GLOBUS MEDICAL

# CALIBER®-L

## Expandable LLIF Spacer

SURGICAL TECHNIQUE GUIDE

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*Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.*

***Life moves us***

# SURGICAL TECHNIQUE GUIDE

# CALIBER®-L

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## Expandable LLIF Spacer

CALIBER®-L is an expandable lateral interbody fusion device designed to streamline insertion and optimize fit. Insertion of CALIBER®-L is performed at a contracted height to ease insertion. Controlled distraction maximizes indirect decompression through disc height restoration. Continuous expansion resists migration by optimizing fit.

## Minimized Impaction

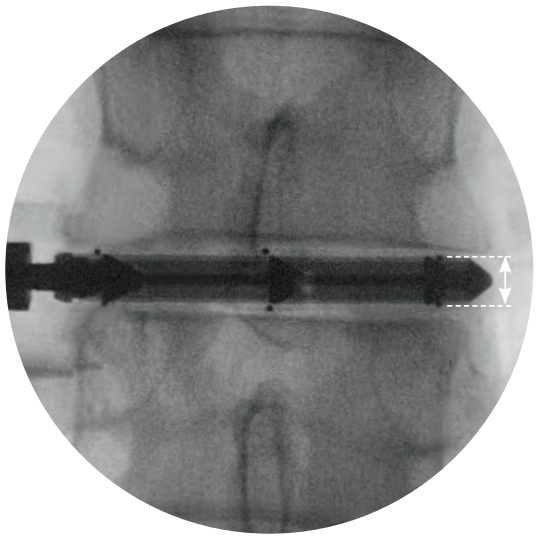
Preserves endplate integrity which, may help reduce subsidence.

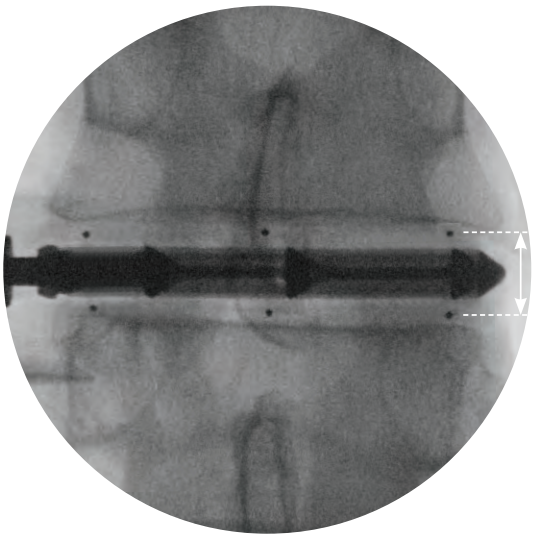
## Controlled Extraction

Designed to maximize indirect decompression through disc height restoration.

## Continuous Expansion

Helps to resist migration by optimizing fit.



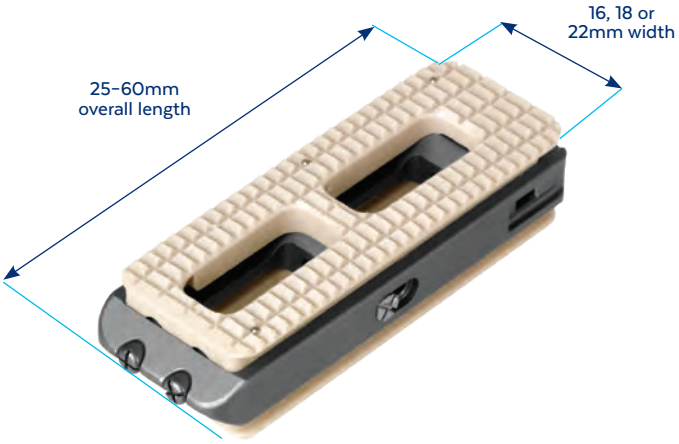


# **IMPLANT** OVERVIEW

- Contracted insertion height helps minimize impaction force
- Controlled continuous expansion and distraction aids in restoration of disc height
- Axial graft chamber to help promote fusion
- Automatic locking for stability

- Multiple footprints:
  - 16 wide: 25–40mm
  - 18 wide: 40–60mm
  - 22 wide: 40–60mm
- Starting heights: 7–12mm

- One instrument for both insertion and expansion
- Slim design for minimally invasive surgery (MIS) applications
- Radiolucent PEEK endplates for radiographic assessment
- Up to 5mm of expansion




## Parallel and Lordotic Options

Parallel

6° and 10° Lordotic

## Coronal Tapered Option

Leading Taper

Trailing Taper



*Additionally available

# **INSTRUMENT** OVERVIEW

## DISC PREP INSTRUMENTS

Bayonetted Annulotomy Knife 675.405S

Cobb Elevator, Straight, 20mm 675.503

Cobb Elevator, Straight, 10mm 675.504

Cobb, 7° Up-Angled, 20mm 675.504

Cobb, 7° Up-Angled, 10mm 675.515

## DISC PREP INSTRUMENTS (CONT'D)

Disc Box Cutter, 6mm 675.507

Disc Rotary Cutter 675.506

Rasp 675.505

Thin Rasp, 12x20mm 675.510

Penfield, Bayonetted, Pull 675.173

Disc Rongeurs, 4mm 625.305,
Disc Rongeurs, 6mm 625.307

Kerrisons, 4mm 625.202,
Kerrisons, 6mm 625.203

## SCRAPERS

| | Height | Part No. |
|---|---|---|
|  | 7mm | 675.607 |
|  | 9mm | 675.609 |
|  | 11mm | 675.611 |
|  | 13mm | 675.613 |
|  | 15mm | 675.615 |
|  | 17mm | 675.617 |

## CURETTES

Bone Curette, 7.5x11.5mm, Straight 625.407

Bone Curette, 7.5x11.5mm, Up-Angled 625.408

Ring Curette, 10mm, Straight 675.518

## CURETTES (CONT'D)

Ring Curette, 10mm, 7° Up-Angled 675.519

Ring Curette, 10mm 625.401

Ring Curette, 15mm 625.402

Cobb Elevator, Angled, 18mm 625.102

Cup Curette, 6.5x9.5mm, Straight 675.525

Cup Curette, 6.5x9.5mm, 15° Up-Angled 675.526

Cup Curette, 6.5x9.5mm, 90° Up-Angled 675.527

## HANDLES

T-Handle 675.005

L-Handle 679.010

## TRIALS

Trial, Parallel

Trial, Lordotic

| 18mm Static Trials | | |
|---|---|---|
| Parallel | Height | Part No. |
|  | 5mm | 675.006 |
|  | 7mm | 675.007 |
| 10° Lordotic | Height | Part No. |
|  | 5mm | 675.065 |
|  | 7mm | 675.067 |

| 22mm Static Trials | | |
|---|---|---|
| Parallel | Height | Part No. |
|  | 5mm | 675.043 |
| | - | - |
| 10° Lordotic | Height | Part No. |
|  | 5mm | 675.365 |
|  | 7mm | 675.367 |

## TRIALS (CONT'D)

Adjustable Trial, Parallel

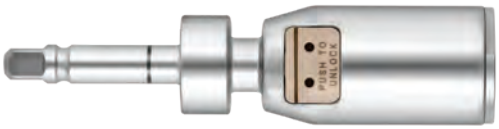
| 16mm Adjustable Trials | | |
|---|---|---|
| Sagittal Profile | Height | Part No. |
| Parallel | 7–15mm | 694.126 |

| 18mm Adjustable Trials | | |
|---|---|---|
| Sagittal Profile | Height | Part No. |
| Parallel | 7–15mm | 694.110 |
| 6° Lordotic | 8–16mm | 694.112 |

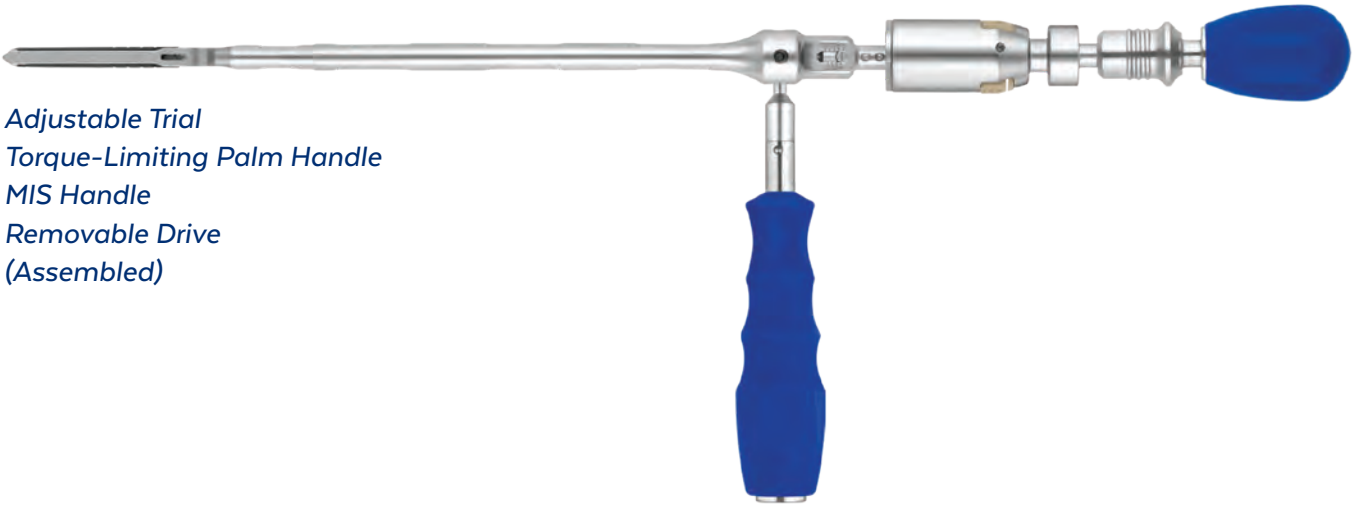
| 22mm Adjustable Trials | | |
|---|---|---|
| Sagittal Profile | Height | Part No. |
| Parallel | 7–15mm | 694.201 |
| 6° Lordotic | 8–16mm | 694.202 |

MIS Handle 673.003

Torque-Limiting Palm Handle 694.002



Removable Drive 694.218



*Adjustable Trial*
*Torque-Limiting Palm Handle*
*MIS Handle*
*Removable Drive*
*(Assembled)*

## IMPLANT INSERTION INSTRUMENTS

Lateral Inserter Fork, 16mm 694.116
Lateral Inserter Fork, 18mm 694.103
Lateral Inserter Fork, 22mm 694.303

Lateral Inserter Tube 694.104

Inserter Handle 694.005

2.5mm Torque-Limiting Driver, 3.0Nm 694.106

*Lateral Inserter Fork, 18mm*
*Inserter Tube*
*Inserter Handle*
*2.5mm Torque-Limiting Driver, 3.0Nm*
*(Assembled)*

## IMPLANT INSERTION INSTRUMENTS (CONT'D)

Insertion Sleeve 675.501

Implant Insertion Tool 664.500

*Implant Insertion Tool and Insertion Sleeve (Assembled)*

## ADDITIONAL INSTRUMENTS

Slide Hammer 694.018

Spanner Wrench 687.509

# SURGICAL TECHNIQUE

# CALIBER®-L

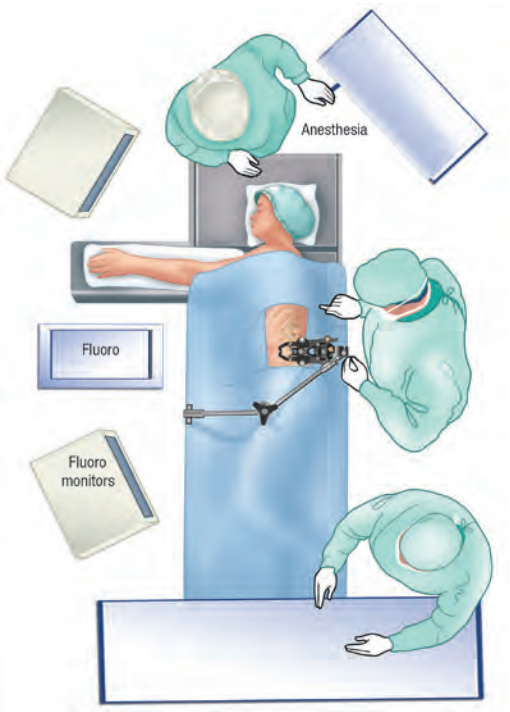
Refer to the device insert (also printed at the back of this guide) for important information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

## STEP 1 PATIENT POSITIONING

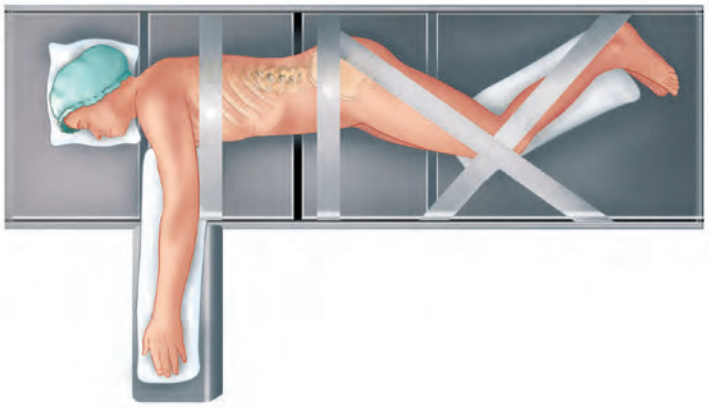
The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown below.

The patient is then secured to the table at the following locations: 1) Just beneath the iliac crest; 2) over the thoracic region, just under the shoulder; 3) from the back of the table, over the ankle, and past the knee to the front of the table.

The table should be flexed to open the interval between the 12th rib and iliac crest, and provide direct access to the disc space as shown below.




**Patient positioning**



**Patient secured to table**

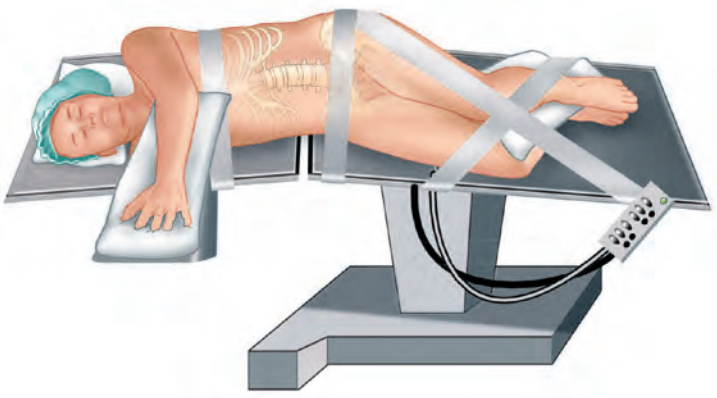


**Table flexed**

# PATIENT POSITIONING (CONT'D)

## X-Ray Confirmation

Fluoroscopy is used to ensure that the spine is oriented in a straight lateral position. The table should be adjusted so that the C-arm provides straight AP images when at 0° and straight lateral images at 90°.

