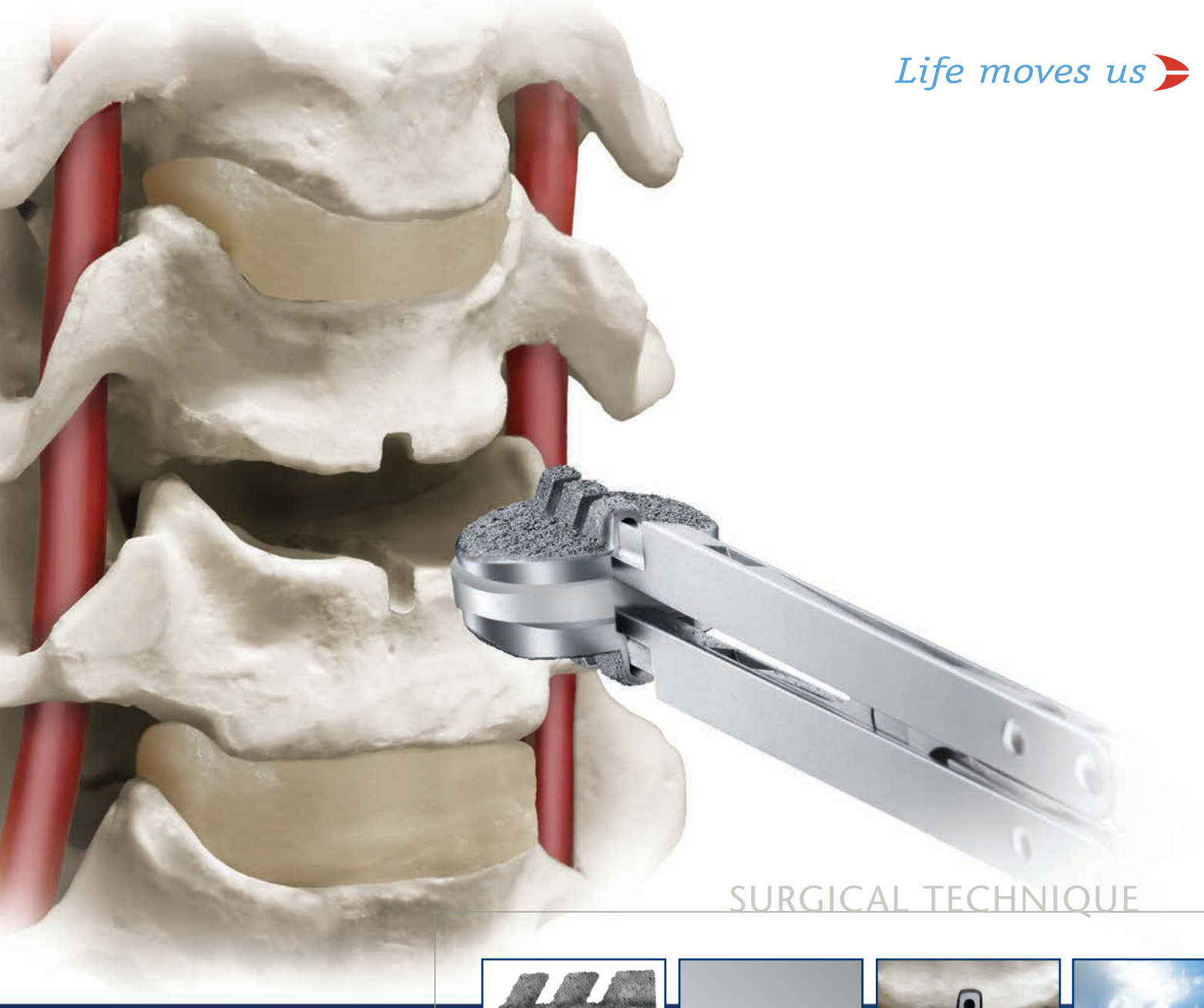
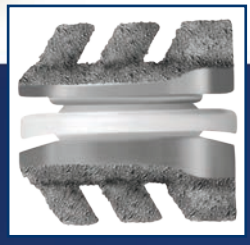
Life moves us



SURGICAL TECHNIQUE



SECURE®-C

Cervical Artificial Disc

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

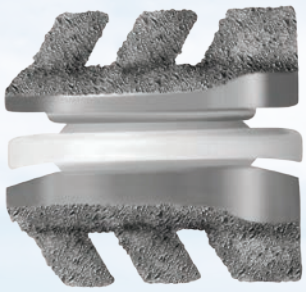
The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

SECURE®-C

Cervical Artificial Disc



The SECURE®-C Cervical Artificial Disc is a motion-sparing technology designed as an alternative to fusion. Through its selectively constrained design, SECURE®-C is designed to allow up to ±15° motion in flexion-extension and up to ±10° motion in lateral bending. The design is intended to allow unlimited axial rotation and to permit sagittal plane translation of ±1.25mm. SECURE®-C is offered in two sagittal profile options (0° and 6°) to adapt to the patient's anatomy. Specialized surgical instruments provide streamlined implant delivery in three basics steps: Trial—Chisel—Insert.

SECURE®-C Cervical Artificial Disc

Please see below for indications, contraindications, warnings and precautions. Refer to the package insert for additional information on clinical study results and other information not provided in this surgical technique.

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the order of a Physician.

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 a 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 radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. 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.

CONTRAINDICATIONS

The SECURE®-C Cervical Artificial Disc should not be implanted in patients with the following conditions:

- Active systemic infection or localized infection at the surgical site
- Osteoporosis or osteopenia defined as a DEXA bone mineral density T-score ≤ -1
- Allergy or sensitivity to cobalt, chromium, molybdenum, titanium or polyethylene
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3mm and/or >11° rotational difference from that of either adjacent level
- Severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height >50%, an absence of motion (<2°) as this may lead to a limited range of motion and may encourage bone formation (e.g. heterotopic ossification, fusion)
- Severe facet joint arthropathy
- Significant cervical anatomical deformity or 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) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis)
- Symptoms attributed to more than one vertebral level

WARNINGS

The SECURE®-C Cervical Artificial Disc should only be used by surgeons who are experienced with anterior cervical spinal procedures and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the SECURE®-C Cervical Artificial Disc should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

Correct selection of the appropriate implant size and correct placement of the device are essential to ensure optimal performance and function of the device. Please refer to the SECURE®-C Cervical Artificial Disc Surgical Technique manual for step-by-step instructions on the required surgical technique, including determining the correct implant size.

Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this device. Care should be taken to identify and protect these structures during surgery.

Heterotopic Ossification (HO) is a potential complication associated with cervical total disc replacement devices, which could result in reduced motion. It is recommended that bone wax is used following removal of osteophytes during surgery, to possibly reduce HO bone formation. The short-term postoperative use of non-steroidal anti-inflammatory drugs (NSAIDs), is recommended to possibly reduce the chance of developing HO.

PRECAUTIONS

The safety and effectiveness of this device has not been established in patients with the following conditions:

- Intractable radiculopathy or myelopathy due to pathology at more than one level and/or pathology not localized to the disc space;
- Skeletally immature patients, pediatric or adolescent children (<21 years old), or those over the age of 60;
- Prior fusion at an adjacent vertebral level;
- Prior surgery at the level to be treated;
- Progressive symptoms and signs of spinal cord/nerve root compression with less than six weeks of conservative treatment;
- Facet joint disease or degeneration at the involved level;
- Neck or arm pain of unknown etiology;
- Neck pain alone;
- Paget's disease, osteomalacia, or other metabolic bone disease;
- Rheumatoid arthritis or other autoimmune disease;
- Neuromuscular disorders such as muscular dystrophy, spinal muscular atrophy, amyotrophic lateral sclerosis;
- Severe insulin dependent diabetes;
- Systemic disease including AIDS, HIV, and Hepatitis;
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids);
- Active malignancy (including spinal metastases);
- Acute mental illness or substance abuse; and
- Pregnancy.

Pre-operative
Patient selection is extremely important. In selecting patients for a cervical total disc replacement, the following factors can be of extreme importance to the success of the procedure: the patient's occupation or activity level; a condition of senility, mental illness, alcoholism or drug abuse; and certain degenerative diseases (e.g., degenerative scoliosis or ankylosing spondylitis) that may be so advanced at the time of implantation that the expected useful life of the device is substantially decreased.

In order to minimize the risk of periprosthetic vertebral fractures, surgeons must consider all co-morbidities, past and present medications, previous treatments, etc. A screening questionnaire for osteopenia or osteoporosis, SCORE (Simple Calculated Osteoporosis Risk Estimation), may be used to screen patients to determine if a DEXA bone mineral density measurement is necessary. If DEXA is performed, the patient should be excluded from receiving the device if the DEXA bone density measured T score is < -1.0, as the patient may be osteoporotic or osteopenic.

The patient should be informed of the potential adverse effects (risks/complications) contained in this insert (see POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH).

Preoperative planning may be used to estimate the required implant size, and to assure that the appropriate range of sizes is available for surgery. The procedure should not take place if the appropriate range of sizes will not be available.

Examine all instruments prior to surgery for wear or damage. Instruments which have been used excessively may be more likely to break. Replace any worn or damaged instruments.

Intra-operative
The SECURE®-C Cervical Artificial Disc implant should not be used with components or instruments of spinal systems from other manufacturers. Refer to the SECURE®-C surgical technique manual for step-by-step instructions.

Use aseptic technique when removing the SECURE®-C Cervical Artificial Disc implants from the innermost packaging. Carefully inspect each component and its packaging for any signs of damage, including damage to the sterile barrier. Do not use SECURE®-C implants if the packaging is damaged or the implant shows signs of damage.

Use care when handling the SECURE®-C Cervical Artificial Disc implant to ensure that it does not come in contact with objects that could damage the implant. Exercise care to ensure that implantation instruments do not contact the highly polished articulating surfaces of the endplates. Damaged implants are no longer functionally reliable.

To prevent unnecessary damage to the bearing surfaces, ensure that tissue or other debris is not trapped within the device.

Surgical implants must never be re-used or re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

When preparing the disc space, remove anterior or posterior osteophytes as needed, taking care to minimize bone removal. Avoid excessive bone removal as this may weaken the vertebral endplates or vertebral body. Correct positioning of the trial is critical prior to performing chisel cuts. Care should be taken to correctly position the trial during this step. Ensure proper alignment and placement of device components as misalignment may cause excessive wear and/or early failure of the device. Bone wax should be placed into any exposed bleeding bone.

Post-operative
Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device. Patients are recommended to wear a cervical collar for a few weeks following surgery, follow a therapy program for active range of motion exercises, and to avoid lifting above the shoulders, heavy lifting, repetitive bending and prolonged or strenuous activities. The time period of these recommendations is managed by the treating physician, taking into consideration the individual patient's condition as well as the stability and functioning of the implant. A two week postoperative course of non-steroidal anti-inflammatories (NSAIDs) is recommended to potentially reduce the incidence of heterotopic ossification (HO).

MRI Safety Information


Non-clinical testing has demonstrated that the SECURE®-C implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5Tesla or 3Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SECURE®-C implant is expected to produce a maximum temperature rise of 1.4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the device when imaged with a gradient echo pulse sequence and a 3Tesla MRI system.

SECURE®-C
CERVICAL ARTIFICIAL DISC

Motion Preservation

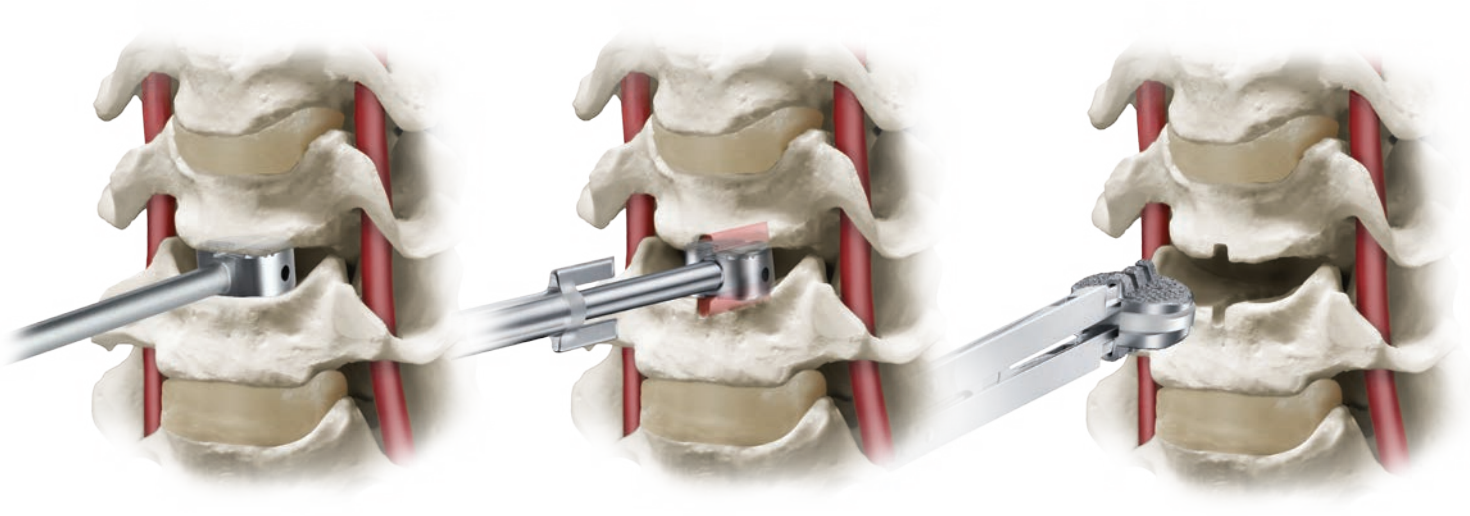
SECURE®-C is designed to allow motion through its selectively contrained design, which provides articulation and sagittal plane translation. Clinical trial patients randomized and treated with SECURE®-C demonstrated an average flexion-extension range of motion of 9.3° and sagittal translation of 1.2mm at 24 months.[1]

Optimal Fit

SECURE®-C is available in two sagittal profiles (0° and 6°) and a range of footprints and heights to fit the disc space and curvature of the cervical spine. Clinical trial patients randomized and treated with SECURE®-C showed an average disc height of 5.7mm at 24 months, compared to 3.8mm preoperatively.[1]

Streamlined Technique

Specialized instrumentation allows device placement in three basic steps: Trial—Chisel—Insert.



