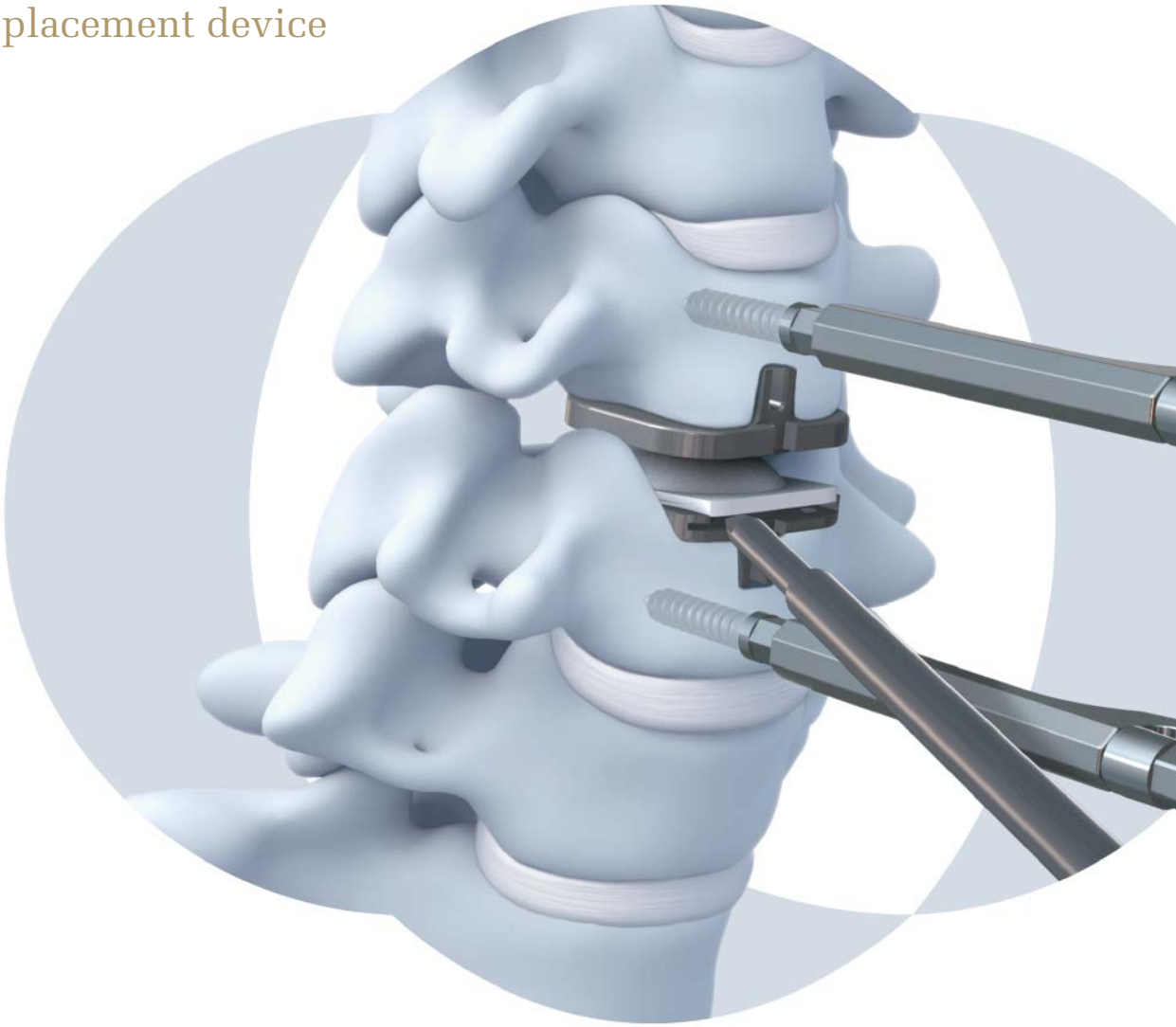
DePuy Synthes
SPINE
COMPANIES OF Johnson & Johnson

PRODISC® C REMOVAL SYSTEM

Instrumentation to assist with the removal of the PRODISC C Total Disc Replacement device



