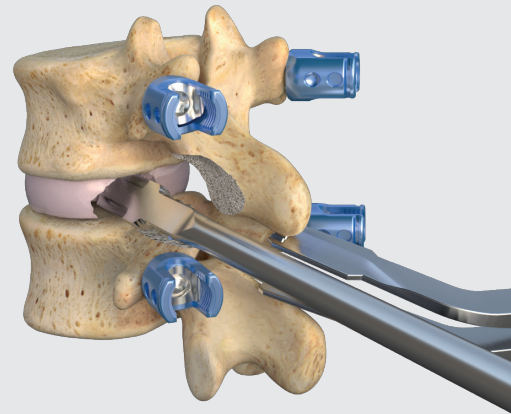


Fig. 2 Loosening of the disc material with a shaver

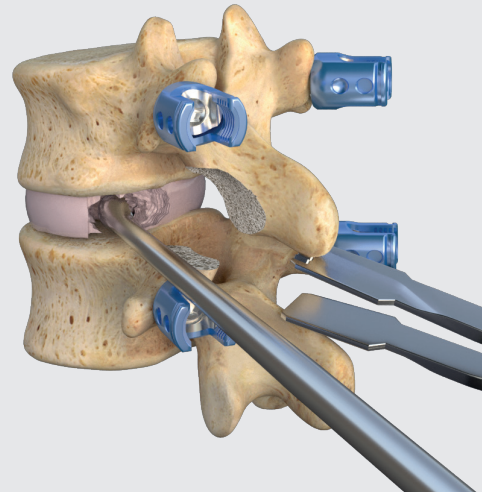


Fig. 3 Discectomy with curette



# Preparing the disc space

RI-1020\*  
ROCCIA Ring Endplate Scraper  
Straight



RI-1030  
ROCCIA Box Endplate Scraper  
Straight



RI-1050  
ROCCIA Rasp Curved 45°



FI-4107\*\*  
FAVO Shaver, 7 mm, parallel



GI-3101\*\*\*  
T-Handle



For more extensive curettage, the ROCCIA Box Endplate Scraper is also available (Fig. 4). The surface of the remaining cartilaginous layer of the base plate and cover plate 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.

- \* Representative for other Ring Endplate Scrapers
- \*\* Representative for other Box Endplate Scrapers
- \*\*\* Representative for other Rasps
- \*\*\*\* Representative for other shaver sizes  
see ROCCIA and FAVO Instruments

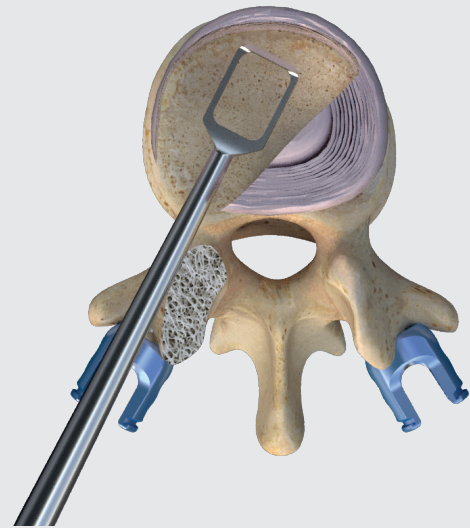


Fig. 4 Box endplate scraper for extensive removal of disc material

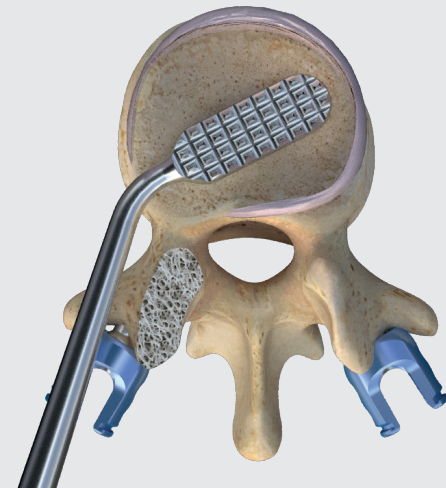


Fig. 5 Rasp for roughening the cover plates

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

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

# Distracting the disc space

FI-4207\*  
FAVO Paddle Sizer 7 mm,  
parallel



GI-3101\*\*  
T-Handle



Blunt FAVO Paddle sizers with depth marking are available for distraction. The paddle sizers are connected to the 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 paddle sizer corresponding to the disc height is first inserted into the disc space and erected by 90° rotation (Fig. 6). 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 sizer is under tension and provides a feeling of stability. Standard lamina spreader forceps can additionally be used for distraction.

