Cervical Arthroplasty (TECHNIQUES)

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PRINCIPLES

INDICATIONS & REQUIREMENTS

Dr. Mummaneni: "The arthroplasty is really for younger patients between the ages of, say, 20 and maybe 50 or so, patients who have good range of motion of their neck, and normal facet joints. If you already have your facet joints with a lot of bone spurs in patients who are 60-plus, you can't restore motion to those patients, because we're not doing anything to the joints in the back. The ones who are candidates for this operation at 1 level [are people who] have normal range of motion going in, and they have neck and arm pain from a herniated disc."

The right patient is < 50 yo with preserved disc height;
modern indications have expanded:

- older patients are OK but look for bony anatomy, esp. facet degeneration (fixed inlay core designs [such as Prodisc-C] shield facets so facetogenic pain is minimized).
- collapsed disc is not a big deal (even if 50 perc or more).

NASS Clinical Guidelines for Cervical Radiculopathy from Degenerative Disorders (2010):
ACDF and TDA are suggested as comparable treatments, resulting in ***similarly successful*** short term outcomes, for single level degenerative cervical radiculopathy (grade of recommendation: B).

- FDA approved for 1 and 2 contiguous levels (C3-7) for Mobi-C, 1 level for all other designs.
- indication – intractable symptomatic cervical disc disease:
  - **A) neck pain**
  - **B) radiculopathy** (arm pain)
  - **C) neurological deficit** (myelopathy)

+ abnormality localized to disc level with at least one of the following radiologic finding:
    a) herniated nucleus pulposus
    b) spondylosis (defined by the presence of osteophytes)
    c) visible loss of disc height compared to adjacent levels.

N.B. **neural decompression has to be main indication for surgery**, incl. single level myelopathy.

- patient is candidate until proven otherwise.
- **skeletally mature** patients (> 21 yo).
- **always consent for ACDF**!!!!
- patients should have failed at least **6 weeks of conservative treatment**.
- *not approved to be combined with ACDF* (neither at adjacent nor at distant levels).

CONTRAINDICATIONS

- compromised vertebral bodies at the index level - previous trauma (fracture callus, malunion), anatomical deformity or disease (e.g., *ankylosing spondylitis, rheumatoid arthritis*).
- kyphosis
- instability on ***resting lateral*** or ***flexion/extension*** radiographs (translation > 3.0-3.5 mm, and/or > 11° angular difference to that of either adjacent level).
- ossification of posterior longitudinal ligament (OPLL) – TDR may lead to neurological injury
- osteopenia with **DEXA** T-score ≤ -2.5 for Prodisc C, ≤ -1.5 for Mobi-C, ≤ -1.0 for Secure-C (risk of atraumatic periprosthetic fractures); use **SCORE questionnaire** to determine who needs DEXA. p. Op220 >>
- severe facet joint disease.
- severe spondylosis - bridging osteophytes, loss of disc height > 50% (slightly obsolete requirement), absence of motion (< 2°) → may lead to a limited ROM and bone formation (e.g. heterotopic ossification, fusion)
    - surgical release of collapsed disc spaces can lead to a highly osteogenic environment.
    - extremely collapsed disc spaces can lead to the placement of a "tight" implant that would limit motion and further encourage bone formation and fusion.
- active infection (at the disc or systemic)
- allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, titanium, hydroxyapatite, or polyethylene).
    N.B. look for Ni allergy – all implants have some nickel in alloy.

WARNINGS

Heterotopic Ossification (HO) is a potential complication associated with artificial cervical discs and could lead to reduced cervical motion.

- prophylaxis:
    1) use bone wax after bone (osteophyte) removal
    2) postop NSAID

Implant height ≥ 8 mm → postop neck pain from disc space overdistraction.

PRECAUTIONS

- patients < 21 or > 60-67 years old.
- prior cervical spine surgery, including prior surgery at the index level.
- > 2 diseased or immobile cervical spine levels requiring surgical intervention.

- disc height < 3 mm measured from the center of the disc in a neutral position.
- disc height < 20% of AP width of the inferior vertebral body?
- significant kyphotic deformity / significant reversal of lordosis.
- taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids)
- ***severe diabetes mellitus*** requiring daily insulin – only a precaution.
- BMI > 40
- AIDS, HIV, and Hepatitis
- prior fusion at an adjacent vertebral level
- neck pain alone
- rheumatoid arthritis
- muscular dystrophy, spinal muscular atrophy, or amyotrophic lateral sclerosis
- Paget's disease, osteomalacia, or other metabolic bone disease
- active malignancy (including spinal metastases)
- acute mental illness or substance abuse
- pregnancy
- not clear if ***cord compression with cord T2 signal*** is a contraindication (TDR may leave dynamic cord micro-traumatization unaddressed – cord injury may continue – better avoid TDR if cord shows T2 signal).

IMPLANT SELECTION

Mandatory preop tests:

1. CT
2. Dynamic XR – amount of mobility at index level – inducing hypermobility in already hypermobile patient risks spinal cord injury or implant insert extrusion (seen on CT as prevertebral lucent mass and loss of implant height).

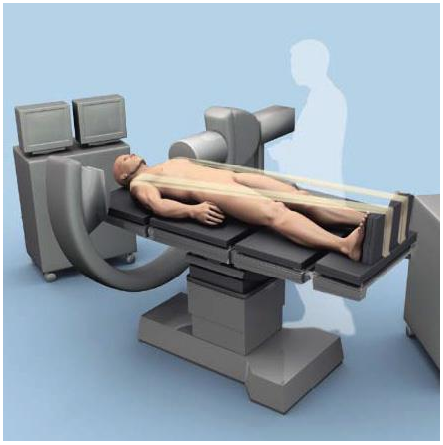
Level of insert constraint is a key parameter in implants (e.g. Mobi-C is least constrained – risk of hypermobility complications)

SURGERY

Intraop KETOROLAC!
Preop CT – to measure implant size (also to check bony anatomy, facet disease) - look at superior vertebra endplate width - dictates width of implants.

PATIENT POSITION

- maintain **normal lordotic ("neutral")** position to avoid hyperextension (roll can be used to support neck).
- use gel donut (instead of horseshoe headholder) – easier for C-arm
- rotation of the head should be prevented using tape or a chin strap to the bed.
- head weights are not recommended - distracted adjacent disc spaces give false impression of disc height.
- **both vertebral bodies** of the affected level **must be clearly visible** on fluoroscopy (if needed, shoulders can be taped for better visualization (footboard may be used to maintain the patient's position).




Note: if visualization is poor, switch to ACDF

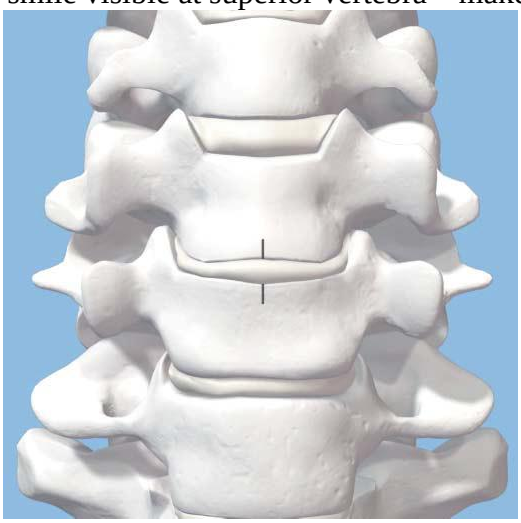
C-ARM

- prepare for C-arm use that allows cephalad and caudad movement.
- set the C-arm to capture true A/P and lateral views before final draping.
- as the C-arm is moved frequently, consider taping the floor to mark the best C-arm positions to eliminate variations in film view.
- **must see the index level on XR** (vs. ACDF - could be done under direct vision) – if cannot, proceed with fusion!

DISCECTOMY

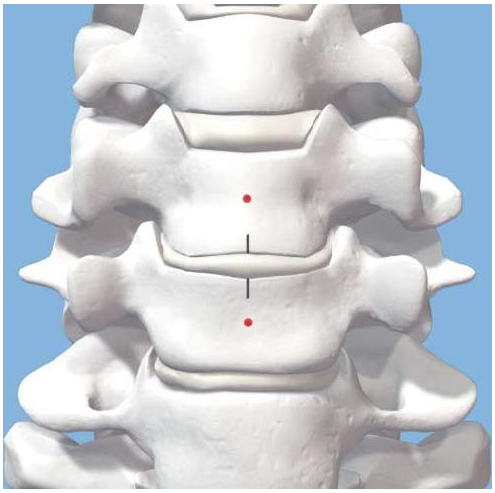
Differences from ACDF:

- center the exposure on midline – very important to see where midline is
  - fluoroscopy is not always helpful (use radiolucent Mayfield base and horseshoe headholder)
  - once verified correct disc level, before anything else, while longus colli still attached (easy to see where midline is) – mark midline with drill divot on bony apophyseal ring on vertebrae above and below the disc (make it more conspicuous with a marker).
  - also make anterior smile visible at superior vertebra – makes midline better visible:

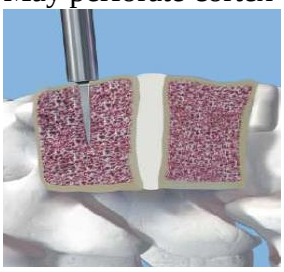


- minimize soft tissue trauma - limiting retraction ischemia, minimal dissection of the longus coli, minimal periosteal dissection and less electrocautery use (use bipolar cautery rather than monopolar Bovie).

- Caspar Pin > 5 mm (or 2/3 away) from each endplate (esp. if implant has keels), centered on midline in coronal plane, parallel with the vertebral endplates in order to ensure **parallel** distraction.



May perforate cortex with awl:



Remobilization of disc space (to restore disc height) is critical to the success of the surgery!

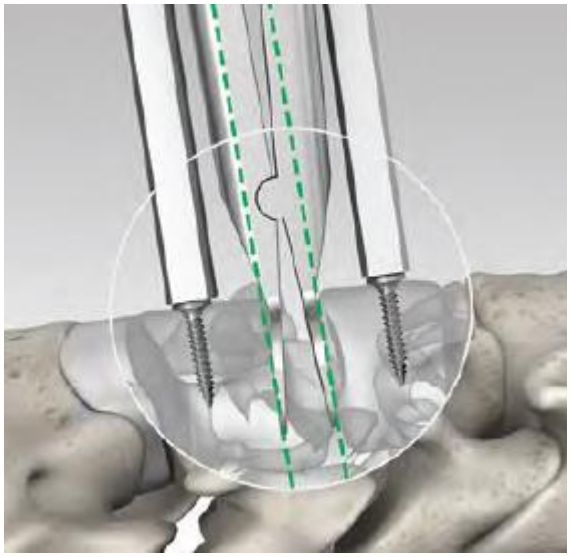
N.B. Caspar Distraction alone may not properly distract posteriorly – use distraction on Distraction Forceps first and then fixate distracted position with Caspar Pins.

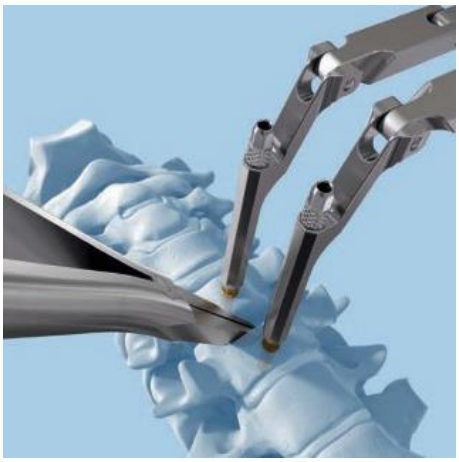
H: **Distraction Forceps**: insert to back of disc space (i.e. on apophyseal ring to avoid endplate perforation) under fluoroscopy → release Caspar Distractor → use Distraction Forceps to create parallel distraction; when the desired height is obtained, lock the Caspar Distractor (Retainer) to hold distraction and then remove Distraction Forceps.

N.B. avoid overdistraction as this can lead to nerve root tension or improper implant selection.

— need to **release posterior longitudinal ligament (PLL)** – it helps to obtain parallel distraction and remobilize segment – but also may destabilize! (it is easier and safer to remove PLL when distraction is applied – PLL prevents distractor from slipping onto cord, tightened PLL fibers are easier to cut)

Mobi-C Paddle Distractor, 15 mm in depth: Prodisc-C Vertebral Distractor:

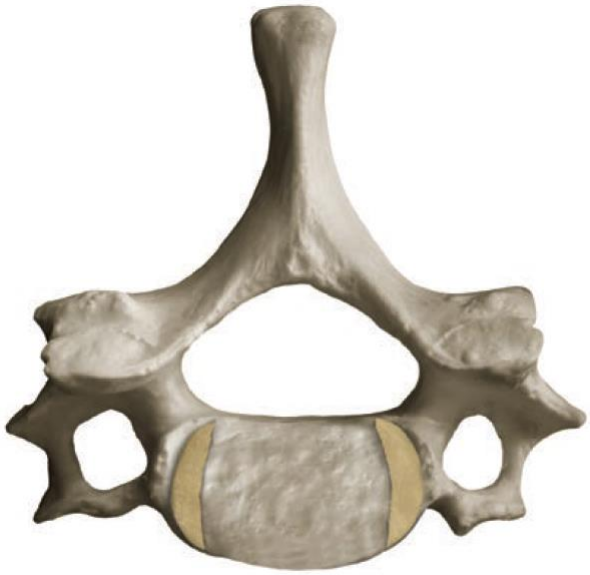




- ***do not remove anterior osteophytes**** – unroofed cancellous bone will promote further osteophyte growth (but as needed, address large, significant ***anterior osteophytes*** if they visually obstruct disc removal).

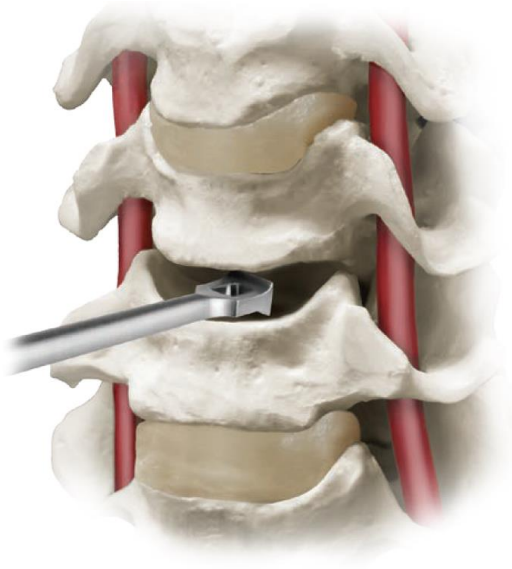
*no concern for anterior plate fitting (as in ACDF)

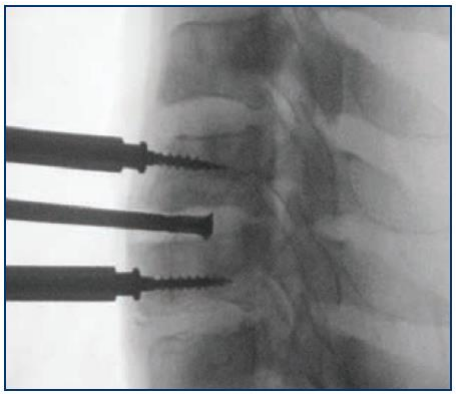
- complete disc removal manual scraping (i.e. without burrs - burrs tend to overdo bone removal; some use burrs on reverse spin – less bone destruction and more cautery effect), between the unci, preserving the bony endplate* and annular rim: *leave > 90% of endplate intact



Axial view of disc with lateral annular rim intact

Secure-C Box Curette and Rake can be utilized to remove disc material and the cartilaginous endplates:





Box Curette 601.026

Rake 614.001

- two areas that may need remodeling:
  1) ***posterior osteophytes*** (esp. on the superior vertebral endplate); if those are big, it will require lots of undercutting - endplates will subside, - so big posterior osteophytes do better ACDF!
  2) release the foramen bilaterally* i.e. it is desirable to remove ***posterior 1/3 of uncovertebral joints*** to achieve thorough foraminotomy.

     *in ACDF, it is enough to decompress only symptomatic side, but for TDR bony work must be symmetric (do not count on indirect decompression as in ACDF!)
- posteriorly, there should be no bony obstruction that would interfere with the trial and optimal placement of device.
- liberally cover any bleeding bone with **bone wax** to help prevent heterotopic ossification.

Bottom line – decompression is #1 task, then need to remobilize & remodel disc space just enough (too little → limited ROM → autofusion; too much endplate remodeling → highly osteogenic environment → autofusion)

TRIAL

- use the largest footprint and the smallest height needed to restore the natural disc
  - 90-100% use 5 mm.
  - height is measured at posterior lips.
  - recommendation is to choose smaller height – easier to preserve motion (vs. cages for ACDF – use taller cage as need compression to promote fusion).

CUTTING KEEL

- trial serves as jig.
- cut under lateral fluoroscopy
- leave chisel in place (while assembling implant) – works for hemostasis
- clean trough of keel with nerve hook - to remove bony debris.
- ***irrigate well*** to get rid of released bone marrow with osteogenetic substances.

IMPLANTATION

- under fluoroscopy.
- ***center of rotation (COR) of implant*** (in sagittal plane) should be positioned at the midline of the vertebral body or slightly posterior.
- avoid excessive cranial, caudal, or lateral corrections during insertion.
- ensure that the implant doesn't exceed posterior margin of vertebral body.
- **copious saline lavage** is recommended to ***remove osteogenic stimuli*** (blood/bone marrow); also bone wax front parts of keel troughs.
- it is OK if implant plates have some fishmouthing (i.e. posteriorly plates towards kissing).
- may check for implant ROM on fluoroscopy after implantation – by moving head up and down.

POST-OP MANAGEMENT

- ambulate the day of surgery; discharge, based on surgeon preference, often the first day post-op.
- optional soft collar for 1-2 weeks, based on surgeon preference (Secure-C recommends "cervical collar for a few weeks")
- **short-term NSAID**; Dr. Hisey uses 200 mg/d IBUPROFEN for 6 weeks (others recommend only 1-2 weeks of INDOMETHACIN) – to prevent heterotopic ossification.