SURGICAL TECHNIQUE

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Image intensifier control

PRODISC C REMOVAL SYSTEM

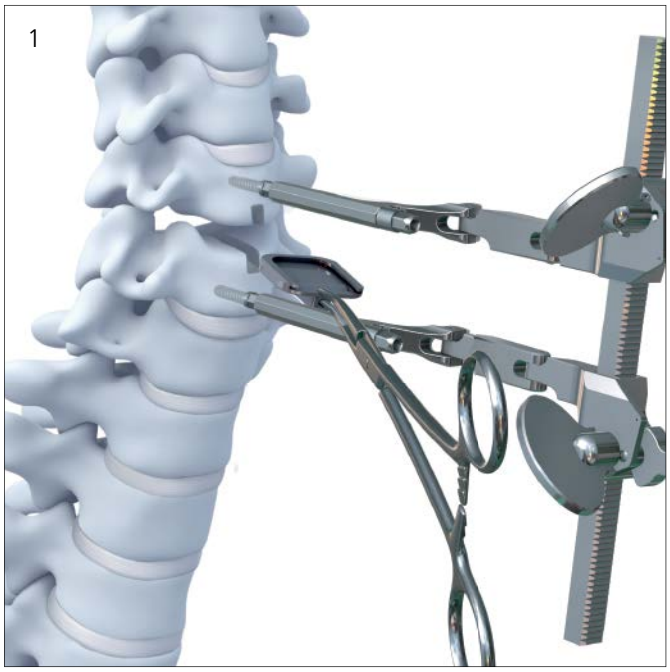
Instrumentation to assist with the removal of the PRODISC C Total Disc Replacement device.

The PRODISC C Removal System is a set of instruments to assist with the removal of the PRODISC C prosthesis after implantation.

Generally, removal of the PRODISC C implant should be performed by disassembly of components.

Contact DePuy Synthes Spine to receive instruction regarding data collection including histopathological, mechanical, and adverse event information. Please provide descriptive information about the gross appearance of the device in situ, as well as descriptions of the removal method, i.e., intact or in pieces. The PRODISC C Total Disc Replacement implant should be removed as carefully as possible to keep the implant and surrounding tissue intact. All explanted devices must be returned to DePuy Synthes Spine for analysis.

Note: **All implant removals must be reported immediately to the DePuy Synthes Spine Complaint Handling Unit (800-752-0128).**



PREOPERATIVE CONSIDERATIONS

To prepare for revision surgery, it is important to gather as much information as possible about the original procedure and the clinical status of the patient, including images.

Patient Positioning

Imaging is used frequently throughout the PRODISC C removal procedure. Set up the OR table, patient and C-arm to allow circumferential use of fluoroscopy at the operative level, and for unobstructed cranial and caudal movement of the C-arm, avoiding frequent passage in and out of the sterile field (Figure 2).

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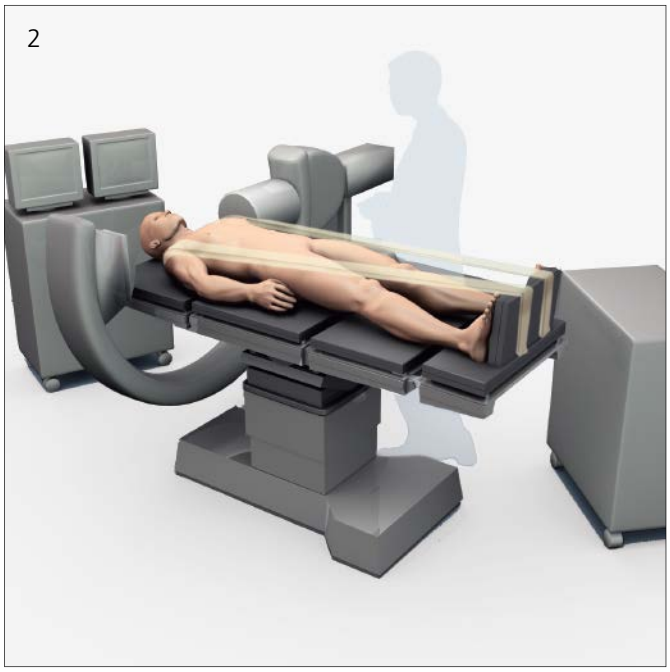


APPROACH

Approach the operative level through the original anterior incision. Expose, identify and isolate the PRODISC C implant from any overlying scar tissue. Excise any bony tissue from the anterior aspect of the endplates and keels to expose the implant-bone junction.