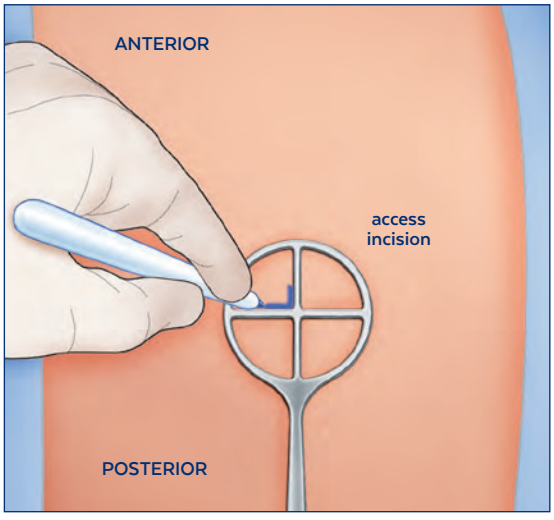
Lateral image

AP image

## Incision Location

The operative area is carefully cleaned and the **Incision Locator** is used under fluoroscopy to identify the middle of the disc space to be fused. An access incision mark is then traced on the patient's skin to indicate the position and insertion site for the retractor. Position the desired retractor.

Using Incision Locator




Marking incision locations

# STEP 2 DISC PREPARATION

## Annulotomy

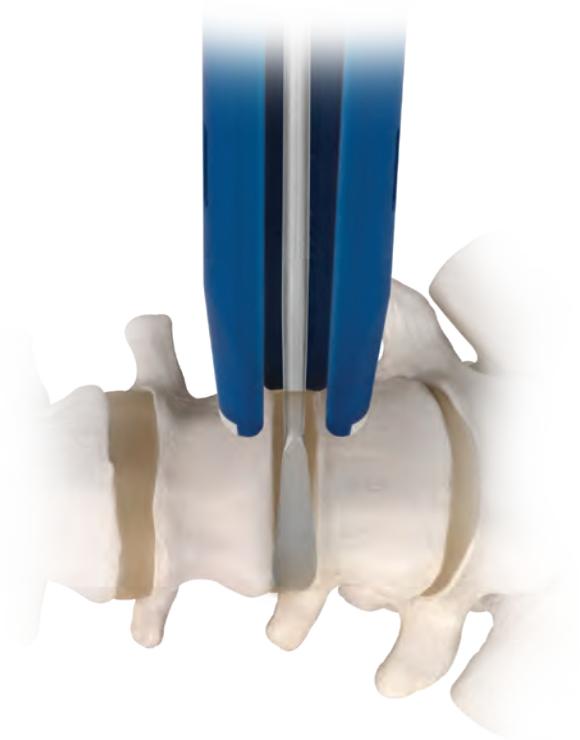
The **Bayonneted Annulotomy Knife** is used to create a window centered in the anterior half of the annulus, large enough for implant insertion.

## Contralateral Annulus Release

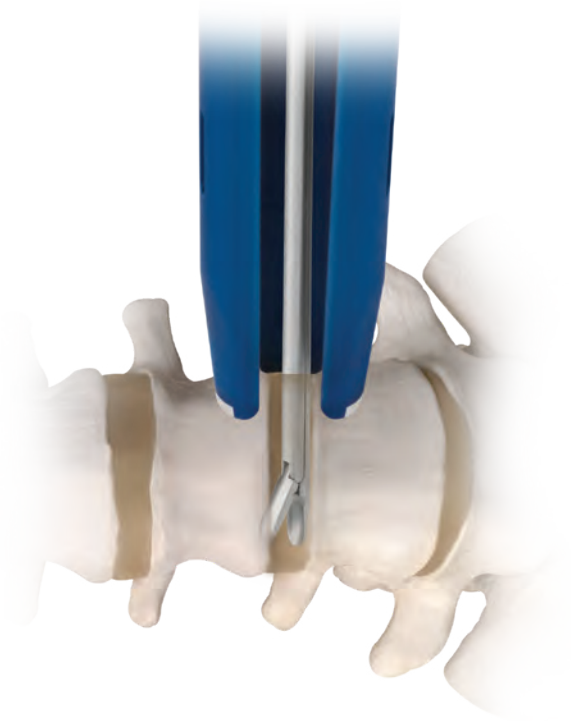
A **Cobb Elevator** is passed along both endplates through the disc space, far enough to provide release of the contralateral annulus. This allows for height restoration upon insertion of the implant.

## Disc Space Preparation

Leaving the posterior annulus intact, remove the intervertebral disc and osteophytes as needed. The **Disc Box Cutter**, **Rotary Cutter**, **Disc Rongeurs**, **Kerrisons**, **Curettes**, **Scrapers**, and **Rasps** are available for disc removal and endplate preparation, as shown at left.



Using Cobb Elevator

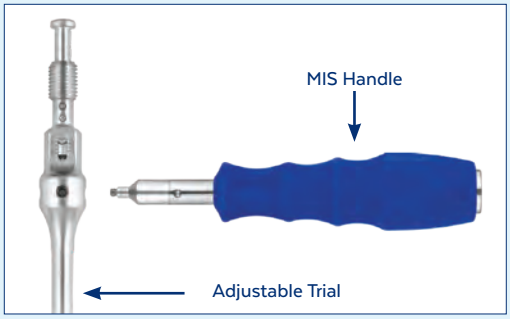


Using Disc Rongeur

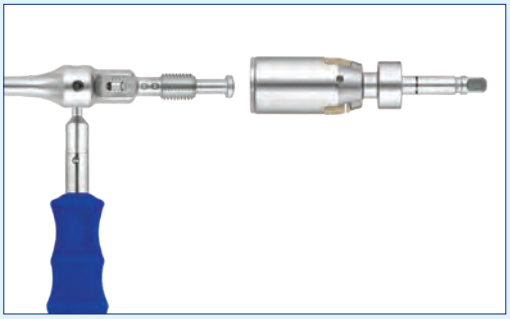
# STEP 3 DISTRACTION AND IMPLANT SIZING

## Option A: Using the Adjustable Trial

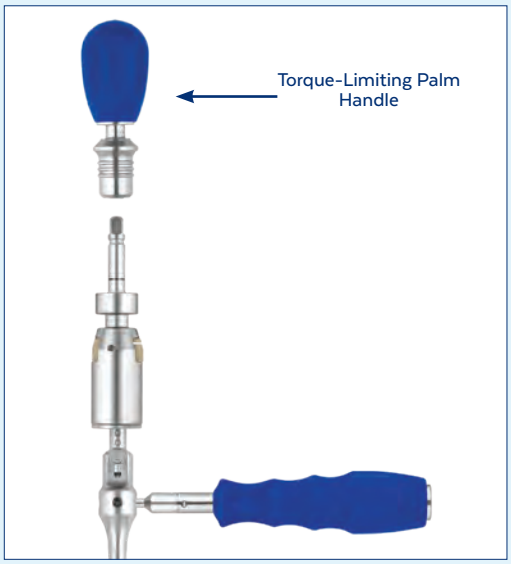
### ASSEMBLING THE ADJUSTABLE TRIAL ASSEMBLY



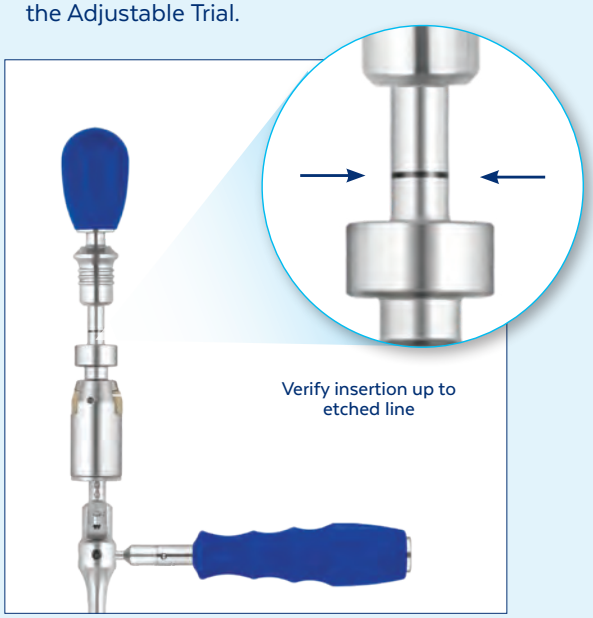

1. Screw in the MIS Handle to the **Adjustable Trial**.



2. Attach the **Removable Drive** to the back end of the Adjustable Trial.




3. After inserting the Adjustable Trial Assembly into the disc space, attach the **Torque-Limiting Palm Handle**, to expand the trial.




4. Verify attachment of Torque-Limiting Palm Handle up to the etched line on the Removable Drive.

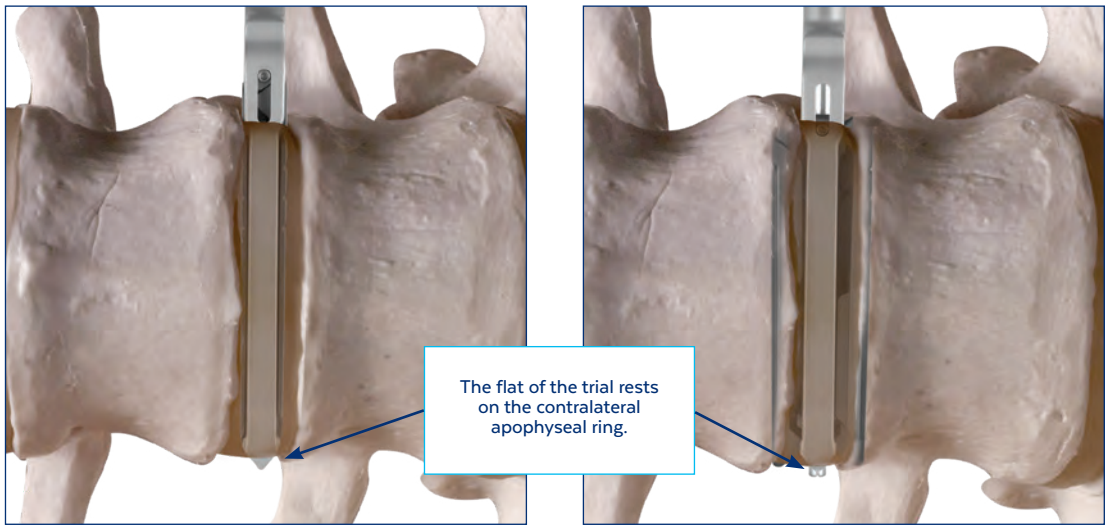
*Adjustable Trial, MIS Handle, Removable Drive and Torque-Limiting Palm Handle (Assembled)*

## Option A: Using the Adjustable Trial (Cont'd)

Insert the Adjustable Trial Assembly into the disc space at its contracted height until the flat of the trial rests on the contralateral apophyseal ring. Determine implant length before trial expansion.

Expand the trial gradually to the desired height by rotating the palm handle clockwise. Use caution while expanding the trial to avoid excessive distraction and damage to the endplates.


**Measurement Indicators on Adjustable Trial Assembly**




**Trial inserted at contracted height**

**Trial expanded to final height**

Determine which height best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment. The final implant height may be confirmed using fluoroscopy.

*Note: Alternatively, the Shaver may be used for distraction. Begin with the smallest Shaver and use larger sizes until the desired distraction is achieved. Use caution while using Shavers to avoid damage to the endplate.*


**Indicator on Adjustable Trial Assembly shows disc height between 9mm and 10mm**

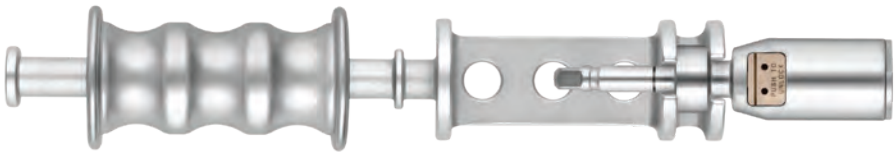
## Implant Selection (Height)

After the disc height is measured with the Adjustable Trial Assembly, select an implant with a height range that will span the measured height. For example, if a height between 9mm and 10mm is measured using the trial, then either a 9mm to 13mm parallel implant or a 8mm to 11mm lordotic implant may be used.

# DISTRACTION AND IMPLANT SIZING (CONT'D)

## Option A: Using the Adjustable Trial (Cont'd)

When removing the Adjustable Trial Assembly, contract the trial completely, remove the Torque-Limiting Palm Handle and attach the **Slide Hammer** to the Removable Drive.

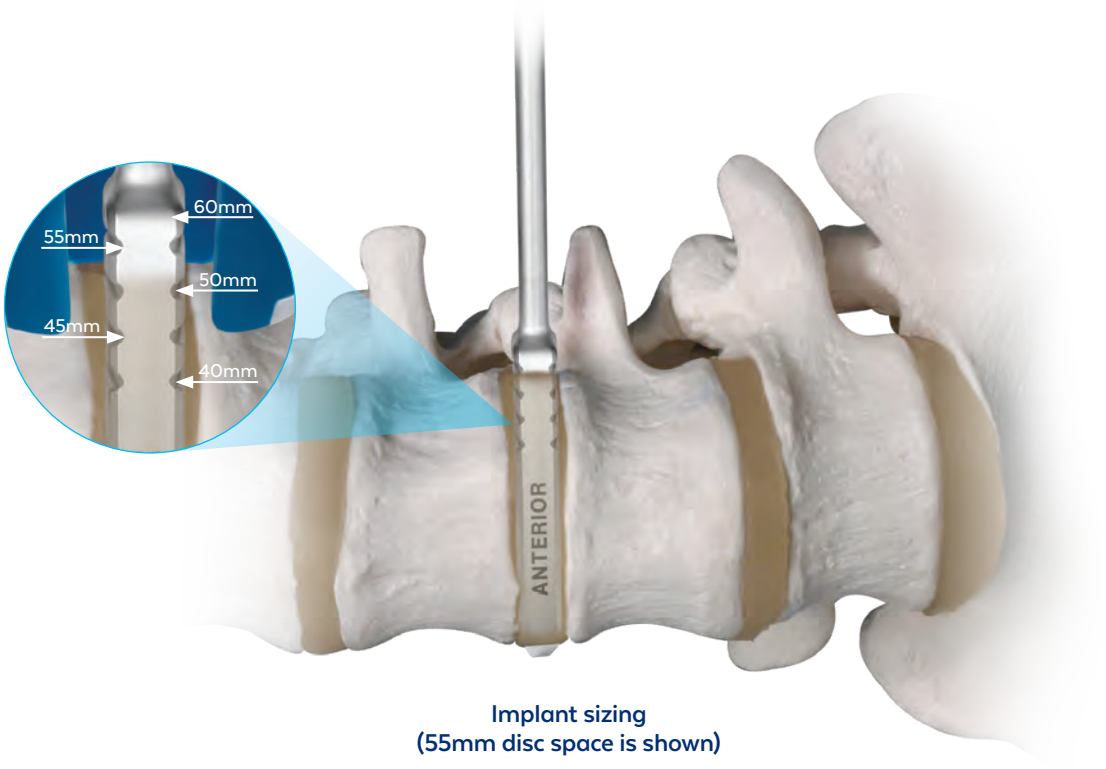


Slide Hammer attached to the Removable Drive

## Option B: Using the Static Trial

To determine the appropriate implant size for the desired segment, first insert the smallest **TransContinental® Trial** into the disc space, moving to larger trials as needed. Determine which trial best fits the prepared disc space. Select the implant with a length 5mm greater than measured using the trial. A secure fit is desirable in order to maintain disc height and stabilize the segment. Use AP fluoroscopy to confirm that the implant is centered and lateral fluoroscopy to ensure that the implant is in the appropriate AP position.