  Tsung-Hsi Tu et al., Heterotopic ossification after cervical total disc replacement: determination by CT and effects on clinical outcomes, *J Neurosurg Spine 14:457–465, 2011 457*
- back to office work in 1-2 weeks.
- PT: isometric strengthening, active ROM typically at 2 weeks.
- restrict overhead activity, repetitive neck movements, and heavy lifting for 6 weeks.
- at 6 weeks - may go onto treadmill.
- at 3 months:
  do full sports
  military goes back to duty at 3 mos (at 4 mos allowed to jump with parachutes).
- **dynamic XR (AP and lateral)** at 4-6 weeks (later, PRN).

MRI-CONDITIONAL

Safe up to 3.0 Tesla

- ***maximum temperature rise*** after 15 minutes of continuous scanning:

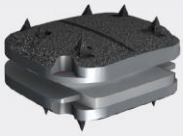
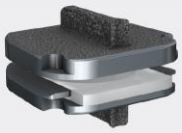
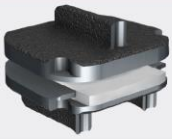
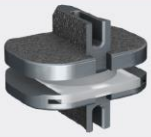
Mobi-C®	< 3 ºC
SECURE®-C	1.4°C
Prodisc® C Vivo	1.1°C for 1.5 T and 1.9°C for 3.0 T

- ***image artifact*** (gradient echo pulse sequence, 3T) caused by the device extends:

29 mm	from Mobi-C®
25-35 mm	from Prodisc® C Vivo
20 mm	from SECURE®-C

PRODISC® C VIVO (CENTINEL SPINE)

See brochure >>

Device	prodisc. C Vivo	prodisc. C SK	prodisc. C Nova	prodisc. C
Product Image				
First Year of Clinical Use	2009	2019	2009	2002
Number of Implantations	Over 225,000 implantations of the prodisc technology platform[1]			
FDA PMA Approval	2022			2007
Published Studies	Over 540 published studies on the prodisc technology platform[2]			
Kinematics	prodisc CORE Technology – fixed core with an optimized core radius			
Endplate Design	Domed Superior Endplate	Flat Superior Endplate		
Endplate Fixation	Unique Lateral Spikes, that provide equivalent fixation to keeled devices[3]	Smaller Central Keels	Tri-keels, designed to improve fixation in certain endplate morphologies	Larger Central Keels
Surgical Technique	Streamlined, one-step keel-less implantation	Simplified keel preparation technique		Traditional keel cutting technique
Endplate Footprint Shape	Optimized trapezoidal footprint, designed to reduce the amount of intraoperative remodeling			Rectangular footprint

DESIGN

SK (Small Keel)

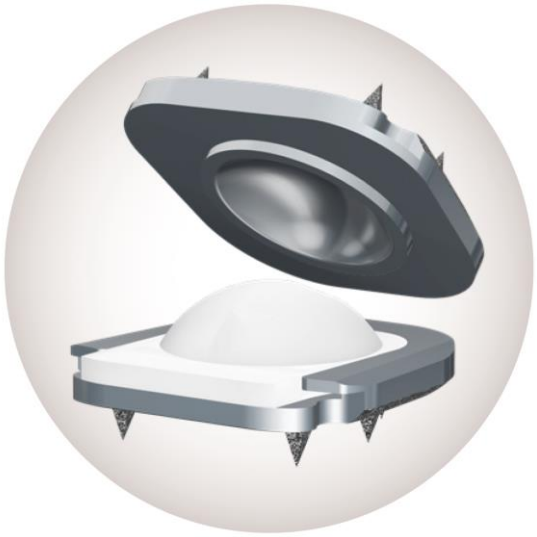
Has flat superior plate – fits flat degenerated disc; for concave anatomy disc, keel does not fully engage in the center of track (use "Vivo" instead).
N.B. it is difficult to cut keel for C3-4 level.

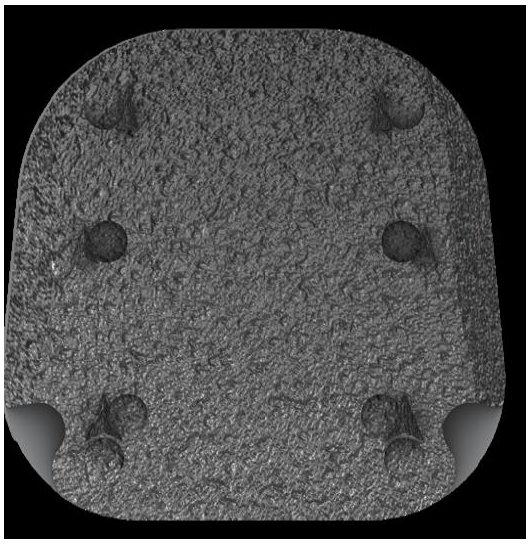
VIVO

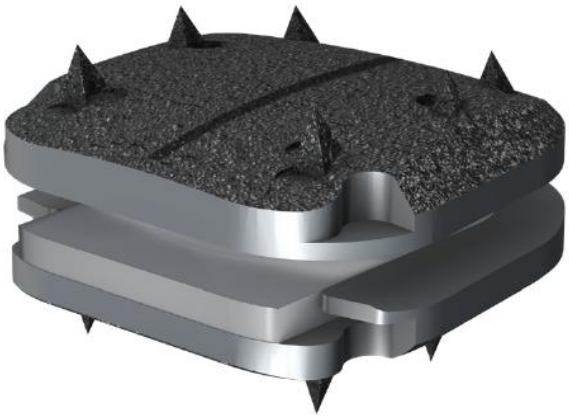
Two reasons why "Vivo" is the most popular:

1. Has spikes for fixation (no need to cut keel – saves the step) - biomechanical study showed no difference of endplate pushout strength compared to keel.
2. Has convex superior plate – fits concave vertebral endplate better

Convex superior plate for anatomical fixation.
Trapezoidal footprint design for optimal anatomical maximum endplate coverage.



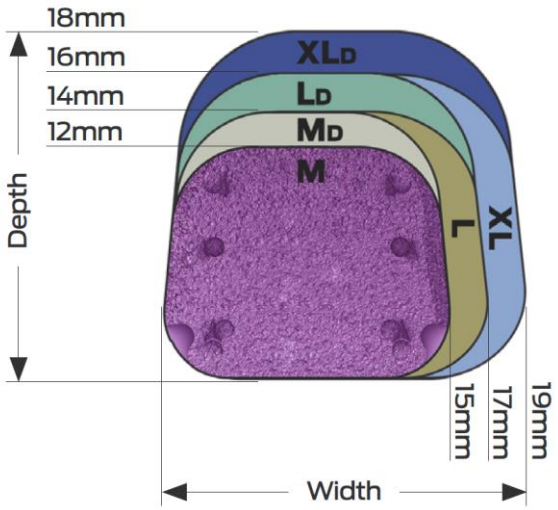




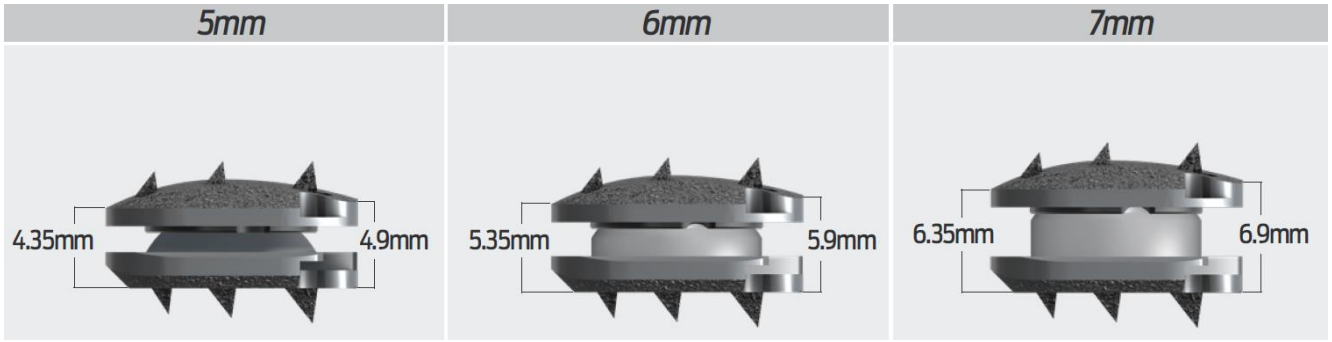
Coating - titanium porous (plasma spray coated) allows bony on-growth, aiding in long-term fixation.
Endplates - CoCrMo alloy; six spikes.
Inlay - ultra-high molecular weight polyethylene (UHMWPE); pre-assembled snap-locked into a tray detail in the inferior endplate

SIZES

Six endplate footprints (medium, medium deep, large, large deep, extra large, extra large deep):



5 mm, 6 mm and 7 mm heights:

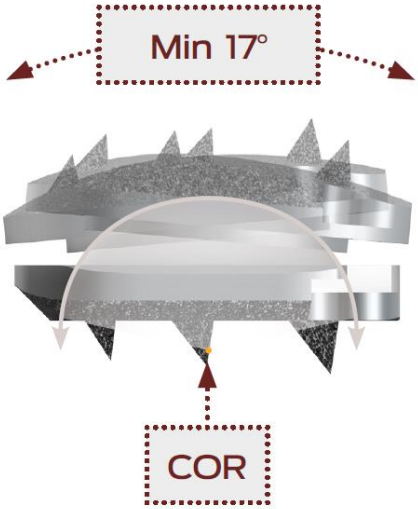


KINEMATICS

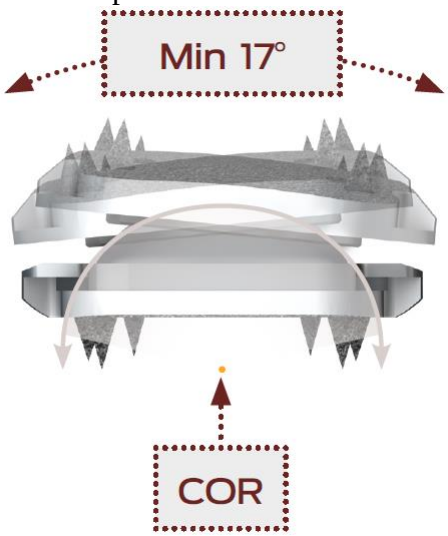
COR (center of rotation) is located just below the inferior endplate.

A/P translation occurs with flexion/extension, rotation.

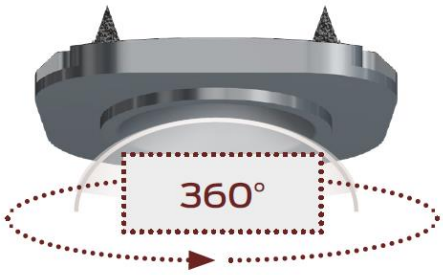
Flexion/Extension radius is in accordance with the kinematics of the intact spine; 17º for 5 mm implants, 20º for other implants:



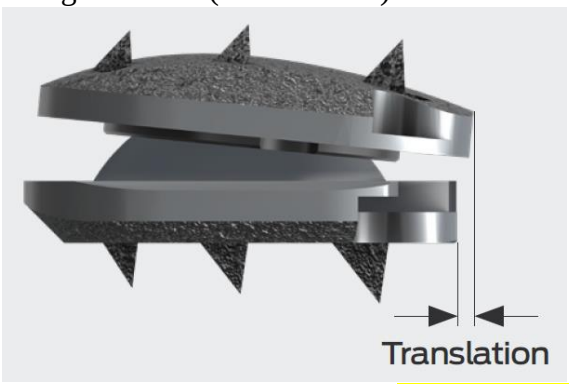
Lateral Bending - physiological range of motion in lateral bending is maintained; 17º for 5 mm implants, 20º for other implants:



Axial Rotation is unconstrained, i.e. limited by the anatomical structures and not by the prosthesis:



Translation is through rotation (max 0.5 mm):



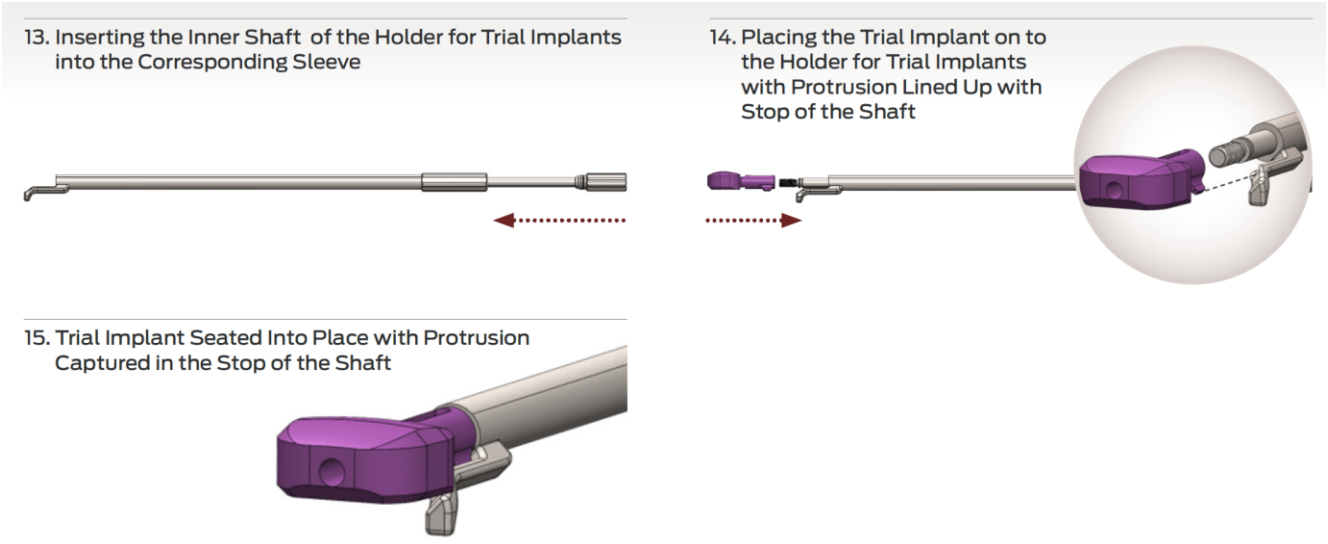
N.B. inlay is locked in the inferior endplate – prevents translation and, thus, load on facets! (major advantage over competitors!)

SURGERY

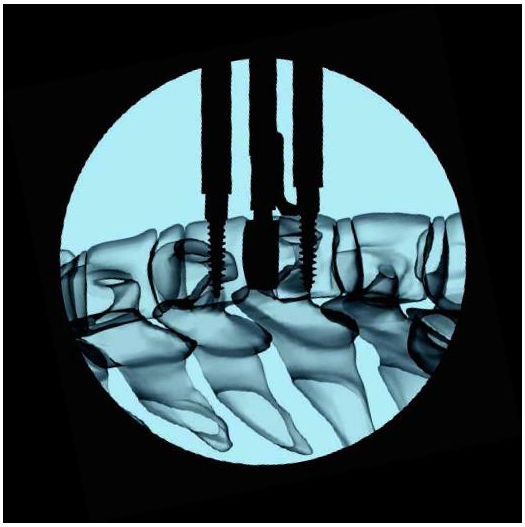
Surgery 5-minute video (technique demo starts at 2:22) >>

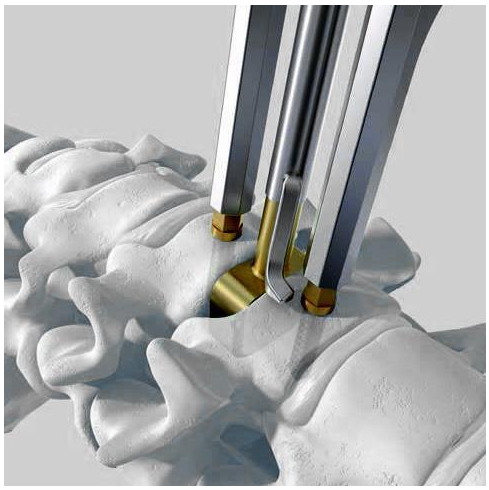
TRIAL

- prosthesis center of rotation (COR) should be positioned at the midline of the vertebral body or slightly posterior.



- if the stop does not allow the trial implant to go deep enough, the stop can be adjusted by turning the trial shaft counter clockwise (1 rev = 0.5 mm*), enabling the trial implant to be advanced slightly deeper:





*do not unscrew stop more than 4 mm or contact to trial implant may be lost; H: use next size trial implant instead

IMPLANT ASSEMBLY

Spacer Clamp M/MD (Heights 5mm - 7mm)
03.670.305 - 03.670.307

Implant Holder
03.670.201 - 03.670.203

Spacer Clamp L/LD (Heights 5mm - 7mm)
03.670.315 - 03.670.317

Shaft for Implant Holder
03.670.213

Spacer Clamp XL/XLD (Heights 5mm - 7mm)
03.670.325 - 03.670.327

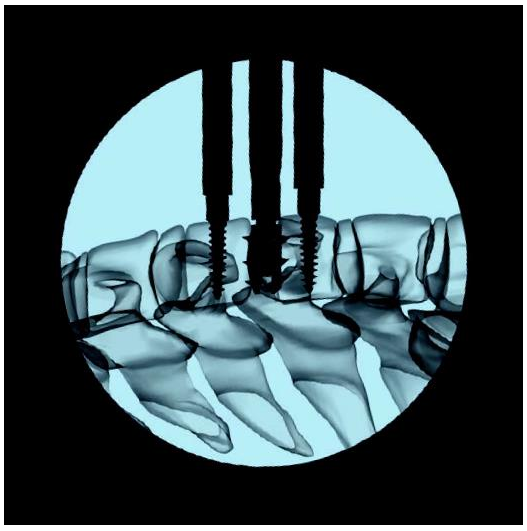
Stop for Implant Holder (Optional)
03.670.212

- choose Spacer Clamp size M/MD, L/LD or XL/XLD.
- attach Spacer Clamp to the prosthesis until the arms snap into the holding features in the implant.
- attach the corresponding Implant Holder (M/MD, L/LD or XL/XLD) to Spacer Clamp, making sure that the lateral projections of Spacer Clamp are captured in the arms of Implant Holder.
- tighten the Implant Holder to the Spacer Clamp turning the head of the inner shaft clockwise.
- pull the implant en-bloc out of the packaging tray:

IMPLANTATION

- without or with optional stop on Implant Holder:


- apply distraction as necessary.
- ensure black midline on the superior plate faces cranially and align it with the midline marking of the vertebral body.
- advance under fluoroscopy:

- Spacer Clamp includes two grooves that visualize the anterior margin of the implant under lateral fluoroscopy.