- \* Representative for other paddle sizers  
see FAVO Instruments
- \*\* Representative of other T-handles  
see General instruments

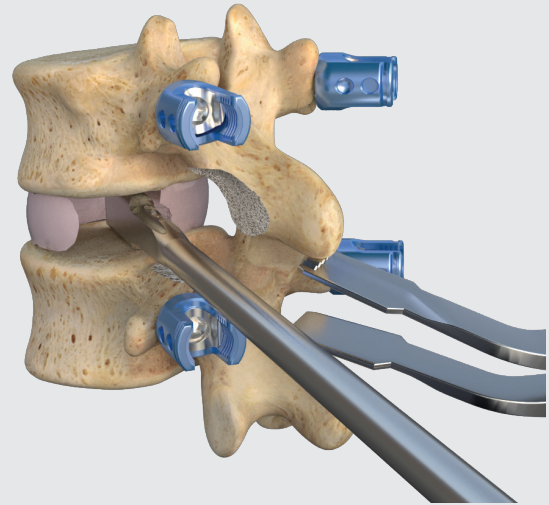


Fig. 6 Spreading the disc space with the Paddle Sizer

**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 sizer

FI-4207\*  
FAVO Paddle Sizer 7 mm,  
parallel



GI-3101\*\*  
T-Handle



To determine the size of the disc space, the blunt paddle sizer with depth markings are available. Trial sizer can be selected on the basis of these measurements.

An appropriate trial sizer with 5° or 15° lordosis is available for each definitive cage size. The height of the trial sizer corresponds to the height of the final implant excluding tothing. Due to the tothing, the final implant is approx. 0.8 mm higher than the trial sizer.

\* Representative for other paddle sizers,  
see FAVO Instruments

\*\* Representative for other T-handles  
see General instruments

## Determining the cage sizes with the trial sizers

FI-T07112805\*  
FAVO S-TLIF Trial Height 7mm,  
5°



GI-3101\*\*  
T-Handle



The trial sizer combines all three possible implant lengths 28, 33 and 38 mm, in the respective height. The height of the implant should be similar to the normal disc height. The trial sizers are colourmarked analogously to the packaging of the implant to be implanted later on. Should the image converter control require a larger lordosis, the sizer with 5° and 15° lordosis angle is also available.

Silony Medical recommends selecting the largest possible implant to maintain a maximal support surface including the anterior and posterior cortical area of the endplates. The trial sizer is carefully inserted into the intervertebral space by applying mild pressure (Fig. 7).

The length is determined in the image converter by means of X-ray markings on the trial sizer, which show the different lengths in the lateral X-ray image. (Fig. 8). To ensure that the height of the intervertebral disc is preserved after loosening the distraction, the sizer must fit between the end plates after full distraction of the segment.

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

If the trial sizer does not sufficiently fill in the intervertebral disc space, the next larger trial sizer 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.