The trial's anterior side is labeled "Anterior."




Implant sizing
(55mm disc space is shown)

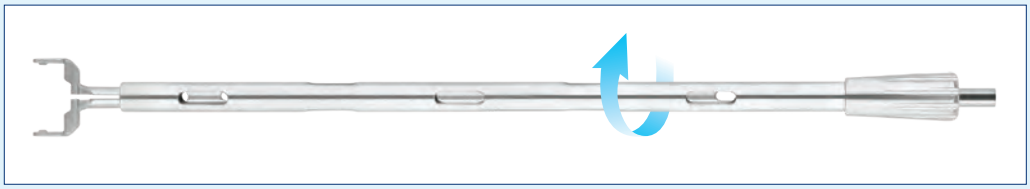
# STEP 4 IMPLANT INSERTION

Select the appropriately sized implant and pack autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bonematerial into the implant.

## ASSEMBLING THE IMPLANT INSERTER

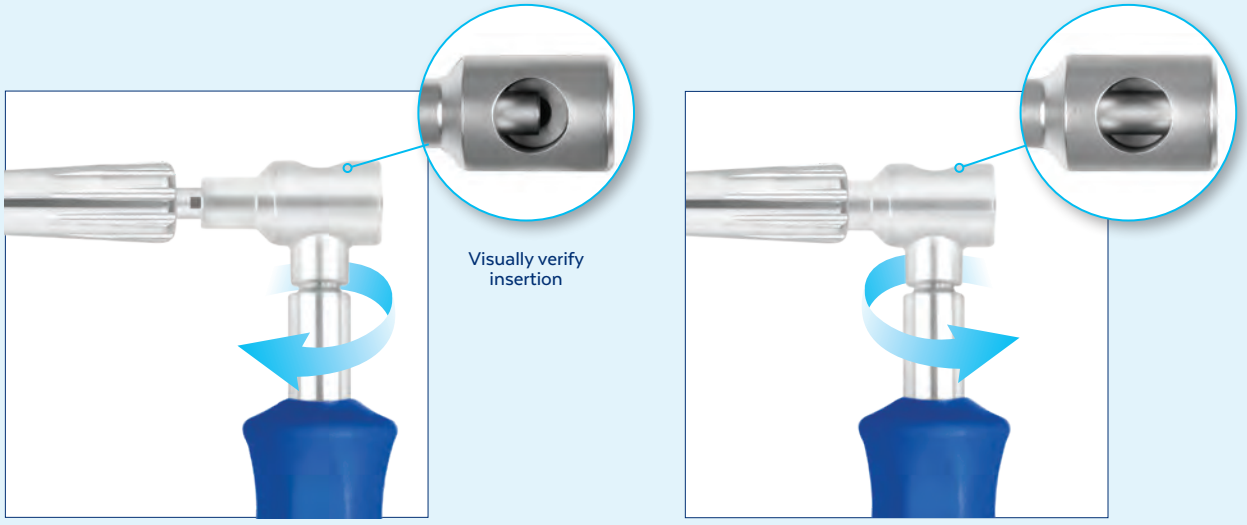
1. Select the appropriate **Inserter Fork** that matches the width of the implant.

2. Thread the fork at least two full rotations into the **Inserter Tube.**



3. Ensure that the **Inserter Handle** is in the unlocked position by rotating the handle counterclockwise until it stops.

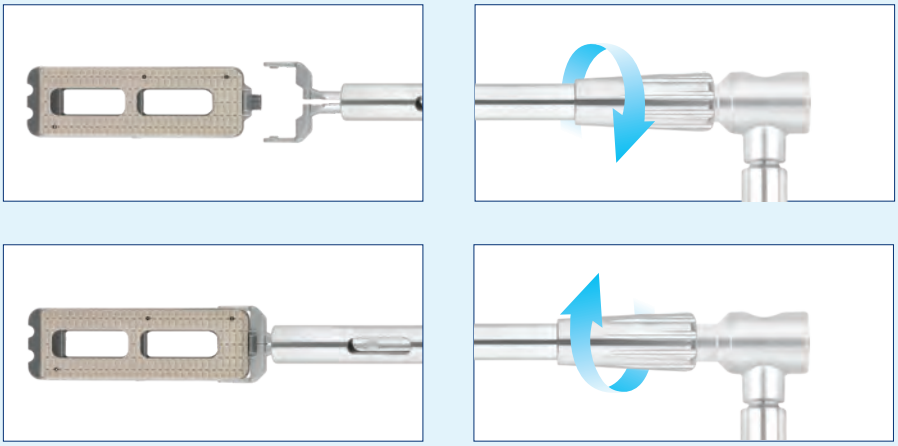
   Attach the handle onto the back of the Inserter Fork Assembly. Once the handle is fully seated onto the fork, rotate the handle clockwise until it stops, to lock the position.



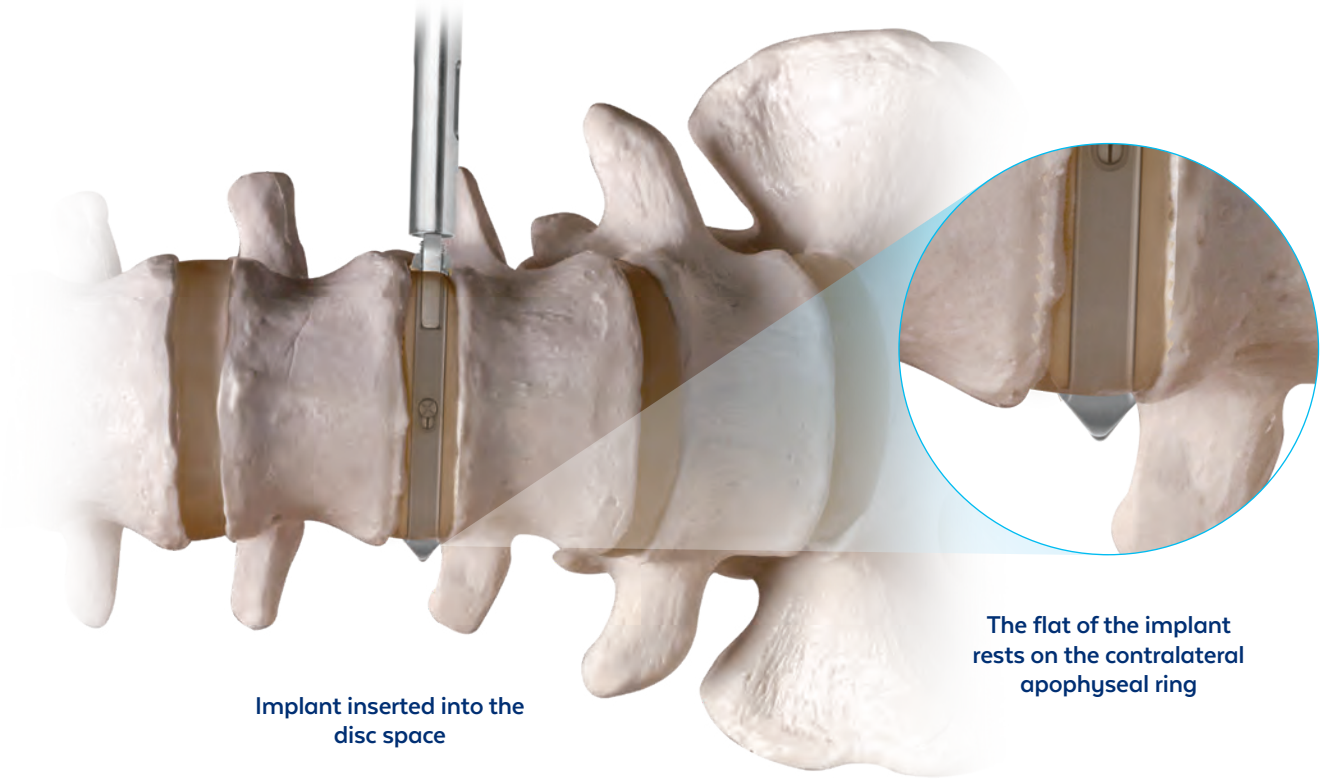
# IMPLANT INSERTION (CONT'D)

## IMPLANT ATTACHMENT

With the Inserter Tube fully threaded counterclockwise, attach the implant by placing it between the tips of the Inserter Fork. Finger-tighten the tube clockwise until the implant is secure.



Insert the implant into the disc space using the Implant Inserter Assembly until the flat on the implant rests on the contralateral apophyseal ring of the vertebrae. If force is required to facilitate implant insertion, impact the back of the Inserter Handle.

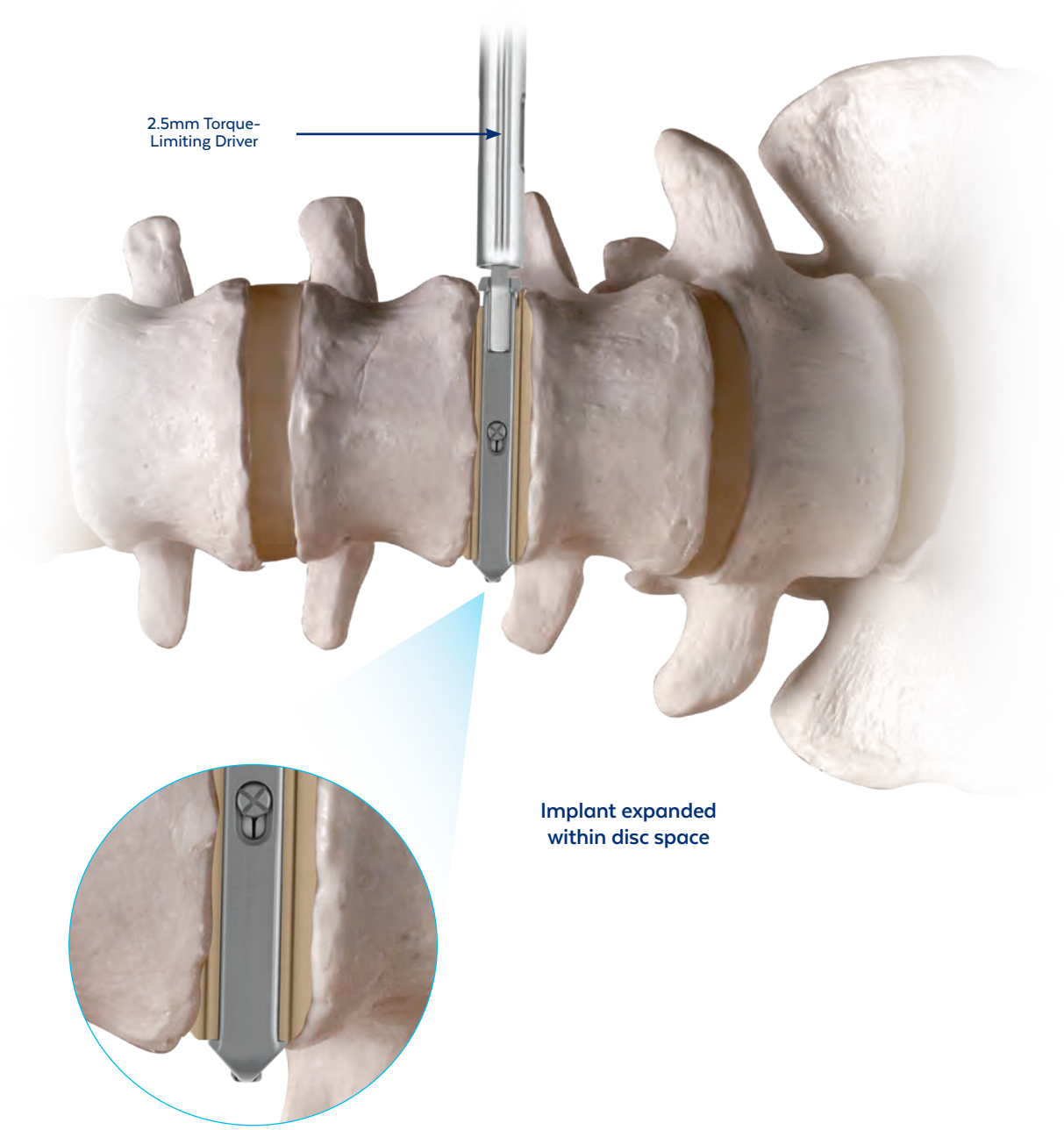


**Implant inserted into the disc space**

**The flat of the implant rests on the contralateral apophyseal ring**

# STEP 5 IMPLANT EXPANSION

Insert the **2.5mm Torque-Limiting Driver, 3.0Nm** into the Implant Inserter Assembly and rotate clockwise to expand the implant to the appropriate height.

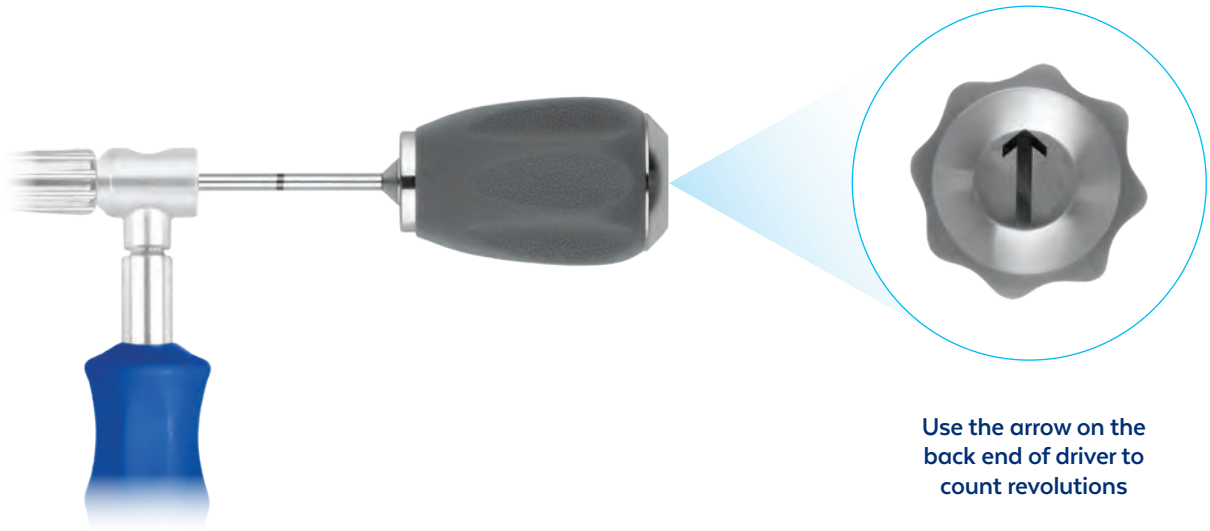


# IMPLANT EXPANSION (CONT'D)

## Determining Implant Height

Expansion of the implant should be determined by the tactile feel of the implant in the disc space as it is expanded. This is determined by gently toggling the implant in the AP direction until the desired fit is achieved.

The overall height can be determined by counting the number of revolutions of the 2.5mm Torque-Limiting Driver. Depending on the implant, 1.25 or 1.5 revolutions equate to 1mm of expansion. The etched arrow at the back of the 2.5mm Torque-Limiting Driver may be used to help indicate revolutions.



