CALIBER®

Expandable Lumbar Fusion Device

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®

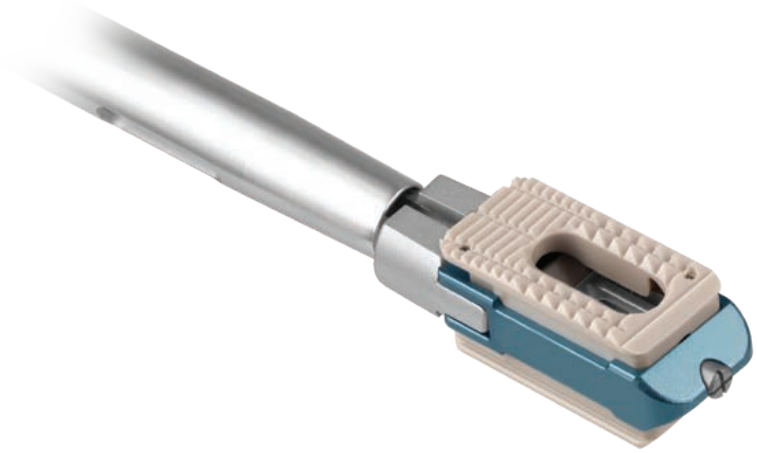
CALIBER®

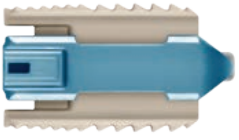
Expandable Lumbar Fusion Device

CALIBER® is an innovative expandable lumbar fusion device that represents the future of minimally invasive surgery (MIS) by optimizing endplate-to-endplate fit and minimizing insertion force.

Insertion of CALIBER® is performed at a contracted height to help reduce the amount of nerve root retraction required and to preserve musculoskeletal composition.

Continuous expansion of CALIBER® helps to restore disc height, while controlled distraction helps to properly tension the annulus and surrounding ligaments.



Contracted	Partially Expanded	Fully Expanded
		

Minimal Impaction

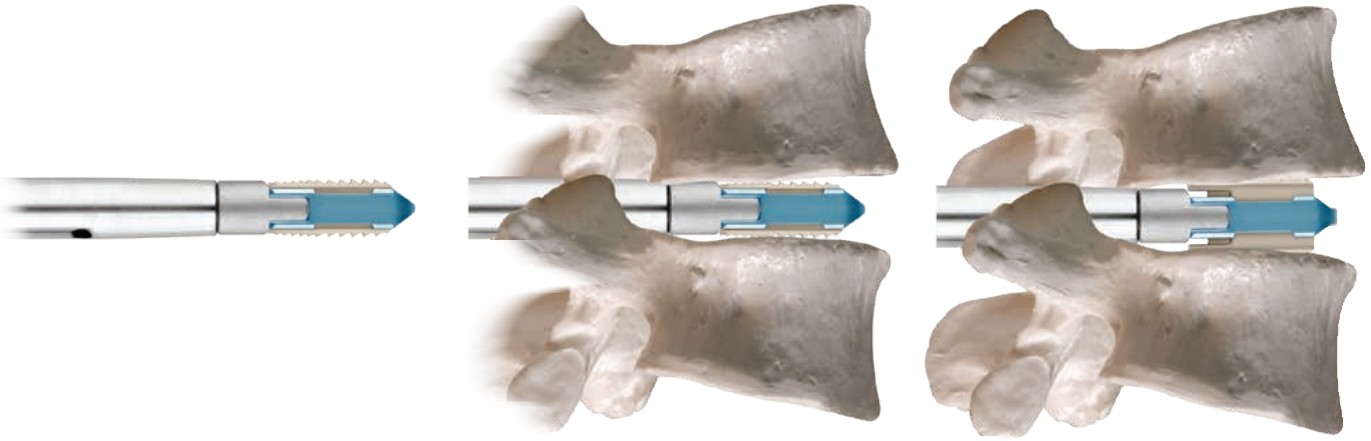
Contracted insertion height eases insertion into the disc space, helping to reduce musculoskeletal disruption and the amount of nerve root retraction required

