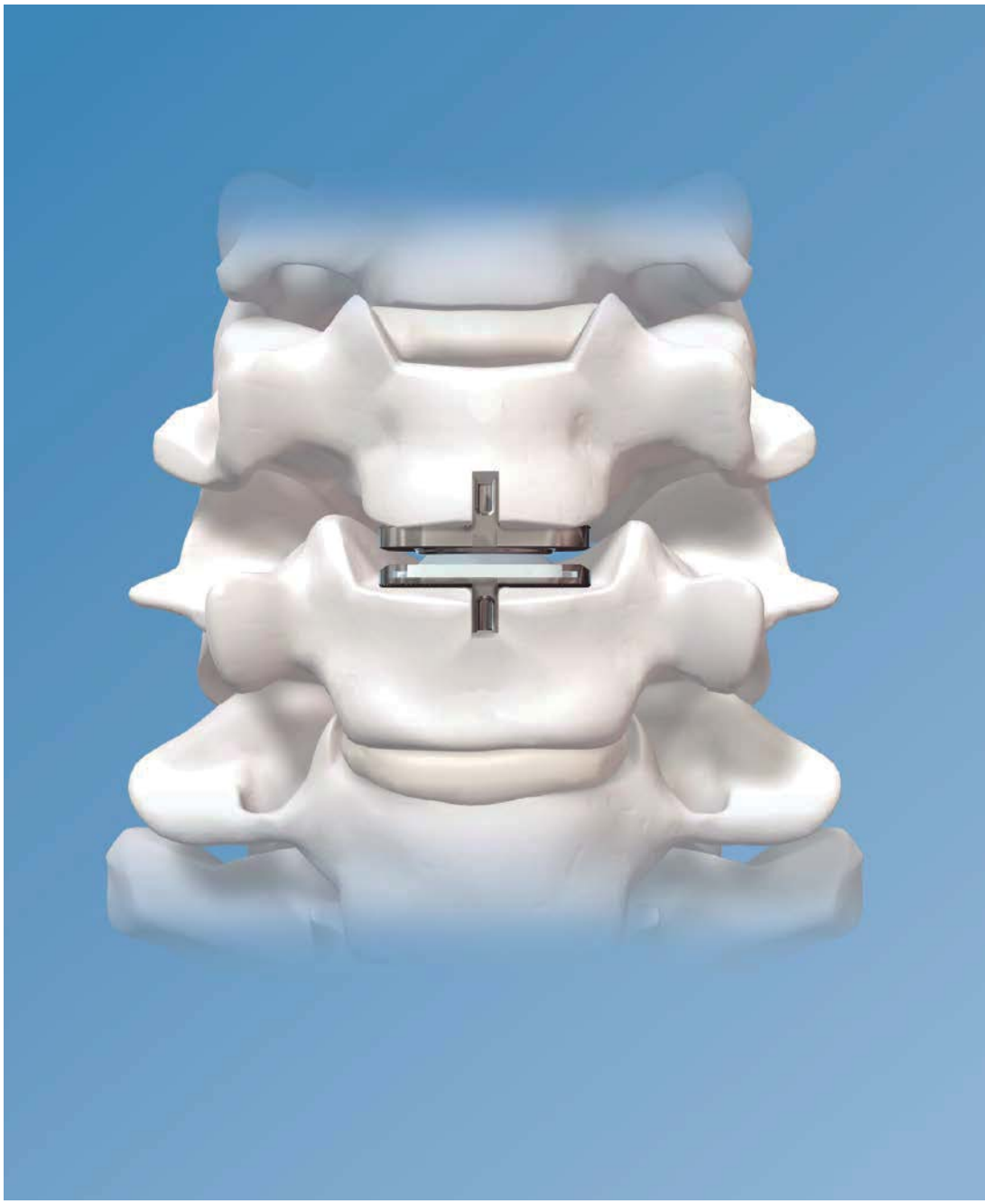
ProDisc-C Total Disc Replacement.
Product information.

