

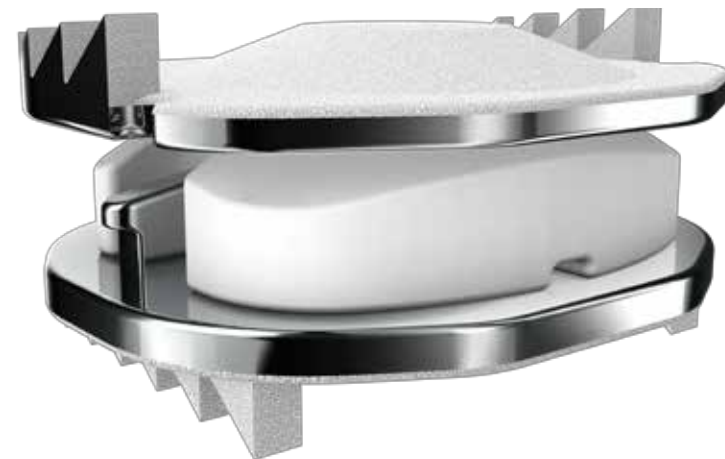
Mobi-C[®]
CERVICAL DISC

Surgical Technique
TWO-LEVEL



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

PATIENT SELECTION

- See the indications, contraindications, and other patient selection details in the device description and instructions for use guidelines at the end of this document.
- A minimal anterior-posterior (A/P) depth of 14mm at the affected levels is required and should be verified by X-ray pre-operatively. This measurement will then be verified intra-operatively by direct measurement with the A/P Depth Gauge.

PATIENT POSITIONING

Patient positioning is critical to ensure proper orientation and alignment of the prostheses. The patient should be positioned in anatomic lordosis to avoid hyperextension. This position should be maintained throughout the surgery and rotation of the head should also be prevented.

SURGERY APPROACH AND PROCEDURE

The surgical approach is identical to that of a classic anterior cervical arthrodesis. However, the surgical procedure differs from an ACDF in four key ways. The operating surgeon will want to:

- Obtain a parallel distraction with an opening of the posterior aspect of the disc space.
- Release the foramen bilaterally.
- Establish the normal, healthy disc height.
- Place the implant in the center of the vertebral bodies for optimal biomechanical success.

For patients that need a Mobi-C at two levels, surgeon preference dictates which level to address first. However, it may be easier to complete the most diseased level first to ensure adequate height, lordosis, and sagittal balance restoration. Then repeat the technique on the second level.

Important: Radiographic visualization will be required throughout the procedure to assure accurate instrument and prosthesis positioning.

OPTIONAL

LEVEL CONFIRMATION WITH FLUOROSCOPY

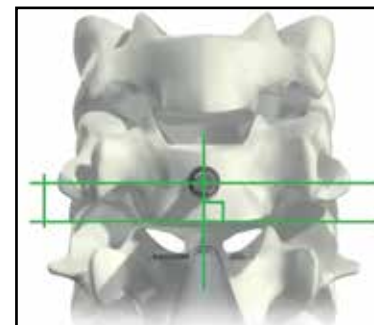
A pin can be inserted into the affected disc; then confirm the appropriate level with fluoroscopy.

OPTIONAL

PIN PLACEMENT FOR CONFIRMATION OF MIDLINE

Position the Pin (MB904R) on the midline using the Pin Holder (MB903R) about 5mm from the inferior edge of the superior vertebral body.

Use fluoroscopy to confirm proper positioning of the Pin. Once confirmed, the Pin can be removed and replaced by a Retractor Fixation Pin (IG008R) using the Fixation Pin Driver (IG009R).



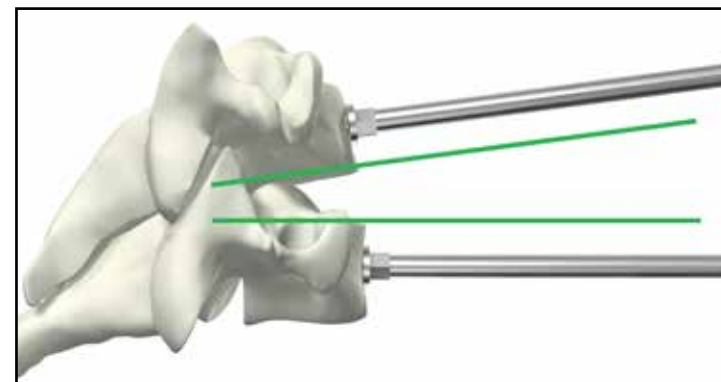
RETRACTION FIXATION PIN PLACEMENT

If the optional pin for centering was not used, insert the Retractor Fixation Pin using the Fixation Pin Driver about 5mm from the edge of the superior and inferior vertebral bodies. It is important to place the pins:

- No less than 5mm off the endplates so as not to interfere with the use of future instrumentation.
- **Parallel with the vertebral endplates in order to ensure parallel distraction.**

Use fluoroscopy to confirm proper positioning of the Retractor Fixation Pins.

Important: More so than during an ACDF, centering the prosthesis in relation to the vertebral bodies is crucial to the Mobi-C's biomechanical success. Midline placement of the Retractor Fixation Pins will provide a visual reference for midline prosthesis placement.

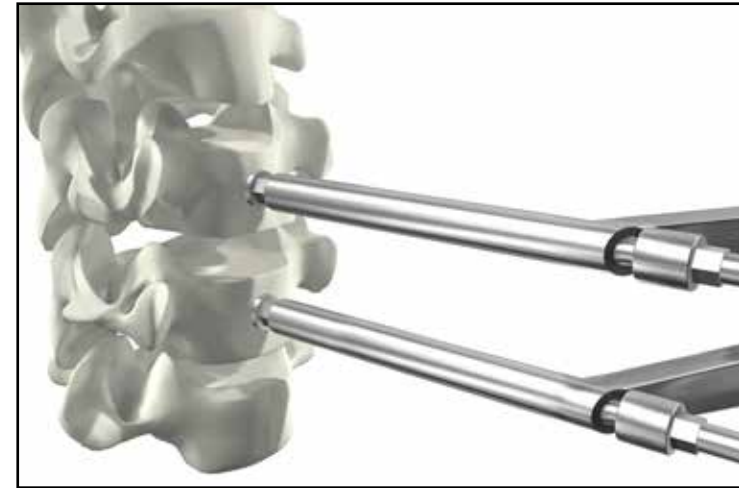


ATTACH CASPAR RETRACTOR

Attach the Caspar Retractor (IG007R) to the Retractor Fixation Pins.

Screw a Fixation Nut (IG010R) on the end of each Retractor Fixation Pin to hold the retractor in place.

Use the Caspar Retractor as needed to distract and maintain the desired height for performing the discectomy; maintain height by turning the screw tab on the retractor.

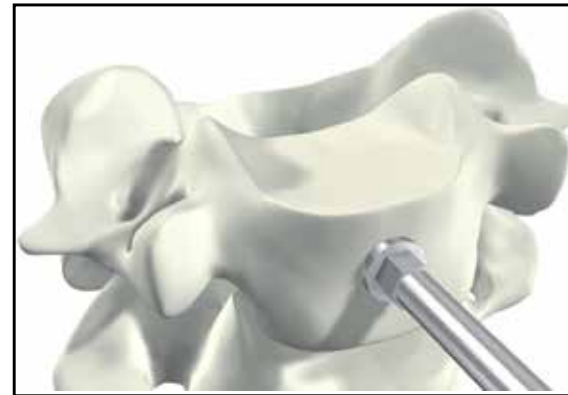


COMPLETE DISCECTOMY

Perform a complete discectomy of the disc space between the unci and back to the posterior ligament.* Take care to release the foramen bilaterally.

It is important to remove all anterior and posterior osteophytes on the superior and inferior vertebral endplates. Liberally cover bleeding bone with bone wax. To prevent weakening of the endplates, use of a burr is discouraged during endplate preparation.