- apply ***slight compression with Caspar pins*** - to help the spikes on the implant to penetrate into the vertebral bodies.
- before removing Spacer Clamp, make sure everything looks good on XR.
- release implant:
  - rotate the shaft of the implant holder two full turns in the counterclockwise direction.
  - move the implant holder laterally—left-to-right a few times—until the spacer clamp disconnects from the implant.


REMOVAL

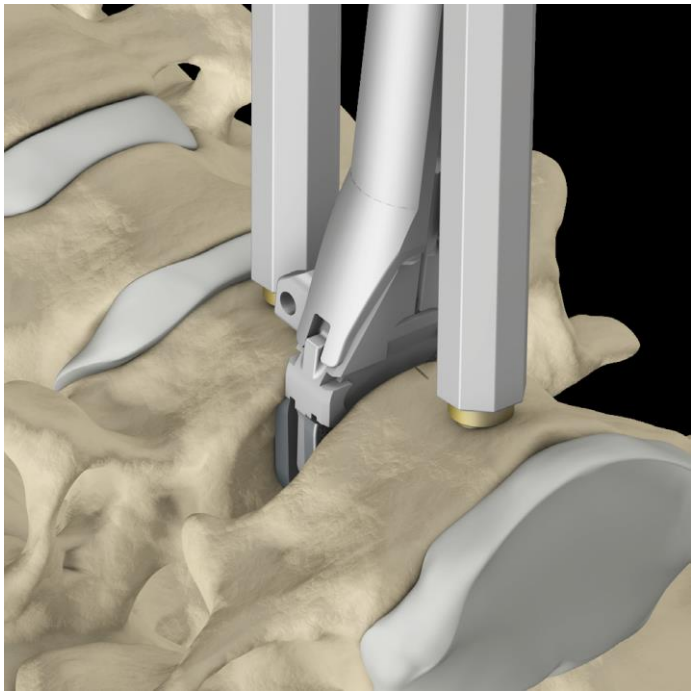
- distract disc space using Vertebral Distractor Forceps and Caspar pins.
- attach the appropriate Remover Clamp to corresponding Implant Holder with ***minimal thread engagement*** without tightening the head of the inner shaft of the implant holder.
  Note: if thread of the shaft is fully engaged and tightened, Remover Clamp cannot be attached to the implant.

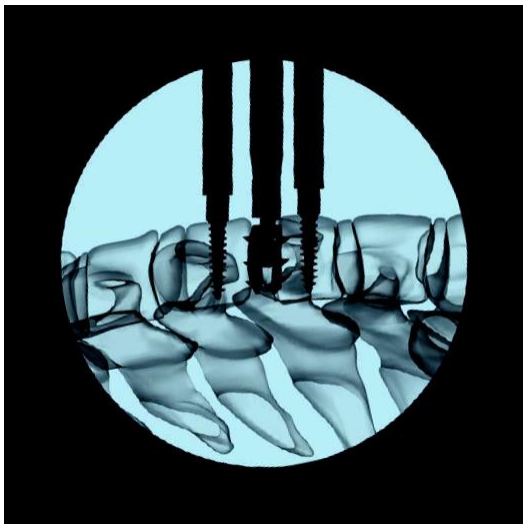
Remover Clamp (M/MD, L/LD, XL/XLD)
03.670.400, 03.670.410, 03.670.420

Implant Holder
03.670.201 - 03.670.203

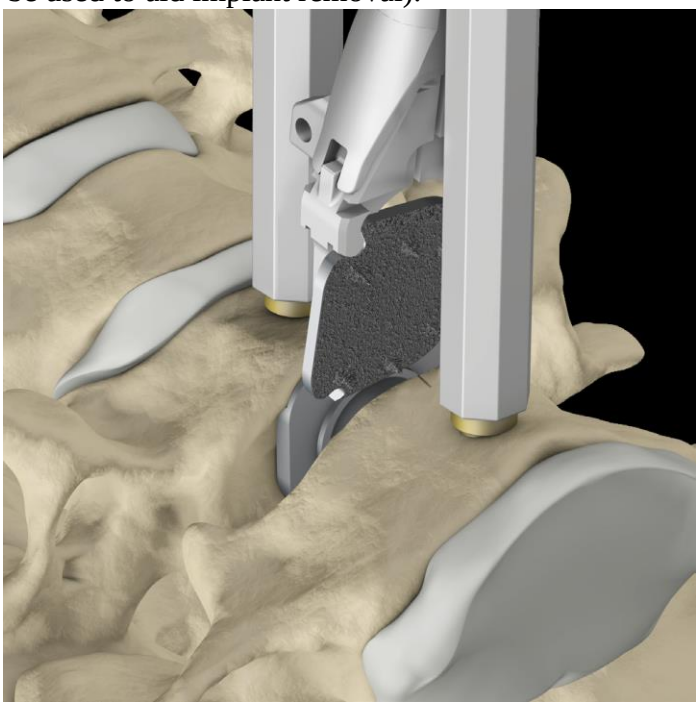
Shaft for Implant Holder
03.670.213

- attach the Remover Clamp assembly to inferior plate and securely attach it by turning the head of the Implant Holder Shaft in clockwise direction; verify implant attachment under fluoroscopy.
  Note: surface edged with "inside" must be oriented towards the center of the disc space with respect to the implant endplate being removed

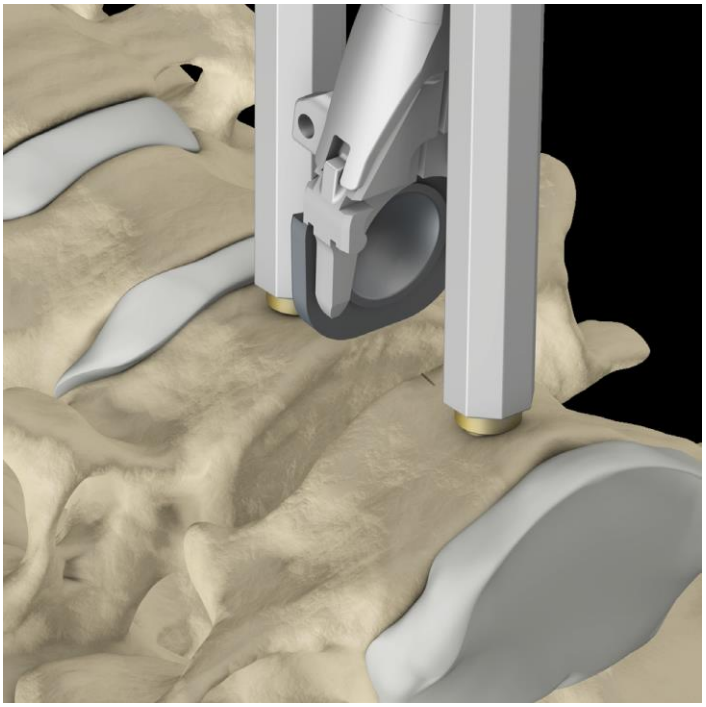




- remove inferior plate by cautiously pulling the Implant Holder (Slotted Mallet or Slide Hammer can be used to aid implant removal).



- superior plate can be removed using the Remover Clamps or forceps.



OUTCOME

Prodisc-C decreases adjacent level surgery rate 4 times (vs. ACDF) at 7 years.

SECURE-C (GLOBUS)

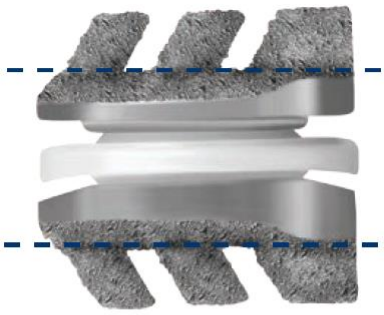
See brochure >>

DESIGN

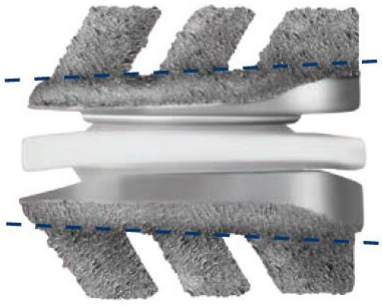
- ±15° motion in flexion-extension.
- ±10° motion in lateral bending.
- unlimited axial rotation.
- sagittal plane translation of ±1.25mm.

SECURE-C ENDPLATES

- cobalt chromium molybdenum (CoCrMo) with titanium plasma spray coating.
- two **sagittal profiles** (0° and 6°):

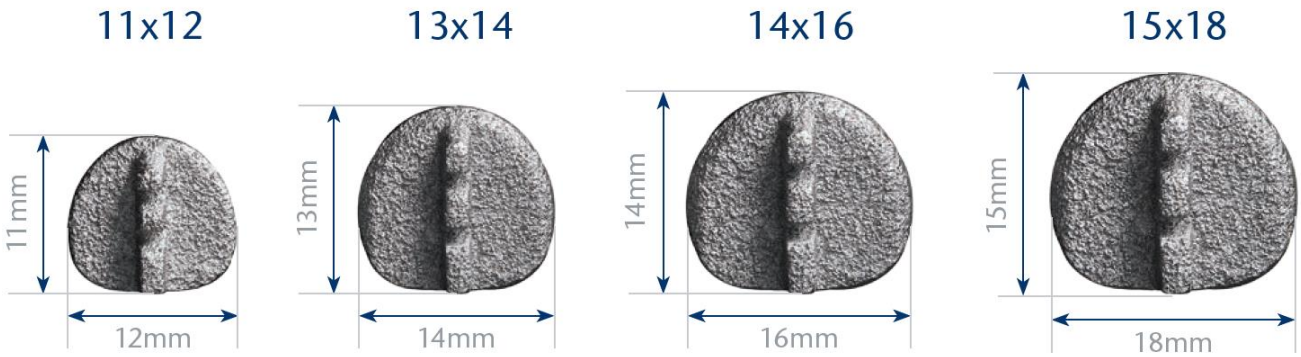


0° Profile

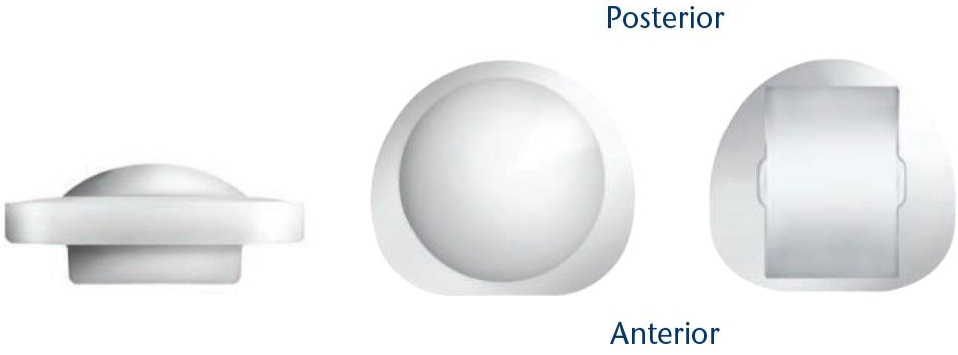


6° Profile

- four **footprint sizes** (11x12, 13x14, 14x16, 15x18 mm):



SECURE-C CORES



- ultra–high molecular weight polyethylene (UHMWPE)
- spherical and cylindrical articulation with endplates
- heights 6–12 mm in 1 mm increments

SURGERY

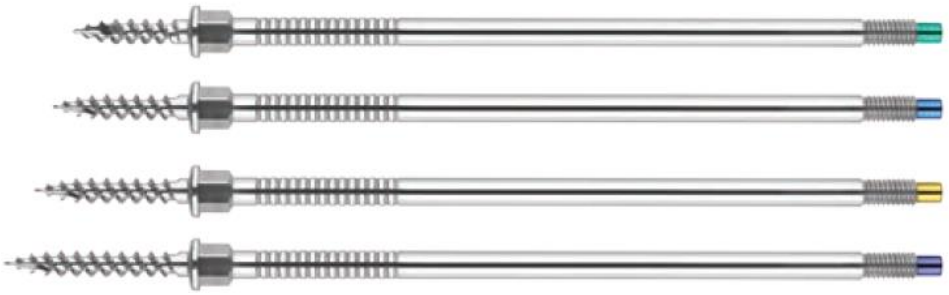
Distraction Pins

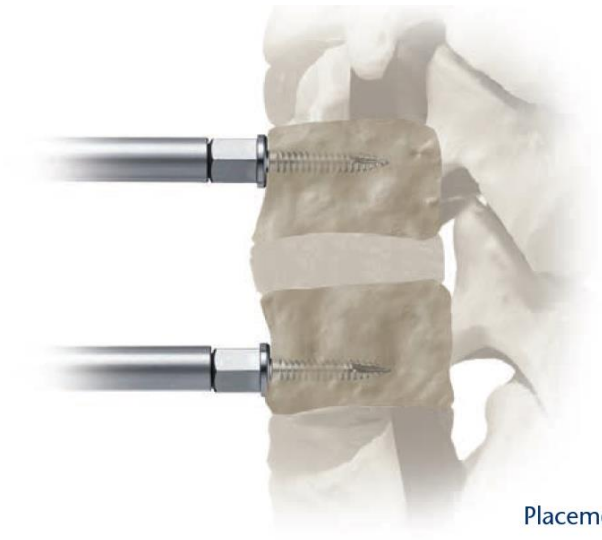
12mm 665.612

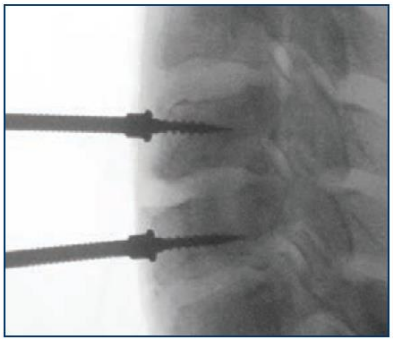
14mm 665.614

16mm 665.616

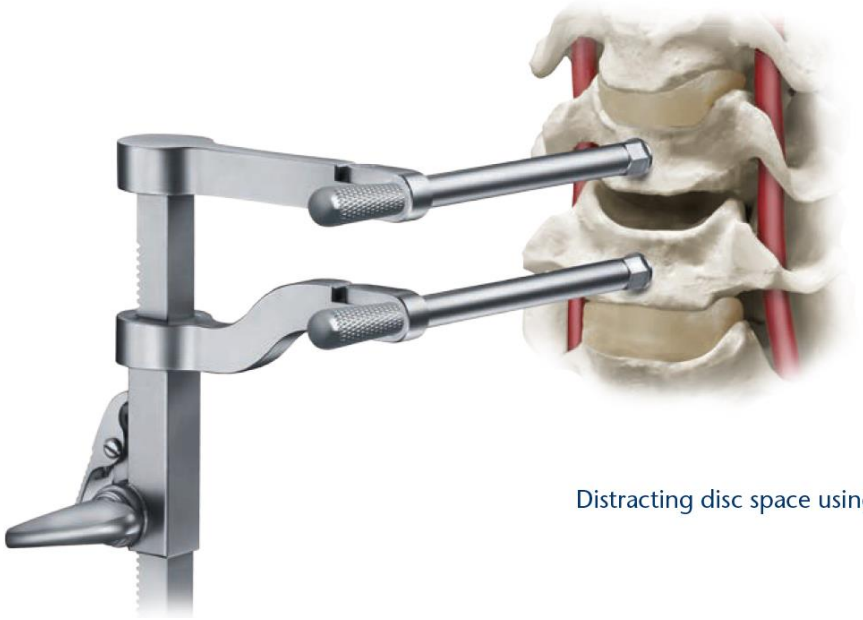
18mm 665.618

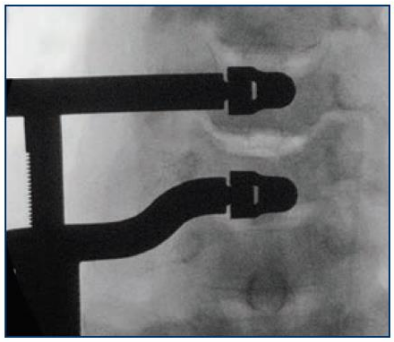






Placement of Distraction Pins

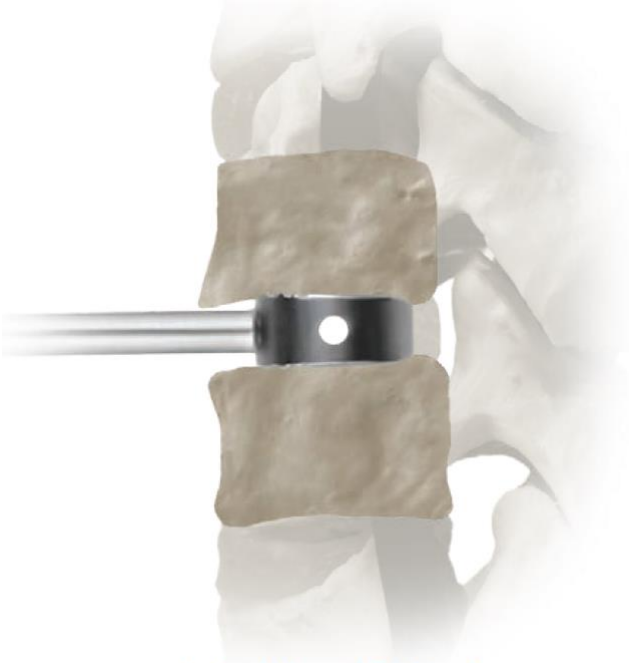




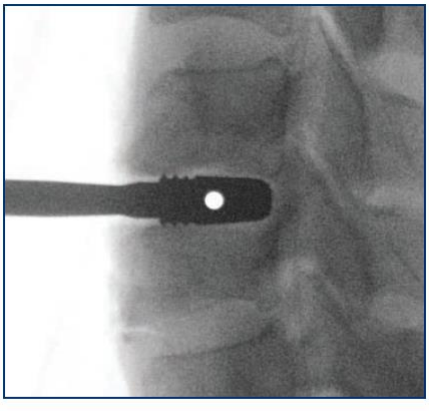
Distracting disc space using Distractor

1. TRIAL

In the lateral view, position the center hole of the Trial 1-2 mm posterior to the sagittal vertebral midline:



