

ProDisc-C Removal System.

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

Technique Guide



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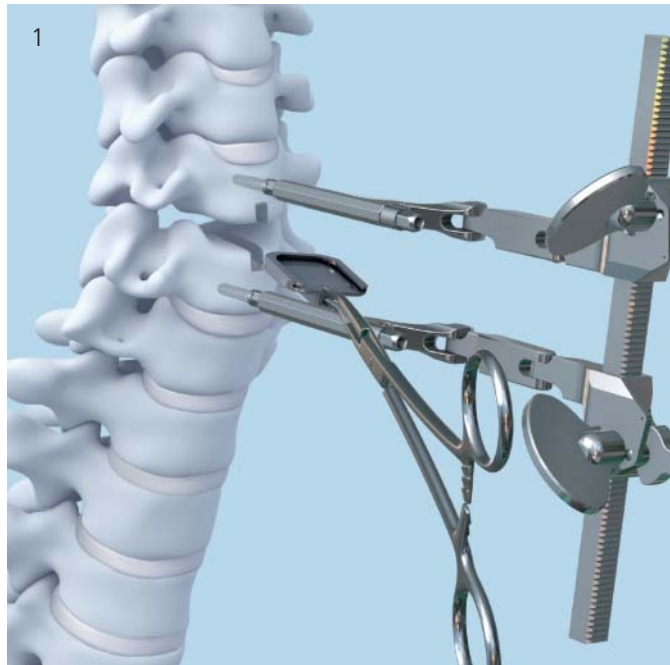
ProDisc-C Removal System. Instrumentation to assist with the removal of the ProDisc-C Total Disc Replacement device.

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 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 Synthes Spine for analysis.

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

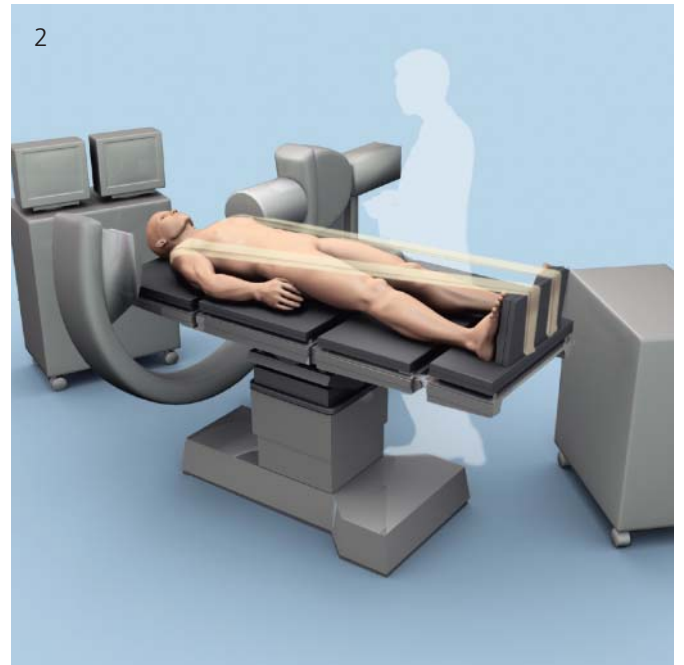


Preoperative Considerations

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

- 1 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).



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.