Use the Caspar Retractor as needed to maintain or modify distraction.



**Note: Release of the posterior longitudinal ligament (PLL) may help to obtain parallel distraction. The extent of decompression is left to surgeon discretion based on patient pathology and history.*

DISCECTOMY AND TRIALING

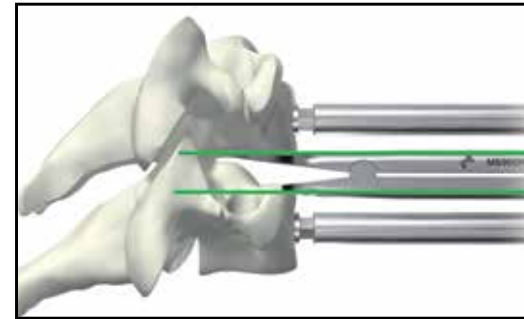
PARALLEL DISTRACTION

Insert the Distraction Forceps (MB900R)* as posterior as possible, then release the Caspar Retractor.

Use the Distraction Forceps to create parallel distraction. When the desired height is obtained, lock the Caspar Retractor to maintain the distraction.

Remove the Distraction Forceps.

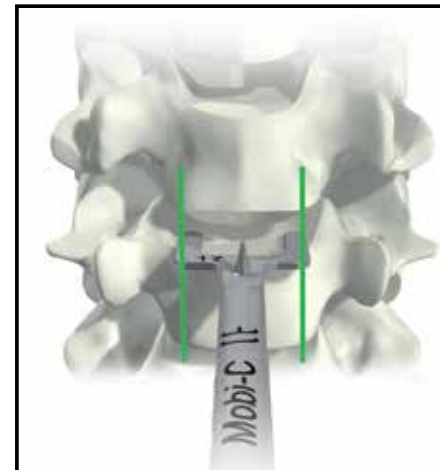
Important: It is important to achieve parallel distraction.



**Note: The Rigid Distraction Forceps (MB9074R) are available for difficult to distract discs.*

WIDTH DETERMINATION

Insert the Width Gauge (implants are available in 15, 17, and 19mm widths) into the disc space. Position the Width Gauge flat on the inferior endplate in contact with the base of the uncus bilaterally.*



**Note: The center reference point, located on the Width Gauge, confirms location of the vertebral midline.*

DEPTH MEASUREMENT

Using the A/P Depth Gauge (MB906R), the depth of the vertebral endplates (inferior usually) is determined by placing the hook of the gauge over the posterior edges of the vertebral endplates.*



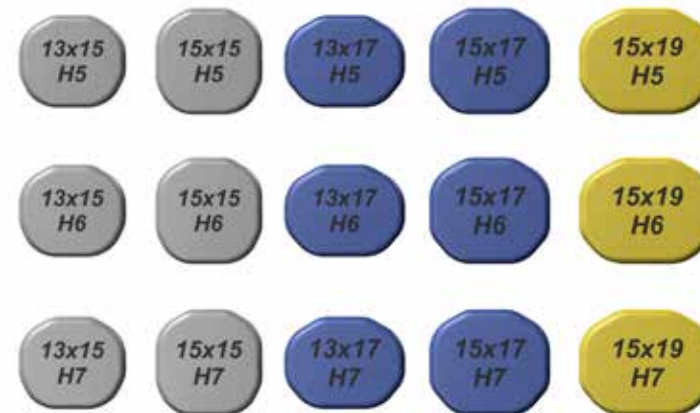
**Note: It is important to remove all anterior and posterior osteophytes to get an accurate depth*



TRIAL SELECTION

The depth and width measurements previously taken help determine the Trial size to use. The Trial will determine the final implant height to be used as well as implant footprint (width and depth). Each footprint size is color coded by width and there is one trial for every size (footprint/height).

Heights are available in 5, 6, and 7mm. Trialing should begin with the smallest height first (5mm) and should not exceed the height of healthy adjacent discs.



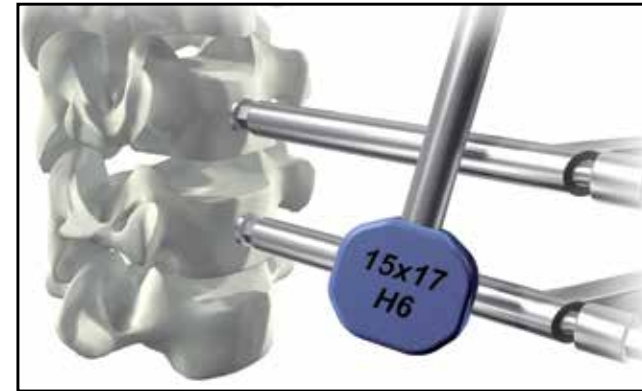
Implant footprints include (in mm):

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

DISCECTOMY AND TRIALING

TRIAL ASSEMBLY TO THE TRIAL IMPLANT HOLDER

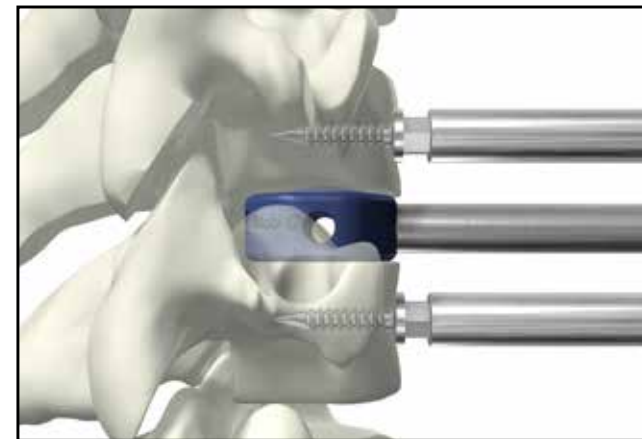
The selected Trial is threaded onto the Trial Implant Holder (MB917R) and secured by screwing the knob at the end of the holder.



IMPLANT TRIALING

Under fluoroscopy, gently tap the Trial into the disc space without going into the canal until the apex of the Trial is positioned centrally as compared to the superior and inferior vertebrae.

Important: It is imperative to cover a maximum of the vertebral endplates without exceeding their depth.

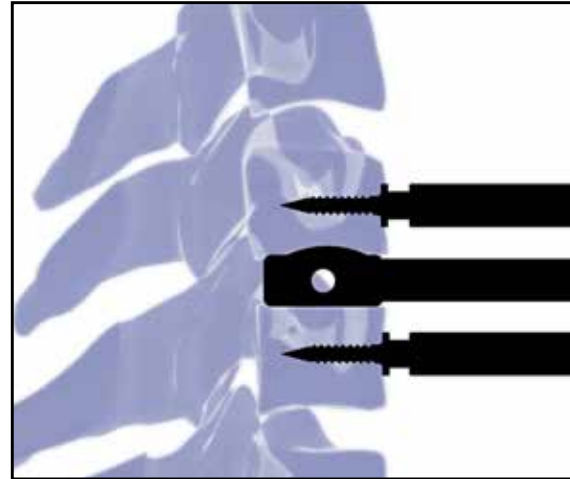


Release the Caspar Retractor to assess tension and fit.* Once released, take a lateral X-ray to validate height and depth selection and an A/P** X-ray to assess central placement and width. The holes in the Trial, front and side, facilitate verification of position (center and rotation).

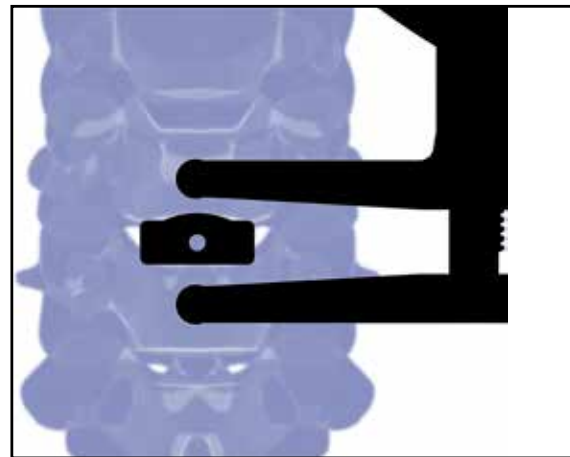
For height selection, it is important to not exceed the height of healthy adjacent discs nor to over-distract while still obtaining stability of the Trial in the intervertebral space.