Trial Chisel Insert

1. Refer to package insert for clinical study results

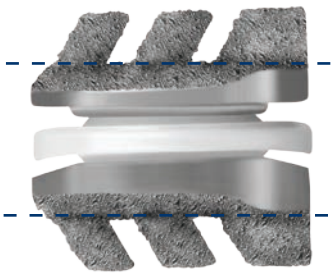
CONTENTS

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

IMPLANT OVERVIEW

SECURE®-C Cervical Artificial Disc

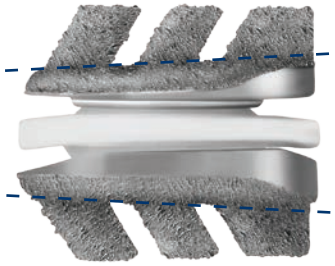
- Designed to allow:
  - Flexion/extension up to ±15°
  - Lateral bending up to ±10°
  - Unconstrained axial rotation
  - Anterior-posterior translation ±1.25mm
- Designed to maintain or restore disc height



0° Profile

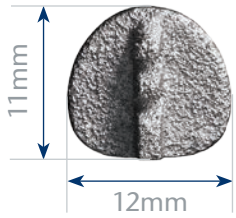
SECURE®-C Endplates

- Four footprint sizes (11x12mm, 13x14mm, 14x16mm and 15x18mm)
- Two sagittal profiles (0° & 6°)
- Cobalt chromium molybdenum (CoCrMo) with titanium plasma spray coating
- Spherical and cylindrical articulations designed to allow translation
- Initial fixation from multiple serrated keels
- Engagement feature on inferior surface of core secures the core between the endplates

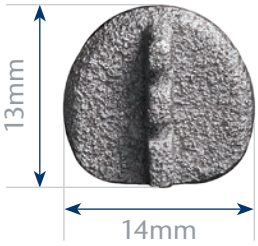


6° Profile

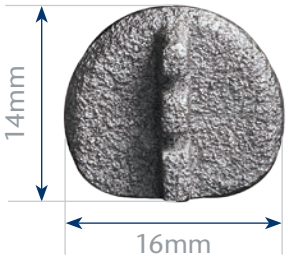
11x12



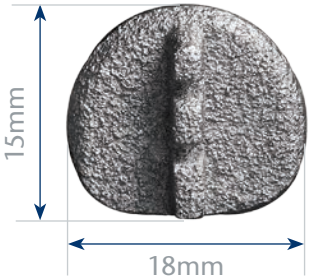
13x14



14x16



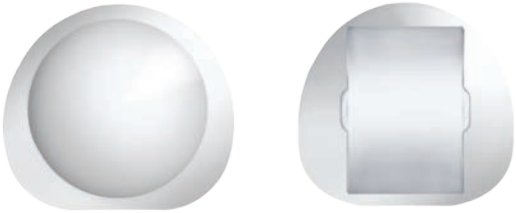
15x18



SECURE®-C Cores

- Spherical and cylindrical articulation with endplates
- Heights of 6–12mm in 1mm increments
- Ultra–high molecular weight polyethylene (UHMWPE)

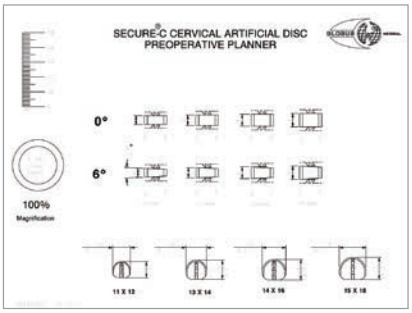
Posterior



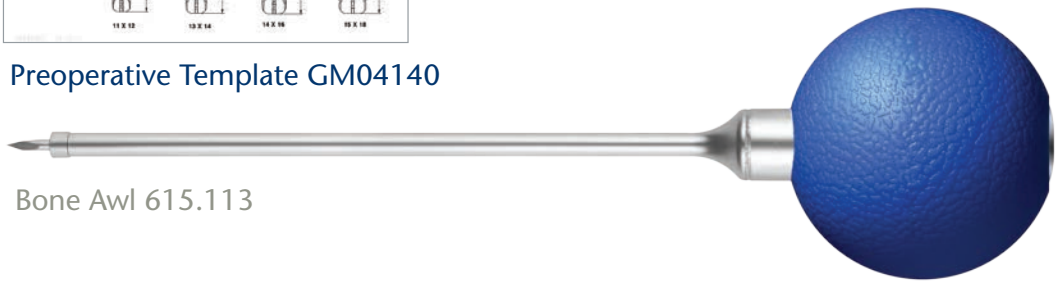
Anterior

INSTRUMENT OVERVIEW

Preparation Instruments



Preoperative Template GM04140



Bone Awl 615.113

Pin Driver 665.608

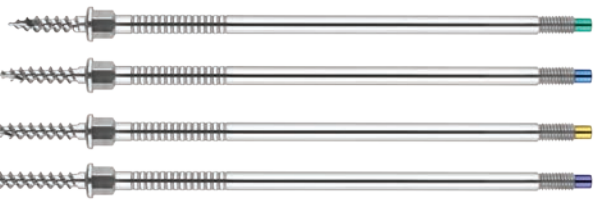
Distraction Pins

12mm 665.612

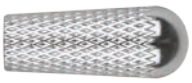
14mm 665.614

16mm 665.616

18mm 665.618



Distractor, Right 601.021



Locking Nut 665.606

Distractor, Left 601.020

*Items highlighted in gray are additionally available.

Preparation Instruments (cont'd)

Box Curette 601.026

Rake 614.001

T-Handle 614.006

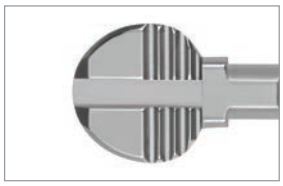
Cervical Scrapers *Attach to T-Handle 614.006*

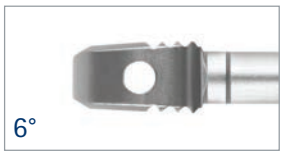
Height	Angle	Part Number
7mm	0°	614.007
8mm	0°	614.008
9mm	0°	614.009
10mm	0°	614.010
11mm	0°	614.011
12mm	0°	614.012

7mm	6°	614.607
8mm	6°	614.608
9mm	6°	614.609
10mm	6°	614.610
11mm	6°	614.611
12mm	6°	614.612

*Items highlighted in gray are additionally available.

Trials, 11x12 *Attach to T-Handle 614.006*

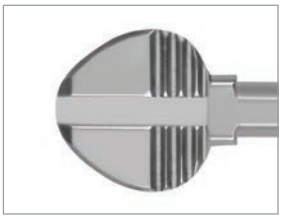


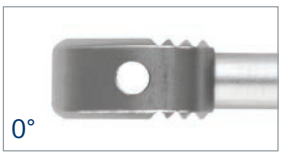


Height	Angle	Part Number
6mm	0°	614.206
7mm	0°	614.207
8mm	0°	614.208
9mm	0°	614.209
10mm	0°	614.210
11mm	0°	614.211
12mm	0°	614.212

6mm	6°	614.306
7mm	6°	614.307
8mm	6°	614.308
9mm	6°	614.309
10mm	6°	614.310
11mm	6°	614.311
12mm	6°	614.312

Trials, 13x14 *Attach to T-Handle 614.006*



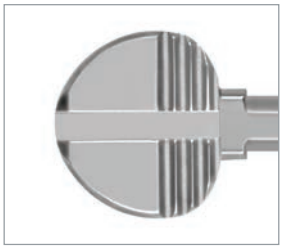


Height	Angle	Part Number
6mm	0°	614.406
7mm	0°	614.407
8mm	0°	614.408
9mm	0°	614.409
10mm	0°	614.410
11mm	0°	614.411
12mm	0°	614.412

6mm	6°	614.506
7mm	6°	614.507
8mm	6°	614.508
9mm	6°	614.509
10mm	6°	614.510
11mm	6°	614.511
12mm	6°	614.512

*Items highlighted in gray are additionally available.

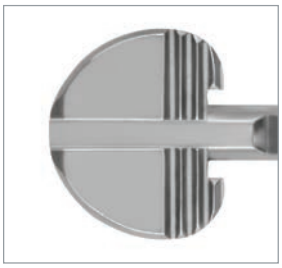
Trials, 14x16 *Attach to T-Handle 614.006*



Height	Angle	Part Number
6mm	0°	614.106
7mm	0°	614.107
8mm	0°	614.108
9mm	0°	614.109
10mm	0°	614.110
11mm	0°	614.111
12mm	0°	614.112

6mm	6°	614.913
7mm	6°	614.907
8mm	6°	614.908
9mm	6°	614.909
10mm	6°	614.910
11mm	6°	614.911
12mm	6°	614.912

Trials, 15x18 *Attach to T-Handle 614.006*



Height	Angle	Part Number
6mm	0°	614.126
7mm	0°	614.127
8mm	0°	614.128
9mm	0°	614.129
10mm	0°	614.130
11mm	0°	614.131
12mm	0°	614.132

6mm	6°	614.926
7mm	6°	614.927
8mm	6°	614.928
9mm	6°	614.929
10mm	6°	614.930
11mm	6°	614.931
12mm	6°	614.932

*Items highlighted in gray are additionally available.

SECURE®-C Chisels

Broaching Chisel

Keel Chisel

Keel Chisel, Narrow

	Broaching Chisel	Keel Chisel	Keel Chisel, Narrow
Height	Part Number	Part Number	Part Number
6mm	614.756	614.826	614.726
7mm	614.757	614.827	614.727
8mm	614.758	614.828	614.728
9mm	614.759	614.829	614.729
10mm	614.760	614.830	614.730
11mm	614.761	614.831	614.731
12mm	614.762	614.832	614.732

Chisel End Cap 614.800

Adjustable Trial and Chisel Stops

Adjustable Trial Stop 614.024

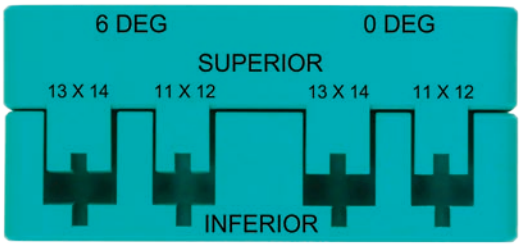
Adjustable Chisel Stop 614.025

*Items highlighted in gray are additionally available.

Bone Preparation Instrument

Nerve Hook 614.020

Implant Assembly



Implant Loading Block 614.916

Hammers

Hammer 603.008

Slide Hammer 614.802

*Items highlighted in gray are additionally available.

Milling Guide

Stabilizer Pin 614.862

Milling Guide	
Height	Part Number
6/7mm	614.850
8/9mm	614.852
10mm	614.853
11mm	614.854
12mm	614.855

Mill Guide Handle 622.005

Mill, Quick Connection 614.861

Mill, 5 Notch 614.863
Mill, Hex 614.864
Mill, Tri-Flat 614.865

Mill, Round 614.866
Mill, Flat 614.867
Mill, Star 614.868

Mill, Step 614.869
Mill, Quad-Flat 614.870
Mill, MRL 614.871

Mill, 5 Notch, D2 614.891
Mill, Flat, D2 614.892

Mill, Star, D2 614.893
Mill, Step, D2 614.894

Mill, Quad-Flat, D2 614.895
Mill, MRL, D2 614.896

Insertion Instruments

Narrow Implant Holder 614.805

Implant Holder 614.906

Single Endplate Positioner 614.019

Double Endplate Positioner 614.017

SECURE®-C SURGICAL TECHNIQUE

Step 1 Preoperative Planning and Positioning

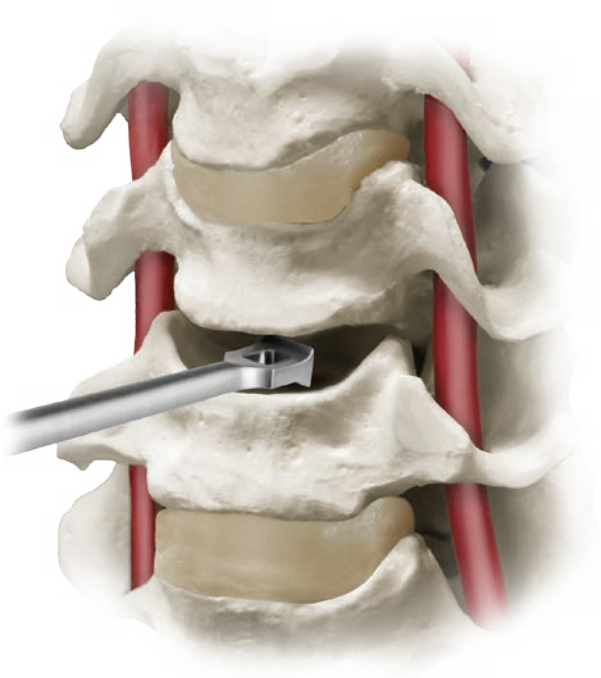
Prior to surgery, the approximate footprint, profile, and height of the SECURE®-C Cervical Artificial Disc can be determined using **Preoperative Templates**. These templates show all implant combinations in a variety of magnifications for use with radiographs and MRI scans.

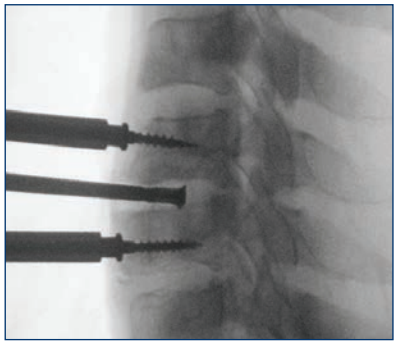
The patient is placed under anesthesia and positioned supine in the neutral position. A neck roll may be used under the patient's neck to maintain support and neutral position of the vertebral endplates. The operative area is carefully cleaned, and an incision is made at the appropriate level(s).