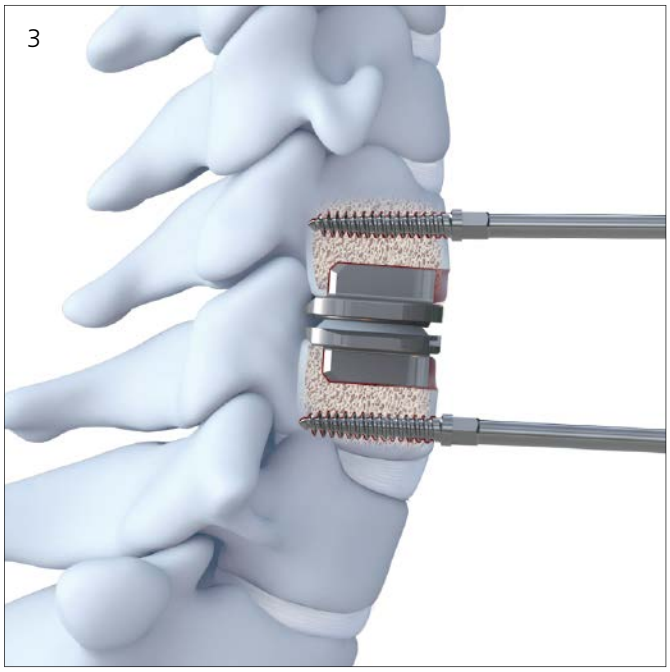
DISTRACTION

Instruments

03.820.100	Awl, 12 mm
03.820.101	Self-Retaining Screwdriver
03.820.102– 03.820.105	Retainer Screws, 3.5 mm x 12 mm, 14 mm, 16 mm, and 18 mm
03.820.106– 03.820.109	Retainer Screws (Rescue), 4.5 mm x 13 mm, 15 mm, 17 mm, and 19 mm
03.820.110	Retainer Nut
03.820.111	Vertebral Body Retainer
03.820.462	Vertebral Distractor, 3 mm tip

Removal of the PRODISC C implant is best performed with the operative level in distraction. Insert distraction pins or retainer screws into the vertebral bodies parallel to the operative disc space and within the distal one-third of the vertebral body (Figure 3).

- Perforate the anterior cortex with the awl, using lateral fluoroscopy to ensure its trajectory is parallel to the affected endplate.

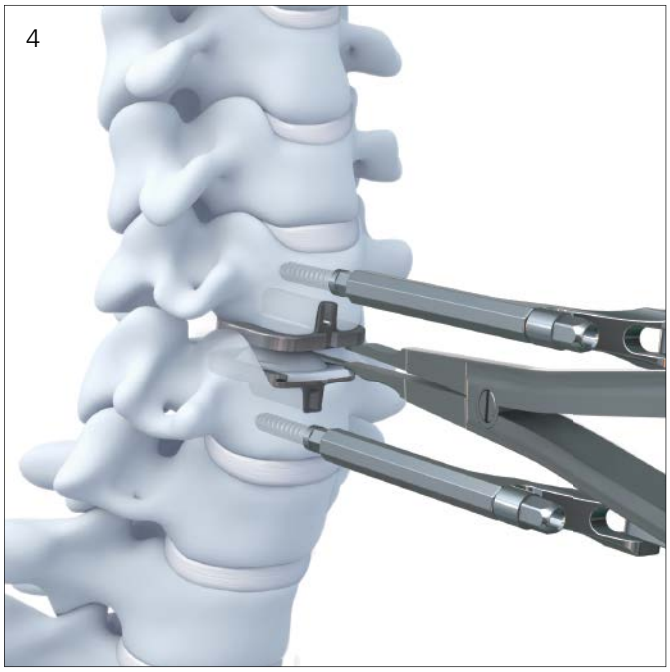

3

Insert distraction pins or retainer screws which are long enough to engage the posterior cortex, using fluoroscopy to confirm trajectory and screw depth. Attach either an interbody distractor or the vertebral body retainer. Under lateral fluoroscopic control, use the vertebral body distractor with a 3 mm tip to distract the disc space lateral to the inlay dome in a parallel manner to gain access to the implant (Figure 4). Retain the distracted segment by adjusting the interbody distractor or the vertebral body retainer (Figure 5).

