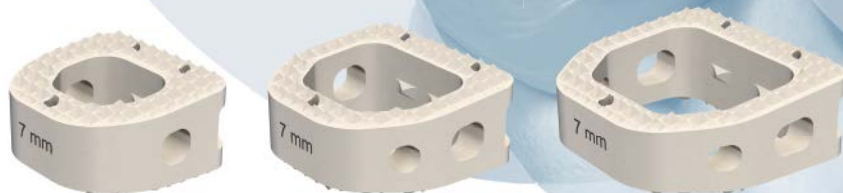


# ACIS<sup>®</sup>—ANTERIOR CERVICAL INTERBODY SPACER

An enhanced system of  
implants and instruments  
for interbody fusion.



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SURGICAL TECHNIQUE



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# ACIS—ANTERIOR CERVICAL INTERBODY SPACER

An enhanced system of implants and instruments for interbody fusion.

## ACIS SPACERS

### Material

PEEK\* Optima™ radiolucent material with a modulus of elasticity between cortical and cancellous bone,<sup>1</sup> allowing optimal load sharing.

### Anatomical sizing

Spacers are offered in three axial footprints, eight heights and three sagittal profiles to accommodate individual patient anatomy and surgical techniques.\*\*

### Implant heights

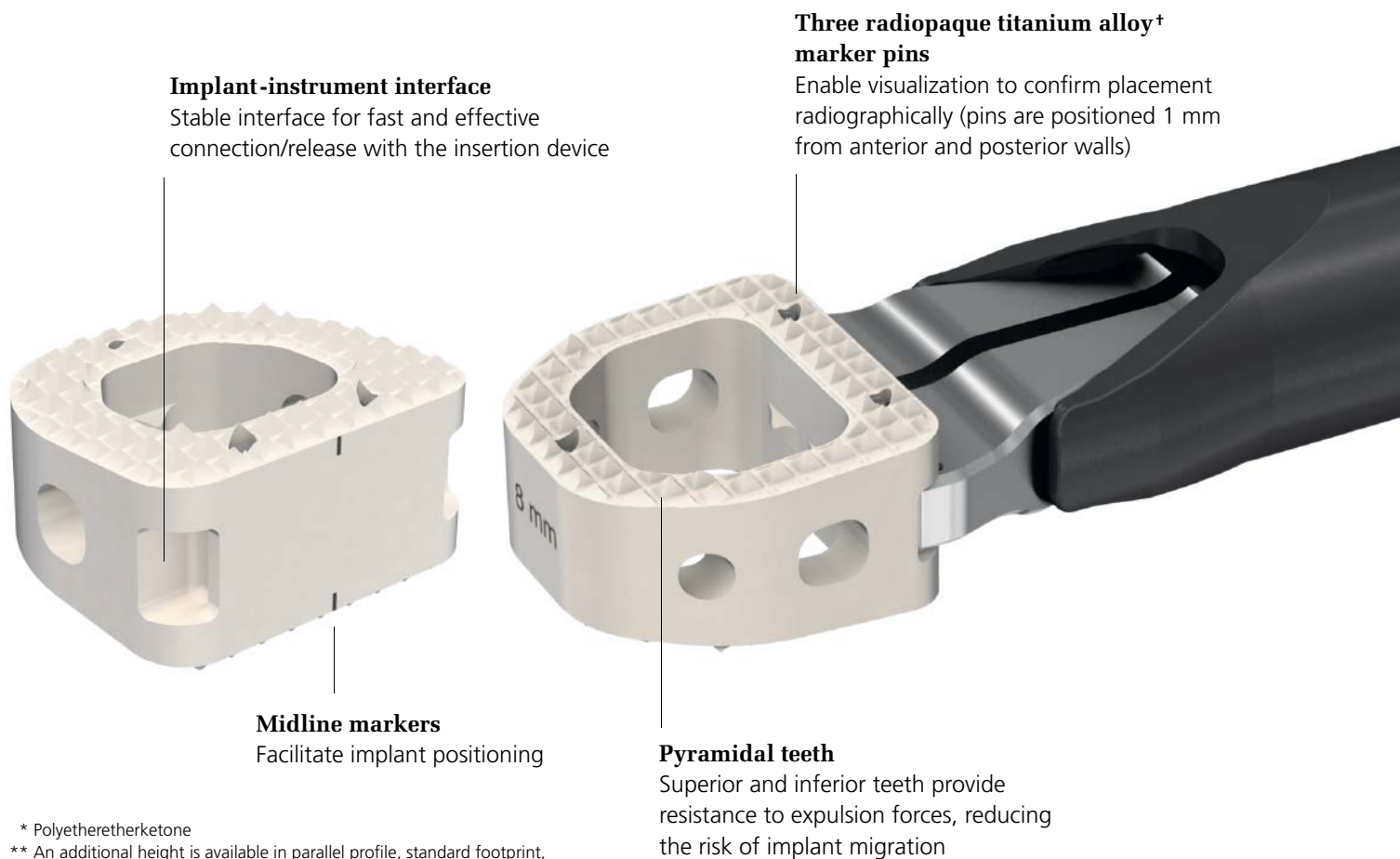
5 mm–12 mm in 1 mm increments (measured at anterior of implant for lordotic and convex). 4 mm height available in parallel profile, standard footprint.

### Axial lumen

Large lumen maximizes area for packing autogenous bone graft allowing fusion to occur through the spacer.

### Lateral windows

Create additional surface area for bone growth.



\* Polyetheretherketone

\*\* An additional height is available in parallel profile, standard footprint, convex is available in standard only

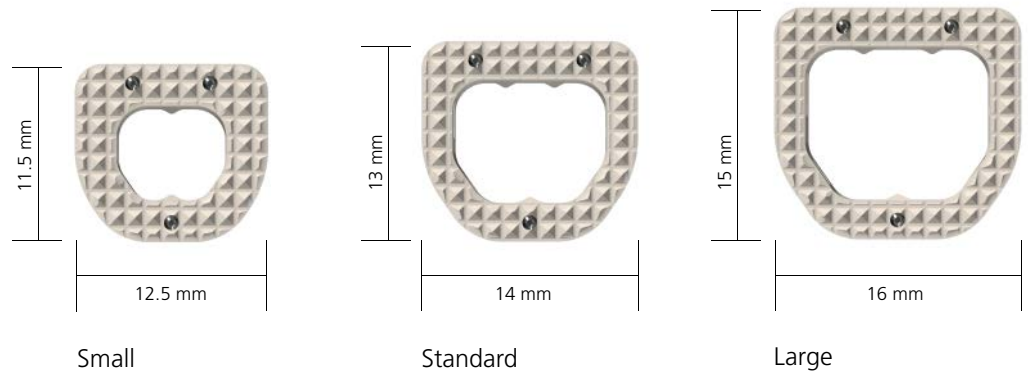
† Ti-6Al-4V

1. Data provided by Invivio PEEK-Optima brochure (PO-ENG-SUR-01 (09/07.01)).

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**Three Footprints**

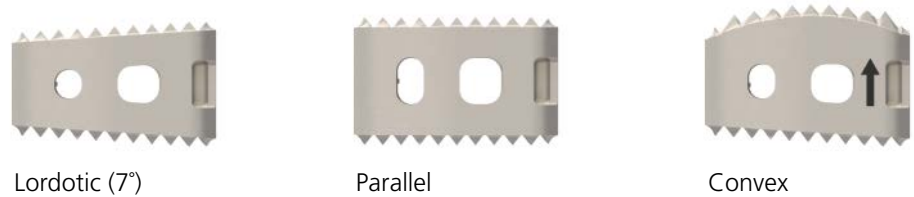
- Small
- Standard
- Large



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**Three Sagittal Profiles**

- Lordotic (7°)
- Parallel
- Convex



---

**MR Conditional**

The ACIS System device is labeled MR Conditional where it has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

Please refer to page 8 for further information.



## ACIS INSTRUMENTS

The ACIS Instrumentation Set is designed to streamline the ACDF procedure. The instruments utilize ergonomic and efficient designs for ease of use of the ACIS system.

