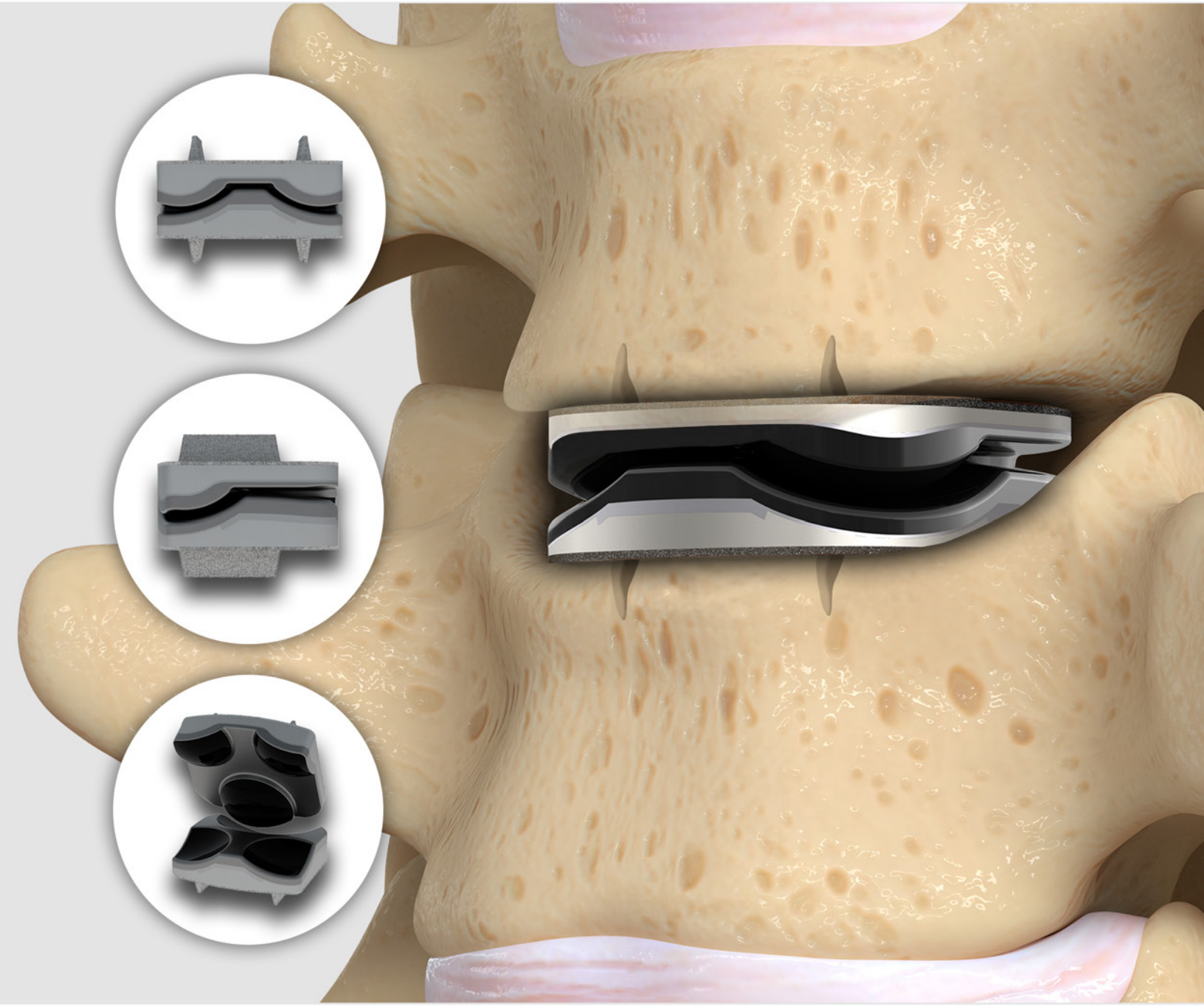
SURGICAL TECHNIQUE

TRIADYME®-C
POWERED BY TRI-LOBE TECHNOLOGY



CERVICAL TOTAL DISC REPLACEMENT (cTDR)

DYMICRON®
REPLACE. RESTORE. REVITALIZE.

TRIADYME®-C

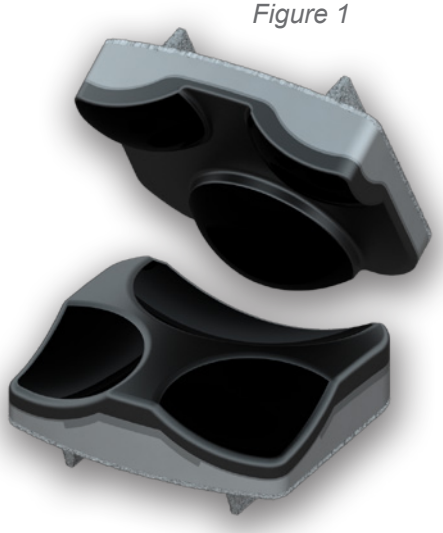
TABLE OF CONTENTS

The Triadyme®-C Cervical Total Disc Replacement surgical technique shown in this guide was developed and intended for spine surgeons, and it is for illustrative purposes only. The technique actually employed in each case will always be dependent upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. This information does not purport to replace the comprehensive training surgeons have received, and Triadyme®-C should be implanted only by surgeons who are experienced in the surgical procedure and who have undergone adequate training with this device. A lack of adequate experience and/or training may lead to higher incidence of adverse events, such as vascular or neurological complications. Thoroughly read and understand the Triadyme®-C Surgical Technique Guide prior to implantation of a disc. Results will vary based on health, weight, activity, and other patient-specific conditions. Not all patients are candidates for this product and/or procedure. The Triadyme®-C device is not available in the USA or its territories.

Device Description

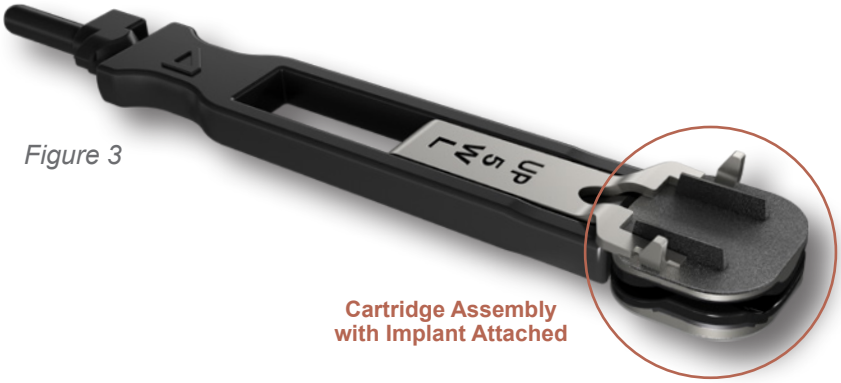
The Dymicron® Triadyme®-C Cervical Total Disc Replacement is a two-piece articulating cervical disc prosthesis (Figures 1 & 2) that is inserted into the intervertebral space as a single unit, utilizing an anterior cervical approach. The disc prothesis, which is inserted into the cervical spine in order to replace a degenerated native disc removed through a standard discectomy procedure, is designed to allow motion of the functional spinal unit following implantation. The Triadyme®-C disc is sterile-packaged and pre-loaded onto a disposable Inserter Cartridge (Figure 3). This cartridge is fitted with a stainless-steel spring clip which holds the two halves of the implant together before and during implantation.

Figure 1



Triadyme®-C Cervical Total Disc Replacement

Figure 3



Cartridge Assembly with Implant Attached

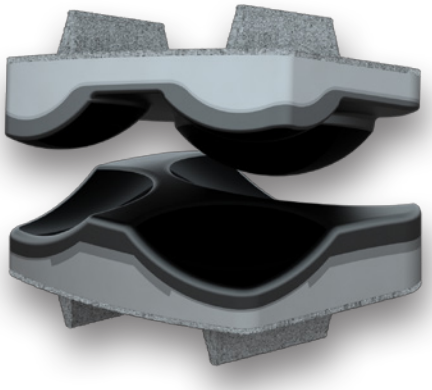


Figure 2

TRIADYME®-C

Device Description

Both endplates of the Triadyme®-C Cervical Disc contain dual keels which provide initial fixation of the device to the superior and inferior vertebral bodies. The keels are press-fit into channels that have been pre-cut into the vertebral bodies using size-specific chisels. A commercially pure Titanium Plasma Spray (TPS) coating covers the disc's endplates and keels, accommodating osseointegration for long-term fixation (Figure 4).

The articulation mechanism of the Triadyme®-C cervical disc consists of three spherical lobes mating to three non-congruent, spherical pockets. Motion of the cervical spine segment is approximated by the movement of the three lobes within their associated pockets.

The articulating bearing surfaces of the Triadyme®-C cervical disc are composed of biocompatible Polycrystalline Diamond (PCD), a substance that exhibits the unparalleled properties for which natural diamond is known, but with significantly enhanced fracture resistance. PCD exhibits very low friction and extreme wear resistance. Each half of the Triadyme®-C disc is manufactured by sintering the PCD bearing material, along with the titanium carbide/titanium alloy substrate material, as a monobloc (Figure 4).