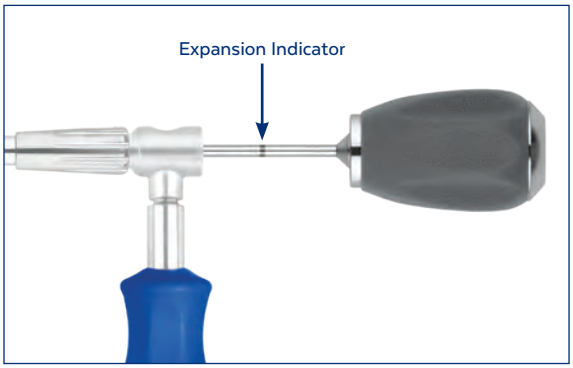
Use the arrow on the back end of driver to count revolutions

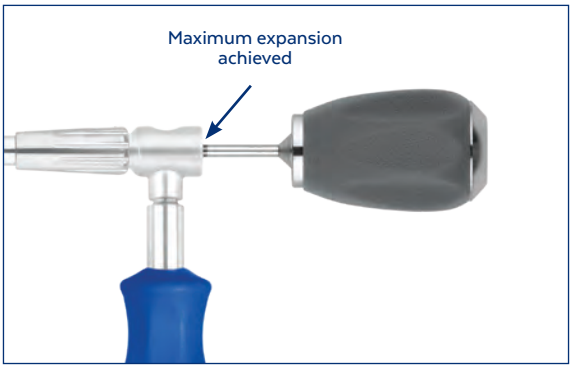
| Revolutions Required | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Implant Size | Final Height (mm) | | | | | | | | | | |
| | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 7-10mm | 0 | 1.5 | 3 | MAX | - | - | - | - | - | - | - |
| 8-11mm | - | 0 | 1.5 | 3 | MAX | - | - | - | - | - | - |
| 9-12mm | - | - | 0 | 1.5 | 3 | MAX | - | - | - | - | - |
| 9-13mm | - | - | 0 | 1.5 | 3 | 4.5 | MAX | - | - | - | - |
| 10-13mm | - | - | - | 0 | 1.5 | 3 | MAX | - | - | - | - |
| 10-14mm | - | - | - | 0 | 1.5 | 3 | 4.5 | MAX | - | - | - |
| 11-15mm | - | - | - | - | 0 | 1.5 | 3 | 4.5 | MAX | - | - |
| 11-16mm | - | - | - | - | 0 | 1.25 | 2.5 | 3.75 | 5 | MAX | - |
| 12-16mm | - | - | - | - | - | 0 | 1.5 | 3 | 4.5 | MAX | - |
| 12-17mm | - | - | - | - | - | 0 | 1.25 | 2.5 | 3.75 | 5 | MAX |

The 2.5mm Torque-Limiting Driver allows the user to identify when the implant has reached its maximum height expansion, or when the implant is exerting the maximum allowable distraction force on the vertebral endplates.

*Use caution while expanding the implant to avoid excessive distraction and damage to the endplates.*

The maximum expansion of an implant can be visually verified by the etched ring on the driver, as shown below. Maximum expansion is achieved when the etched ring is flush with the handle.



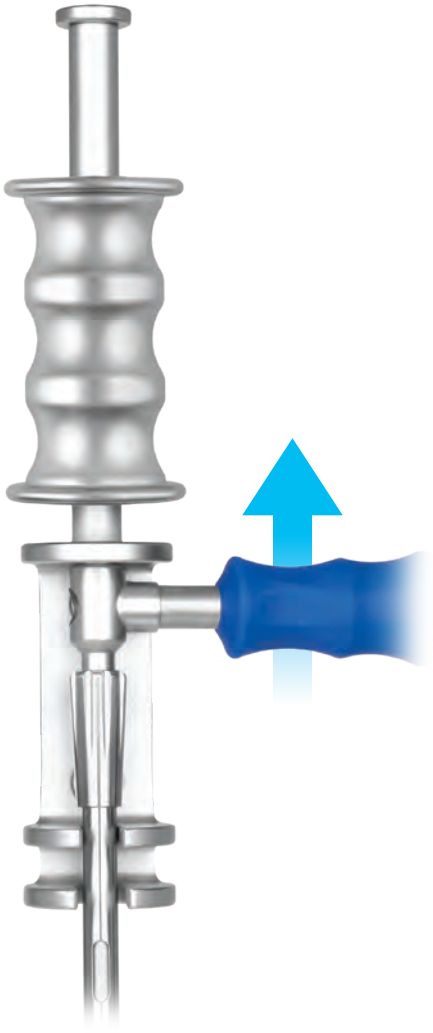

Implant Inserter Assembly

## STEP 6 RADIOGRAPHIC CONFIRMATION

Using fluoroscopy, verify the final position of the implant before disengaging the Implant Inserter Assembly. Once the desired position is achieved, disengage the assembly from the implant by first removing the 2.5mm Torque-Limiting Driver. Then rotate the Inserter Tube counterclockwise using the **Spanner Wrench** and rock the assembly cephalad/caudal until the implant is disengaged.

## OPTIONAL: IMPLANT REMOVAL

For implant removal, the implant height may be reduced by inserting the 2.5mm Torque-Limiting Driver into the set screw and rotating counterclockwise. Alternatively, the Impant Inserter Assembly may be repositioned onto the implant and the Slide Hammer may be used to remove the implant. Forceps or other manual surgical instruments may also be used to grasp and extract the implant.



**Using the Slide Hammer**

# SUPPLEMENTAL FIXATION

In addition to the described interbody fusion technique, supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) must be used at the appropriate level(s).

REVOLVE® is a posterior stabilization system designed for minimally invasive surgery (MIS), in which virtually every step of the MIS has been enhanced.

## REVOLVE® Stabilization System

### REVOLVE® Locking Technology

Non-threaded locking caps eliminate cross threading. Challenges with cap placement are also eliminated.

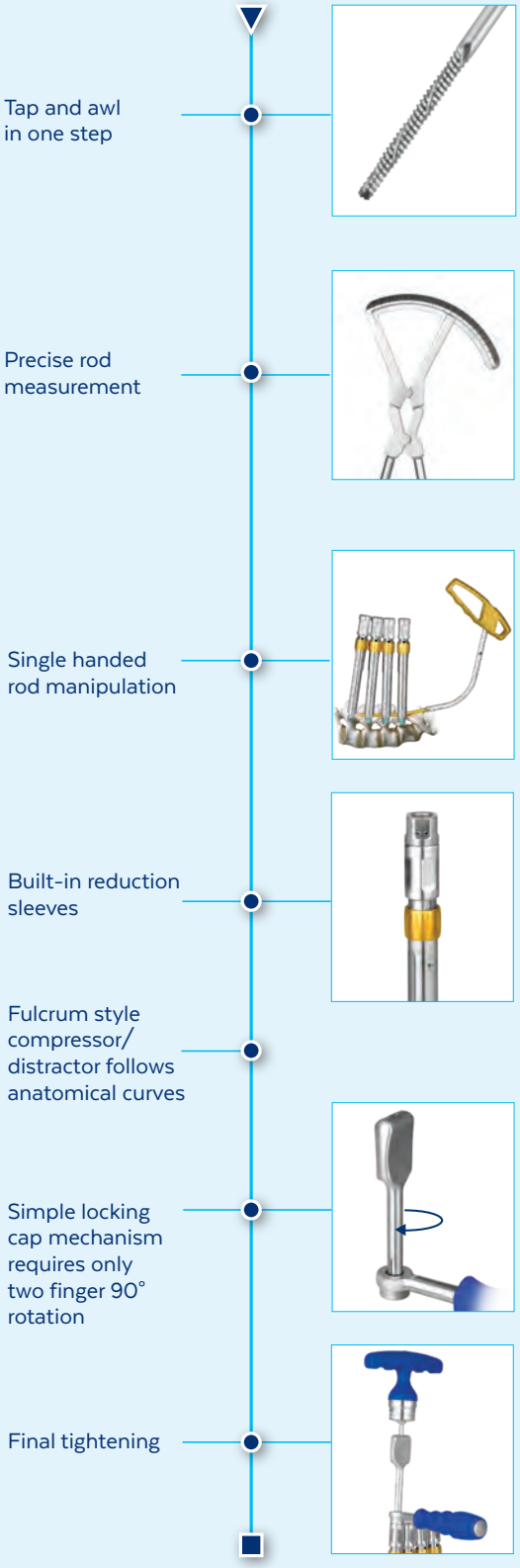
### Powerful Rod Reduction

Provides fixation irrespective of complexity, due to integrated, streamlined rod reduction and a strong screw-sleeve connection.

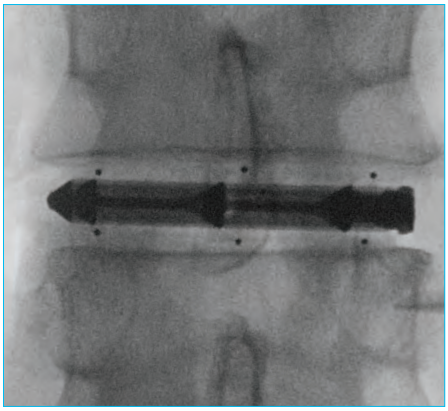
### Multi-Level Capability

The system adapts to surgeon needs, with capabilities for trauma, tumor, and deformity applications.

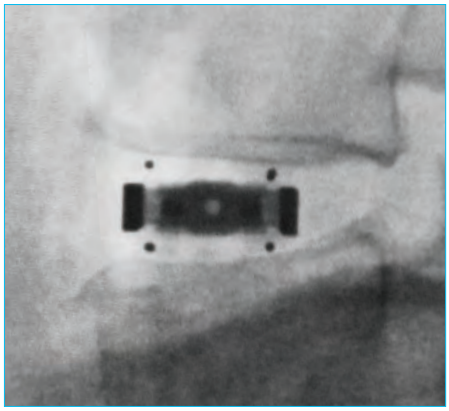
**REVOLVE® ENHANCES EVERY STEP OF A MIS PROCEDURE**



# FINAL POSITION (AP VIEW)



# FINAL POSITION (LATERAL VIEW)



# CALIBER®-L
# 16mm SET 994.940

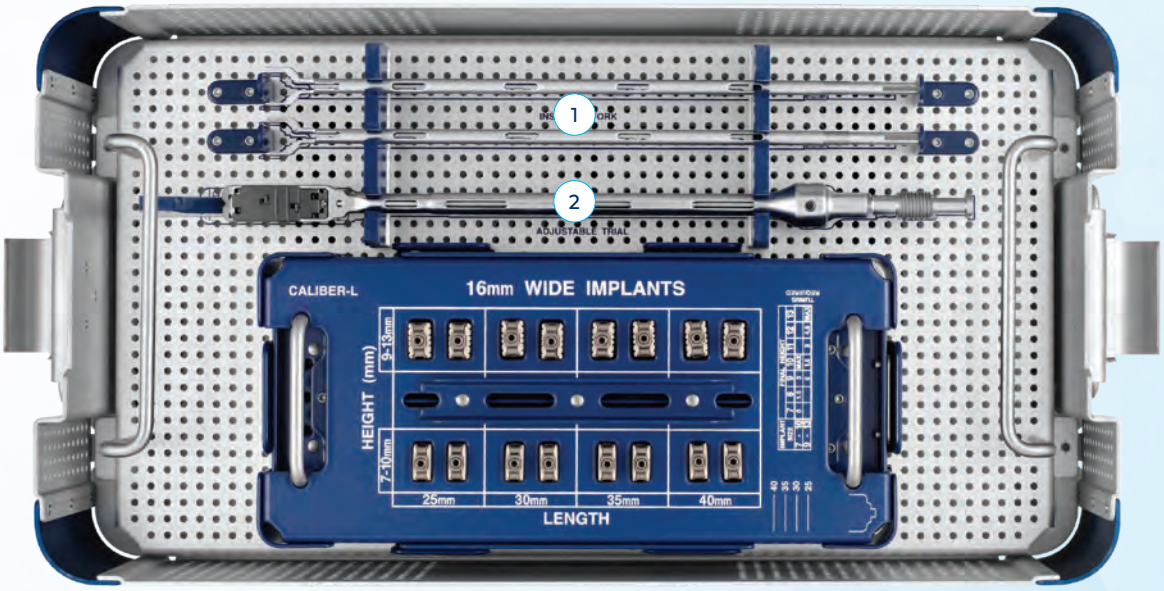
## Implants

| Part No. | Description | Qty |
|---|---|---|
| 194.900 | CALIBER®-L Spacer 16x25mm, 7–10mm | 2 |
| 194.901 | CALIBER®-L Spacer 16x30mm, 7–10mm | 2 |
| 194.902 | CALIBER®-L Spacer 16x35mm, 7–10mm | 2 |
| 194.903 | CALIBER®-L Spacer 16x40mm, 7–10mm | 2 |
| 194.905 | CALIBER®-L Spacer 16x25mm, 9–13mm | 2 |
| 194.906 | CALIBER®-L Spacer 16x30mm, 9–13mm | 2 |
| 194.907 | CALIBER®-L Spacer 16x35mm, 9–13mm | 2 |
| 194.908 | CALIBER®-L Spacer 16x40mm, 9–13mm | 2 |

## Instruments

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 694.116 | Lateral Inserter Fork, 16mm | 2 |
| 2 | 694.126 | 16mm Adjustable Trial | 1 |
| | 994.013 | CALIBER®-L 16mm Graphic Case | |

# CALIBER®-L
## 16mm SET 994.940



# CALIBER®-L
# 18mm SET 994.910

## CALIBER®-L Spacers

| Part No. | Description | Qty |
|---|---|---|
| 194.082 | 18x40mm, 10–13mm, Lordotic | 2 |
| 194.083 | 18x45mm, 10–13mm, Lordotic | 2 |
| 194.084 | 18x50mm, 10–13mm, Lordotic | 2 |
| 194.085 | 18x55mm, 10–13mm, Lordotic | 2 |
| 194.086 | 18x60mm, 10–13mm, Lordotic | 2 |
| 194.140 | 18x40mm, 9–13mm | 2 |
| 194.145 | 18x45mm, 9–13mm | 2 |
| 194.150 | 18x50mm, 9–13mm | 2 |
| 194.155 | 18x55mm, 9–13mm | 2 |
| 194.160 | 18x60mm, 9–13mm | 2 |
| 194.240 | 18x40mm, 11–16mm | 2 |
| 194.245 | 18x45mm, 11–16mm | 2 |
| 194.250 | 18x50mm, 11–16mm | 2 |
| 194.255 | 18x55mm, 11–16mm | 2 |
| 194.260 | 18x60mm, 11–16mm | 2 |
| 194.540 | 18x40mm, 12–17mm, Lordotic | 2 |
| 194.545 | 18x45mm, 12–17mm, Lordotic | 2 |
| 194.550 | 18x50mm, 12–17mm, Lordotic | 2 |
| 194.555 | 18x55mm, 12–17mm, Lordotic | 2 |
| 194.560 | 18x60mm, 12–17mm, Lordotic | 2 |
| 194.840 | 18x40mm, 7–10mm | 2 |
| 194.845 | 18x45mm, 7–10mm | 2 |
| 194.850 | 18x50mm, 7–10mm | 2 |
| 194.855 | 18x55mm, 7–10mm | 2 |
| 194.860 | 18x60mm, 7–10mm | 2 |
| 194.940 | 18x40, 8–11mm, Lordotic | 2 |
| 194.945 | 18x45, 8–11mm, Lordotic | 2 |
| 194.950 | 18x50, 8–11mm, Lordotic | 2 |
| 194.955 | 18x55, 8–11mm, Lordotic | 2 |
| 194.960 | 18x60, 8–11mm, Lordotic | 2 |

