



Monaco

3D PRINTED EXPANDABLE SPACER SYSTEM



Surgical Technique Guide

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PARALLEL

ANGULAR



Overview

The Monaco Expandable Spacer System is a titanium alloy market-leading solution that is inserted through conventional Posterior Lumbar Interbody Fusion (PLIF) and Transforaminal Lumbar Interbody Fusion (TLIF) approaches. Once inserted into the disc space, the Monaco expandable cage, with tactile sensitivity, can be expanded continuously with minimal turns of the distraction mechanism. The implant height can increase to restore disc space height and reduce subsidence.

Monaco implants can be placed seamlessly into the disc space due to their low profile and bulleted design. The implant can be inserted, expanded, and rapidly post packed through a proprietary inserter, optimizing surgical efficiency. The Monaco interbody system provides restoration of sagittal alignment with customizable degrees of lordosis and was designed to induce lordosis in an anatomical fashion, unique to what is currently on the market.

The Monaco Expandable Spacer System represents the next generation of expandable technology.

This is intended as a guide only. There are multiple techniques for the delivery of Lumbar Cages as with any surgical procedure. A surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warnings.

Value Proposition

The Monaco Expandable Spacer System provides a robust expandable titanium cage with instrumentation that delivers control and performance to clinicians through tactile feedback and reliable graft delivery for the PLIF/TLIF approach.

Its unique design minimizes both neural retraction and insertion force, accommodates a larger graft channel, and provides controlled expansion to restore disc height.

The wide array of implant options and expansive instrumentation delivers a streamlined, efficient procedural sequence that can address even the most difficult pathologies.

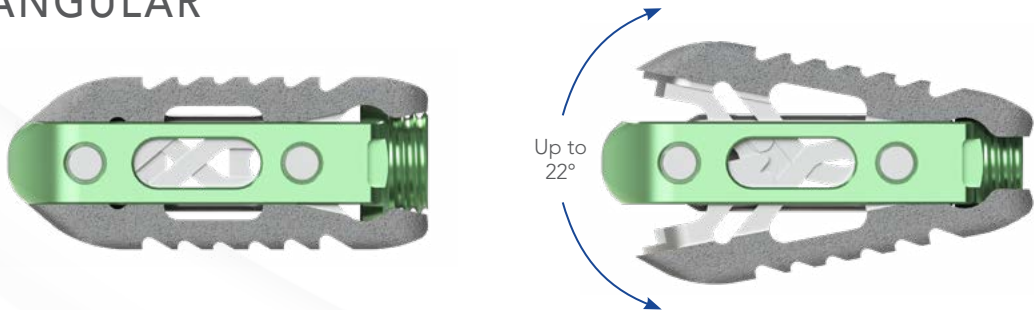
PARALLEL



Parallel Implant Sizes		
Heights (mm)	Widths (mm)	Lengths (mm)
7 – 10, 9 – 14, & 13 – 18	9, 10.5, & 12	22, 26, & 30

**Expansion varies based on implant height*

ANGULAR



Angular Implant Sizes (Max Angle 22°)		
Heights (mm)	Widths (mm)	Lengths (mm)
7, 9, 11, 13, & 15	9, 10.5, & 12	22, 26, & 30

**Expansion varies based on implant height*

System Features

- Titanium Alloy Implant with 3D Printed Textured Titanium Endplates Promotes Immediate Mechanical Fixation & Potentially Upregulating the Production of Osteogenic Factors that are Critical for Bone Growth & Fusion
- Inserted at a Reduced Height to Minimize Impaction & Preserve Endplate Integrity
- Automatic Locking Once Desired Expansion Height is Achieved Without Loss of Height Restoration Helps to Streamline Procedure
- Large Graft Window with the Ability to Pack Bone Graft After Being Expanded, Assists with Sentinel & Columnar Fusion Through the Implant
- There is No Loss of Length When the Implant is Fully Expanded – Length is Not Compromised
- Controlled & Continuous In Situ Expansion Allows for Foraminal & Disc Height Restoration
- When Expanded in the Disc Space, the Implant Optimizes Endplate-to-Endplate Fit to Assist in the Restoration of Normal Alignment
- Bulleted Tip Simplifies Insertion in Collapsed Degenerative Discs Without Compromising the Apophyseal Ring
- Adjustable Trials Reduces Trailing Steps & Accurately Determines Optimal Implant & Disc Height
- Multiple Footprints With Effective Sizing Allows for Minimally Invasive Surgery (MIS) Approach & Optimal Fit for Larger Patient Anatomies
- Streamlined Instrumentation Provides the Surgeon Minimal Tissue Disruption & Nerve Retraction While Restoring Patient Alignment

1 PREPARATION

Endplate Preparation

Perform a complete discectomy and prep the endplates using an open or MIS procedure.

The Tube is designed to work with all the Moraco disc prep instruments for a MIS procedure (*Figure 1*).

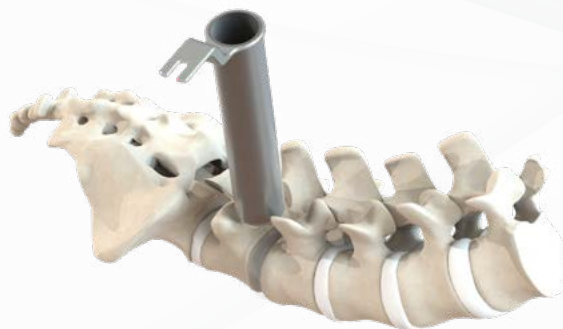


Figure 1

Shaver

Attach the T-Handle to the Shaver. Turn the T-Handle to activate the Shaver (*Figure 2*). Turn the silver knob to change the angle the Shaver up to 75° (*Figure 2*).

Note: The Shaver angles up (away from the handle orientation). Make sure the instrument is orientated correctly so as the Shaver is angled into the disc space.