Triadyme®-C Material Layers

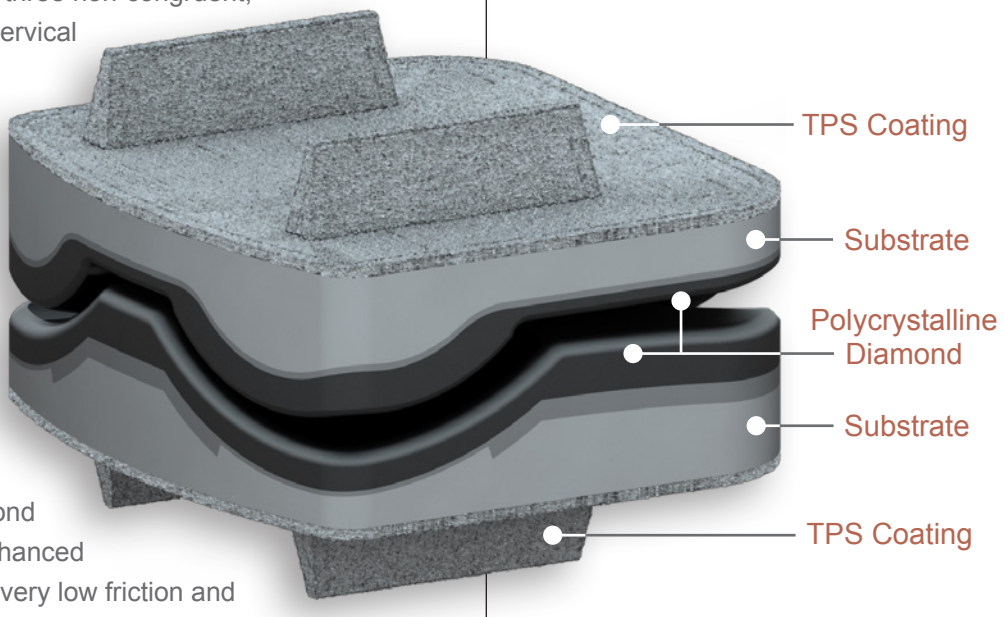


Figure 4

Device Sizing

Four different footprint sizes are available for the device, with three different disc heights for each footprint, accommodating a wide variety of vertebral sizes. The Triadyme®-C implant is available in three heights (5, 6, and 7mm) and two widths (14.5 and 16.5mm) denoted as Narrow and Wide (Figure 5). The Narrow implants come in two lengths (Short = 13mm, Long = 15mm) and the Wide implants come in two slightly longer lengths (Short = 13.5mm, Long = 15.5mm).

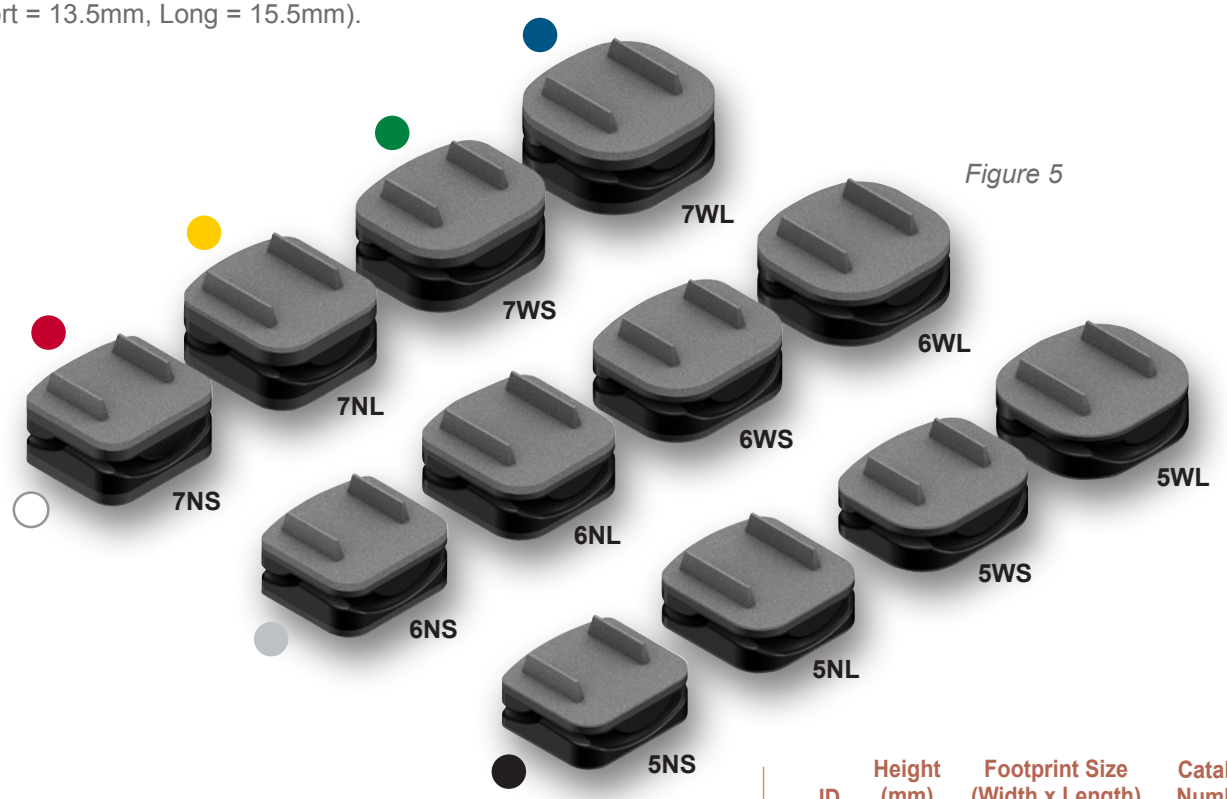


Figure 5

Triadyme®-C Sizes & Catalog Numbers

The implant sizes are identified by 3-digit alphanumeric and color code schemes:

- The first digit identifies the implant height as 5, 6, or 7mm
- A 5mm height implant is color-coded as Black, 6mm as Grey, and 7mm as White
- The second digit identifies the width (N = Narrow, W = Wide)
- The third digit identifies the length (S = Short, L = Long)
- A Narrow-Short (NS) implant is color-coded as Red, Narrow-Long (NL) as Yellow, Wide-Short (WS) as Green, and Wide Long (WL) as Blue

ID	Height (mm)	Footprint Size (Width x Length)	Catalog Number
5NS	5	14.5mm x 13mm	CS-5A
5NL	5	14.5mm x 15mm	CS-5B
5WS	5	16.5mm x 13.5mm	CS-5C
5WL	5	16.5mm x 15.5mm	CS-5D
6NS	6	14.5mm x 13mm	CS-6A
6NL	6	14.5mm x 15mm	CS-6B
6WS	6	16.5mm x 13.5mm	CS-6C
6WL	6	16.5mm x 15.5mm	CS-6D
7NS	7	14.5mm x 13mm	CS-7A
7NL	7	14.5mm x 15mm	CS-7B
7WS	7	16.5mm x 13.5mm	CS-7C
7WL	7	16.5mm x 15.5mm	CS-7D

Instrumentation

The instruments (Figure 6) are reusable and are validated to be cleaned and sterilized per Instrument Cleaning/ Sterilization Instructions. A description of the instruments included in the Triadyme®-C instrument set is listed in the Set Contents and Layout section on page 25.

Quick Release Handles are used with multiple instruments in the Triadyme®-C set, including Rasps, Trials, Chisels, and Implant Cartridge Assemblies. Each instrument is connected to a Quick Release Handle by seating the handle's distal end completely into the proximal end of the instrument, then rotating the handle clockwise ninety degrees (90°) to lock it into position. A click can be felt and heard when the instrument is properly seated and locked (Figure 7). To release an instrument from the Quick Release Handle, while depressing the clip on the side of the handle, twist the handle ninety degrees (90°) counter-clockwise, and pull it out (Figure 8).

Figure 6

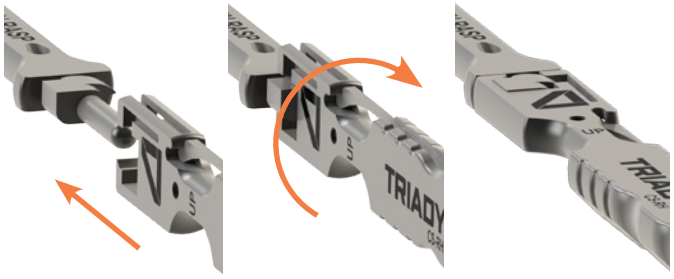


Figure 7

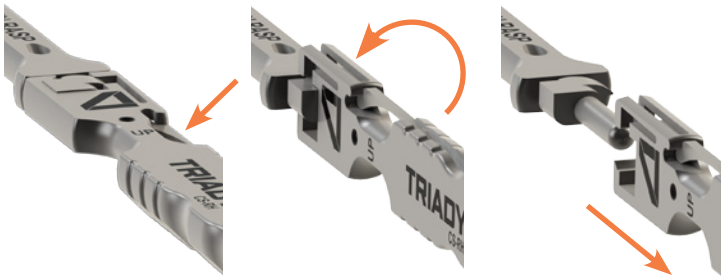


Figure 8

Patient Selection

Review the indications, contraindications and warnings for the Triadyme®-C device within this document. These criteria should be used in qualifying a patient for the Triadyme®-C device. The degree of disc collapse at the operative level should be considered only a relative contraindication for arthroplasty and will be strongly dependent upon the experience level of the individual surgeon with this technique. Similarly, the age of the patient should be considered less important and take secondary position to the actual pathology at the operative level and how amenable this pathology is to adequate decompression and disc space distraction with concurrent preservation of the bony endplates. Finally, even though severe facet arthrosis is rare and is a contraindication for disc arthroplasty, a moderate or lesser degree of facet degeneration is only a relative contraindication for disc arthroplasty and should be evaluated in the context of each individual patient's clinical history, physical examination, and radiographic findings.

With this in mind, it is of paramount importance to perform a thorough review of patient history, physical exam, and imaging studies to identify possible contraindications to total cervical disc replacement and to identify the appropriate symptomatic level. Upon reviewing all pertinent information, determine whether a bone density scan is appropriate.

