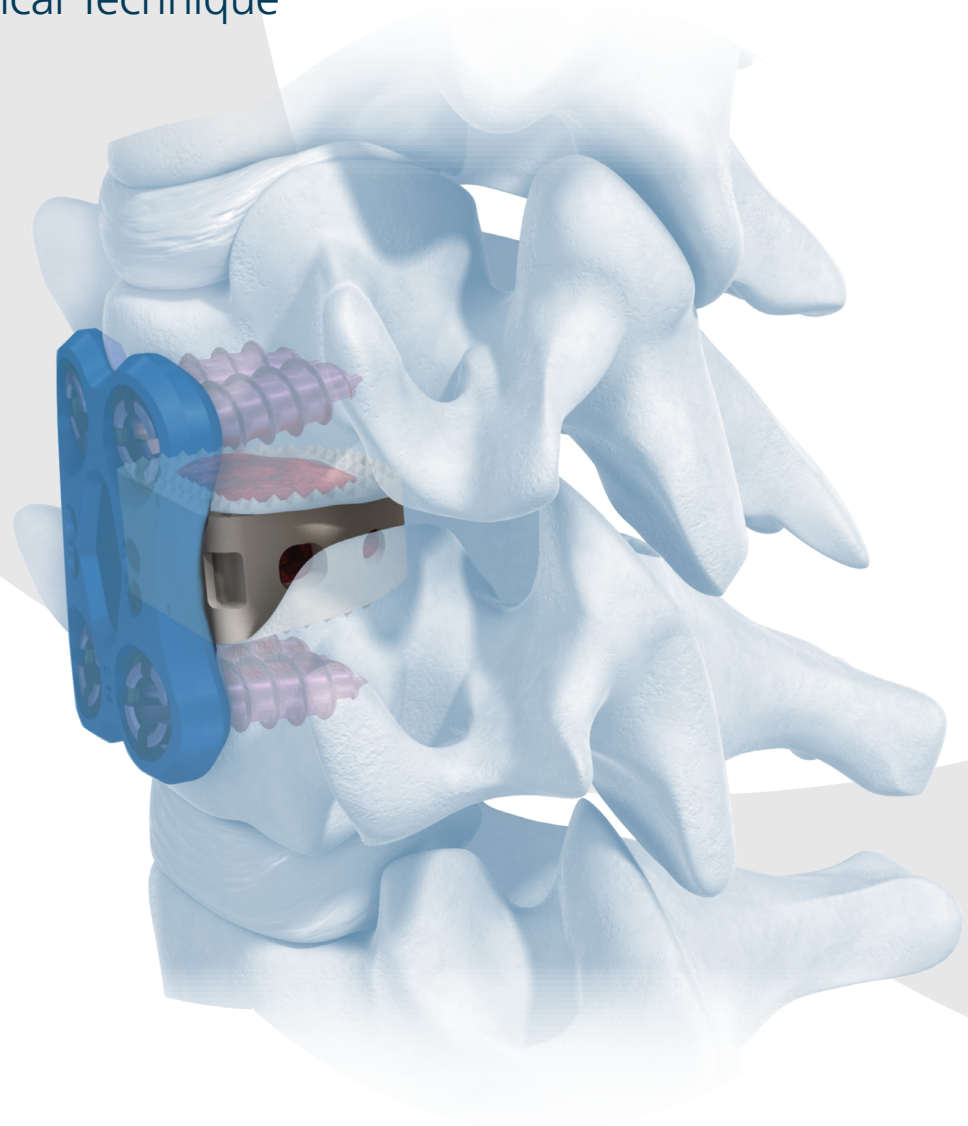
ACIS® Anterior Cervical Interbody System

A System of implants and instruments for interbody fusion available in both PEEK and PROTI 360°™ Titanium Integrated Technology

Surgical Technique



DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Contents

 Image intensifier control

ACIS® Anterior Cervical Interbody Spacer System

A system of implants and instruments for interbody fusion.

ACIS® Spacer PEEK System and ACIS ProTi 360°™ System

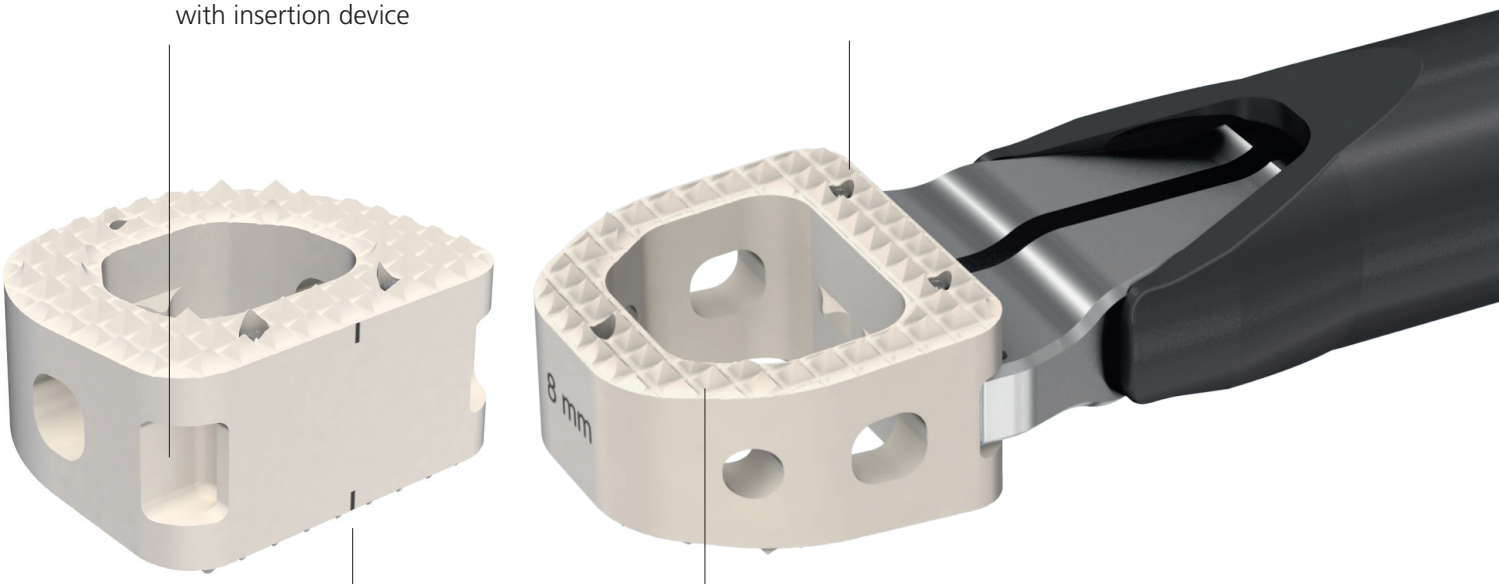
Available Materials
PEEK-OPTIMA®* radiolucent material with a modulus of elasticity between cortical and cancellous bone,[1] allowing optimal load sharing. The ACIS ProTi 360° System incorporates titanium integrated technology.