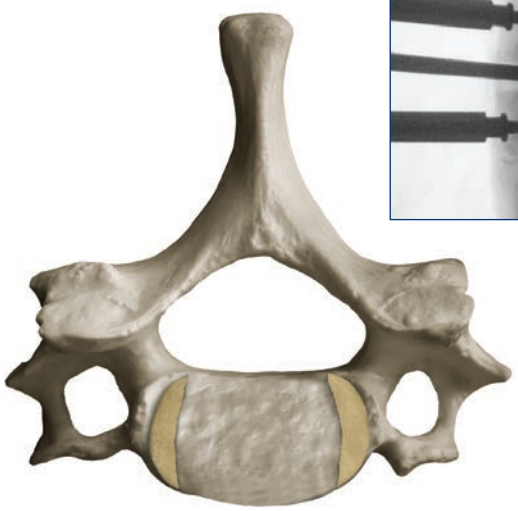
Note: Intraoperative fluoroscopy is necessary during the surgical technique to confirm trial and implant placement. Visualization of the index level on lateral fluoroscopy is required.

Step 2 Disc Preparation

An anterior cervical approach is used. A discectomy is performed using standard disc preparation instruments, leaving the lateral annular rim intact. The **Box Curette** and **Rake** can be utilized to remove disc material and the cartilaginous endplates for receiving the implants. The posterior longitudinal ligament may need to be released to remobilize the segment. Perform any necessary decompression of the nerve roots and spinal cord, including foraminal decompression. Remove posterior osteophytes as needed, taking care to minimize bone removal. Avoid excessive bone removal as this may weaken the vertebral endplates or vertebral body.







Axial view of disc with lateral annular rim intact

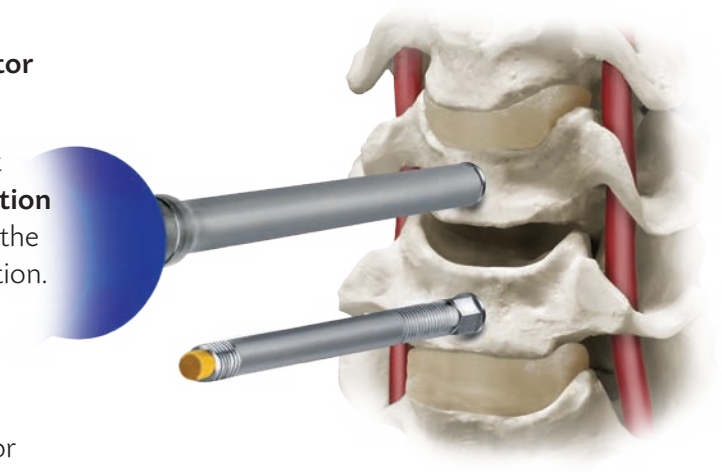
Screwdriver for
Pins 665.608

Step 3 Distraction

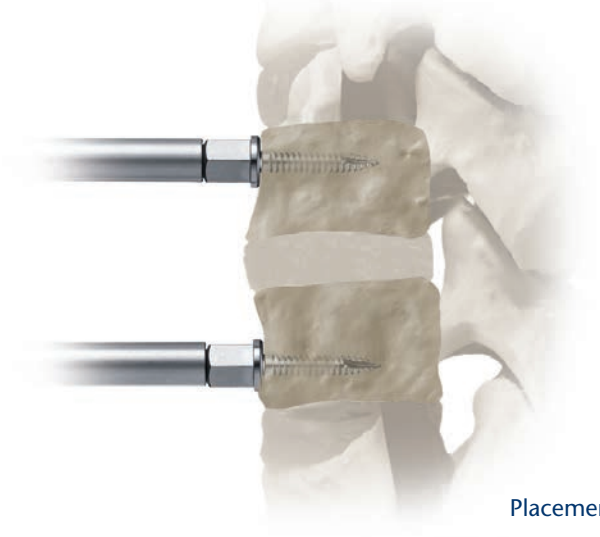
Distraction may be accomplished using the **Distractor** available in this system or other standard methods.

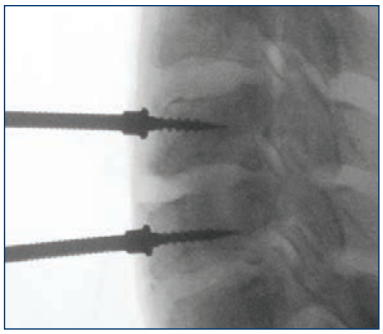
To use the Distractor, first determine pin placement within the vertebral bodies. Ensure that the **Distraction Pins** are inserted into the vertebral body parallel to the endplates, leaving adequate room for bone preparation. Place the pins into adjacent vertebra using the **Pin Driver**.

Place the Distractor (Right or Left, depending on preference) over the pins until seated. The Distractor may be secured to the Distractor Pins with the **Locking Nut**. Turn the ratchet handle to distract to the desired level, being careful not to over-distract the segment.

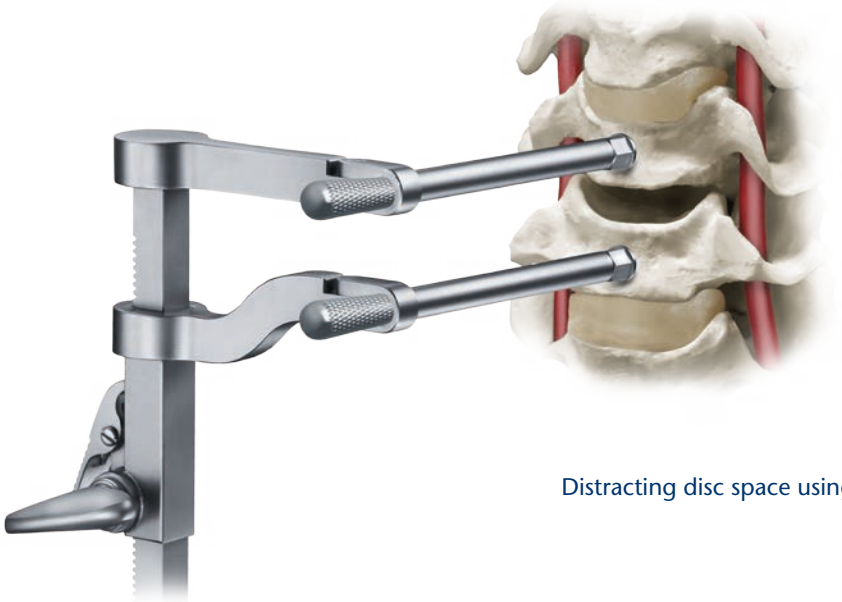


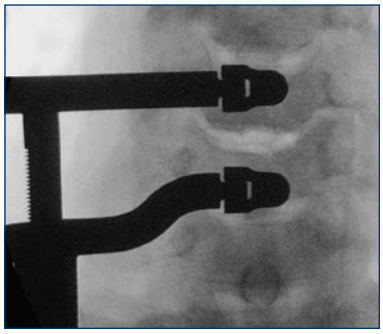
Insertion of Distraction Pins





Placement of Distraction Pins





Distracting disc space using Distractor

Step 4 Trialing

The **Trial** is used to determine the correct footprint, profile, and height of the SECURE®-C implant for the disc space. Begin by selecting the 6mm Trial corresponding to the footprint and profile approximated during preoperative planning. Attach the Trial to the **T-Handle**. Insert the Trial into the disc space by gently tapping the T-Handle with the **Hammer** until it reaches the desired location.

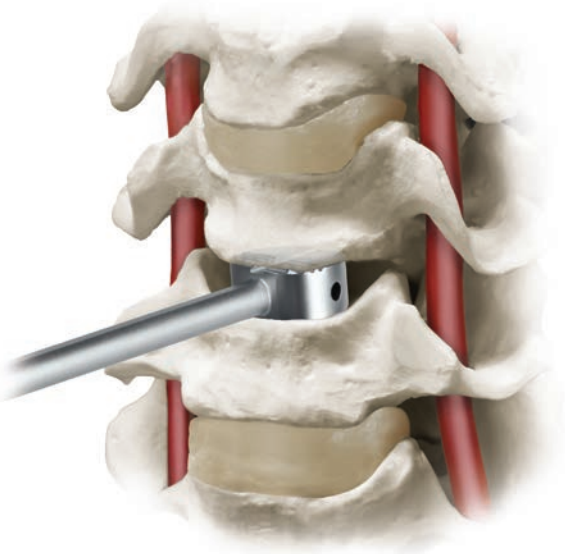
The center of the Trial should be positioned along the vertebral midline in the coronal plane, as determined by AP fluoroscopy. Reference the uncinate process to confirm midline in the coronal plane. In the lateral view, position the center hole of the Trial 1-2mm posterior to the sagittal vertebral midline.

Once the Trial is in proper position, assess the footprint and profile of the Trial. Choose the largest footprint to maximize surface contact with the vertebral endplates.

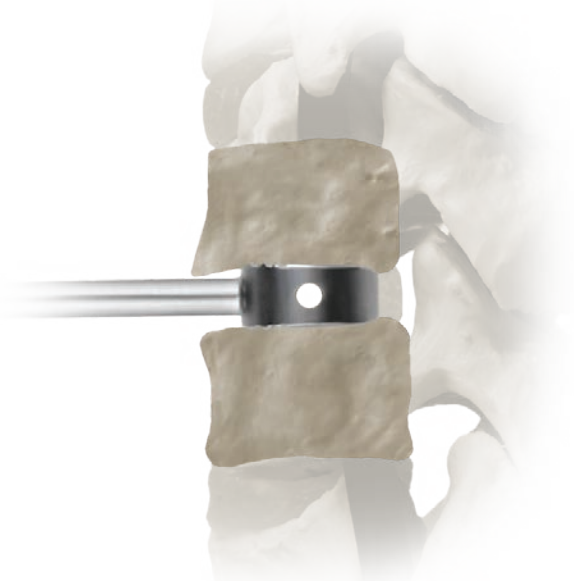
Determine the appropriate 0° or 6° profile.

Once the footprint and profile are determined, the correct height is chosen by sequentially using Trials of increasing heights until the appropriate fit is achieved and confirmed by radiographic evaluation. Release any distraction to allow as much contact as possible between the Trial and the vertebral endplates prior to confirming the correct size. If the Trial is loose in the disc space, choose a Trial height that fits with minimum resistance. Avoid over-distraction by choosing the correct Trial height. The T-Handle may be removed to asses Trial position.

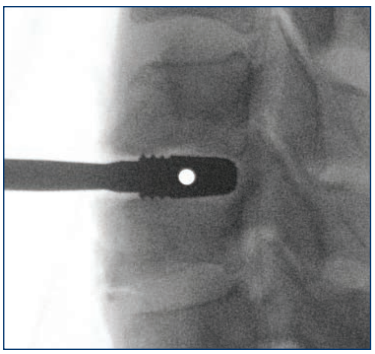
Note: Correct positioning of the Trial is critical prior to performing chisel cuts. Care should be taken to correctly position the Trial during this step.



Insertion of Trial into disc space



Lateral View of Trial in disc space



Radiographic image of Trial inserted

Trialing (cont'd)

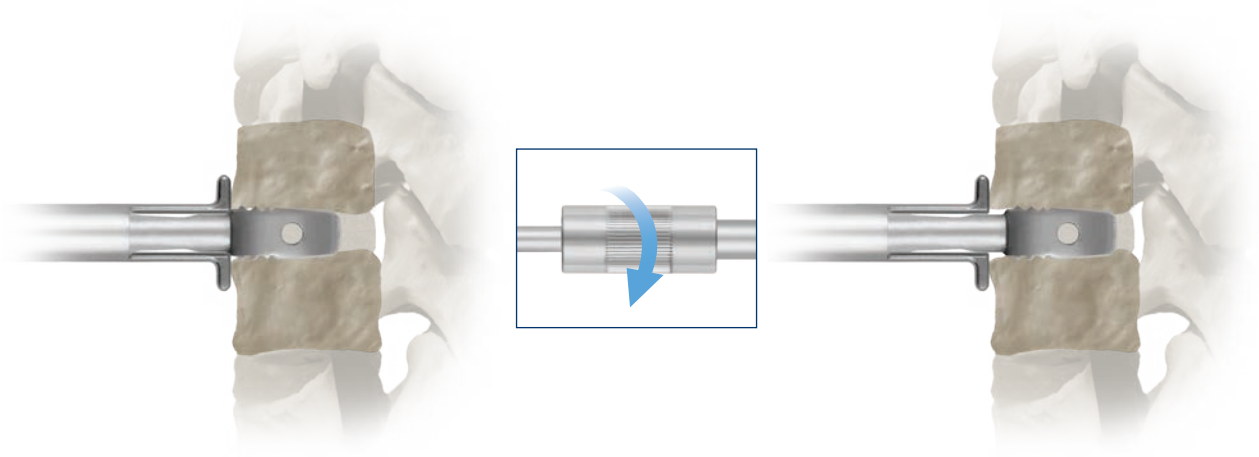
An optional **Adjustable Trial Stop** may be used during trialing. Slide the Adjustable Trial Stop over the Trial.

Adjustable Trial Stop over the Trial

Move the knurled end of the Adjustable Trial Stop forward by rotating clockwise until the T-Handle can be attached to the Trial. Ensure the Adjustable Trial Stop is fully seated between the T-Handle and Trial by moving the knurled end backward (rotate counterclockwise).

T-Handle connected to the Trial with the Adjustable Trial Stop placed over the Trial

Insert the Trial into the disc space by gently tapping the T-Handle with the Hammer. Under lateral fluoroscopy, check the position of the Trial. The center hole of the Trial should be 1–2mm posterior to the sagittal vertebral midline. Adjust the Adjustable Trial Stop forward by rotating the knurled end clockwise such that the Trial is in proper position. One full rotation equals 1mm. Confirm positioning under lateral fluoroscopy.



Positioning of the Trial can be adjusted by rotating the knurled end of the stop

Once proper position is achieved, remove the T-Handle and the Adjustable Trial Stop.

Step 5 Bone Preparation

Once the implant size (11x12mm, 13x14mm, 14x16mm or 15x18mm), profile (0° or 6°) and height requirements (6–12mm) have been determined, the bone must be prepared to receive the implant.