Figure 9

Surgical Technique

Step 1: Patient Positioning and Operative Level Confirmation

Proper patient positioning is critical to the proper placement of the Triadyme®-C disc and, ultimately, to the success of the procedure.

- Place the patient supine.
- Ensure the patient's neck is positioned neutrally and supported dorsally with a soft roll to avoid hyperextension and to provide adequate support during the surgical procedure (Figure 9).

Surgical Technique

Step 1: Patient Positioning and Operative Level Confirmation (continued)

- Ensure that the patient's head and neck are correctly aligned, free from tilt or rotation. This may be achieved by visualizing an imaginary line down the patient's midline which equally bisects their nose, chin, and sternum (Figure 10).
- Using A/P and lateral fluoroscopy, confirm that the patient's cervical spine is in the correct neutral position and that it is properly aligned (Figure 11).
- To maintain proper alignment and to eliminate movement during the procedure, it is recommended that the patient's head be secured to the table. This may be achieved by using a chin strap or by taping the head to the operative table frame (Figure 12).

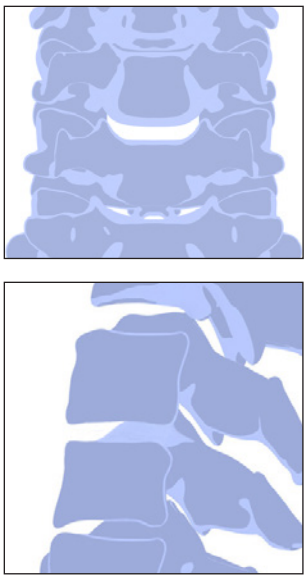


Figure 11

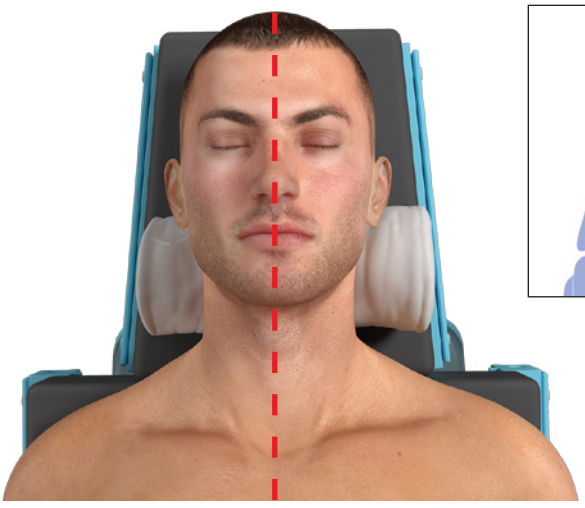


Figure 10

Figure 12

Step 1: Patient Positioning and Operative Level Confirmation (continued)

For surgery involving the lower levels (C6/C7), caudal translation of the patient's shoulders during lateral fluoro imaging may help ensure adequate visualization of the entire disc space. (This may be achieved by securing tape to the patient's shoulders/arms and pulling caudally while obtaining lateral fluoro images.) If lateral fluoroscopic visualization is not achievable, cervical arthroplasty at that level may be very challenging or not possible.

Prior to final surgical site prep and draping, confirm the proper operative level(s) and approach trajectory utilizing a guidewire or other appropriate radiopaque instrument via lateral fluoroscopy (Figure 13). For one-level implantation, ensure that the guidewire is parallel to the operative level disc space; and, utilizing a skin pen, mark this trajectory and the incision placement on the patient (Figure 14). Ensuring the incision is in line with this trajectory will allow for optimal retractor placement and surgical site visualization.

Figure 13

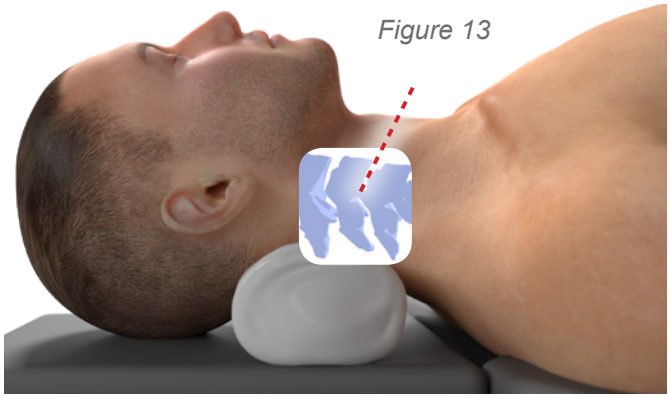


Figure 14

TIPS & TRICKS | **The inability to reproduce neutral alignment in the sagittal plane may result in improper implant position.**

Surgical Technique

Step 1: Patient Positioning and Operative Level Confirmation (continued)

For two-level implantation, position the guide wire parallel to the disc spaces of the operative levels, centered on the vertebral body between them. Utilizing a skin pen, mark this trajectory and incision site on the patient (Figure 15). Ensuring the incision is in line with this trajectory will allow for optimal retractor placement and surgical site visualization.

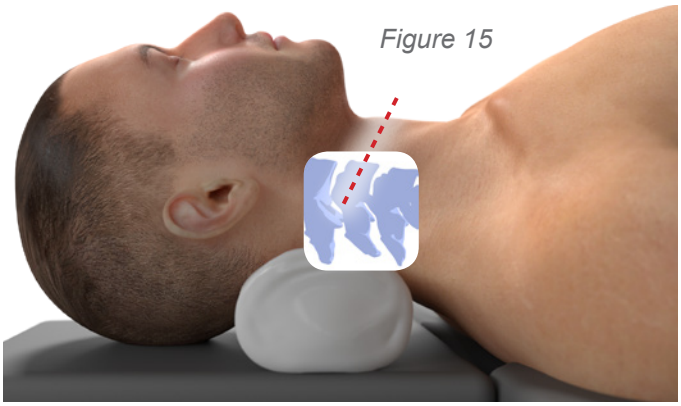


Figure 15

Step 2: Exposure and Midline Identification

Based on surgeon preference, a right- or left-sided approach to the cervical spine is selected. A transverse incision is used, followed by a blunt dissection of the muscles (muscle-splitting technique) through an avascular dissection plane.

The infrahyoid (strap) muscles, trachea, and esophagus are medially retracted, and the carotid sheath, along with its contents, is retracted laterally. By way of hand-held retractors, initial exposure of the anterior vertebral column and the Longus-Coli muscles is achieved. After the Anterior Longitudinal Ligament, disc space and vertebral bodies are exposed, the Longus-Coli muscles are subperiosteally elevated. Self-retaining, radiolucent retractor blades are placed underneath the Longus-Coli muscles for lateral retraction. For longitudinal retraction, either self-retaining, radiolucent retractors or Caspar distraction pins may be used to provide visualization of the index segment.

Step 2: Exposure and Midline Identification (continued)

TIPS & TRICKS

- **Minimize soft tissue trauma by limiting retraction ischemia, by minimizing dissection of the Longus Coli, and through judicious electrocautery use.**
- **Ensure the exposure incision is sufficient in length to allow necessary retraction for complete visualization of the disc space.**
- **Radiolucent retractor blades should be utilized to ensure unobstructed fluoroscopic visualization of the disc space, instrumentation, and implant.**
- **Once set, the retractor blades should be lined up in the same trajectory as initially marked on the patient to ensure maximal visualization of the disc space.**

It is critical to the function of the implant and success of the surgery that the implant is centered medial-laterally in the operative disc space. Therefore, radiographically verifying and clearly marking the midline of the segment is essential. It is recommended that a biopsy needle or similar instrument be placed in the presumptive midline of the intervertebral disc and viewed via true A/P fluoroscopy (Figure 16). The position of the needle can then be moved until it is verified to be in the exact midline of the disc, directly between the uncinate processes. The midline of the index level should then be marked in a manner such that the mark remains easily identifiable throughout the procedure. For example, use a Bovie to burn a mark on the anterior face of the superior and inferior vertebral bodies in line with the midline-placed needle (Figure 17). Once the mark is in place, the needle is removed.

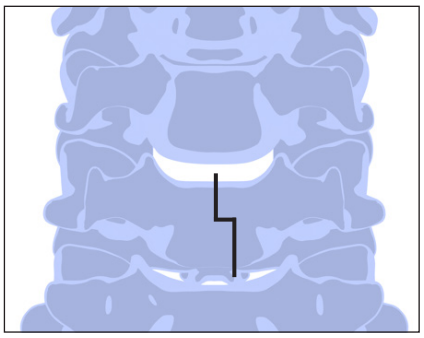


Figure 16

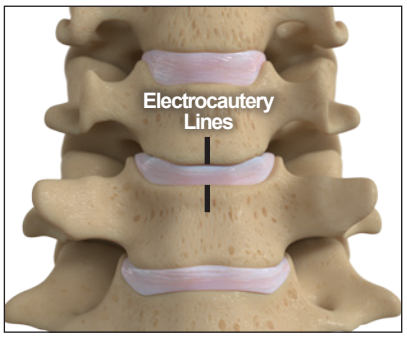


Figure 17

TIPS & TRICKS

- **The needle used to mark the midline of the disc space may be bent in a bayonetted manner (stairstep like) to improve the visualization of its placement.**

Surgical Technique

Step 3: Caspar Pin and Distractor Placement

It is important to place the pins in the following manner:

- Select the appropriate length Caspar pins, ensuring that the tips of the fully inserted pins will not violate the posterior cortex of the vertebral bodies.
- Insert the Caspar pins using the Caspar pin driver.
- Center the pins on midline in the coronal plane using the electrocautery markings as a reference (Figure 18).
- Place the inferior Caspar distractor pin parallel to the endplate of the operative level and orthogonal to the face of the vertebral body, then place the second Caspar pin parallel to the first one in both the coronal and sagittal planes (Figures 18 & 19). Caspar pins should be positioned at least 5mm from the endplates of the operative level.
- Confirm proper positioning using A/P and lateral fluoroscopy (Figure 19).