Controlled Disc Height Restoration

Controlled continuous expansion and distraction helps restore disc height and helps to reduce the risk of over-distraction

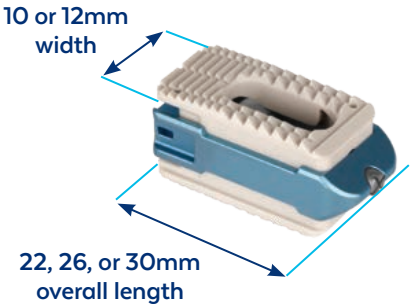
Optimized Fit

When expanded in the disc space, the implant optimizes endplate-to-endplate fit

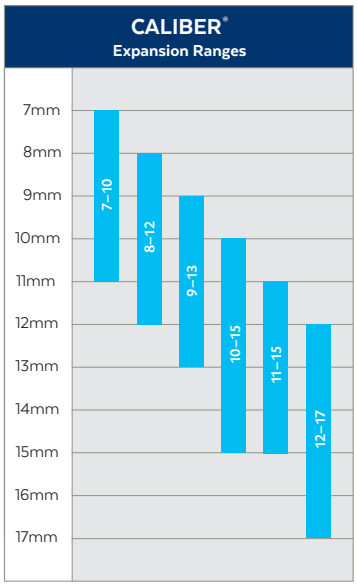


IMPLANT OVERVIEW

- Contracted insertion height helps minimize impaction force
- Controlled continuous expansion and distraction aids in restoration of disc height
- Axial graft chamber promotes fusion
- Automatic locking for stability
- Four easily identifiable radiographic markers facilitate positioning
- Convex profile fits anatomy



Starting Heights: 7–12mm with up to 5mm of expansion

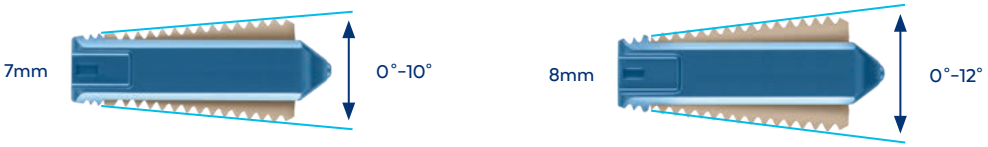


- Five footprints: 10x22, 10x26, 10x30, 12x26, and 12x30mm
- Height expansion options from 7–17mm
- 4°, 12°, 15° and adjustable lordotic option, ideal for L5/S1 disc space

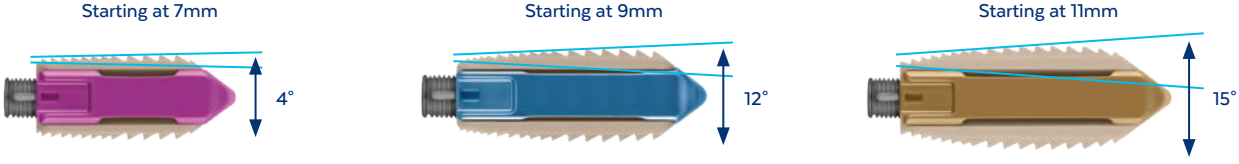
- One instrument for both insertion and expansion
- Slim design for MIS applications
- PEEK endplates for radiographic assessment
- Up to 5mm of expansion

Multiple Saggital Profiles

Lordotic Expansion



Parallel Expansion



INSTRUMENT OVERVIEW

SIZER/SHAVERS

	Height	Part No.
	7mm	668.507
	8mm	668.508
	9mm	668.509
	10mm	668.510
	11mm	668.511

	Height	Part No.
	12mm	668.512
	13mm	668.513
	14mm	668.514
	15mm	668.515
	16mm	668.516
	17mm	668.517