Confirm satisfactory position of the Trial before chiseling (midline on AP, 1-2mm posterior to midline on lateral). To create the initial cut, select either the **Broaching Chisel** or **Keel Chisel** matching the Trial height.

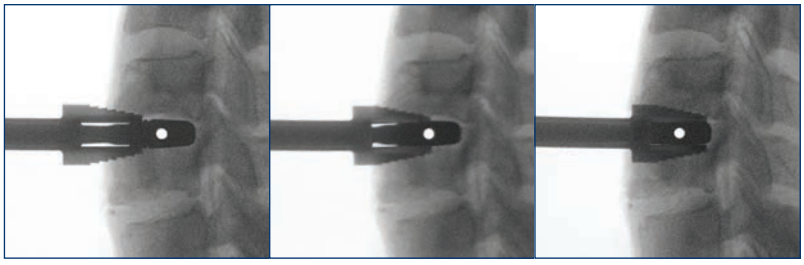
Slide the Chisel over the Trial. Attach the **Chisel End Cap** to the back of the Chisel and gently tap the Chisel End Cap with the Hammer. If the vertebral cortex is particularly hard or sclerotic and the Chisel does not readily cut into bone, a **Mill** may be used to perforate the cortex (see p.16). Always ensure that the Trial position remains the same during and between chiseling or milling steps.

Impact the Chisel until it is fully seated into the vertebral body. The Chisel is fully seated when the proximal end of the Trial shaft is flush with the impaction surface of the Chisel End Cap.

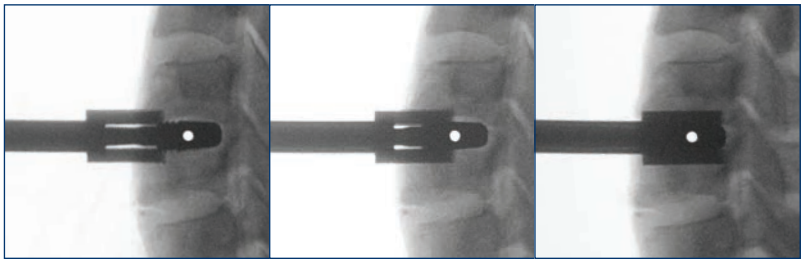
The Chisel can be removed using the **Slide Hammer.** Repeat with the proper size Keel Chisel and remove the Trial. Clear the chisel cuts with the **Nerve Hook** to ensure that all bony material is removed.

Note: Fluoroscopy should be taken at each step to ensure proper trajectory.

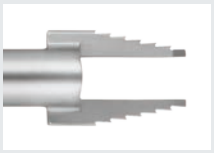
Broaching Chisel



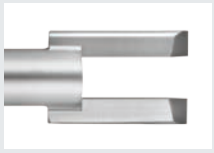
Keel Chisel



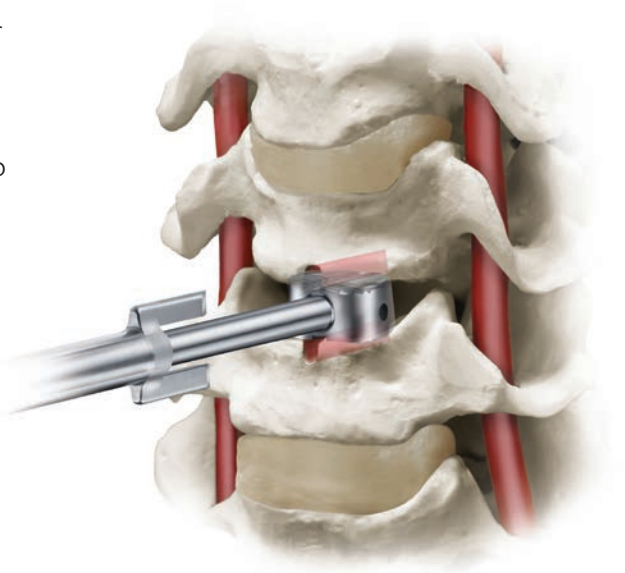
Chisel Selection



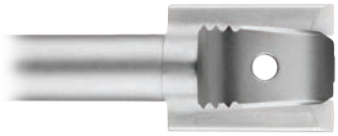
Broaching Chisel
Removes cortical bone and creates initial cut



Keel Chisel
Creates final cut



Chiseling slots for receiving multiple serrated keels



Trial with chisel fully seated, for 13x14, 14x16 and 15x18 Trials

Trial with chisel seated, for 11x12 Trials

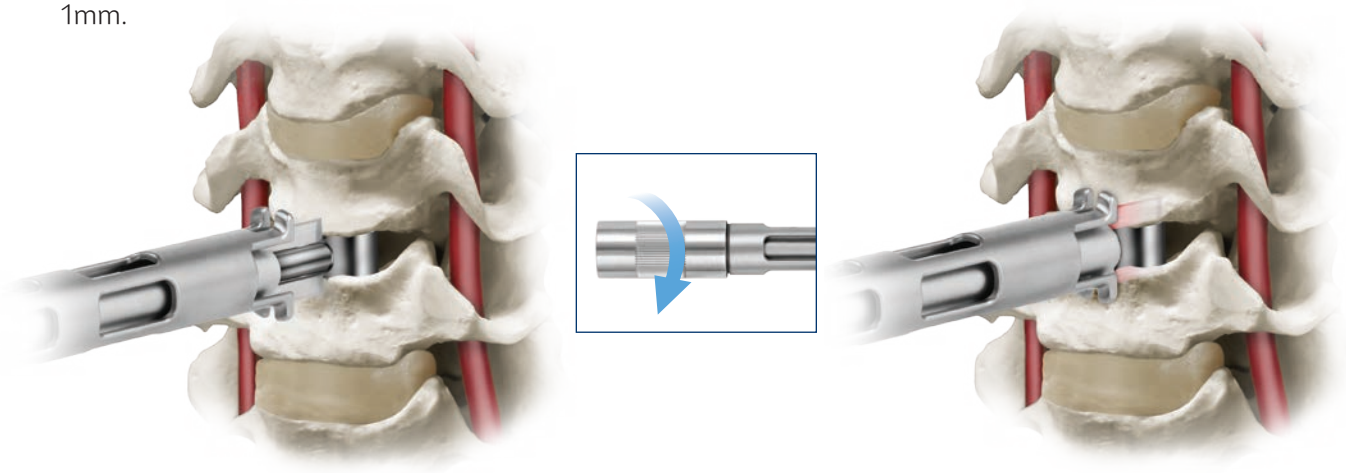
When Chisel End Cap reaches proximal end of the Trial, chisel is fully seated on Trial

Bone Preparation (cont'd)

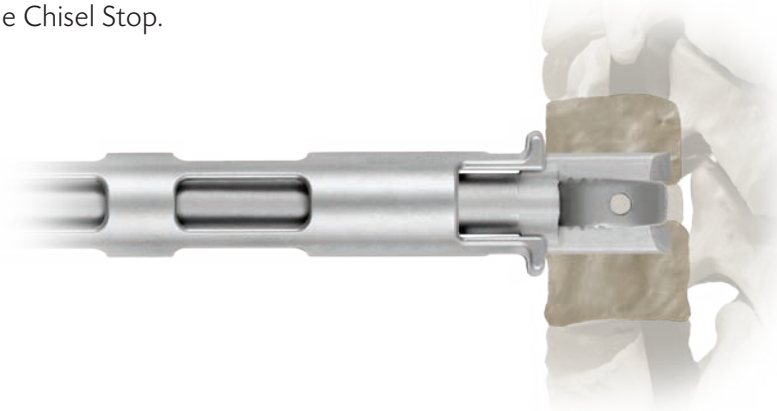
An optional **Adjustable Chisel Stop** may be used during chiseling. Slide the selected Broaching Chisel or Keel Chisel (cooresponding to the Trial height) over the Trial. Move the knurled end of the Adjustable Chisel Stop fully backward by rotating counterclockwise. Slide the stop over the Trial. Gently tap with the Hammer.

Adjustable Chisel Stop over the Keel Chisel and the Trial

Impact the knurled end of the Adjustable Chisel Stop until it bottoms out on the vertebral body. Advance the Chisel over the Trial by moving the knurled end of the Adjustable Chisel Stop forward (rotate clockwise) and gently tapping with the Hammer. One full rotation of the knurled end is equal to 1mm.



The Chisel is fully seated when the proximal end of the Trial shaft is flush with the impaction surface of the Adjustable Chisel Stop.



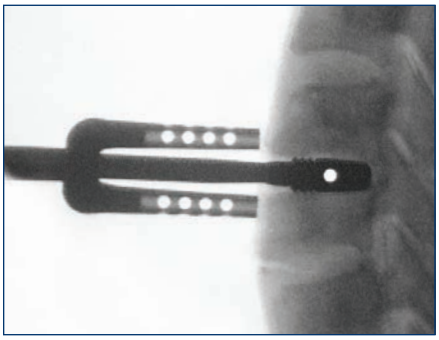
Adjustable Chisel Stop and Trial position with the Keel Chisel fully seated

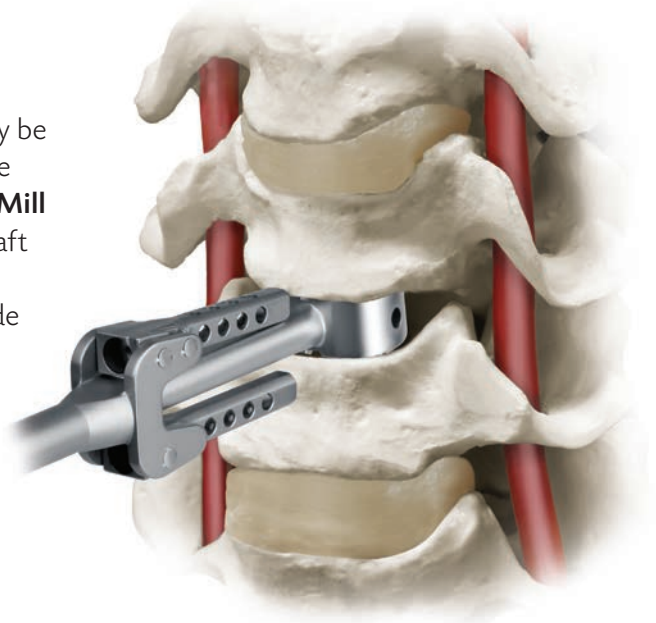
Remove the Adjustable Chisel Stop. The Chisel can be removed using the Slide Hammer. Repeat with the cooresponding size Keel Chisel. Remove the Adjustable Chisel Stop, Chisel and Trial.

Note: Fluoroscopy should be taken at each step to ensure proper trajectory.

Bone Preparation (Optional)

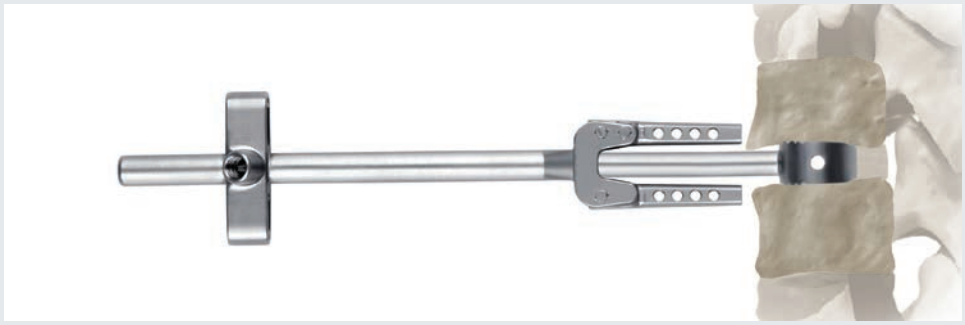
In the event of hard or sclerotic cortical bone, a Mill may be used to prepare for the chisel cut. Select the appropriate **Milling Guide** to match the Trial height and attach the **Mill Guide Handle.** Slide the Milling Guide over the Trial shaft until the proximal end of the Trial shaft is flush with the back of the mill. Rotate the knurled end of the Mill Guide Handle clockwise to tighten.



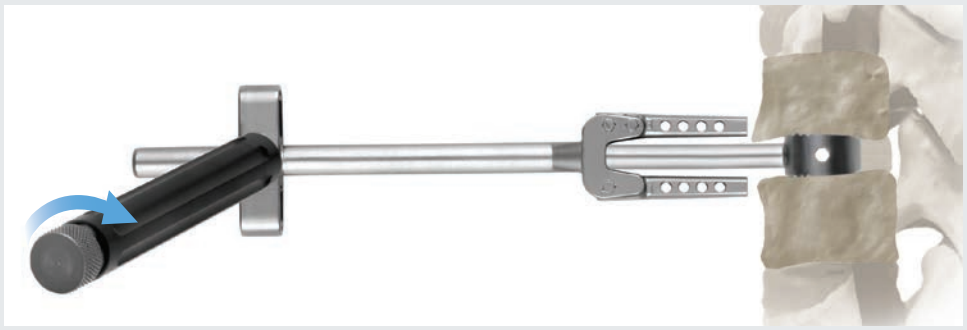


Milling Guide sliding over the Trial

Milling Guide Assembly



Slide Milling Guide over Trial

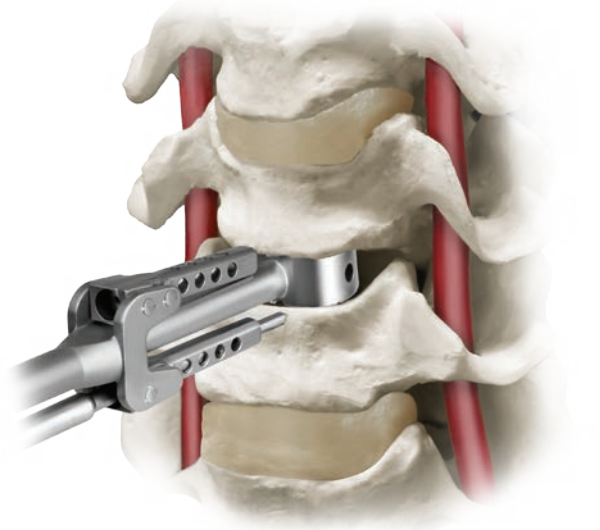


Attach the Mill Guide Handle to the Milling Guide by rotating the knurled end clockwise.