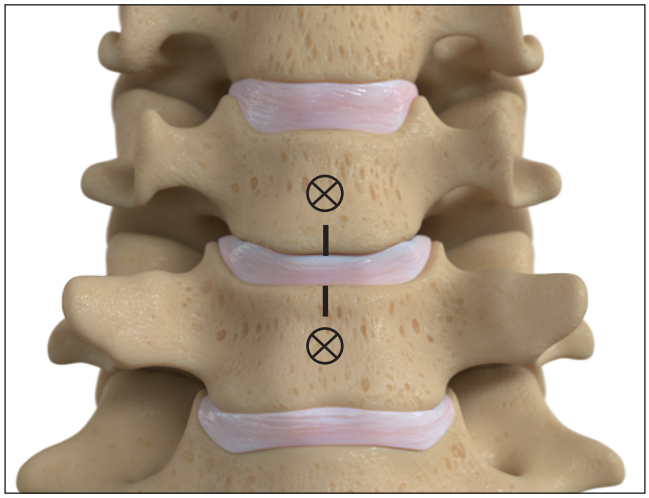


Figure 18

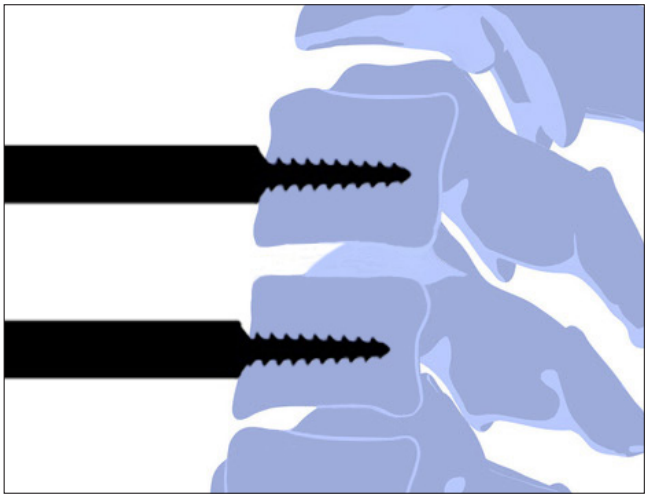


Figure 19

Step 3: Caspar Pin and Distractor Placement (continued)

- Slide the Caspar distractor onto the Caspar pins. (Figure 20)
- Apply only slight initial tension to the operative disc space with the Caspar distractor.

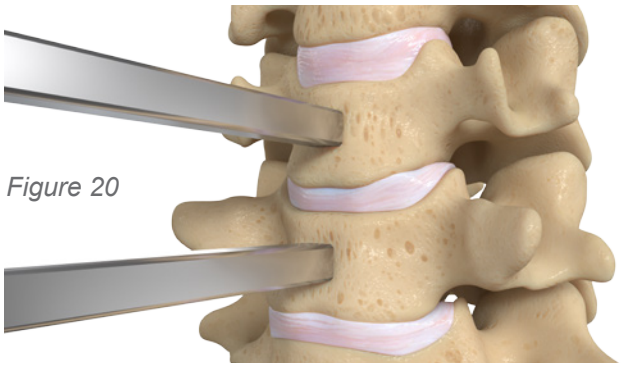


Figure 20

TIPS & TRICKS

- **Do not use the Caspar Distractor to distract the operative segment. The Caspar Distractor is meant to serve as a stabilizer and retainer of the vertebral bodies.**
- **Actual distraction of the vertebral bodies will be performed using the disc space Spreader instrument.**

Step 4: Discectomy, Decompression, and Disc Space Mobilization

Complete and thorough discectomy, decompression, and mobilization of the disc space are essential to ensure a successful outcome. The diseased disc space must be completely re-mobilized, and the disc height restored, in order to ensure a proper Triadyme®-C implantation.

Perform an annulotomy centered on the disc space and wide enough to create adequate visualization of the uncovertebral joints. Standard rongeurs and curettes should be used to remove the intervertebral disc material back to the posterior longitudinal ligament (PLL). Curettes and kerrisons are recommended for disc material removal in order to protect the integrity of the vertebral body endplates. If use of a burr/drill cannot be avoided, careful attention must be shown to protect from violating the thin cortical bony layer of the endplates.

Surgical Technique

Step 4: Discectomy, Decompression, and Disc Space Mobilization (continued)

Once the preliminary discectomy is achieved, additional disc height restoration and mobilization should be sought using the disc space Spreader instrument (Figure 21). Place the paddles of the disc space Spreader (Figure 22) as far posterior into the disc space as is safely possible (Figure 23). Release the tension on the Caspar Distractor and use the disc space Spreader to distract the vertebral bodies in a parallel manner (Figure 24). Once distracted, lock the Caspar Distractor to maintain and stabilize the vertebral bodies in that position while the rest of the disc space preparation is accomplished (Figure 25).

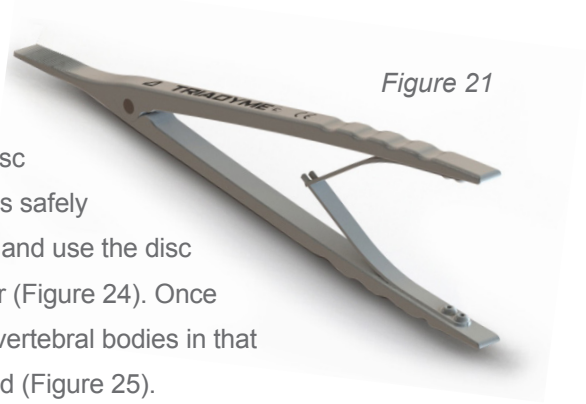


Figure 21

Figure 22

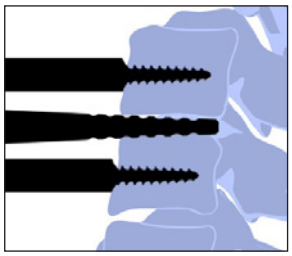


Figure 23

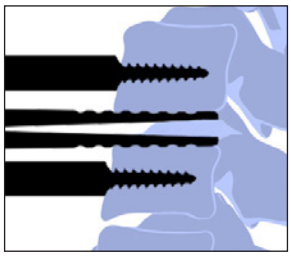


Figure 24

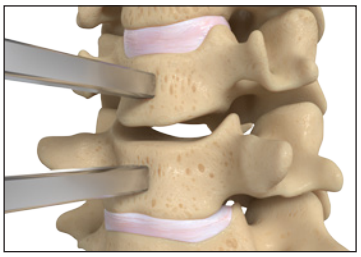


Figure 25

TIPS & TRICKS

- **The lack of adequate posterior disc height restoration and mobilization may result in suboptimal anterior placement of the prosthesis, which will negatively impact the performance of the Triadyme®-C cervical disc replacement.**
- **The height of healthy adjacent level discs and facet joints may be used as a guide for determining the proper amount of disc height restoration.**
- **Care should be taken to not over-distract the disc space.**

Step 4: Discectomy, Decompression, and Disc Space Mobilization (continued)

Endplate cartilage should be removed in a manner that preserves the integrity of the underlying cortical bone. Two Rasps (open and solid) are provided in the Triadyme®-C instrument set and are used with Quick Release Handles to help prepare the vertebral body endplates (Figure 26).

Release of the posterior longitudinal ligament (PLL) may aid in posterior mobilization and parallel distraction of the disc space. Release should be bilateral and symmetrical.

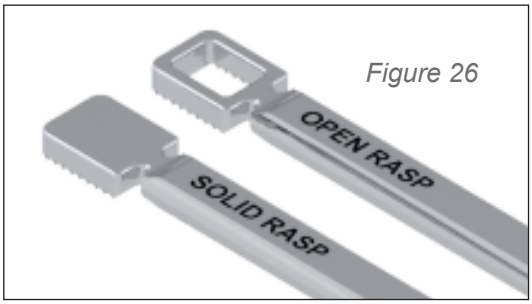


Figure 26

Care should be taken to ensure complete, bilateral decompression of the foramen while maintaining the integrity of the weight-bearing portion of the endplates. All posterior osteophytes should be removed from the vertebral bodies, as well as any large, anatomically significant anterior osteophytes that may interfere with the implantation of the Triadyme®-C disc.

Slight, symmetrical resection ("squaring off") of the posterior medial borders of the uncinate processes may be desirable, as it will allow for implantation of the widest implant possible. Resection of the uncinate processes should be limited to the posterior third of the disc space along the inferior endplate and should always be bilateral and symmetrical. Failure to perform a bilateral symmetrical resection could result in suboptimal implant positioning. Thorough irrigation should follow any bony resection.

TIPS & TRICKS

- **Release of the posterior longitudinal ligament is recommended, especially in cases involving a herniated disc.**

Surgical Technique

Step 5: Trial Placement and Assessment

After the decompression and endplate preparation are completed, Trials of the exact implant height and footprint are used to determine the proper implant size. The Trials are arranged in the Triadyme®-C instrument case according to length (short and long), width (narrow and wide), and height (5, 6, and 7 mm). Based on estimations from adjacent level discs, start with the largest footprint and shortest height Trial. Once the starting Trial is chosen and attached to the Quick Release Handle, insert the Trial into the disc space centered medial-laterally through visualization of its position relative to the uncinate processes, as well as by lining up the midline marking on the Trial head with the midline marks previously placed on the vertebral bodies.