\* Representative for other trial sizes  
see FAVO S-TLIF Trials

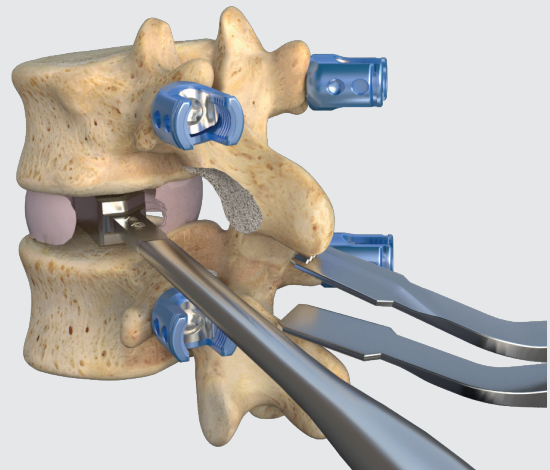


Fig. 7 Inserting the trial sizer

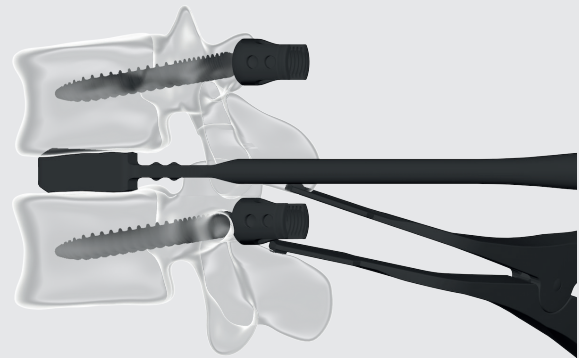


Fig. 8 Image converter control during insertion of the trial sizer

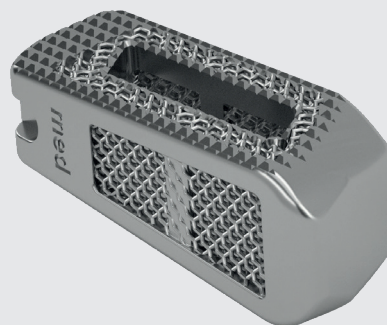
**NOTE:** Correctly selecting the cage size has a decisive impact on the success of the instrumentation and fusion.

## Multitude of cage sizes

To optimize the treatment of the patient, a wide range of FAVO S-TLIF sizes is available.

The portfolio comprises sizes in 9 anterior heights (7 – 13 mm in 1-mm increments, and heights of 15mm and 17mm), three footprints (28x11, 33x11, 38x11 mm) and lordotic angles (5°, 10°, 15°) that allow the restoration of the sagittal profile.

The trial size with the particular colour code corresponds to the packaging of the implant to be implanted later on.



## Filling of the cage

FI-4020  
FAVO Inserter M4,  
dismountable



FI-4050  
FAVO S-TLIF Loading Block



FI-4051  
FAVO S-TLIF Bone Graft Pusher



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 substitute material either before or after implantation of the cage in order to achieve the largest possible fusion surface area.

The selected implant is screwed onto the respective FAVO Inserter, enabling the cage to be definitively inserted without requiring any further instrument change.

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 autologous bone material (or the homologous bone or the bone substitute material) must be inserted well compressed into the cage.

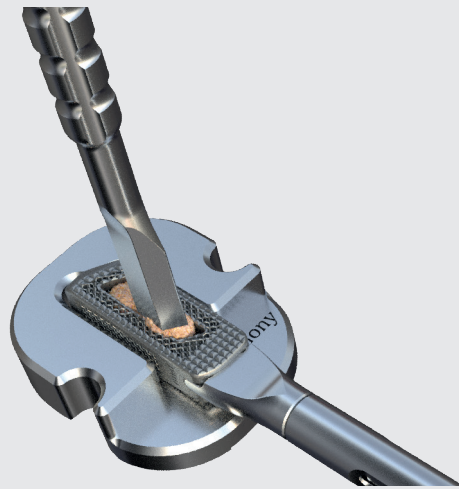


Fig. 9 Filling the cage with bone material in the loading block with pusher

# Inserting the cage

FI-4020  
FAVO Inserter M4,  
dismountable



RI-1355  
ROCCIA Slotted Mallet, solid



The trial sizer is removed just shortly before definitively placing the implant in order to prevent subsequent sinking.

For firm connection between cage and insertion instrument the turning handle of the insertion instrument is rotated in the direction of the closed lock (Fig. 10).

To release the cage, turn the knob in the direction of the open lock (Fig. 11).

The filled implant is carefully inserted into the disc space and the correct alignment of the implant is verified (Fig. 12). Slight pressure or careful hammering with the ROCCIA Slotted Mallet on the implant holder may be required.

