GLOBUS MEDICAL

SECURE®-C

Cervical Artificial Disc

TECHNICAL OVERVIEW

Life moves us

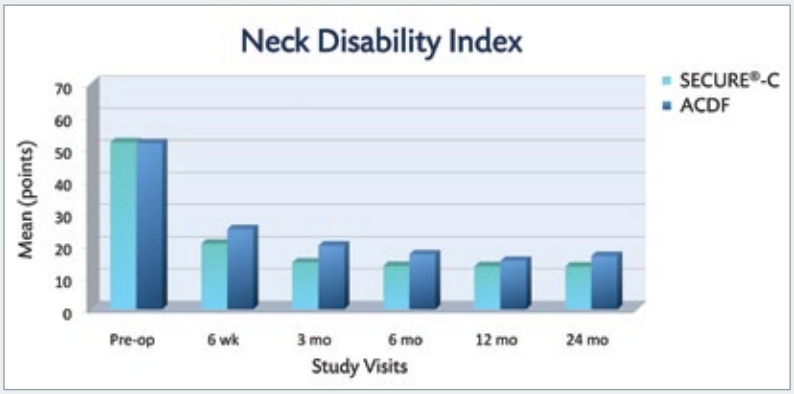
SECURE®-C
Cervical Artificial Disc

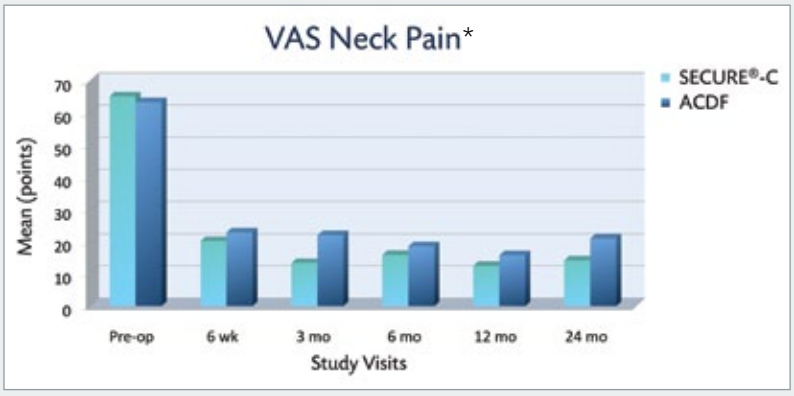
SECURE®-C is designed to preserve motion for patients suffering from intractable radiculopathy or myelopathy due to a single-level abnormality localized to the disc space.

Superior Results

SECURE®-C demonstrated statistical superiority in overall success to Anterior Cervical Discectomy and Fusion (ACDF) in the multicenter IDE clinical trial. The device provides patients the potential for motion preservation versus a rigid fusion with an ACDF. In addition, mean Neck Disability Index and mean Visual Analog Scale (VAS) neck and arm pain scores showed postoperative improvement in the IDE trial.

For the patients in the IDE trial who reported return to work data, SECURE®-C patients returned to work on average 6 days faster than the control group (mean 44 days versus 50 days). Ninety-six percent (96%) of the patients who received the SECURE®-C disc were at least mostly satisfied with the results of surgery versus 85% of the control group at 24 months postoperative.