Ball and socket implant

Secure fixation

Proven materials

Zero-profile implant



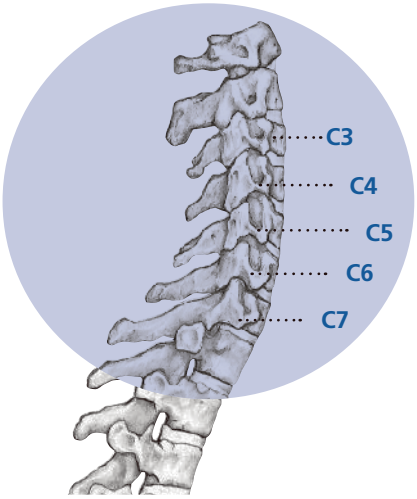
SYNTHES® Spine

Instruments and implants approved by the AO Foundation

ProDisc-C Total Disc Replacement

Indications

The ProDisc-C Total Disc Replacement is indicated in skeletally mature patients for reconstruction of a single disc from C3–C7 following discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or loss of disc height. The ProDisc-C Total Disc Replacement is implanted via an open anterior approach. Patients receiving the ProDisc-C Total Disc Replacement should have failed at least six weeks of nonoperative treatment prior to implantation of the ProDisc-C Total Disc Replacement.



Contraindications

The ProDisc-C Total Disc Replacement should not be implanted in patients with the following conditions:

– Active systemic infection or infection localized to the site of implantation
– Osteoporosis defined as DEXA bone density measured T-score ≤ -2.5
– Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation > 3 mm and/or > 11° of rotational difference to either adjacent level
– Allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
– Severe spondylosis characterized by bridging osteophytes or a loss of disc height > 50% or an absence of motion (< 2°), as this may lead to limited range of motion and may encourage bone formation (e.g., heterotopic ossification, fusion)
– Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion)

Please refer to packaging insert for the full list of indications, contraindications, warnings and/or precautions.

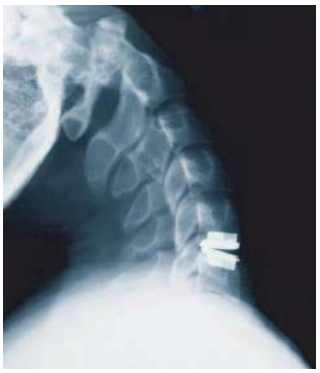
Design principles

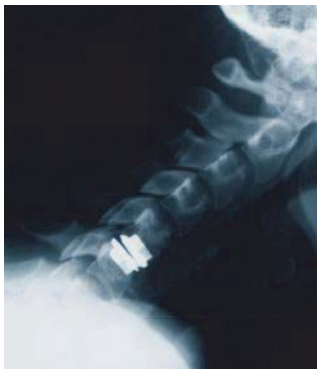
The ProDisc-C Total Disc Replacement is part of the Synthes Spine ProDisc product line, which consists of implants and instruments designed to restore motion and functionality to diseased spinal segments. The ProDisc-C Total Disc Replacement for the cervical spine (C3–C7) is based on the same design principles as the clinically successful ProDisc-L Total Disc Replacement for the lumbar spine (L3–S1):

– Ball and socket design
– Secure fixation
– Zero profile
– Proven materials
– Anatomic sizing

Motion

The ProDisc-C Total Disc Replacement is one of the first commercially available spinal arthroplasty devices for the cervical spine. In a multicenter prospective IDE clinical trial, patients receiving the ProDisc-C Total Disc Replacement demonstrated a mean range of motion of 9.4° in flexion/extension at 24 months.





Design Philosophy

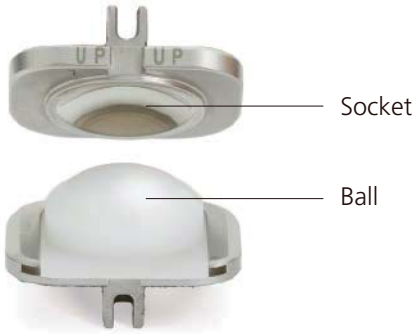
Ball and socket design

The ProDisc-C Total Disc Replacement utilizes a semiconstrained ball and socket design to provide the potential for motion in the cervical spine.

The ProDisc-C Total Disc Replacement is composed of three components which form a ball and socket joint with a fixed center of rotation:

– a polyethylene inlay is locked into the inferior endplate, forming the ball
– a dome in the superior endplate forms the socket

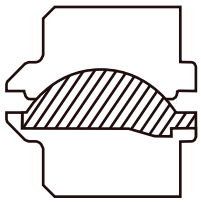
Together, these implant components enable controlled and predictable segmental motion that complements the natural kinematics of the cervical spine.



Controlled and predictable motion

The ProDisc-C Total Disc Replacement allows a normal range of motion while providing segmental stability through controlled translation. The highly conforming surfaces of the superior endplate and polyethylene inlay prevent the endplates from translating independently.