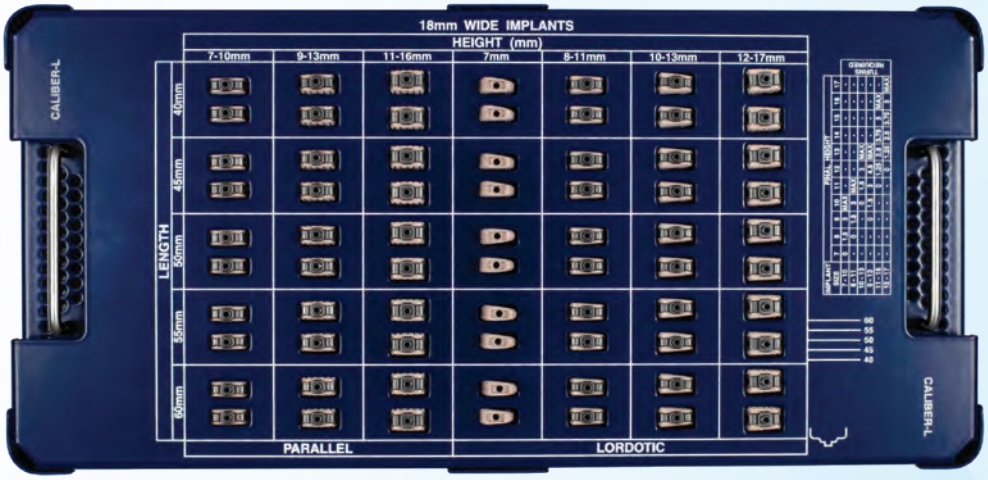
## TransContinental® Spacers

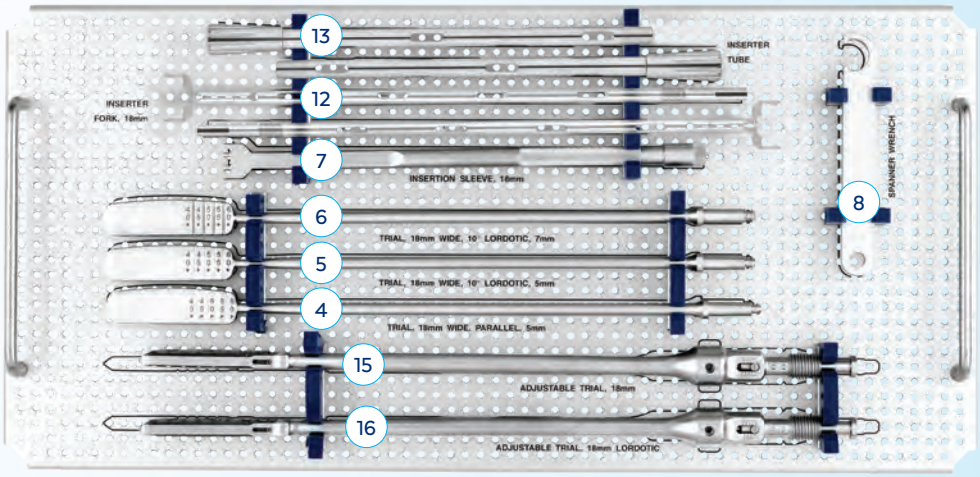
| Part No. | Description | Qty |
|---|---|---|
| 375.067 | 18mm Wide, Small, 10°, 7mm | 2 |
| 375.267 | 18mm Wide, Medium, 10°, 7mm | 2 |
| 375.467 | 18mm Wide, Large, 10°, 7mm | 2 |
| 375.667 | 18mm Wide, X-Large, 10deg, 7mm | 2 |
| 375.867 | 18mm Wide, X-Small, 10°, 7mm | 2 |

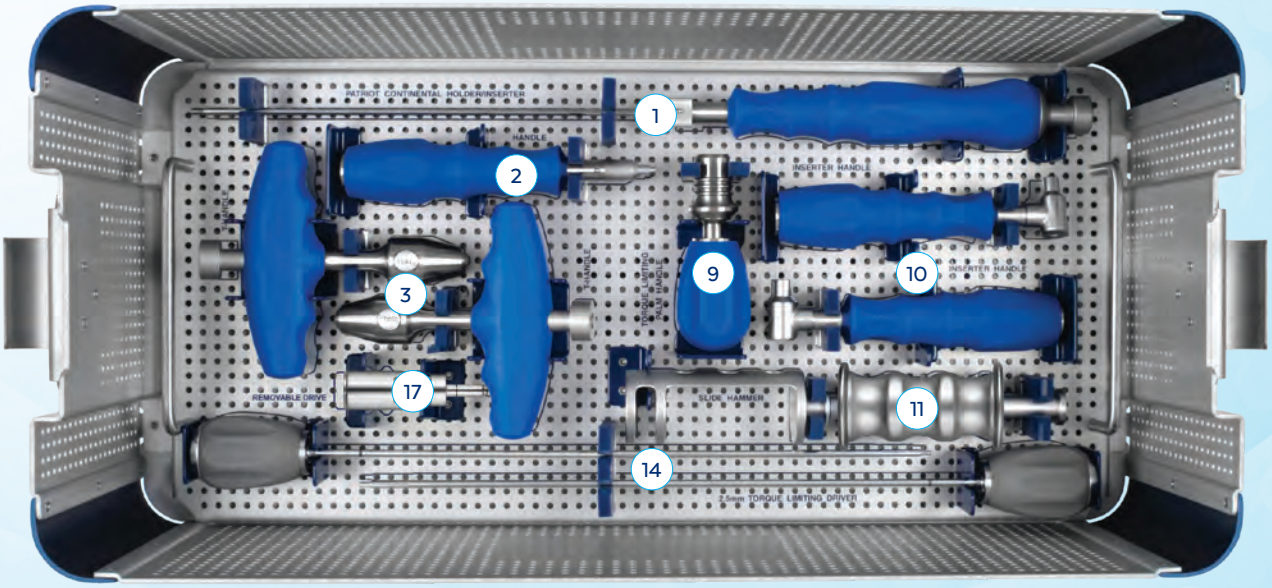
## Instruments

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 664.500 | PATRIOT® CONTINENTAL® Holder/Inserter | 1 |
| 2 | 673.003 | MIS Handle | 1 |
| 3 | 675.005 | T-Handle with Impaction Cap | 2 |
| 4 | 675.006 | TransContinental® LLIF Trial, 0°, 5mm | 1 |
| 5 | 675.065 | TransContinental® 18mm Trial, 10° Lordotic, 5mm | 1 |
| 6 | 675.067 | TransContinental® 18mm Trial, 10° Lordotic, 7mm | 1 |
| 7 | 675.501 | Insertion Sleeve | 1 |
| 8 | 687.509 | Spanner Wrench | 1 |
| 9 | 694.002 | Torque-Limiting Palm Handle | 1 |
| 10 | 694.005 | Inserter Handle | 2 |
| 11 | 694.018 | Slide Hammer | 1 |
| 12 | 694.103 | Lateral Inserter Fork, 18mm | 2 |
| 13 | 694.104 | Lateral Inserter Tube | 2 |
| 14 | 694.106 | 2.5mm Torque-Limiting Driver, 3.0Nm | 2 |
| 15 | 694.110 | Adjustable Trial, 18mm | 1 |
| 16 | 694.112 | Adjustable Trial, 18mm Lordotic | 1 |
| 17 | 694.218 | Removable Drive | 1 |
| | 994.050 | CALIBER®-L 18mm Graphic Case | |

# CALIBER®-L
## 18mm SET 994.910



# CALIBER®-L
# 22mm SET 994.920

## CALIBER®-L Spacers

| Part No. | Description | Qty |
|---|---|---|
| 594.082 | 22x40mm, 10–13mm, Lordotic | 2 |
| 594.083 | 22x45mm, 10–13mm, Lordotic | 2 |
| 594.084 | 22x50mm, 10–13mm, Lordotic | 2 |
| 594.085 | 22x55mm, 10–13mm, Lordotic | 2 |
| 594.086 | 22x60mm, 10–13mm, Lordotic | 2 |
| 594.140 | 22x40mm, 9–13mm | 2 |
| 594.145 | 22x45mm, 9–13mm | 2 |
| 594.150 | 22x50mm, 9–13mm | 2 |
| 594.155 | 22x55mm, 9–13mm | 2 |
| 594.160 | 22x60mm, 9–13mm | 2 |
| 594.240 | 22x40mm, 10–15mm | 2 |
| 594.245 | 22x45mm, 10–15mm | 2 |
| 594.250 | 22x35mm, 10–15mm | 2 |
| 594.255 | 22x55mm, 10–15mm | 2 |
| 594.260 | 22x60mm, 10–15mm | 2 |
| 594.540 | 22x40mm, 12–17mm, Lordotic | 2 |
| 594.545 | 22x45mm, 12–17mm, Lordotic | 2 |
| 594.550 | 22x50mm, 12–17mm, Lordotic | 2 |
| 594.555 | 22x55mm, 12–17mm, Lordotic | 2 |
| 594.560 | 22x60mm, 12–17mm, Lordotic | 2 |
| 594.840 | 22x40mm, 7–10mm | 2 |
| 594.845 | 22x45mm, 7–10mm | 2 |
| 594.850 | 22x50mm, 7–10mm | 2 |
| 594.855 | 22x55mm, 7–10mm | 2 |
| 594.860 | 22x60mm, 7–10mm | 2 |
| 594.940 | 22x40, 8–11mm, Lordotic | 2 |
| 594.945 | 22x45, 8–11mm, Lordotic | 2 |
| 594.950 | 22x50, 8–11mm, Lordotic | 2 |
| 594.955 | 22x55, 8–11mm, Lordotic | 2 |
| 594.960 | 22x60, 8–11mm, Lordotic | 2 |

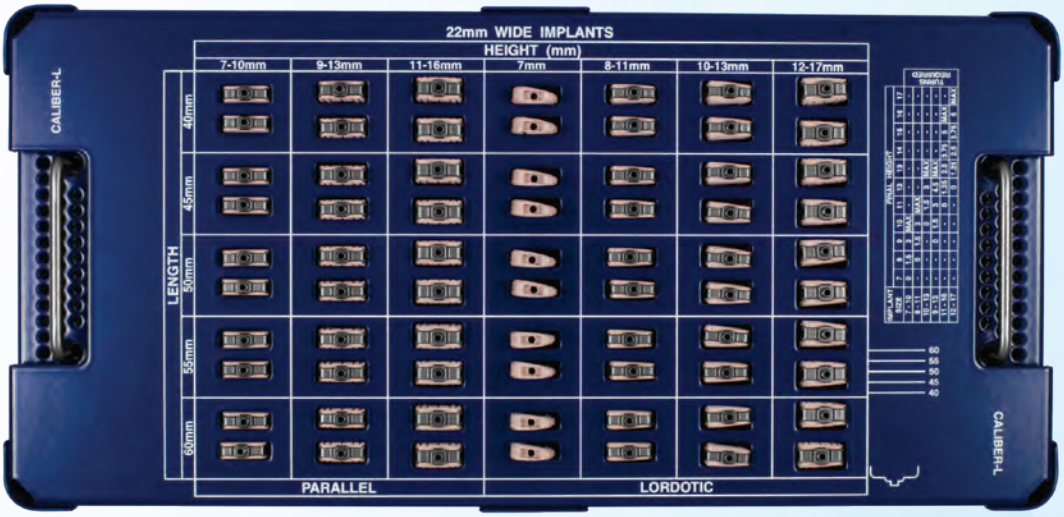
## TransContinental® Spacers

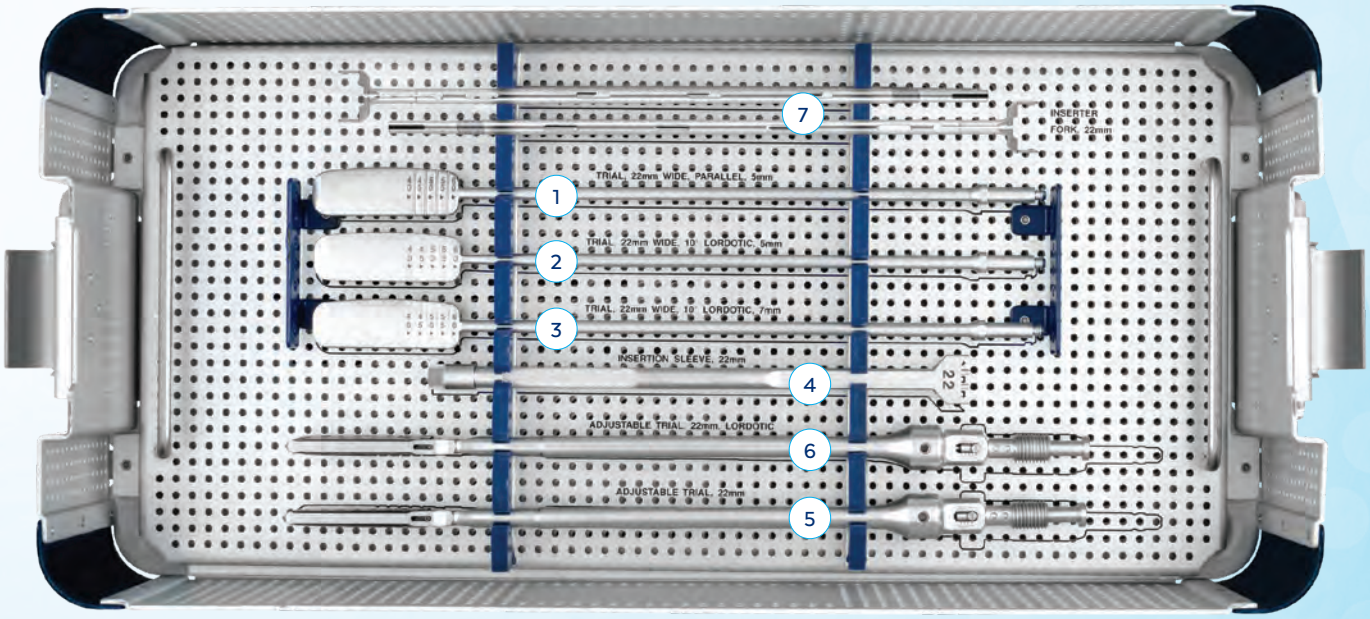
| Part No. | Description | Qty |
|---|---|---|
| 375.167 | TransContinental® Spacer, 22mm Wide, Small, 10°, 7mm | 2 |
| 375.367 | TransContinental® Spacer, 22mm Wide, Medium, 10°, 7mm | 2 |
| 375.567 | TransContinental® Spacer, 22mm Wide, Large, 10°, 7mm | 2 |
| 375.767 | TransContinental® Spacer, 22mm Wide, X-Large, 10°, 7mm | 2 |
| 375.967 | TransContinental® Spacer, 22mm Wide, X-Small, 10°, 7mm | 2 |