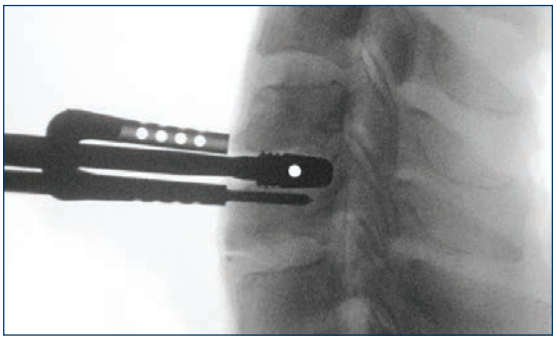
Bone Preparation (Optional) (cont'd)

Insert the **Stabilizer Pin** into the inferior or superior slot of the Milling Guide and gently tap into the vertebral body. The Mill can be driven by a variety of rotary surgical power tools. Select the appropriate Mill bit and assemble to the power tool. The power tool speed must be set between 30,000 and 60,000 r.p.m. Introduce the bit into the Milling Guide until it touches the anterior cortex. Under live fluoroscopy and full power, gently advance the Mill into the vertebral body until it reaches the Mill stop. Gently sweep the Mill until it is parallel to the Milling Guide to complete the preparation. Repeat this procedure for the opposite vertebral body. Rotate the knurled end of the Mill Guide Handle counter clockwise to loosen and remove the Mill and Milling Guide, while leaving the Trial in the disc space.

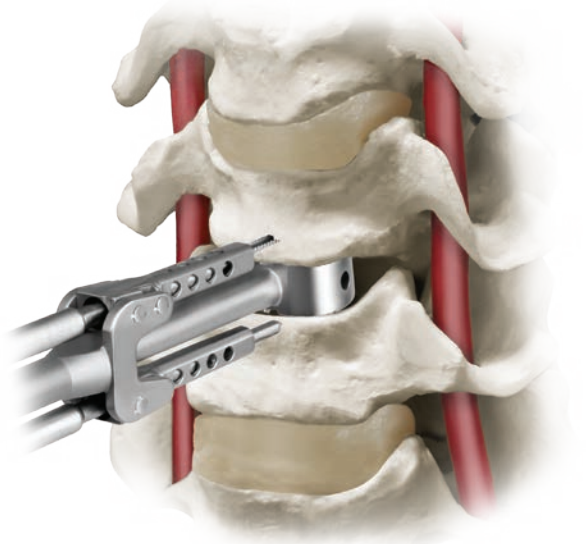
Return to chiseling to complete bone preparation. Always ensure that the Trial position remains the same during and between chiseling or milling steps.



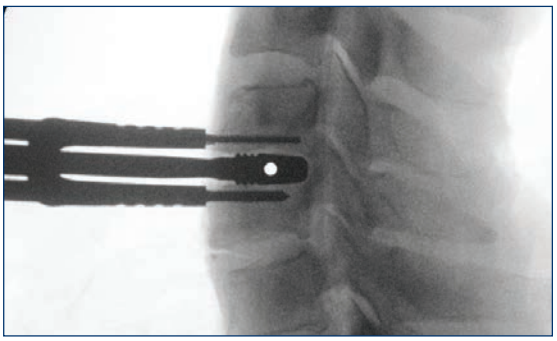
Stabilizer Pin inserted into the Milling Guide



Lateral fluoroscopy image of
Stabilizer Pin in the vertebral body



Mill Bit inserted into the Milling Guide



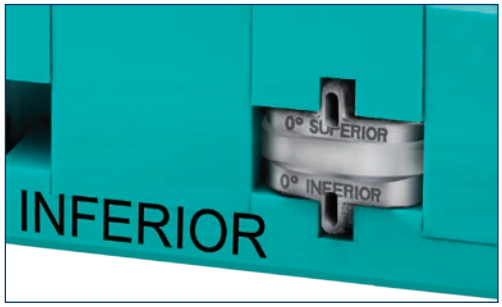
Lateral fluoroscopy image of Stabilizer Pin
and Mill in the vertebral body

Step 6 Implant Assembly

Narrow Implant Holder 614.906

Select the appropriate size SECURE®-C endplates and core, and open the sterile packaging.

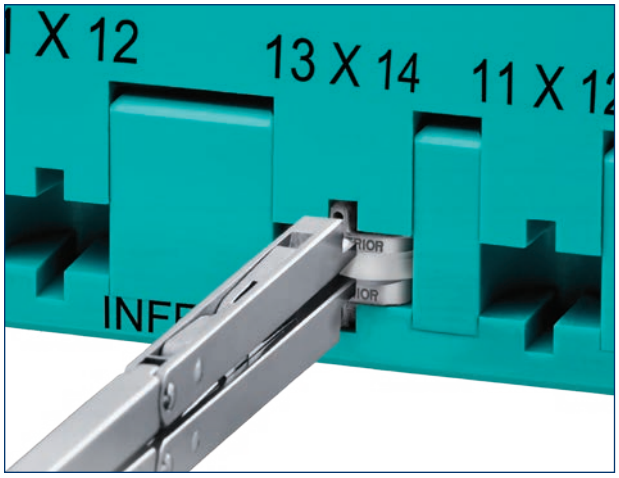
Implant Selection		
6mm Height (0°, 6°)	**7–12mm Heights (0°, 6°)**	
Endplates and Cores	**Endplates**	**Core**
11x12mm	11x12mm	11x12mm
13x14mm	13x14mm	13x14mm
14x16mm	14x16mm	14x16mm
15x18mm	15x18mm	
Cores and Endplates packaged together	*Cores and Endplates packaged separately*	



Implant Loading Block with implant correctly loaded

Insert the two endplates and the single core into the appropriate slot in the **Implant Loading Block** as shown at left. Ensure correct placement of mating surfaces. The endplate marked 'INFERIOR' is placed into the slot marked 'INFERIOR'.

Attach the **Implant Holder** or **Narrow Implant Holder** to the implant and rotate the locking nut to secure the Implant Holder in position. Ensure that the implant is inserted in a neutral position, with both endplates parallel. Do not over-tighten the Implant Holder, or the implant may not be inserted in a neutral position.

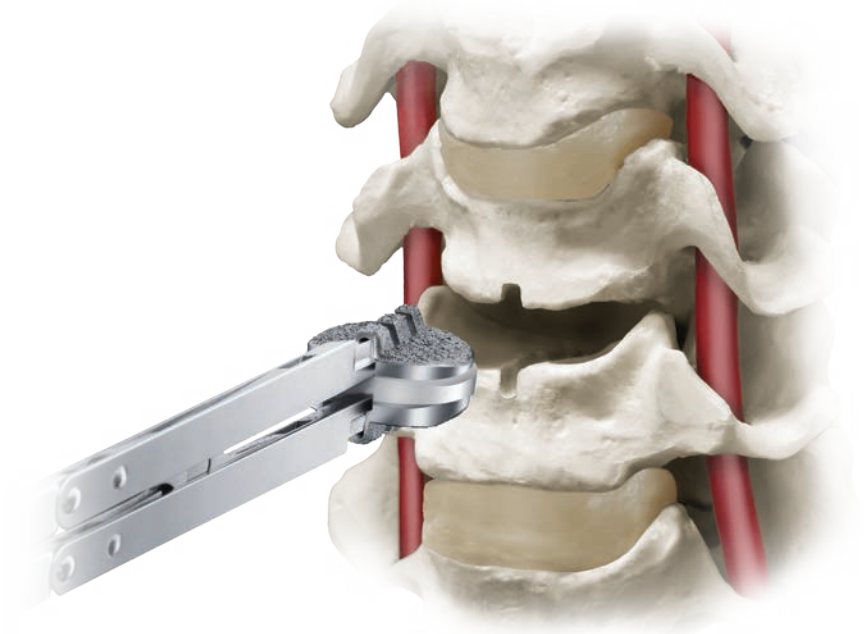


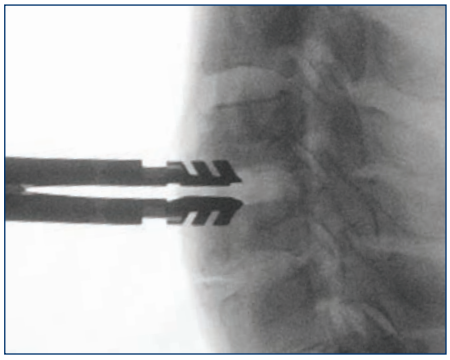
Attaching the Implant Holder

Implant loaded onto Holder in neutral position

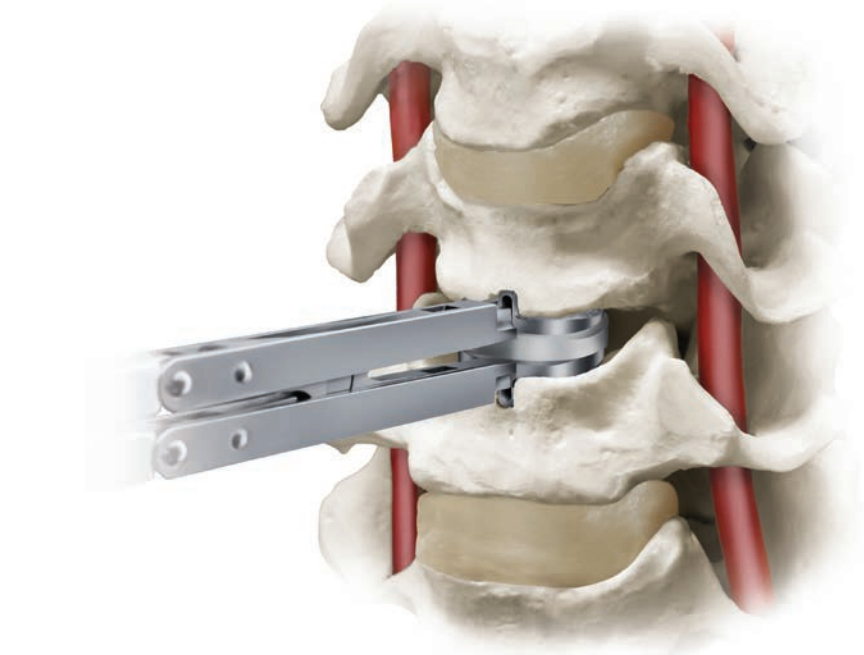
Step 7 Insertion

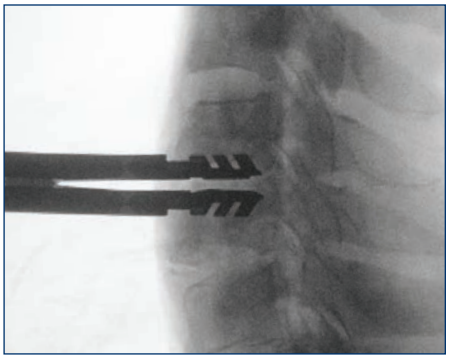
Confirm orientation of the SECURE®-C implant. The endplate marked 'SUPERIOR' is oriented toward the cephalad vertebra. The SECURE®-C implant assembly is inserted into the chisel cuts, as shown below, and gently impacted using the Hammer. Distraction may be used initially to open the space and ease insertion. Release distraction once the implant is partially inserted. The center of the implant should be positioned along the vertebral midline in the coronal plane. In the lateral view, the center of the implant should be 1-2mm posterior to the sagittal vertebral midline.





Insertion of implant into disc space





Implant inserted

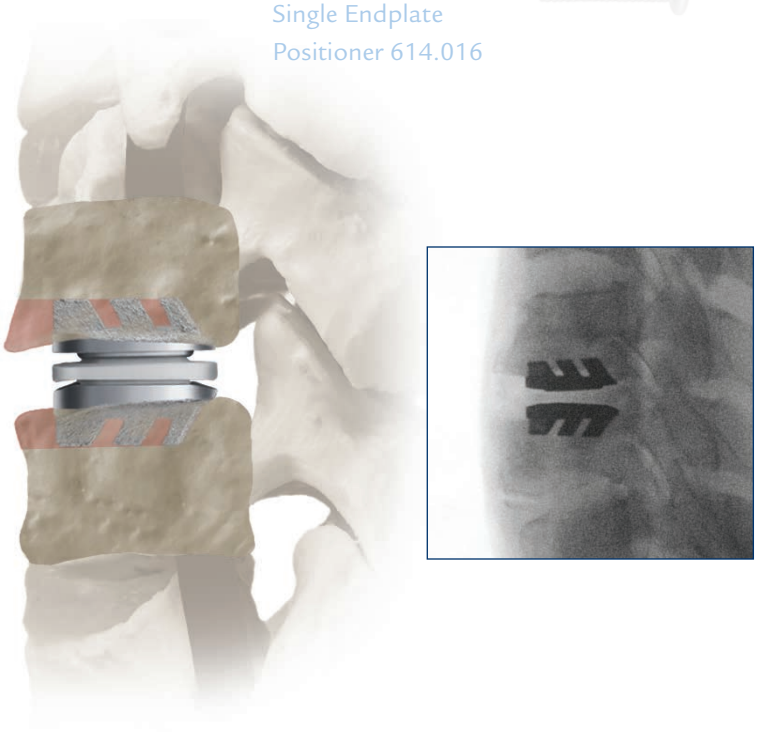
Single Endplate
Positioner 614.016

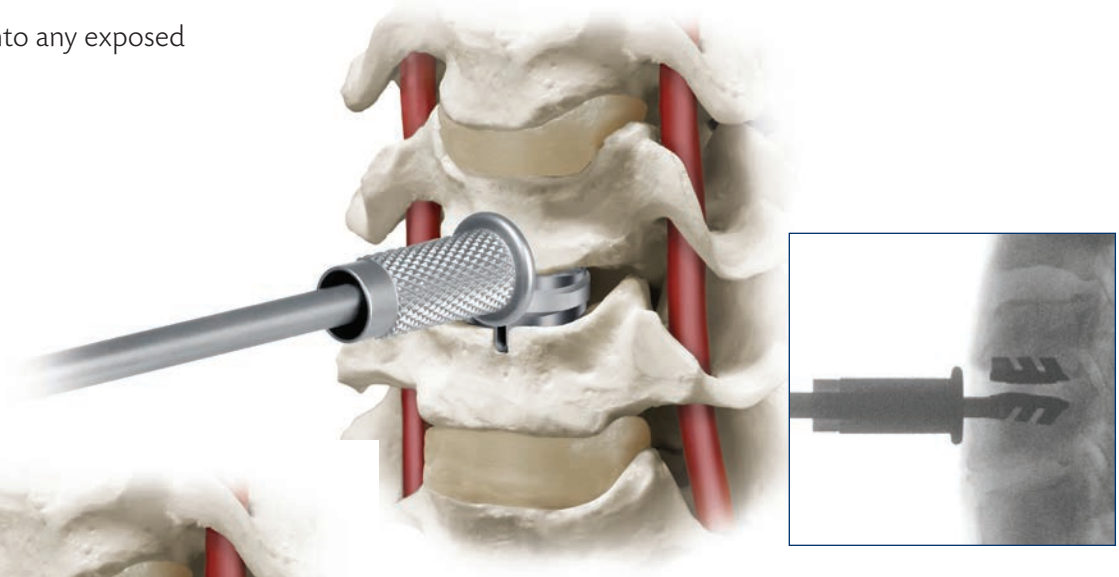
To remove the Implant Holder or Narrow Implant Holder from the implant, fully loosen the locking nut to release the handle. If necessary, grip the Implant Holder with two fingers and gently rock the holder slightly in the cephalad/caudal direction. The distal tips of the Implant Holder will release from the implant. The Implant Holder is removed and the SECURE®-C assembly is now in position.