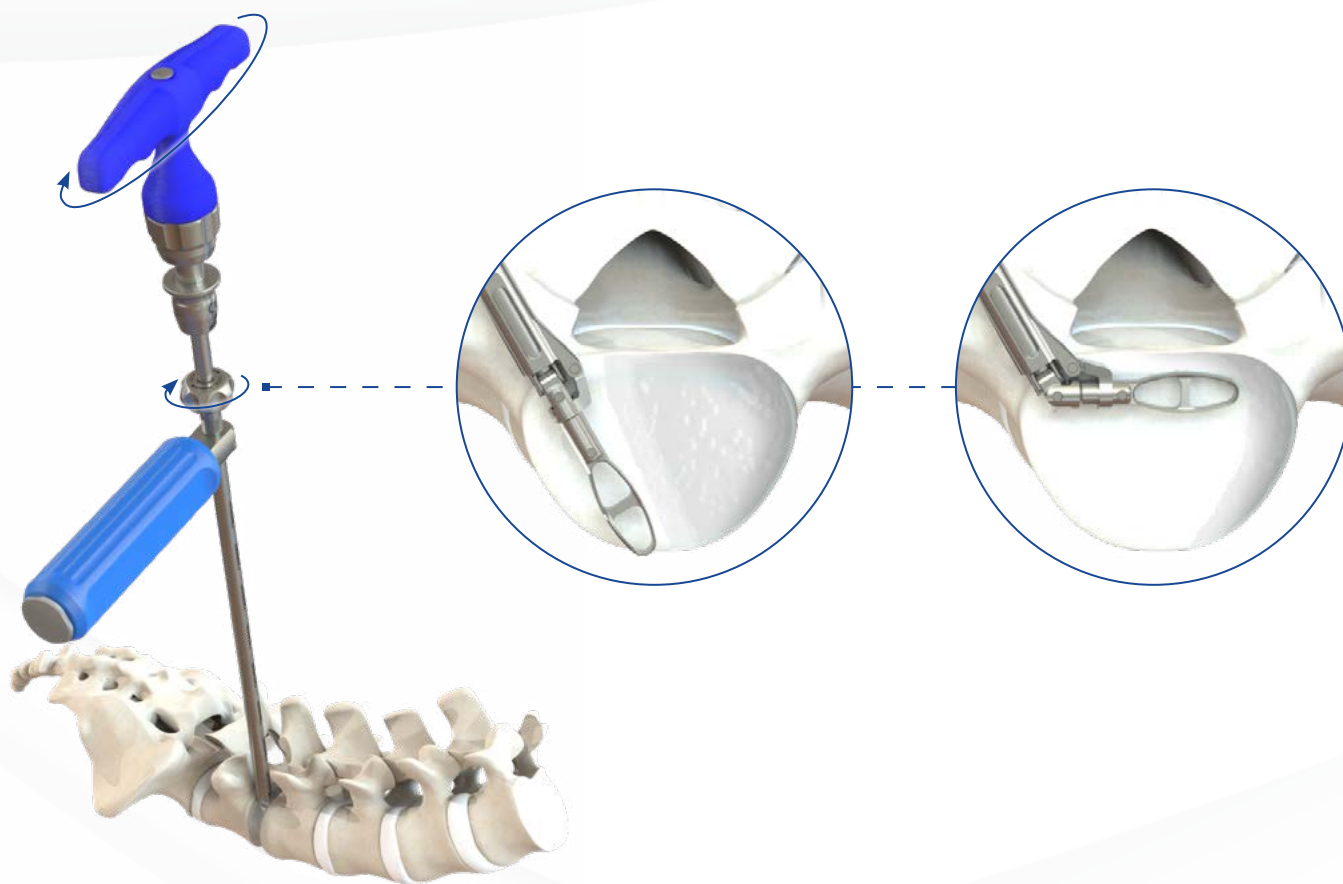
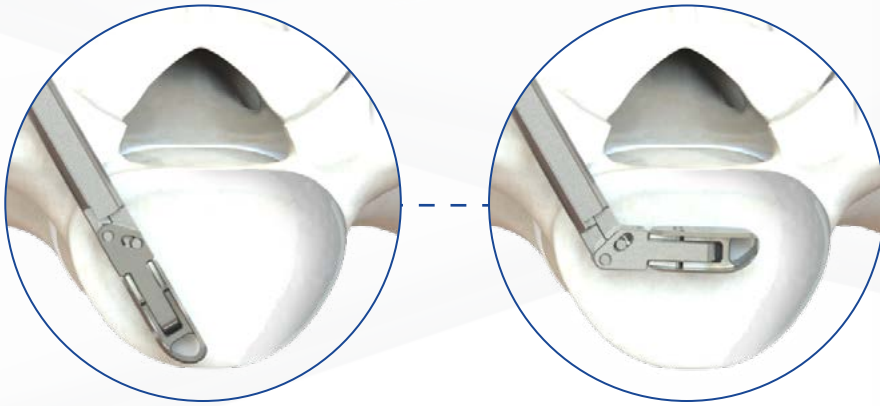


Figure 2



Scrapper

Insert the Scrapper in to the disc space. Turn the silver knob to change the angle of the Scrapper up to 75° (Figure 3).