Translation is limited to rotation of the superior endplate around the ball in the inferior endplate.



Range of motion

The ProDisc-C Total Disc Replacement is designed to allow the potential for a normal range of motion in flexion/extension, lateral bending and axial rotation.[1]

20°†

Lateral bending

20°†

Axial Rotation

unconstrained

†L5, LD5, XL5 and XLD5 sizes allow 17.5° in flexion/extension and lateral bending

Cervical spine motion

Motion patterns in the cervical spine have been extensively investigated and reported on in literature. Key published findings are:

–The instantaneous center of rotation (COR), is fixed during motion[2,3]

–Typically, the COR of a motion segment is located in the posterior portion of the inferior vertebral body[3]

–Translation is coupled with rotation[3]

The instantaneous COR is fixed during motion. It can be calculated with radiographic studies. (Figure 1)

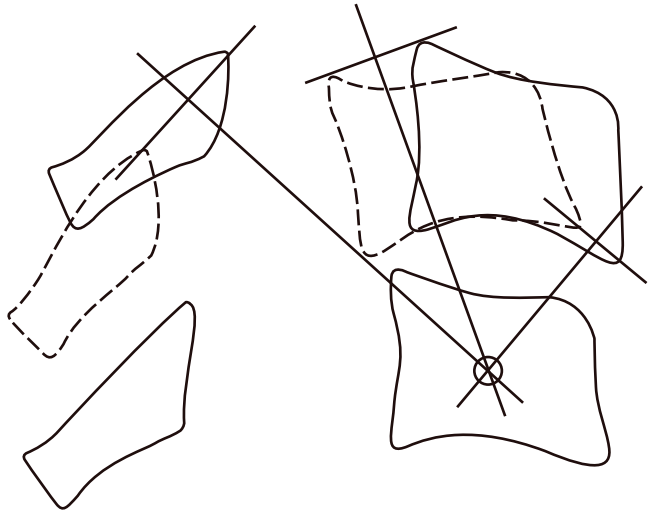


Figure 1
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ProDisc-C motion

The ProDisc-C Total Disc Replacement has been designed to complement the natural kinematics of the spine:

– The ProDisc-C COR is fixed during motion

– The ProDisc-C COR is located in the inferior vertebral body

– The ProDisc-C implant allows translation only when coupled with rotation

– Resists shear forces

"When a cervical vertebra moves from full extension to full flexion its path appears to lie along an arc whose center lies somewhere below the moving vertebra."[3] (Figure 2)

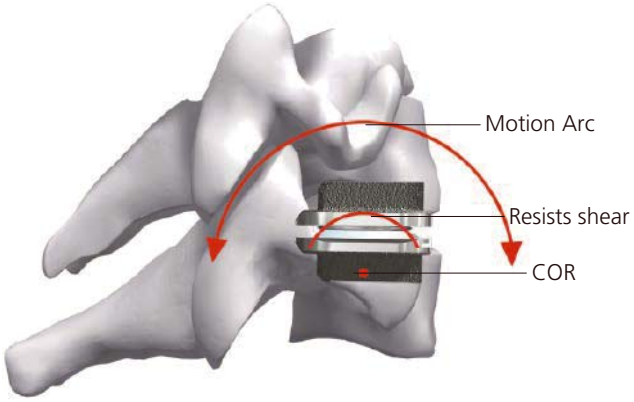

Figure 2

Coupled motion

Rotational translation

The ProDisc-C Total Disc Replacement allows translation only when coupled with rotation. This rotational translation is a function of the fixed COR.

"Essentially a tilting type of motion… produces less linear displacement ('translation') than in a gliding type of motion."[2] (Figure 3)

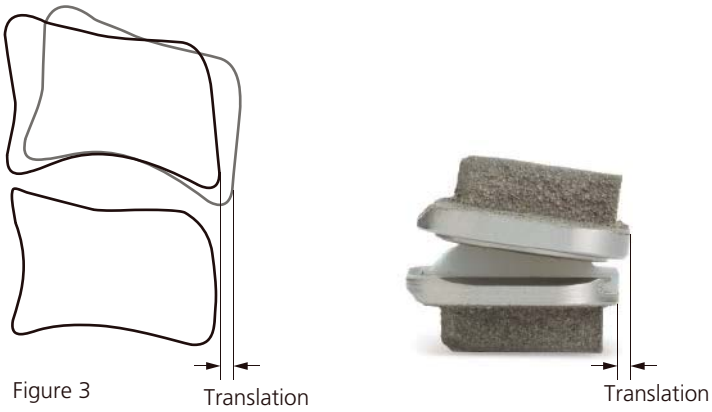

Figure 3

Center of rotation (COR)