To remove the Trial, put the Caspar Retractor back into slight tension.

Important: Take care to not over distract the segment while removing the Trial.



**Note: If the inferior endplate of the superior vertebra is flat, use a curette to prepare room for the dome of the prosthesis.*



***Note: The Trial Implant Holder can be removed and re-engaged to take an unobstructed A/P X-ray.*

IMPLANT ASSEMBLY TO THE UNIVERSAL INSERTER

Important: Visually inspect the implant assembly while loading to the Universal Inserter. If any part of the implant or disposable implant holder is damaged or unassembled, do not use.

Before assembly, verify that the stop adjustment dial is set to the zero position (Figure 1) on the Universal Inserter (MB9001R).

Load the implant with disposable implant holder (PEEK) onto the Universal Inserter. Turn the impaction knob on the Universal Inserter until the assembly is completely threaded onto, and just in contact with the Universal Inserter (Figure 2).

Visual control of contact can be confirmed using the window on the Universal Inserter. The word "UP", indicating the top of the prosthesis, becomes completely viewable when the correct position is obtained.

Important: Take care to stop threading as soon as full contact is achieved in order to avoid opening the disposable implant holder and releasing the implant.

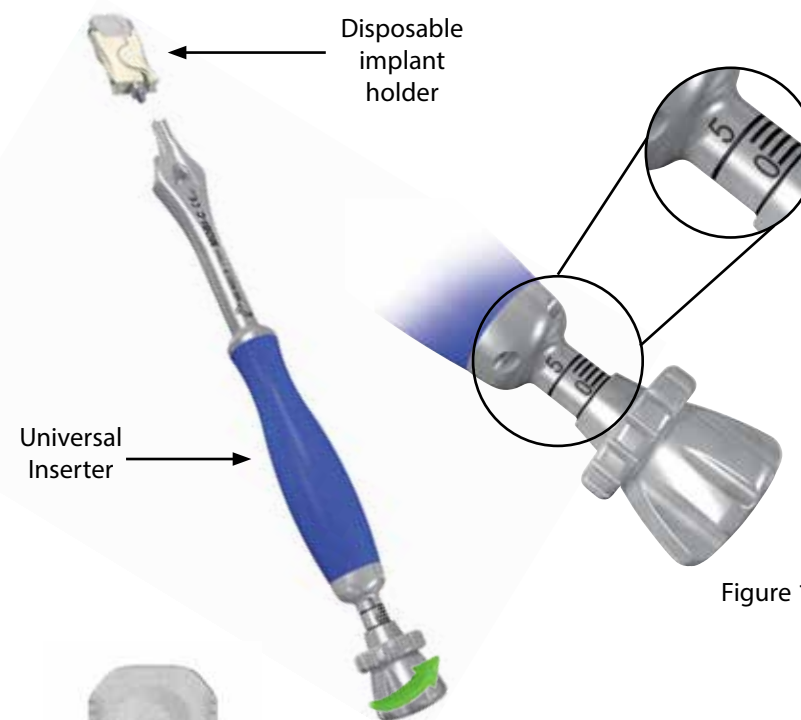
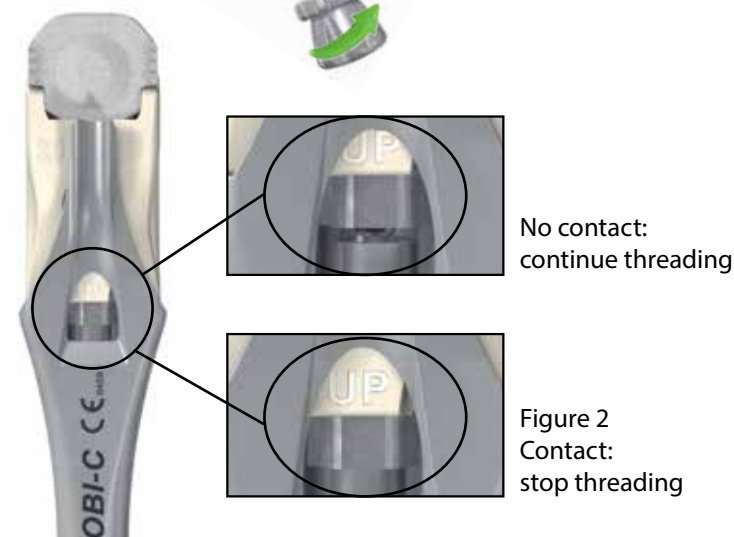


Figure 1



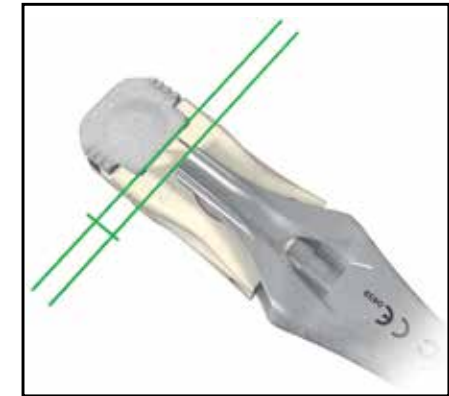
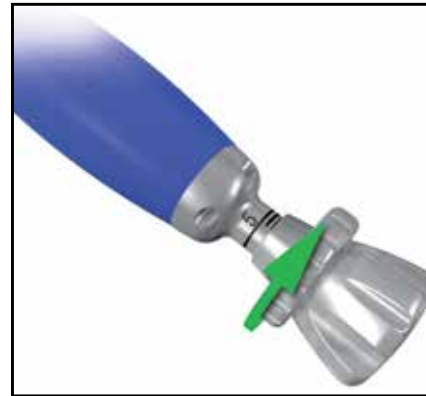
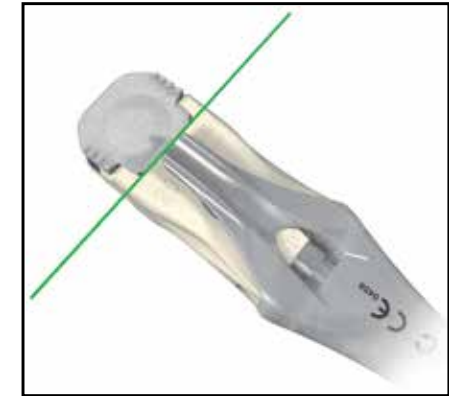
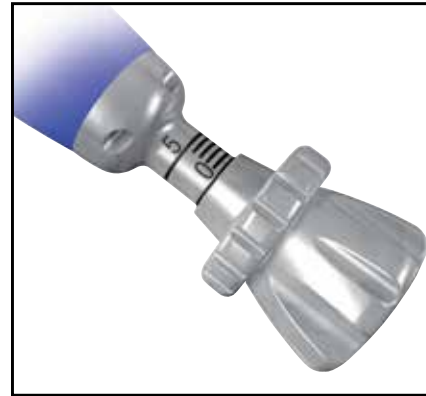
No contact:
continue threading

Figure 2
Contact:
stop threading

STOP ADJUSTMENT

The Universal Inserter has a stop (to be set initially at zero). This stop allows for setting the insertion depth of the prosthesis from 0 to 5mm.

The stop adjustment is indexed (1 turn = 1mm).