### Multiple implant insertion options

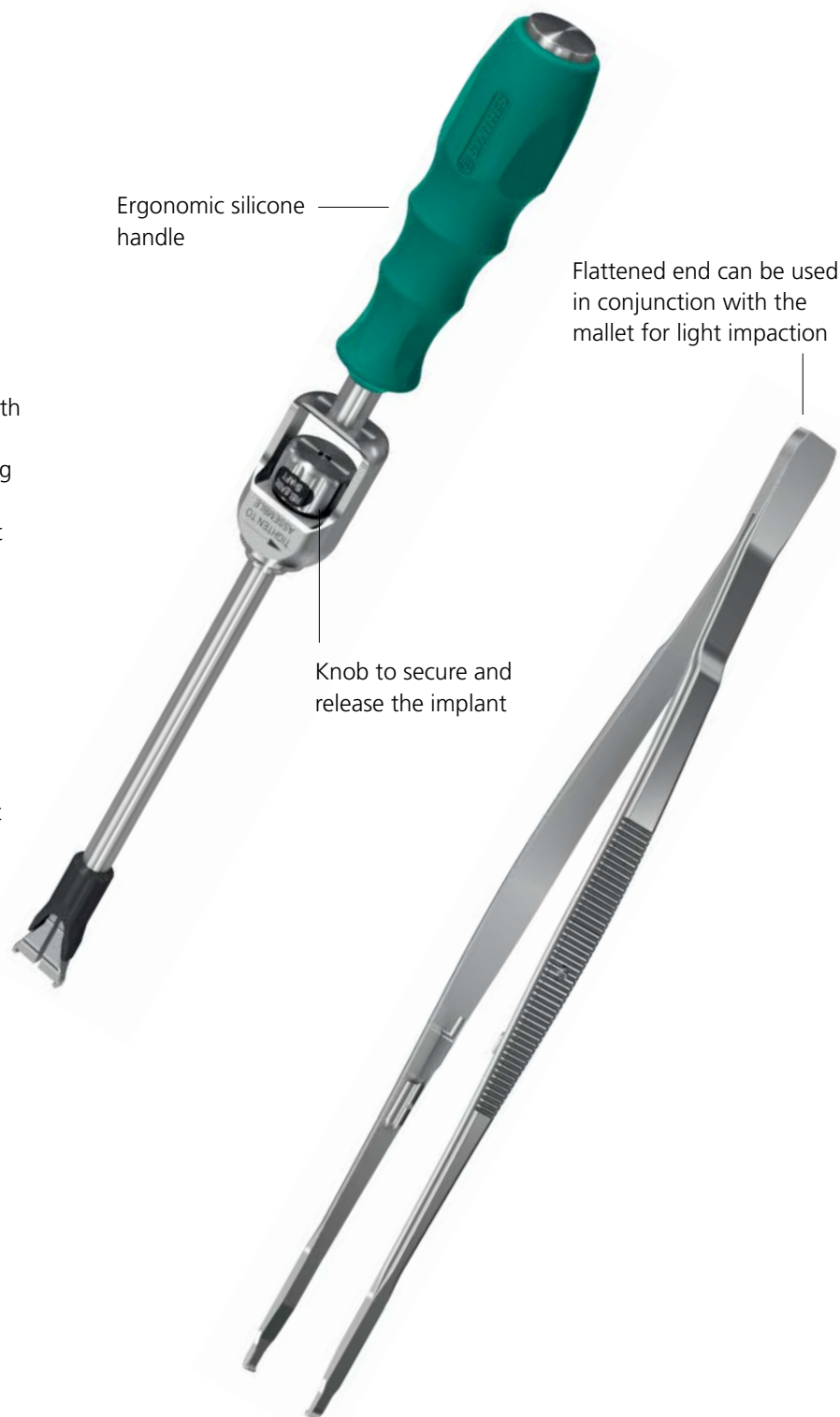
The ACIS instrumentation set allows two options for implant insertion that allow for secure, controlled implant delivery.

### Implant inserter

- Rigid interface for secure connection with the implant
- Slim implant interface for visibility during insertion
- Multiple shaft options with and without depth stops to accommodate surgeon preference
- Can be used in conjunction with the slotted mallet for insertion and removal

### Implant holder

- Alternative implant insertion instrument allows for precision control
- Quick implant engagement and disengagement with one click squeeze-lock mechanism
- Thin design allows for excellent visibility



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**Streamlined trialing**

- Thin, preassembled trials allow for visibility during trialing
- Double-sided to minimize passing steps and for quick height comparisons
- Color-coded by sagittal profile



Blue (lordotic)



Purple (parallel)



Yellow (convex)

Double lines denote larger size (even size)

Single line denotes smaller size (odd size)

# AO PRINCIPLES

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In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.<sup>1</sup> They are:

- Anatomic reduction
- Stable internal fixation
- Preservation of blood supply
- Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.<sup>2</sup>

1. Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin Heidelberg New York: Springer. 1991.

2. Ibid.



# INDICATIONS AND CONTRAINDICATIONS

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## **Indications**

The Synthes ACIS System is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of nonoperative treatment. The interior of the Synthes ACIS should be packed with autogenous bone graft material and implanted via an anterior approach. The Synthes ACIS is intended to be used with supplemental fixation.

## **Contraindications**

- Use of the Synthes ACIS system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials
- Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patient
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions. These patients may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure
- Any condition not described in the indications for use

Please refer to the package insert (GP2868) for the full list of indications and precautions.

# MRI INFORMATION

The Synthes ACIS System devices are labeled MR Conditional according to the terminology specified in ASTM F 2503, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Non-clinical testing of the Synthes ACIS devices demonstrated that the implant is MR Conditional. A patient with a Synthes ACIS device may be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla and 3.0-Tesla
- Highest spatial gradient magnetic field of 3000-G/cm (300 mT/cm) or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode for 15 minutes of scanning

To minimize heating, the scan time should be as short as possible, and the SAR as low as possible.

**Note: In non-clinical testing, a Synthes ACIS device with the largest titanium alloy marker pins was tested for heating and results showed no additional RF heating effects compared to the reference test with removed implant at 1.5T and 3.0T. Patients may be safely scanned in the MRI chamber at the above conditions.**

The above field conditions tested in a 1.5T and a 3.0T Philips Achieva (Philips Healthcare, Software release 3.2.1) and the 3T Philips Ingenia (Philips Healthcare, Software release 4.1.1 SP1). MR scanner should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. Synthes MR Conditional Synthes ACIS devices may have the potential to cause artifact in the diagnostic imaging.

## Artifact Information

A representative implant has been evaluated in the MRI chamber and worst case artifact information is provided below. Artifacts created by Synthes ACIS devices may prevent the lumen from being visible in some MR sequences. However, during clinical routine scanning even smaller image artifacts are expected for most of the protocols. Direction and size of the artifact will strongly depend on the slice orientation and the phase encoding direction of the used protocol.

The image artifact extends up to approximately 6 mm from the Synthes ACIS devices, both inside and outside the device lumen when scanned in nonclinical testing in a 1.5 Tesla Philips Achieva (Philips Healthcare, Software release 3.2.1) and in the 3 Tesla Philips Ingenia (Philips Healthcare, Software release 4.1.1 SP1) using the following sequences:

- For FFE sequence: TR 100ms, TE 15ms, flip angle 30° worst case artifact will extend approximately 4.5 mm from the implant
- For SE sequence: Scan duration: 4 min, TR 500ms, TE 20ms, flip angle 70°, worst-case artifact will extend approximately 5 mm from the implant



# PREPARATION AND APPROACH

## Preoperative planning

All necessary imaging studies should be available to plan implant placement and visualize individual patient anatomy.

## Patient positioning

- Position the patient in a supine position on a radiolucent operating table. Ensure that the neck of the patient is in a neutral position and supported by a cushion. When treating C6–C7 make sure that the shoulders do not limit the x-ray monitoring. For all cases both vertebrae should be completely visible.



Using the standard anterior cervical surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following the appropriate technique for the given indication.



**Approach**

**Distraction instruments and pins**

03.841.058 Distractor Pin Driver

03.841.056 Cervical Distractor

Distractor Pin

02.600.022 12 mm

02.600.024 14 mm

02.600.026 16 mm

or

Retainer Screw

03.820.102 3.5 mm x 12 mm

03.820.103 3.5 mm x 14 mm

03.820.104 3.5 mm x 16 mm

03.820.105 3.5 mm x 18 mm

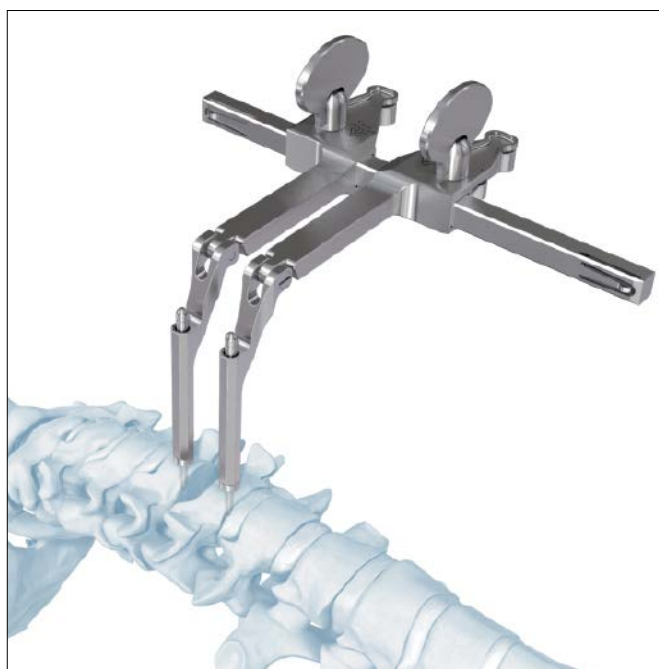
**Optional**

03.820.110 Retainer Nut\*

For distraction, insert the distractor pins into adjacent vertebral bodies. Pin placement is based upon the pathology, extent of decompression required, and sagittal alignment. Use the distractor pin driver to insert the distractor pins.