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. (PEEK only)

Three radiopaque marker pins†
Enable visualization to confirm placement radiographically (pins are positioned 1 mm from anterior and posterior walls)

Implant-instrument interface
Stable interface facilitates connection/release with insertion device



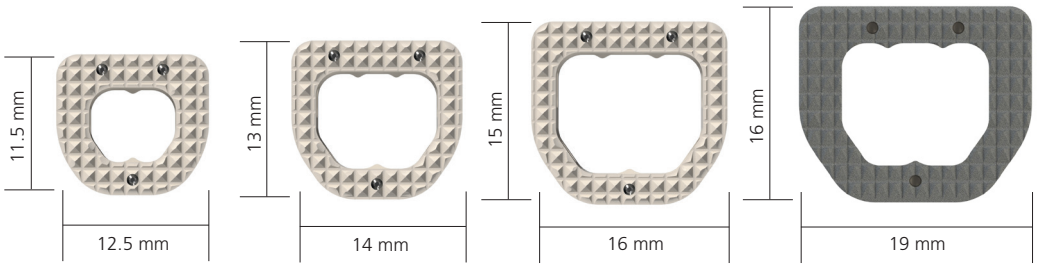
Midline markers
Facilitate implant positioning (PEEK only)

Pyramidal teeth
Superior and inferior teeth designed to provide resistance

* Polyetheretherketone
† PEEK System: Titanium alloy (Ti-6Al-4V). PROTI 360° System: Tantalum
1. Data provided by Invibio PEEK-Optima brochure (PO-ENG-SUR-01 (09/07.01)).
PEEK-OPTIMA® is a registered trademark of Invibio Ltd.

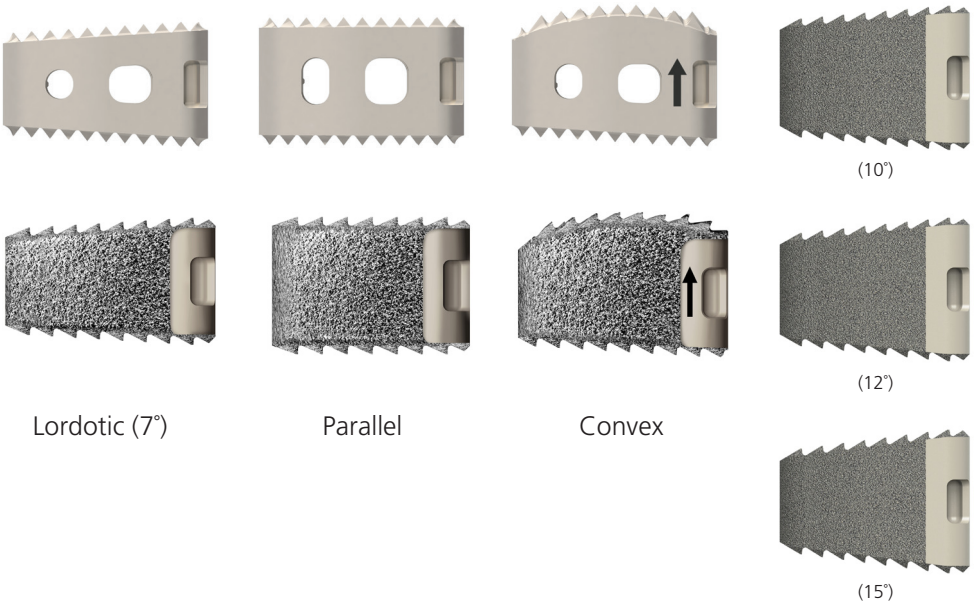
Two Material Options
- PEEK
- PROTI 360°™ Titanium Integrated Technology

Four Footprints
- Small
- Standard
- Large
- X-Large (Hyperlordotic available in Standard, Large and X-large. X-large only available in hyperlordotic)



Small | Standard | Large | X-Large (hyperlordotic)

Four Sagittal Profiles
- Lordotic (7°)
- Parallel
- Convex
- Hyperlordotic PROTI 360°™ System



Lordotic (7°) | Parallel | Convex | Hyperlordotic

MR Conditional (PEEK only)
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 9 for further information.

ACIS Instruments

The ACIS Instrumentation Set is designed to streamline the ACDF procedure. The instruments are designed to utilize ergonomic and efficient designs that enable ease of use of the ACIS System.