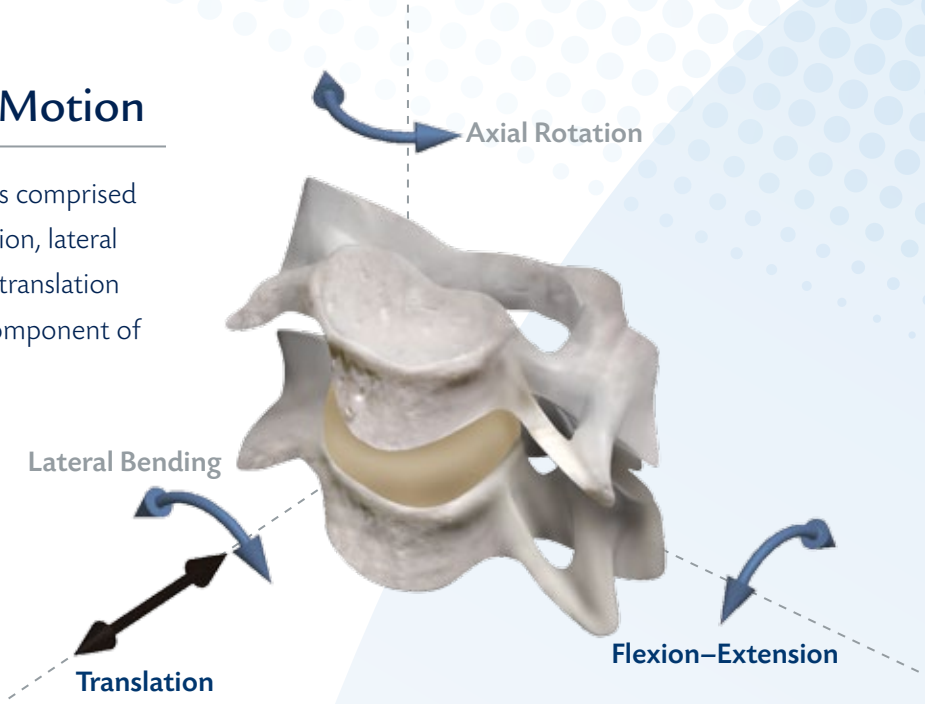


*Per FDA, VAS data excludes one site in which some scores were reported verbally rather than written.

Natural Biomechanical Motion

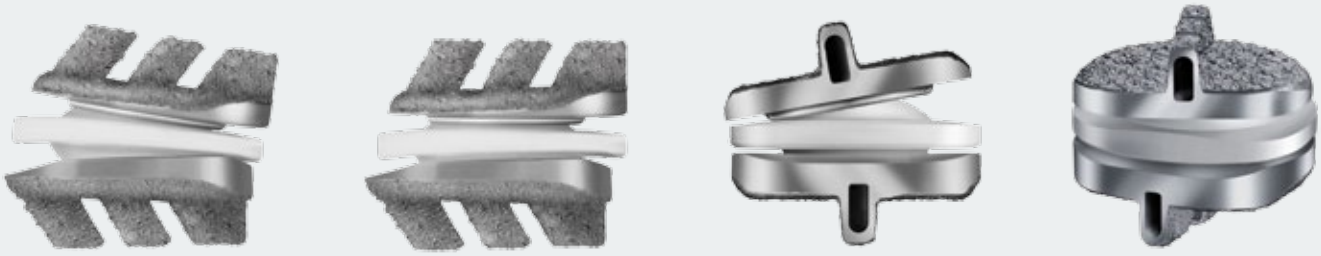
The natural motion of the cervical spine is comprised of three primary motions: flexion–extension, lateral bending and axial rotation. Sagittal plane translation has also been identified as a significant component of cervical motion.[1]

C5-C6 Motion[1]	
Flexion–Extension	9.9°
Sagittal Plane Translation	1.2mm
Lateral Bending	6.5°
Axial Rotation	5.0°



Selectively Constrained Design

SECURE®-C is designed to allow ±15° flexion–extension motion, ±10° lateral bending motion, unconstrained axial rotation, and ±1.25mm translation. The spherical and cylindrical surfaces are designed to accommodate the instantaneous axis of rotation and provide sagittal plane translation during flexion–extension.



Flexion/Extension
±15°

Translation
±1.25mm

Lateral Bending
±10°

Axial Rotation
Unconstrained

1. Panjabi MM, Crisco JJ, Vasavada A, Oda T, Cholewicki J, Nibu K, Shin E. Mechanical properties of the human cervical spine as shown by three-dimensional load-displacement curves. Spine 26(24):2692-2700, 2001.