Lateral View of Trial in disc space



Radiographic image of Trial inserted

Optional - **Adjustable Trial Stop** - used only during trialing:

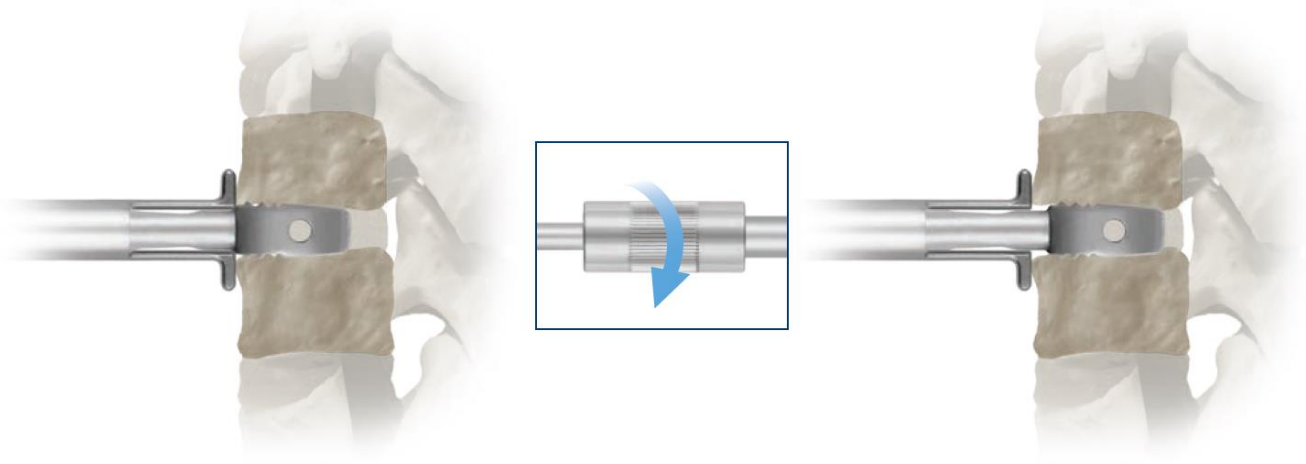
Adjustable Trial Stop 614.024

- slide Adjustable Trial Stop over Trial:

Adjustable Trial Stop over the Trial

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

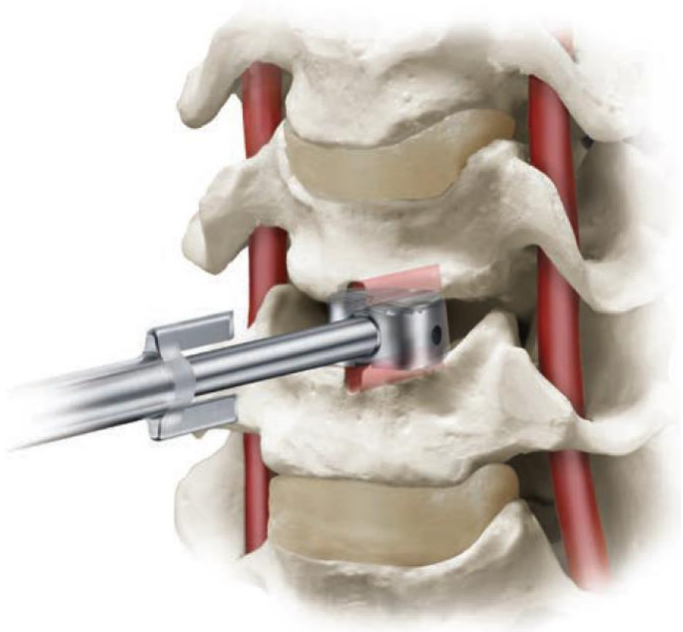
- adjust Adjustable Trial Stop forward by rotating the knurled end clockwise such that Trial is in proper position. One full rotation equals 1 mm.



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

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

2A. CHISEL



N.B. Correct positioning of the trial is critical prior to performing chisel cuts!

Broaching Chisel

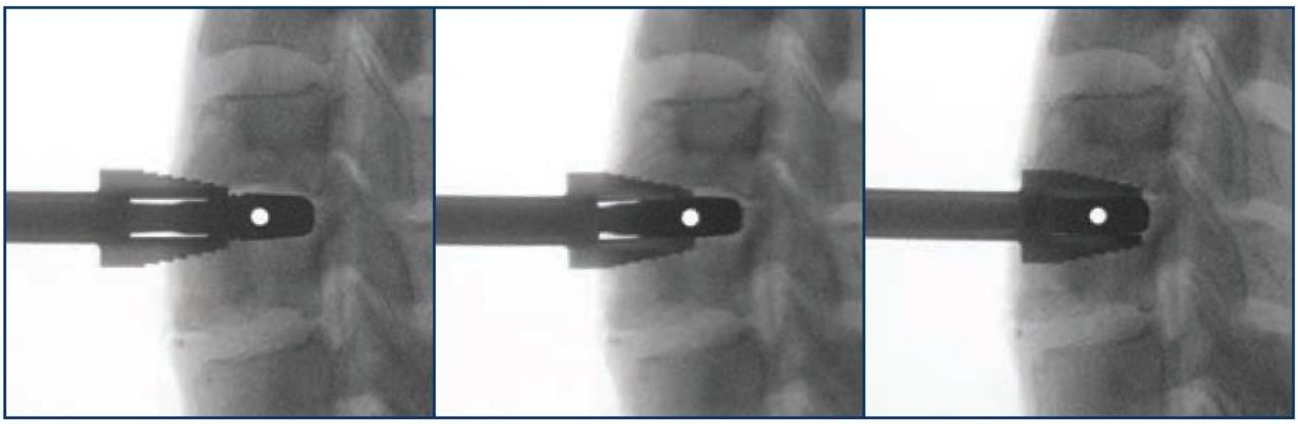
Keel Chisel

Keel Chisel, Narrow

Chisel End Cap 614.800

- to create the initial cut, select **Broaching Chisel** (removes cortical bone and creates initial cut).
- slide Chisel over Trial, attach Chisel End Cap to the back of the Chisel.
- gently tap Chisel End Cap with Hammer:

Broaching Chisel



- stop when the proximal end of Trial shaft is flush with impaction surface of Chisel End Cap:

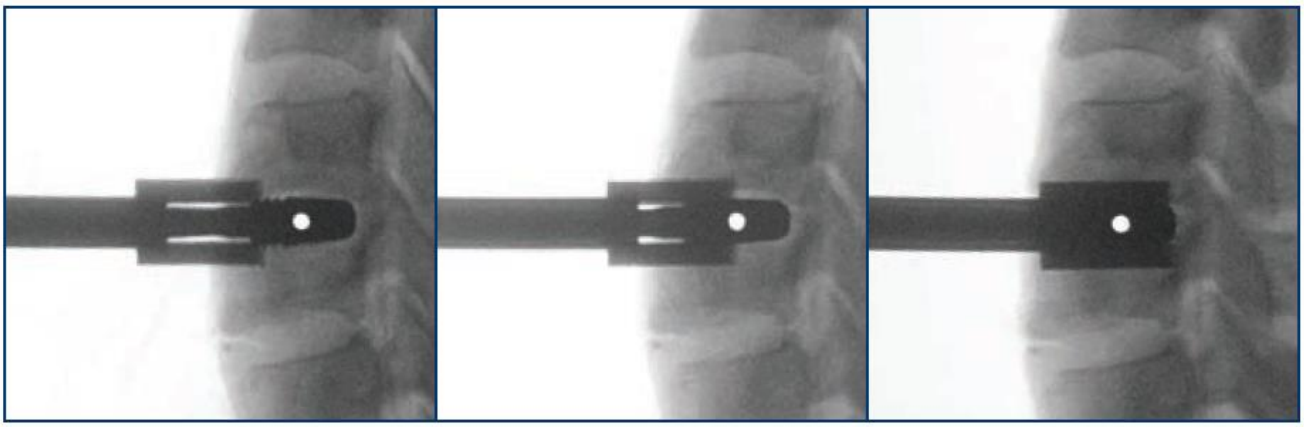
When Chisel End Cap reaches proximal end of the Trial, chisel is fully seated on Trial

- Chisel can be removed using Slide Hammer.
- repeat with the proper size **Keel Chisel**

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

Trial with chisel seated, for 11x12 Trials

Keel Chisel



- remove Trial.
- clear chisel cuts with Nerve Hook to ensure that all bony material is removed.
- if the vertebral cortex is particularly hard or sclerotic and Chisel does not readily cut into bone, a Mill may be used to perforate the cortex (see 2b).

N.B. always ensure that ***Trial position remains the same*** during and between chiseling or milling steps!

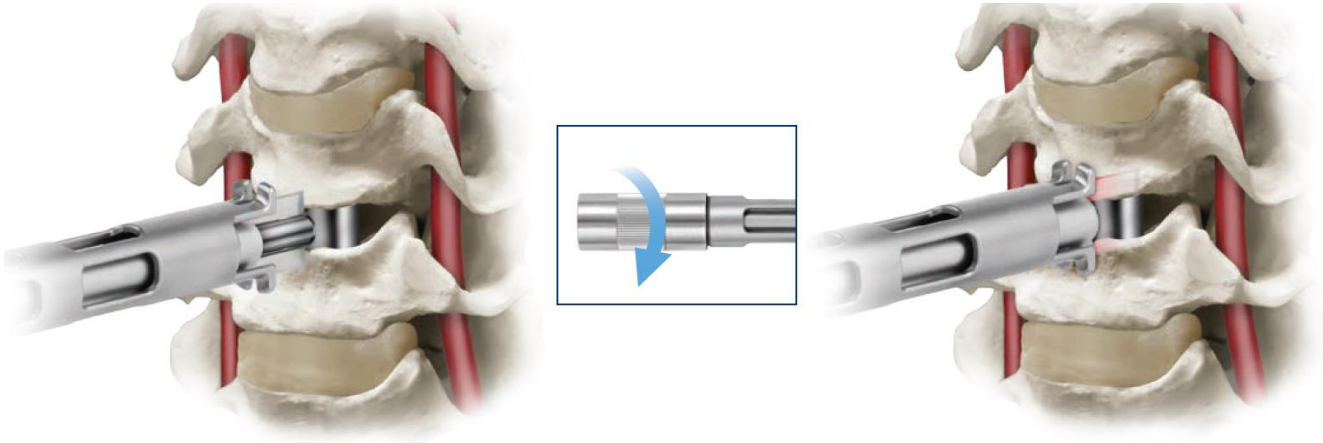
Optional - **Adjustable Chisel Stop**.

Adjustable Chisel Stop 614.025

- slide selected Broaching Chisel or Keel Chisel (corresponding to Trial height) over Trial:

Adjustable Chisel Stop over the Keel Chisel and the Trial

- move knurled end of Adjustable Chisel Stop fully backward by rotating counterclockwise.
- slide Stop over Trial.
- gently tap with Hammer.
- impact the knurled end of Adjustable Chisel Stop until it bottoms out on the vertebral body.
- advance Chisel over Trial by moving knurled end of Adjustable Chisel Stop forward (rotate clockwise) and gently tapping with Hammer.
- one full rotation of knurled end is equal to 1 mm.



- Chisel is fully seated when proximal end of Trial shaft is flush with impaction surface of Adjustable Chisel Stop:

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

2B. MILL

In the event of hard or sclerotic cortical bone, a Mill may be used to prepare for the chisel cut.

Milling guide:

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

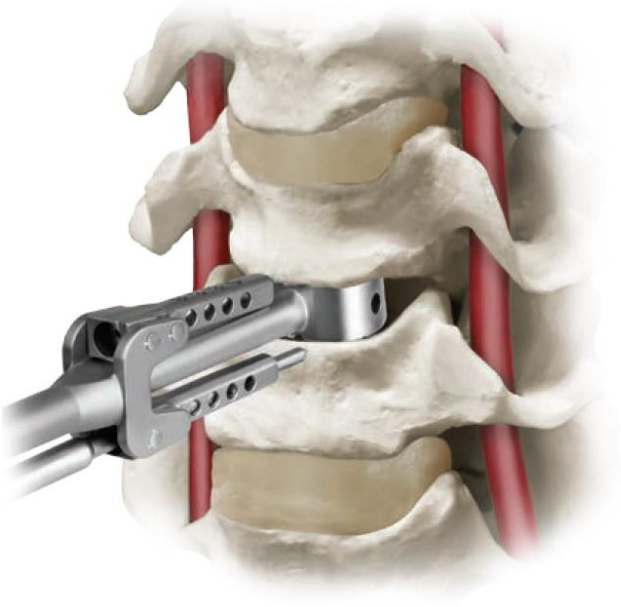
- slide Milling Guide over Trial shaft until the proximal end of Trial shaft is flush with the back of the mill:

- rotate the knurled end of Mill Guide Handle clockwise to tighten:

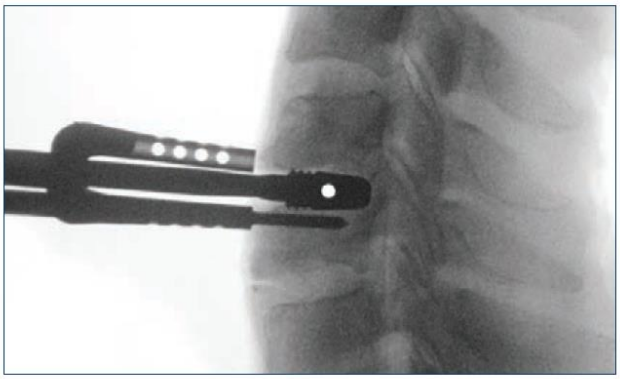
Mill Guide Handle 622.005

- insert Stabilizer Pin into the inferior or superior slot of the Milling Guide and gently tap into the vertebral body:

Stabilizer Pin 614.862



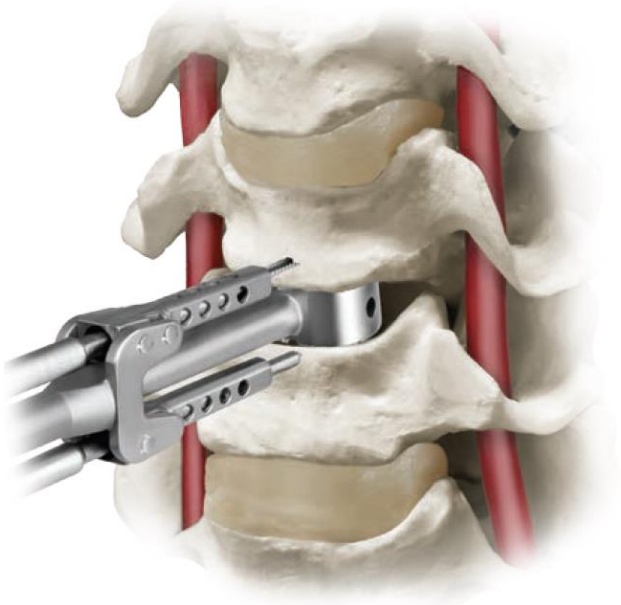
Stabilizer Pin inserted into the Milling Guide



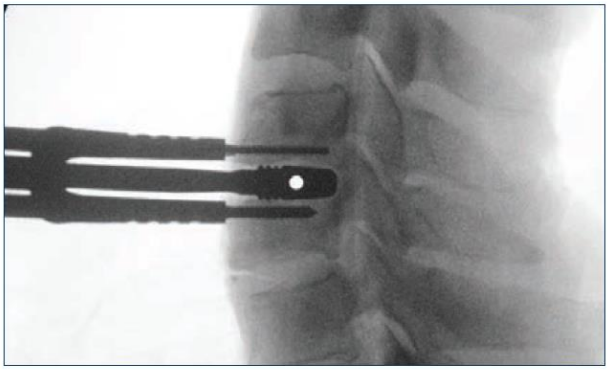
Lateral fluoroscopy image of Stabilizer Pin in the vertebral body

- 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:

Mill, Quick Connection 614.861



Mill Bit inserted into the Milling Guide

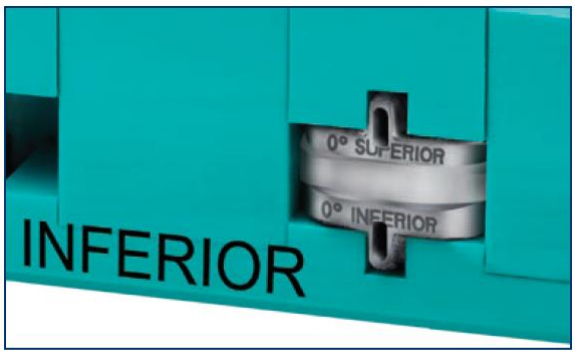


Lateral fluoroscopy image of Stabilizer Pin and Mill in the vertebral body

- 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.