Place the cervical distractor over the pins. Use the knobs to adjust the distractor to the appropriate position.

**Note:** It is not recommended to over-distract the disc space. Distraction should not deviate excessively from measurements taken from pre-surgery radiographs and should be released during trialing and implant insertion steps.



\* For use with retainer screws only

# ENDPLATE PREPARATION

## Optional technique

### Instruments

03.820.113	Slotted Mallet
03.841.150	ACIS Endplate Rasp
03.841.025– 03.841.032	Trial Rasp, Lordotic, 5 mm–12 mm
03.841.125– 03.841.132	Trial Rasp, Parallel, 5 mm–12 mm

If preferred, prior to trialing, trial rasps or the endplate rasp may be used to prepare endplates by sequentially inserting and removing rasps to create an area of bleeding bone.



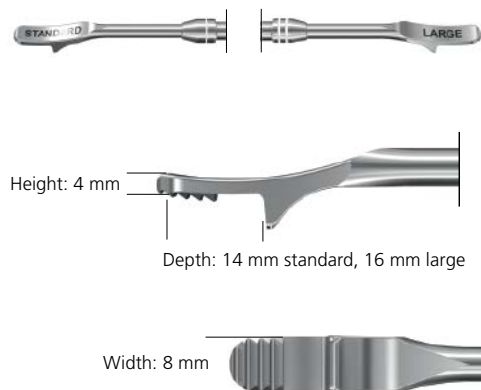
### Trial rasp notes

- Trial rasps have anterior stops designed to limit AP depth (1.5 mm from the anterior edge of the vertebral body)
- These stops provide a visual indication of the rasp location. You should stop insertion once the stop contacts the vertebral body
- Trial rasps have .75 mm teeth on each side and an overall height of 0.4 mm less than the implant height to create the correct sized void after bone removal

**Caution:** In order to avoid subsidence, do not be aggressive when removing bone with the endplate rasp or trial rasps.

### Endplate rasp notes

- The endplate rasp is double sided with a standard depth on one side and a large depth on the other side. These are indicated by one (standard) and two (large) white bands on the shaft as well as etchings on the rear side of the rasp
- The depth is limited by a stop
- Depths are 14 mm for the standard and 16 mm for the large
- The width is 8 mm and the height of the rasp is 4 mm



# IMPLANT SIZING

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## 1

### Determine the appropriate implant

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#### Instruments

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03.841.005– 03.841.011	Double-Sided Trial Spacer, Lordotic, Standard, 5 mm–12 mm
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03.841.105– 03.841.111	Double-Sided Trial Spacer, Parallel, Standard, 5 mm–12 mm
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03.841.205– 03.841.211	Double-Sided Trial Spacer, Convex, Standard, 5 mm–12 mm
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03.841.305– 03.841.311	Double-Sided Trial Spacer, Lordotic, Large, 5 mm–12 mm
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03.841.405– 03.841.411	Double-Sided Trial Spacer, Parallel, Large, 5 mm–12 mm
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03.841.605– 03.841.611	Double-Sided Trial Spacer, Lordotic, Small, 5 mm–12 mm
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03.841.705– 03.841.711	Double-Sided Trial Spacer, Parallel, Small, 5 mm–12 mm
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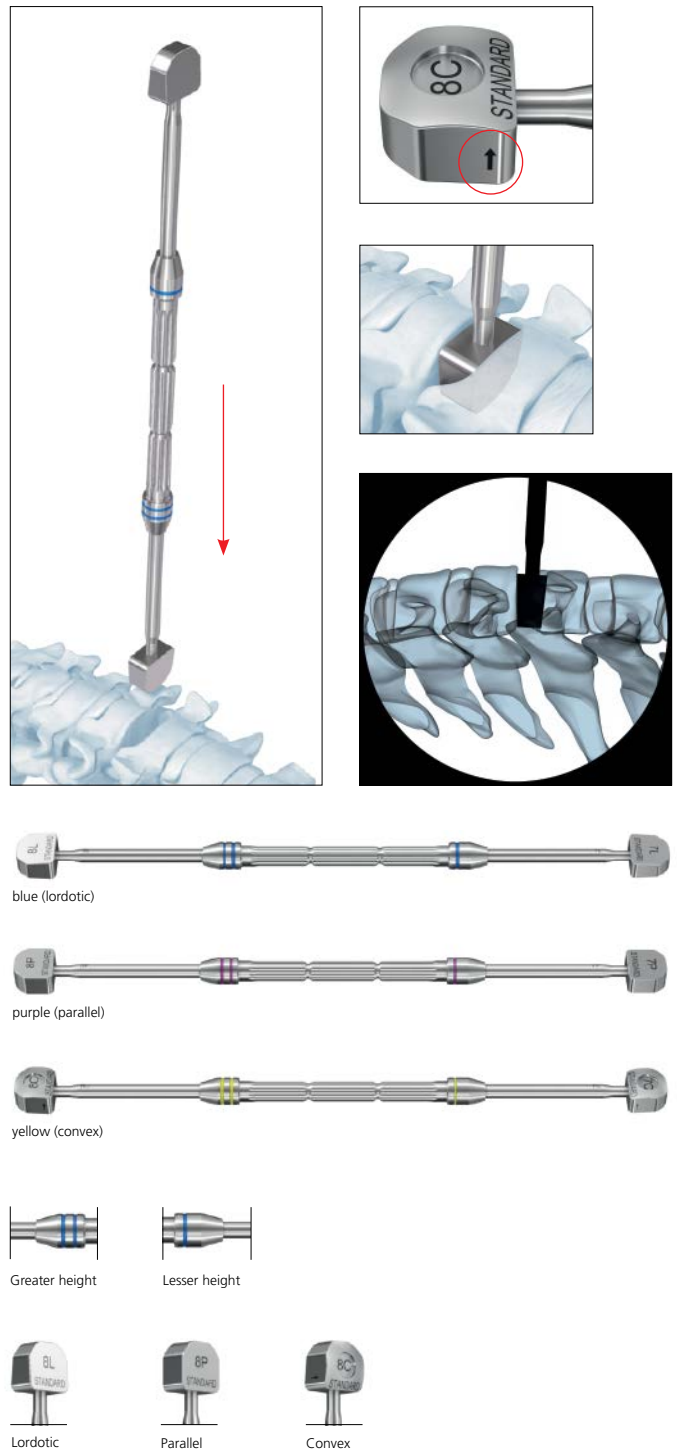
Selection of the trial spacer depends on the height, width and depth of the intervertebral space, the preparation technique and the patient's anatomy. Based on the pre-operative imaging and surgical technique, choose a standard, large or small footprint trial spacer with parallel, lordotic or convex sagittal shape of the appropriate height.

Verify the trial spacer size and carefully insert it into the disc space. When using the convex trials, verify that they are in the correct cranial/caudal alignment prior to insertion.

**Notes**

- The trial spacers do not have a depth stop; an image intensifier should be used to visualize and check the position during insertion
- The trial spacers are double sided with different heights on either side. Colored bands on the shaft indicate which side is of lesser (one band) or greater (two bands) height. In addition heights are etched on the cranial and caudal surfaces of the trial spacers
- Trial spacers are color coded by sagittal shape: blue, purple, and yellow bands indicate that a trial spacer is lordotic, parallel, or convex. The spacers are also etched on the cranial and caudal surfaces indicating the sagittal shape: "L" for lordotic, "P" for parallel and "C" for convex
- The footprint sizes are indicated by the etchings "Small", "Standard" and "Large" on the cranial and caudal surfaces of the trial implants
- With the segment fully distracted, the trial spacer must fit tightly and accurately between the end plates
- The convex trial spacers have an arrow indicating the cranial direction. The parallel and lordotic trials do not have an indicated cranial or caudal side

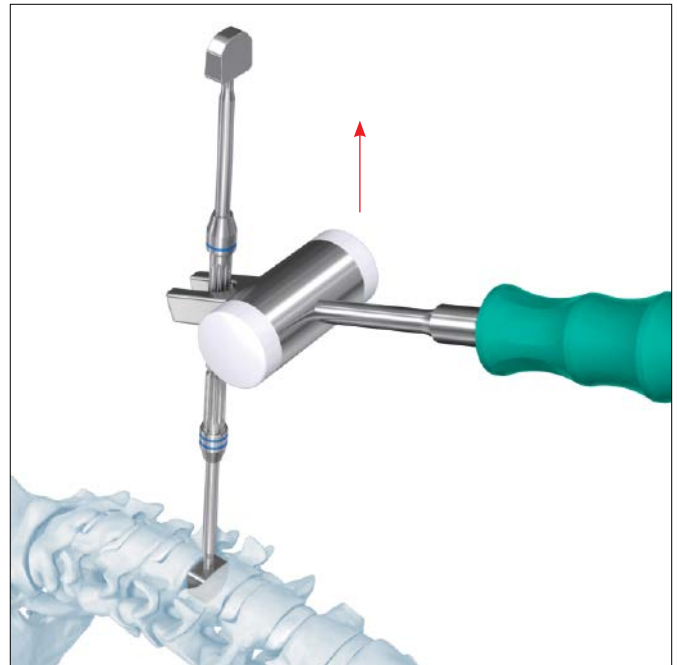
**Caution:** To minimize potential to overdistract, it is recommended to trial with smaller height trial spacers before trialing with taller height trial spacers.