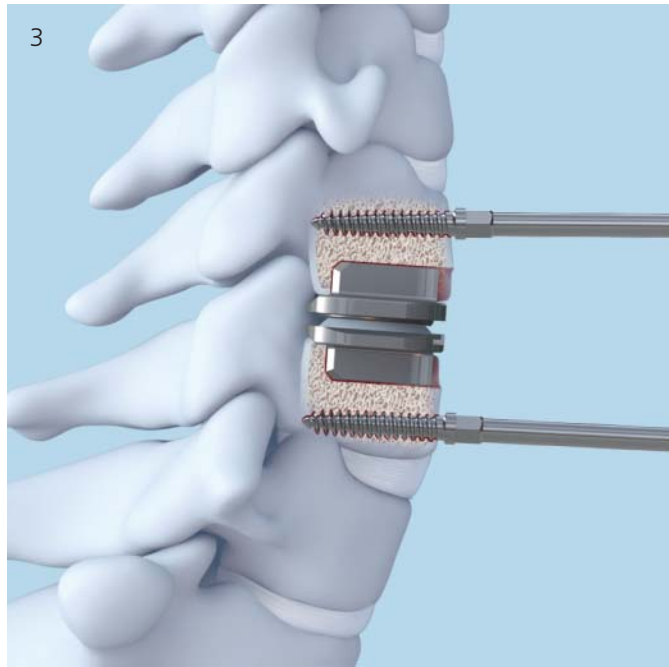
Distraction

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).

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

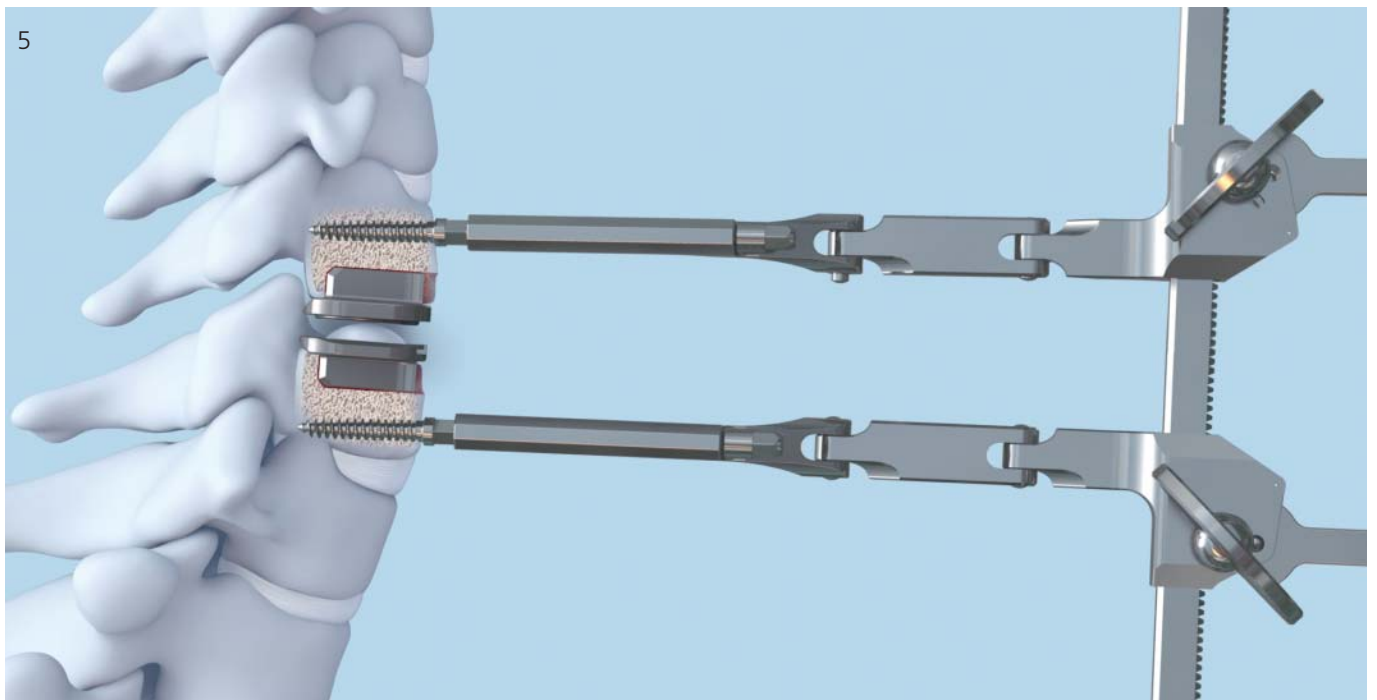
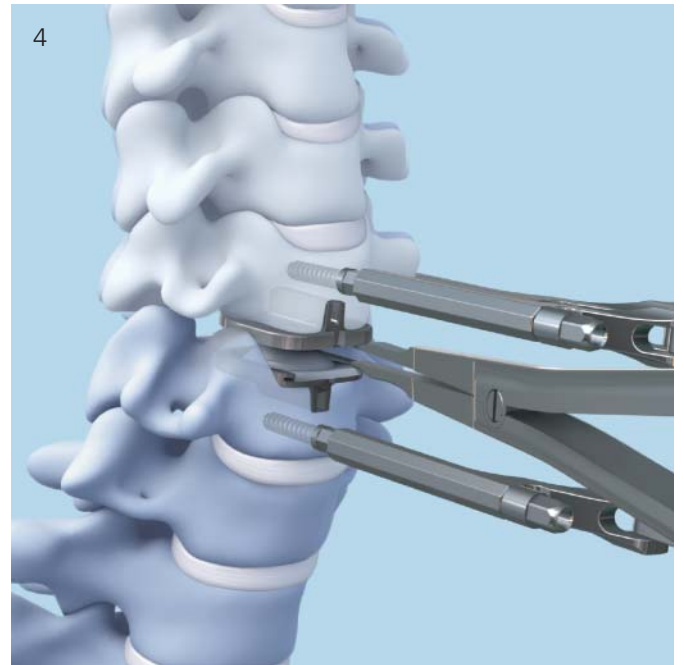