3. INSERT

- 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':

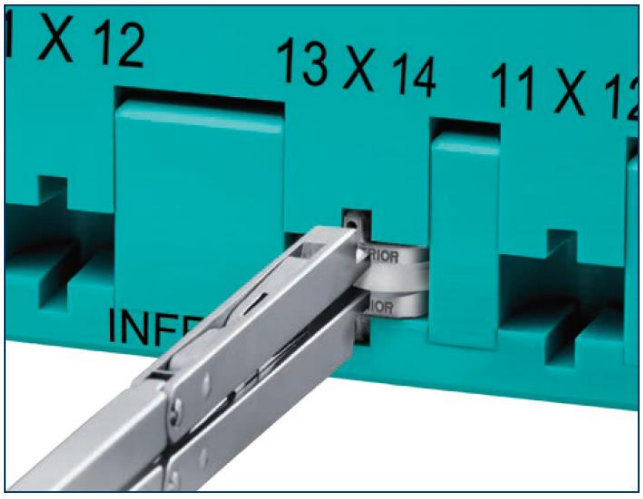


Implant Loading Block with implant correctly loaded

- 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

Narrow Implant Holder 614.805

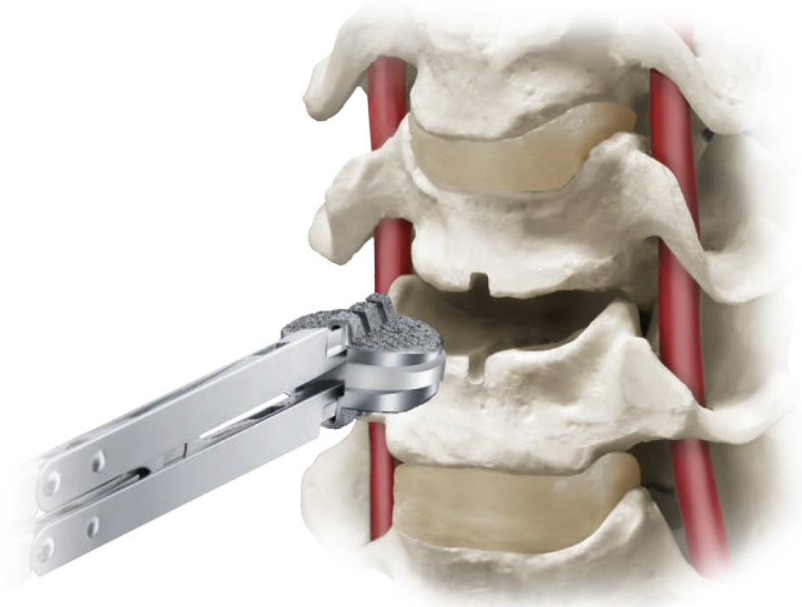
Implant Holder 614.906

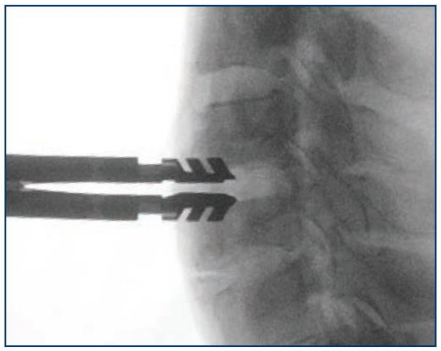


Attaching the Implant Holder

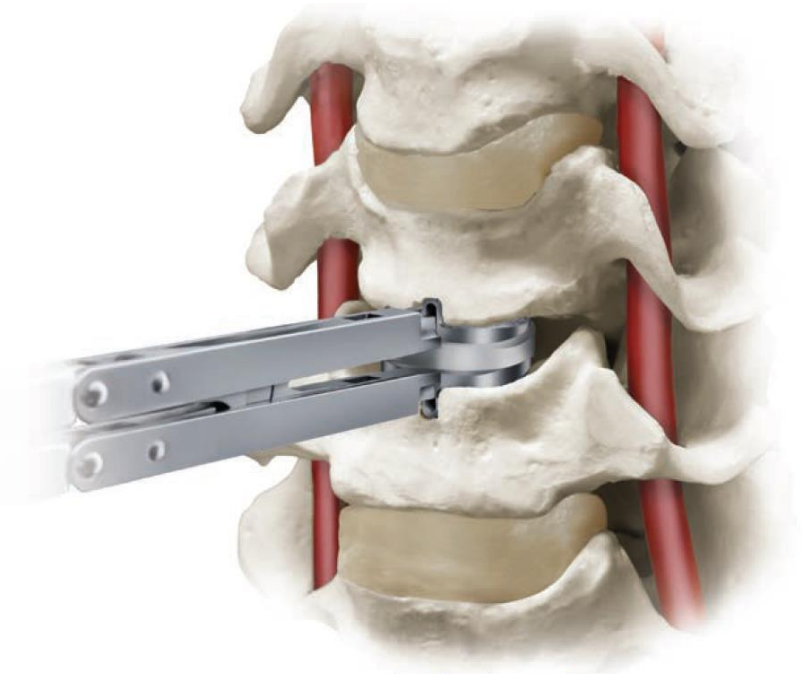
Implant loaded onto Holder in neutral position

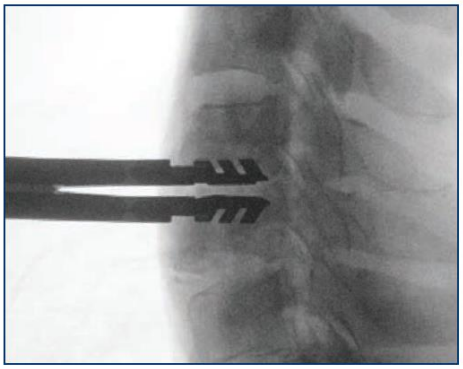
- implant assembly is inserted into the chisel cuts and gently impacted using the Hammer. Distraction may be used initially to open the space and ease insertion. Release distraction once the implant is partially inserted. The center of the implant should be positioned along the vertebral midline in the 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

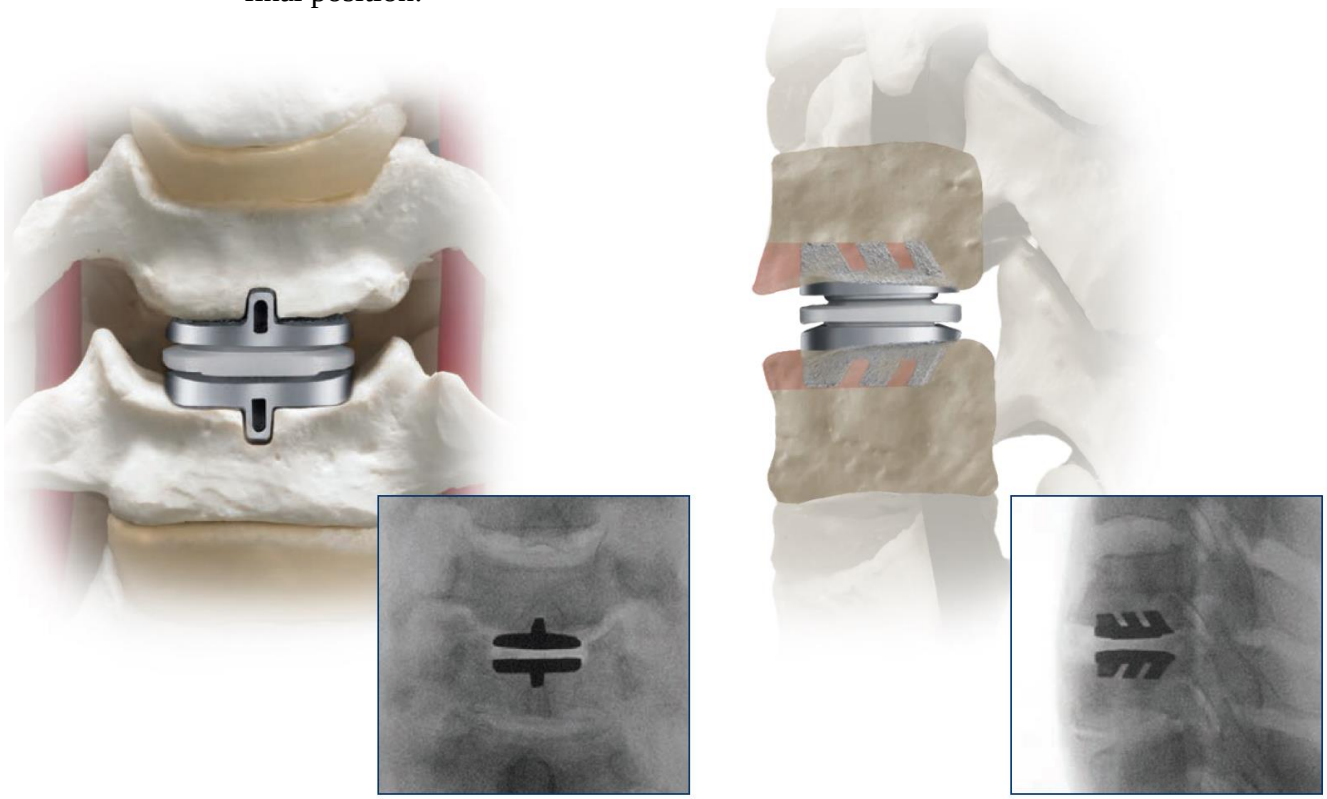
- to remove the Implant Holder from the implant, fully loosen the locking nut to release the handle.

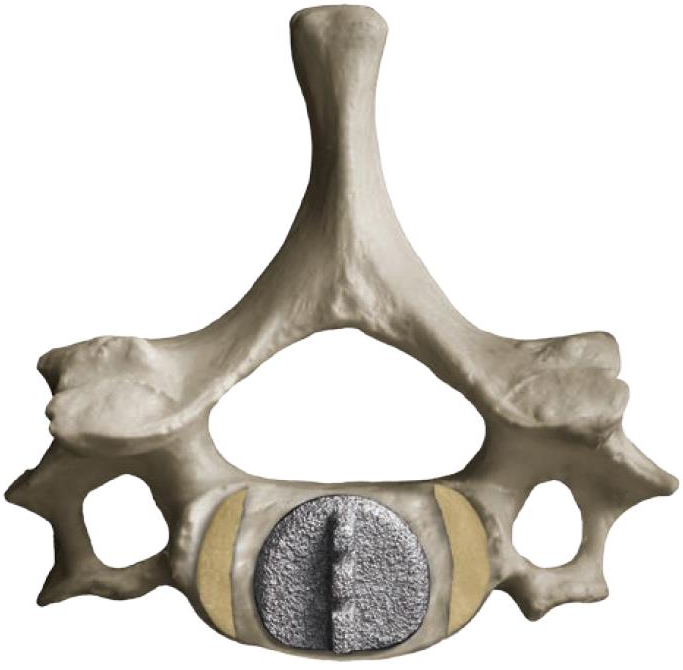
— if necessary, grip Implant Holder with two fingers and gently rock the holder slightly in the cephalad/caudal direction.

— distal tips of the Implant Holder will release from the implant.

N.B. do not rock Implant Holder in medial/lateral direction as tips may bend or break.

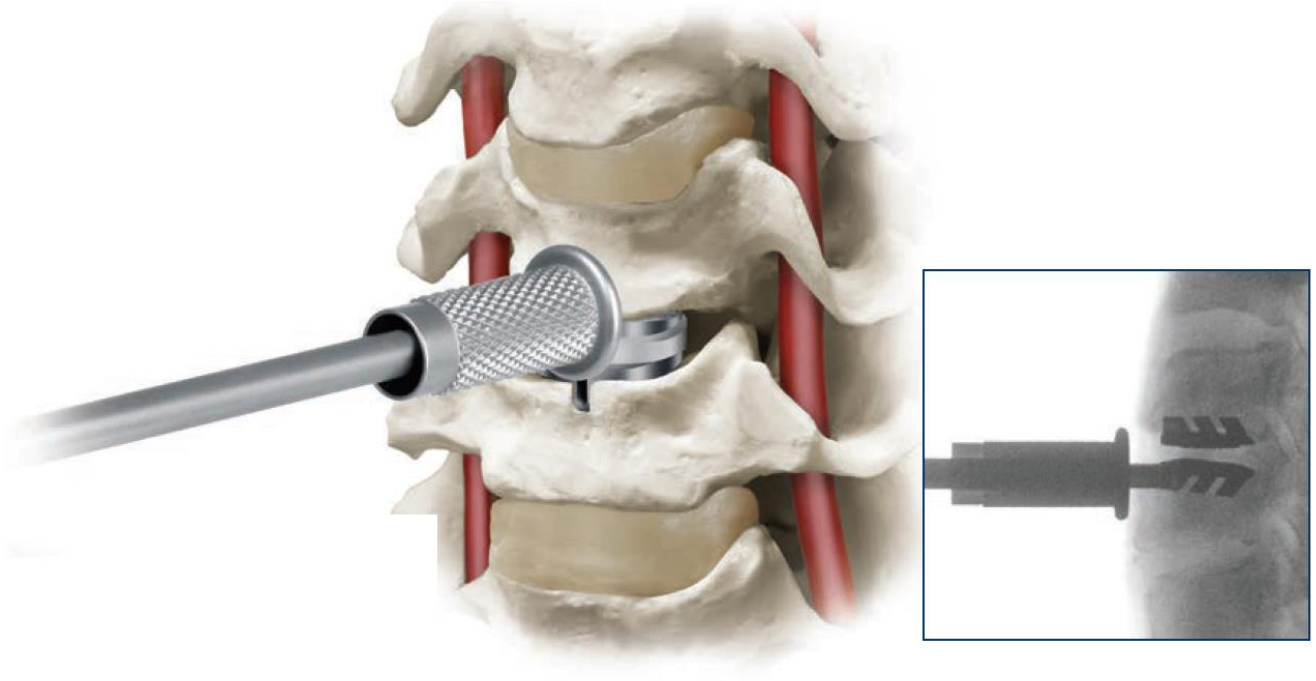
- final position:





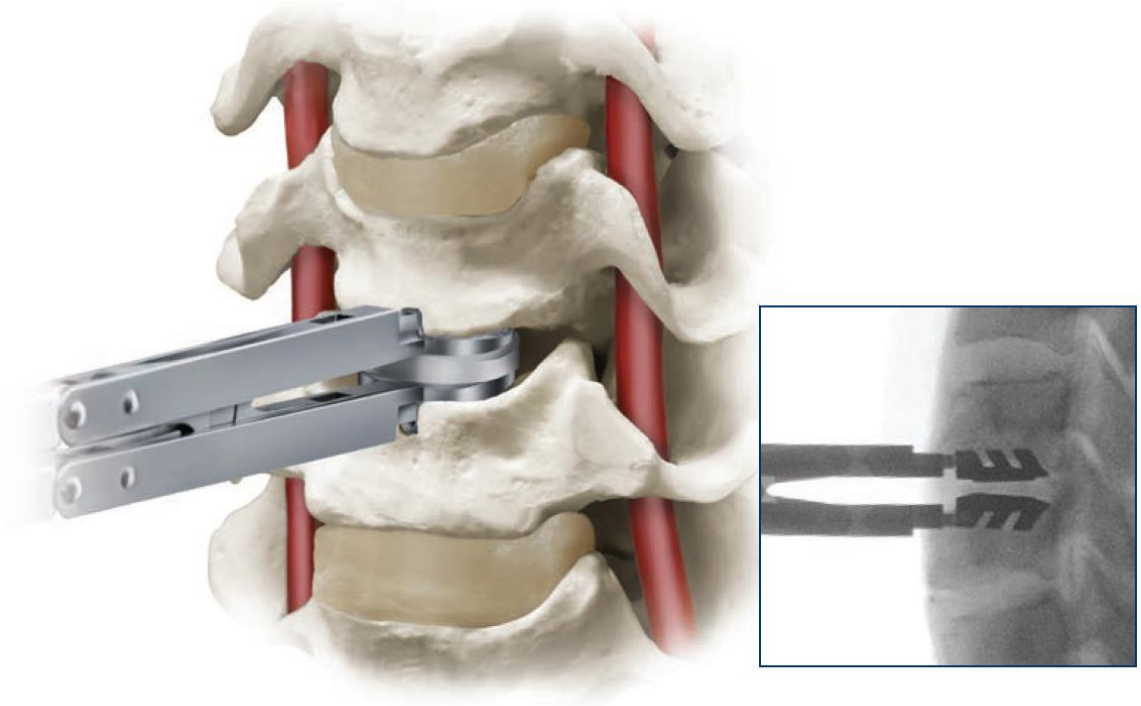
Optional – Implant adjustment by tapping with Positioner:

Single Endplate Positioner 614.019



Final positioning using Single Endplate Positioner

Double Endplate Positioner 614.017



Final positioning using Double Endplate Positioner

REMOVAL

- implant may be removed or revised using standard forceps or Kochers.
- in the event of significant bony ingrowth, Keel Chisels may be used to separate the implant endplates from the bone.
- do not use Implant Holder as a removal tool as the tips may bend or break.

OUTCOMES

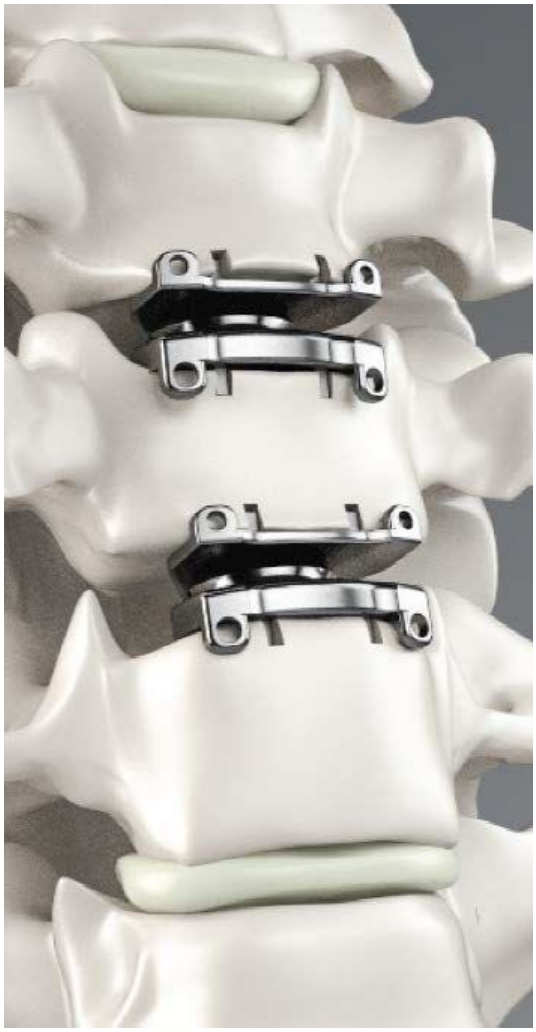
At 7 years

- mean ROM 9.1º, translation 1.1 mm
- reoperation rate – 4.2% (vs. 15.3% with ACDF)
- adjacent level surgeries – 4.7 % (vs. 16.0% with ACDF)

NUNEC™ (PIONEER SURGICAL TECHNOLOGY)

PRESTIGE (MEDTRONIC)

See brochures >>



Mobi-C cervical disc (ZIMMER-BIOMET, ex-LDR)

- brochure >>

DESIGN

- cobalt, chromium, molybdenum (CoCrMo per ISO 5832-12) alloy superior and inferior plates.
  N.B. no nickel – OK for patients with Ni allergy!
- ultra-high molecular weight polyethylene (UHMWPE per ISO 5834-2) mobile insert

- inner contact surfaces of the superior and inferior spinal plates are spherical and flat, respectively - fully congruent contact surfaces between the spinal plates and mobile insert.
- two lateral stops of the inferior plate controls and limits the mobility of the mobile insert.
- spinal plates feature two rows of teeth to allow for initial and long term fixation and stability.
- titanium (per ASTM F1580) and hydroxyapatite (per ISO 13779) plasma spray coating is applied to the bony interface surfaces of the superior and inferior spinal plates.