If necessary, trials can be carefully tapped with the mallet to help advance the trial into the disc space. The forked end of the mallet can be utilized on the knurled portion of the shaft of the trial for assistance during removal.

**Important**

- The height of the trial spacer is 0.5 mm less than that of the corresponding implant to account for penetration of the teeth into the vertebral end plate
- Trial spacers are not for implantation and must be removed before insertion of the ACIS implant





# IMPLANT INSERTION

## Option A. Implant inserter

### 1

#### Attach implant to implant inserter

##### Instruments

03.841.050	ACIS Implant Inserter
and	
03.841.059	Inner Shaft, Standard, for ACIS Implant Inserter
or	
03.841.057	Inner Shaft with Stops, Small, for ACIS Implant Inserter
or	
03.841.060	Inner Shaft with Stops, Standard, for ACIS Implant Inserter
or	
03.841.061	Inner Shaft, Small, for ACIS Implant Inserter

Select the ACIS implant that corresponds to the footprint, shape and height determined using the trial implant.

Refer to page 25 for ACIS insertion device assembly. If desired, the insertion device can be combined with an inner shaft with stop. It has a depth stop that will contact the anterior edge of the vertebral body when the ACIS implant is inserted approximately 1 mm beyond the anterior edge of the vertebral body.

Attach the implant to the ACIS insertion device by aligning the recessed grooves located on the side walls of the implant with the prolonged tabs of the instrument tip and engaging those.

**Note:** Turn the knob clockwise to secure the implant.

Ensure that the implant is held flush against the insertion device and securely in the tabs.



## 2

### Pack implant with bone graft

#### Instruments

03.841.054 Graft Packing Instrument

03.841.055 Graft Packing Block

Autogenous bone graft may be collected in the collecting area of the graft packing block.

Place the appropriate ACIS implant into the packing block. Small and standard implants can be packed in the side marked as "Standard." Large footprint implants can be packed on the side marked as "Large."

The graft packing instrument may be used to pack the autogenous graft material into the implant lumen.

#### Notes

- To ensure optimal contact with the vertebral endplates it is important to fill the implant lumen fully
- A table on page 27 shows the approximate autogenous bone graft volume that the ACIS implants hold, depending on the footprint, height and sagittal profile

**Caution:** Excessive impaction of the implant with the cancellous bone impactor should be avoided to prevent possible implant damage.



### 3 Insert implant

#### Instruments

03.841.050	ACIS Implant Inserter
03.841.059	Inner Shaft Without Stops for ACIS Implant Inserter

#### Optional instruments

03.820.113	Mallet
03.841.057	Inner Shaft With Stops for Small ACIS Implant Inserter
03.841.060	Inner Shaft With Stops for ACIS Implant Inserter
03.841.061	Inner Shaft Without Stops for Small ACIS Implant Inserter

Confirm the implant is securely attached. Carefully insert the implant into the distracted segment, ensuring that the orientation of the implant is correct (convex only).

If necessary, controlled and light hammering with the mallet can be used to help advance the implant into the intervertebral disc space.



Turn the knob in a counterclockwise direction to release the implant from the implant inserter.

Remove the implant inserter and if required, use the flat impactor to seat the implant into its final position, if needed.

**Notes**

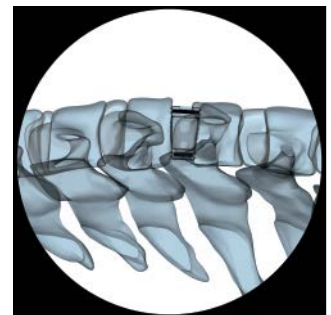
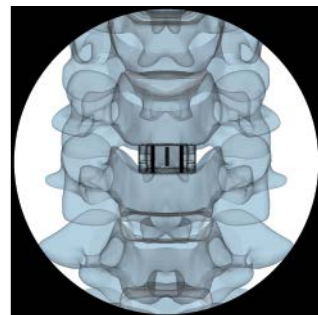
- For the convex implant, the correct orientation is with the convex surface pointing cranially. This is also indicated by an arrow etched on the implant side wall, pointing cranially
- The parallel and lordotic versions have a symmetrical sagittal profile and therefore no special orientation is recommended



- **Important:** Verify final implant position relative to the vertebral bodies in the AP and lateral direction with the help of intraoperative imaging. Position should be verified even when utilizing the implant inserter in conjunction with the shaft with a stop. The PEEK spacer has three x-ray markers incorporated into the implant to enable accurate intraoperative radiographic assessment of the implant position.

**Notes**

- 1.0 mm diameter TAV pins as X-ray markers
- Distance between pins and the anterior and posterior walls of the implant is approx. 1.0 mm (see page 27 for details)
- Posterior pin is centered



\* Ti-6Al-4V

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**Option B. Implant holder**

**1**  
**Attach implant to implant holder**

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**Instrument**

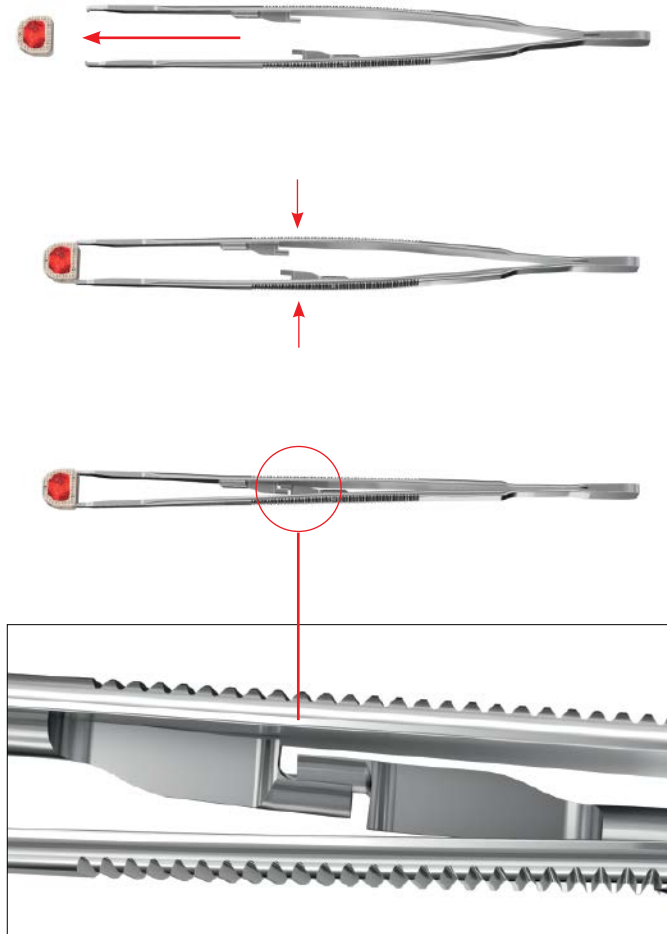
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03.841.053 ACIS Implant Holder

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Select the ACIS implant that corresponds to the footprint, shape and height determined using the trial implant.

Attach the implant to the ACIS implant holder by aligning the recessed grooves located on the side walls of the implant with the prolonged tabs of the instrument tip. Engage the squeeze-lock by applying slight pressure on the arms of the implant holder.



## 2

### Pack implant with bone graft

#### Instruments

03.841.054 Graft Packing Instrument

03.841.055 Graft Packing Block

Autogenous bone graft may be collected in the collecting area of the graft packing block.

Place the appropriate ACIS implant into the packing block. Small and standard implants can be packed in the side marked as "Standard." Large footprint implants can be packed on the side marked as "Large."

The graft packing instrument may be used to pack the autogenous graft material into the implant lumen.

#### Notes

- To ensure optimal contact with the vertebral endplates it is important to fill the implant lumen fully
- A table on page 27 shows the approximate autogenous bone graft volume that the ACIS implants hold, depending on the footprint, height and sagittal profile

**Caution:** Excessive impaction of the implant with the cancellous bone impactor should be avoided to prevent possible implant damage.



### 3

#### Insert implant

##### Instrument

03.841.053 ACIS Implant Holder

##### Optional instruments

03.617.981 Impactor, flat

03.820.113 Mallet

Confirm the implant is securely attached. Carefully insert the implant into the distracted segment, ensuring that the orientation of the implant is correct. Each convex implant is etched with an arrow pointing cranially on the left lateral wall to indicate the correct cranial/caudal alignment. The lordotic and parallel implants have a symmetrical sagittal profile and therefore do not require specific orientation.