Note: Do not rock the Implant Holder or Narrow Implant Holder in the medial/lateral direction as the tips may bend or break.

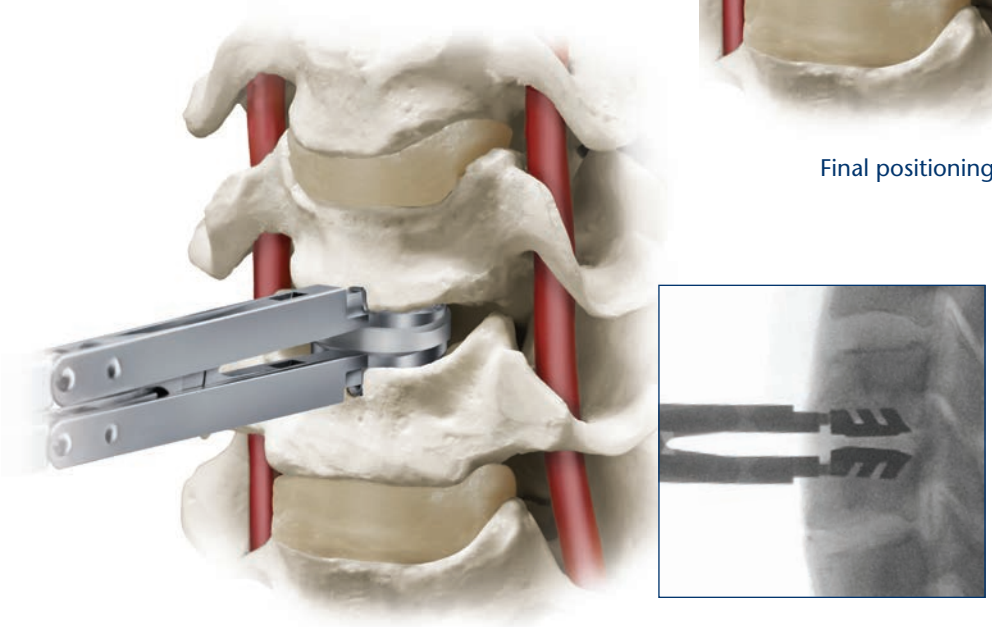
If further implant positioning is needed, the **Single Endplate Positioner** or **Double Endplate Positioner** may be used to gently tap the implant into final position.

Place bone wax onto any exposed bleeding bone.



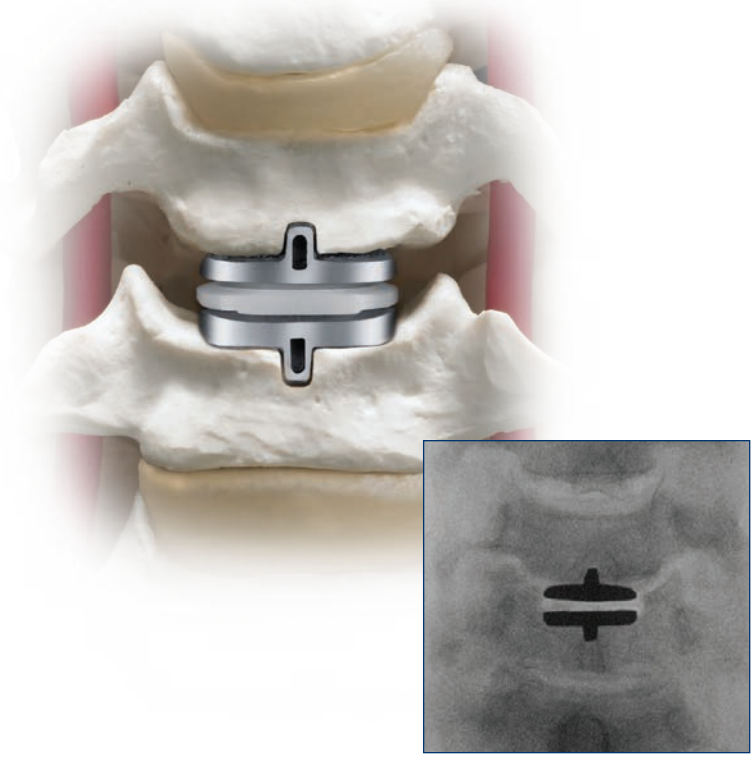


Final positioning using Single Endplate Positioner

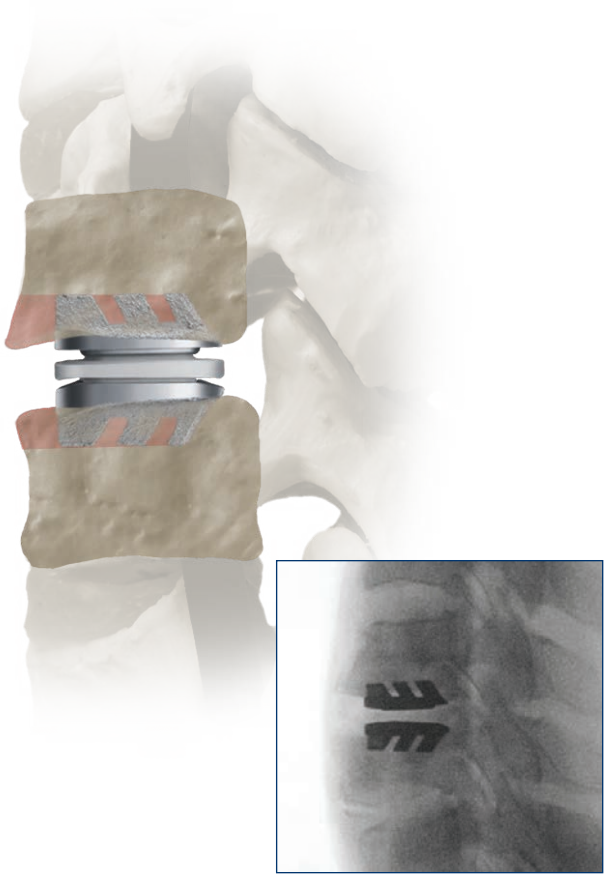


Final positioning using Double Endplate Positioner

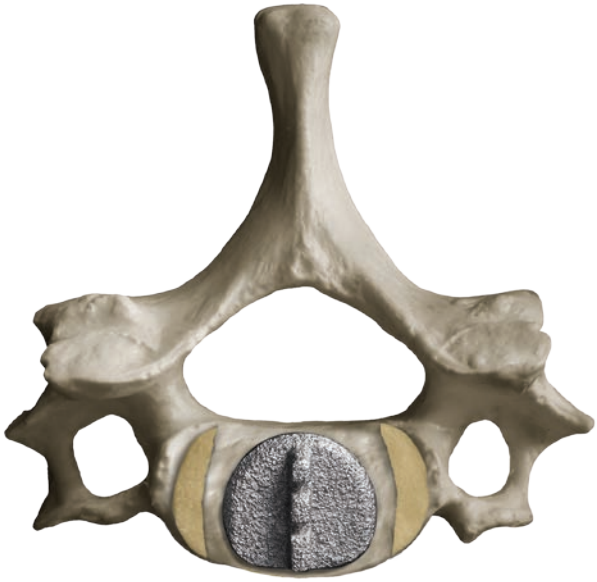
Final Position



Anterior view of SECURE®-C implant in final position



Lateral view of SECURE®-C implant in final position



Axial view of SECURE®-C implant in final position

OPTIONAL: Removal or Revision

The SECURE®-C implant may be removed or revised using standard forceps or kochers. In the event of significant bony ingrowth, the Keel Chisels may be used to separate the implant endplates from the bone.

Note: Do not use the Implant Holder or Narrow Implant Holder as a removal tool as the tips may bend or break.

Postoperative Care

Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device. Patients are recommended to wear a cervical collar for a few weeks following surgery, follow a therapy program for active range of motion exercises, and to avoid lifting above the shoulders, heavy lifting, repetitive bending and prolonged or strenuous activities. The time period of these recommendations is managed by the treating physician, taking into consideration the individual patient's condition as well as the stability and functioning of the implant. A two week postoperative course of non-steroidal anti-inflammatories (NSAIDs) is recommended to potentially reduce the incidence of heterotopic ossification (HO).

SECURE®-C STERILE-PACKED IMPLANTS

SECURE®-C Implant Set 914.910

SECURE®-C Endplate Assemblies (Qty 2 each)

0° Angle		6° Angle	
Part No.	Footprint	Part No.	Footprint
714.100S	11x12	714.106S	11x12
714.200S	13x14	714.206S	13x14
714.300S	14x16	714.306S	14x16
714.400S	15x18	714.406S	15x18

SECURE®-C Cores

Footprint	7mm (Qty 2)	8mm (Qty 2)	9mm (Qty 1)	10mm	11mm	12mm
11x12	414.107S	414.108S	414.109S	414.110S	414.111S	414.112S
13x14	414.207S	414.208S	414.209S	414.210S	414.211S	414.212S
14x16	414.307S	414.308S	414.309S	414.310S	414.311S	414.312S

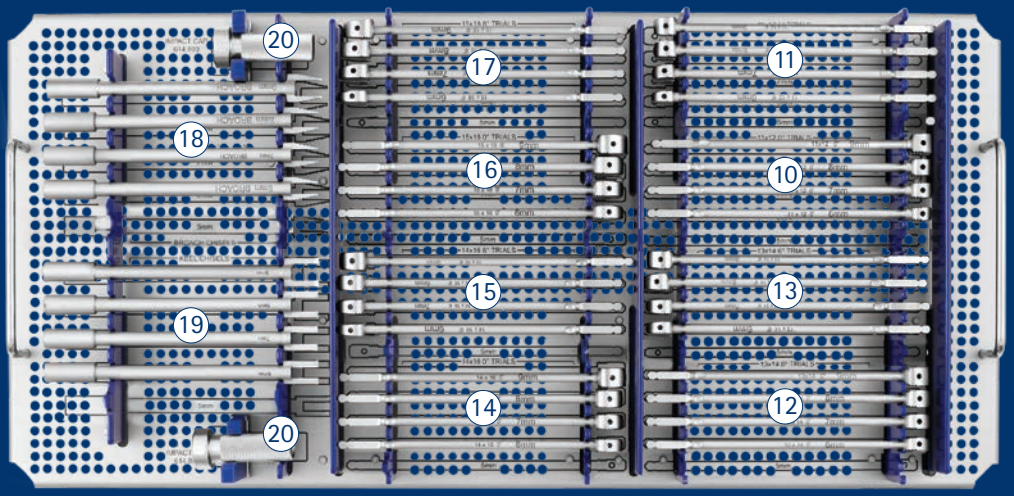
SECURE®-C 6mm Endplate and Core Assemblies (Qty 2 each)

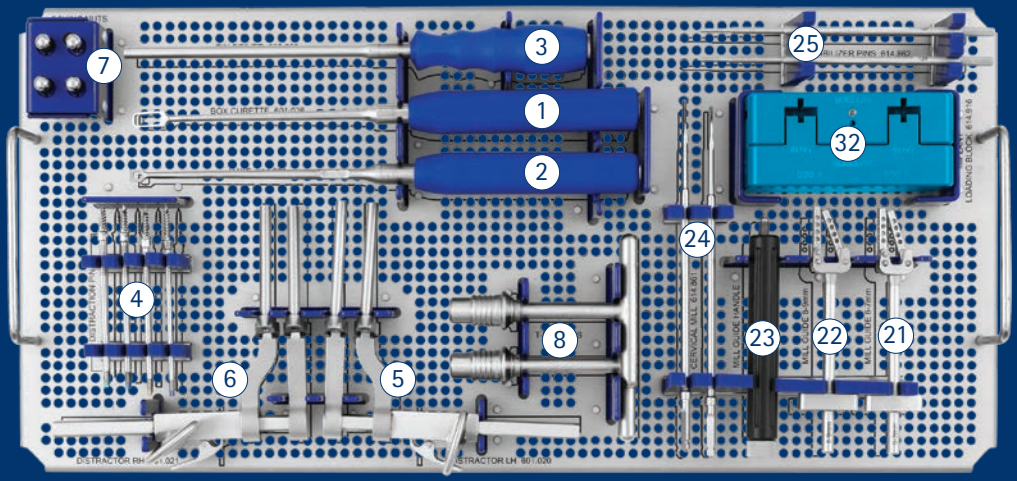
6° Angle		0° Angle	
Part No.	Footprint	Part No.	Footprint
714.166S	11x12	714.176S	11x12
714.266S	13x14	714.276S	13x14
714.366S	14x16	714.376S	14x16
714.466S	15x18	714.476S	15x18

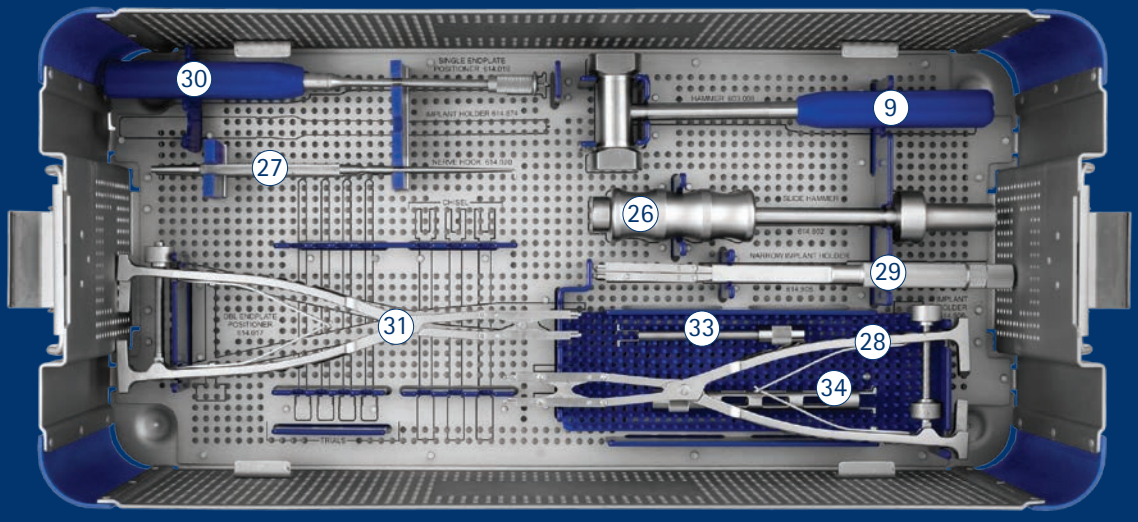
914.005 SECURE®-C Implant Carrying Case
GM041401 SECURE®-C Preoperative Template

*Items highlighted in gray are additionally available.