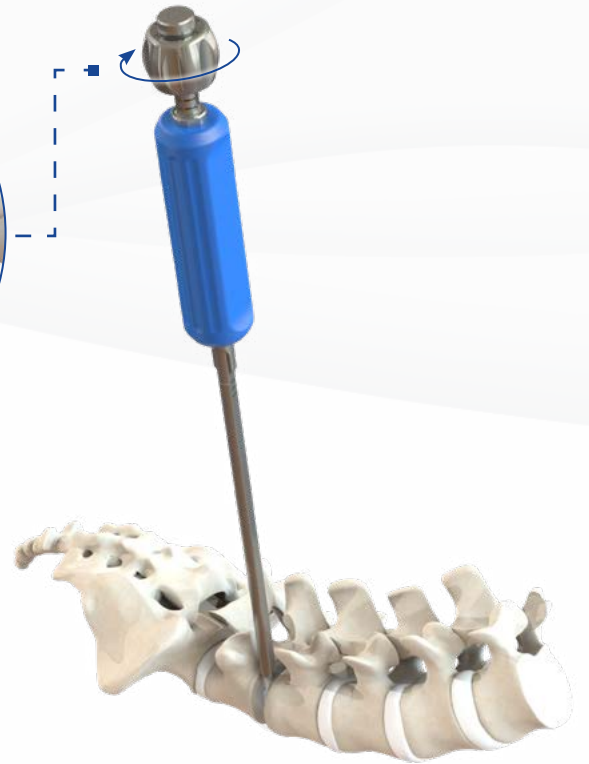
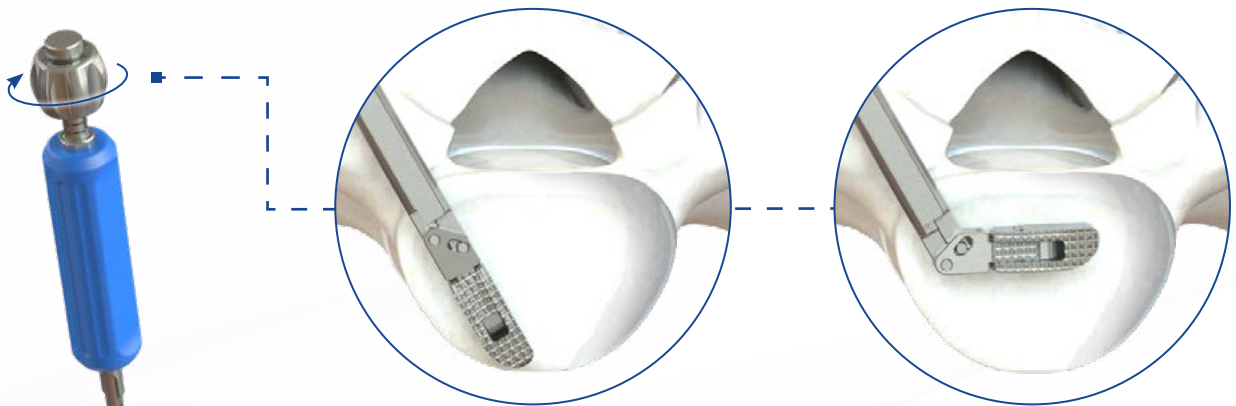


Figure 3



Rasp

Insert the Rasp in to the disc space. Turn the silver knob to change the angle of the Rasp up to 75° (Figure 4).

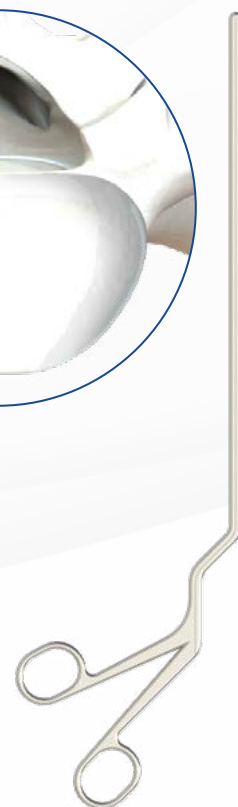
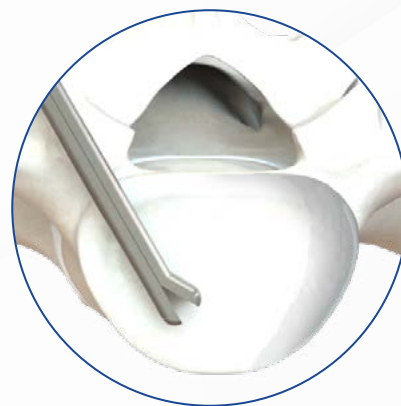


Figure 4

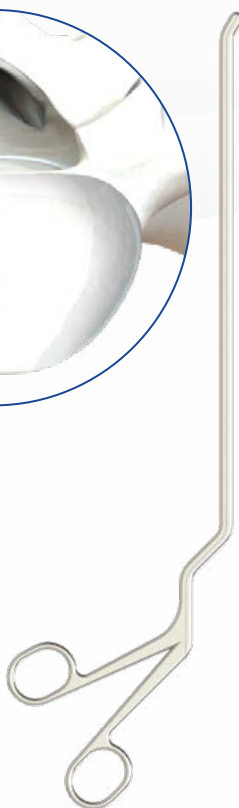
1 PREPARATION (CONT.)

Pituitary

The Monaco disc prep instruments come standard with a Straight, Up Biting, and Curved Pituitary.



Straight Pituitary



Up Biting Pituitary



Curved Pituitary

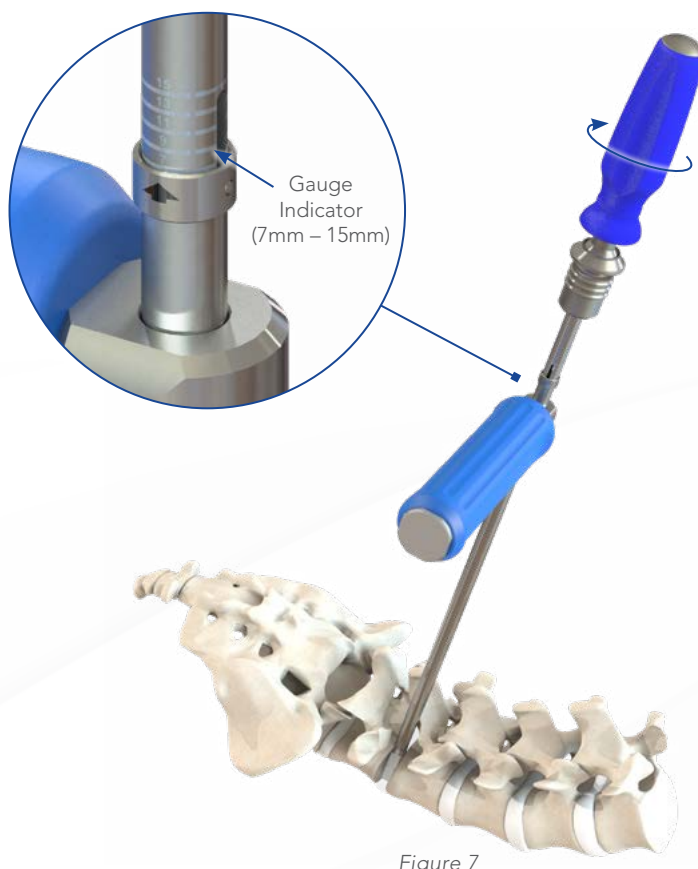
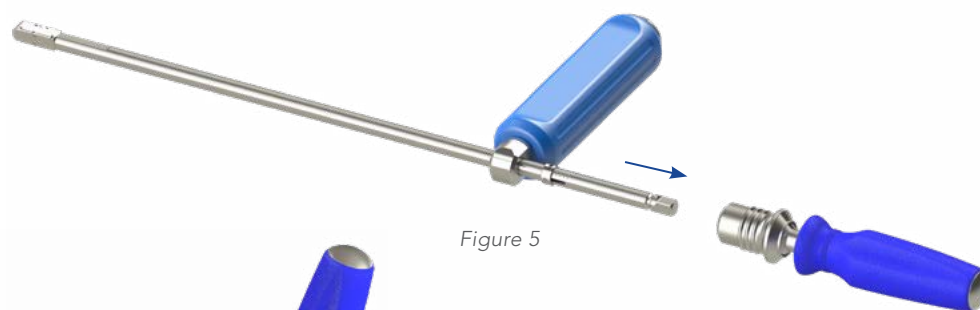
2 SIZING