Multiple implant insertion options

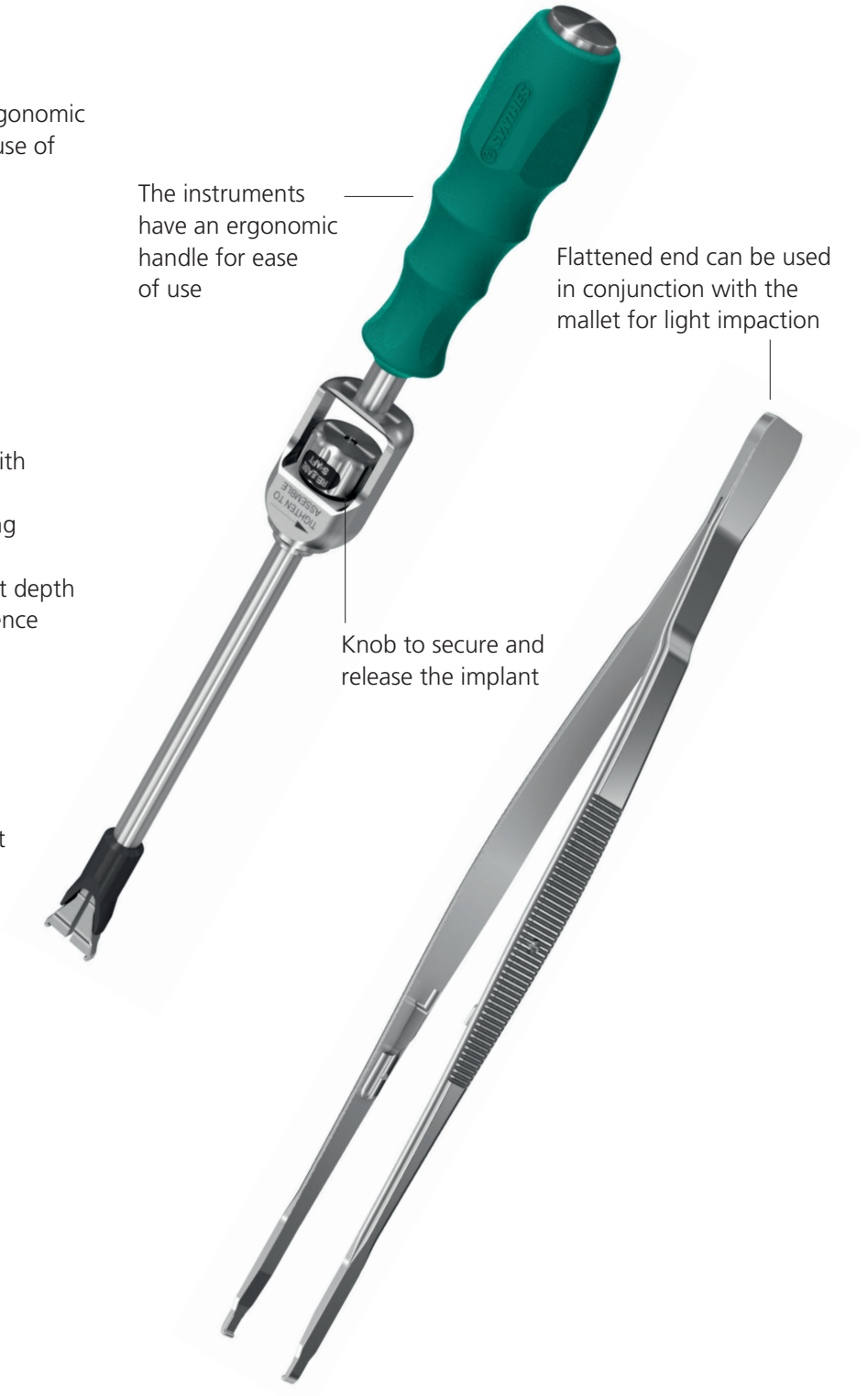
The ACIS Instrumentation Set provides two options for implant insertion that allow for secure, controlled implant delivery.

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

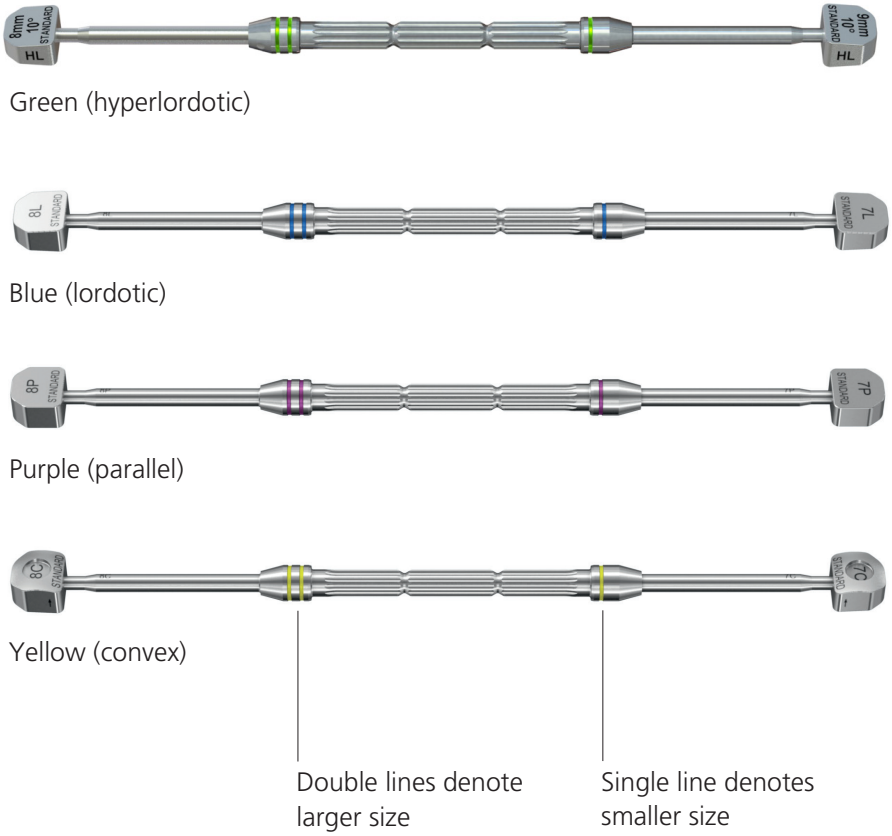
Implant holder

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



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



AO Principles

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.[1] 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.[2]

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

ACIS Spacer (PEEK) System

Indications

The DePuy 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 spacer of the DePuy Synthes ACIS should be packed with autogenous bone graft material and implanted via an anterior approach. The DePuy Synthes ACIS is intended to be used with supplemental fixation.

Contraindications

- Use of the DePuy 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

Warnings

One of the risks of any surgical procedure is death. Other potential risks which may require additional surgery, include:

- device component fracture
- loss of fixation
- pseudarthrosis (i.e., non-union)
- fracture of the vertebrae*
- neurological injury*
- vascular or visceral injury*

*These risks can also be associated with general risks of surgery.

DO NOT USE devices that are received in opened or damaged packages. DO NOT USE past the expiration date.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

The components of this device are manufactured from a radiolucent polymer and a titanium alloy.

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

ACIS PROTI 360° System including hyperlordotic cages

Cervical System Indications

The ACIS ProTi 360°™ Cervical Interbody System are interbody fusion devices indicated at one or more levels of the cervical spine C2-T1 in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have at least six weeks of non-operative treatment. The cervical implants are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical and/or corticocancellous bone. These devices are intended to be used with supplemental fixation.