Notes: **Use only the 3.5 mm diameter, color-coded screws. The 4.5 mm diameter screws should only be used as "rescue" screws.**

Do not distract using the vertebral body retainer as this can lead to bending of the screws or excessive force on the vertebral body.

Caution: **Avoid overdistraction as this can lead to nerve root overextension.**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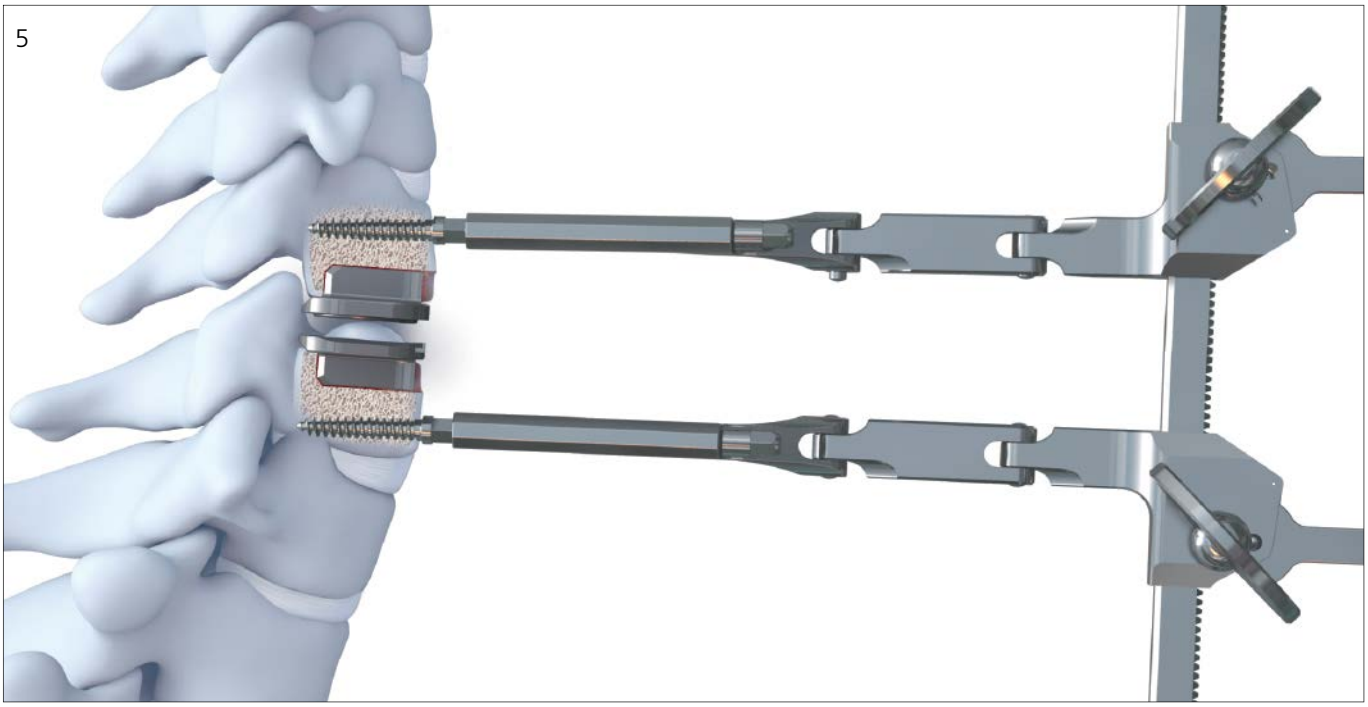
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1