Parallel Adjustable Gauge

The Parallel Adjustable Gauge can be used to distract and/or measure the disc space. Attach the Parallel Adjustable Gauge to the Axial Torque Limiting Handle by pulling back the handle collar and inserting it into the adapter connection (*Figure 5*). Pull the adapter to ensure it is connected securely.

Insert the construct into the disc space (*Figure 6*). AP and lateral fluoroscopy can be used to confirm position.

Once placement is confirmed, the Parallel Adjustable Gauge can be expanded by turning the Axial Torque Limiting Handle clockwise (*Figure 7*). Monitor under fluoroscopy while turning handle until the gauge is expanded in the disc space. The indicator at the top of the Parallel Adjustable Gauge will measure the disc space (*Figure 7*).



2 SIZING (CONT.)

Trial (Optional)

Based on the disc space measurements from the Parallel Adjustable Gauge, select the appropriate sized Trial (Figure 8).

To ensure correct alignment, line up tangs on the Inserter to the Trial head (Figure 9). Once the Trial is properly aligned and seated on the end of the Inserter, turn the silver knob clockwise to thread it onto the (Figure 9).



Figure 8

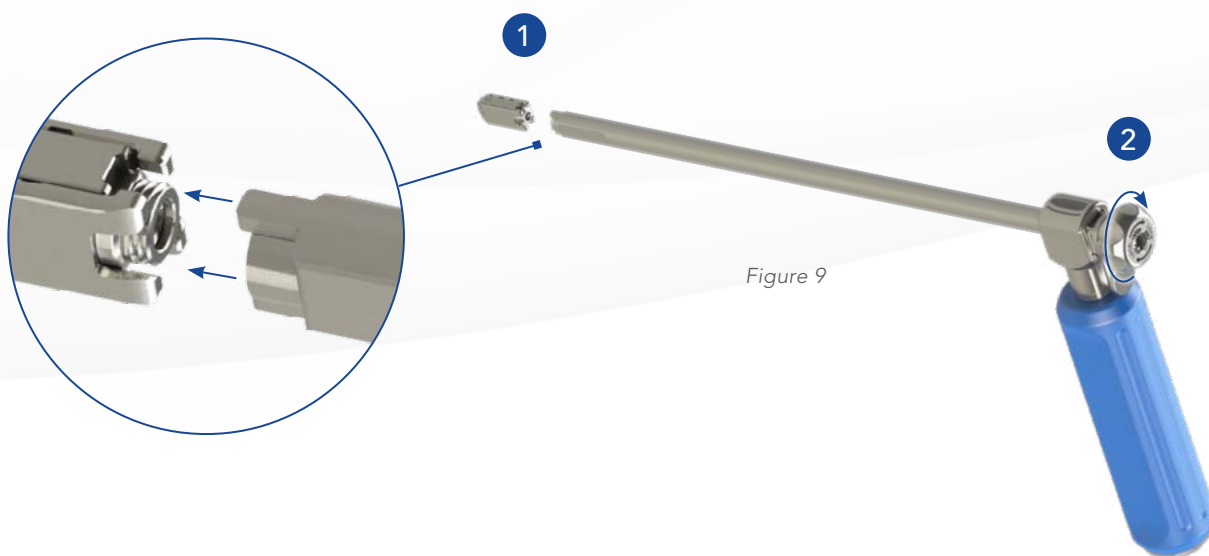


Figure 9

Pick the Parallel Driver that corresponds with the Trial size selected (Figure 10).

Attach the Parallel Driver to the Axial Torque Limiting Handle by pulling back the handle collar and inserting it into the adapter connection. Pull the adapter to ensure it is connected securely.



Figure 10

Insert the trial into disc space (*Figure 11*). Use AP and lateral fluoroscopy to confirm position of the trial.

Once the Trial is fully inserted and positioned correctly, insert the Parallel Driver through the back of the Inserter. The indicator orientation needs to align with the orientation indicator located on the inserter handle (*Figure 12*).



Note: Before inserting driver, confirm that the indicator is set at the starting position.