Contraindications

The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

Warnings

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. All instruments must be cleaned and sterilized prior to surgery.
4. As with all orthopaedic implants, DePuy Synthes Spine Interbody Systems should never be reused under any circumstances.
5. The DePuy Synthes Spine Interbody System should never be used with dissimilar materials.
6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

MRI Information

ACIS Spacer (PEEK) System

The DePuy Synthes ACIS PEEK 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 DePuy Synthes ACIS PEEK devices demonstrated that the implant is MR Conditional. A patient with a DePuy Synthes ACIS PEEK 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.

Precaution: In non-clinical testing, a DePuy Synthes ACIS PEEK 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. DePuy Synthes MR Conditional DePuy Synthes ACIS PEEK 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 DePuy Synthes ACIS PEEK 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 DePuy Synthes ACIS PEEK 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

ACIS PROTI 360° System

MAGNETIC RESONANCE (MR) COMPATIBILITY FOR ACIS® PROTI 360° IMPLANTS INCLUDING HYPERLORDOTIC CAGES

Non-clinical testing has demonstrated that the ACIS® PROTI 360° Implants is MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3.0T with quadrature driven coil
- Maximum spatial field gradient of 1900 gauss/cm (19.0 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the ACIS® PROTI 360° Implant is expected to produce a maximum temperature rise of less than 6.1°C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by these devices extends approximately 12mm from the implant when imaged with a gradient echo pulse sequence and a 3.0T MRI system.

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 C7–T1 make sure that the shoulders do not limit the x-ray monitoring. For all cases both vertebrae should be completely visible. See Fig. 1

Fig. 1

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. See Fig. 2

Fig. 2

Approach

Distraction instruments and pins (See Fig. 3)	
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*

Fig. 3

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. See Fig. 4

Warning: 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.

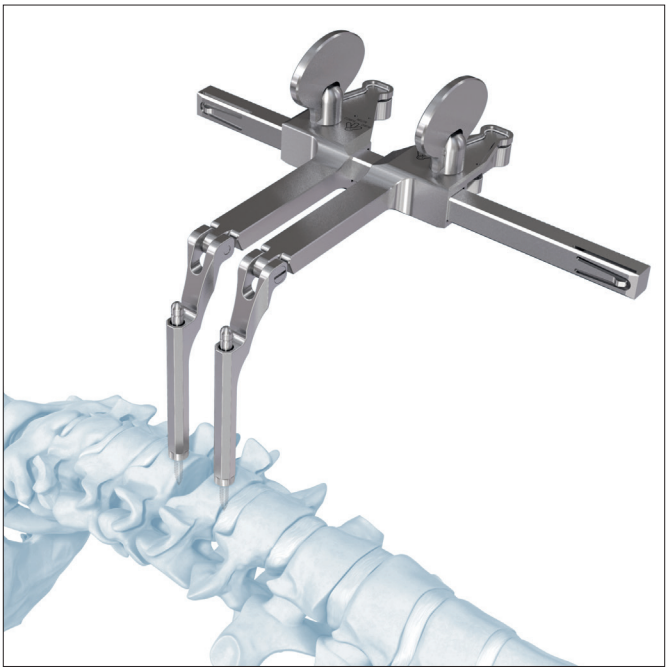


Fig. 4

* 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. See Fig. 5

Warning:

- **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**

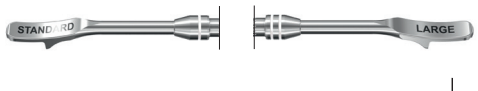
Endplate Rasp Notes: See Fig. 6

- **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**

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

Fig. 5

Fig. 6



Depth: 14 mm standard, 16

Implant Sizing

1

Determine the appropriate implant

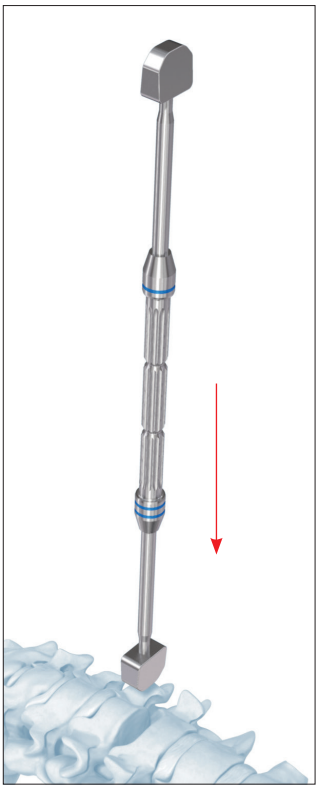
Selection of the trial spacer depends on the height, width and depth of the intervertebral space, the preparation technique and the patient's anatomy. Based on the pre-operative imaging and surgical technique, choose a standard, large or small footprint trial spacer with parallel, lordotic or convex sagittal shape of the appropriate height. X-large hyperlordotic trial spacers are also available to choose from.

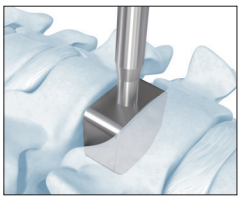
Verify the trial spacer size and carefully insert it into the disc space. When using the convex trials, verify that they are in the correct cranial/caudal alignment prior to insertion.