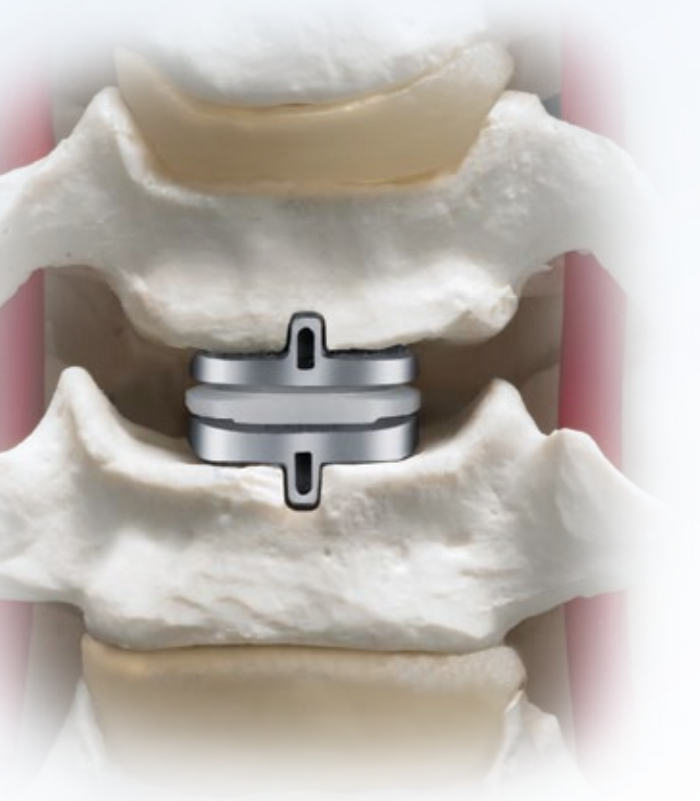
Biomechanical Motion

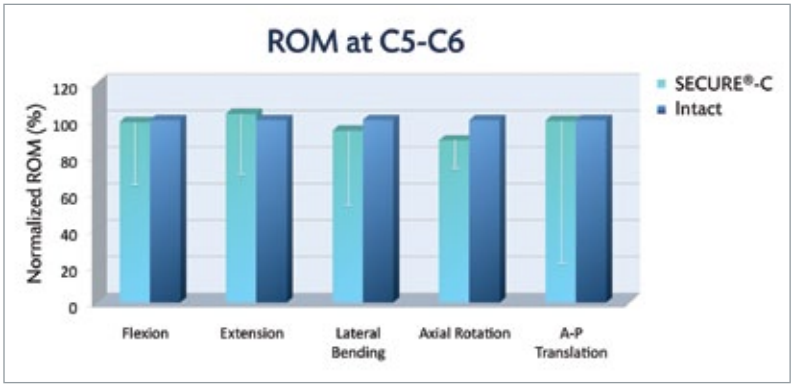
A biomechanical cadaver study[2] was conducted to compare the range of motion (ROM) of SECURE®-C to the intact cervical spine in flexion–extension, lateral bending and axial rotation. The results show that SECURE®-C may be capable of maintaining motion similar to the natural cervical spine.

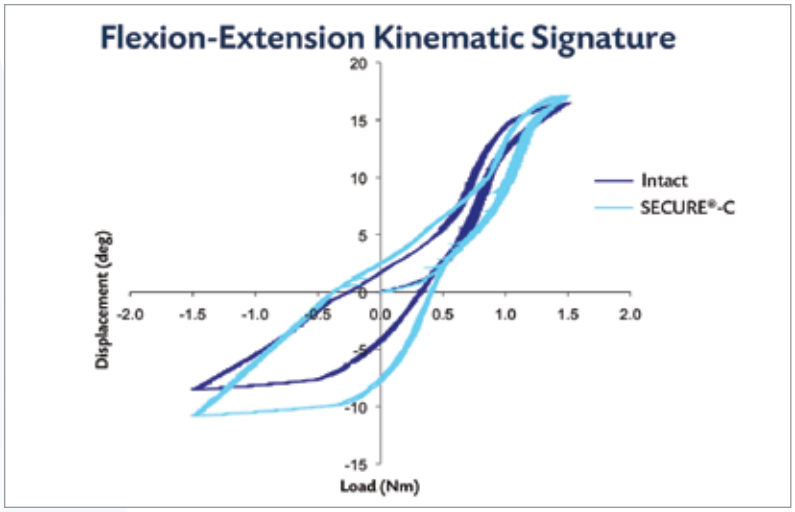
Study Design

7 cadaveric spine specimens
Hybrid test protocol
- 1.5Nm moment
- Flexion/Extension (F/E)
- Lateral Bending
- Axial Rotation

Tested intact spine
Tested spine with SECURE®-C at C5-6
Results normalized to the intact spine





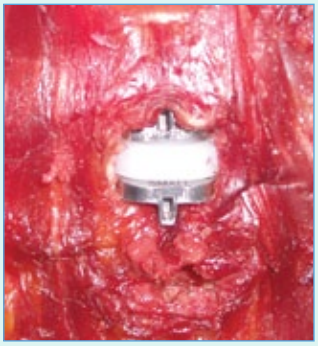


SECURE®-C may maintain motion similar to that of the natural cervical spine.