CERVICAL INSTRUMENT SET







Cervical Instrument Set 914.902

	Instruments		Qty
1	601.026	Box Curette	1
2	614.001	Rake	1
3	665.608	Pin Driver	1
4	665.612	Distraction Pin, 12mm	2
	665.614	Distraction Pin, 14mm	2
	665.616	Distraction Pin, 16mm	2
	665.618	Distraction Pin, 18mm	2
5	601.020	Distractor, Left	1
6	601.021	Distractor, Right	1
7	665.606	Locking Nut	4
8	614.006	T-Handle	2
9	603.008	Hammer	1
10	614.206	Trial, 11x12, 0°, 6mm	1
	614.207	Trial, 11x12, 0°, 7mm	1
	614.208	Trial, 11x12, 0°, 8mm	1
	614.209	Trial, 11x12, 0°, 9mm	1
11	614.306	Trial, 11x12, 6°, 6mm	1
	614.307	Trial, 11x12, 6°, 7mm	1
	614.308	Trial, 11x12, 6°, 8mm	1
	614.309	Trial, 11x12, 6°, 9mm	1
12	614.406	Trial, 13x14, 0°, 6mm	1
	614.407	Trial, 13x14, 0°, 7mm	1
	614.408	Trial, 13x14, 0°, 8mm	1
	614.409	Trial, 13x14, 0°, 9mm	1
13	614.506	Trial, 13x14, 6°, 6mm	1
	614.507	Trial, 13x14, 6°, 7mm	1
	614.508	Trial, 13x14, 6°, 8mm	1
	614.509	Trial, 13x14, 6°, 9mm	1
14	614.106	Trial, 14x16, 0°, 6mm	1
	614.107	Trial, 14x16, 0°, 7mm	1
	614.108	Trial, 14x16, 0°, 8mm	1
	614.109	Trial, 14x16, 0°, 9mm	1
15	614.913	Trial, 14x16, 6°, 6mm	1
	614.907	Trial, 14x16, 6°, 7mm	1
	614.908	Trial, 14x16, 6°, 8mm	1
	614.909	Trial, 14x16, 6°, 9mm	1

	Instruments		Qty
16	614.126	Trial, 15x18, 0°, 6mm	1
	614.127	Trial, 15x18, 0°, 7mm	1
	614.128	Trial, 15x18, 0°, 8mm	1
	614.129	Trial, 15x18, 0°, 9mm	1
17	614.926	Trial, 15x18, 6°, 6mm	1
	614.927	Trial, 15x18, 6°, 7mm	1
	614.928	Trial, 15x18, 6°, 8mm	1
	614.929	Trial, 15x18, 6°, 9mm	1
18	614.756	Broaching Chisel, 6mm	1
	614.757	Broaching Chisel, 7mm	1
	614.758	Broaching Chisel, 8mm	1
	614.759	Broaching Chisel, 9mm	1
19	614.826	Keel Chisel, 6mm	1
	614.827	Keel Chisel, 7mm	1
	614.828	Keel Chisel, 8mm	1
	614.829	Keel Chisel, 9mm	1
20	614.800	Chisel End Cap	2
21	614.850	Milling Guide, 6/7mm	1
22	614.852	Milling Guide, 8/9mm	1
23	622.005	Mill Guide Handle	1
24	614.861	Mill, Quick Connection	2
25	614.862	Stabilizer Pin	2
26	614.802	Slide Hammer	1
27	614.020	Nerve Hook	1
28	614.906	Implant Holder	1
29	614.805	Narrow Implant Holder	1
30	614.019	Single Endplate Positioner	1
31	614.017	Double Endplate Positioner	1
32	614.916	Implant Loading Block	1
33	614.024	Adjustable Trial Stop	1
34	614.025	Adjustable Chisel Stop	1
	914.003	SECURE®-C Graphic Case	

Additionally Available

614.007 Cervical Scraper, 7mm, 0°
614.008 Cervical Scraper, 8mm, 0°
614.009 Cervical Scraper, 9mm, 0°
614.607 Cervical Scraper, 7mm, 6°
614.608 Cervical Scraper, 8mm, 6°
614.609 Cervical Scraper, 9mm, 6°
614.010 Cervical Scraper, 10mm, 0°
614.011 Cervical Scraper, 11mm, 0°
614.012 Cervical Scraper, 12mm, 0°
614.610 Cervical Scraper, 10mm, 6°
614.611 Cervical Scraper, 11mm, 6°
614.612 Cervical Scraper, 12mm, 6°

614.726 Keel Chisel, Narrow, 6mm
614.727 Keel Chisel, Narrow, 7mm
614.728 Keel Chisel, Narrow, 8mm
614.729 Keel Chisel, Narrow, 9mm
614.730 Keel Chisel, Narrow, 10mm
614.731 Keel Chisel, Narrow, 11mm
614.732 Keel Chisel, Narrow, 12mm

614.830 Keel Chisel, 10mm
614.831 Keel Chisel, 11mm
614.832 Keel Chisel, 12mm

614.760 Broaching Chisel, 10mm
614.761 Broaching Chisel, 11mm
614.762 Broaching Chisel, 12mm

614.863 Mill, 5 Notch
614.864 Mill, Hex
614.865 Mill, Tri-Flat
614.866 Mill, Round
614.867 Mill, Flat
614.868 Mill, Star
614.869 Mill, Step
614.870 Mill, Quad-Flat
614.871 Mill, MRL

614.891 Mill, 5 Notch, D2
614.892 Mill, Flat, D2
614.893 Mill, Star, D2
614.894 Mill, Step, D2
614.895 Mill, Quad-Flat, D2
614.896 Mill, MRL, D2

Additionally Available

614.853 Milling Guide, 10mm
614.854 Milling Guide, 11mm
614.855 Milling Guide, 12mm

614.210 Trial, 11x12, 0°, 10mm
614.211 Trial, 11x12, 0°, 11mm
614.212 Trial, 11x12, 0°, 12mm

614.310 Trial, 11x12, 6°, 10mm
614.311 Trial, 11x12, 6°, 11mm
614.312 Trial, 11x12, 6°, 12mm

614.410 Trial, 13x14, 0°, 10mm
614.411 Trial, 13x14, 0°, 11mm
614.412 Trial, 13x14, 0°, 12mm

614.510 Trial, 13x14, 6°, 10mm
614.511 Trial, 13x14, 6°, 11mm
614.512 Trial, 13x14, 6°, 12mm

614.110 Trial, 14x16, 0°, 10mm
614.111 Trial, 14x16, 0°, 11mm
614.112 Trial, 14x16, 0°, 12mm

614.910 Trial, 14x16, 6°, 10mm
614.911 Trial, 14x16, 6°, 11mm
614.912 Trial, 14x16, 6°, 12mm

614.130 Trial, 15x18, 0°, 10mm
614.131 Trial, 15x18, 0°, 11mm
614.132 Trial, 15x18, 0°, 12mm

614.930 Trial, 15x18, 6°, 10mm
614.931 Trial, 15x18, 6°, 11mm
614.932 Trial, 15x18, 6°, 12mm

615.113 Bone Awl

IMPORTANT INFORMATION ON THE SECURE®-C CERVICAL ARTIFICIAL DISC

How Supplied
Implant Components – Sterile Surgical instruments – Non-Sterile (unless otherwise noted on the package label)

DESCRIPTION

The SECURE®-C Cervical Artificial Disc (SECURE®-C) is an articulating intervertebral device comprised of two endplates and a central core, and is inserted using an anterior cervical approach. The superior and inferior cobalt-chrome alloy (CoCrMo per ISO 5832-12, ASTM F1537) endplates feature multiple serrated keels and a commercially pure titanium plasma spray coating (per ISO 5832-2, ASTM F1580, F1978, F1147, and C-633) on the bone contacting surfaces. The sliding core is composed of ultra-high molecular weight polyethylene (UHMWPE per ISO 5834-2, ASTM F648), with a spherical superior interface and a cylindrical inferior interface articulating with the endplates.

SECURE®-C implants are offered in a variety of configurations to accommodate varied patient anatomy. Implant footprints are as follows (AP depth x ML width): 11x12mm, 13x14mm, 14x16mm and 15x18mm. SECURE®-C provides 0° or 6° lordosis options in its neutral position. Implant heights range from 6mm to 12mm, in 1mm increments. A list of SECURE®-C implants is provided in **Table 1**.

The SECURE®-C Cervical Artificial Disc is designed to allow motion in flexion and extension up to 30° (±15°), and in lateral bending to 20° (±10°). The design is intended to also allow unlimited axial rotation, and is constrained by ligaments and posterior elements. The device is also designed to permit translation of ±1.25mm in the sagittal plane.

Table 1. SECURE®-C Cervical Artificial Disc Implants

Part #	Description	Part #	Description
414.107S	SECURE®-C Core, 11x12, 7mm	414.312S	SECURE®-C Core, 14x16, 12mm
414.108S	SECURE®-C Core, 11x12, 8mm	714.100S	SECURE®-C Endplate Assembly, 11x12, 0°
414.109S	SECURE®-C Core, 11x12, 9mm	714.106S	SECURE®-C Endplate Assembly, 11x12, 6°
414.110S	SECURE®-C Core, 11x12, 10mm	714.166S	SECURE®-C Endplate and Core Assembly, 11x12, 6mm, 6°
414.111S	SECURE®-C Core, 11x12, 11mm	714.176S	SECURE®-C Endplate and Core Assembly, 11x12, 6mm, 0°
414.112S	SECURE®-C Core, 11x12, 12mm	714.200S	SECURE®-C Endplate Assembly, 13x14, 0°
414.207S	SECURE®-C Core, 13x14, 7mm	714.206S	SECURE®-C Endplate Assembly, 13x14, 6°
414.208S	SECURE®-C Core, 13x14, 8mm	714.266S	SECURE®-C Endplate and Core Assembly, 13x14, 6mm, 6°
414.209S	SECURE®-C Core, 13x14, 9mm	714.276S	SECURE®-C Endplate and Core Assembly, 13x14, 6mm, 0°
414.210S	SECURE®-C Core, 13x14, 10mm	714.300S	SECURE®-C Endplate Assembly, 14x16, 0°
414.211S	SECURE®-C Core, 13x14, 11mm	714.306S	SECURE®-C Endplate Assembly, 14x16, 6°
414.212S	SECURE®-C Core, 13x14, 12mm	714.366S	SECURE®-C Endplate and Core Assembly, 14x16, 6mm, 6°
414.307S	SECURE®-C Core, 14x16, 7mm	714.376S	SECURE®-C Endplate and Core Assembly, 14x16, 6mm, 0°
414.308S	SECURE®-C Core, 14x16, 8mm	714.400S	SECURE®-C Endplate Assembly, 15x18, 0°
414.309S	SECURE®-C Core, 14x16, 9mm	714.406S	SECURE®-C Endplate Assembly, 15x18, 6°
414.310S	SECURE®-C Core, 14x16, 10mm	714.466S	SECURE®-C Endplate and Core Assembly, 15x18, 6mm, 6°
414.311S	SECURE®-C Core, 14x16, 11mm	714.476S	SECURE®-C Endplate and Core Assembly, 15x18, 6mm, 0°

SECURE®-C devices are implanted using instruments specific to the device, as well as manual surgical instruments. Instruments specifically designed for implanting SECURE®-C consist of trials, milling guides, broaching chisels, keel chisels, chisel endcap, implant holding block, implant holders, and endplate positioners. Manual surgical instruments include instruments for cervical distraction, discectomy preparation, and milling.

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 a 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 radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. 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.

CONTRAINDICATIONS

The SECURE®-C Cervical Artificial Disc should not be implanted in patients with the following conditions:

- Active systemic infection or localized infection at the surgical site
- Osteoporosis or osteopenia defined as a DEXA bone mineral density T-score ≤ -1
- Allergy or sensitivity to cobalt, chromium, molybdenum, titanium or polyethylene
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3mm and/or >11° rotational difference from that of either adjacent level
- Severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height >50%, an absence of motion (<2°) as this may lead to a limited range of motion and may encourage bone formation (e.g. heterotopic ossification, fusion)
- Severe facet joint arthropathy
- Significant cervical anatomical deformity or 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) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis)
- Symptoms attributed to more than one vertebral level

WARNINGS

The SECURE®-C Cervical Artificial Disc should only be used by surgeons who are experienced with anterior cervical spinal procedures and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the SECURE®-C Cervical Artificial Disc should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

Correct selection of the appropriate implant size and correct placement of the device are essential to ensure optimal performance and function of the device. Please refer to the SECURE®-C Cervical Artificial Disc Surgical Technique manual for step-by-step instructions on the required surgical technique, including determining the correct implant size.

Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this device. Care should be taken to identify and protect these structures during surgery.

Heterotopic Ossification (HO) is a potential complication associated with cervical total disc replacement devices, which could result in reduced motion. It is recommended that bone wax is used following removal of osteophytes during surgery, to possibly reduce HO bone formation. The short-term postoperative use of non-steroidal anti-inflammatory drugs (NSAIDs), is recommended to possibly reduce the chance of developing HO.

PRECAUTIONS

The safety and effectiveness of this device has not been established in patients with the following conditions:

IMPORTANT INFORMATION ON THE SECURE®-C CERVICAL ARTIFICIAL DISC

- Intractable radiculopathy or myelopathy due to pathology at more than one level and/or pathology not localized to the disc space;
- Skeletally immature patients, pediatric or adolescent children (<21 years old), or those over the age of 60;
- Prior fusion at an adjacent vertebral level;
- Prior surgery at the level to be treated;
- Progressive symptoms and signs of spinal cord/nerve root compression with less than six weeks of conservative treatment;
- Facet joint disease or degeneration at the involved level;
- Neck or arm pain of unknown etiology;
- Neck pain alone;
- Paget's disease, osteomalacia, or other metabolic bone disease;
- Rheumatoid arthritis or other autoimmune disease;
- Neuromuscular disorders such as muscular dystrophy, spinal muscular atrophy, amyotrophic lateral sclerosis;
- Severe insulin dependent diabetes;
- Systemic disease including AIDS, HIV, and Hepatitis;
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids);
- Active malignancy (including spinal metastases);
- Acute mental illness or substance abuse; and
- Pregnancy.

Pre-operative

Patient selection is extremely important. In selecting patients for a cervical total disc replacement, the following factors can be of extreme importance to the success of the procedure: the patient's occupation or activity level; a condition of senility, mental illness, alcoholism or drug abuse; and certain degenerative diseases (e.g., degenerative scoliosis or ankylosing spondylitis) that may be so advanced at the time of implantation that the expected useful life of the device is substantially decreased.

In order to minimize the risk of periprosthetic vertebral fractures, surgeons must consider all co-morbidities, past and present medications, previous treatments, etc. A screening questionnaire for osteopenia or osteoporosis, SCORE (Simple Calculated Osteoporosis Risk Estimation), may be used to screen patients to determine if a DEXA bone mineral density measurement is necessary. If DEXA is performed, the patient should be excluded from receiving the device if the DEXA bone density measured T score is < -1.0, as the patient may be osteoporotic or osteopenic.

The patient should be informed of the potential adverse effects (risks/complications) contained in this insert (see POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH).

Preoperative planning may be used to estimate the required implant size, and to assure that the appropriate range of sizes is available for surgery. The procedure should not take place if the appropriate range of sizes will not be available.

Examine all instruments prior to surgery for wear or damage. Instruments which have been used excessively may be more likely to break. Replace any worn or damaged instruments.

Intra-operative

The SECURE®-C Cervical Artificial Disc implant should not be used with components or instruments of spinal systems from other manufacturers. Refer to the SECURE®-C surgical technique manual for step-by-step instructions.

Use aseptic technique when removing the SECURE®-C Cervical Artificial Disc implants from the innermost packaging. Carefully inspect each component and its packaging for any signs of damage, including damage to the sterile barrier. Do not use SECURE®-C implants if the packaging is damaged or the implant shows signs of damage.

Use care when handling the SECURE®-C Cervical Artificial Disc implant to ensure that it does not come in contact with objects that could damage the implant. Exercise care to ensure that implantation instruments do not contact the highly polished articulating surfaces of the endplates. Damaged implants are no longer functionally reliable.

To prevent unnecessary damage to the bearing surfaces, ensure that tissue or other debris is not trapped within the device.

Surgical implants must never be re-used or re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

When preparing the disc space, remove anterior or posterior osteophytes as needed, taking care to minimize bone removal. Avoid excessive bone removal as this may weaken the vertebral endplates or vertebral body. Correct positioning of the trial is critical prior to performing chisel cuts. Care should be taken to correctly position the trial during this step. Ensure proper alignment and placement of device components as misalignment may cause excessive wear and/or early failure of the device. Bone wax should be placed into any exposed bleeding bone.

Post-operative

Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device. Patients are recommended to wear a cervical collar for a few weeks following surgery, follow a therapy program for active range of motion exercises, and to avoid lifting above the shoulders, heavy lifting, repetitive bending and prolonged or strenuous activities. The time period of these recommendations is managed by the treating physician, taking into consideration the individual patient's condition as well as the stability and functioning of the implant. A two week postoperative course of non-steroidal anti-inflammatories (NSAIDs) is recommended to potentially reduce the incidence of heterotopic ossification (HO).

MRI Safety Information

Non-clinical testing has demonstrated that the SECURE®-C implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5Tesla or 3Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SECURE®-C implant is expected to produce a maximum temperature rise of 1.4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the device when imaged with a gradient echo pulse sequence and a 3Tesla MRI system.

POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The potential adverse effects (risks/complications) associated with the use of the SECURE®-C Cervical Artificial Disc include: (1) those associated with any surgical procedure; (2) those associated with anterior cervical spine surgery; and (3) those associated with a cervical artificial disc device, including the SECURE®-C Cervical Artificial Disc. However, the cause of these adverse events is not exclusive to these categories. In addition to these risks, listed below, there is also the risk that surgery may not be effective in relieving symptoms, or may cause worsening of symptoms. Additional surgery may be required to correct some of the adverse effects.

1. Risks associated with any surgical procedure include: abscess; cellulitis; wound dehiscence; wound, local, and/or systemic infection; wound necrosis; edema; hematoma; heart and vascular complications; hypertension; thrombosis; ischemia; embolism; thromboembolism; hemorrhage; thrombophlebitis; adverse reactions to anesthesia; pulmonary complications; organ, nerve or muscular damage; gastrointestinal or genitourinary compromise; seizure, convulsion, or changes to mental status; complications of pregnancy including miscarriage and fetal birth defects; inability to resume activities of daily living; and death.
2. Risks associated with anterior cervical spine surgery include: dysphagia; dysphasia; dysphonia; hoarseness; vocal cord paralysis; laryngeal palsy; sore throat; recurring aspirations; nerve deficits or damage; tracheal, esophageal, or pharyngeal perforation; airway obstruction; external chylorrhea; warmth or tingling in the extremities; deficit or damage to the spinal cord, nerve roots, or nerves possibly resulting in paralysis or pain; dural tears or leaking; cerebrospinal fistula; discitis, arachnoiditis, and other types of inflammation; loss of disc height; loss of proper curvature, correction, height or reduction of the spine; vertebral slipping; scarring, herniation or degeneration of adjacent discs; surrounding soft tissue damage, spinal stenosis; spondylolysis; otitis media; fistula; vascular damage and/or rupture; and headache.

3. Risks associated with a cervical artificial disc device, including the SECURE®-C Cervical Artificial Disc, include: early or late loosening of the components; disassembly; bending or breakage of any or all of the components; implant migration; implant malpositioning; loss of purchase; sizing issues with components; anatomical or technical difficulties; implant fracture; bone fracture; skin penetration, irritation, pain, and/or bursitis resulting from pressure on the skin from component parts in patients with inadequate tissue coverage over the implant; foreign body reaction to the implant including possible tumor formation, autoimmune disease, metallosis, and/or scarring; possible tissue reaction; bone resorption; bone formation (including heterotopic ossification) that may reduce spinal motion or result in a fusion, either at the treated level or at adjacent levels; development of new radiculopathy, myelopathy, or pain; tissue or nerve damage caused by improper positioning or placement of implants or instruments; bending or breakage of a surgical instrument, as well as the possibility of a fragment of a broken instrument remaining in the patient; loss of neurological function; decreased strength of extremities; decreased reflexes; cord or nerve root injury; loss of bowel and/or bladder control or other types of urological system compromise; and interference with radiographic imaging because of the presence of the implant.

For the specific adverse events that occurred in the clinical study of the SECURE®-C Cervical Artificial Disc, please see the Safety Results in the CLINICAL STUDY section below. Some of the most common adverse events experienced by study patients were: neck and/or arm pain, dysesthesia, back and/or leg pain, musculoskeletal events (excluding spinal events), and difficulty swallowing.

CLINICAL STUDY

The clinical investigation of the SECURE®-C Cervical Artificial Disc was conducted under an approved IDE (G050075). The study was a prospective, multi-center, two-arm, randomized, unmasked, concurrently controlled, non-inferiority trial to assess the safety and effectiveness of the SECURE®-C Cervical Artificial Disc compared to anterior cervical discectomy and fusion (ACDF) using a plate and structural allograft for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy or myelopathy due to a single-level abnormality localized to the disc space. The first five patients at each site were treated with the SECURE®-C device; subsequent patients were randomized in a 1:1 ratio at each site to receive either the SECURE®-C or control treatment. The purpose of the study was to determine whether the SECURE®-C Cervical Artificial Disc was non-inferior to the control.

Patients were treated between July 7, 2005 and April 25, 2008. A total of 380 patients were enrolled at 18 sites. Of these patients, 89 were non-randomly assigned to SECURE®-C. Of the randomized patients, 151 patients were randomized to SECURE®-C and 140 to control ACDF treatment. Final analysis was conducted after all patients had reached the two year time point. The database for this PMA reflected data collected through January 31, 2011.

PACKAGING

SECURE®-C implants are supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the implants from the packaging using aseptic technique.

The instrument sets are provided non-sterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery. All instruments should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. The Narrow Implant Holder is disassembled by unthreading the handle/sleeve and removing it from the working end. The Single Endplate Positioner is disassembled by unthreading the adjustable stop. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

STERILIZATION

SECURE®-C Cervical Artificial Disc implants are provided STERILE. Re-sterilization of the implants is not recommended. The polyethylene components may not be re-sterilized for any reason. No implant should be re-used once it comes into contact with human tissue or body fluid.

Sterile SECURE®-C implants are sterilized by gamma radiation using a standard medical device sterilization dose of 25-40kGy. This dose was validated using the VD_{MAX} method according to ANSI/AAMI/ISO 11137-2:2006 Sterilization of Healthcare Products. Sterilization validation was performed to assure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile implants are packaged in a heat sealed, double foil pouch. The expiration date is provided on the package label. Do not use if expired. These implants are considered sterile unless the packaging has been opened or damaged. Carefully inspect each component and its packaging for any damage. Do not use if the packaging or the implant is damaged.

All instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Prior to sterilization, confirm that all instruments that can be disassembled remain disassembled and any handles remain detached, as described above in the CLEANING section. (Instruments may be reassembled following sterilization.) Only sterile products should be placed in the operative field.

The Cervical Instruments used with the SECURE®-C Cervical Artificial Disc are provided non-sterile, and have been validated following ANSI/AAMI/ISO 17665-1:2006 Guidelines for Steam Sterility Validation to assure a Sterility Assurance Level (SAL) of 10^{-6}. The use of an FDA cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.*

The Cervical Instruments used with the SECURE®-C Cervical Artificial Disc are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum (wrapped)	132° C (270° F)	4 minutes	30 minutes
Steam	Gravity displacement (wrapped)	132° C (270° F)	15 minutes	45 minutes

IMPORTANT INFORMATION ON THE SECURE®-C CERVICAL ARTIFICIAL DISC

Always immediately clean and re-sterilize instruments that have been used in surgery. This process must be performed before handling or (if applicable) returning to Globus Medical.

These parameters are validated to sterilize these instruments. The autoclave must be properly installed, maintained, and calibrated.

CONFORMANCE TO STANDARDS

The SECURE®-C endplates are manufactured from cobalt-chrome-molybdenum alloy, CoCrMo, as specified in ASTM F1537 (and ISO 5832-12). The superior and inferior surfaces of the SECURE®-C endplates are plasma sprayed with commercially pure titanium, as specified in ASTM F1580, F1978, F1147 and C-633 (and ISO 5832-2). The SECURE®-C cores are manufactured from ultra-high molecular weight polyethylene, UHMWPE, as specified in ASTM F648 (and ISO 5834-2).

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871) or at www.globusmedical.com. A complete Summary of Safety and Effectiveness (SSED), surgical technique, and labeling information for SECURE®-C may be obtained at www.fda.gov by searching PMA number P100003.

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Globus Medical. Further, if any of the implanted system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or may have caused or contributed to the death or serious injury of a patient, Globus Medical should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, and the nature of the complaint. Complaints may also be reported directly to Medwatch at http://www.fda.gov/medwatch. You will be contacted by Globus Medical to provide specific information for an Enhanced Surveillance Study, for specific information regarding your clinical experience regarding the complaint and overall experience with the device. In the event that the SECURE®-C device requires removal for any reason, follow the instructions provided below in the DEVICE RETRIEVAL section.

DEVICE RETRIEVAL

Should it be necessary to explant a SECURE®-C Cervical Artificial Disc device, please contact Globus Medical to receive instructions regarding data collection, including histopathological, mechanical, patient and adverse event information. Please refer to the SECURE®-C Cervical Artificial Disc Surgical Technique for step-by-step instructions on the required surgical technique for device retrieval. All explanted devices must be returned to Globus Medical for analysis, in a leakproof container, with the date of explantation, explanting surgeon, and any known information regarding initial implantation, reasons for removal, and adverse event information. Please note that the explanted SECURE®-C device should be removed as carefully as possible in order to keep the implant and surrounding tissue intact. Also, please provide descriptive information about the gross appearance of the device in situ, as well as descriptions of the removal methods, i.e., intact or in pieces. Globus Medical will request additional information regarding the reason for removal, patient information and associated clinical outcomes.

NOTE: All implant removals must be reported immediately to Globus Medical.

Limited warranty and disclaimer: Globus Medical 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.

CAUTION: Federal (U.S.A) Law Restricts this Device to Sale by or on the order of a Physician.

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Notes

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