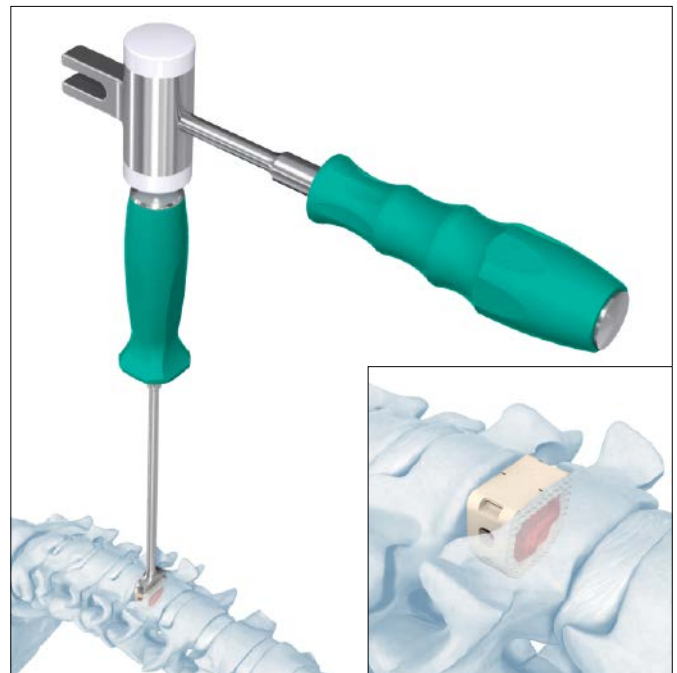
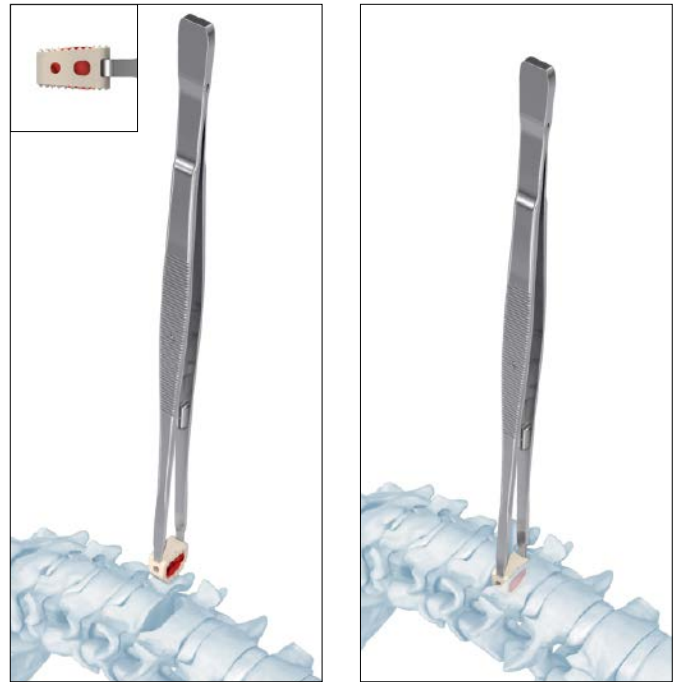
Release the implant holder by applying slight pressure on the arms of the implant holder and disengaging the squeeze-lock. Remove the holder and if required use the flat impactor to seat the implant into its final position.

- Use image intensifier to confirm the position of the implant.

#### Precautions

- **The implant holder does not feature a depth stop. Image intensifier control should be used to check the position during insertion**
- **Excessive tilting of the implant holder must be avoided to prevent implant separation or damage**

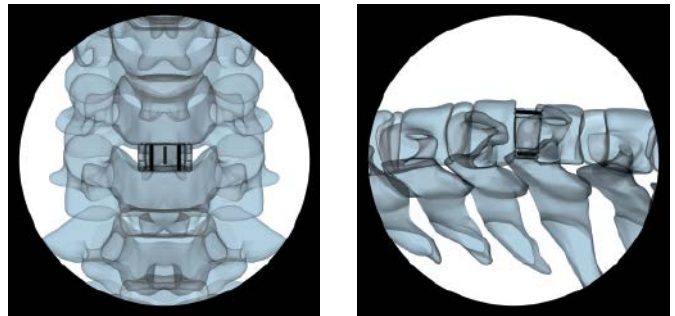
**Warning:** Excessive impaction must be avoided to prevent implant damage or inserting the implant too deep.



ⓘ **Important:** Verify final implant position relative to the vertebral bodies in the AP and lateral direction with the help of an intraoperative X-ray. The ACIS implant has three X-ray markers incorporated into the implant to enable accurate intraoperative radiographic assessment of the implant position.

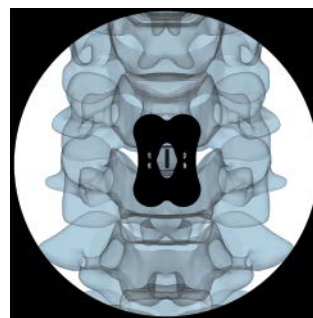
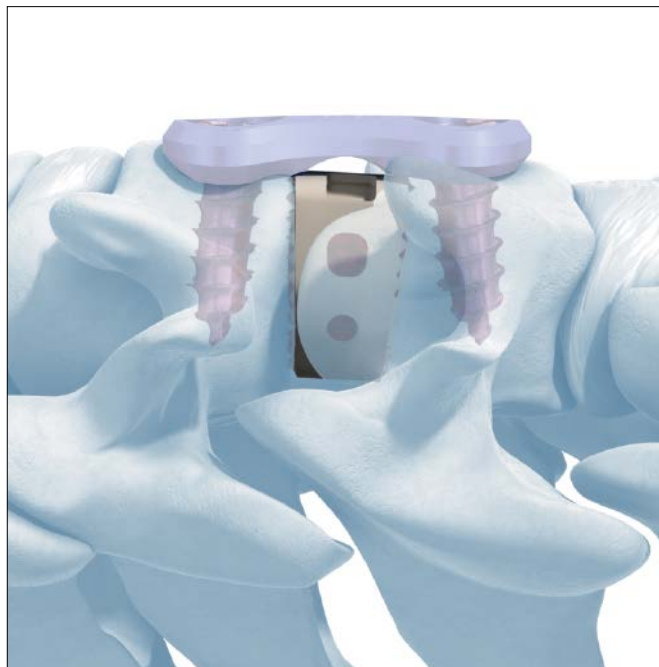
**Notes**

- 1.0 mm diameter TAV pins as X-ray markers
- Distance between pins and the anterior and posterior walls of the implant is approx. 1.0 mm (see page 27 for details)
- Posterior pin is centered





Complete the procedure by following the surgical technique for the specific device to be used as supplemental fixation, such as the Synthes Vectra Anterior Cervical Plate System.



# IMPLANT REMOVAL

## Implant removal

### Instruments

03.841.050	ACIS Implant Inserter
03.841.051	Knob for ACIS Implant Inserter
03.841.059	Inner Shaft Without Stops for ACIS Implant Inserter

### Optional instruments

03.841.061	Inner Shaft Without Stops for Small ACIS Implant Inserter
03.820.113	Mallet

Attach the inserter to the spacer in the disc space by aligning the pronged tabs of the instrument tip to the recessed grooves located on the side walls of the implant taking care not to push the implant towards the posterior. Tighten the knob clockwise until the spacer has a rigid connection to inserter shaft. Once the implant is securely attached, remove the implant from the disc space.

The forked portion mallet may also be used along the shaft of the inserter to assist in the removal.



# IMPLANT INSERTER ASSEMBLY INSTRUCTIONS

## Assembly instructions

### Instruments

03.841.050	ACIS Implant Inserter
03.841.051	Knob for ACIS Implant Inserter
03.841.059	Inner Shaft Without Stops for ACIS Implant Inserter