Results:

Compared to 100% intact:

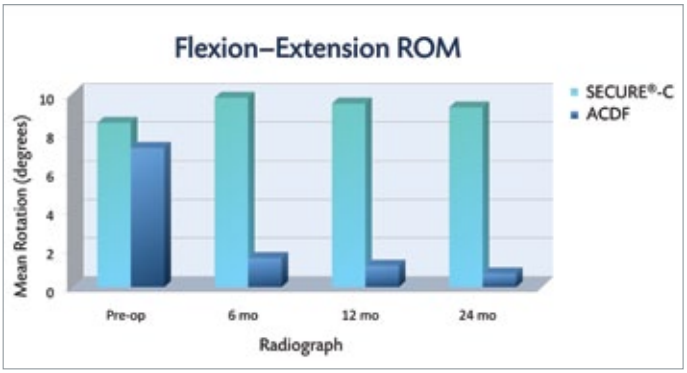
Flexion	99%
Extension	103%
Lateral Bending	94%
Axial Rotation	89%
Translation	99%



2. Muzumdar, Aditya, et al. "Biomechanical analysis following implantation of a cervical artificial disc: An in vitro study." Globus Medical Research. September 2009.

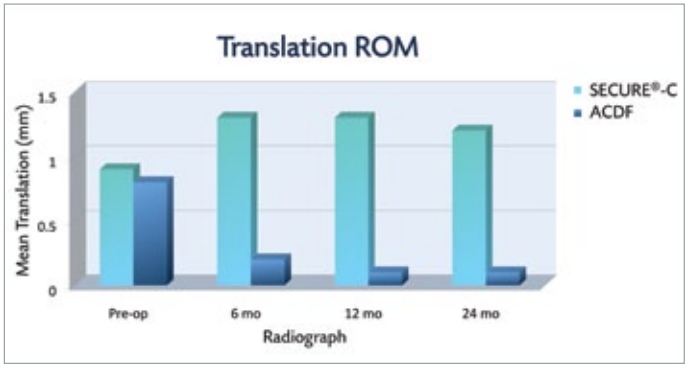
Clinical Motion

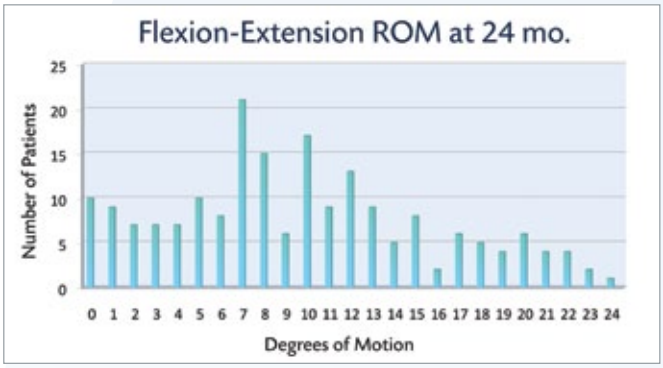
The multicenter IDE clinical trial demonstrated that 85% of patients treated with the SECURE®-C who returned for 24 month follow-up had ≥4° of flexion–extension motion or maintenance of motion relative to the preoperative baseline. Patients demonstrated an average flexion–extension range of motion of 9.3° and sagittal plane translation of 1.2 mm at 24 months.



Motion Outcomes

SECURE®-C may provide a motion profile similar to that of the natural spine. SECURE®-C is designed to permit sagittal plane translation without rigidly constraining the center of rotation.





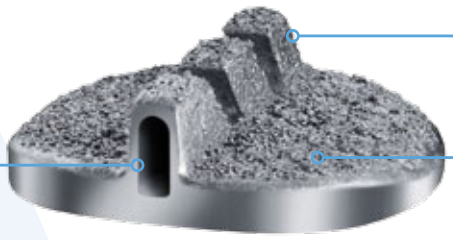
For more information please refer to the SECURE®-C Cervical Artificial Disc IDE Clinical Study Overview.

	Human Spine[3]	SECURE®-C[4]	ProDisc-C[5]	Prestige[5]
Design	Motion Segment	Selectively Constrained	Ball and Socket	Ball and Trough
Flexion–Extension (Mean)	9.9°	9.3°	9.36°	7.73°
Sagittal Plane Translation (Mean)	1.2mm	1.2mm	(not reported)	0.28mm

3. Panjabi MM, Crisco JJ, Vasavada A, Oda T, Cholewicki J, Nibu K, Shin E. Mechanical properties of the human cervical spine as shown by three-dimensional load-displacement curves. Spine 26(24):2692-2700, 2001.
4. SECURE®-C PMA P100003: SSED
5. Upadhyaya CD, Wu J-C, Trost G, Haid RW, Traynelis VC, Tay B, Coric D, and Mummaneni PV. Analysis of the three United States Food and Drug Administration investigational device exemption cervical arthroplasty trials. J Neurosurgery Spine 16:216-228, 2012.