Slight Caspar distraction may assist with initial insertion of the Trial into the disc space. However, once the Trial is introduced, all distraction should be released during Trial placement so that accurate sizing can be determined.

Gently tap the Trial into the disc space under fluoroscopic guidance. It is important that the Trial be advanced all the way back to the posterior margin of the disc space (Figure 27). If significant vertebral endplate is left uncovered anteriorly, choose a longer implant trial (Figure 28). Proper orthogonal orientation of the trial is confirmed via lateral fluoroscopy utilizing the hole through the middle of the Trial head (Figure 29).

The Trial should fit snugly within the disc space without causing over-distraction. If insertion of the Trial into the disc space requires more than gentle tapping, consideration should be given to selecting a shorter height Trial or performing additional disc space preparation and/or mobilization. With the Trial in place, reference normal adjacent-level disc heights, facet joints, and spinous processes to ensure correct trial height selection without over-distraction.

After the Trial is properly placed, lock the Caspar distractor in that position.

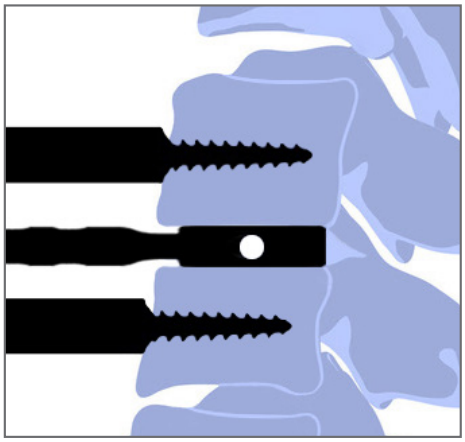


Figure 27

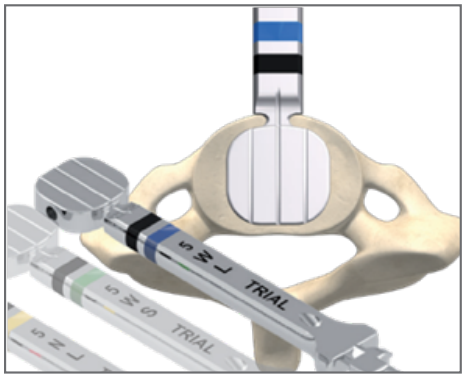
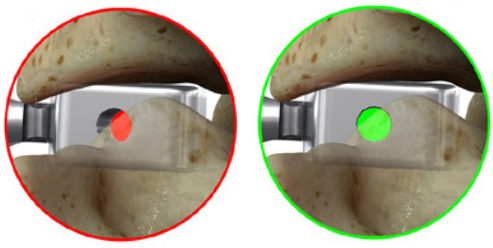


Figure 28



Incorrect Lateral Rotation

Correct Position

Figure 29

Step 5: Trial Placement and Assessment (continued)

TIPS & TRICKS

- **Before Trialing, Chiseling, or Implanting, it is recommended to confirm with A/P fluoroscopy that the patient's head and neck remain properly positioned and that no rotation has occurred.**
- **Select the largest footprint that will provide optimal A/P and lateral coverage of the endplates. Fluoroscopy may be helpful in determining this.**
- **Start with a 5 mm height Trial. (Most implanted cervical artificial discs are 5mm, a minority are 6mm, and only rarely are 7 mm implants used).**
- **Though the Trial and Chisel must be fully advanced to the posterior margin of the disc space in order to properly position the Implant, take care to ensure nothing advances beyond the posterior margin.**

Once the proper footprint and height Trial is determined, note the size (for example, "5NS") marked on the Trial shaft. Also note the color-coding on the Trial shaft (such as Red and Black) (Figure 30). This size marking and color coding will allow for quick and accurate selection of the matching size Chisels and Implants throughout the rest of the procedure.

Prior to removing the Trial, ensure the Caspar distractor is locked. This will help stabilize the segment during the next step of the procedure.

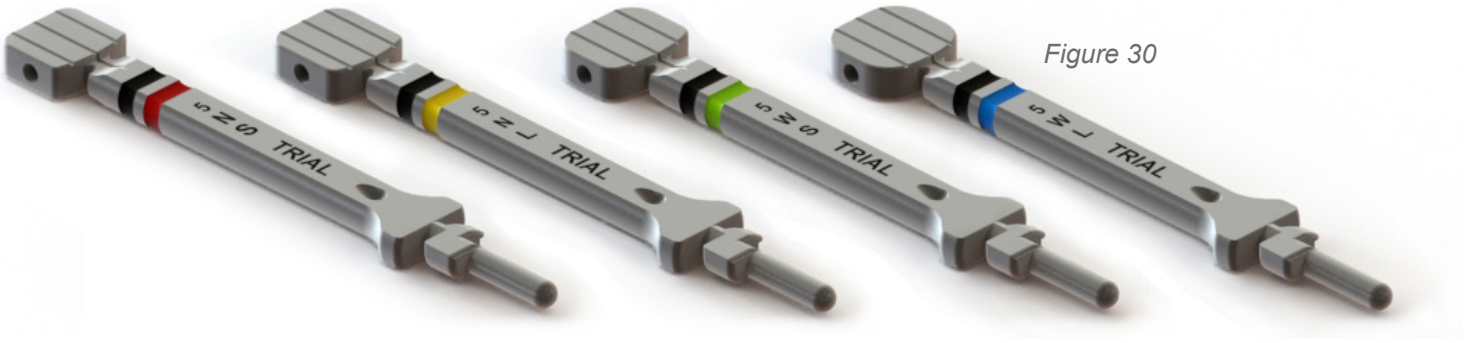


Figure 30

Surgical Technique

Step 6: Keel Preparation (Chiseling)

Select the Chisel corresponding to the size of the selected Trial and affix it to a Quick Release Handle (Figure 31). Gently progress the front of the Chisel into the disc space up to a point just prior to the keel blades engaging the vertebrae. Ensure that the Chisel is centered medial-laterally by visualizing its position relative to the uncinate processes, as well as by aligning the midline markings on the Chisel head with the midline marks previously placed on the vertebral bodies.

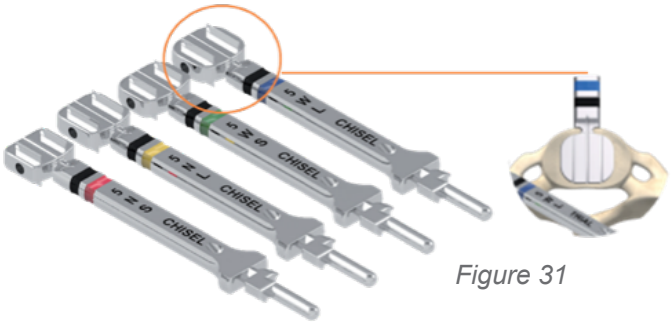


Figure 31

Gently tap the Chisel into the disc space under lateral fluoroscopic guidance. The trajectory of the Chisel should remain on midline and orthogonal to the disc space while advancing (Figure 32). Care should be taken to precisely position the Chisel so that the distal end of its head is advanced all the way to — but no further than — the posterior margin of the disc space. (Figure 33). **Leave the Chisel in place until the proper size implant is loaded and ready to deploy.**

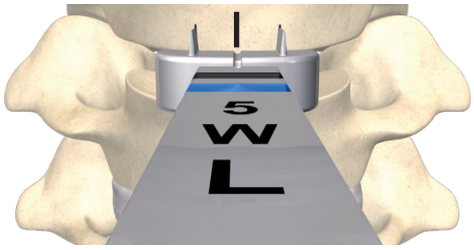


Figure 32

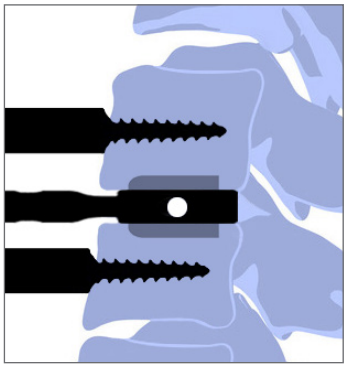


Figure 33

Carefully advance the Chisel until the distal end of its head is positioned at the posterior margin of the disc space.

TIPS & TRICKS

- **After removing the Chisel and before inserting the Implant, trace the Chisel blade tracks with a nerve hook or similar instrument to ensure they are clear of bony debris and ready to receive the Implant keels.**
- **Prior to inserting the Implant, thoroughly irrigate the disc space and Chisel blade tracks.**

Step 7: Implant Loading and Insertion

Implant Loading

To ease the locating of the vertebral body keel cuts, leave the Chisel in place until the implant is ready to be inserted. Choose the proper size implant based on the size of the Trial and Chisel used. All implants are double sealed in sterile packaging, attached to a disposable Implant Cartridge that connects to the same Quick Release Handle used with the other instruments. A retractable metal retainer clip on the end of the Implant Cartridge holds the implant together (Figure 34) and retracts with contact against the anterior lip of the vertebral bodies as the implant is advanced into the disc space (Figure 35). **Do not remove the implant from the Implant Cartridge prior to insertion into the disc space, and do not manually pull back on the metal retainer clip.**

The implant size and the word “UP” are etched into the superior retainer clip. Ensure that the implant size corresponds to the Trial and Chisel size used, and that the word “UP” is in the cranial direction.