Under X-ray control, the cage is inserted into the disc space. The neurogenic structures should be protected.



Fig. 10 Turning in the direction of the closed lock firmly connects the insertion instrument to the cage

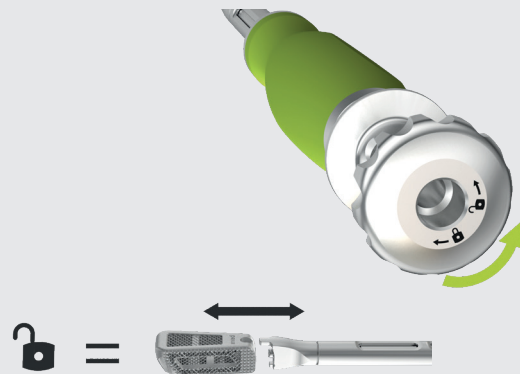


Fig. 11 Turning in the direction of the open lock releases the cage from the insertion tool again

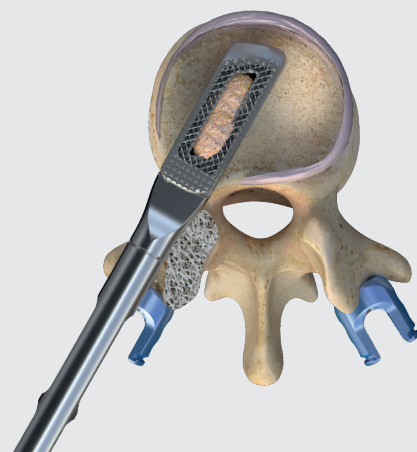


Fig. 12 Inserting the filled cage into the disc space

## Optimal position of the FAVO® S-TLIF Cage

If possible, the inserter is left in the cage until an AP image and a lateral image with the image converter confirm the correct position of the cage.

The optimal position of the implanted FAVO S-TLIF cage (Figure 13, Figure 14) should be  $35^{\circ} \pm 10$  in the axial plane and positioned as anterior as is safe, close to the anterior vertebral endplate rim. In X-ray view, the optimal position and correct insertion angle can be confirmed by the implant located close to the anterior third of the disc space, the two lateral cage windows should display a clear shape and with the web in the middle.

The more anterior the cage is positioned, the better lordosis can be achieved in the respective section of the spine. Avoid a position too far posterior. Bicortical support is ideal.

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

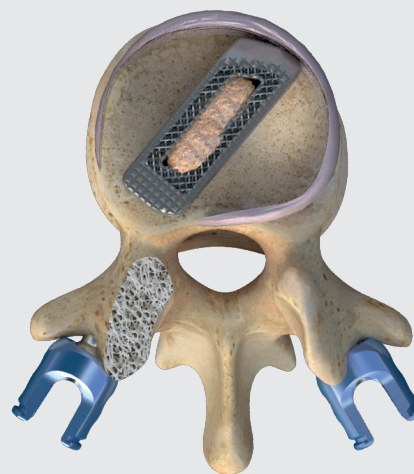


Fig. 13 Optimal position of the filled S-TLIF Cage

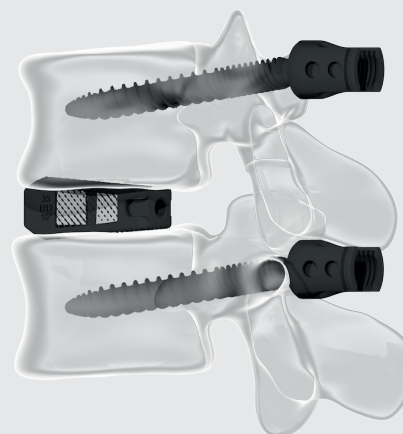


Fig. 14 X-ray control in the lateral projection

**NOTE:** Due to the rough surface of the implant that provides good primary stability, the insertion in exact angle should be considered carefully to avoid corrections afterwards.

**NOTE:** Posterior tension band wiring with an internal fixation system (i.e. VERTICALE Posterior Spinal Fixator) is necessary. Tension band wiring supports the biomechanical stability of the motion segment of the spine and the stability of the S-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.