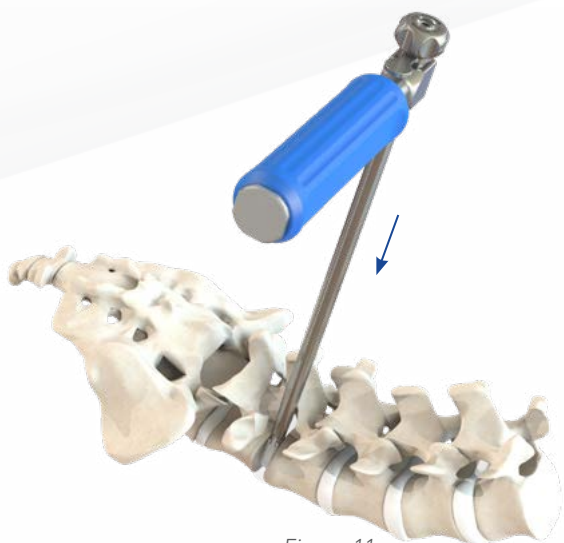


Figure 11

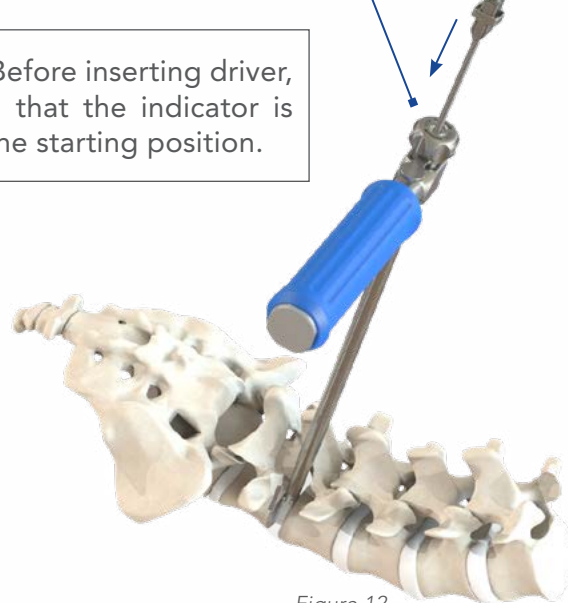


Figure 12

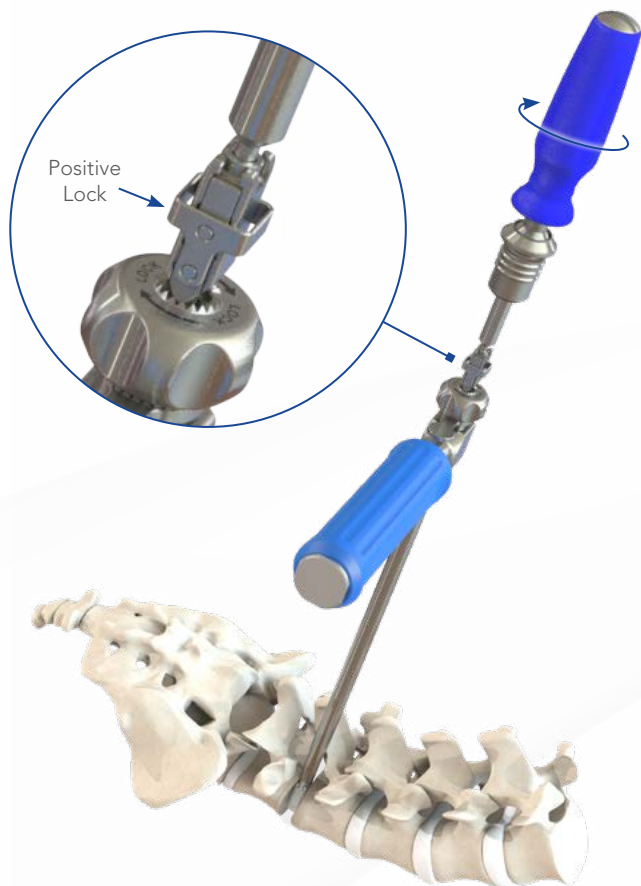


Figure 13

Turn the Axial Torque Limiting Handle clockwise to expand the Trial. The Parallel Driver's indicator is a visual indicator that will expand in correlation with the Trial. The positive stop in the center will not allow it to expand more than it is intended to (*Figure 13*).

Remove the entire construct by turning the Axial Torque Limiting Handle counter-clockwise to fully decompress the Trial and then gently pulling the Inserter straight out.

3 IMPLANT

Select the implant size (Figure 14) that corresponds with the Trial and attach it to the Inserter. To ensure correct alignment, line up tangs on the Inserter to the Implant (Figure 15). Once the Implant is properly aligned and seated on the end of the Inserter, turn the silver knob clockwise to thread it onto the (Figure 15).



Figure 14

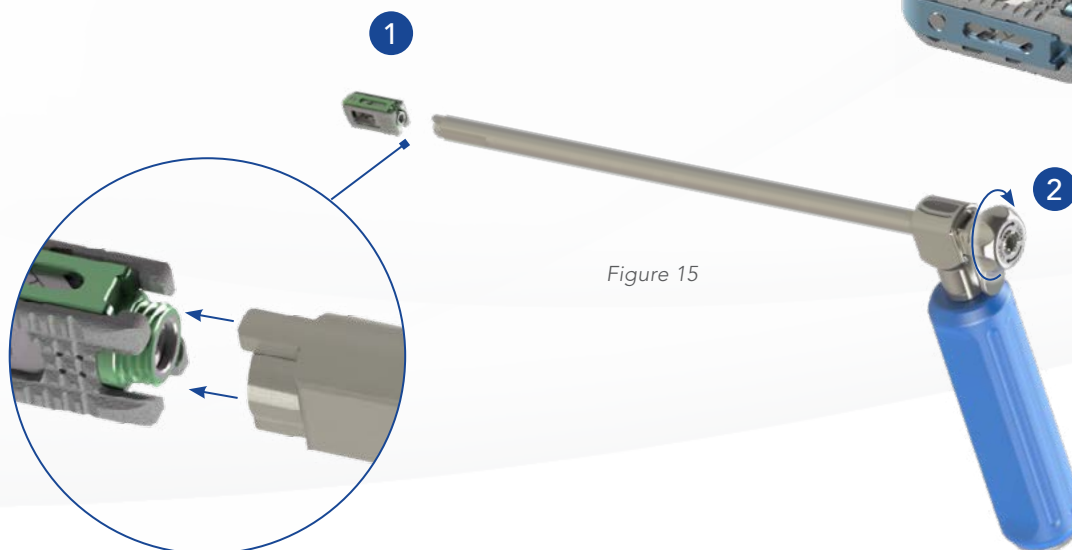


Figure 15

Insert the implant into disc space (Figure 16). Use AP and lateral fluoroscopy to confirm position of the implant.