Poly inlay removal

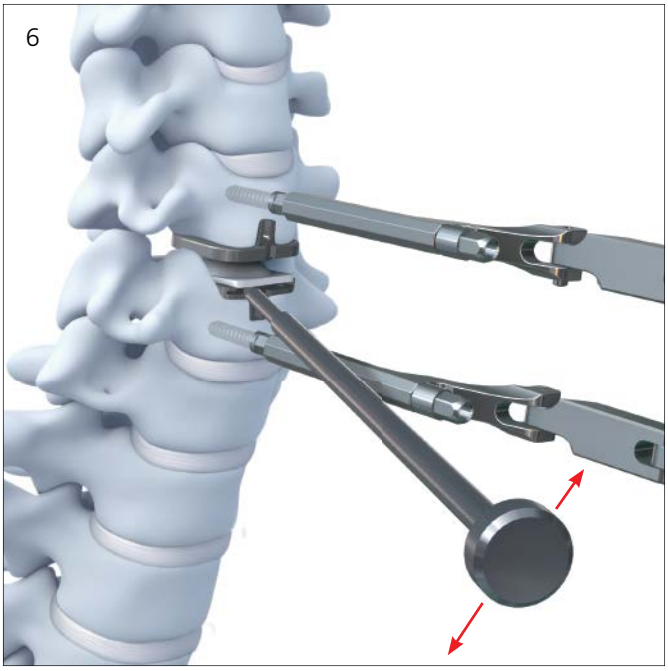
Instruments	
03.820.459	Inlay Separator, tapered
	Kocher style forceps

When removing the polyethylene inlay, ensure there is adequate clearance between the dome of the polyethylene inlay and the superior endplate.

Remove the polyethylene inlay by inserting the inlay separator between the polyethylene inlay and the inferior endplate (do not use a mallet). Tilt the inlay separator in a cranial or caudal direction to pry the inlay free of the snap-lock mechanism. Retrieve the inlay using Kocher style forceps.

Caution: **Insert the inlay separator by hand. Do not use the slotted mallet. Do not apply excessive force posteriorly.**

6



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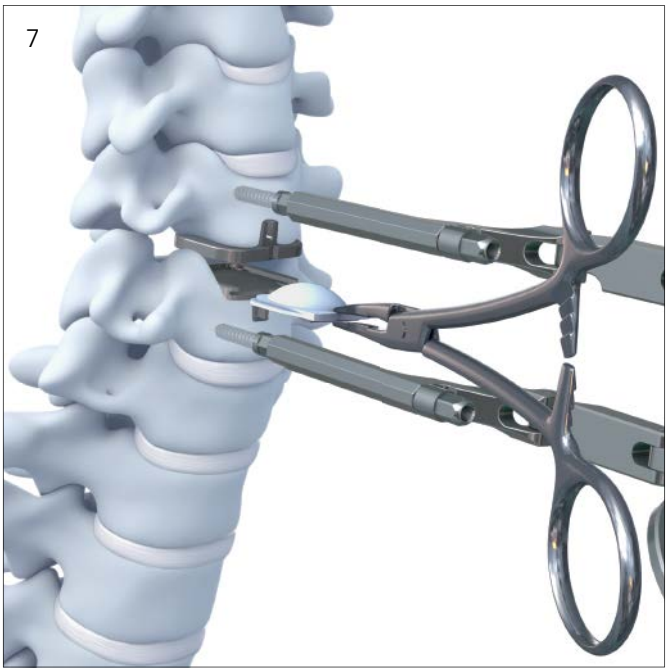

2
Superior endplate removal

Instruments	
03.820.452– 03.820.454	Forked Osteotomes, medium, large or extra large
03.820.456– 03.820.457	Straight Osteotomes, medium and large
	Kocher style forceps

The forked osteotomes facilitate separation of the metal endplates from the vertebral bodies. Insert the appropriate forked osteotomes between the metal endplate and the vertebral body (Figure 8).

Lever the osteotome to disengage the metal endplate from the bone, and to unseat the keel from the vertebral body. Retrieve the endplate using Kocher style forceps.

Straight osteotomes may also be helpful to separate the metal endplate from the vertebral body.