# CORRECTING THE POSITION OF THE FAVO S-TLIF CAGE

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

# Correcting the position of the FAVO S-TLIF Cage

RI-1343  
ROCCIA Hooked Implant Driver,  
reinforced



RI-1355  
ROCCIA Slotted Mallet, solid



RI-1340  
ROCCIA Implant Driver Straight



FI-4020  
FAVO Inserter M4,  
dismountable



The small tip of the ROCCIA Hooked Implant Driver is carefully inserted through the posterior opening of the cage (Fig. 15). The cage can then be hit into the desired position with the slotted mallet. Thanks to its special shape, the hooked implant driver ensures a certain axial guidance during impaction.

The ROCCIA Implant Driver Straight is positioned straight onto the lateral posterior front of the cage (Fig. 16). The cage can then be carefully moved into the desired position with the slotted mallet.

The inserter has been designed to fulfil multiple functions. Using the rotating handle, the two instrument components can be disassembled so that both individual components are available for use. The main body can be attached to the cage after removal of the inner core and act as a driver by slightly hammering (Fig. 17). The cage can then be placed more anterior. The correcting should be performed under image converter control.

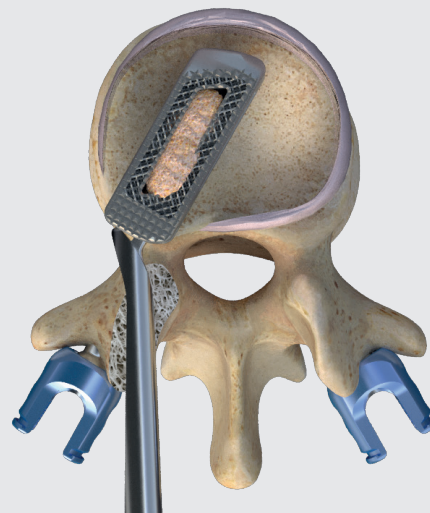


Fig. 15 Hooked Implant Driver for correcting the position of the cage

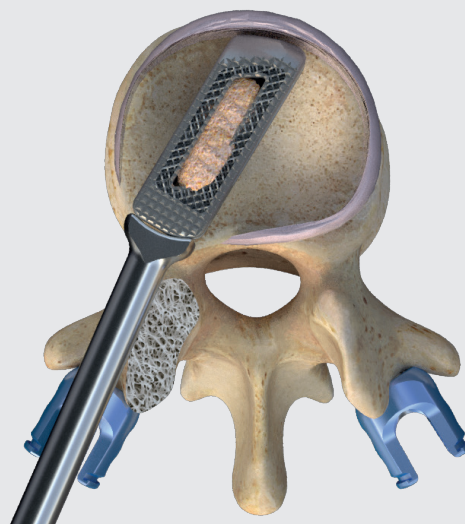


Fig. 16 Straight Implant Driver to finalize the position of the cage



Fig. 17 Main body of FAVO Inserter as a driver

# Revision

FI-4020  
FAVO Inserter M4,  
dismountable



To remove the FAVO S-TLIF implant, the inner core of the FAVO 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. 18).



Fig. 18 Revision of the FAVO S-TLIF Cage

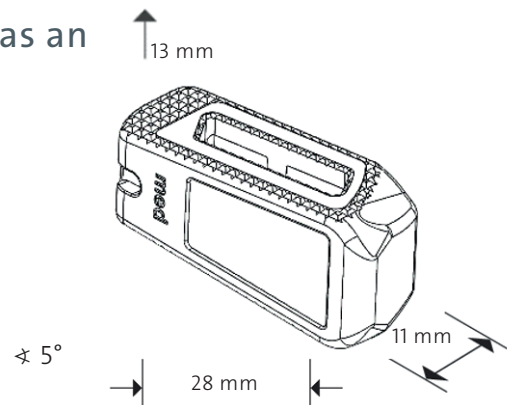
# FAVO® S-TLIF PRODUCT INFORMATION

FAVO® S-TLIF Implants by article number .....	PI 02
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# FAVO® S-TLIF Implants

## Article number explanation for the cage, as an example

FAVO S-TLIF Cage, 13 x 11 x 28 mm, 5° lor.