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- ① Insert distraction pins or retainer screws which are long enough to engage the posterior cortex, using fluoroscopy to confirm trajectory and screw depth. Attach either an interbody distractor or the vertebral body retainer. Under lateral fluoroscopic 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 overdistract as this can lead to nerve root overextension.



Implant Removal

1

Poly inlay removal

Instruments

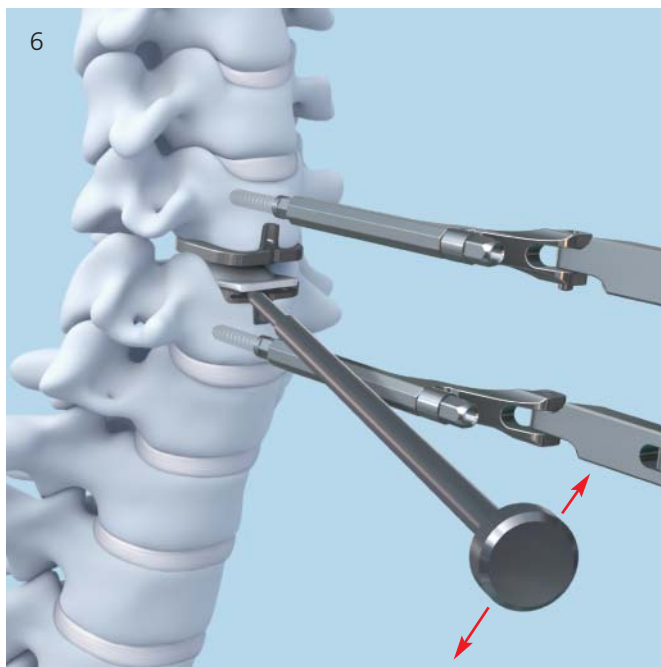
03.820.459 Inlay Separator, tapered

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.