### Optional instruments

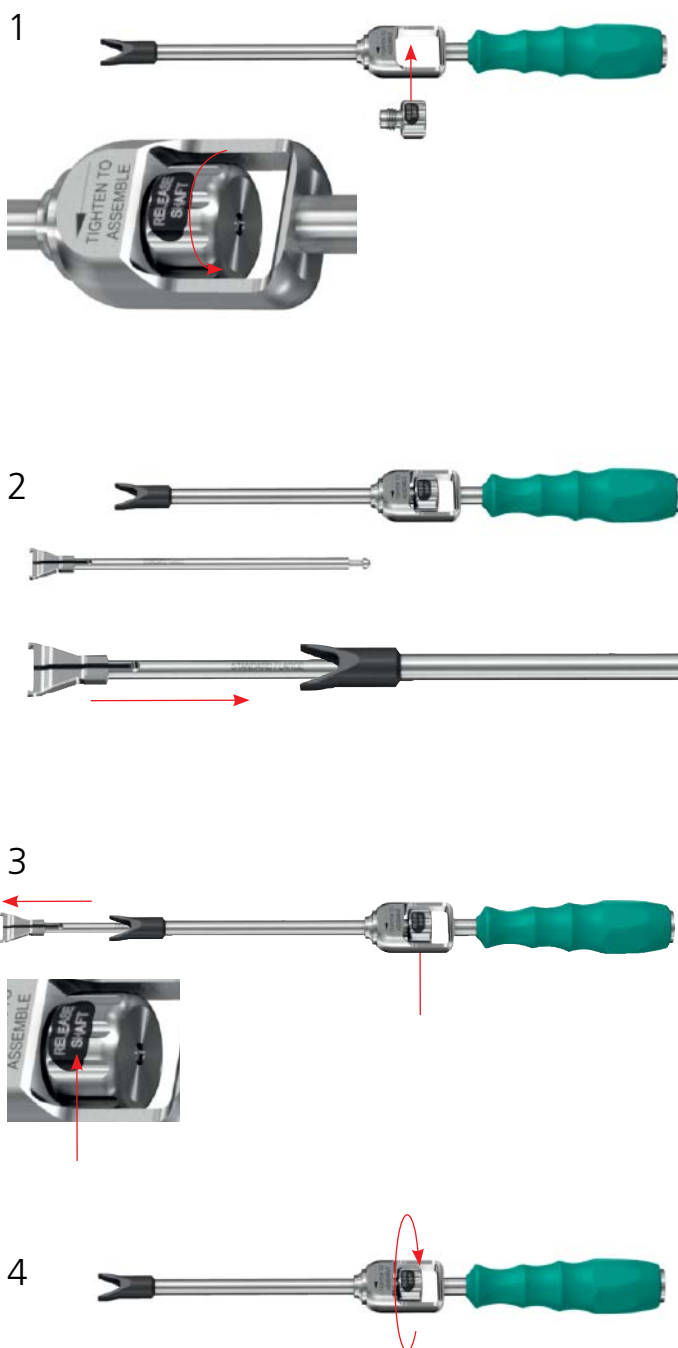
03.841.057	Inner Shaft With Stops for Small ACIS Implant Inserter
03.841.060	Inner Shaft With Stops for ACIS Implant Inserter
03.841.061	Inner Shaft Without Stops for Small ACIS Implant Inserter

## Assembly

1. Attach the implant inserter knob by screwing the knob counterclockwise (in the direction labeled "Tighten to Assemble") until it stops.
2. Install the inner shaft into the cannulated portion of the inserter handle until the release button on the knob clicks into place.

## Disassembly

3. Press the button on the knob to release the shaft.
4. Remove the knob by turning clockwise.



# ACIS IMPLANT OPTIONS

## ACIS IMPLANTS

### ACIS implants

- Supplied sterile and non-sterile
- Implant material: PEEK with titanium alloy (Ti-6Al-4V) radiographic marker pins



	Lordotic Sterile	Non-Sterile	Parallel Sterile	Non-Sterile	Convex Sterile	Non-Sterile
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### Standard

Footprint: 14 mm x 13 mm

5 mm	08.843.005S	08.843.005	08.843.105S	08.843.105	08.843.205S	08.843.205
6 mm	08.843.006S	08.843.006	08.843.106S	08.843.106	08.843.206S	08.843.206
7 mm	08.843.007S	08.843.007	08.843.107S	08.843.107	08.843.207S	08.843.207
8 mm	08.843.008S	08.843.008	08.843.108S	08.843.108	08.843.208S	08.843.208
9 mm	08.843.009S	08.843.009	08.843.109S	08.843.109	08.843.209S	08.843.209
10 mm	08.843.010S	08.843.010	08.843.110S	08.843.110	08.843.210S	08.843.210
11 mm	08.843.011S	08.843.011	08.843.111S	08.843.111	08.843.211S	08.843.211
12 mm	08.843.012S	08.843.012	08.843.112S	08.843.112	08.843.212S	08.843.212

### Large

Footprint: 16 mm x 15 mm

5 mm	08.843.305S	08.843.305	08.843.405S	08.843.405	–	–
6 mm	08.843.306S	08.843.306	08.843.406S	08.843.406	–	–
7 mm	08.843.307S	08.843.307	08.843.407S	08.843.407	–	–
8 mm	08.843.308S	08.843.308	08.843.408S	08.843.408	–	–
9 mm	08.843.309S	08.843.309	08.843.409S	08.843.409	–	–
10 mm	08.843.310S	08.843.310	08.843.410S	08.843.410	–	–
11 mm	08.843.311S	08.843.311	08.843.411S	08.843.411	–	–
12 mm	08.843.312S	08.843.312	08.843.412S	08.843.412	–	–

### Small

Footprint: 12.5 mm x 11.5 mm

5 mm	08.843.605S	08.843.605	08.843.705S	08.843.705	–	–
6 mm	08.843.606S	08.843.606	08.843.706S	08.843.706	–	–
7 mm	08.843.607S	08.843.607	08.843.707S	08.843.707	–	–
8 mm	08.843.608S	08.843.608	08.843.708S	08.843.708	–	–
9 mm	08.843.609S	08.843.609	08.843.709S	08.843.709	–	–
10 mm	08.843.610S	08.843.610	08.843.710S	08.843.710	–	–
11 mm	08.843.611S	08.843.611	08.843.711S	08.843.711	–	–
12 mm	08.843.612S	08.843.612	08.843.712S	08.843.712	–	–

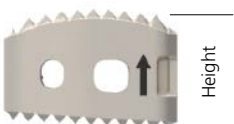
# ACIS IMPLANT OPTIONS

## Autogenous bone graft volume

The table below shows the approximate autogenous bone graft volume (in cc) that ACIS implants will hold, depending on the footprints, heights and sagittal profiles.

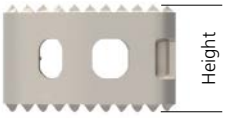
### Convex

	5	6	7	8	9	10	11	12
Standard	0.4	0.5	0.6	0.6	0.7	0.8	0.9	1.0



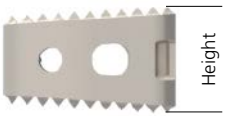
### Parallel

	5	6	7	8	9	10	11	12
Small	0.2	0.2	0.3	0.3	0.4	0.4	0.5	0.5
Standard	0.3	0.4	0.5	0.6	0.7	0.7	0.8	0.9
Large	0.5	0.6	0.8	0.9	1.0	1.1	1.2	1.4



### Lordotic

	5	6	7	8	9	10	11	12
Small	0.2	0.2	0.2	0.3	0.3	0.4	0.4	0.5
Standard	0.3	0.3	0.4	0.5	0.6	0.7	0.8	0.8
Large	0.4	0.5	0.6	0.8	0.9	1.0	1.1	1.2



## Implant height

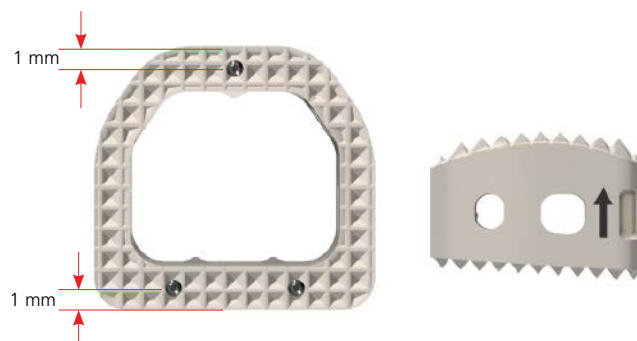
- Heights are measured at the anterior edge of the implant and the height includes the teeth
- Lordotic implants have a 7 degree angle of lordosis
- The height of the posterior edge of the standard lordotic implant is 1.6 mm shorter than the anterior edge (the difference in the small lordotic spacer is 1.4 mm and difference of the large lordotic spacer is 1.8 mm)
- Convex implants have a domed cranial endplate and a 3.5 degree angle of lordosis on the caudal endplate
- The height of the posterior edge of the implant for the standard convex spacer is 1.4 mm shorter than the anterior heights

## Three radiographic marker pins

Enable visualization of the implant position


- 1.0 mm diameter TAV pins
- Distance between pins and the anterior and posterior walls of the implant is approx. 1.0 mm
- Posterior pin is centered
- Distance between anterior pins and lateral walls of the implant varies between the different footprint sizes:
 

Small	3.0 mm
Standard	4.0 mm
Large	5.0 mm




# INSTRUMENTS

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02.600.022	Distractor Pin 12 mm	
02.600.024	14 mm	
02.600.026	16 mm	
02.600.028	18 mm	


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03.617.981	Impactor, flat	
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03.820.113	Mallet	
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03.841.050	ACIS Implant Inserter	
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03.841.053	ACIS Implant Holder	
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03.841.054	Graft Packing Instrument	
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03.841.055	Graft Packing Block	
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03.841.057 Inner Shaft With Stops for Small ACIS Implant Holder



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03.841.056 Cervical Distractor



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03.841.058 Distractor Pin Driver



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03.841.059 Inner Shaft, Standard for ACIS Implant Inserter



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03.841.060 Inner Shaft with Stops, Standard for ACIS Implant Inserter



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03.841.061 Inner Shaft, Small for ACIS Implant Inserter



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03.841.150 ACIS Endplate Rasp



**Double-sided trials**

**Standard Footprint (14 mm x 13 mm)**

Lordotic	Parallel	Convex	Height (mm)
03.841.005	03.841.105	03.841.205	5/6
03.841.007	03.841.107	03.841.207	7/8
03.841.009	03.841.109	03.841.209	9/10
03.841.011	03.841.111	03.841.211	11/12