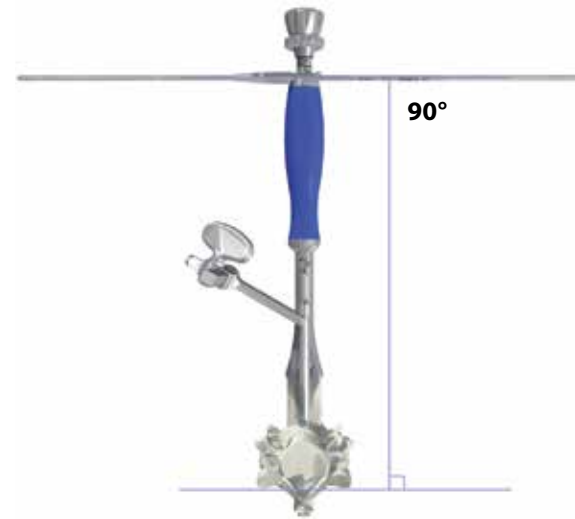
PROSTHESIS INSERTION

Position the Universal Inserter in the axis of the disc.*
This position can be verified visually; the groove on the Universal Inserter should align with the midline.

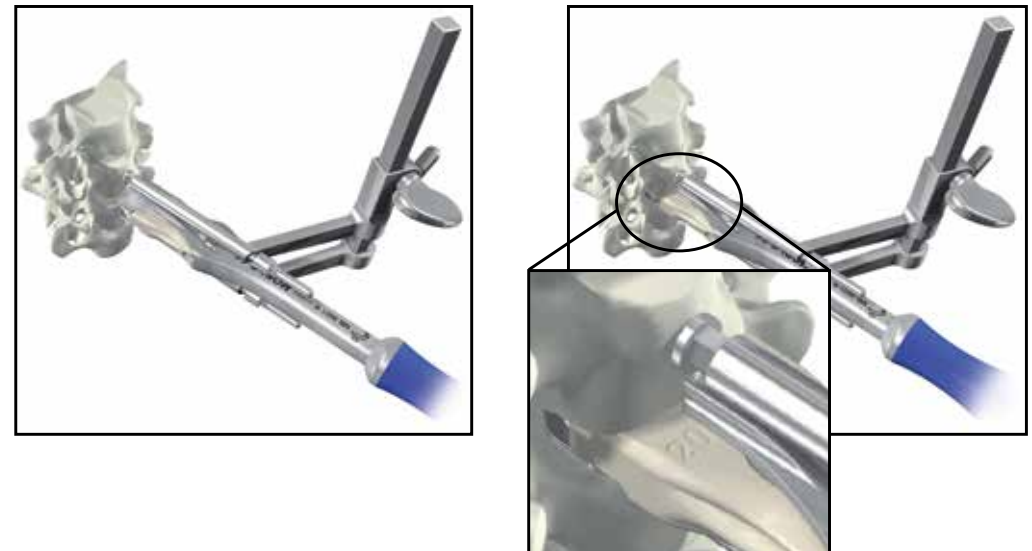
In order to verify the correct position and rotation of the Universal Inserter, use the Inserter Level (MB9072R) (as shown in the illustration to the right).

The prosthesis is inserted progressively, under fluoroscopy, into the disc space by tapping lightly on the Universal Inserter's impaction knob with a mallet until the device is centered on the vertebrae anterior-posterior.

Important: If at any time during surgery the implant comes apart from the disposable implant holder, do not attempt to reassemble. Select and use a new pre-assembled implant with disposable implant holder.



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

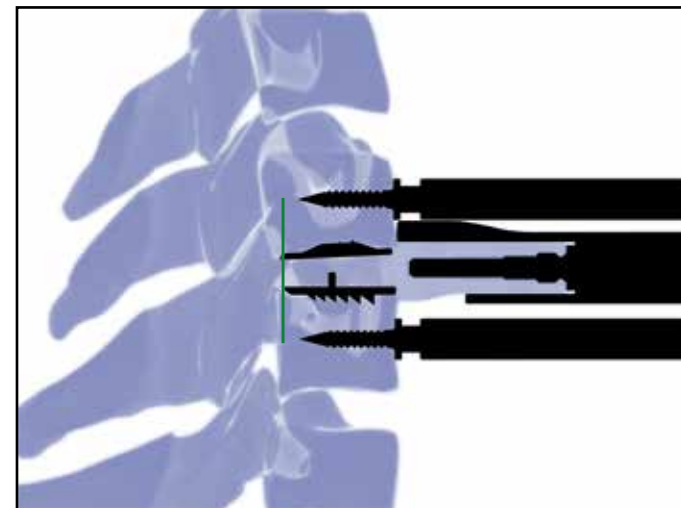
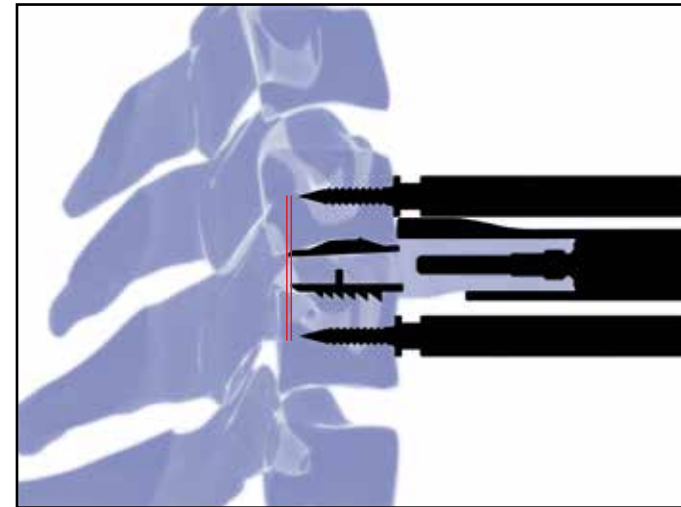


POSITION VERIFICATION - LATERAL VIEW

Use fluoroscopy to assess implant position.

Release the Caspar Retractor to permit the vertebral endplates to align in parallel. The anterior-posterior position of the prosthesis in the intervertebral space can be adjusted, if necessary, with millimetric adjustment of the Universal Inserter's stop.

From the lateral view, visual assessment of the alignment of the tabs on the inferior plate is used to control the position of the prosthesis in rotation.



Millimetric
readjustment of
prosthesis position
under fluoroscopy

UNIVERSAL INSERTER REMOVAL

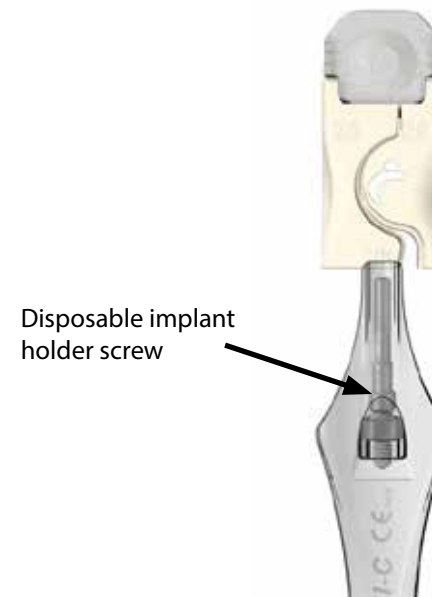
As soon as optimal positioning of the prosthesis is confirmed, continue to turn the Universal Inserter impaction knob (in the direction of the arrow) with the help of the Unlocking Key (MB9073R)* in order to release the screw on the disposable implant holder.

When the holder screw is removed, the disposable implant holder is released and the Universal Inserter can be disengaged from the holder. Carefully remove the Universal Inserter. Take care not to move the implant.

Important: Continue to turn until the screw is completely released from the disposable holder.