2

Superior endplate removal

Instruments

03.820.452– Forked Osteotomes,
03.820.454 medium, large or extra large

03.820.456– Straight Osteotomes,
03.820.457 medium and large

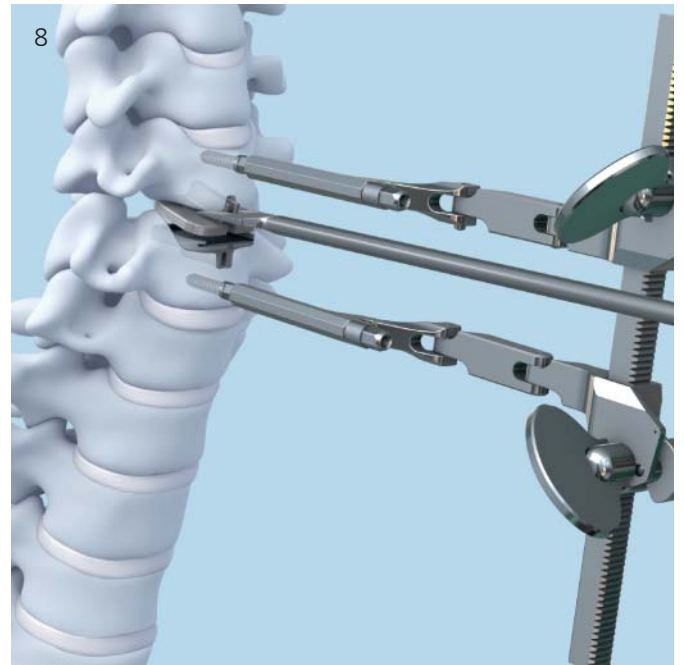
Kocher style forceps

- 1 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.

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



3

Inferior endplate removal

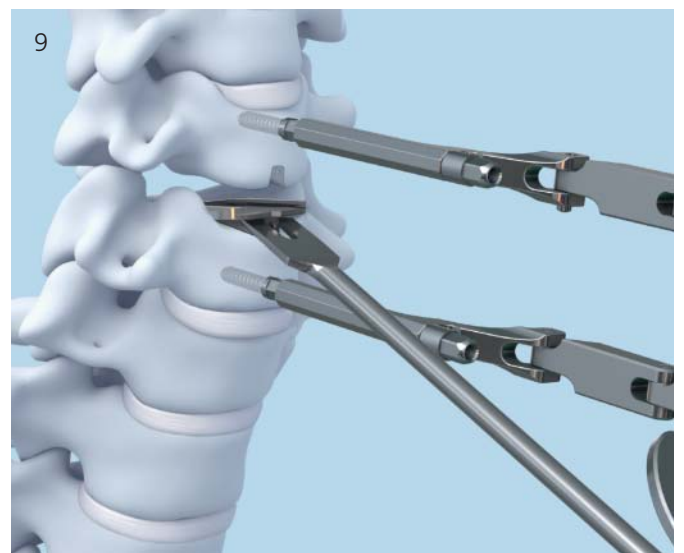
Instruments

03.820.452– Forked Osteotomes,
03.820.454 medium, large or extra large

Kocher style forceps

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

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



Instruments

From Standard ProDisc-C Set

03.820.100 Awl, 12 mm



03.820.101 Self-Retaining Screwdriver



03.820.102 Retainer Screws
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

03.820.452 Forked Osteotomes
Medium
03.820.453 Large
03.820.454 Extra large



03.820.453

03.820.456 Straight Osteotomes
Medium
03.820.457 Large



03.820.456

03.820.459 Inlay Separator, tapered



03.820.462 Vertebral Body Distractor, 3 mm tip



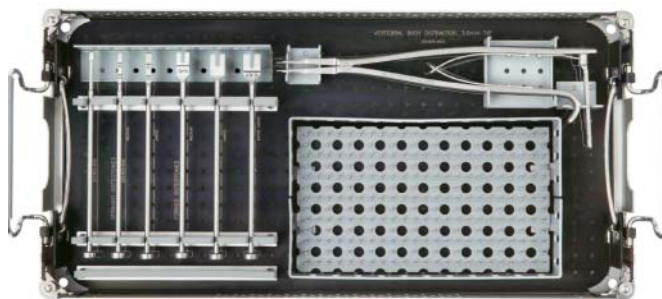
ProDisc-C Removal Instrument Set (01.820.005E)

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 http://www.synthes.com/sites/NA/MedicalCommunity/Pages/Cleaning_and_Sterilization.aspx or to the below listed inserts, which will be included in the shipping container:

- Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
- Processing Non-sterile Synthes Implants—DJ1304



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