## Instruments

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 6675.043 | TransContinental® 22mm Trial, Parallel, 5mm | 1 |
| 2 | 675.365 | TransContinental® 22mm Trial, 10° Lordotic, 5mm | 1 |
| 3 | 675.367 | TransContinental® 22mm Trial, 10° Lordotic, 7mm | 1 |
| 4 | 675.522 | Insertion Sleeve, 22mm | 1 |
| 5 | 694.201 | Adjustable Trial, 22mm | 1 |
| 6 | 694.202 | Adjustable Trial, 22mm Lordotic | 1 |
| 7 | 694.303 | Lateral Inserter Fork, 22mm | 2 |
| | 994.011 | Implants 22mm Graphic Case | |

# CALIBER®-L
## 22mm SET 994.920



# CALIBER®-L
# CORONAL TAPERED SET 994.9300

| Part No. | Description | Qty |
|---|---|---|
| 194.001 | 18x40mm, 8–11mm, Trailing Taper | 2 |
| 194.002 | 18x45mm, 8–11mm, Trailing Taper | 2 |
| 194.003 | 18x50mm, 8–11mm, Trailing Taper | 2 |
| 194.004 | 18x55mm, 8–11mm, Trailing Taper | 2 |
| 194.005 | 18x60mm, 8–11mm, Trailing Taper | 2 |
| 194.011 | 18x40mm, 8–11mm, Leading Taper | 1 |
| 194.012 | 18x45mm, 8–11mm, Leading Taper | 1 |
| 194.013 | 18x50mm, 8–11mm, Leading Taper | 1 |
| 194.014 | 18x55mm, 8–11mm, Leading Taper | 1 |
| 194.015 | 18x60mm, 8–11mm, Leading Taper | 1 |
| 194.021 | 18x40mm, 9–12mm, Trailing Taper, Lordotic | 2 |
| 194.022 | 18x45mm, 9–12mm, Trailing Taper, Lordotic | 2 |
| 194.023 | 18x50mm, 9–12mm, Trailing Taper, Lordotic | 2 |
| 194.024 | 18x55mm, 9–12mm, Trailing Taper, Lordotic | 2 |
| 194.025 | 18x60mm, 9–12mm, Trailing Taper, Lordotic | 2 |
| 194.031 | 18x40mm, 9–12mm, Leading Taper, Lordotic | 1 |
| 194.032 | 18x45mm, 9–12mm, Leading Taper, Lordotic | 1 |
| 194.033 | 18x50mm, 9–12mm, Leading Taper, Lordotic | 1 |
| 194.034 | 18x55mm, 9–12mm, Leading Taper, Lordotic | 1 |
| 194.035 | 18x60mm, 9–12mm, Leading Taper, Lordotic | 1 |
| 194.041 | 18x40mm, 10–14mm, Trailing Taper | 2 |
| 194.042 | 18x45mm, 10–14mm, Trailing Taper | 2 |
| 194.043 | 18x50mm, 10–14mm, Trailing Taper | 2 |
| 194.044 | 18x55mm, 10–14mm, Trailing Taper | 2 |
| 194.045 | 18x60mm, 10–14mm, Trailing Taper | 2 |
| 194.051 | 18x40mm, 10–14mm, Leading Taper | 1 |
| 194.052 | 18x45mm, 10–14mm, Leading Taper | 1 |
| 194.053 | 18x50mm, 10–14mm, Leading Taper | 1 |
| 194.054 | 18x55mm, 10–14mm, Leading Taper | 1 |
| 194.055 | 18x60mm, 10–14mm, Leading Taper | 1 |

| Part No. | Description | Qty |
|---|---|---|
| 194.061 | 18x40mm, 11–15mm, Trailing Taper, Lordotic | 1 |
| 194.062 | 18x45mm, 11–15mm, Trailing Taper, Lordotic | 1 |
| 194.063 | 18x50mm, 11–15mm, Trailing Taper, Lordotic | 1 |
| 194.064 | 18x55mm, 11–15mm, Trailing Taper, Lordotic | 1 |
| 194.065 | 18x60mm, 11–15mm, Trailing Taper, Lordotic | 1 |
| 194.071 | 18x40mm, 11–15mm, Leading Taper, Lordotic | 1 |
| 194.072 | 18x45mm, 11–15mm, Leading Taper, Lordotic | 1 |
| 194.073 | 18x50mm, 11–15mm, Leading Taper, Lordotic | 1 |
| 194.074 | 18x55mm, 11–15mm, Leading Taper, Lordotic | 1 |
| 194.075 | 18x60mm, 11–15mm, Leading Taper, Lordotic | 1 |
| 194.101 | 18x40mm, 12–16mm, Trailing Taper | 2 |
| 194.102 | 18x45mm, 12–16mm, Trailing Taper | 2 |
| 194.103 | 18x50mm, 12–16mm, Trailing Taper | 2 |
| 194.104 | 18x55mm, 12–16mm, Trailing Taper | 2 |
| 194.105 | 18x60mm, 12–16mm, Trailing Taper | 2 |
| 194.201 | 18x40mm, 12–16mm, Leading Taper | 1 |
| 194.202 | 18x45mm, 12–16mm, Leading Taper | 1 |
| 194.203 | 18x50mm, 12–16mm, Leading Taper | 1 |
| 194.204 | 18x55mm, 12–16mm, Leading Taper | 1 |
| 194.205 | 18x60mm, 12–16mm, Leading Taper | 1 |
| 994.012 | CALIBER®-L Coronal Tapered Implant Graphic Case | |

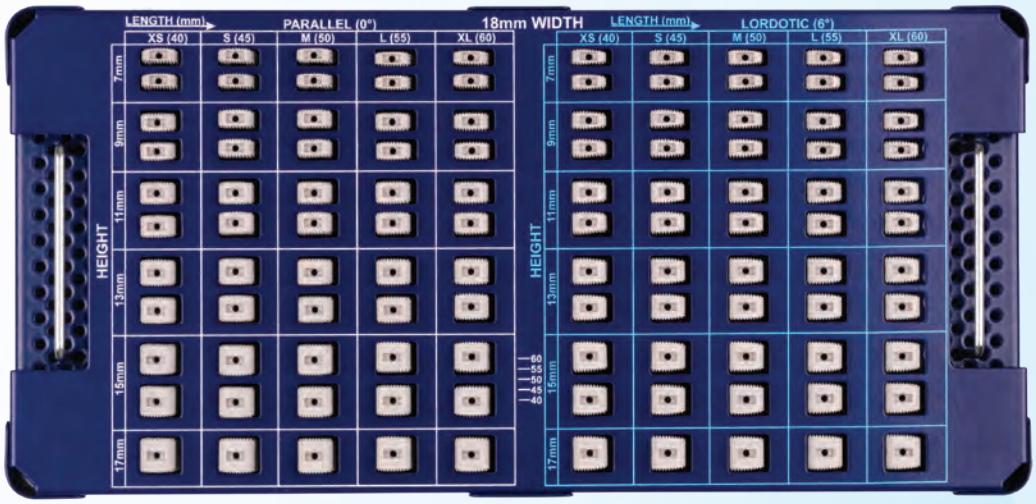
# CALIBER®-L
## CORONAL TAPERED SET 994.9300

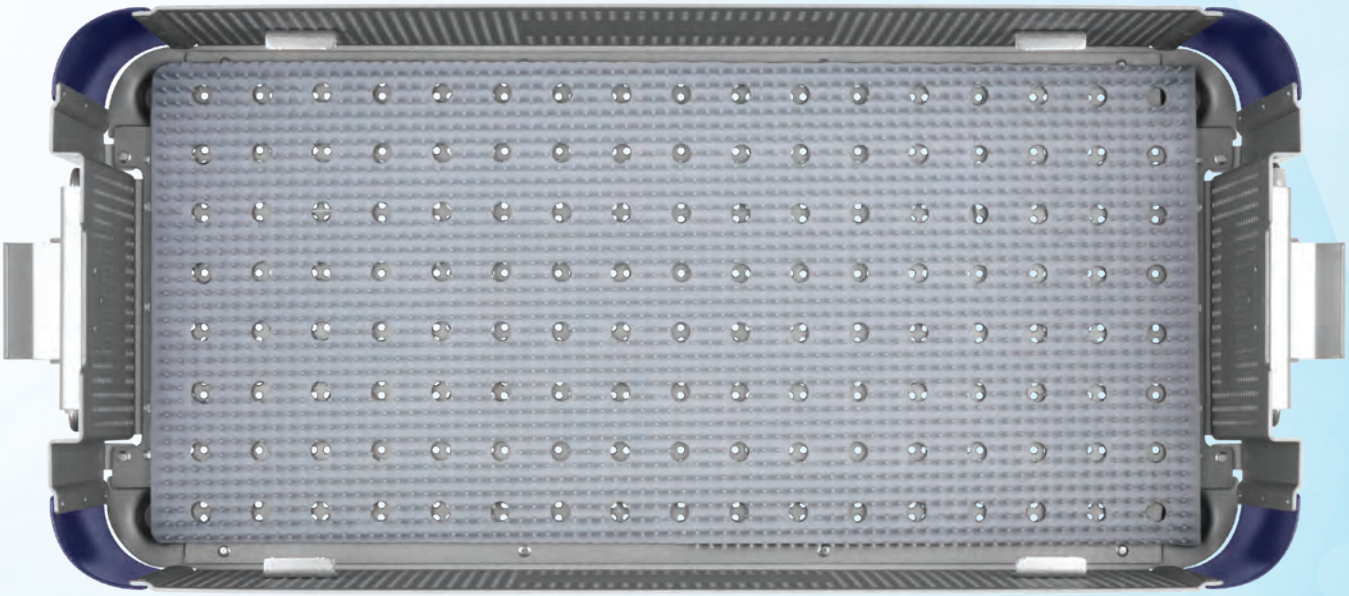
# TransContinental®
# IMPLANT SET 975.916

| Part No. | Description | Qty |
|---|---|---|
| 375.007 | TransContinental® Spacer, Small, 0°, 7mm | 2 |
| 375.009 | TransContinental® Spacer, Small, 0°, 9mm | 2 |
| 375.011 | TransContinental® Spacer, Small, 0°, 11mm | 2 |
| 375.013 | TransContinental® Spacer, Small, 0°, 13mm | 2 |
| 375.015 | TransContinental® Spacer, Small, 0°, 15mm | 2 |
| 375.017 | TransContinental® Spacer, Small, 0°, 17mm | 1 |
| 375.107 | TransContinental® Spacer, Small, 6°, 7mm | 2 |
| 375.109 | TransContinental® Spacer, Small, 6°, 9mm | 2 |
| 375.111 | TransContinental® Spacer, Small, 6°, 11mm | 2 |
| 375.113 | TransContinental® Spacer, Small, 6°, 13mm | 2 |
| 375.115 | TransContinental® Spacer, Small, 6°, 15mm | 2 |
| 375.117 | TransContinental® Spacer, Small, 6°, 17mm | 1 |
| 375.207 | TransContinental® Spacer, Medium, 0°, 7mm | 2 |
| 375.209 | TransContinental® Spacer, Medium, 0°, 9mm | 2 |
| 375.211 | TransContinental® Spacer, Medium, 0°, 11mm | 2 |
| 375.213 | TransContinental® Spacer, Medium, 0°, 13mm | 2 |
| 375.215 | TransContinental® Spacer, Medium, 0°, 15mm | 2 |
| 375.217 | TransContinental® Spacer, Medium, 0°, 17mm | 1 |
| 375.307 | TransContinental® Spacer, Medium, 6°, 7mm | 2 |
| 375.309 | TransContinental® Spacer, Medium, 6°, 9mm | 2 |
| 375.311 | TransContinental® Spacer, Medium, 6°, 11mm | 2 |
| 375.313 | TransContinental® Spacer, Medium, 6°, 13mm | 2 |
| 375.315 | TransContinental® Spacer, Medium, 6°, 15mm | 2 |
| 375.317 | TransContinental® Spacer, Medium, 6°, 17mm | 1 |
| 375.407 | TransContinental® Spacer, Large, 0°, 7mm | 2 |
| 375.409 | TransContinental® Spacer, Large, 0°, 9mm | 2 |
| 375.411 | TransContinental® Spacer, Large, 0°, 11mm | 2 |
| 375.413 | TransContinental® Spacer, Large, 0°, 13mm | 2 |
| 375.415 | TransContinental® Spacer, Large, 0°, 15mm | 2 |
| 375.417 | TransContinental® Spacer, Large, 0°, 17mm | 1 |
| 375.507 | TransContinental® Spacer, Large, 6°, 7mm | 2 |
| 375.509 | TransContinental® Spacer, Large, 6°, 9mm | 2 |
| 375.511 | TransContinental® Spacer, Large, 6°, 11mm | 2 |
| 375.513 | TransContinental® Spacer, Large, 6°, 13mm | 2 |
| 375.515 | TransContinental® Spacer, Large, 6°, 15mm | 2 |
| 375.517 | TransContinental® Spacer, Large, 6°, 17mm | 1 |

| Part No. | Description | Qty |
|---|---|---|
| 375.607 | TransContinental® Spacer, X-Large, 0°, 7mm | 2 |
| 375.609 | TransContinental® Spacer, X-Large, 0°, 9mm | 2 |
| 375.611 | TransContinental® Spacer, X-Large, 0°, 11mm | 2 |
| 375.613 | TransContinental® Spacer, X-Large, 0°, 13mm | 2 |
| 375.615 | TransContinental® Spacer, X-Large, 0°, 15mm | 2 |
| 375.617 | TransContinental® Spacer, X-Large, 0°, 17mm | 1 |
| 375.707 | TransContinental® Spacer, X-Large, 6°, 7mm | 2 |
| 375.709 | TransContinental® Spacer, X-Large, 6°, 9mm | 2 |
| 375.711 | TransContinental® Spacer, X-Large, 6°, 11mm | 2 |
| 375.713 | TransContinental® Spacer, X-Large, 6°, 13mm | 2 |
| 375.715 | TransContinental® Spacer, X-Large, 6°, 15mm | 2 |
| 375.717 | TransContinental® Spacer, X-Large, 6°, 17mm | 1 |
| 375.807 | TransContinental® Spacer, X-Small, 0°, 7mm | 2 |
| 375.809 | TransContinental® Spacer, X-Small, 0°, 9mm | 2 |
| 375.811 | TransContinental® Spacer, X-Small, 0°, 11mm | 2 |
| 375.813 | TransContinental® Spacer, X-Small, 0°, 13mm | 2 |
| 375.815 | TransContinental® Spacer, X-Small, 0°, 15mm | 2 |
| 375.817 | TransContinental® Spacer, X-Small, 0°, 17mm | 1 |
| 375.907 | TransContinental® Spacer, X-Small, 6°, 7mm | 2 |
| 375.909 | TransContinental® Spacer, X-Small, 6°, 9mm | 2 |
| 375.911 | TransContinental® Spacer, X-Small, 6°, 11mm | 2 |
| 375.913 | TransContinental® Spacer, X-Small, 6°, 13mm | 2 |
| 375.915 | TransContinental® Spacer, X-Small, 6°, 15mm | 2 |
| 375.917 | TransContinental® Spacer, X-Small, 6°, 17mm | 1 |
| 975.011 | TransContinental® Implant Graphic Case | |