Additional Attributes

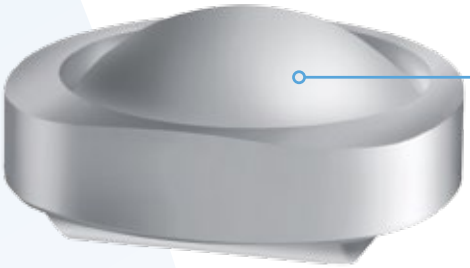
In addition to allowing the potential for cervical motion, SECURE®-C is designed to facilitate a streamlined procedure, promote bony fixation and minimize wear debris.



Initial fixation from multiple serrated keels

Single step insertion facilitated by endplate recess feature

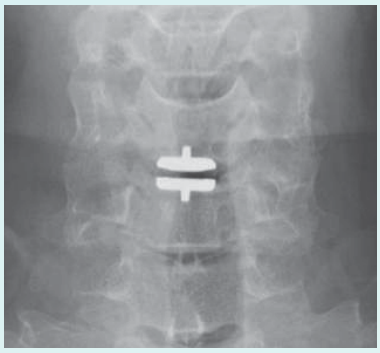
Titanium plasma spray coating designed to allow for bony ongrowth



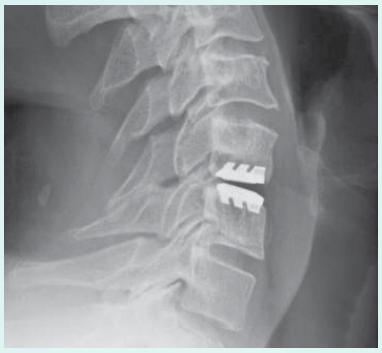
Ultra-high molecular weight polyethylene (UHMWPE) core designed to minimize wear debris

Engagement recess designed to secure core between endplates

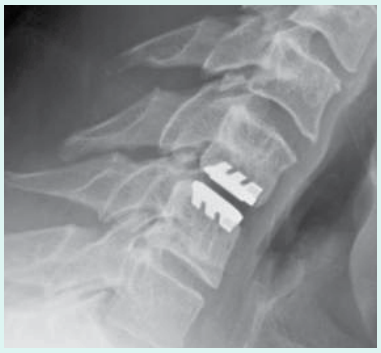
Endplates manufactured from cobalt-chromium molybdenum alloy (CoCrMo)