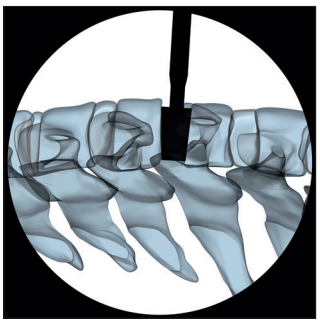
Precautions:

- **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** See Fig 7
- **Trial spacers are color coded by sagittal shape: blue, purple, yellow and green bands indicate that a trial spacer is lordotic, parallel, convex or hyperlordotic. The spacers are also etched on the cranial and caudal surfaces indicating the sagittal shape:"L" for lordotic, "HL" for hyperlordotic, "P" for parallel and "C" for convex**
- **The footprint sizes are indicated by "small", "standard", "large" and "X-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**
- **To minimize potential to overdistract, it is recommended to trial with smaller height trial spacers before trialing with taller height trial spacers.**

Warning: **The trial spacers do not have a depth stop; an image intensifier should be used to visualize and check the position during insertion**







green (hyperlordotic)

blue (lordotic)

purple (parallel)

yellow (convex)

Fig. 7

Greater height

Lesser height

Lordotic

Parallel

Convex

Hyperlordotic

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. See Fig. 8

Note:

- **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**

Precaution: **Trial spacers are not for implantation and must be removed before insertion of the ACIS Implant**

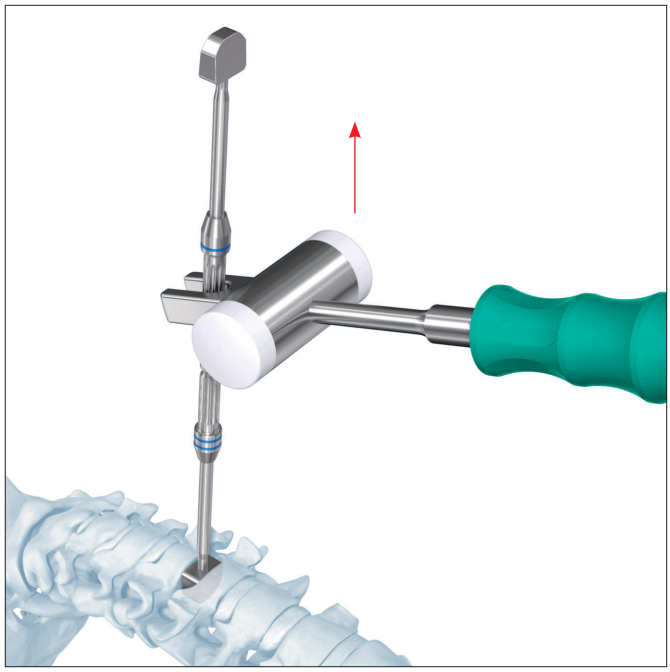
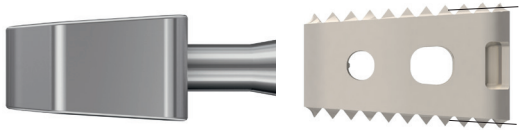


Fig. 8



Trial height: (0.5 mm less than spacer height)

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 not pictured here. 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. See Fig. 9

Precautions:

- **Ensure that the implant is held flush against the insertion device and securely in the tabs.**
- **Turn the knob clockwise to secure the implant.**

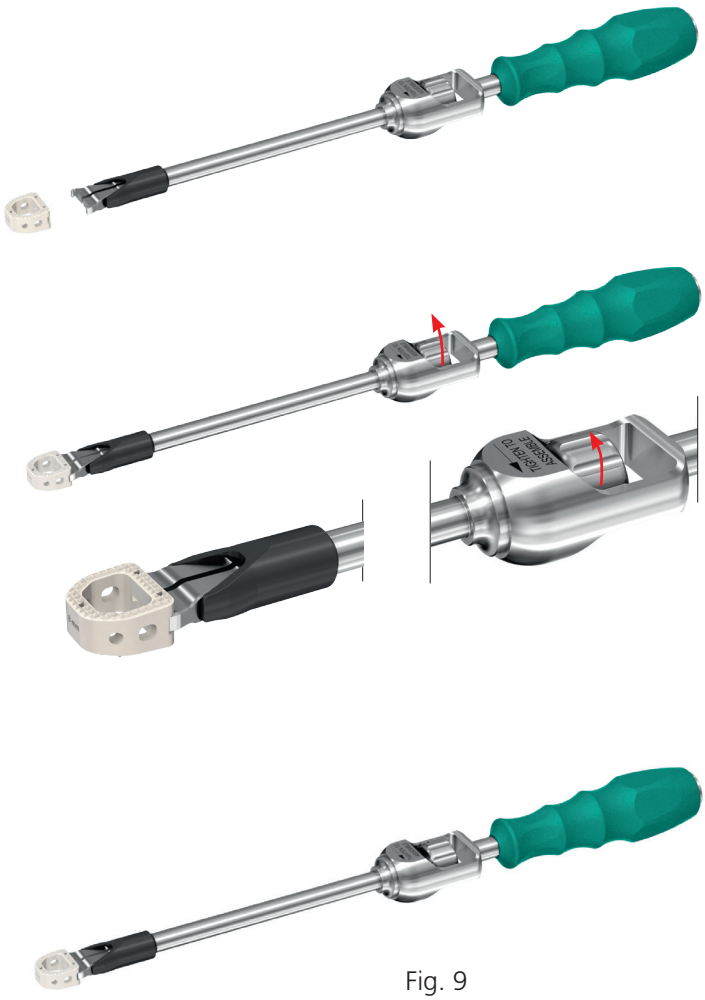


Fig. 9

2
Pack implant with bone graft

Instruments	
03.841.054	Graft Packing Instrument
03.841.055	Graft Packing Block

ACIS® Spacer PEEK System: indicated to be packed with autogenous bone graft only

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

(PEEK Only) 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 graft material into the implant lumen.
See Fig. 10

The ACIS ProTi 360°™ Implants are indicated to be packed with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Precautions:
- **To ensure optimal contact with the vertebral endplates it is important to fill the implant lumen fully.**
- **Excessive impaction of the implant with the cancellous bone impactor should be avoided to prevent possible implant damage.**

Fig. 10

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). See Fig. 11

If necessary, controlled and light hammering with the mallet can be used to help advance the implant into the intervertebral disc space. See Fig. 12

Note: **The PROTI 360° Spinal Implant may require additional tamping during insertion.**

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

Fig. 11

Fig. 12

Turn the knob in a counterclockwise direction to release the implant from the implant inserter. See Fig. 13

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

Precautions:

- **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**
- **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 markets incorporated into the implant to enable accurate intraoperative radiographic assessment of the implant position.** See Fig. 14

Note:

- **1.0 mm diameter pins as X-ray markers†**
- **Distance between pins and the anterior and posterior walls of the implant is approx. 1.0 mm (see page 30 for details)**
- **Posterior pin is centered**