Mean location and distribution of instantaneous COR.[3] (Figure 4)

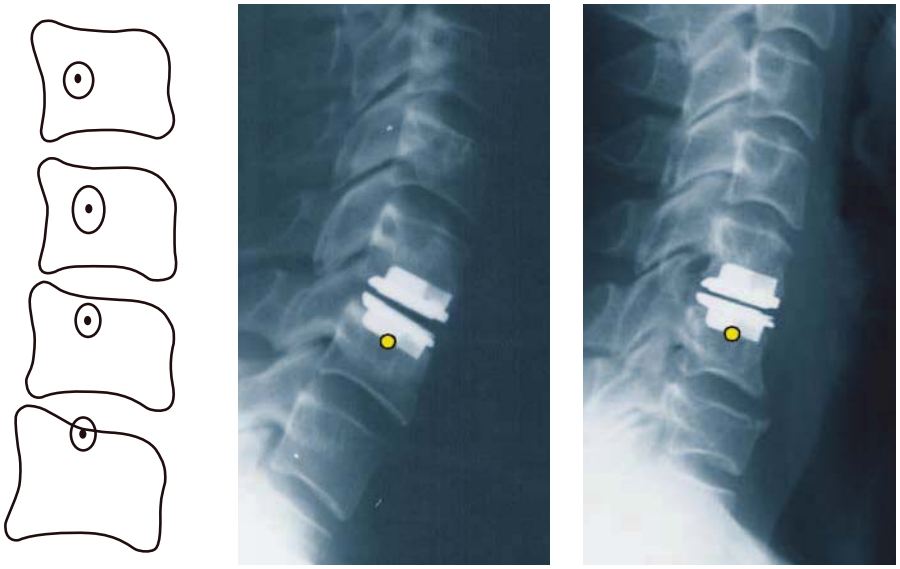

Figure 4
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Proper sizing and posterior placement of ProDisc-C Total Disc Replacement with COR location shown

Biomechanical Testing

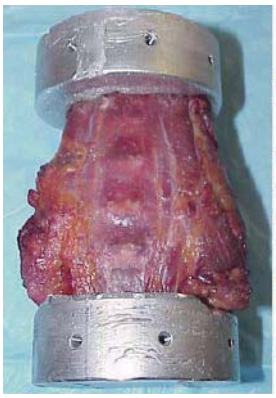
Data collected in multiple biomechanical tests comparing the ProDisc-C Total Disc Replacement to an intact spine indicate that ProDisc-C motion patterns are similar to the motion patterns of an intact spine.

Puttlitz, et al, *Spine,* 2004 compared ProDisc-C Total Disc Replacement to an intact spine:

"…data indicate that a ball-and-socket design produced normal physiologic motion. Further, coupled motion patterns were maintained after implantation of the device."

DiAngelo, et al, *Neurosurgical Focus,* 2004 compared ProDisc-C Total Disc Replacement to an intact spine and to fusion:

"ProDisc-C implant maintained the biomechanical integrity of the cervical spine. … [With] maintenance of normal motion at all segments of the spine...
...fusion significantly reduced motion at the surgical site, which was compensated for by increased motion at the adjacent segments."[5] (Figure 5)



Intact Spine

ProDisc-C (C5–6)

Fusion (C5–6)
Figure 5
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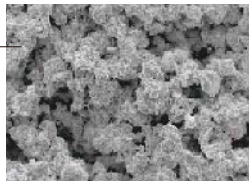
Journal of Neurosurgical Focus

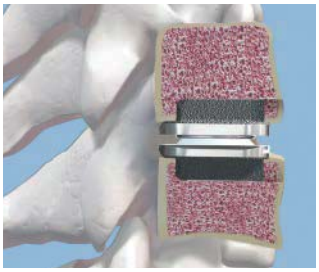
Secure fixation with zero-profile
The ProDisc-C Total Disc Replacement is anchored to the vertebral bodies via a patented central keel and porous plasma-sprayed titanium coating.