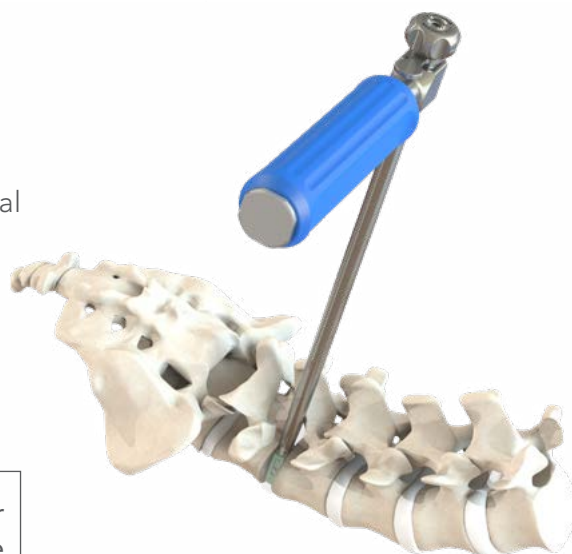


Figure 16

Optional: The Implant can be pre-packed with bone graft or have the graft material delivered in situ. If pre-packing the Implant, use the Packing Block and Graft Tamp (Figure 17).

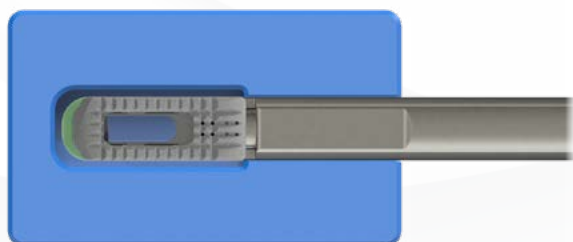


Figure 17

Insert the implant into disc space (*Figure 18*). Use AP and lateral fluoroscopy to confirm position of the trial.

Once the implant is fully inserted and positioned correctly, insert the Parallel Driver through the back of the Inserter. The indicator orientation needs to align with the orientation indicator located on the inserter handle (*Figure 18*).

Turn the Axial Torque Limiting Handle clockwise to expand the Implant. The Parallel Driver's indicator is a visual indicator that will expand in correlation with the Implant. The positive stop in the center will not allow it to expand more than it is intended to (*Figure 19*).

Once the implant has been delivered and expanded to optimal height, remove the Axial Limiting Handle by gently pulling straight out (*Figure 20*).

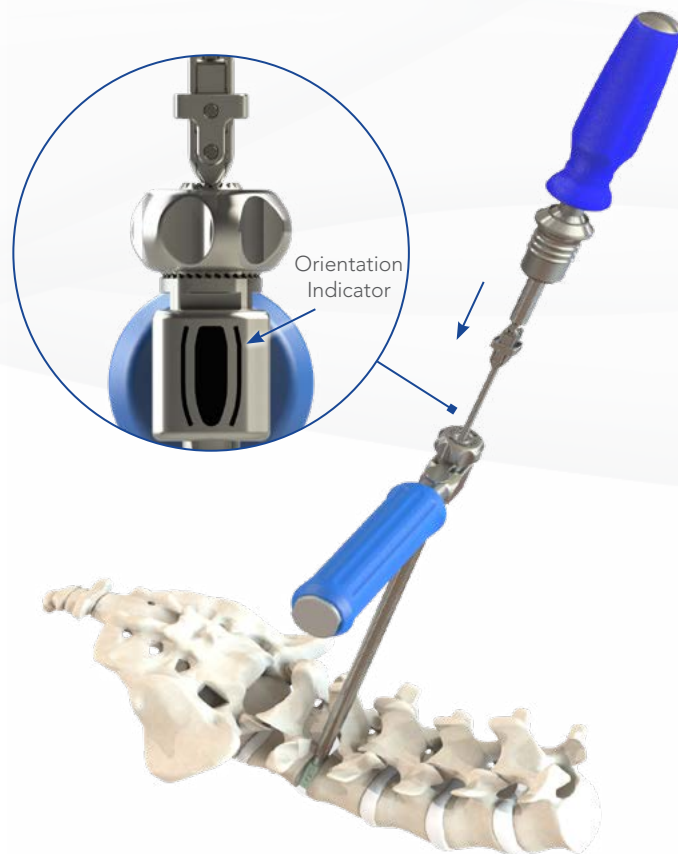


Figure 18

Note: Before inserting driver, confirm that the indicator is set at the starting position.