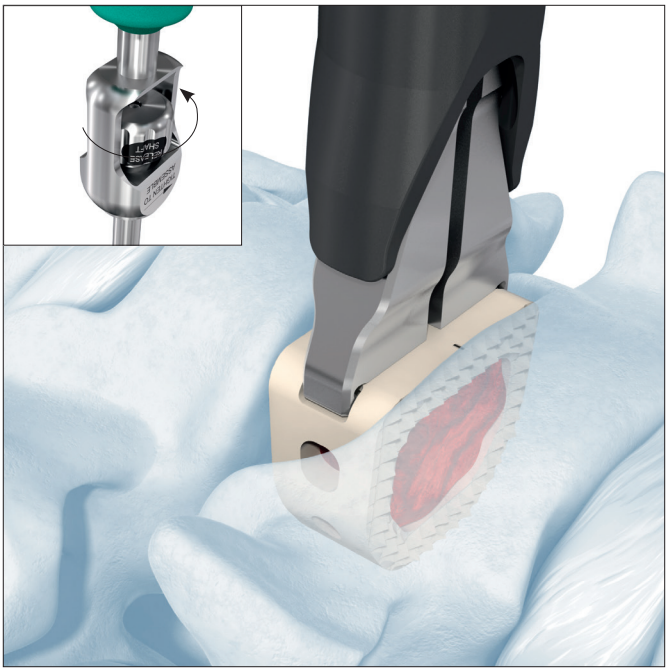
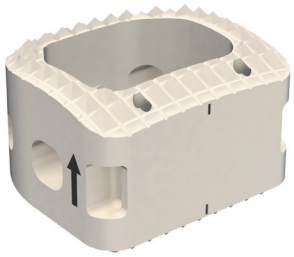


Fig. 13



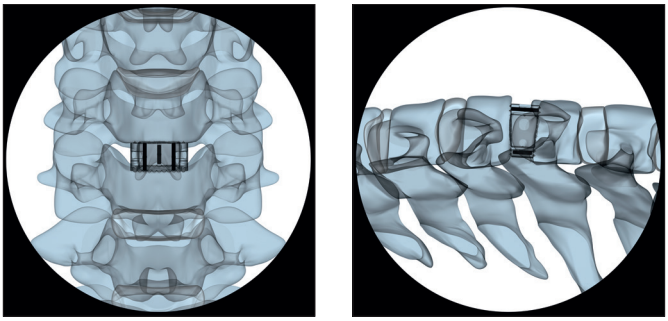


Fig. 14

† PEEK System: Titanium alloy (Ti-6Al-4V), PROTI 360° System: Tantalum

Option B. Implant holder

1

Attach implant to implant holder

Instrument

03.841.053	ACIS Implant Holder

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. See Fig. 15

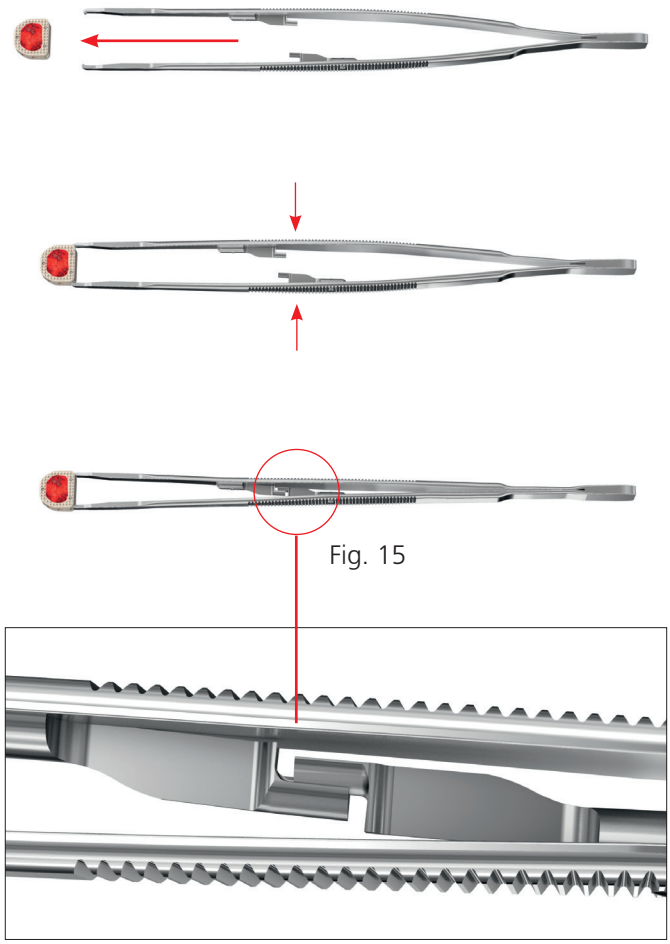


Fig. 15

2
Pack implant with bone graft

Instruments	
03.841.054	Graft Packing Instrument
03.841.055	Graft Packing Block

ACIS® Spacer PEEK System: indicated to be packed with autogenous bone graft only

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

(PEEK Only) 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.

The ACIS ProTi 360°™ Implants are indicated to be packed with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Precautions:
- **To ensure optimal contact with the vertebral endplates it is important to fill the implant lumen fully**
- **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. See Fig 16