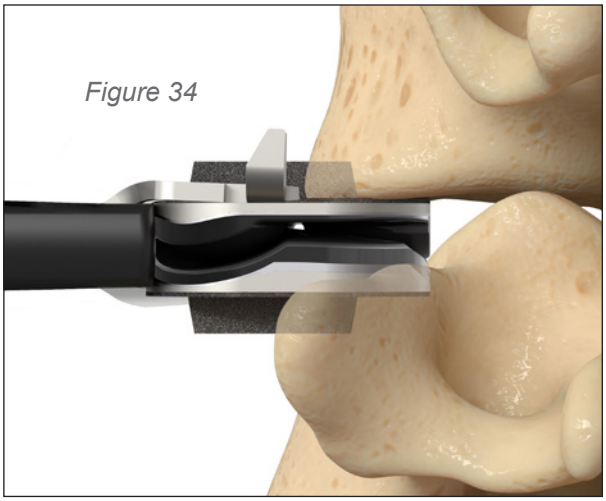


Figure 34

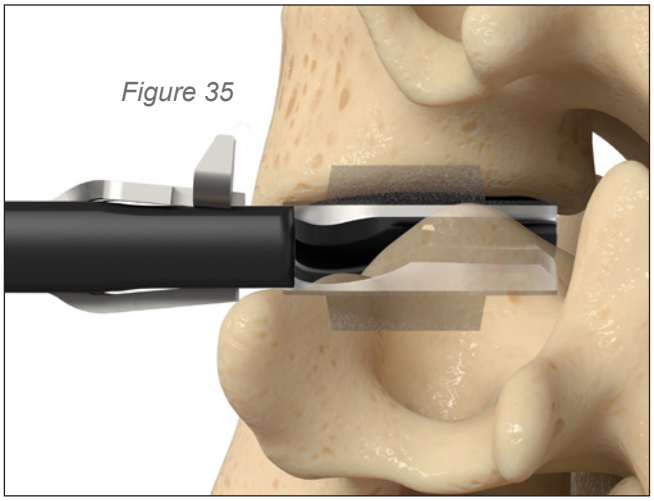


Figure 35

Casper Pins not shown.

Step 7: Implant Loading and Insertion (continued)

Triadyme®-C Insertion

Using the Slide Hammer included in the instrument set, remove the Chisel instrument just prior to implantation of the Triadyme®-C implant, in order to make locating the chisel cuts easier.

Align the Triadyme®-C Implant with midline. Gently advance the Implant into the disc space up to the point where the Implant keels line up with the chisel cuts (Figure 36). Verify that the Implant and the Quick Release Handle are directly in line with the disc space, and gently tap the Implant into place, ensuring the implant keels stay aligned with the chisel cuts. Employ lateral fluoroscopy to ensure that the Implant is driven in parallel to the vertebral body endplates and is properly advanced to its correct A/P position (as close as possible to the posterior margin of the disc space).

As the Triadyme®-C Implant is progressed into the disc space, the retainer clip will retract along the length of the Implant Cartridge. Once the device has reached the appropriate depth (confirmed by fluoroscopy), pull straight back on the Quick Connect Handle to remove the Inserter Cartridge, leaving the Triadyme®-C Implant in place. Confirm proper positioning of the Triadyme®-C Implant using fluoroscopy. If the Implant needs to be advanced further (Figure 36), do so by simply using the Quick Connect Handle/Implant Cartridge assembly as a tamp, ensuring the word “UP” on the retracted retainer clip is facing the cranial direction (Figure 37).

If the Implant needs to be repositioned, it will need to be removed from the disc space. If necessary, use the Extraction Instrument as described in the Implant Removal section of this guide. Replace with a new Implant.

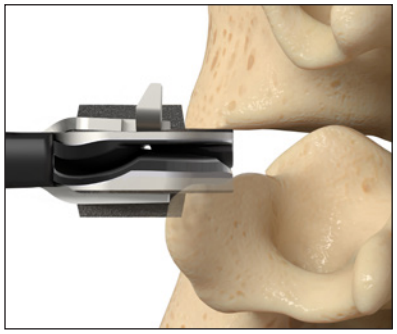


Figure 36

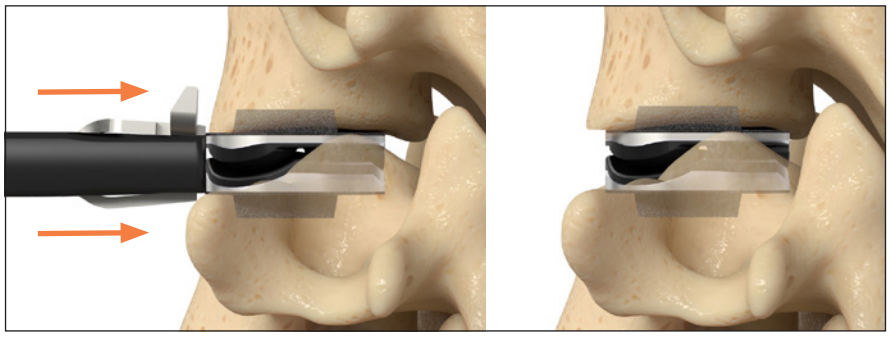


Figure 37

Casper Pins not shown.

TIPS & TRICKS

- **It is important to ensure that the Implant keels are aligned and engaged with the Chisel cuts prior to tapping the implant into place. Once the Implant’s keels have progressed into the vertebral bodies, the Implant Cartridge will not be able to be used to steer or change the Implant’s trajectory.**
- **If the Implant Cartridge is used as a tamp to advance the implant, ensure that the metal tongue on the Implant Cartridge’s distal tip (Figure 38) is precisely placed into the small gap between the implant halves before tamping.**

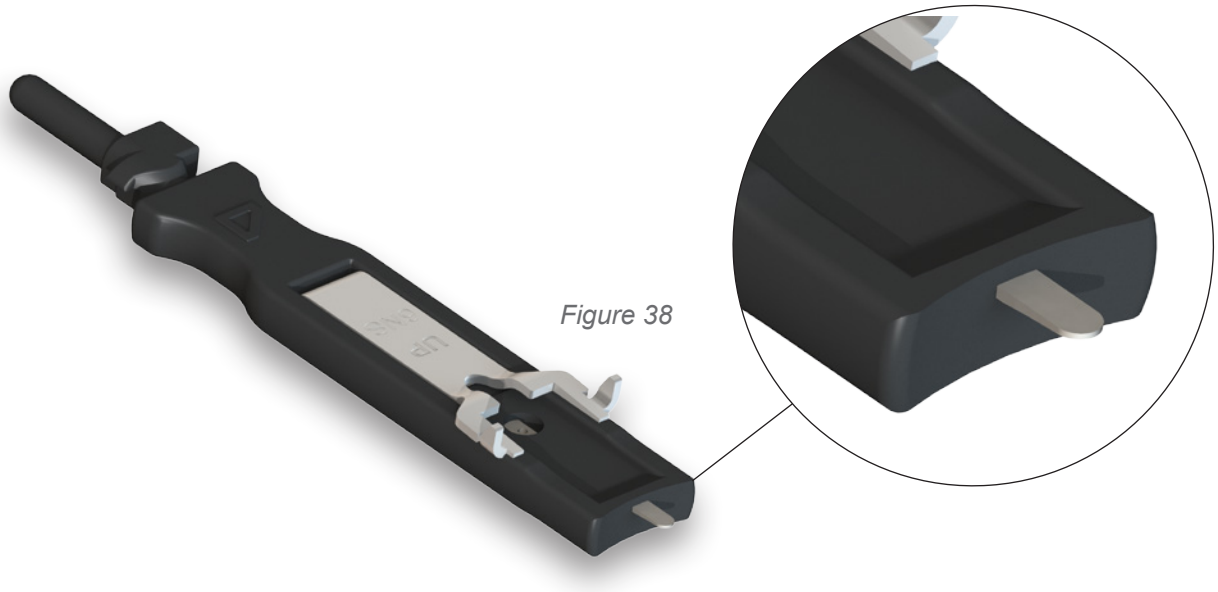


Figure 38

Surgical Technique

Step 8: Final Implant Assessment

Gentle compression with the Caspar distractor may be used to ensure complete seating of the Triadyme®-C Implant. Remove the Caspar distractor and pins, and confirm proper placement of the Triadyme®-C Implant via A/P and lateral fluoroscopy (Figure 39). Thoroughly irrigate and aspirate the space to remove any loose particles. Place bone wax/hemostatic agent into the holes created by the Caspar pins and onto any other bleeding bony surfaces exposed during anterior osteophyte removal.

Close the wound in normal fashion.