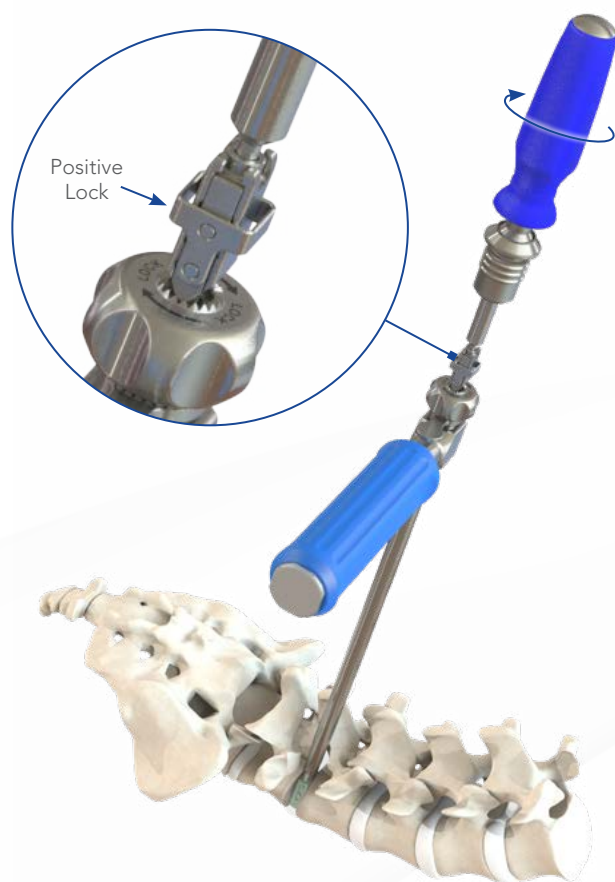


Figure 19

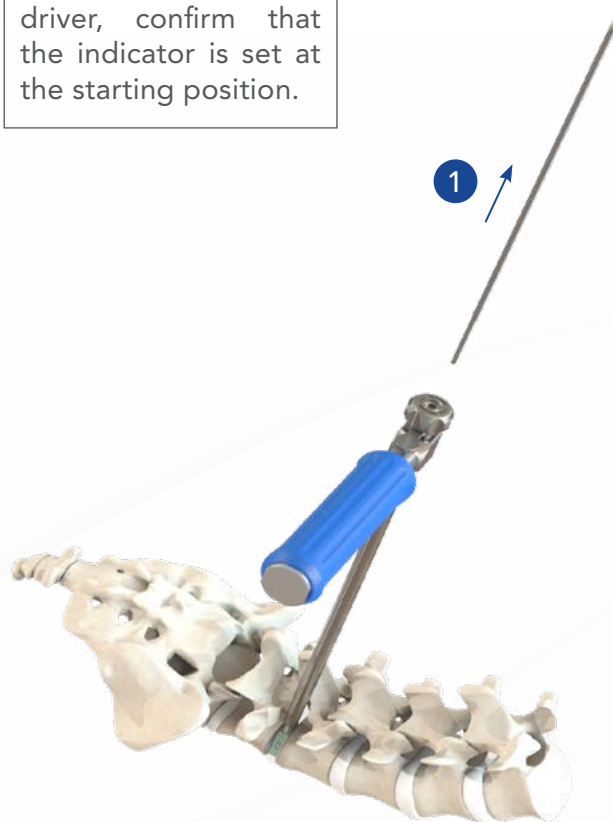


Figure 20

4 GRAFT MATERIAL DELIVERY

In Situ Graft Material Delivery

Implant can be pre-packed with bone graft and/or have the graft material delivered in situ.

Insert the Bone Graft Funnel into the back of the Inserter and turn clockwise to secure (Figure 21).

Place the graft material into the funnel and use the Bone Graft Tamp to deliver the material into the Implant (Figure 22).

After delivering all the material, remove Bone Graft Tamp by gently pulling it straight out. Remove the Bone Graft Funnel by turning it counter-clockwise and then pulling it gently straight out of the Inserter (Figure 23).

Note: Care should be used when using the Bone Graft Funnel and/or Graft Tamp to avoid altering the final position of the implant. Re-positioning of the Implant may be difficult or not possible after the graft material has been delivered.

Use AP and lateral fluoroscopy to confirm final position.

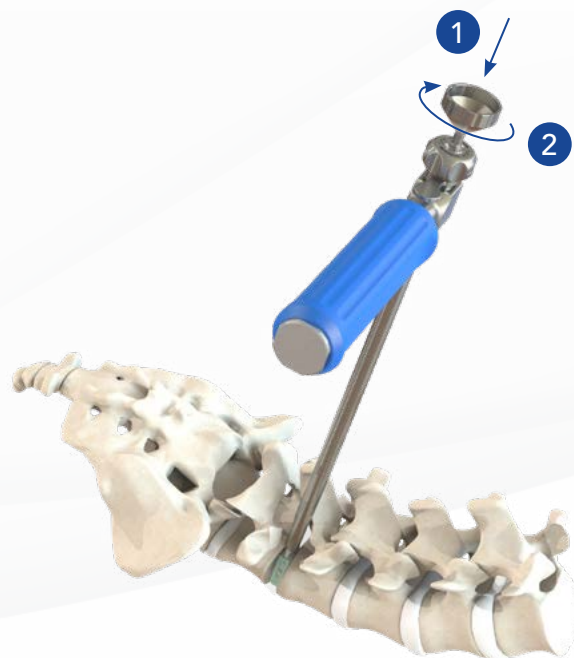


Figure 21

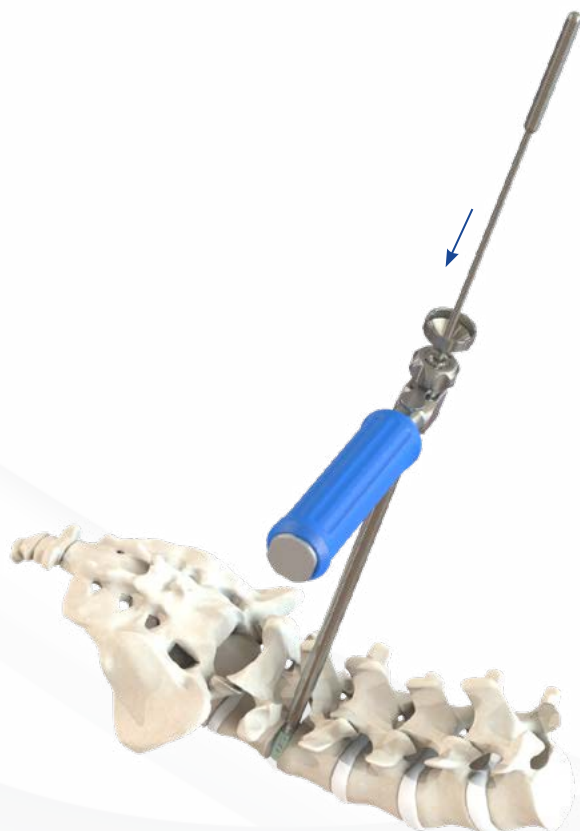


Figure 22

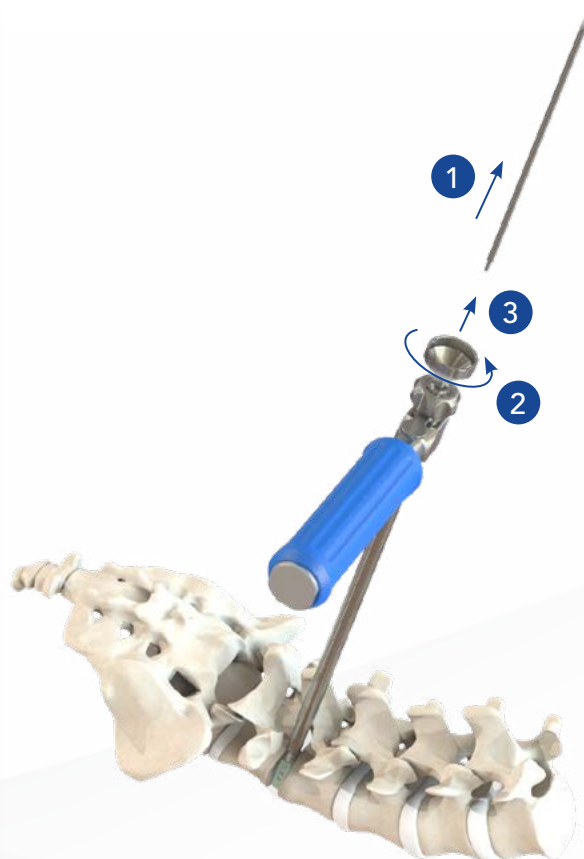


Figure 23

5 FINAL POSITION

In Situ Graft Material Delivery

Turn the silver knob on the Inserter counter-clockwise to release Inserter from the Implant. After the Inserter has been released from Implant, remove Inserter by pulling it gently straight out (Figure 24).