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

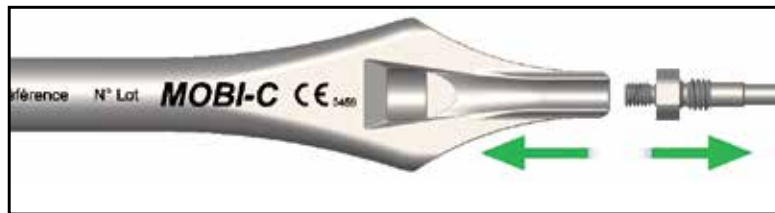


DISPOSABLE IMPLANT HOLDER REMOVAL

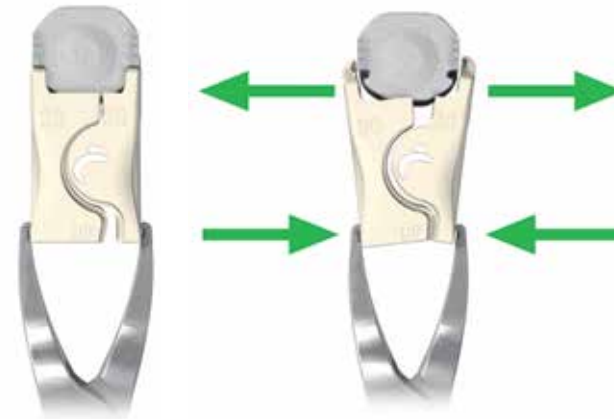
Using the Extraction Forceps (MB9075R), grasp the end of the disposable implant holder at the side notches. Take care not to move the implant.

Extract the holder by simply pulling back the extraction forceps along the axis of the disc.*

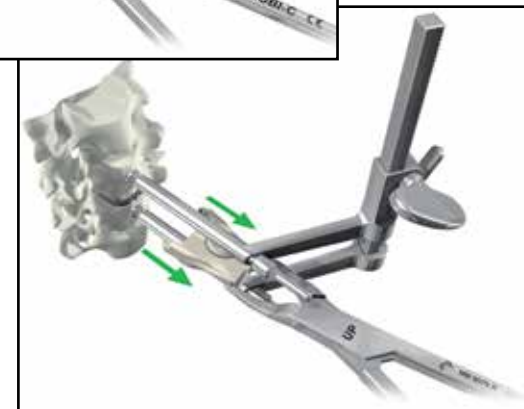
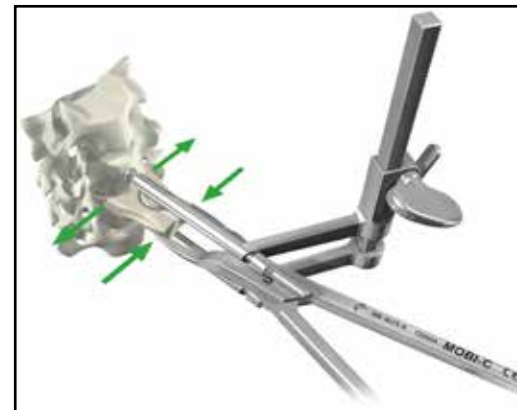
Important: Do not forget to remove and dispose of the holder screw by pulling back and unscrewing the Universal Inserter's impaction knob.



If after removing the disposable implant holder, one or both of the plates are proud of the vertebral body, the Plate Impactor (MB942R) can be used to adjust the position of an individual plate. Place the Plate Impactor on the anterior face of the proud plate and gently mallet the handle of the Impactor to push the plate posterior.



**Note: In the case of any resistance while removing the holder, it is advised to remove one side at a time with forceps.*



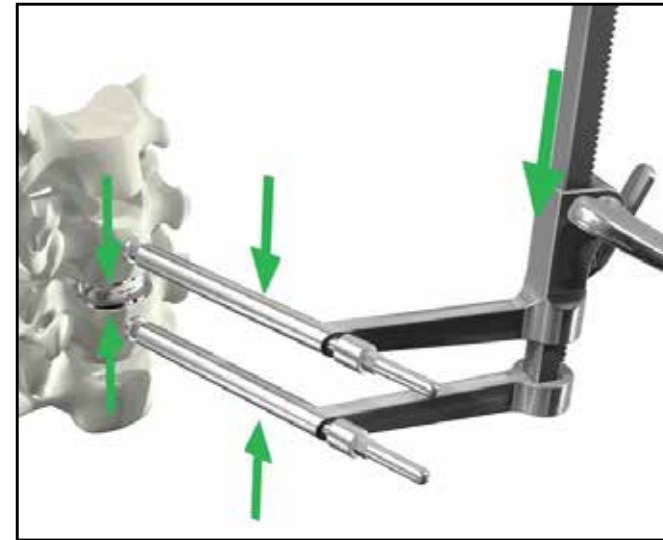
REMOVAL OF DISPOSABLE IMPLANT HOLDER & POSITION ASSESSMENT

FINAL VERTEBRAL COMPRESSION

Once final position is obtained, change the Caspar Retractor's tension into compression to allow seating of the implant teeth into the vertebrae.

Once the compression is achieved, remove the two Fixation Nuts and the Caspar Retractor. In preparation for the next level to be treated, leave the Retractor Fixation Pin in the middle vertebral body in place and remove the most inferior or superior Retractor Fixation Pin.

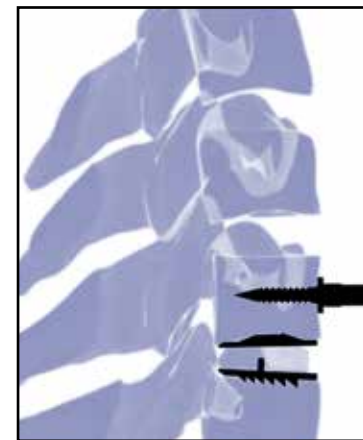
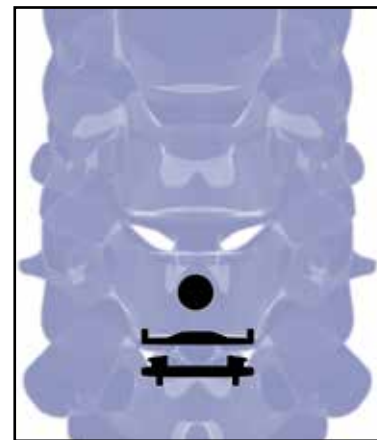
Place bone wax as needed in the holes created by the Retractor Fixation Pins to reduce bleeding.



FINAL POSITION ASSESSMENT

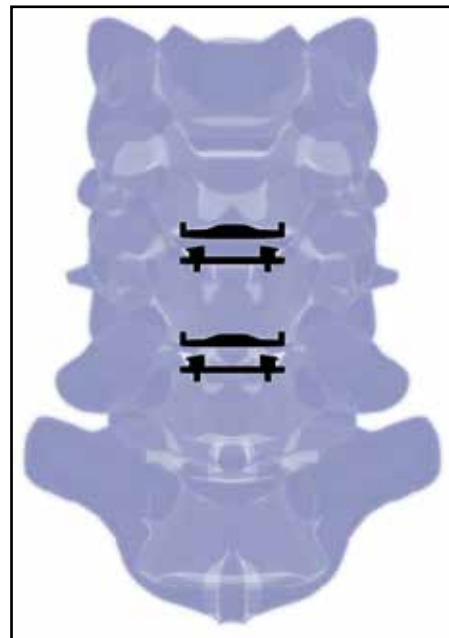
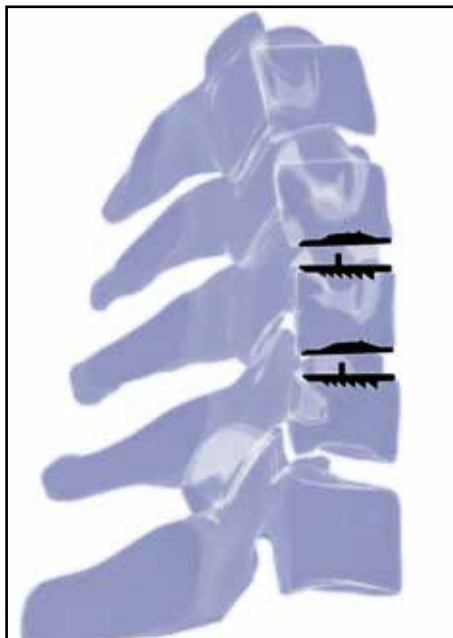
A/P and lateral fluoroscopy will confirm correct positioning of the prosthesis.