Patented central keel:
– provides immediate stability in three planes
– facilitates midline implant placement

Porous plasma-sprayed titanium coating:
– covers all bone contacting surfaces
– promotes bony ongrowth



Zero-profile implant:
– does not contact anterior soft tissue structures after implantation



Proven materials

The ProDisc-C endplates are composed of cobalt chromium molybdenum (CoCrMo) and the inlay is composed of ultra-high molecular weight polyethylene (UHMWPE). The CoCrMo/UHMWPE articulation has a long history of clinical use:

– used in spinal arthroplasty since 1987
– most common articulation materials found in total joint replacements
  – 84% of total hips[6]
  – 99% of total knees[6]

In vitro wear rates depend on numerous testing parameters such as load, range of motion and motion patterns. Due to lower loads and range of motion, clinical wear rates in the spine are significantly less than in hips and knees. (Figure 6)

Wear rates are significantly less than total joints

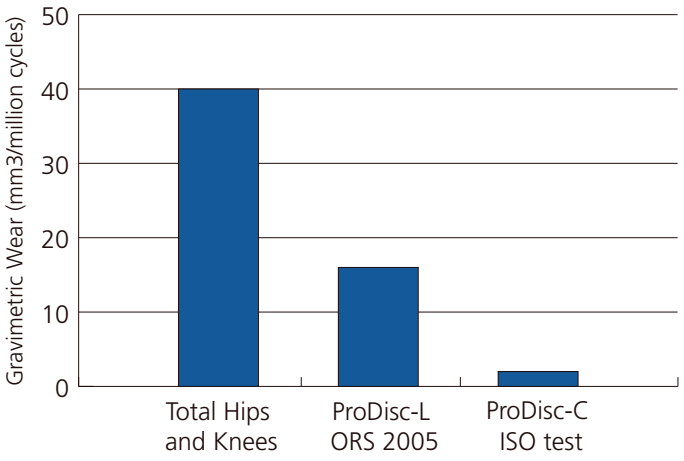
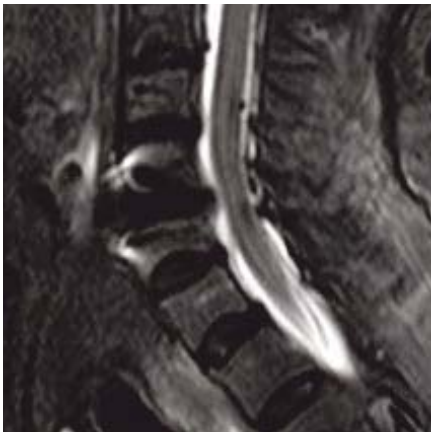


Figure 6

MRI Information

The ProDisc-C Total Disc Replacement is labeled MR Conditional, where it has been demonstrated to pose no known hazards in a specified MR enviroment with specified conditions of use. For further information please refer to the product package insert.

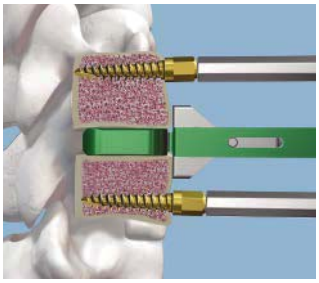
ProDisc-C MRI T2 1.5T



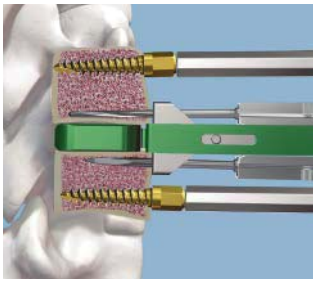
Technique, Safety and Sizing

Safe and reproducible surgical technique
The ProDisc-C system offers a safe and reproducible technique through intuitive instrumentation. Implantation of the ProDisc-C Total Disc Replacement is achieved in 3 simple steps.

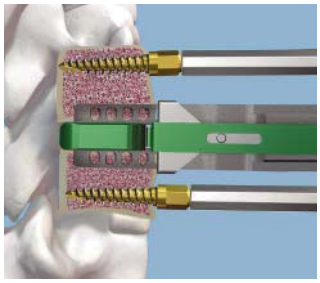
1. Trial



2. Keel preparation

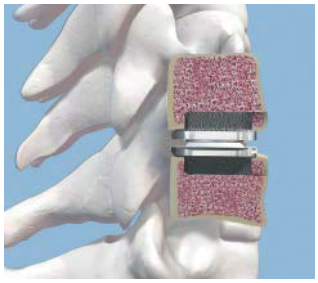


Milling



Chiseling

3. Implant



Safety and effectiveness
The ProDisc-C Total Disc Replacement was evaluated for safety and effectiveness as part of an FDA-regulated IDE clinical study. The prospective, randomized trial was conducted at 13 centers across the United States.