Mobi-C disc has three parts:

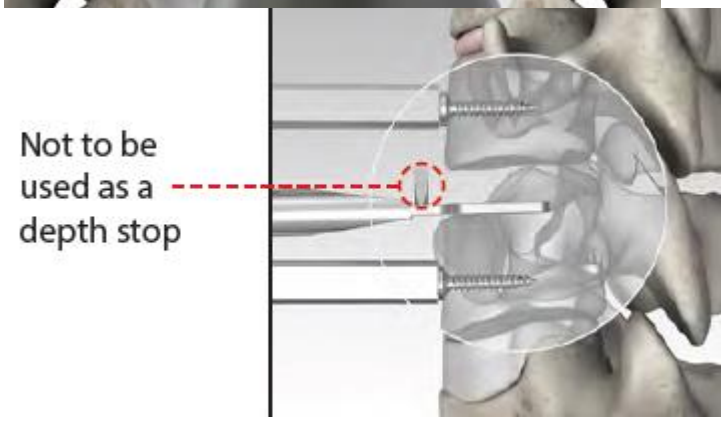
1. Two **metal plates**:
   - plates are made of a mix of metals (cobalt, chromium, and molybdenum).
   - plates have teeth on top and bottom that help hold plates to vertebrae.
   - teeth are pressed into bone with no bone cut out - bone sparing technique.
   - outside of metal plates are sprayed with coating (hydroxyapatite) - helps vertebrae to grow and attach to metal plates for long term stability.
2. **Plastic insert** - made from polyethylene.
   - insert is flat on bottom and round on top.

- Mobi-C comes preassembled on a disposable radiolucent PEEK cartridge.

TRIAL

WIDTH

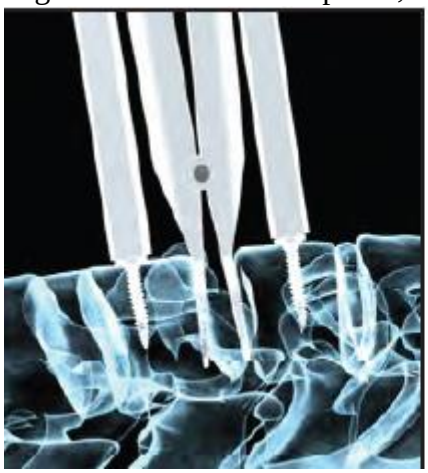
- insert the Width Gauge ("fork") into the disc space under lateral fluoroscopy.
- Width Gauges correspond to the implant widths of 15, 17, and 19 mm.
- position the Width Gauge flat on the inferior endplate in contact with the base of the uncus bilaterally (shape uncus with drill bit as needed).
- if the Width Gauge can be moved side-to-side more than 2 mm, trial the next larger width.
- the center reference point, located on the Width Gauge, confirms location of the vertebral midline; it is *not a depth stop and should not come in contact with the anterior face of the vertebra*:

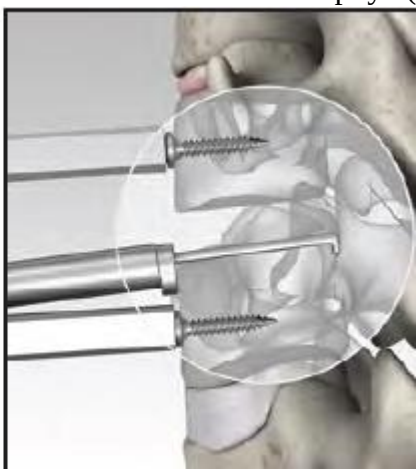


DEPTH

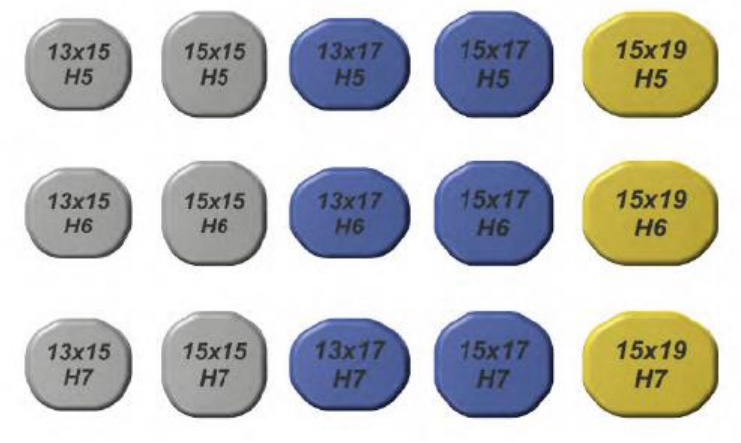
It is extremely important to achieve <u>complete A/P coverage</u>.

- implants only come in 13 and 15 mm depths.
- Depth Gauge is available for depth measurement - place the hook of the gauge over the posterior edge of the vertebral endplates; do not include anterior osteophyte(s) in judgment of depth:





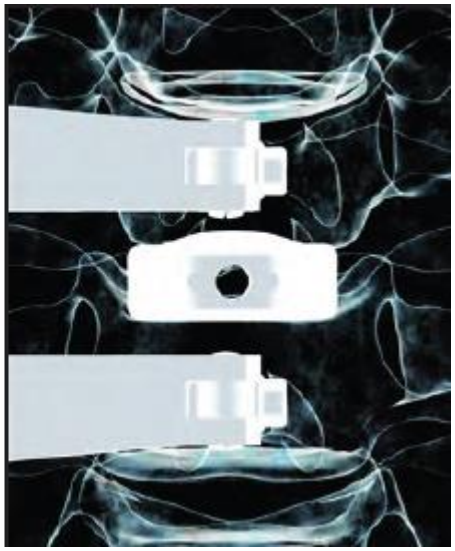
HEIGHT



Implant footprints include (in mm):

Depth	13	13	15	15	15
Width	15	17	15	17	19

- each footprint size is color coded by width.
- heights are available in 5, 6, and 7 mm.
- trialing should begin with the smallest height first (5 mm) and should not exceed the height of healthy adjacent discs.
- 85% of implanted Mobi-Cs are 5 mm, rarely a 7 mm.
- insert Trial → release the Caspar Distractor → lateral X-ray to validate height and depth selection and an A/P X-ray to assess central placement and width; holes in the Trial, front and side, facilitate verification of position (center and rotation).
- do not overstuff height - reference healthy adjacent discs and facets.
- if the inferior endplate of the superior vertebra is flat, use a curette to prepare room for the dome of the device.
- Trial Implant Holder can be removed to take an unobstructed A/P X-ray, then re-engaged for Trial removal.



IMPLANTATION

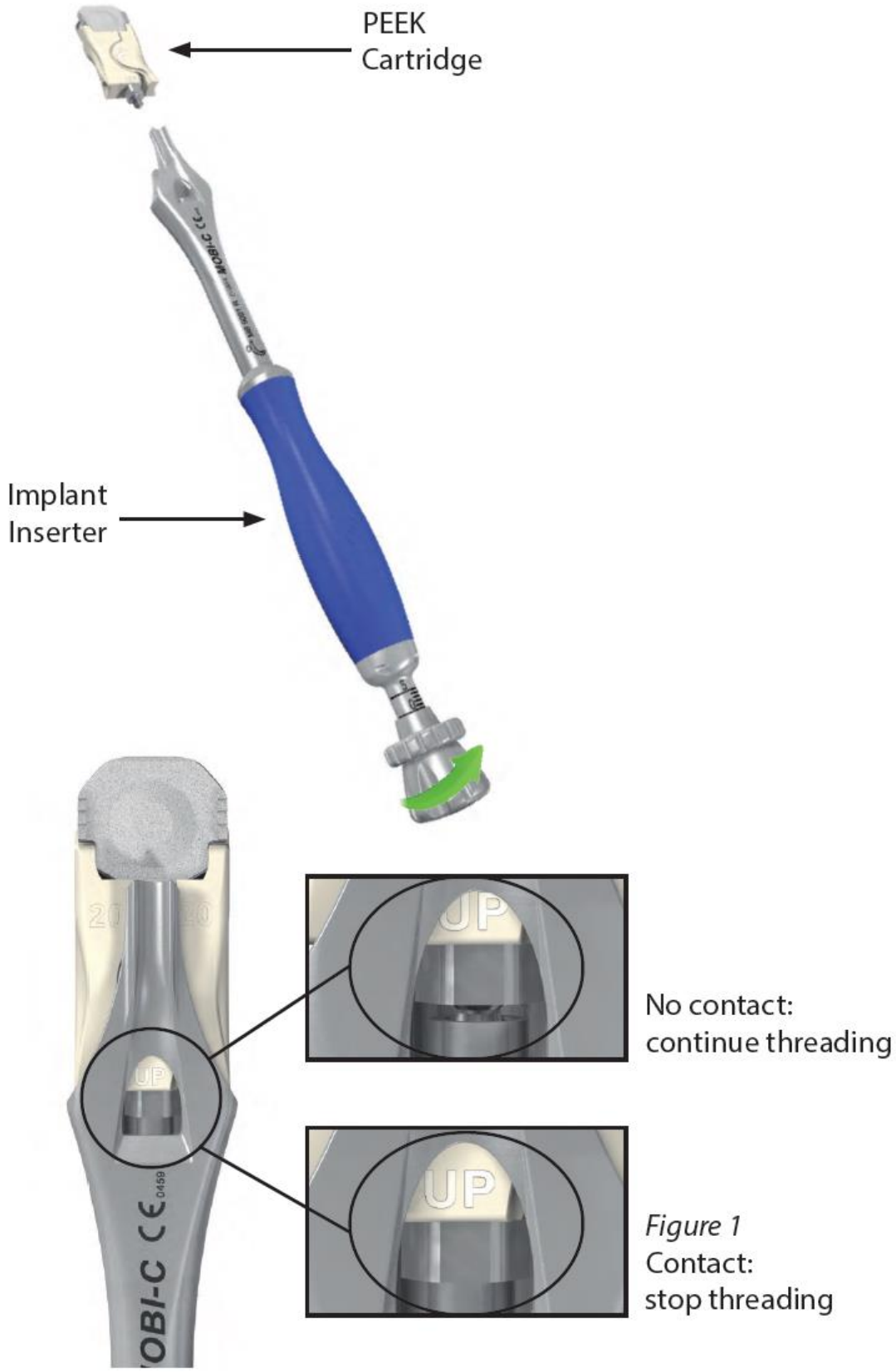
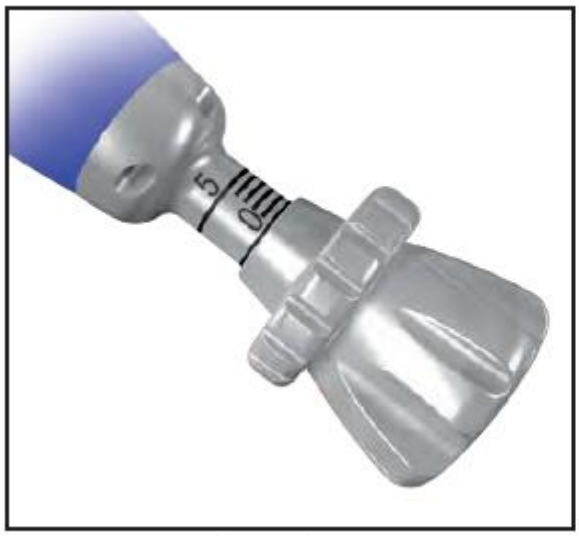


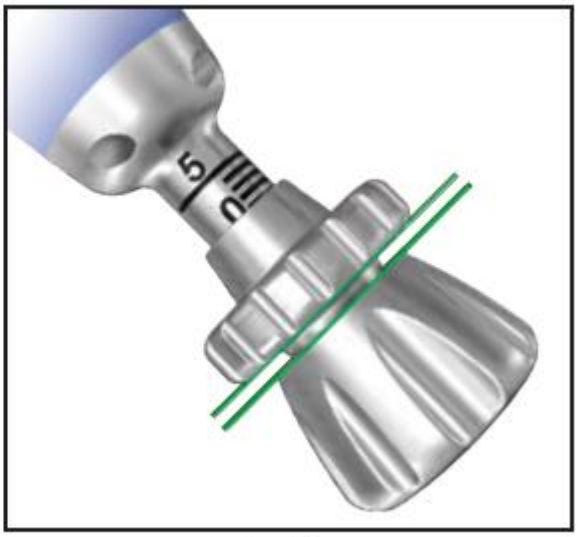
Figure 1

- load the preassembled implant assembly onto the Implant Inserter. Turn the impaction knob on the Implant Inserter until the cartridge screw is completely threaded onto, and just in contact with the Implant Inserter.
- visual control of contact can be confirmed using the window.
- on the Implant Inserter. **The word "UP",** indicating the top of the device, **becomes completely visible** when the correct position is obtained.
  Important: stop threading as soon as full contact is achieved - to avoid premature opening of the PEEK cartridge and releasing the implant.

DEPTH STOP ADJUSTMENT



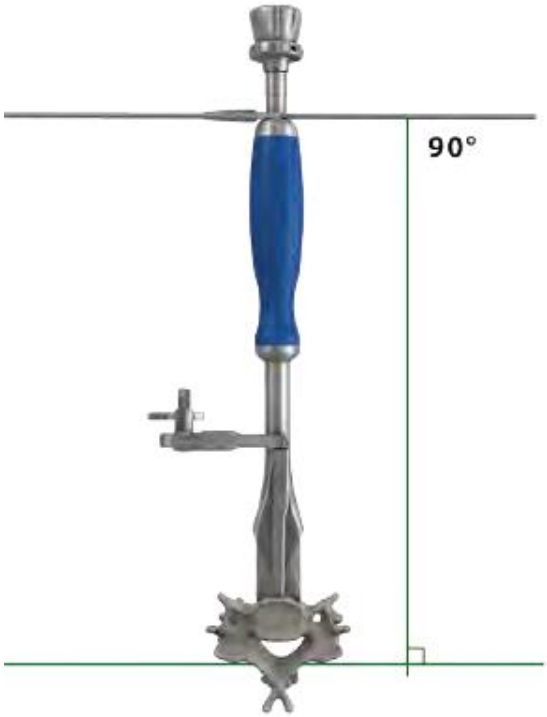
Set at 0mm

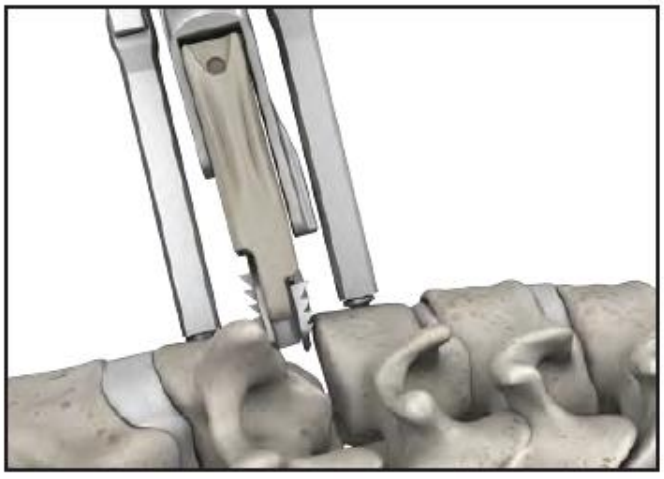


Set at 1mm

- Implant Inserter has a depth stop adjustment collar, which should be set initially at zero; zero setting will place the anterior edge of the implant flush with the anterior aspect of the vertebral body.
- depth stop allows for setting the insertion depth of the device from 0 to 5 mm.
- stop adjustment is indexed, one full turn (360°) equals 1 mm.
- at each full turn of the depth stop collar, there is a tactile feel of the ball detent dropping into a groove.

VERIFY INSERTION TRAJECTORY

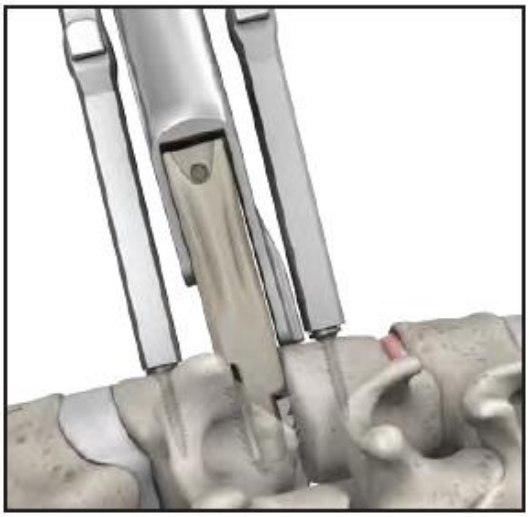




- position the Implant Inserter in the A/P axis of the disc. This position can be verified visually; the groove on the Implant Inserter should align with midline.
- in order to verify the correct position and axial rotation about the transverse plane of the Implant Inserter, use the **Inserter Level** – it should be parallel to the OR table.
- it is important to set the correct axial rotation prior to impacting the device into the disc space. Axial rotation maneuvers of the device should be avoided once the device is in the disc space.