# TransContinental®
# IMPLANT SET 975.916

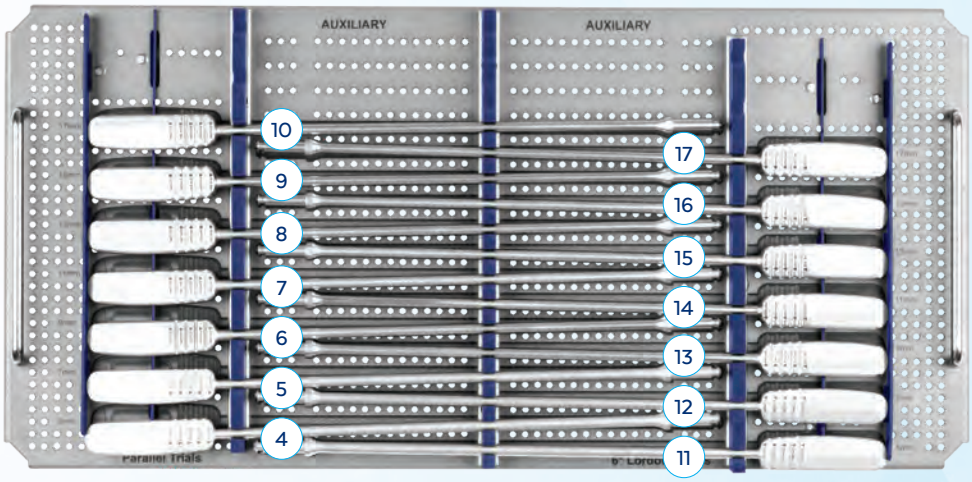


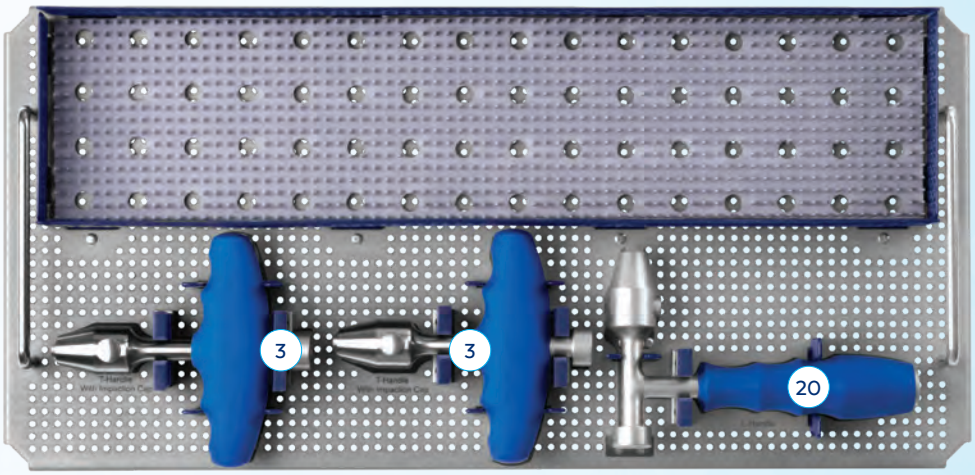



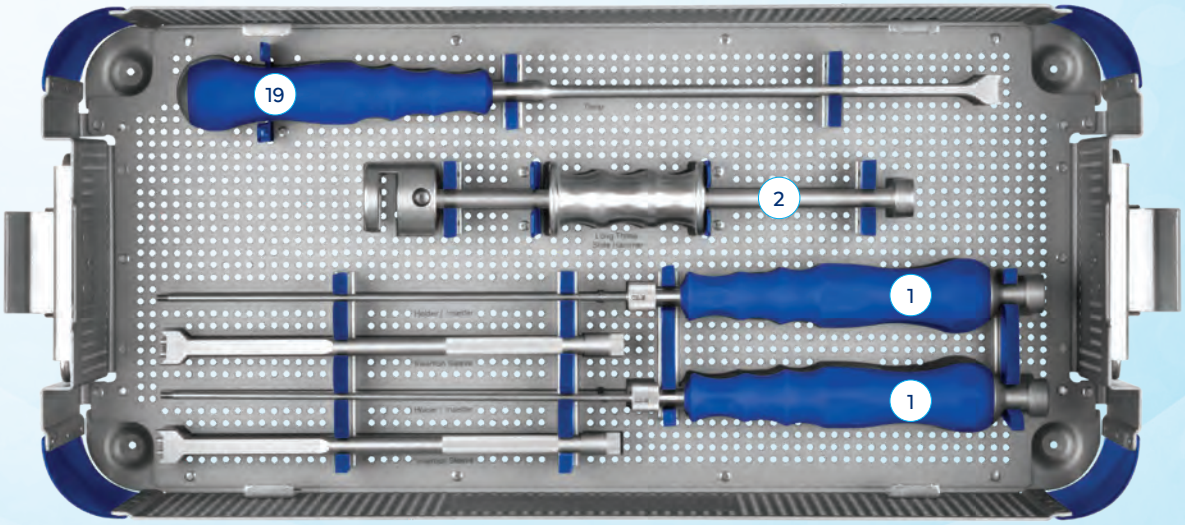
# TransContinental®
# LLIF INSERTION INSTRUMENTS SET 975.915

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 664.500 | PATRIOT® CONTINENTAL® Holder/Inserter | 2 |
| 2 | 675.004 | Long Throw Slide Hammer | 1 |
| 3 | 675.005 | T-Handle with Impaction Cap | 2 |
| 4 | 675.006 | TransContinental® Trial, Parallel, 5mm | 1 |
| 5 | 675.007 | TransContinental® Trial, Parallel, 7mm | 1 |
| 6 | 675.009 | TransContinental® Trial, Parallel, 9mm | 1 |
| 7 | 675.011 | TransContinental® Trial, Parallel, 11mm | 1 |
| 8 | 675.013 | TransContinental® Trial, Parallel, 13mm | 1 |
| 9 | 675.015 | TransContinental® Trial, Parallel, 15mm | 1 |
| 10 | 675.017 | TransContinental® Trial, Parallel, 17mm | 1 |
| 11 | 675.106 | TransContinental® Trial, Lordotic, 5mm | 1 |
| 12 | 675.107 | TransContinental® Trial, Lordotic, 7mm | 1 |
| 13 | 675.109 | TransContinental® Trial, Lordotic, 9mm | 1 |
| 14 | 675.111 | TransContinental® Trial, Lordotic, 11mm | 1 |
| 15 | 675.113 | TransContinental® Trial, Lordotic, 13mm | 1 |
| 16 | 675.115 | TransContinental® Trial, Lordotic, 15mm | 1 |
| 17 | 675.117 | TransContinental® Trial, Lordotic, 17mm | 1 |
| 18 | 675.501 | Insertion Sleeve | 2 |
| 19 | 675.502 | Tamp | 1 |
| 20 | 679.010 | L-Handle | 1 |
| | 975.007 | TransContinental® Insertion Graphic Case | |

# TransContinental®
# LLIF INSERTION INSTRUMENTS SET 975.915



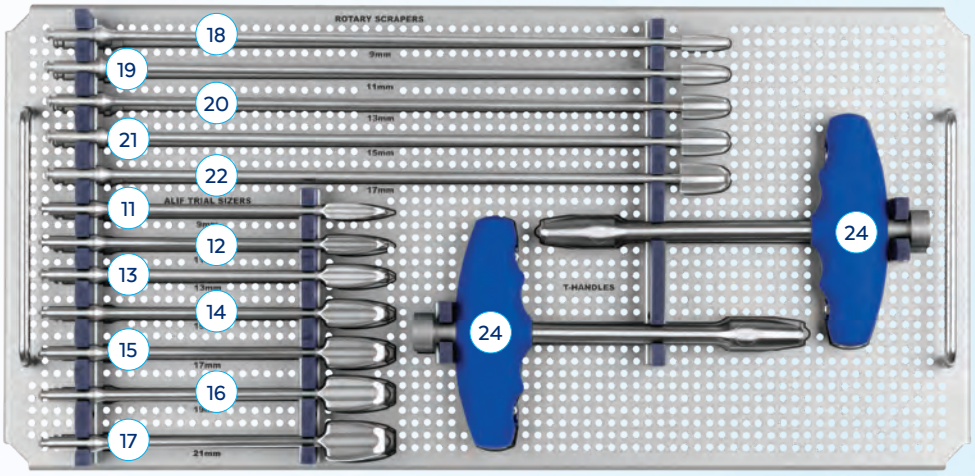



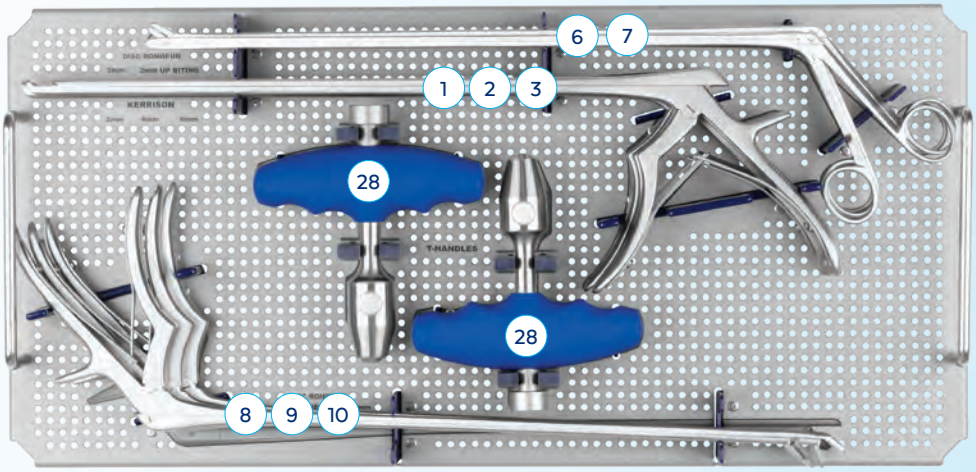



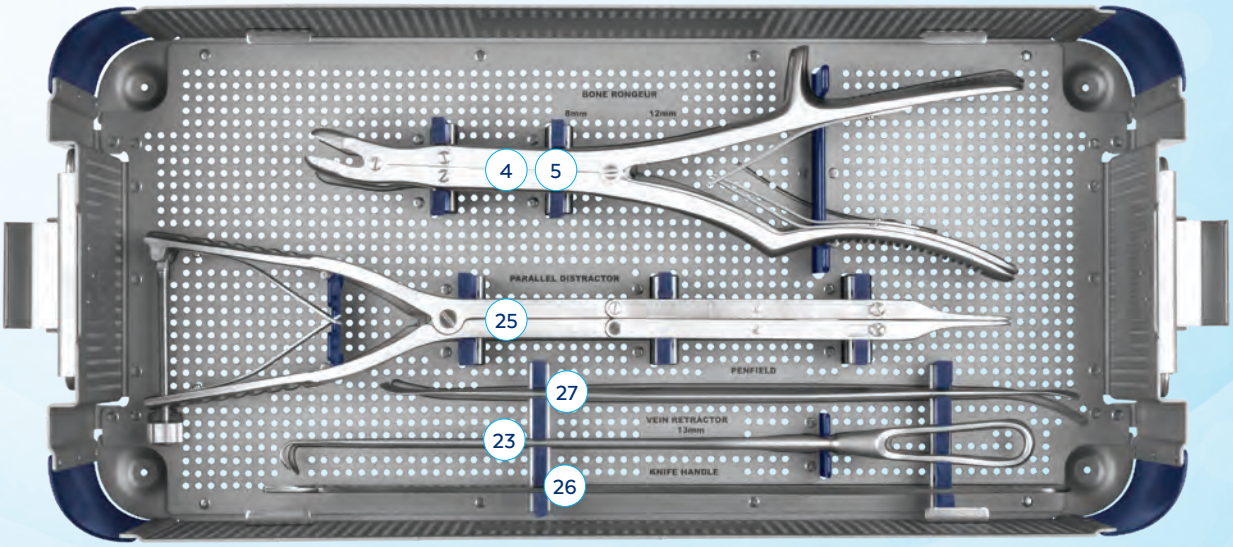
# ANTERIOR DISC PREP I
# INSTRUMENT SET 925.901

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 6625.201 | Kerrison, 2mm | 1 |
| 2 | 625.202 | Kerrison, 4mm | 1 |
| 3 | 625.203 | Kerrison, 6mm | 1 |
| 4 | 625.301 | Bone Rongeur, Double Acting, 8mm | 1 |
| 5 | 625.302 | Bone Rongeur, Double Acting, 12mm | 1 |
| 6 | 625.303 | Disc Rongeur, 2mm | 1 |
| 7 | 625.304 | Disc Rongeur, 2mm, Up Biting | 1 |
| 8 | 625.305 | Disc Rongeur, 4mm | 1 |
| 9 | 625.306 | Disc Rongeur, 4mm, Up Biting | 1 |
| 10 | 625.307 | Disc Rongeur, 6mm | 1 |
| 11 | 625.609 | ALIF Trial Sizer, 9mm | 1 |
| 12 | 625.611 | ALIF Trial Sizer, 11mm | 1 |
| 13 | 625.613 | ALIF Trial Sizer, 13mm | 1 |
| 14 | 625.615 | ALIF Trial Sizer, 15mm | 1 |
| 15 | 625.617 | ALIF Trial Sizer, 17mm | 1 |
| 16 | 625.619 | ALIF Trial Sizer, 19mm | 1 |
| 17 | 625.621 | ALIF Trial Sizer, 21mm | 1 |
| 18 | 625.709 | Rotary Scraper, 9mm | 1 |
| 19 | 625.711 | Rotary Scraper, 11mm | 1 |
| 20 | 625.713 | Rotary Scraper, 13mm | 1 |
| 21 | 625.715 | Rotary Scraper, 15mm | 1 |
| 22 | 625.717 | Rotary Scraper, 17mm | 1 |
| 23 | 625.801 | Vein Retractor | 1 |
| 24 | 625.804 | T-Handle with Impaction Cap, Long | 2 |
| 25 | 625.805 | Parallel Distractor | 1 |
| 26 | 625.806 | Knife Handle | 1 |
| 27 | 625.811 | Long Penfield | 1 |
| 28 | 675.005 | T-Handle with Impaction Cap | 2 |
| | 925.101 | Graphic Case I | |

# ANTERIOR DISC PREP I
## INSTRUMENT SET 925.901



# ANTERIOR DISC PREP II
# INSTRUMENT SET 925.902

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 6625.101 | Cobb Elevator, 18mm | 1 |
| 2 | 625.102 | Cobb Elevator, Angled, 18mm | 1 |
| 3 | 625.103 | Cobb Elevator, 23mm | 1 |
| 4 | 625.104 | Cobb Elevator, Angled, 23mm | 1 |
| 5 | 625.401 | Ring Curette, 10mm | 1 |
| 6 | 625.402 | Ring Curette, 15mm | 1 |
| 7 | 625.403 | Bone Curette, 3.5mm x 5.5mm, Straight | 1 |
| 8 | 625.404 | Bone Curette, 3.5mm x 5.5mm, Up-Angled | 1 |
| 9 | 625.405 | Bone Curette, 5.5mm x 8.5mm, Straight | 1 |
| 10 | 625.406 | Bone Curette, 5.5mm x 8.5mm, Up-Angled | 1 |
| 11 | 625.407 | Bone Curette, 7.5mm x 11.5mm, Straight | 1 |
| 12 | 625.408 | Bone Curette, 7.5mm x 11.5mm, Up-Angled | 1 |
| 13 | 625.501 | Dual Rasp | 1 |
| 14 | 625.502 | Angled Rasp | 1 |
| 15 | 625.803 | Osteotome, 16mm x 20mm | 1 |
| | 925.102 | Graphic Case II | |