**Large Footprint (16 mm x 15 mm)**

Lordotic	Parallel	Height (mm)
03.841.305	03.841.405	5/6
03.841.307	03.841.407	7/8
03.841.309	03.841.409	9/10
03.841.311	03.841.411	11/12



**Small Footprint (12.5 mm x 11.5 mm)**

Lordotic	Parallel	Height (mm)
03.841.605	03.841.705	5/6
03.841.607	03.841.707	7/8
03.841.609	03.841.709	9/10
03.841.611	03.841.711	11/12



**Trial rasps**

Lordotic	Parallel	Height (mm)
03.841.025	03.841.125	5
03.841.026	03.841.126	6
03.841.027	03.841.127	7
03.841.028	03.841.128	8
03.841.029	03.841.129	9
03.841.030	03.841.130	10
03.841.031	03.841.131	11
03.841.032	03.841.132	12





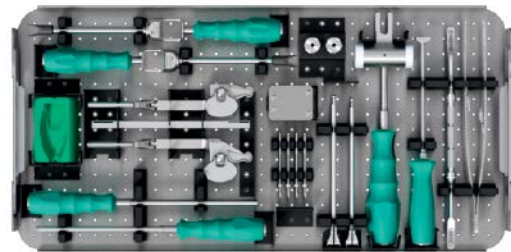
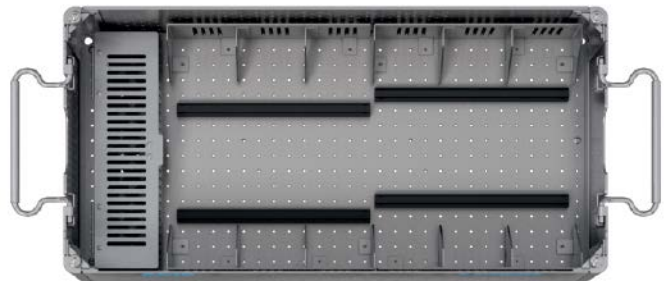
# ACIS INSTRUMENT SET (01.841.001)

## Graphic Case

60.841.001 Graphic Case for ACIS Instruments

## Instruments

- 02.600.022 Distractor Pin, 12 mm, 2 ea.
- 02.600.024 Distractor Pin, 14 mm, 4 ea.
- 02.600.026 Distractor Pin, 16 mm, 2 ea.
- 03.617.981 Impactor, Flat
- 03.820.113 Mallet
- 03.841.050 ACIS Implant Inserter, 2 ea.
- 03.841.053 ACIS Implant Holder
- 03.841.054 Graft Packing Instrument
- 03.841.055 Graft Packing Block
- 03.841.056 Cervical Distractor
- 03.841.057 Inner Shaft with Stops, Small for ACIS Implant Inserter
- 03.841.058 Distractor Pin Driver, 2 ea.
- 03.841.059 Inner Shaft with Stops, Standard for ACIS Implant Inserter, 2 ea.
- 03.841.060 Inner Shaft with Stops, Standard for ACIS Implant Inserter
- 03.841.061 Inner Shaft, Small for ACIS Implant Inserter
- 03.841.150 ACIS Endplate Rasp



For detailed cleaning and sterilization instructions, please refer to:  
[www.synthes.com/cleaning-sterilization](http://www.synthes.com/cleaning-sterilization)  
In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.

## TRIAL SPACER SETS

### ACIS Lordotic Trial Spacer Set (01.841.002)

60.841.002	Module for Standard Lordotic Trial Set
	Double-Sided Trial Spacer, Lordotic
03.841.005	5 mm/6 mm height
03.841.007	7 mm/8 mm height
03.841.009	9 mm/10 mm height
03.841.011	11 mm/12 mm height



### ACIS Parallel Trial Spacer Set (01.841.003)

60.841.003	Module for Standard Parallel Trial Set
	Double-Sided Trial Spacer, Parallel
03.841.105	5 mm/6 mm height
03.841.107	7 mm/8 mm height
03.841.109	9 mm/10 mm height
03.841.111	11 mm/12 mm height

### ACIS Large Parallel Trial Spacer Set (01.841.006)

60.841.006	Module for Large Parallel Trial Set
	Double-Sided Trial Spacer Parallel/Large
03.841.405	5 mm/6 mm height
03.841.407	7 mm/8 mm height
03.841.409	9 mm/10 mm height
03.841.411	11 mm/12 mm height

### ACIS Convex Trial Spacer Set (01.841.004)

60.841.004	Module for Standard Convex Trial Set
	Double-Sided Trial Spacer Convex
03.841.205	5 mm/6 mm height
03.841.207	7 mm/8 mm height
03.841.209	9 mm/10 mm height
03.841.211	11 mm/12 mm height

### ACIS Small Lordotic Trial Set (01.841.009)

03.841.009	Module for Small Lordotic Trial Set
	Double-Sided Trial Spacer Small/Lordotic
03.841.605	5 mm/6 mm height
03.841.607	7 mm/8 mm height
03.841.609	9 mm/10 mm height
03.841.611	11 mm/12 mm height

### ACIS Large Lordotic Trial Spacer Set (01.841.005)

60.841.005	Module for Large Lordotic Trial Set
	Double-Sided Trial Spacer Lordotic/Large
03.841.305	5 mm/6 mm height
03.841.307	7 mm/8 mm height
03.841.309	9 mm/10 mm height
03.841.311	11 mm/12 mm height

### ACIS Small Parallel Trial Set (01.841.010)

03.841.010	Module for Small Parallel Trial Set
	Double-Sided Trial Spacer Small/Parallel
03.841.705	5 mm/6 mm height
03.841.707	7 mm/8 mm height
03.841.709	9 mm/10 mm height
03.841.711	11 mm/12 mm height

## TRIAL RASPS SETS

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### **ACIS Lordotic Trial Rasp Set (01.841.007)**

60.841.007      Module for Lordotic Trial Rasps

Trial Rasp–Lordotic

03.841.025      5 mm height

03.841.026      6 mm height

03.841.027      7 mm height

03.841.028      8 mm height

03.841.029      9 mm height

03.841.030      10 mm height

03.841.031      11 mm height

03.841.032      12 mm height



### **ACIS Parallel Trial Rasp Set (01.841.008)**

60.841.008      Module for Parallel Trial Rasps

Trial Rasp–Parallel

03.841.125      5 mm height

03.841.126      6 mm height

03.841.127      7 mm height

03.841.128      8 mm height

03.841.129      9 mm height

03.841.130      10 mm height

03.841.131      11 mm height

03.841.132      12 mm height

## IMPLANT SETS

60.843.011 Graphic Case for ACIS Implants

### ACIS Lordotic Implant Set (01.843.012)

60.843.012 Module for ACIS Standard Lordotic Implants

ACIS Implant Lordotic/Standard

08.843.005 5 mm height, 3 ea.

08.843.006 6 mm height, 3 ea.

08.843.007 7 mm height, 3 ea.

08.843.008 8 mm height, 3 ea.

08.843.009 9 mm height, 3 ea.

08.843.010 10 mm height, 3 ea.

08.843.011 11 mm height, 1 ea.

08.843.012 12 mm height, 1 ea.



08.843.007



### ACIS Parallel Implant Set (01.843.013)

60.843.013 Module for ACIS Standard Parallel Implants

ACIS Implant Parallel/Standard

08.843.105 5 mm height, 3 ea.

08.843.106 6 mm height, 3 ea.

08.843.107 7 mm height, 3 ea.

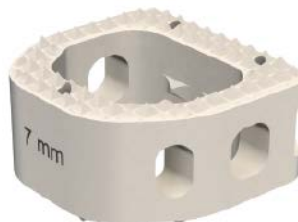
08.843.108 8 mm height, 3 ea.

08.843.109 9 mm height, 3 ea.

08.843.110 10 mm height, 3 ea.

08.843.111 11 mm height, 1 ea.

08.843.112 12 mm height, 1 ea.



08.843.107



### ACIS Convex Implant Set (01.843.014)

60.843.014 Module for ACIS Standard Convex Implants

ACIS Implant Convex/Standard

08.843.205 5 mm height, 3 ea.

08.843.206 6 mm height, 3 ea.

08.843.207 7 mm height, 3 ea.

08.843.208 8 mm height, 3 ea.

08.843.209 9 mm height, 3 ea.

08.843.210 10 mm height, 3 ea.

08.843.211 11 mm height, 1 ea.

08.843.212 12 mm height, 1 ea.



08.843.207



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**ACIS Large Lordotic Implant Set (01.843.015)**

60.843.015 Module for ACIS Large Lordotic Implants

ACIS Implant Lordotic/Large

08.843.305 5 mm height, 3 ea.

08.843.306 6 mm height, 3 ea.

08.843.307 7 mm height, 3 ea.