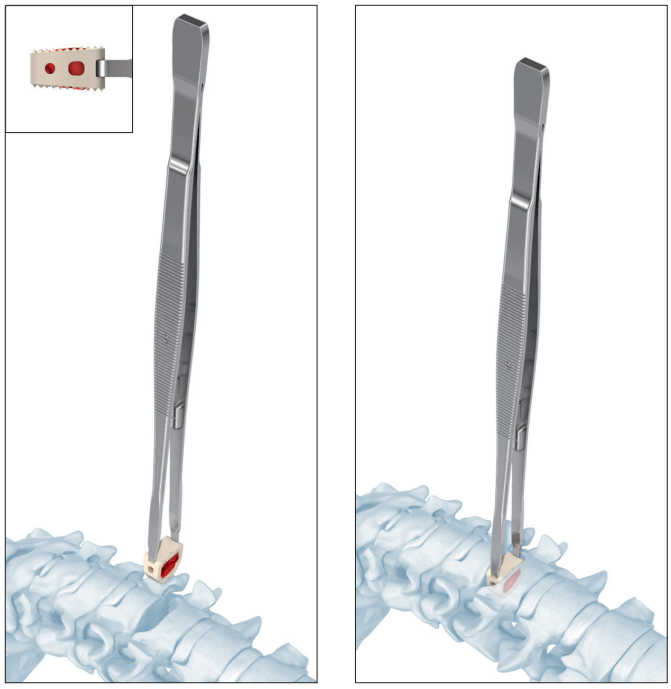


Fig. 16

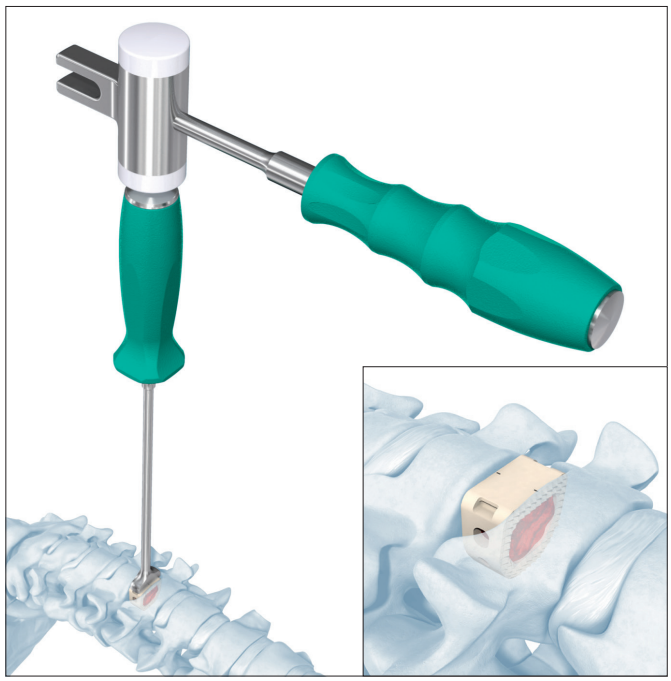
Release the implant holder by applying slight pressure on the arms of the implant holder and disengaging the squeeze-lock. Remove the holder and if required use the flat impactor to seat the implant into its final position.

Use image intensifier to confirm the position of the implant.

Note: **The PROTI 360° Spinal Implant may require additional tapping during insertion**

Warning:

- **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**
- **Excessive impaction must be avoided to prevent implant damage or inserting the implant too deep**



Tip: **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.**
See Fig. 17

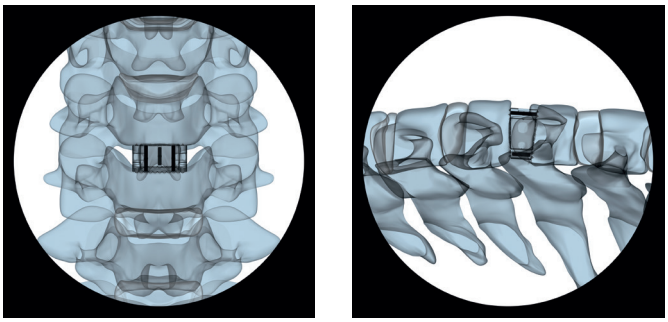


Fig. 17

Tips:
- **1.0 mm diameter pins as X-ray markers†**
- **Distance between pins and the anterior and posterior walls of the implant is approx. 1.0 mm**
- **Posterior pin is centered**

† PEEK System: Titanium alloy (Ti-6Al-4V), PROTI 360° System: Tantalum

Complete the procedure by following the surgical technique for the specific device to be used as supplemental fixation, such as the DePuy Synthes Vectra Anterior Cervical Plate System.* See Fig. 18

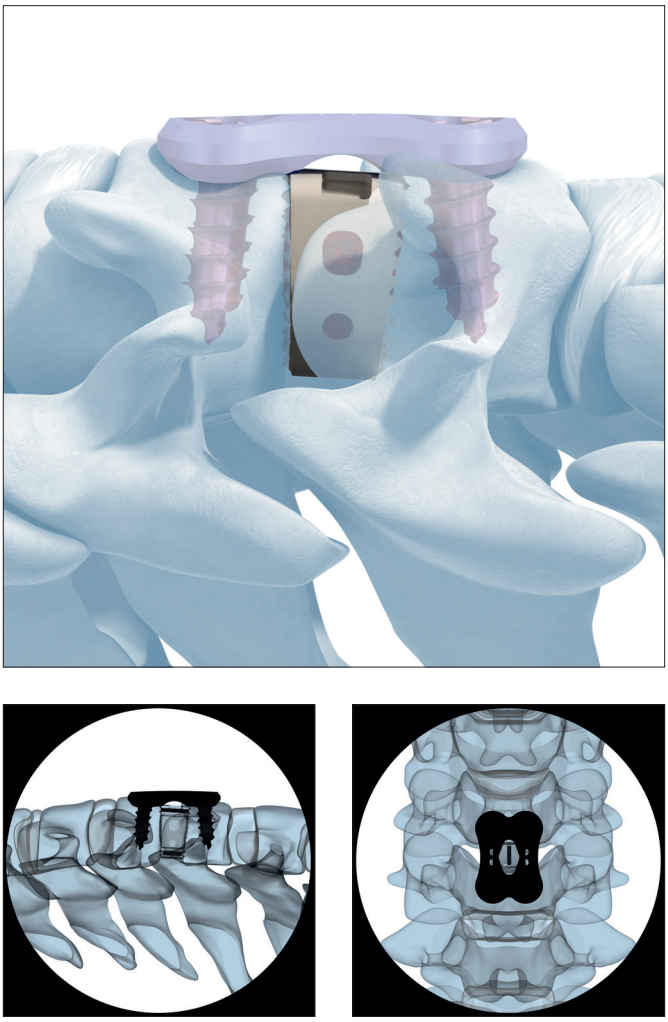


Fig. 18

* Vectra, Vectra-T and Vectra-One Technique Guide

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 posteriorly. 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. See Fig. 19a, b and c

The forked portion mallet may also be used along the shaft of the inserter to assist in the removal. See Fig. 20