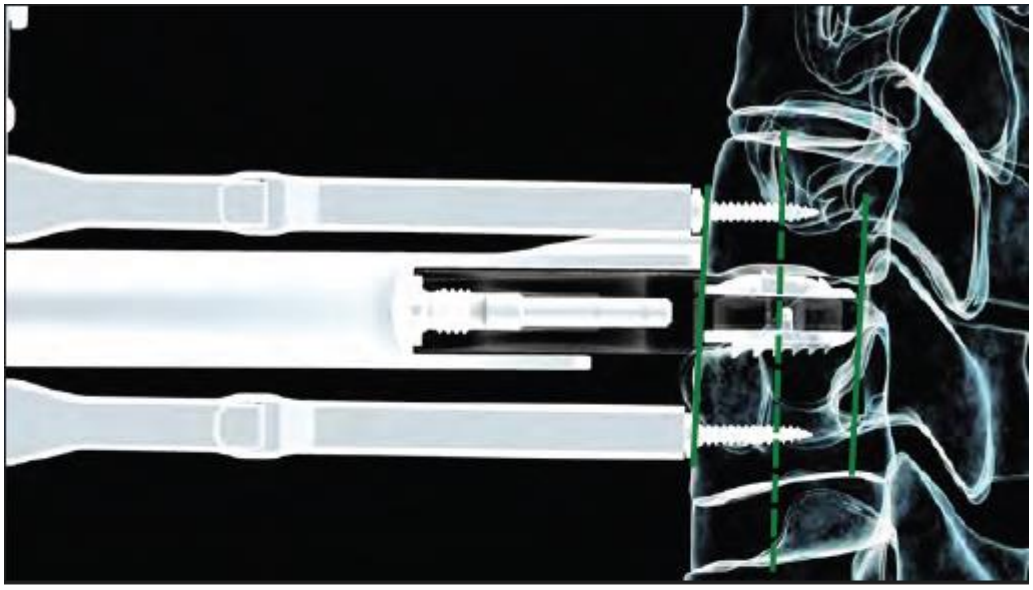
DEVICE INSERTION

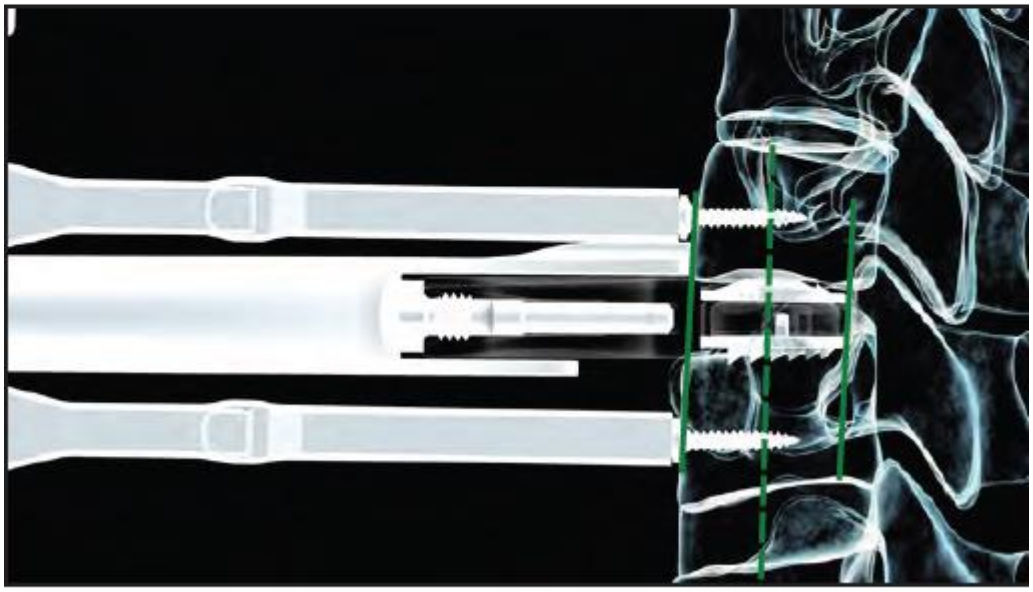
*Note: Take care to center the device on the vertebral endplates.



- under fluoroscopy, insert the device progressively into the disc space by tapping lightly on the Implant Inserter's impaction knob with a mallet until the device is centered on the vertebrae anterior-posterior and medial-lateral.
- implant should be centered, regardless of endplate coverage.
- during and after insertion, avoid lateral and rotational movements of the implant-to-PEEK cartridge assembly.
- if at any time prior to achieving final position the implant comes apart from the PEEK cartridge, *do not attempt to reassemble*. Select and use a new pre-assembled implant.
- if reinsertion is needed, check implant assembly to PEEK cartridge before reinsertion.

POSITION VERIFICATION - LATERAL VIEW





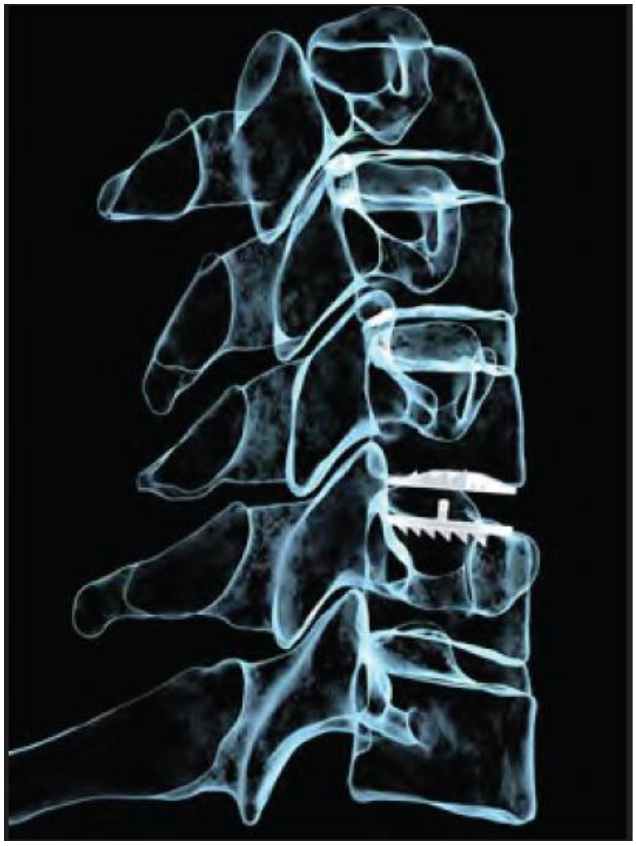
*Note: Tabs are 0.5mm posterior to the device midline.

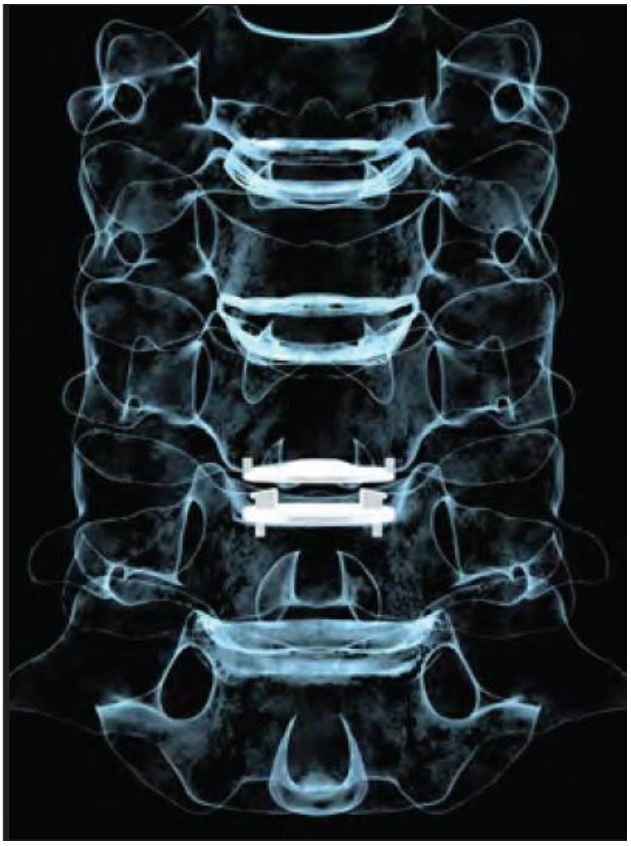
- use fluoroscopy to assess implant position.
- release the Caspar Distractor to permit the vertebral endplates to align in parallel.
- from the lateral view, assess the implant's A/P position.
- if necessary, the posterior position of the device in the intervertebral space can be adjusted - adjust the Implant Inserter's depth stop knob, mallet lightly on the Implant Inserter's impaction knob until the desired posterior position is achieved. The implant should be centered.
- alignment of the tabs* on the inferior plate is used to assess the position of the device in rotation. Two tabs can be seen if the device is rotated.

  N.B. if necessary to correct a rotated device or for lateral implant adjustments, ***distraction of the disc space is required*** to prevent implant-to-PEEK cartridge disassembly in situ.

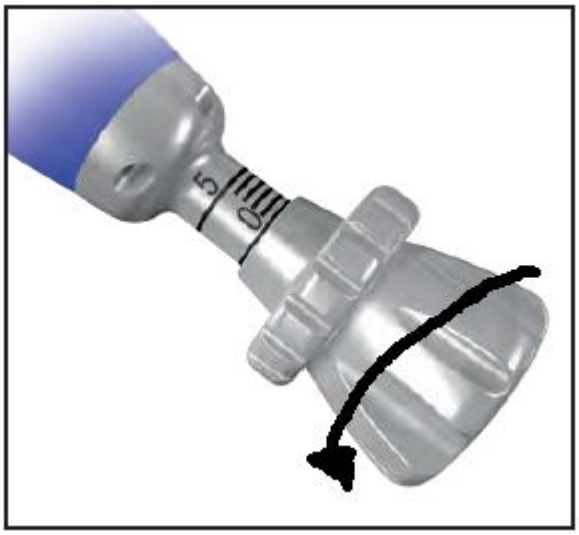
FINAL POSITION ASSESSMENT

- always do A/P and lateral fluoroscopy to confirm correct positioning of the device:





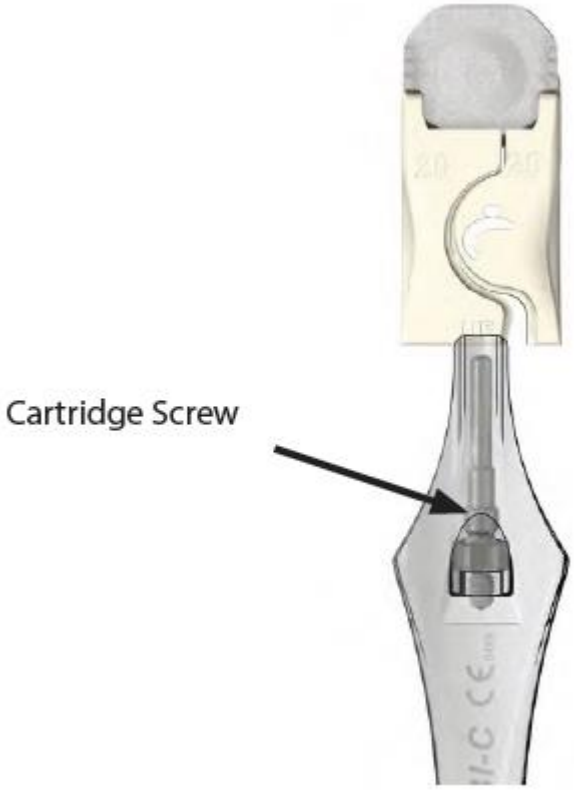
N.B. for AP view, need to remove inserter but leave **pin** inside PEEK cartridge (in case will need to pull implant for readjustment) – undo big knob counterclockwise:

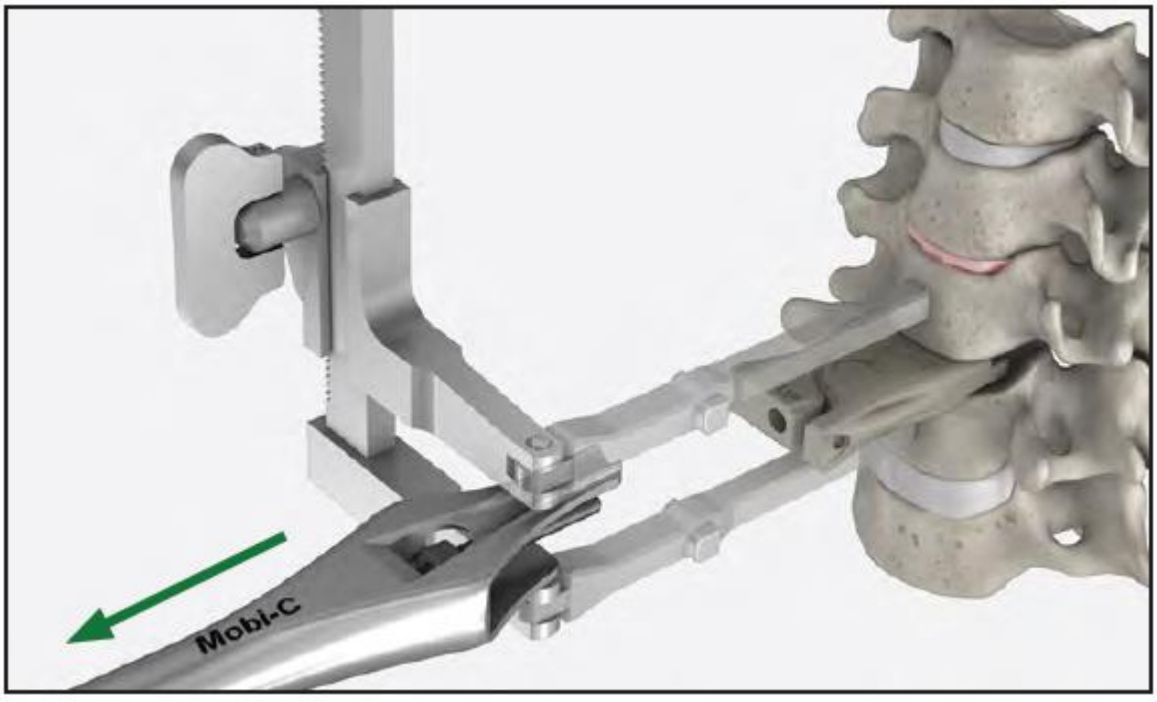


To reengage inserter, turn big knob clockwise; keep turning further with blue donut to completely disengage **pin** from PEEK cartridge (**pin** has a reverse thread) – see below ↓

IMPLANT INSERTER REMOVAL

*Note: Never use the Unlocking Key while loading the device.

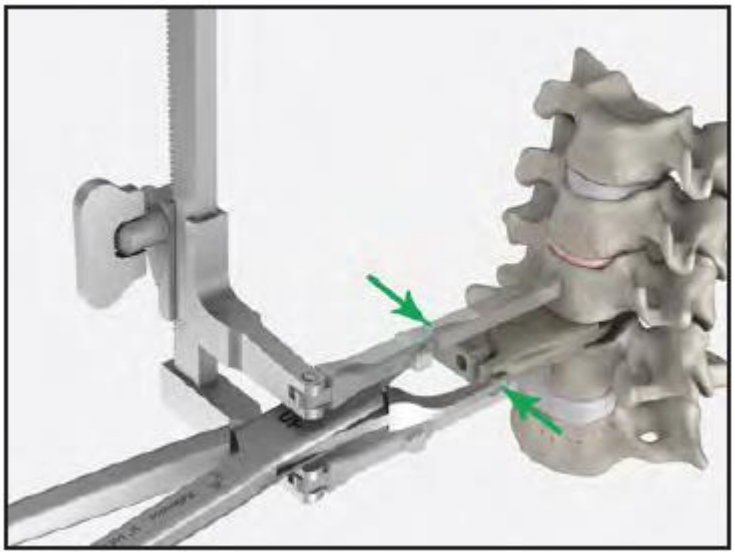


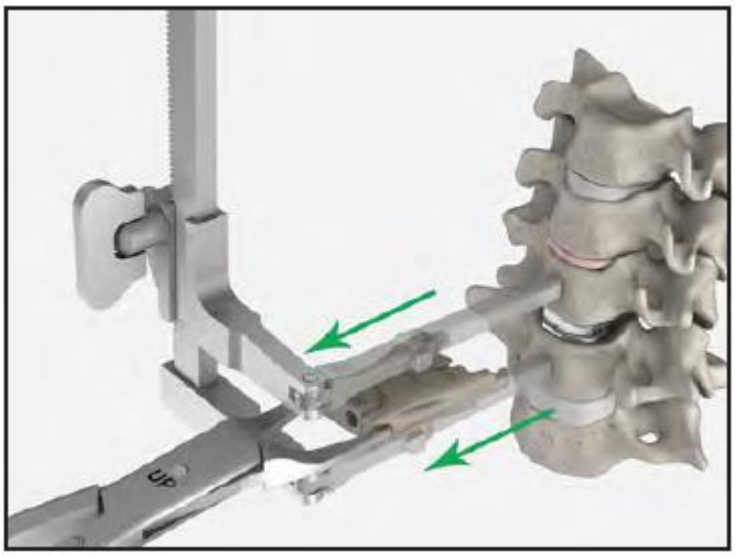


- Once optimal device position is confirmed and the Caspar Distractor is released, apply initial ***Caspar Distraction compression to set lateral implant teeth into the bone***. This will help keep the device in place during PEEK cartridge disassembly and removal.
- Turn the Implant Inserter impaction knob **clockwise** with the help of the Unlocking Key (MB9073R) in order to release the cartridge screw.* **Turn Unlocking Key approximately 20 times** to fully release the screw from the PEEK cartridge (continue to turn until the cartridge screw is completely released from the PEEK cartridge)
- removal of the cartridge screw releases the PEEK cartridge, allowing the Implant Inserter to be disengaged from the cartridge. Carefully remove the Implant Inserter in a straight line. Take care not to move the implant.

PEEK CARTRIDGE REMOVAL

- Using the **Extraction Forceps** (MB9075R), grasp the proximal ends of the two piece PEEK cartridge at the side notches. Take care not to move the implant.
- Squeeze the forceps to release the PEEK cartridge from the implant, then extract the cartridge by pulling back the forceps along the axis of the disc.* The PEEK cartridge is disposable.