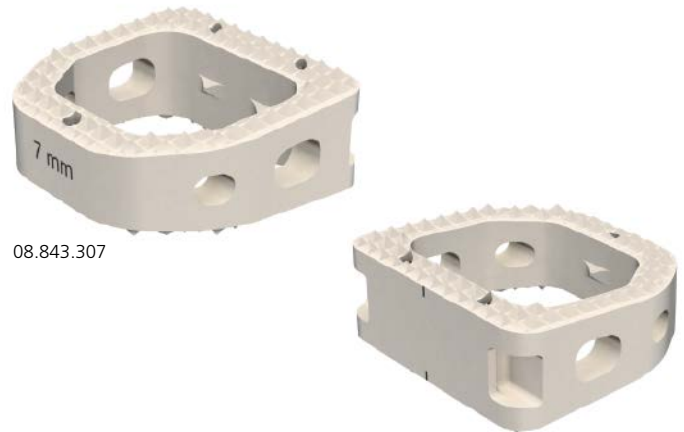
08.843.308 8 mm height, 3 ea.

08.843.309 9 mm height, 3 ea.

08.843.310 10 mm height, 3 ea.

08.843.311 11 mm height, 1 ea.

08.843.312 12 mm height, 1 ea.



**ACIS Large Parallel Implant Set (01.843.016)**

60.843.016 Module for ACIS Large Parallel Implants

ACIS Implant Parallel/Large

08.843.405 5 mm height, 3 ea.

08.843.406 6 mm height, 3 ea.

08.843.407 7 mm height, 3 ea.

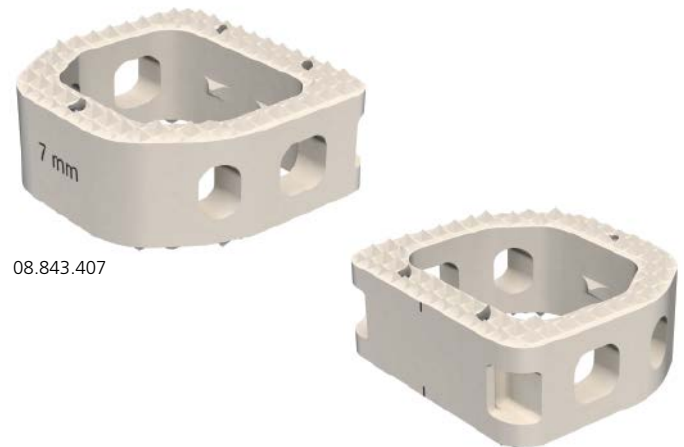
08.843.408 8 mm height, 3 ea.

08.843.409 9 mm height, 3 ea.

08.843.410 10 mm height, 3 ea.

08.843.411 11 mm height, 1 ea.

08.843.412 12 mm height, 1 ea.



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**ACIS Small Lordotic Implant Set (01.843.019)**

60.843.019 Module for ACIS Small Lordotic Implants

ACIS Implant Lordotic/Small

08.843.605 5 mm height, 3 ea.

08.843.606 6 mm height, 3 ea.

08.843.607 7 mm height, 3 ea.

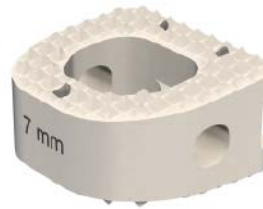
08.843.608 8 mm height, 3 ea.

08.843.609 9 mm height, 3 ea.

08.843.610 10 mm height, 3 ea.

08.843.611 11 mm height, 1 ea.

08.843.612 12 mm height, 1 ea.



08.843.607



**ACIS Small Parallel Implant Set (01.843.020)**

60.843.020 Module for ACIS Small Parallel Implants

ACIS Implant Parallel/Small

08.843.705 5 mm height, 3 ea.

08.843.706 6 mm height, 3 ea.

08.843.707 7 mm height, 3 ea.

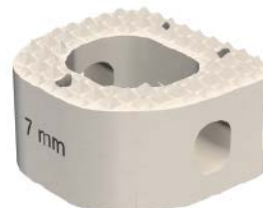
08.843.708 8 mm height, 3 ea.

08.843.709 9 mm height, 3 ea.

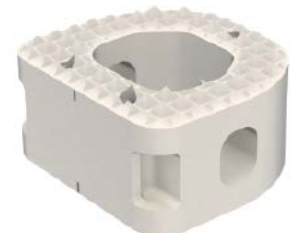
08.843.710 10 mm height, 3 ea.

08.843.711 11 mm height, 1 ea.

08.843.712 12 mm height, 1 ea.



08.843.707



## STERILE IMPLANT SETS

### ACIS Lordotic Sterile Implant Set (01.843.022)

60.841.100	Carry Case for ACIS Implants
	ACIS Implant, Sterile Lordotic/Standard
08.843.005S	5 mm height, 3 ea.
08.843.006S	6 mm height, 3 ea.
08.843.007S	7 mm height, 3 ea.
08.843.008S	8 mm height, 3 ea.
08.843.009S	9 mm height, 3 ea.
08.843.010S	10 mm height, 3 ea.
08.843.011S	11 mm height, 1 ea.
08.843.012S	12 mm height, 1 ea.

### ACIS Parallel Sterile Implant Set (01.843.023)

60.841.100	Carry Case for ACIS Implants
	ACIS Implant, Sterile Parallel/Standard
08.843.105S	5 mm height, 3 ea.
08.843.106S	6 mm height, 3 ea.
08.843.107S	7 mm height, 3 ea.
08.843.108S	8 mm height, 3 ea.
08.843.109S	9 mm height, 3 ea.
08.843.110S	10 mm height, 3 ea.
08.843.111S	11 mm height, 1 ea.
08.843.112S	12 mm height, 1 ea.

### ACIS Convex Sterile Implant Set (01.843.024)

60.841.100	Carry Case for ACIS Implants
	ACIS Implant, Sterile Convex/Standard
08.843.205S	5 mm height, 3 ea.
08.843.206S	6 mm height, 3 ea.
08.843.207S	7 mm height, 3 ea.
08.843.208S	8 mm height, 3 ea.
08.843.209S	9 mm height, 3 ea.
08.843.210S	10 mm height, 3 ea.
08.843.211S	11 mm height, 1 ea.
08.843.212S	12 mm height, 1 ea.

### ACIS Large Lordotic Sterile Implant Set (01.843.025)

60.841.100	Carry Case for ACIS Implants
	ACIS Implant, Sterile Lordotic/Large
08.843.305S	5 mm height, 3 ea.
08.843.306S	6 mm height, 3 ea.
08.843.307S	7 mm height, 3 ea.
08.843.308S	8 mm height, 3 ea.
08.843.309S	9 mm height, 3 ea.
08.843.310S	10 mm height, 3 ea.
08.843.311S	11 mm height, 1 ea.
08.843.312S	12 mm height, 1 ea.

### ACIS Large Parallel Sterile Implant Set (01.843.026)

60.841.100	Carry Case for ACIS Implants
	ACIS Implant, Sterile Parallel/Large
08.843.405S	5 mm height, 3 ea.
08.843.406S	6 mm height, 3 ea.
08.843.407S	7 mm height, 3 ea.
08.843.408S	8 mm height, 3 ea.
08.843.409S	9 mm height, 3 ea.
08.843.410S	10 mm height, 3 ea.
08.843.411S	11 mm height, 1 ea.
08.843.412S	12 mm height, 1 ea.

### ACIS Small Lordotic Sterile Implant Set (01.843.029)

60.841.100	Carry Case for ACIS Implants
	ACIS Implant, Sterile Lordotic/Small
08.843.605S	5 mm height, 3 ea.
08.843.606S	6 mm height, 3 ea.
08.843.607S	7 mm height, 3 ea.
08.843.608S	8 mm height, 3 ea.
08.843.609S	9 mm height, 3 ea.
08.843.610S	10 mm height, 3 ea.
08.843.611S	11 mm height, 1 ea.
08.843.612S	12 mm height, 1 ea.

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## **Sterile Implant Sets**

### **ACIS Small Parallel Sterile Implant Set (01.843.030)**

60.841.100	Carry Case for ACIS Implants
	ACIS Implant, Sterile Parallel/Small
08.843.705S	5 mm height, 3 ea.
08.843.706S	6 mm height, 3 ea.
08.843.707S	7 mm height, 3 ea.
08.843.708S	8 mm height, 3 ea.
08.843.709S	9 mm height, 3 ea.
08.843.710S	10 mm height, 3 ea.
08.843.711S	11 mm height, 1 ea.
08.843.712S	12 mm height, 1 ea.

### **Also Available**

#### **Implants**

08.843.104S	ACIS Implant, Sterile Parallel/Standard, 4 mm height
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#### **Graphic Case**

60.841.011	Graphic Case for ACIS Auxiliary Modules
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#### **Instruments**

03.841.051	Knob for ACIS Implant Inserter
03.841.052	ACF Holder
02.600.028	Distractor Pin, 18 mm

#### **Retainer Screws**

03.820.102	3.5 mm x 12 mm
03.820.103	3.5 mm x 14 mm
03.820.104	3.5 mm x 16 mm
03.820.105	3.5 mm x 18 mm
03.820.110	Retainer Nut









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