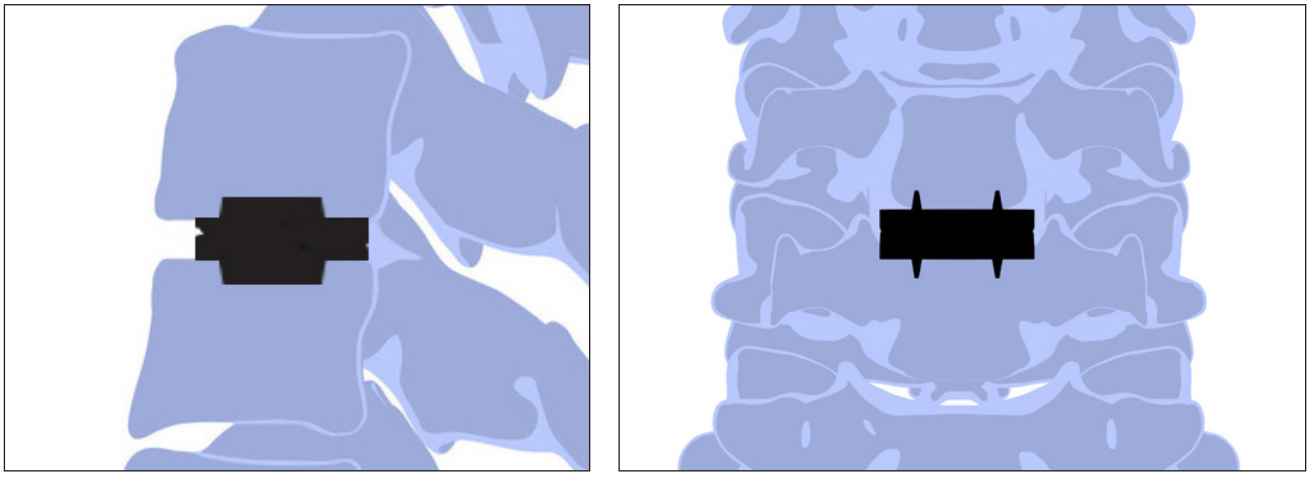


Figure 39

TRIADYME®-C

Surgical Technique

Considerations for Two-Level Implantation

For patients indicated for a Triadyme®-C at two levels, the following technique adaptations should be considered:

- Before beginning the second level, use fluoroscopy to ensure the patient's head and neck are still properly aligned and that no rotation has occurred.
- Complete one level (discectomy through implantation) at a time.
- Consider implanting at the less mobile segment first.
- Pay attention to not "over-stuff" the first level, thus leaving too little space for proper implant sizing at the second level.
- Place the first Caspar pin into the center of and orthogonal to the middle vertebral body, then place the peripheral Caspar pin parallel to the first. After implantation at the first level, move the peripheral Caspar pin to the vertebral body opposite the second operative level, again placing it parallel to the first Caspar pin.

Implant Removal

Extraction Instrumentation and Removal Technique

If the Triadyme®-C needs to be removed from the intervertebral space, use a surgical approach that mimics that which was used to implant the device. Carefully remove any bone that has grown over the anterior aspects of the implant that would interfere with its removal.

Triadyme®-C Extraction Instrumentation is provided in the instrument set and includes (2) Extractor halves, (2) Extractor Pins, and (1) Extractor Pin Driver. Either half of the Extractor can be used with either the superior or inferior portion of the implant. The front of each half of the Extractor instrument is shaped like an osteotome and is meant to be driven between the implant and the vertebral body, centered between the two keels of the implant.

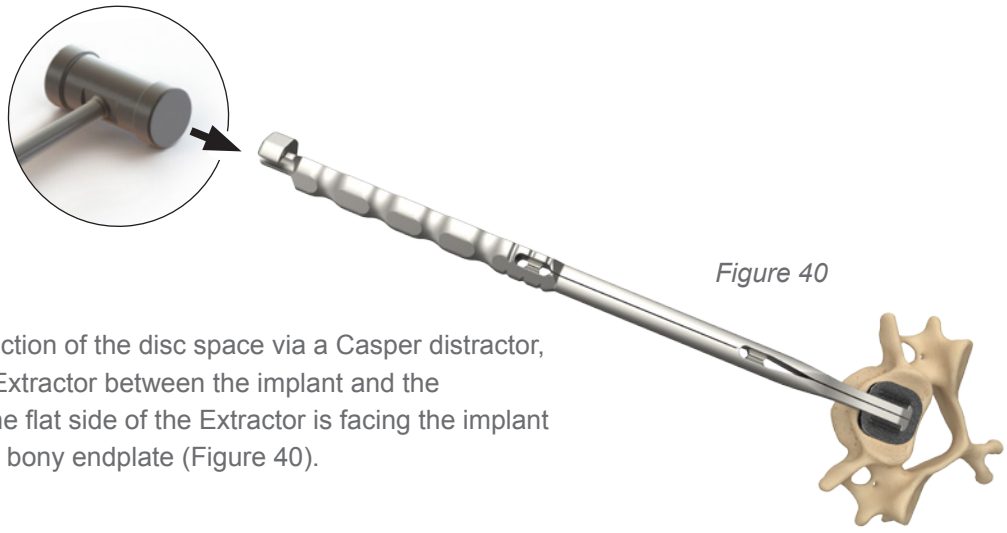


Figure 40

A After application of slight distraction of the disc space via a Casper distractor, carefully advance the implant Extractor between the implant and the vertebral body, ensuring that the flat side of the Extractor is facing the implant and the beveled edge is facing bony endplate (Figure 40).

Implant Removal (continued)

A ledge on the underside of each Extractor half acts as a depth stop. When the Extractor is fully advanced, this ledge abuts against the anterior edge of the implant, providing confirmation that the Extractor is fully seated. Careful fluoroscopic monitoring should be employed to ensure that the instrument is not driven too far posteriorly.

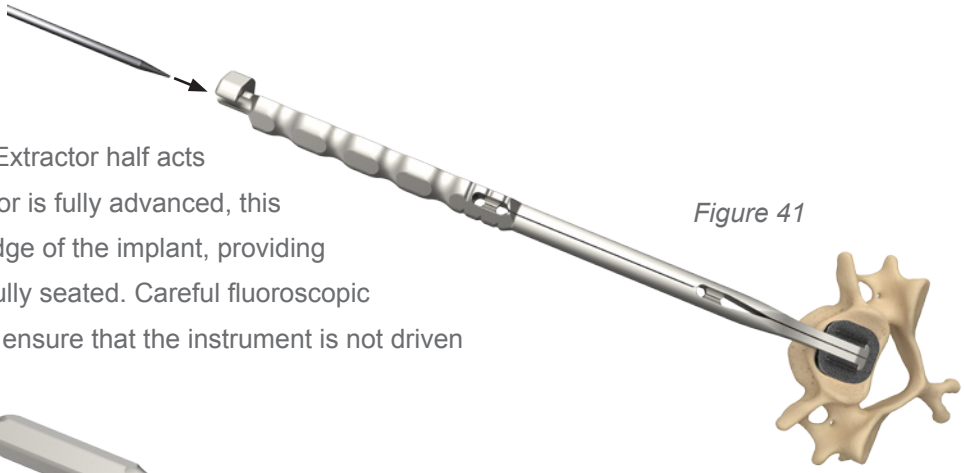


Figure 41

B Place an Extractor Pin down the center hole of the Extractor half with the pointed tip facing distally towards the prongs (Figure 41). Advance the Extractor Pin by turning the Extractor Pin Driver clockwise to hook the distal edges of the implant keels (Figure 42). **When advancing the Extractor Pin, limit the amount of torque being applied by using only two or three fingers to turn the Extractor Pin Driver. The Pin will advance to a hard stop, indicating full deployment of the Extractor prongs. Over-torquing is unnecessary and may damage the Extractor instrumentation.**

Figure 42

TIPS & TRICKS

- **Do not place an Extractor Pin into its Extractor half until that Extractor half has been fully seated, with its depth stop against the implant.**
- **Completely secure one half of the Extractor to the implant by fully advancing its Extractor Pin before inserting the second Extractor half.**
- **A Casper distractor should be used to slightly distract the implanted space prior to impacting the extractor half.**

Surgical Technique

Implant Removal (continued)

C Repeat steps A and B for the other half of the implant, ensuring that the flat Extractor edges are facing each other.

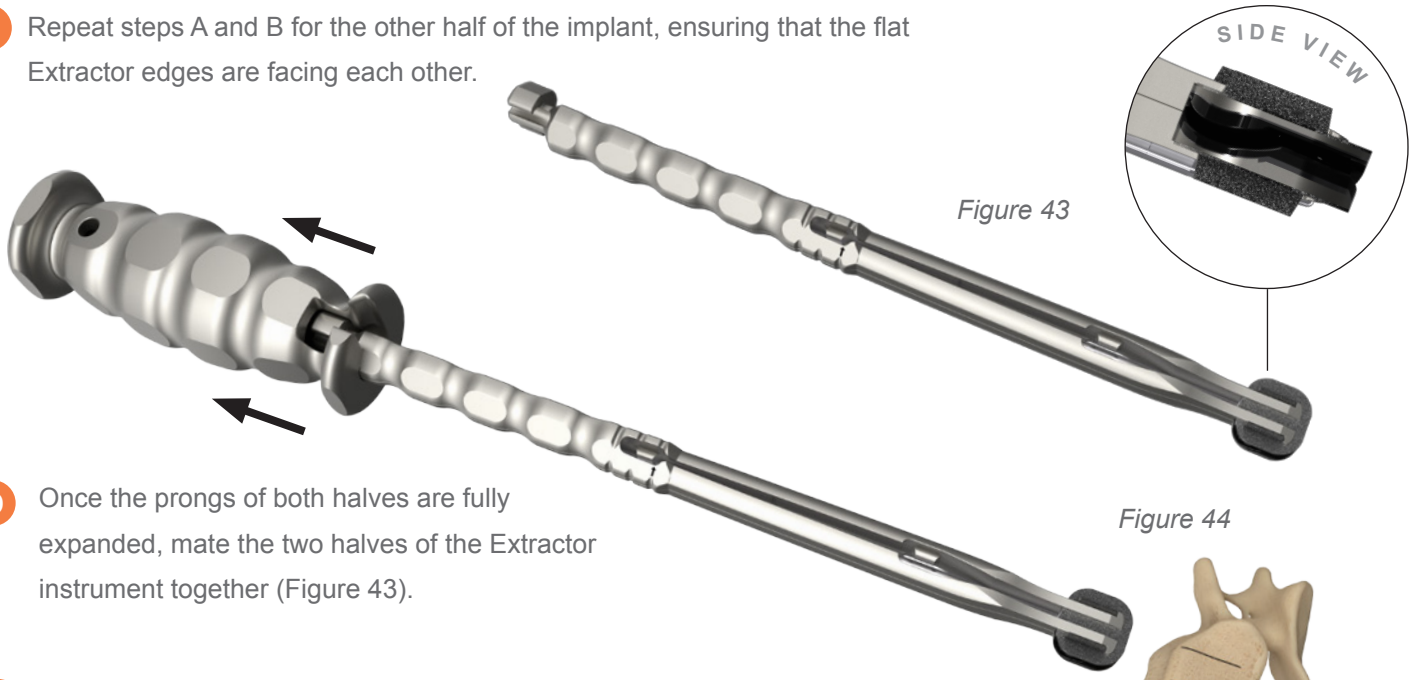


Figure 43

D Once the prongs of both halves are fully expanded, mate the two halves of the Extractor instrument together (Figure 43).