Important: Radiographic visualization will be required throughout the procedure to assure accurate instrument and prosthesis positioning.



For the second implant, repeat the steps described previously in this document for insertion of the first Mobi-C implant.

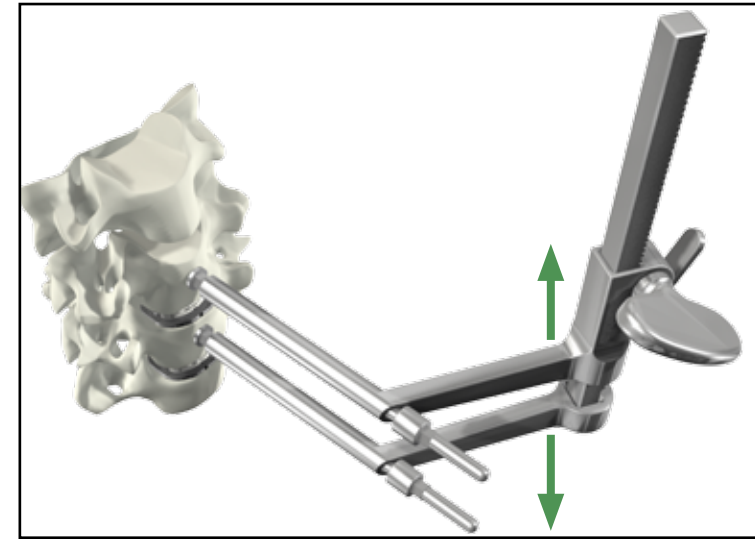
- Place a Retractor Fixation Pin in the opposite superior or inferior vertebral body. Attach the Caspar Retractor and distract to access the second disc.
- Complete the discectomy.
- Measure the depth.
- Trial to determine the final implant size.
- Assemble a Mobi-C prosthesis to the Universal Inserter.
- Insert the Mobi-C.
- Verify the implant's position via radiographic visualization.
- Remove the Universal Inserter and the disposable implant holder.
- Release the Caspar Retractor to achieve vertebral compression of the implant.
- Assess final position of both implants via radiographic visualization.



IMPLANT REMOVAL

DISTRACTION

Centrally insert a Retractor Fixation Pin above and below both endplates. Attach the Caspar Retractor to the pins, distract, and tighten the knob to hold the desired height. Take care to not over distract, when adjusting the height for implant removal.

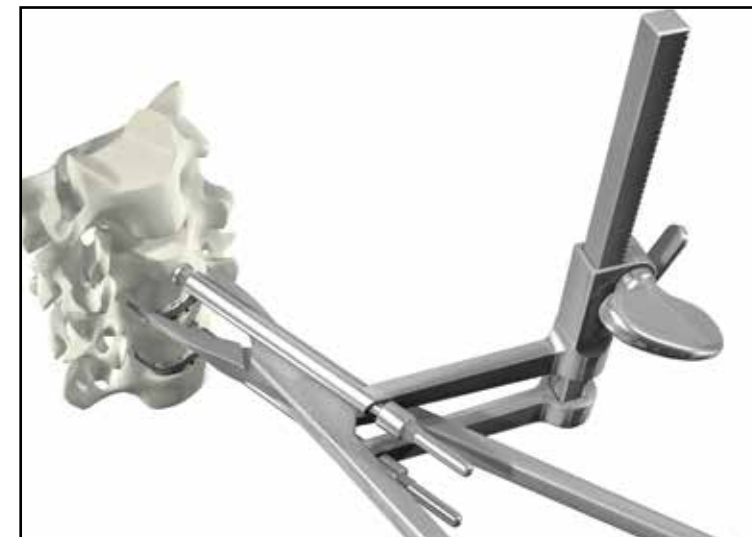


IMPLANT REMOVAL

Using a Penfield #4 or thin osteotome, loosen the inferior and superior bone to implant interface, but do not remove.

Hook the tips of the Extraction Forceps (MB9075R) posterior to the tabs on the inferior plate. Remove the implant.











If the superior plate does not follow with the removal of the inferior plate and insert, a thin osteotome may be needed to finish separating the implant to bone interface. Remove the superior plate from the intervertebral space using a Kocher or similar surgical instrument.



MB 3355	Mobi-C 13x15 H5
MB 3356	Mobi-C 13x15 H6
MB 3357	Mobi-C 13x15 H7
MB 3555	Mobi-C 15x15 H5
MB 3556	Mobi-C 15x15 H6
MB 3557	Mobi-C 15x15 H7
MB 3375	Mobi-C 13x17 H5
MB 3376	Mobi-C 13x17 H6
MB 3377	Mobi-C 13x17 H7
MB 3575	Mobi-C 15x17 H5
MB 3576	Mobi-C 15x17 H6
MB 3577	Mobi-C 15x17 H7
MB 3595	Mobi-C 15x19 H5
MB 3596	Mobi-C 15x19 H6
MB 3597	Mobi-C 15x19 H7

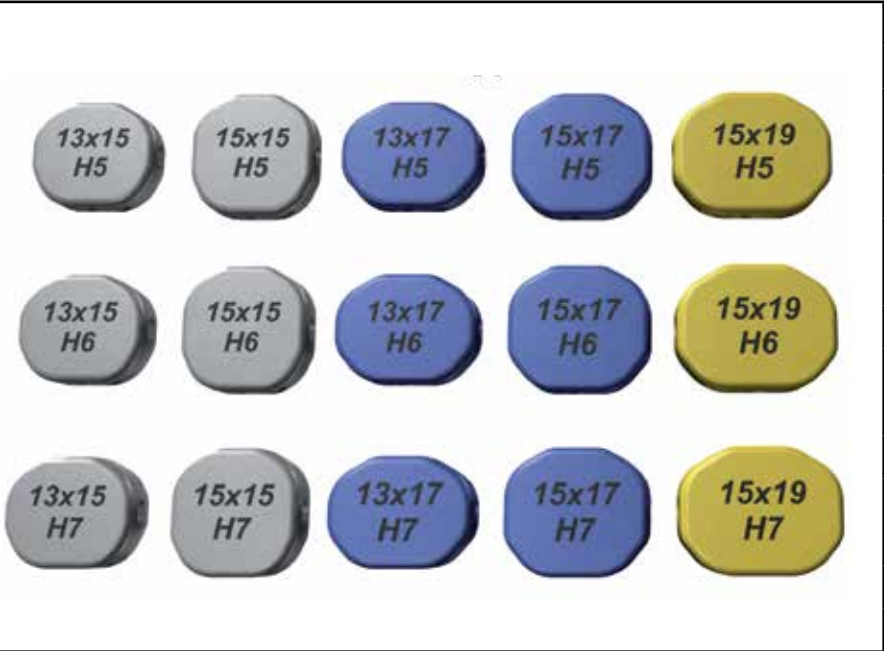


INSTRUMENT SET

1	MB 900 R	Distraction Forceps	
2	MB 903 R	Pin Holder	
3	MB 904 R	Pin	
4	MB 906 R	A/P Depth Gauge	
5	MB 917 R	Trial Implant Holder	
6	MB 942 R	Plate Impactor	
7	MB 943 R	Width Gauge 15mm	
	MB 945 R	Width Gauge 17mm	
	MB 947 R	Width Gauge 19mm	
8	MB 9001 R	Universal Inserter	