SECURE®-C 24 Month
Post-op Neutral Position



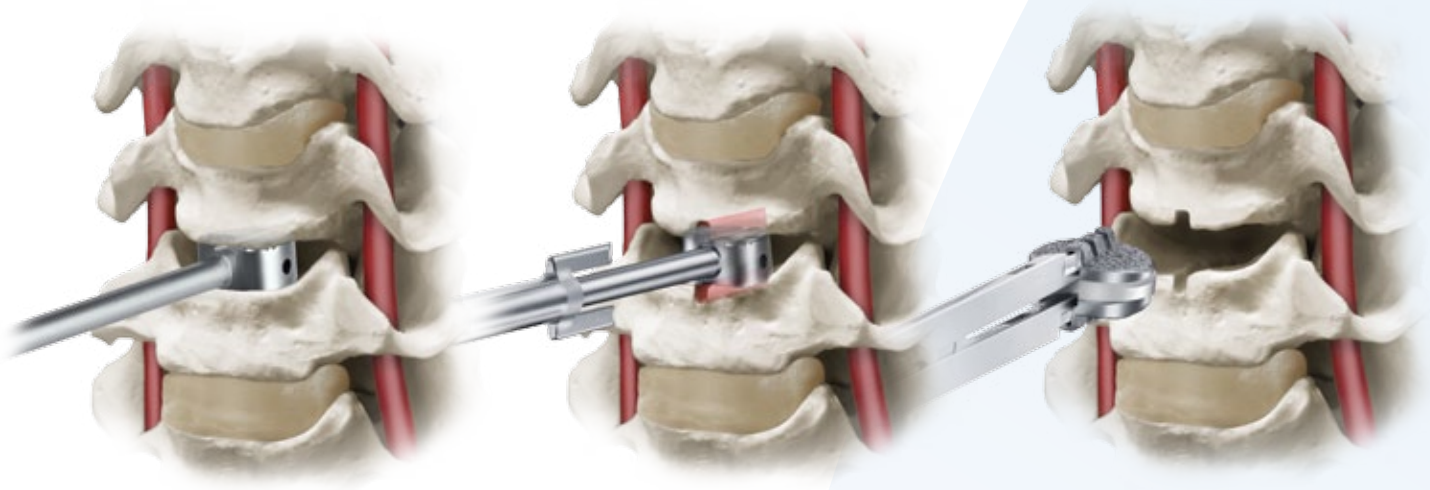
SECURE®-C 24 Month
Post-op Extension



SECURE®-C 24 Month
Post-op Flexion

Streamlined Procedure

Our exclusive instruments and streamlined procedure are designed to allow precise placement of the implant with only three essential steps: Trial–Chisel–Insert.



1. Trial

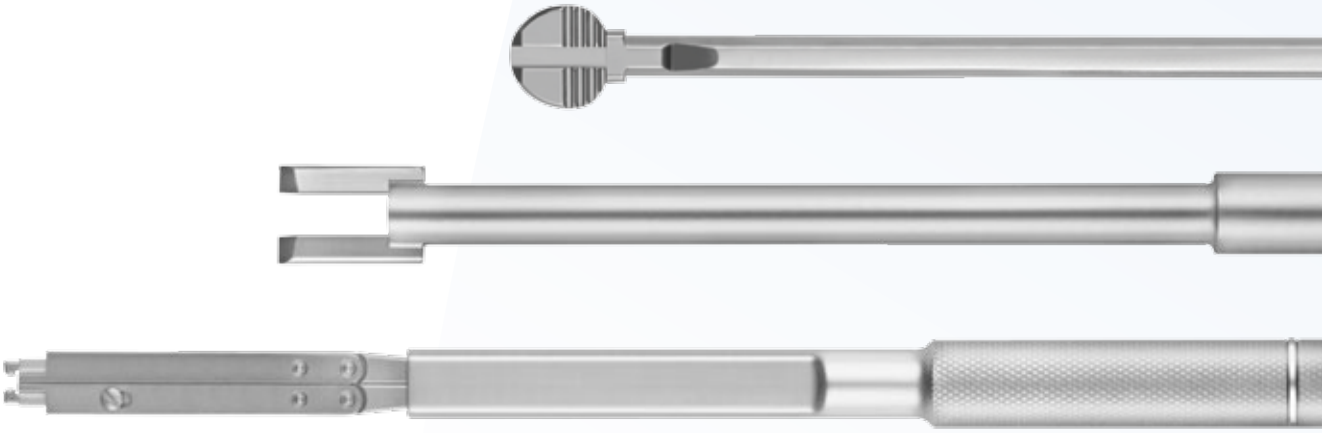
Identify the proper size to match the patient's anatomy

2. Chisel

Specialized chisels designed to reduce trauma during chiseling

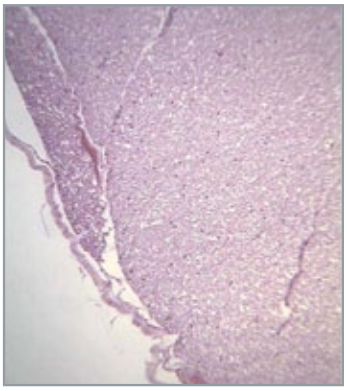
3. Insert

Entire assembly inserted at once



Particulate Study

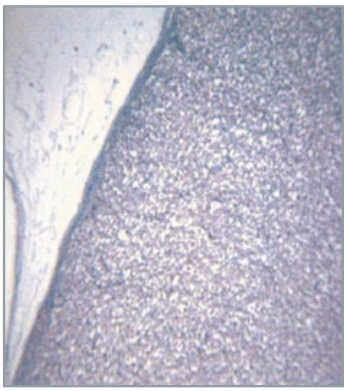
Polyethylene wear particles can form and migrate throughout the life of articulating devices such as SECURE®-C. To evaluate the effect of wear debris in the epidural space, a particulate animal study was conducted.



Spinal Cord of Control Rabbit at 6 months

Objective

The purpose of the study was to evaluate the local and systemic effect of ultra-high molecular weight polyethylene (UHMWPE) particles implanted into the epidural space of New Zealand white rabbits.