E Use the Slide Hammer to disengage and remove the implant from the disc space. Both halves of the implant should come out together (Figure 44).

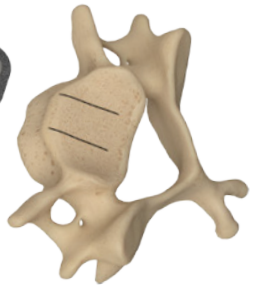


Figure 44

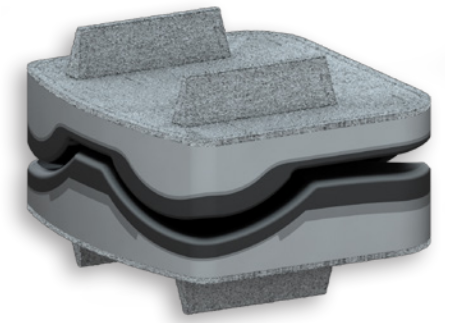
The Extractor instrument is intended for complete removal of the Triadyme®-C implant. Do not use the Extractor instrument to adjust the depth of the implant.

Should it become necessary to remove a Triadyme®-C implant, please contact Dymicron for further instructions regarding all necessary data to be collected. Should it be determined that further analysis of the explanted device is warranted, Dymicron will provide an explant retrieval kit including leak-proof containers and return instructions.

Set Layout and Contents

Implants

CATALOG NUMBER	DESCRIPTION	HEIGHT (mm)	WIDTH x LENGTH (mm)
CS-5A	5NS	5	14.5mm x 13mm
CS-5B	5NL	5	14.5mm x 15mm
CS-5C	5WS	5	16.5mm x 13.5mm
CS-5D	5WL	5	16.5mm x 15.5mm
CS-6A	6NS	6	14.5mm x 13mm
CS-6B	6NL	6	14.5mm x 15mm
CS-6C	6WS	6	16.5mm x 13.5mm
CS-6D	6WL	6	16.5mm x 15.5mm
CS-7A	7NS	7	14.5mm x 13mm
CS-7B	7NL	7	14.5mm x 15mm
CS-7C	7WS	7	16.5mm x 13.5mm
CS-7D	7WL	7	16.5mm x 15.5mm

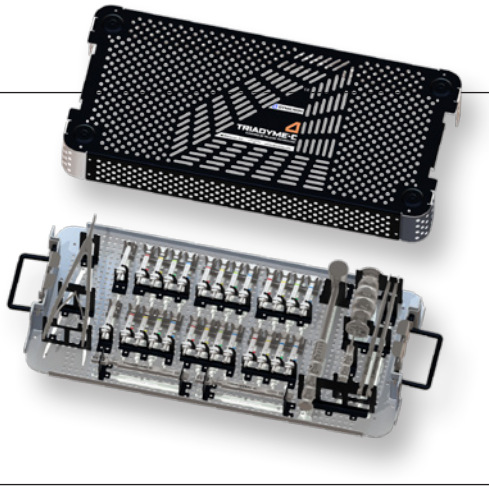


TRIADYME®-C

Set Layout and Contents

Instrumentation

CATALOG NUMBER	DESCRIPTION
CS-IS	Instrument Set
CS-CA	Instrument Case



CATALOG NUMBER	DESCRIPTION
CS-RH	Quick Release Handle

CATALOG NUMBER	DESCRIPTION
CS-Sr	Spreader

CATALOG NUMBER	DESCRIPTION
CS-Rp-1	Solid Rasp
CS-Rp-2	Open Rasp

Set Layout and Contents

Instrumentation

CATALOG NUMBER	DESCRIPTION	COLOR REFERENCE
CS-Tr-5A	5NS Trial (5mm H x 14.5mm W x 13mm L)	
CS-Tr-5B	5NL Trial (5mm H x 14.5mm W x 15mm L)	
CS-Tr-5C	5WS Trial (5mm H x 16.5mm W x 13.5mm L)	
CS-Tr-5D	5WL Trial (5mm H x 16.5mm W x 15.5mm L)	
CS-Tr-6A	6NS Trial (6mm H x 14.5mm W x 13mm L)	
CS-Tr-6B	6NL Trial (6mm H x 14.5mm W x 15mm L)	
CS-Tr-6C	6WS Trial (6mm H x 16.5mm W x 13.5mm L)	
CS-Tr-6D	6WL Trial (6mm H x 16.5mm W x 15.5mm L)	
CS-Tr-7A	7NS Trial (7mm H x 14.5mm W x 13mm L)	
CS-Tr-7B	7NL Trial (7mm H x 14.5mm W x 15mm L)	
CS-Tr-7C	7WS Trial (7mm H x 16.5mm W x 13.5mm L)	
CS-Tr-7D	7WL Trial (7mm H x 16.5mm W x 15.5mm L)	

TRIADYME®-C

Set Layout and Contents

Instrumentation

CATALOG NUMBER	DESCRIPTION	COLOR REFERENCE
CS-Ch-5A	5NS Chisel (5mm H x 14.5mm W x 13mm L)	
CS-Ch-5B	5NL Chisel (5mm H x 14.5mm W x 15mm L)	
CS-Ch-5C	5WS Chisel (5mm H x 16.5mm W x 13.5mm L)	
CS-Ch-5D	5WL Chisel (5mm H x 16.5mm W x 15.5mm L)	
CS-Ch-6A	6NS Chisel (6mm H x 14.5mm W x 13mm L)	
CS-Ch-6B	6NL Chisel (6mm H x 14.5mm W x 15mm L)	
CS-Ch-6C	6WS Chisel (6mm H x 16.5mm W x 13.5mm L)	
CS-Ch-6D	6WL Chisel (6mm H x 16.5mm W x 15.5mm L)	
CS-Ch-7A	7NS Chisel (7mm H x 14.5mm W x 13mm L)	
CS-Ch-7B	7NL Chisel (7mm H x 14.5mm W x 15mm L)	
CS-Ch-7C	7WS Chisel (7mm H x 16.5mm W x 13.5mm L)	
CS-Ch-7D	7WL Chisel (7mm H x 16.5mm W x 15.5mm L)	

Set Layout and Contents

Instrumentation

CATALOG NUMBER	DESCRIPTION
CS-Mt	Mallet

CATALOG NUMBER	DESCRIPTION
CS-SH	Slide Hammer

CATALOG NUMBER	DESCRIPTION
CS-ED	Extractor Pin Driver

CATALOG NUMBER	DESCRIPTION
CS-Ex	Extractor
	(Male Extractor Half)
	(Female Extractor Half)
	(Extractor Pins, x2)

TRIADYME®-C

Indications, Contraindications, and Warnings

Indications

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

Contraindications

The Triadyme®-C device should not be implanted in patients with the following conditions:

- Active systemic infection or infection localized to the site of implantation
- Allergy or sensitivity to the implant materials (titanium, titanium carbide, cobalt, chromium, aluminum, vanadium, tin, molybedenum)
- Osteoporosis, defined as a DXA bone mineral density T-score equal to or less than -2.5
- Marked cervical instability on radiographs (e.g., radiographic signs of subluxation greater than 3.5 mm or angulation of the disc space more than 11 degrees greater than adjacent segments)
- Bridging osteophytes or an absence of motion (less than 2 degrees)
- Significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma)
- Significant kyphotic deformity or significant reversal of lordosis
- Severe facet disease or facet degeneration

Warnings

Correct installation and placement of the device is essential to optimal performance. Implanting the Triadyme®-C device should only be attempted by surgeons who are thoroughly knowledgeable about spinal anatomy and biomechanics, have experience with anterior cervical spinal surgeries, and have hands-on training in the use of this specific device. A lack of adequate experience and/or training may lead to higher incidences of adverse effects, including neurological complications.

Correct selection of the appropriate implant size is extremely important to assure the proper placement and function of the Triadyme®-C device. This technique guide provides step-by-step instructions for selecting and implanting an appropriately sized Triadyme®-C device.

TRIADYME®-C

Warnings (continued)

Due to the proximity of vascular structures, neurological structures, and major organ systems to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage and/or injury to adjacent organs with the use of the Triadyme®-C. Care must be taken to identify and protect these structures.

There is a risk of heterotopic ossification associated with artificial cervical discs, which could lead to reduced cervical motion or fusion.

MRI Safety Information

The Triadyme®-C Cervical Total Disc Replacement is MR Conditional. A patient with the Triadyme®-C Cervical Total Disc Replacement implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Condition of Use/Information
Nominal Values of Static Magnetic Field (T)	1.5 Tesla or 3.0 Tesla
Maximum Spatial Field Gradient (T/m and gauss/cm)	100 T/m (10,000 Gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	There are no Transmit Coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive Knee RF coil, etc.)
Operating Mode of MR system	Normal Operating Mode
Maximum Whole-Body Averaged SAR	2 W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole-body averaged SAR of 2 W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact. Therefore, carefully select pulse sequence parameters if the implant is in the area of interest. The artifact may extent approximately 1.0 cm from the implant.

TRIADYME®-C
POWERED BY TRI-LOBE TECHNOLOGY

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