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MB 9008 R	Trial 13x15 H5mm
MB 9009 R	Trial 13x15 H6mm
MB 9010 R	Trial 13x15 H7mm
MB 9018 R	Trial 15x15 H5mm
MB 9019 R	Trial 15x15 H6mm
MB 9020 R	Trial 15x15 H7mm
MB 9023 R	Trial 13x17 H5mm
MB 9024 R	Trial 13x17 H6mm
MB 9025 R	Trial 13x17 H7mm
MB 9033 R	Trial 15x17 H5mm
MB 9034 R	Trial 15x17 H6mm
MB 9035 R	Trial 15x17 H7mm
MB 9048 R	Trial 15x19 H5mm
MB 9049 R	Trial 15x19 H6mm
MB 9050 R	Trial 15x19 H7mm



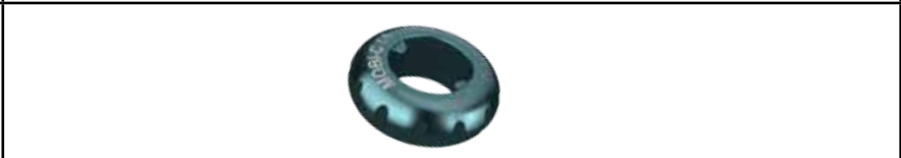
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MB 9072 R	Inserter Level
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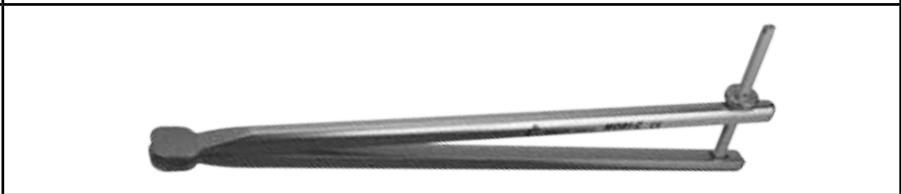
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MB 9073 R	Unlocking Key
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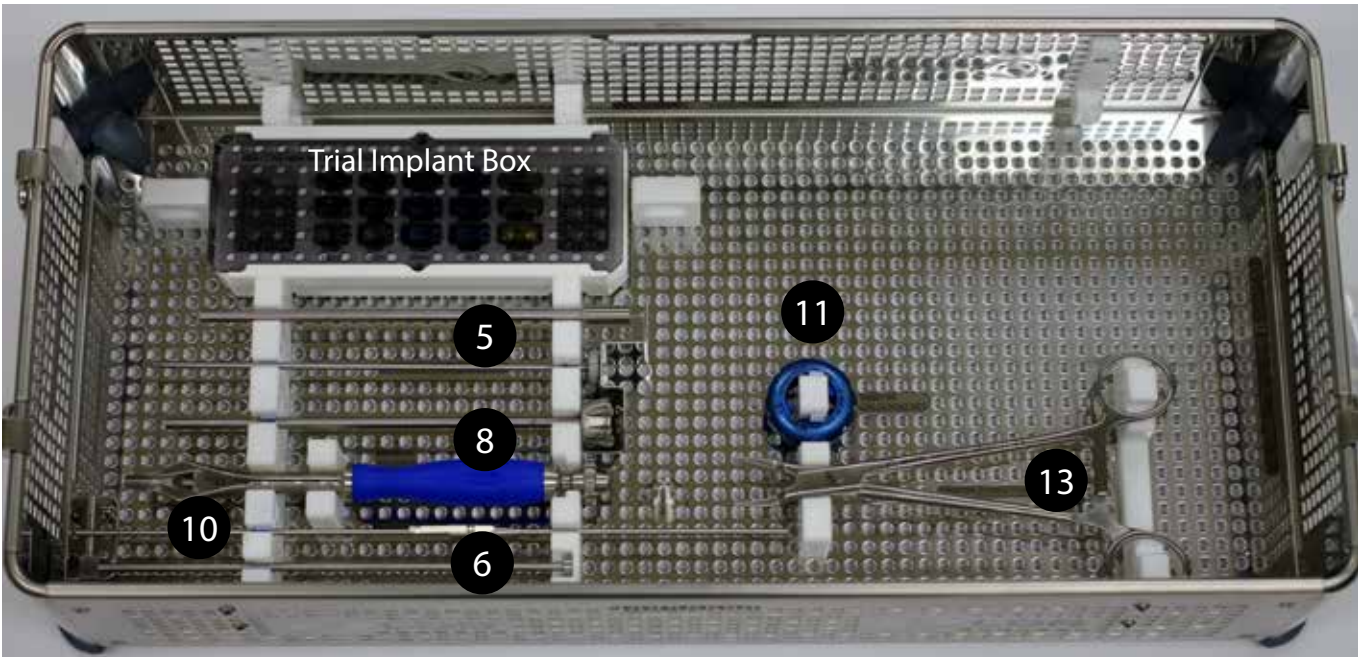
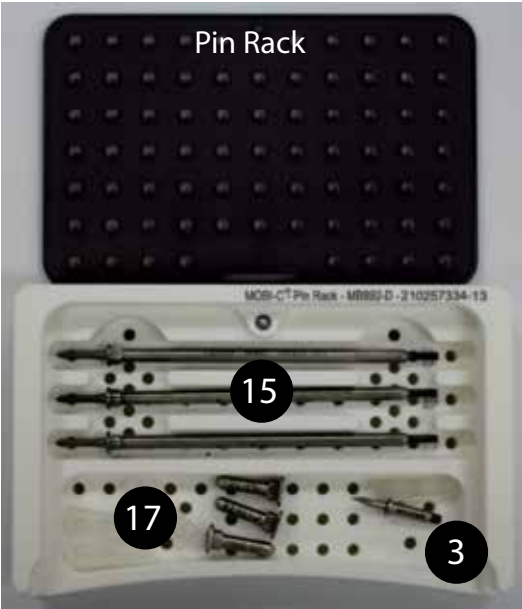
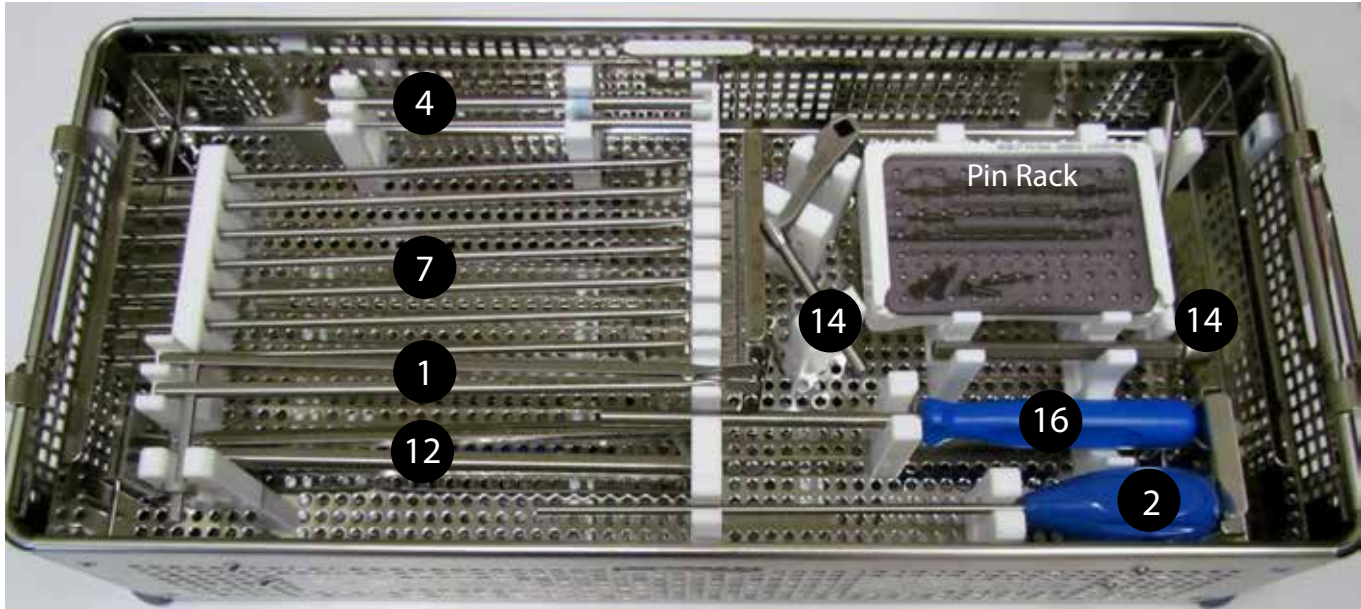
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MB 9074 R	Rigid Distraction Forceps
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INSTRUMENT SET