Spinal Cord of High Dose Rabbit at 6 months

Study Details

Control Group (n=12) – Epidural space injected with saline

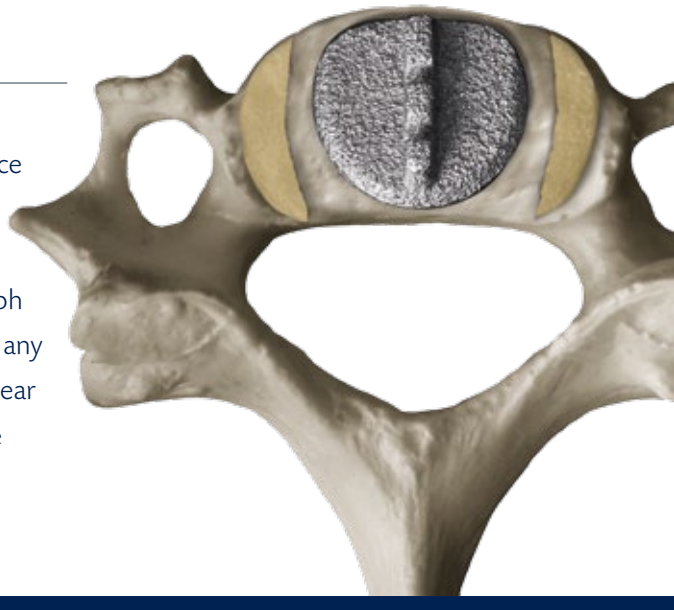
Low Dose Group (n=12) – Epidural space injected with 1 million UHMWPE particles mixed with contrast media

High Dose Group (n=12) – Epidural space injected with 10 million UHMWPE particles mixed with contrast media

Animals were sacrificed at 3 months (n=6 per group) and 6 months (n=6 per group), and gross anatomic, histologic and systemic analysis was performed. Tissues were evaluated using irritant ranking scores (<2.9 indicate non-irritant).

Study Results

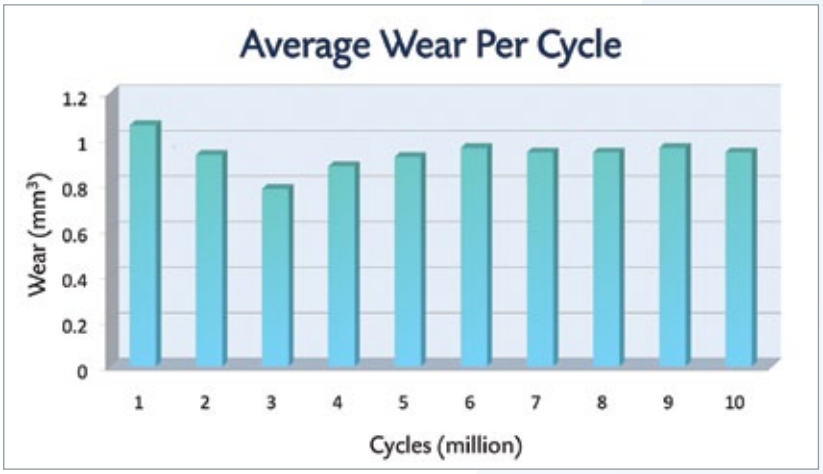
Based on 18 animals studied at 3 months (6 in each group) and 18 animals studied at 6 months (6 in each group) there was no evidence of neurotoxicity, systemic toxicity, or local effects associated with the particulate debris for either the 3 month or 6 month animals. Microscopic evaluation of tissues (muscle, vertebral segments, lymph nodes) and organs (brain, heart, lungs, liver, kidneys) did not reveal any remaining wear debris or local lesions that could be attributed to wear debris. Based on irritant ranking scores, both the low and high dose particulate spinal injections were determined to be non-irritants.