Patients suffering from SCDD at a single level from C3–C7 were randomized 1:1 to receive either a ProDisc-C Total Disc Replacement or an anterior cervical decompression and fusion (ACDF) with cortical ring allograft bone and anterior plate.

When compared to the standard of care, ACDF, the ProDisc-C Total Disc Replacement was shown to provide the same pain relief and high patient satisfaction with fewer reoperations.

ProDisc-C Total Disc Replacement patients in the IDE study demonstrated:
– Significant improvement in pain and disability
– Fewer secondary procedures
– High rate of patient satisfaction

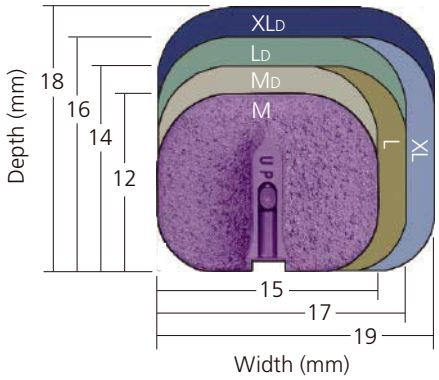
Note: For more information regarding the ProDisc-C IDE study, refer to the summary of Safety and Effectiveness Data at www.fda.gov or the ProDisc-C IDE Clinical study brochure at www.synthesprodisc.com.

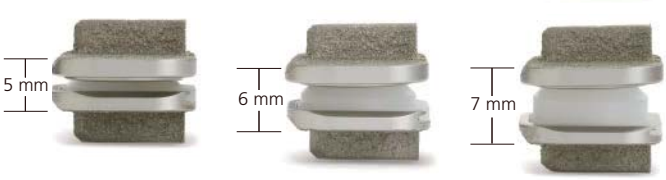
Anatomical sizing

The ProDisc-C Total Disc Replacement is available in 18 anatomic sizes to accommodate a wide range of patient anatomies:

– 6 implant footprints maximize endplate coverage

– 3 implant heights restore normal disc height.





References

1. Manohar M. Panjabi, PhD, DTech, Joseph J. Crisco, PhD, Anita Vasavada, PhD, Takenori Oda, MD, Jacek Cholewicki, PhD, Kimio Nibu, MD, and Eon Shin, BA. "Mechanical Properties of the Human Cervical Spine as Shown by Three-Dimensional Load–Displacement Curves." *Spine* 2001; 24:2692–2700.

2. L. Penning, MD. "Differences in anatomy, motion, development and aging of the upper and lower cervical disk segments." *Clinical Biomechanics* 1988; 3: 37-47.

3. Nikolai Bogduk, Susan Mercer. "Biomechanics of the cervical spine. I: Normal Kinematics." *Clinical Biomechanics,* 2000; 15: 633-648.

4. Christian M. Puttlitz, PhD, Marc Antoine Rousseau, MD, Zheng Xu, BS, Serena Hu, MD, Bobby K-B Tay, MD, and Jeffrey C. Lotz, PhD. "Intervertebral Disc Replacement Maintains Cervical Spine Kinetics." *Spine,* 2004; 29: 2809-2814.

5. Denis J. Diangelo, PhD, Kevin T. Foley, MD, Brian R. Morrow, BSc., John S. Schwab, MSc., Jung Song, PhD., John W. German, MD, and Eve Blair, BSc. "In vitro biomechanics of cervical disc arthroplasty with the ProDisc-C total disc implant." *Neurosurgical Focus,* 2004; 17:44-54.

6. 2005 Hip and Knee Implant Review. Orthopedic Network News. July 2005.