*Note: If the PEEK cartridge is difficult to extract, **rotate one side of the cartridge 90° caudal**, then remove with forceps. Repeat on the remaining side:

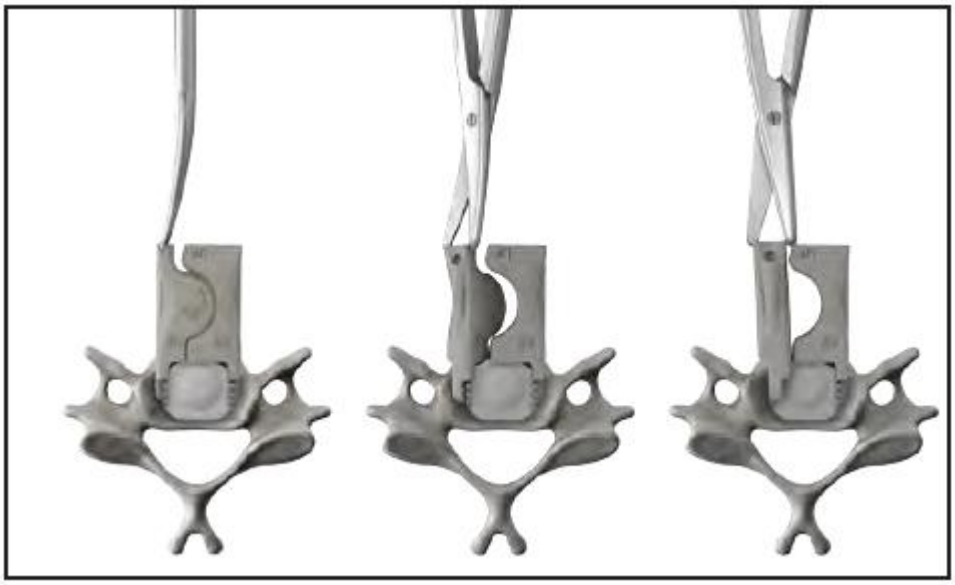
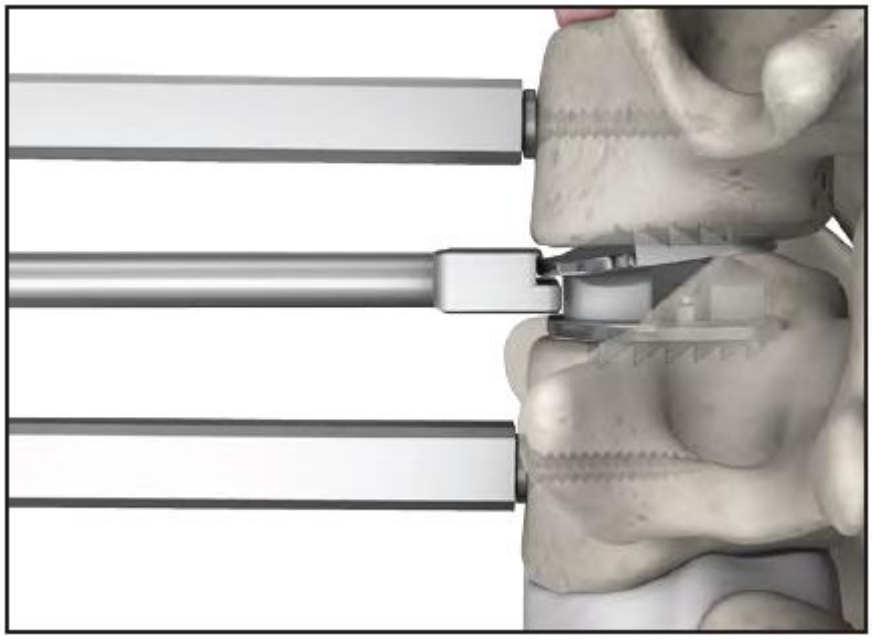


PLATE ADJUSTMENT

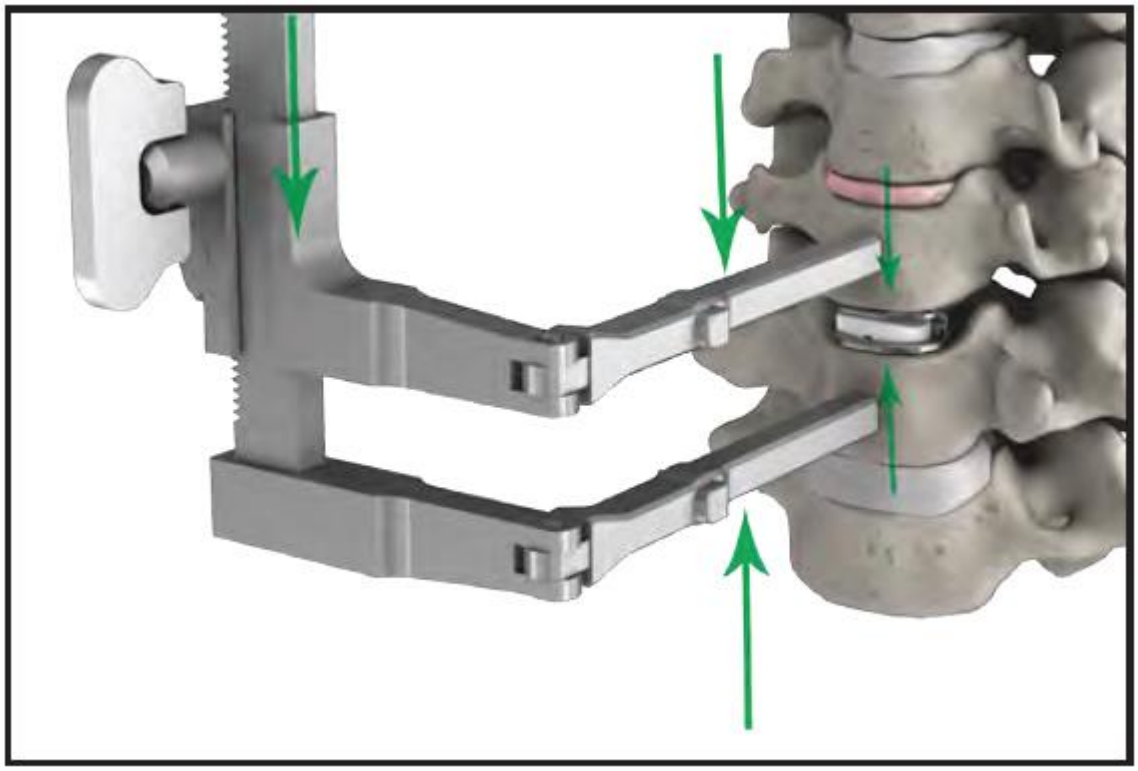
N.B. ***flex and extend neck intraop under fluoro*** to see how plates behave and if need adjustment!

- if after removing the PEEK cartridge one or both of the plates require adjustment, the **Plate Impactor (Tamp)** (MB942R) can be used to adjust the posterior position of an individual plate. Confirm position under fluoroscopy before and after plate adjustment.
- orient the longer lip of the Tamp toward the anterior face of the mobile polyethylene insert. Gently mallet the handle of the Tamp to push the plate posterior.



FINAL VERTEBRAL COMPRESSION

- Once final position is confirmed, apply firm compression using the Caspar Distractor to seat the implant teeth into the vertebrae (does not need to fully go into bone – it will subside postop over time). In a two-level case, perform compression at each level separately.
- Once the compression is achieved, remove the Caspar Distractor.
- Remove all the Caspar Pins. ***Place bone wax as needed in the holes created by the pins*** to reduce bleeding and on any anterior bone surfaces exposed during osteophyte removal.



REMOVAL OF CARTRIDGE SCREW

(by scrub tech on the back table)

- remove and dispose of the cartridge screw by pulling back and unscrewing **counter-clockwise** the Implant Inserter's impaction knob. Removal of the cartridge screw is required for cleaning and in two-level cases for the attachment of a new PEEK cartridge to the Implant Inserter.

1. Pull back handle to seat screw.

2. Rotate handle counter-clockwise.

3. Separate screw from Inserter.

Considerations for 2-level surgery

- place Caspar Pin in the intermediate vertebral body mid-distance between endplates.
- trial and complete implantation of one level.
- leave the Caspar Pin in the middle vertebral body and move the most inferior or superior pin to the opposite most inferior or superior vertebral body. Then repeat the steps described previously in this document for insertion of the first Mobi-C implant:
    - Attach the Caspar Distractor to the pins and distract to access the second disc.
    - Complete the discectomy.
    - Measure the width and depth.
    - Trial to determine the height and final implant size.
    - Assemble a Mobi-C to the Implant Inserter.
    - Insert the Mobi-C.
    - Verify the implant's position via radiographic visualization.
    - Apply **light Caspar Distractor compression** and then remove the Implant Inserter and the PEEK cartridge.
    - Assess final position of both implants via radiographic visualization.
    - Apply **firm vertebral compression with the Caspar Distractor** to seat the implant teeth into the vertebrae.

SPECIAL SITUATIONS

Mobi-C is *not approved to be combined with ACDF*;

Indications to convert to ACDF intraop (place ROI-C in that level):

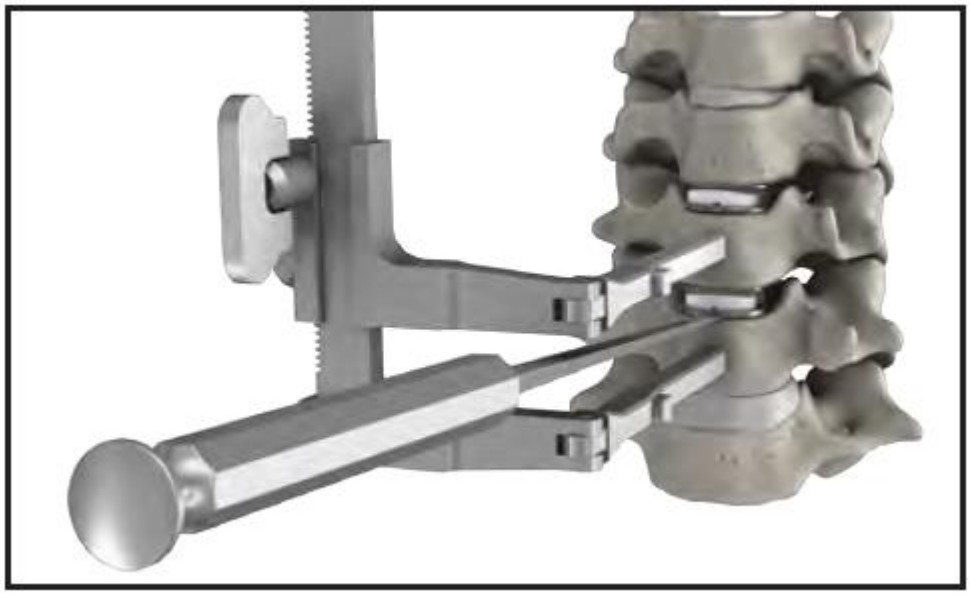
1) too much endplate was removed
2) inability to visualize on XR the index level

Implant removal for revision

- don't need any proprietary instruments.
- apply distraction on Caspar pins.
- using fine osteotome, detach superior titanium plate from bone and remove it with needle holder.
- then the same maneuver on inferior titanium plate.

From User Manual

- DISTRACTION - centrally insert Caspar Pins above and below both endplates. Attach the Caspar Distractor to the pins and distract using the knob. Take care to not over distract, when adjusting the height for implant removal.
- IMPLANT REMOVAL - using a Penfield #4 or thin osteotome, loosen the inferior bone to implant interface. Hook the tips of the Extraction Forceps (MB9075R) posterior to the tabs on the inferior plate. Remove the inferior plate and mobile insert together, taking care to stay in the axis of the intervertebral space.



- using a Penfield #4 or thin osteotome, loosen the superior bone to implant interface. Grab the anterior edge of the superior plate using a Needle Holder. Remove the plate from the disc space.

STUDIES

Kris Radcliff "Replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial" J Neurosurg Spine March 25, 2016

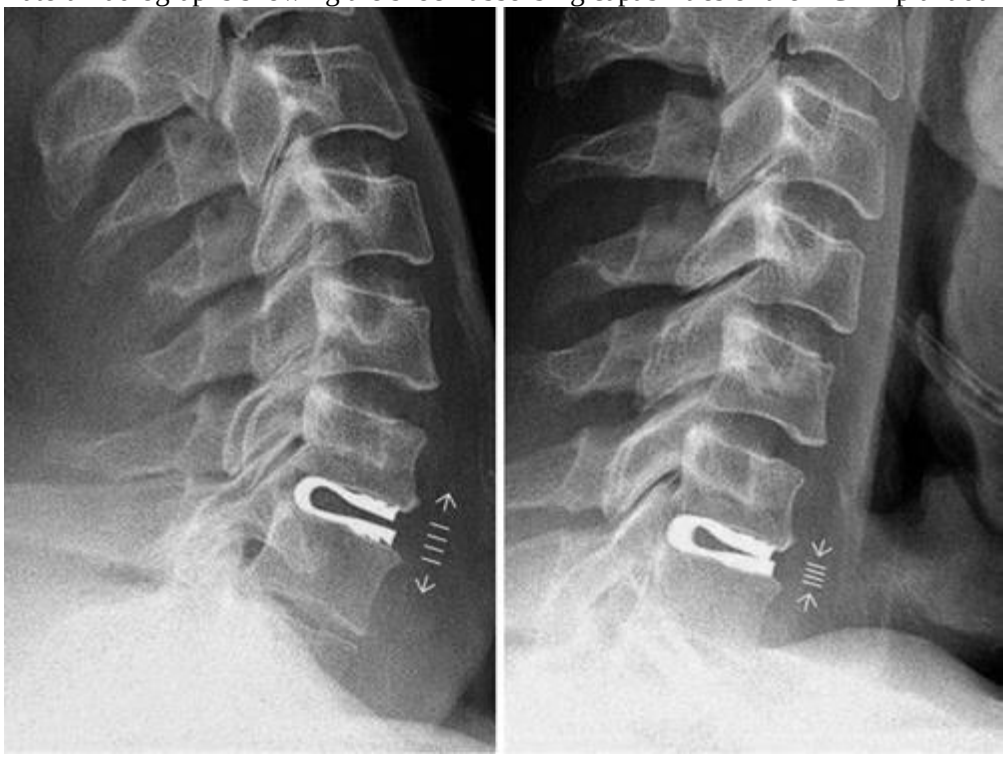
- 5-year results of a prospective, randomized US FDA investigational device exemption (IDE) study
- 24 centers
- 2-level, contiguous, cervical spondylosis.
- 225 patients received the Mobi-C and 105 patients received ACDF.
- Mobi-C patients had significantly more improvement than ACDF patients in terms of Neck Disability Index score, SF-12 Physical Component Summary, and overall satisfaction with treatment at 60 months.
- reoperation rate was significantly lower with Mobi-C (4%) versus ACDF (16%).

- no significant differences in the adverse event rate between groups.

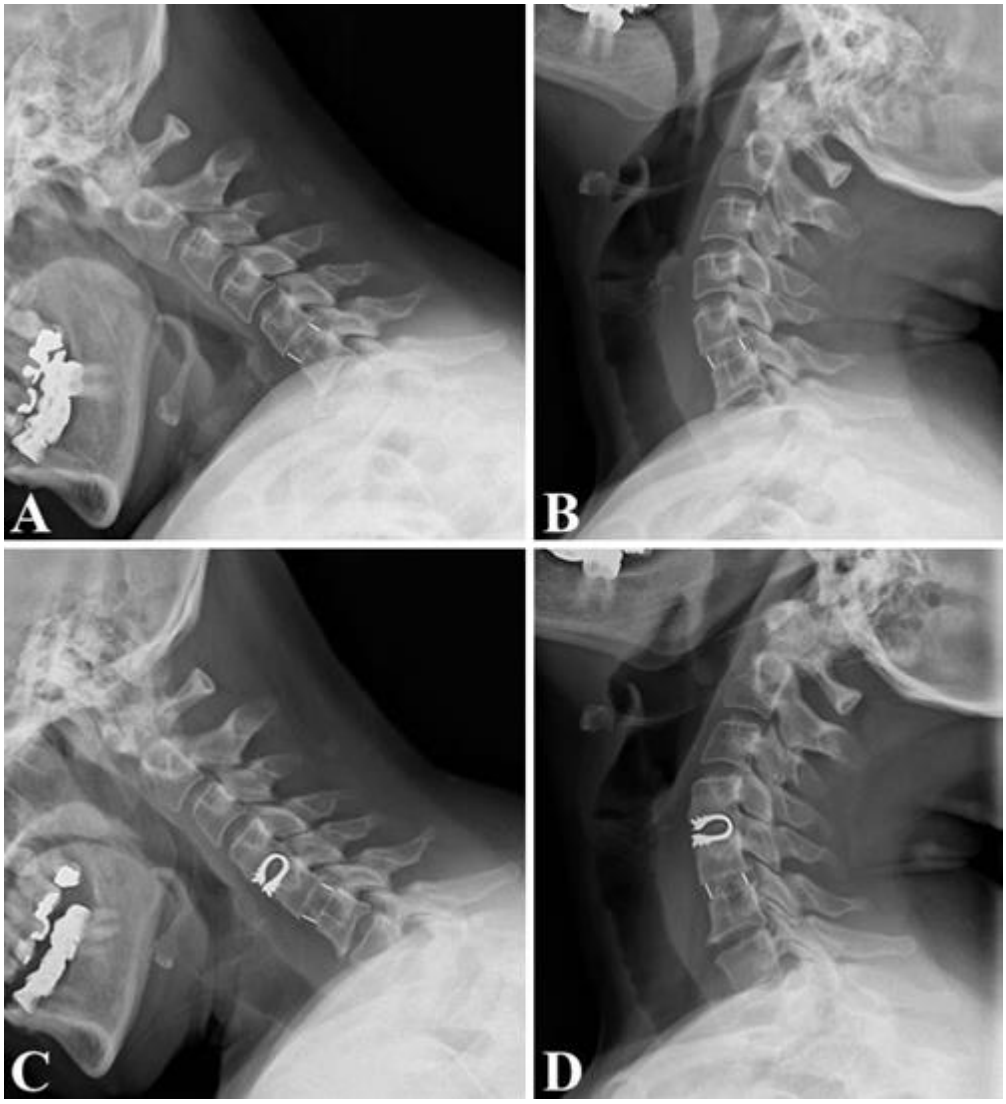
DYNAMIC CERVICAL IMPLANT (DCI)

- provides limited, controlled flexion-extension while limiting axial rotation and lateral bending motions, i.e. maintains index- and adjacent-level ROM, improves sagittal alignment, and may be suitable for patients with facet arthrosis who would otherwise not be candidates for cervical TDR (total disc replacement).
Shock absorption together with maintained motion in the DCI may protect adjacent levels from early degeneration in longer follow-up.

Lateral radiographs showing the shock-absorbing capabilities of the DCI implant during movement:



Preoperative (A and B) and 1-year postoperative (C and D) functional radiographs of DDD at C4–5 with retrolisthesis in extension above cage–fusion at C5–6, dynamically stabilized with an M7 DCI (12 × 14 × 7 mm):


A
B
C
D