Mechanical Testing

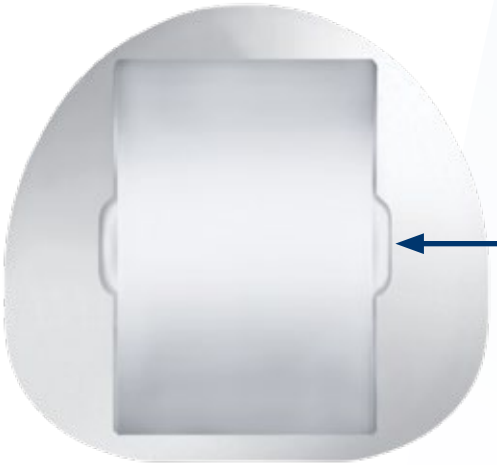
Durability

SECURE®-C is manufactured from proven materials used in total joint arthroplasty for decades.[6] Highly polished cobalt-chrome-molybdenum alloy (CoCrMo) endplates articulate with an ultrahigh molecular weight polyethylene (UHMWPE) core. The combination of these materials achieves wear rates similar to that reported for other metal-on-polyethylene cervical discs, under wear simulation studies.[7] Wear testing was performed on SECURE®-C using a combined motion profile and a constant 150N axial load. Wear rates were relatively constant, remaining below 1mm^3 per million cycle.



Core Stability

SECURE®-C's inferior endplate was designed with a special feature to secure the core and prevent core expulsion while allowing articulation with the endplates. Core stability testing was performed to evaluate the loads required to expulse the SECURE®-C core from the endplates. The results suggest that the SECURE®-C device can resist pushout forces that exceed the shear failure load of the cervical intervertebral disc (20N).[8]



Engagement feature secures core between endplates

Cylindrical Inferior Core

6. Santos EG, Polly DW, Mehbod AA, Saleh K. Disc arthroplasty: lessons learned from total joint arthroplasty. The Spine J 4:182S-189S, 2004.

7. SECURE®-C PMA P100003: SSED

8. Lemaire JP, Skali W, Lavaste F, Tamplier A, Mendes F, Dop A, Sauty V, Laloux E. Intervertebral disc prosthesis. Clin Orthop Rel Res 337:64-76, 1997.

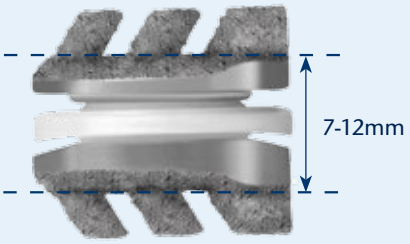
Indications for Use

The SECURE®-C Cervical Artificial Disc is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or functional or neurological deficit) with or without neck pain, or myelopathy due to a single-level abnormality localized to the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height. The SECURE®-C Cervical Artificial Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment prior to implantation of the SECURE®-C Cervical Artificial Disc.

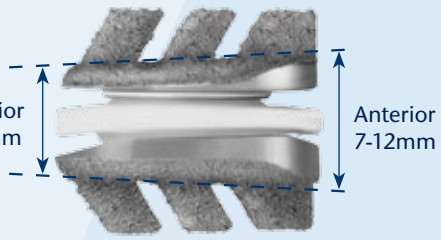
Comprehensive Implant Offering

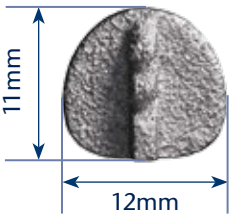
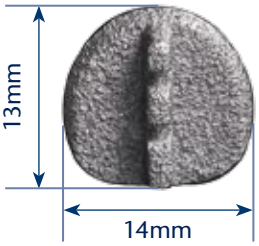
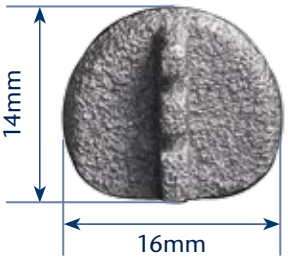
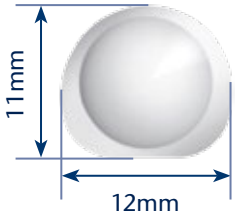
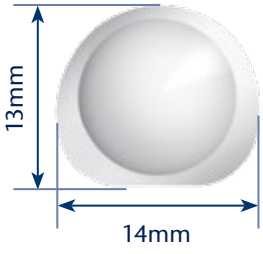
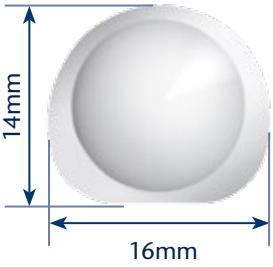
SECURE®-C is offered in two lordotic profiles and three endplate sizes to accommodate varying patient anatomy. The implants are available in heights of 7–12mm as measured from the anterior side. Posterior height for the 6° profile is 1mm less than the anterior height.

0° Profile



6° Profile



	11 x 12	13 x 14	14 x 16
ENDPLATES			
CORES			

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