Caution: **Use forked and straight osteotomes under fluoroscopic control. Do not apply excessive force posteriorly.**

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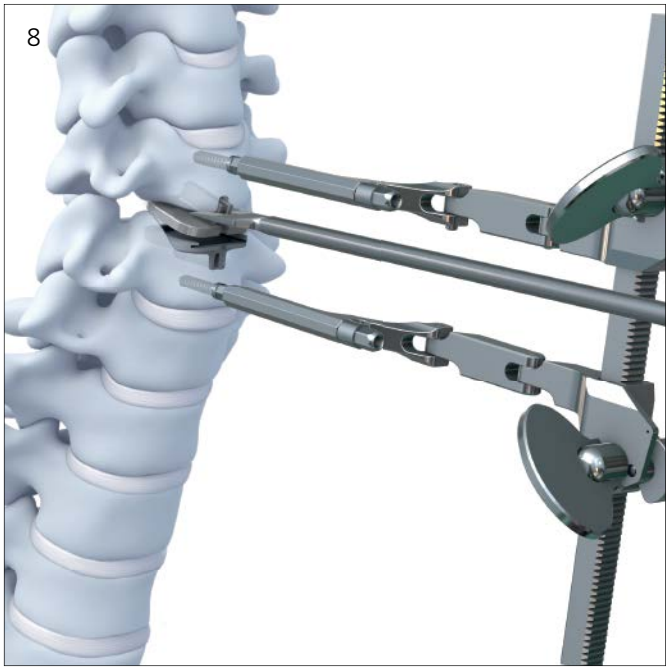

3
Inferior endplate removal

Instruments	
03.820.452– 03.820.454	Forked Osteotomes, medium, large or extra large
	Kocher style forceps

For removal of the inferior metal endplate, repeat Step 2.

Caution: **Use forked and straight osteotomes under fluoroscopic control. Do not apply excessive force posteriorly.**

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INSTRUMENTS

From Standard PRODISC C Set

03.820.100	Awl, 12 mm	
03.820.101	Self-Retaining Screwdriver	
	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	
03.820.106	4.5 mm x 13 mm	
03.820.107	4.5 mm x 15 mm	
03.820.108	4.5 mm x 17 mm	
03.820.109	4.5 mm x 19 mm	
03.820.110	Retainer Nut	
03.820.111	Vertebral Body Retainer	

03.820.113	Slotted Mallet	

From Removal Set

	Forked Osteotomes	
03.820.452	Medium	
03.820.453	Large	03.820.453
03.820.454	Extra large	
	Straight Osteotomes	
03.820.456	Medium	03.820.456
03.820.457	Large	
03.820.459	Inlay Separator, tapered	
03.820.462	Vertebral Body Distractor, 3 mm tip	

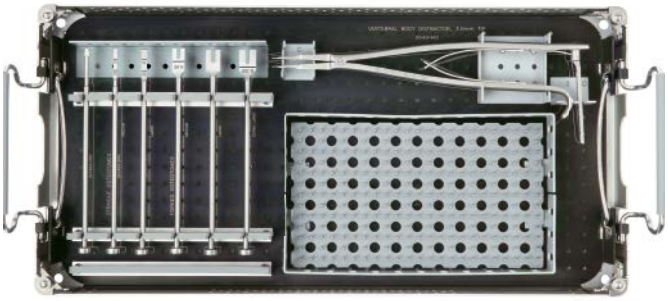
PRODISC C REMOVAL INSTRUMENT SET (01.820.005E)

Graphic Case

60.820.003	Graphic Case, for PRODISC C Removal System

Instruments

03.820.452	Forked Osteotome, medium
03.820.453	Forked Osteotome, large
03.820.454	Forked Osteotome, extra large
03.820.456	Straight Osteotome, medium
03.820.457	Straight Osteotome, large
03.820.459	Inlay Separator, tapered
03.820.462	Vertebral Body Distractor, 3 mm tip



Note: For additional information, please refer to package insert.

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

Limited Warranty and Disclaimer: DePuy Spine Inc. 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.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

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

To order in the U.S. call, Johnson & Johnson Health Care Systems Inc. Customer Support Services at 800-255-2500.

Not all products are currently available in all markets.

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COMPANIES OF Johnson&Johnson

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767-0350
USA

Medos International SÀRL
Chemin-Blanc 38
CH-2400 Le Locle
Switzerland

www.depuysynthes.com

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

Authorized European Representative:
DePuy International, Ltd.
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (0) 113 387 7800
Fax: +44 (0)113 387 7890

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