ProDisc-C Instrument and Implant Set (01.820.003)

Graphic Case

60.820.001 Graphic Case, for ProDisc-C Instruments

Instruments (shipped in graphic case)

03.820.000 Handle, for Trial Implants, 2 ea.

Trial Implants

03.820.025 Medium, 5 mm
03.820.026 Medium, 6 mm
03.820.035 Medium, deep, 5 mm
03.820.036 Medium, deep, 6 mm
03.820.045 Large, 5 mm
03.820.046 Large, 6 mm
03.820.055 Large, deep, 5 mm
03.820.056 Large, deep, 6 mm
03.820.065 Extra large, 5 mm
03.820.066 Extra large, 6 mm
03.820.075 Extra large, deep, 5 mm
03.820.076 Extra large, deep, 6 mm

03.820.100 Awl, 12 mm
03.820.101 Self-Retaining Screwdriver, 2 ea.

Retainer Screws

03.820.102 3.5 mm x 12 mm, 2 ea.
03.820.103 3.5 mm x 14 mm, 2 ea.
03.820.104 3.5 mm x 16 mm, 2 ea.
03.820.105 3.5 mm x 18 mm, 2 ea.
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, 6 ea.
03.820.111 Vertebral Body Retainer
03.820.112 Vertebral Distractor
03.820.113 Slotted Mallet
03.820.114 Milling Guide, 5 mm
03.820.115 Milling Guide, 6 mm
03.820.119 Primary Chisel, 5 mm
03.820.120 Primary Chisel, 6 mm
03.820.122 Secondary Chisel, 5 mm
03.820.123 Secondary Chisel, 6 mm
03.820.126 Keel Cut Cleaner
03.820.127 Implant Remover
03.820.128 Chisel Cleaner
03.820.129 Implant Inserter
03.820.136 Temporary Fixation Pin, Sharp, 2 ea.
03.820.137 Temporary Fixation Pin, Blunt
03.820.143 2.0 mm Hexagonal Screwdriver
03.820.144 Tamp

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.

Instruments (supplied sterile packaged)

03.820.117S	Milling Bit, sterile, 4 ea.
	Inserter Tips, for Medium and Medium Deep Implants, sterile
03.820.130S	5 mm height, 2 ea.
03.820.131S	6 mm height, 2 ea.
	Inserter Tips, for Large and Large Deep Implants, sterile
03.820.133S	5 mm height, 2 ea.
03.820.134S	6 mm height, 2 ea.
03.820.135S	7 mm height
	Inserter Tips, for Extra Large and Extra Large Deep Implants, sterile
03.820.140S	5 mm height, 2 ea.
03.820.141S	6 mm height
03.820.142S	7 mm height

Implants (supplied sterile packaged)

ProDisc-C Total Disc Replacement Implants, sterile

09.820.025S	Medium, 5 mm, 2 ea.
09.820.026S	Medium, 6 mm, 2 ea.
09.820.035S	Medium, deep, 5 mm, 2 ea.
09.820.036S	Medium, deep, 6 mm, 2 ea.
09.820.045S	Large, 5 mm, 2 ea.
09.820.046S	Large, 6 mm, 2 ea.
09.820.047S	Large, 7 mm
09.820.055S	Large, deep, 5 mm, 2 ea.
09.820.056S	Large, deep, 6 mm, 2 ea.
09.820.057S	Large, deep, 7 mm
09.820.065S	Extra large, 5 mm, 2 ea.
09.820.066S	Extra large, 6 mm
09.820.067S	Extra large, 7 mm
09.820.075S	Extra large, deep, 5 mm, 2 ea.
09.820.076S	Extra large, deep, 6 mm
09.820.077S	Extra large, deep, 7 mm

Also Available

Implants

ProDisc-C Total Disc Replacement Implants, sterile

09.820.027S	Medium, 7 mm
09.820.037S	Medium, deep, 7 mm

Instruments

	Trial Implants
03.820.027	Medium, 7 mm
03.820.037	Medium, deep, 7 mm
03.820.047	Large, 7 mm
03.820.057	Large, deep, 7 mm
03.820.067	Extra large, 7 mm
03.820.077	Extra large, deep, 7 mm
03.820.116	Milling Guide, 7 mm
03.820.121	Primary Chisel, 7 mm
03.820.124	Secondary Chisel, 7 mm
03.820.132S	Inserter Tip, for Medium and Medium Deep Implants, 7 mm height, sterile
	Retainer Screws, sterile, 2/pkg.
03.820.102.02S	3.5 mm x 12 mm
03.820.103.02S	3.5 mm x 14 mm
03.820.104.02S	3.5 mm x 16 mm
03.820.105.02S	3.5 mm x 18 mm
03.820.110.02S	Retainer Nut, sterile, 2/pkg.

SYNTHES® Spine

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