13	MB 9075 R	Extraction Forceps	
14	IG 007 R	Caspar Retractor	
15	IG 008 R	Retractor Fixation Pin	
16	IG 009 R	Fixation Pin Driver	
17	IG 010 R	Fixation Nut	
	MB 992	Container	



DEVICE DESCRIPTION AND USE GUIDELINES

DEVICE DESCRIPTION

The Mobi-C® Cervical Disc Prosthesis (Mobi-C®) is a single use device for cervical intervertebral disc replacement at two contiguous levels from C3 to C7 in order to maintain/restore segmental motion and disc height. The components of the Mobi-C® include a cobalt, chromium, molybdenum (CoCrMo per ISO 5832-12) alloy superior spinal plate, an inferior CoCrMo spinal plate, and an ultra high molecular weight polyethylene (UHMWPE per ISO 5834-2) mobile insert. The inner contact surfaces of the superior and inferior spinal plates are spherical and flat, respectively. This allows for fully congruent contact surfaces between the spinal plates and mobile insert. The two lateral stops of the inferior plate controls and limits the mobility of the mobile insert. The spinal plates, both superior and inferior, feature two rows of teeth to allow for initial and long term fixation and stability. A 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. The Mobi-C® is illustrated to the right.



INDICATIONS

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

CONTRAINDICATIONS

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

- Acute or chronic infection, systemic or at the operative site;
- Known allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, titanium, hydroxyapatite, or polyethylene);
- Compromised vertebral bodies at the index level due to previous trauma to the cervical spine or to significant cervical anatomical deformity or disease (e.g., ankylosing spondylitis, rheumatoid arthritis);
- Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or > 11° angular difference to that of either adjacent level;
- Osteoporosis or osteopenia defined as DEXA bone mineral density T-score < -1.5;
- Severe facet joint disease or degeneration.

WARNINGS

- Mobi-C® 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 Mobi-C® 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 is extremely important to assure the placement and function of the device. Information regarding proper implant size selection, implant site preparation, and the use of the instrumentation before, during, and after Mobi-C® surgery is provided in the Mobi-C® Surgical Technique Manual and the Mobi-C® Instrument System Instructions for Use. Users are advised to read and understand the surgical technique manual and instructions for use prior to surgery.
- 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 the device. Care must be taken to identify and protect these structures.
- Heterotopic Ossification (HO) is a potential complication associated with artificial cervical discs and could lead to reduced cervical motion. However, the presence of HO has not been correlated with adverse clinical outcomes involving the Mobi-C® Cervical Disc Prosthesis in the G050212 clinical trial.

PRECAUTIONS

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

- Skeletally immature patients, pediatric or adolescent children (<21 years old), or those over the age of 67;
- Prior cervical spine surgery, including prior surgery at the index level;
- More than two diseased or immobile cervical spine level requiring surgical intervention;
- Disc height less than 3mm measured from the center of the disc in a neutral position and disc height less than 20% of the anterior-posterior width of the inferior vertebral body;
- Significant kyphotic deformity or significant reversal of lordosis;
- Active malignancy;
- Paget's disease, osteomalacia, or other metabolic bone disease;
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids);
- Pregnancy;
- Diabetes mellitus requiring daily insulin management;
- Clinically extreme obesity (class III) as defined by the NIH Clinical Guidelines Body Mass Index (i.e. BMI >40);
- Neck or arm pain of unknown etiology;
- Systemic disease including AIDS, HIV, and Hepatitis;
- Intractable radiculopathy or myelopathy due to pathology at more than two levels and/or pathology not localized to the level of the disc space;
- Prior fusion at an adjacent vertebral level;
- Neck pain alone;
- Rheumatoid arthritis or other autoimmune disease;
- Neuromuscular disorders such as muscular dystrophy, spinal muscular atrophy, or amyotrophic lateral sclerosis;
- Acute mental illness or substance abuse.

Pre-operative

- Patient selection is extremely important. In selecting patients for total disc replacement, the following factors can be of importance to the success of the procedure: the patient's occupation or activity level, prior injury or other ongoing 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.

DEVICE DESCRIPTION AND USE GUIDELINES

PRECAUTIONS CONTINUED

Pre-operative continued

- 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 < -1.5 , as the patient may be osteoporotic or osteopenic.
- The patient should be informed of the potential adverse effects (risks/complications) contained in the insert (see ADVERSE EVENTS).
- 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

- Use aseptic technique when removing the Mobi-C® 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 Mobi-C® implants if the packaging is damaged or the implant shows signs of damage.
- Use care when handling the Mobi-C® to ensure that it does not come in contact with objects that could damage the implant. Damaged implants are no longer functionally reliable. Visual inspection of the prosthesis assembly is recommended prior to implanting the device. If any part of the assembly appears damaged or not fully assembled, do not use.
- To prevent unnecessary damage to the bearing surfaces, ensure that tissue or other debris is not trapped within the device.
- The Mobi-C® should not be used with components or instruments of spinal systems from other manufacturers. See the surgical technique for step by step instructions.
- 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.
- Perform a complete discectomy of the disc space between the unci and up to the posterior ligament. Take care to release the foramen bilaterally. It is important to remove all anterior and posterior osteophytes on the superior and inferior vertebral endplates. Liberally cover bleeding with bone wax. To prevent weakening of the endplates, use of a burr is discouraged during endplate preparation. Use the Caspar Retractor as needed to maintain or modify distraction. Ensure proper alignment and placement of device components as misalignment may cause excessive wear and/or early failure of the device.

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 including the avoidance of heavy lifting, repetitive bending, and prolonged or strenuous activity initially and for a period of weeks to months depending on the individual patient's progress and the stability and functioning of the implant.
- Note to Physician: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

MRI SAFETY INFORMATION



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

- Static magnetic field of 1.5 and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 970 Gauss/cm (9.7 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Mobi-C® Cervical Disc Prosthesis is expected to produce a maximum temperature rise of less than 3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 29 mm from the Mobi-C® Cervical Disc Prosthesis when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

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 LDR Spine USA. 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, LDR Spine USA 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 LDR Spine USA 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 Mobi-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 Mobi-C® Cervical Artificial Disc, please contact LDR Spine USA to receive instructions regarding data collection, including histopathological, mechanical, patient, and adverse event information. Please refer to the Mobi-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 LDR Spine USA 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 Mobi-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. LDR Spine USA will request additional information regarding the reason for removal, patient information, and associated clinical outcomes.

NOTE: All implant removals must be reported immediately to LDR Spine USA.
CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Indications for Use:

The Mobi-C® Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of 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 compared to adjacent levels. The Mobi-C® Cervical Disc Prosthesis is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C® Cervical Disc Prosthesis.

Note: Please refer to the Mobi-C Summary of Safety and Effectiveness Data (PMA P110009) at www.fda.gov for complete study results.



www.ldrmedical.com
www.cervicaldisc.com

United States

13785 Research Boulevard
Suite 200
Austin, Texas 78750
512.344.3333

France

Hôtel de bureau 1
4, rue Gustave Eiffel
10 430 Rosières Près Troyes, FRANCE
+33 (0)3 25 82 32 63

China

Unit 06, Level 16, Building A,
Beijing Global Trade Center #36
North Third Ring Road
East, Dongcheng District,
Beijing, China, 100013
+86 10 58256655

Brazil

Av. Pereira Barreto, 1395-19º Floor
Room 192 to 196
Torre Sul-Bairro Paraíso
Santo André / São Paulo-Brazil
CEP 09190-610
+55 11 4332 7755