Caution: Final position should be confirmed before removing Inserter.

Final position of the Monaco implant (Figure 25 & 26).

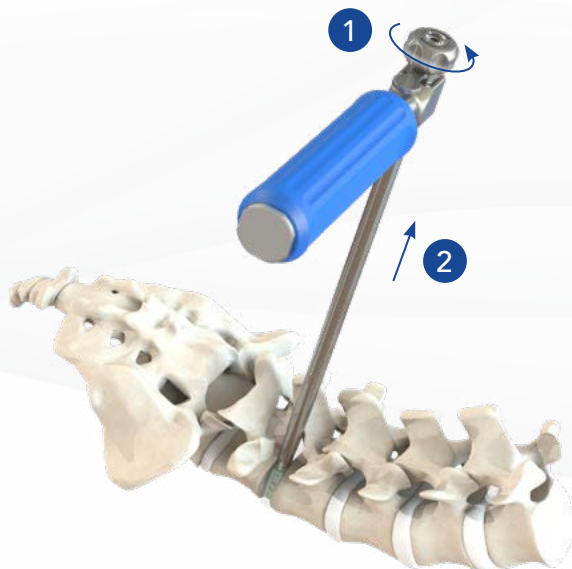


Figure 24



Figure 25

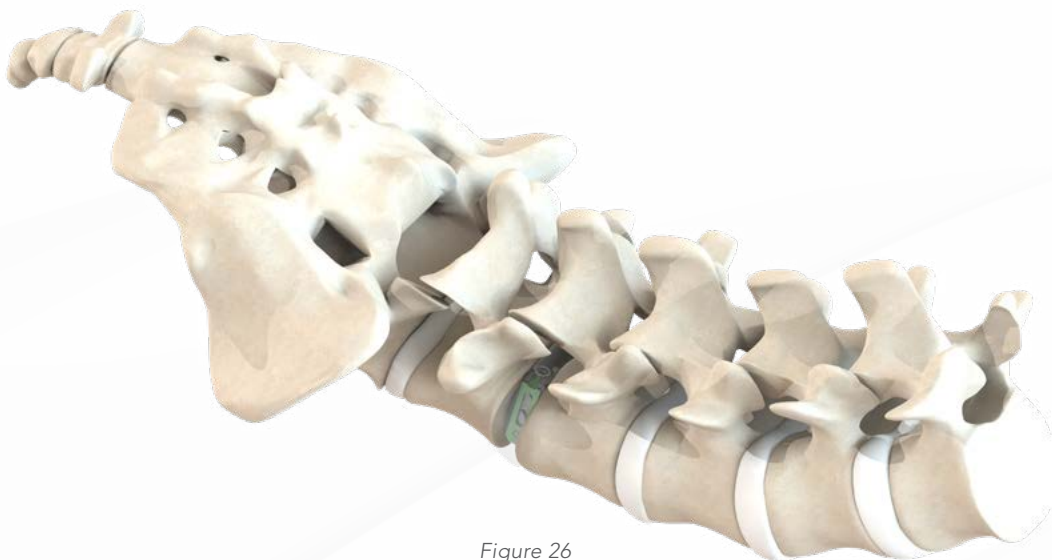


Figure 26

6 REMOVAL/REVISION

If the implant needs to be removed, line up tangs on the Inserter to the Implant. Once the Implant is properly aligned and seated on the end of the Inserter, turn the silver knob clockwise to secure it to the implant (*Figure 27*).

After attaching the Implant to the Inserter, insert the Simple Driver into the back of the Inserter (*Figure 28*). Once the Simple Driver is fully seated into the Implant, turn counter-clockwise to compress the Implant (*Figure 28*).

Remove Implant by gently pulling the whole construct straight out (*Figure 29*).



Figure 27



Figure 28



Figure 29

61-90-001 | Inserter



61-90-002 | Parallel Adjustable Gauge



61-90-003-XX | Trial Head



61-90-004-XX | Parallel Driver with Indicator



61-90-005 | Bone Graft Funnel



61-90-006 | Bone Graft Tamp



61-90-007 | Axial Torque Limiting Handle



61-90-008 | Graft Tamp

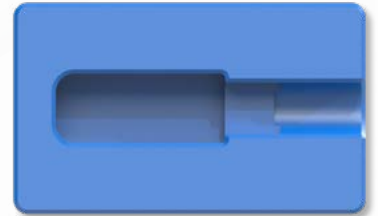


7 INSTRUMENTS (CONT.)

61-90-010 | Simple Inserter



61-90-009 | Packing Block



61-91-001 | Shaver



61-91-002 | Scraper



61-91-003 | Rasp



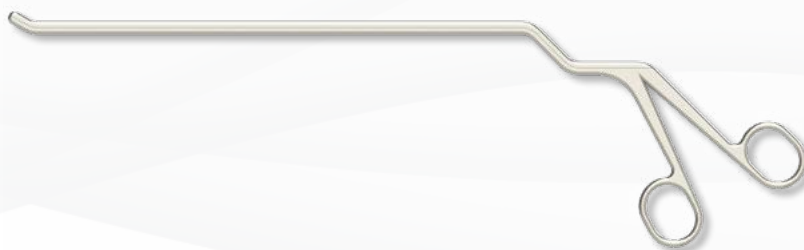
61-91-004 | Tube



61-91-005 | Straight Pituitary



61-91-006 | Up Biting Pituitary



61-91-007 | Curved Pituitary



99-003 | T-Handle





neurostructures.com

4300 Sigma Rd. #130 | Dallas, TX 75244 | Ph/Fax: 800.352.6103

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