Article number	Description	Illustration
S-FST-07112805-S	FAVO S-TLIF Cage 7 x 11 x 28 mm, 5° lor.	
S-FST-08112805-S	FAVO S-TLIF Cage 8 x 11 x 28 mm, 5° lor.	
S-FST-09112805-S	FAVO S-TLIF Cage 9 x 11 x 28 mm, 5° lor.	
S-FST-10112805-S	FAVO S-TLIF Cage 10 x 11 x 28 mm, 5° lor.	
S-FST-11112805-S	FAVO S-TLIF Cage 11 x 11 x 28 mm, 5° lor.	
S-FST-12112805-S	FAVO S-TLIF Cage 12 x 11 x 28 mm, 5° lor.	
S-FST-13112805-S	FAVO S-TLIF Cage 13 x 11 x 28 mm, 5° lor.	
S-FST-09112810-S	FAVO S-TLIF Cage 9 x 11 x 28 mm, 10° lor.	
S-FST-10112810-S	FAVO S-TLIF Cage 10 x 11 x 28 mm, 10° lor.	
S-FST-11112810-S	FAVO S-TLIF Cage 11 x 11 x 28 mm, 10° lor.	
S-FST-12112810-S	FAVO S-TLIF Cage 12 x 11 x 28 mm, 10° lor.	
S-FST-13112810-S	FAVO S-TLIF Cage 13 x 11 x 28 mm, 10° lor.	
S-FST-11281115-S	FAVO S-TLIF Cage 11 x 11 x 28 mm, 15° lor.	
S-FST-12281115-S	FAVO S-TLIF Cage 12 x 11 x 28 mm, 15° lor.	
S-FST-13281115-S	FAVO S-TLIF Cage 13 x 11 x 28 mm, 15° lor.	

System:  
FAVO

Implant type:  
S-TLIF

Configuration:  
28 mm

Material:  
Ti6Al4V ELI

# FAVO® S-TLIF Implants

System:  
FAVO

Implant type:  
S-TLIF

Configuration:  
33 mm

Material:  
Ti6Al4V ELI

Article number	Description	Illustration
S-FST-08113305-S	FAVO S-TLIF Cage 8 x 11 x 33 mm, 5° lor.	
S-FST-09113305-S	FAVO S-TLIF Cage 9 x 11 x 33 mm, 5° lor.	
S-FST-10113305-S	FAVO S-TLIF Cage 10 x 11 x 33 mm, 5° lor.	
S-FST-11113305-S	FAVO S-TLIF Cage 11 x 11 x 33 mm, 5° lor.	
S-FST-12113305-S	FAVO S-TLIF Cage 12 x 11 x 33 mm, 5° lor.	
S-FST-13113305-S	FAVO S-TLIF Cage 13 x 11 x 33 mm, 5° lor.	
S-FST-15113305-S	FAVO S-TLIF Cage 15 x 11 x 33 mm, 5° lor.	
S-FST-10113310-S	FAVO S-TLIF Cage 10 x 11 x 33 mm, 10° lor.	
S-FST-11113310-S	FAVO S-TLIF Cage 11 x 11 x 33 mm, 10° lor.	
S-FST-12113310-S	FAVO S-TLIF Cage 12 x 11 x 33 mm, 10° lor.	
S-FST-13113310-S	FAVO S-TLIF Cage 13 x 11 x 33 mm, 10° lor.	
S-FST-15113310-S	FAVO S-TLIF Cage 15 x 11 x 33 mm, 10° lor.	
S-FST-12113315-S	FAVO S-TLIF Cage 12 x 11 x 33 mm, 15° lor.	
S-FST-13113315-S	FAVO S-TLIF Cage 13 x 11 x 33 mm, 15° lor.	
S-FST-15113315-S	FAVO S-TLIF Cage 15 x 11 x 33 mm, 15° lor.	