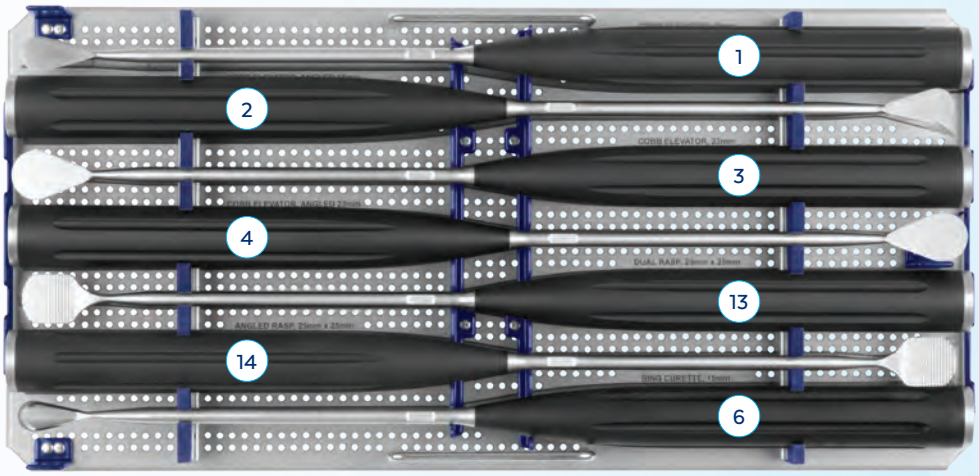
## Additionally Available

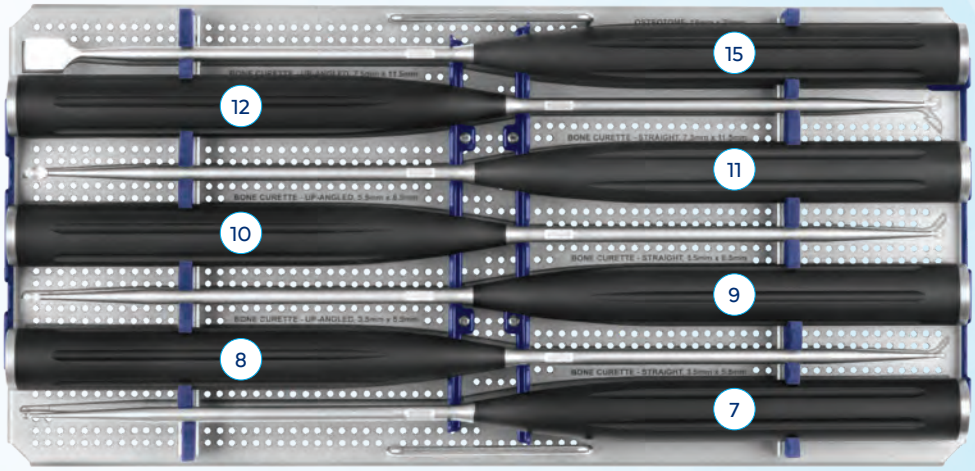
| Part No. | Description |
|---|---|
| 625.409 | Bone Curette, 9.5mm x 14.5mm, Straight |
| 625.410 | Bone Curette, 9.5mm x 14.5mm, Up-Angled |
| 625.411 | Bone Curette, 11.5mm x 17.5mm, Straight |
| 625.412 | Bone Curette, 11.5mm x 17.5mm, Up-Angled |
| 625.413 | Bone Curette, 13.5mm x 20.5mm, Straight |
| 625.414 | Bone Curette, 13.5mm x 20.5mm, Up-Angled |



*Items in gray are additionally available.*

# ANTERIOR DISC PREP II
## INSTRUMENT SET 925.902




# LATERAL DISC PREP
# INSTRUMENT SET 975.914

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 675.002 | Slap Hammer Adapter | 1 |
| 2 | 675.005 | T-Handle with Impaction Cap | 2 |
| 3 | 675.173 | Pennfield, Bayonetted, Pull | 1 |
| 4 | 675.201 | Quick-Connect Guide, 12mm | 2 |
| 5 | 675.503 | Cobb Elevator, 10mm, Straight | 1 |
| 6 | 675.504 | Cobb Elevator, 20mm, Straight | 1 |
| 7 | 675.505 | Rasp | 1 |
| 8 | 675.506 | Disc Rotary Cutter | 1 |
| 9 | 675.507 | Disc Box Cutter, 6mm | 1 |
| 10 | 675.510 | Thin Rasp, 12x20mm | 1 |
| 11 | 675.515 | Cobb Elevator, 10mm, Up-Angled | 1 |
| 12 | 675.516 | Cobb Elevator, 20mm, Up-Angled | 1 |
| 13 | 675.518 | Ring Curette, 10mm, Straight | 1 |
| 14 | 675.519 | Ring Curette, 10mm, 7°, Up-Angled | 1 |
| 15 | 675.525 | Cup Curette, 6.5 x 9.5mm, Straight | 1 |
| 16 | 675.526 | Cup Curette, 6.5 x 9.5mm, 15° Up-Angled | 1 |
| 17 | 675.527 | Cup Curette, 6.5 x 9.5mm, 90° Down-Angled | 1 |
| 18 | 675.607 | Scraper, 7mm | 1 |
| 19 | 675.609 | Scraper, 9mm | 1 |
| 20 | 675.611 | Scraper, 11mm | 1 |
| 21 | 675.613 | Scraper, 13mm | 1 |
| 22 | 675.615 | Scraper, 15mm | 1 |
| 23 | 675.617 | Scraper, 17mm | 1 |
| | 975.008 | TransContinental® Graphic Case - Disc Prep | |

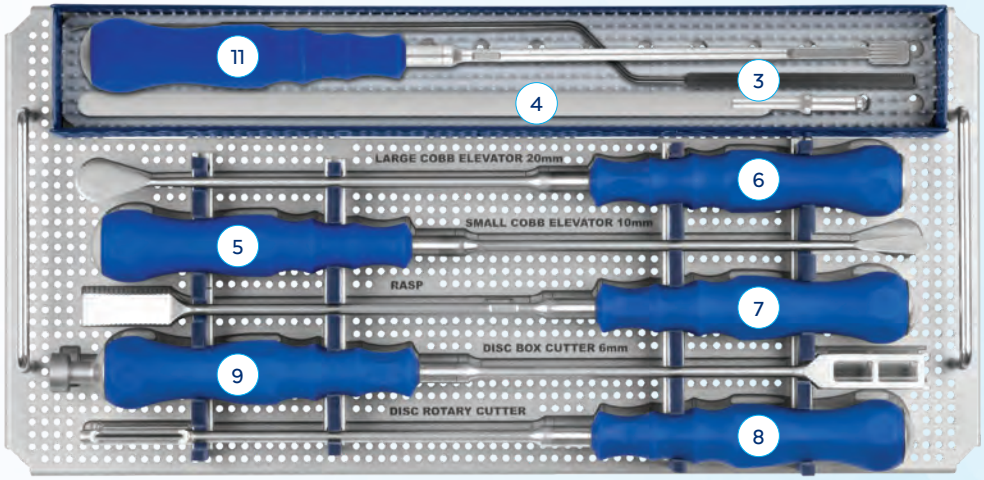
## Additionally Available

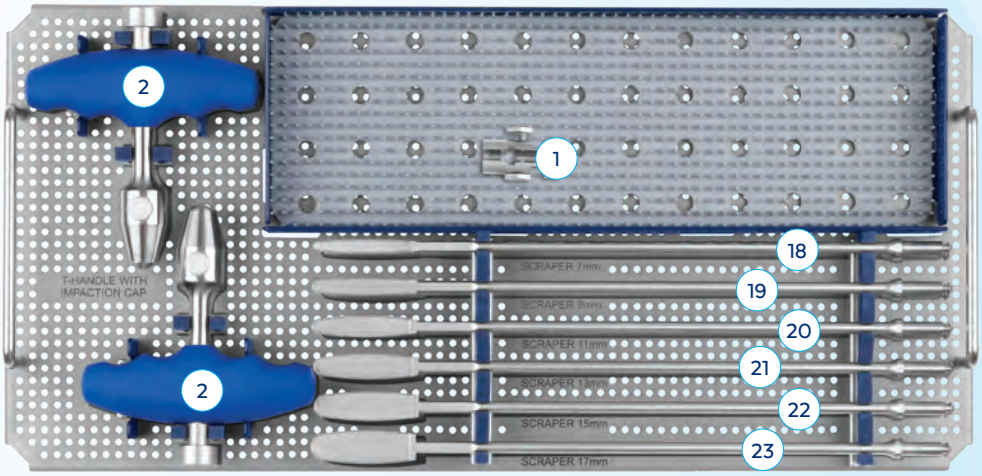
| Part No. | Description |
|---|---|
| 675.170S | Bipolar Forceps Bayonetted, Straight |
| 675.171S | Bipolar Forceps Bayonetted, Angled |

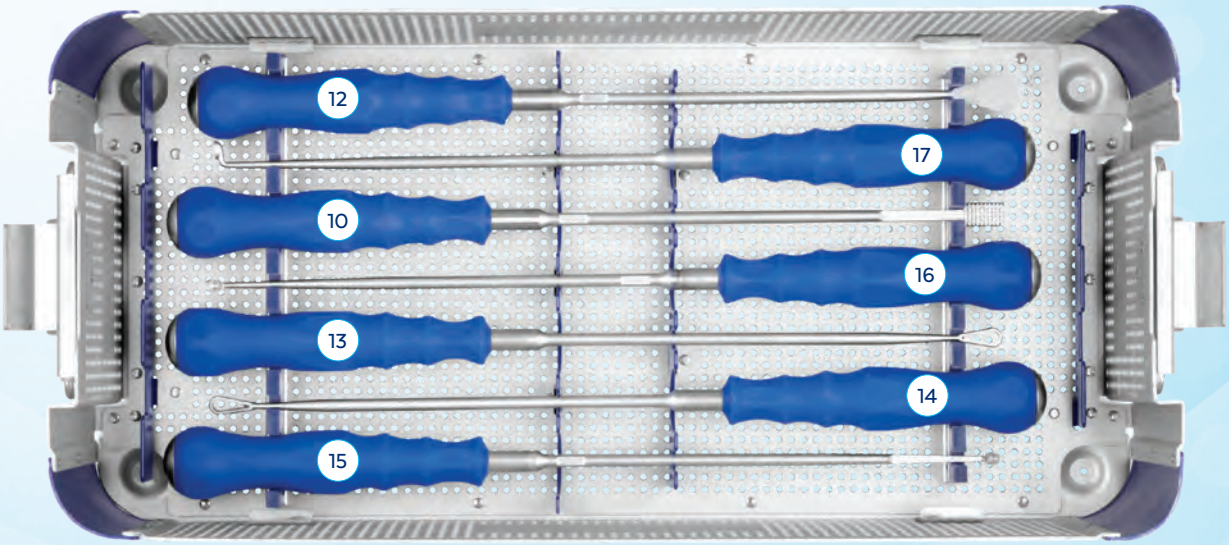


*Items in gray are additionally available.*

# LATERAL DISC PREP
## INSTRUMENT SET 975.914



# IMPORTANT INFORMATION ON THE CALIBER®-L SPACER

**DESCRIPTION**

CALIBER® Spacers are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. CALIBER® Spacers provide different shapes to accommodate various surgical approaches to the lumbar spine (posterior, transforaminal [posterolateral] or lateral). The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

CALIBER® Spacers are manufactured from radiolucent PEEK polymer and titanium alloy per ASTM F2026, F136 and F1295; non-expandable CALIBER® Spacers are manufactured from PEEK only. CALIBER® Spacers contain radiopaque titanium alloy or tantalum markers as specified in ASTM F136, F1295 and F560. CALIBER® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

**INDICATIONS**

CALIBER® Spacers are interbody fusion devices intended for use at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. All CALIBER® TPS coated spacers are indicated for the same use as non-coated PEEK spacers.

CALIBER® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

**WARNINGS**

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:
- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

The components of this system are manufactured from PEEK radiolucent polymer, commercially pure titanium, titanium alloy and tantalum. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

These warnings do not include all adverse effects that could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

Use this device as supplied and in accordance with the handling and use information provided below.

**PRECAUTIONS**

The implantation of intervertebral fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

**MRI SAFETY INFORMATION**


The CALIBER® Spacers are 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 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the CALIBER® Spacers are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

**CONTRAINDICATIONS**

Use of CALIBER® Spacer(s) is contraindicated in patients with the following conditions:
1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
2. Signs of local inflammation.
3. Prior fusion at the level(s) to be treated.
4. Severe osteoporosis, which may prevent adequate fixation.
5. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
6. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
7. Any patient not willing to cooperate with postoperative instruction.
8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Morbid obesity.
11. Pregnancy.
12. Mental illness.
13. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
14. Suspected or documented allergy or intolerance to composite materials.
15. Any case not needing a fusion.
16. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
17. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
18. Spondylolisthesis unable to be reduced to Grade 1.
19. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
20. Any case that requires the mixing of metals from two different components or systems.
21. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
22. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

**COMPLICATIONS AND POSSIBLE ADVERSE EVENTS**

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:
- Loosening, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- Nerve damage, including loss of neurological function (sensory and/or motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome
- Dural tears, cerebral spinal fluid leakage
- Fracture of vertebrae
- Foreign body reaction (allergic) to components or debris
- Vascular or visceral injury
- Change in spinal curvature, loss of correction, height and/or reduction

# IMPORTANT INFORMATION ON THE CALIBER®-L SPACER

- Urinary retention or loss of bladder control or other types of disorders of the urogenital system
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise
- Reproductive system compromise including impotence, sterility, loss of consortium and sexual dysfunction.
- Pain or discomfort
- Bursitis
- Decrease in bone density due to stress shielding
- Loss of bone or fracture of bone above or below the level of surgery
- Bone graft donor site pain, fracture, and/or delayed wound healing
- Restriction of activities
- Lack of effective treatment of symptoms for which surgery was intended
- Need for additional surgical intervention
- Death

**PACKAGING**

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

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

**HANDLING AND USE**

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

**CLEANING**

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

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

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

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

**CONTACT INFORMATION**

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

**STERILIZATION**

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of $10^{-6}$. Sterile products are packaged in a heat sealed container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of $10^{-6}$. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.* It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 $in^2$ total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows::

| Method | Cycle Type | Temperature | Exposure Time | Drying Time |
|---|---|---|---|---|
| Steam | Pre-vacuum | 132°C (270°F) | 4 Minutes | 30 Minutes |
| Steam | Pre-vacuum | 134°C (273°F) | 3 Minutes | 30 Minutes |

*These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.*

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

| SYMBOL TRANSLATION | | | |
|---|---|---|---|
| REF | CATALOGUE NUMBER | STERILE R | STERILIZED BY IRRADIATION |
| LOT | LOT NUMBER | EC REP | AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |
| ⚠ | CAUTION | | MANUFACTURER |
| | SINGLE USE ONLY | | USE BY (YYYY-MM-DD) |
| QTY | QUANTITY | | |

**DI154A Rev J**

# NOTES

# NOTES

Globus Medical
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2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)



CE 0297

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GMTGD78
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