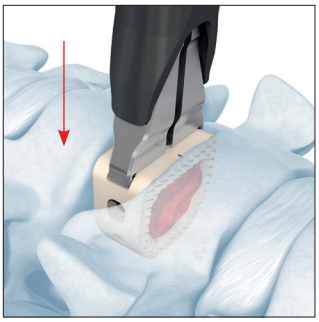


Fig. 19a

Fig. 19b

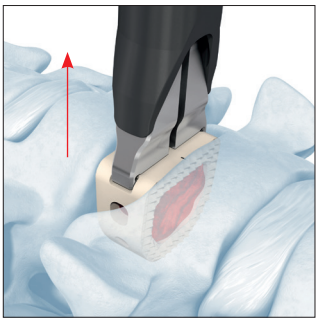


Fig. 19c

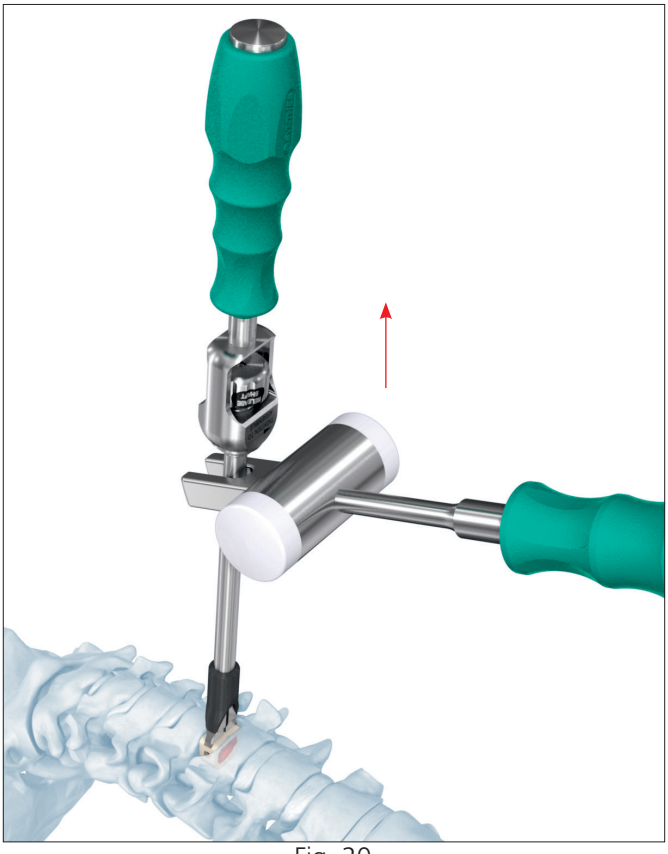


Fig. 20

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

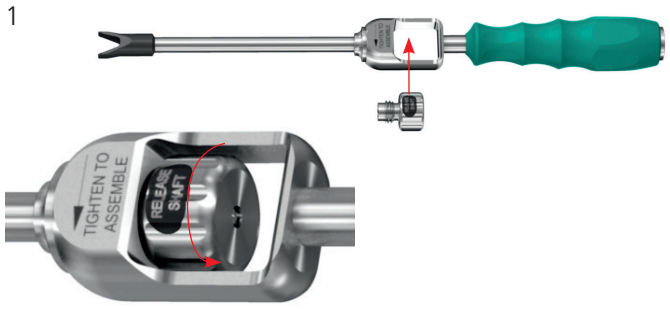
Assembly

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.

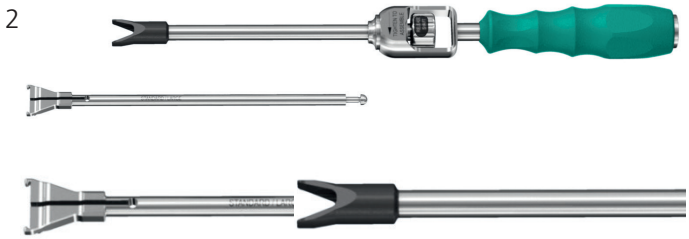
Disassembly

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

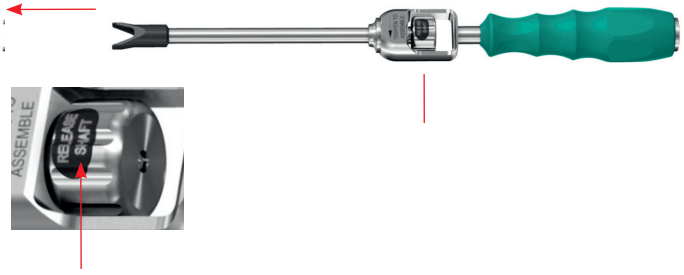
1



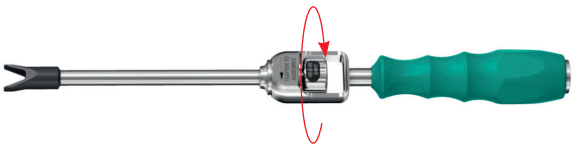
2



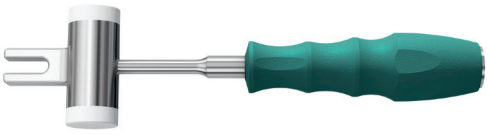
3



4



Instruments

	Distractor Pin	
02.600.022	12 mm	
02.600.024	14 mm	
02.600.026	16 mm	
02.600.028	18 mm	
03.617.981	Impactor, flat	
03.820.113	Mallet	
03.841.050	ACIS Implant Inserter	
03.841.053	ACIS Implant Holder	
03.841.054	Graft Packing Instrument	
03.841.055	Graft Packing Block PEEK Only	

03.841.057	Inner Shaft With Stops for Small ACIS Implant Holder	
03.841.056	Cervical Distractor	
03.841.058	Distractor Pin Driver	
03.841.059	Inner Shaft, Standard for ACIS Implant Inserter	
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	

Limited Warranty and Disclaimer: DePuy Synthes products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

The third party trademarks used herein are the trademarks of their respective owners.

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

For recognized manufacturer, refer to product label.

ACIS® Spacer PEEK System
Manufactured and Distributed by:
Synthes USA, LLC
1101 Synthes Avenue
Monument, CO 80132
USA

ACIS® ProTi 360°™ Anterior Cervical Interbody System
Manufactured by:
Tyber Medical, LLC
83 South Commerce Way, Suite 310
Bethlehem, PA 18017
Phone: +1 (866) 761-0933

Distributed by:
DePuy Spine Inc.
325 Paramount Drive
Raynham, MA 02767
USA
Tel: +1 (800) 227-6633

www.depuysynthes.com

103407661 Rev 1 01/19 SCDS