# FAVO® S-TLIF Implants

Article number	Description	Illustration
S-FST-09113805-S	FAVO S-TLIF Cage 9 x 11 x 38 mm, 5° lor.	
S-FST-10113805-S	FAVO S-TLIF Cage 10 x 11 x 38 mm, 5° lor.	
S-FST-11113805-S	FAVO S-TLIF Cage 11 x 11 x 38 mm, 5° lor.	
S-FST-12113805-S	FAVO S-TLIF Cage 12 x 11 x 38 mm, 5° lor.	
S-FST-13113805-S	FAVO S-TLIF Cage 13 x 11 x 38 mm, 5° lor.	
S-FST-15113805-S	FAVO S-TLIF Cage 15 x 11 x 38 mm, 5° lor.	
S-FST-17113805-S	FAVO S-TLIF Cage 17 x 11 x 38 mm, 5° lor.	
S-FST-11113810-S	FAVO S-TLIF Cage 11 x 11 x 38 mm, 10° lor.	
S-FST-12113810-S	FAVO S-TLIF Cage 12 x 11 x 38 mm, 10° lor.	
S-FST-13113810-S	FAVO S-TLIF Cage 13 x 11 x 38 mm, 10° lor.	
S-FST-15113810-S	FAVO S-TLIF Cage 15 x 11 x 38 mm, 10° lor.	
S-FST-17113810-S	FAVO S-TLIF Cage 17 x 11 x 38 mm, 10° lor.	
S-FST-13113815-S	FAVO S-TLIF Cage 13 x 11 x 38 mm, 15° lor.	
S-FST-15113815-S	FAVO S-TLIF Cage 15 x 11 x 38 mm, 15° lor.	
S-FST-17113815-S	FAVO S-TLIF Cage 17 x 11 x 38 mm, 15° lor.	

System:  
FAVO

Implant type:  
S-TLIF

Configuration:  
38 mm

Material:  
Ti6Al4V ELI

# FAVO® S-TLIF Trial Implants

System:  
FAVO

Instrument type:  
Trial implant

Configuration:  
28-38 mm

Material:  
Stainless Steel

Article number	Description	Illustration
FI-T07112805	FAVO S-TLIF Trial Height 7 mm, 5° lor.	
FI-T08112805	FAVO S-TLIF Trial Height 8 mm, 5° lor.	
FI-T09112805	FAVO S-TLIF Trial Height 9 mm, 5° lor.	
FI-T10112805	FAVO S-TLIF Trial Height 10 mm, 5° lor.	
FI-T11112805	FAVO S-TLIF Trial Height 11 mm, 5° lor.	
FI-T12112805	FAVO S-TLIF Trial Height 12 mm, 5° lor.	
FI-T13112805	FAVO S-TLIF Trial Height 13 mm, 5° lor.	
FI-T15112805	FAVO S-TLIF Trial Height 15 mm, 5° lor.	
FI-T17112805	FAVO S-TLIF Trial Height 17 mm, 5° lor.	

System:  
FAVO

Instrument type:  
Trial implant

Configuration:  
28-38 mm

Material:  
Stainless Steel


Article number	Description	Illustration
FI-T11112815	FAVO S-TLIF Trial Height 11 mm, 15° lor.	
FI-T12112815	FAVO S-TLIF Trial Height 12 mm, 15° lor.	
FI-T13112815	FAVO S-TLIF Trial Height 13 mm, 15° lor.	
FI-T15112815	FAVO S-TLIF Trial Height 15 mm, 15° lor.	
FI-T17112815	FAVO S-TLIF Trial Height 17 mm, 15° lor.	







# FAVO® S-TLIF and ROCCIA® Instruments

Article number	Description	Illustration	Page
RI-1020	ROCCIA Ring Endplate Scraper Straight		8, 9
RI-1021	ROCCIA Ring Endplate Scraper Angled 25°		
RI-1022	ROCCIA Ring Endplate Scraper Curved 45°		
RI-1030	ROCCIA Box Endplate Scraper Straight		9
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RI-1041	ROCCIA Curette Curved Right 45°		8
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FI-4113	FAVO Shaver 13 mm, parallel		
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