T-Handle 601.800

IMPLANT INSERTER COMPONENTS

Inserter Fork, 10mm 694.003

Inserter Fork, 12mm 694.013

Inserter Tube 694.004

Inserter Handle 694.005

2.5mm Torque-Limiting Driver 694.006

2.5mm Torque-Limiting Driver, 2.0N 694.016

Inserter Fork, 10mm 694.003
Inserter Tube 694.004
Inserter Handle 694.005
2.5mm Torque-Limiting Driver, 2.0N 694.016
(Assembled)

OTHER INSTRUMENTS

Slap Hammer 694.008

Spanner Wrench 687.509

SURGICAL TECHNIQUE

CALIBER®

Minimally Invasive Surgery

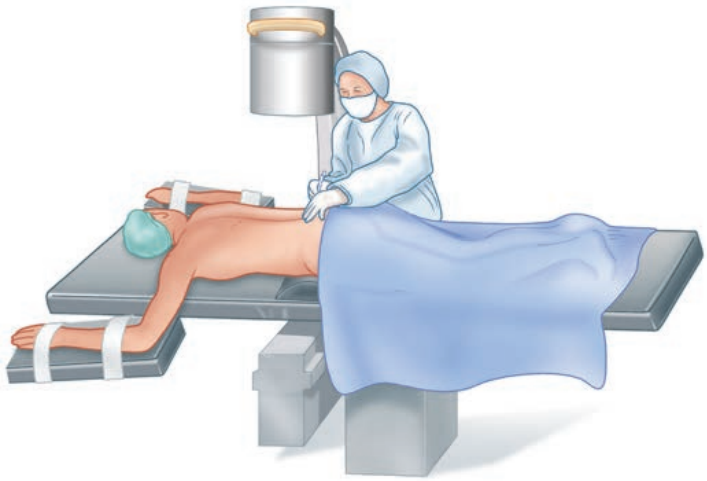
Advances in minimally invasive surgery, in particular, implant systems such as CALIBER® and retractor systems such as MARS™3V, help to lessen the disruption to the patient's anatomic structures. Without compromising surgical goals, minimally invasive surgery for interbody fusion has been shown[1,2] to:

- Reduce soft tissue disruption
- Reduce blood loss
- Reduce scarring
- Reduce postoperative pain
- Shorten hospital stay
- Shorten recovery time

STEP 1 TRANSFORAMINAL ACCESS AND APPROACH

Approach

The patient is placed under anesthesia and positioned prone. Lateral C-arm fluoroscopy or other radiographic methods may be utilized throughout the surgery to ensure the correct implant placement. In addition to the described interbody fusion technique, posterior stabilization, such as REVERE® or REVOLVE®, must be used at the appropriate level(s).



The incision can be made 4–4.5cm lateral to the midline and the trajectory should be in line with the disc. Finger dissect between the multifidus and longissimus muscles until the facet joint is palpable.

1. Peng C.W., Yue W.M., et al. Clinical and Radiological Outcomes of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion. *SPINE* 34: 1385-9, 2009.

2. Kim KT, Lee SH, et al. The Quantitative Analysis of Tissue Injury Markers After Mini-Open Lumbar Fusion. *SPINE* 6: 712-716, 2006.

STEP 2 USING THE RETRACTOR

MARS™3V dilators may be used to retract soft tissue and surround the facet. Keep downward pressure on the dilators and twist as needed when approaching the facet. With the initial dilator in place, a series of cannulas are progressively passed over the initial dilator.

Ensure that the retractor is in the fully closed position and the blades are securely attached to the frame.

Before removing the cannulas, articulate all three blades with one full clockwise rotation of the silver knobs. Articulating the blades in this manner will help prevent tissue creep as the cannulas are removed.

Note: The following sets are required to use the MARS™3V Retractor:
- *998.901 MARS™3V Retractor Instrument Set*
- *998.902 MARS™ Instrument II Set*
- *932.903 MARS™ Instrument III Set*

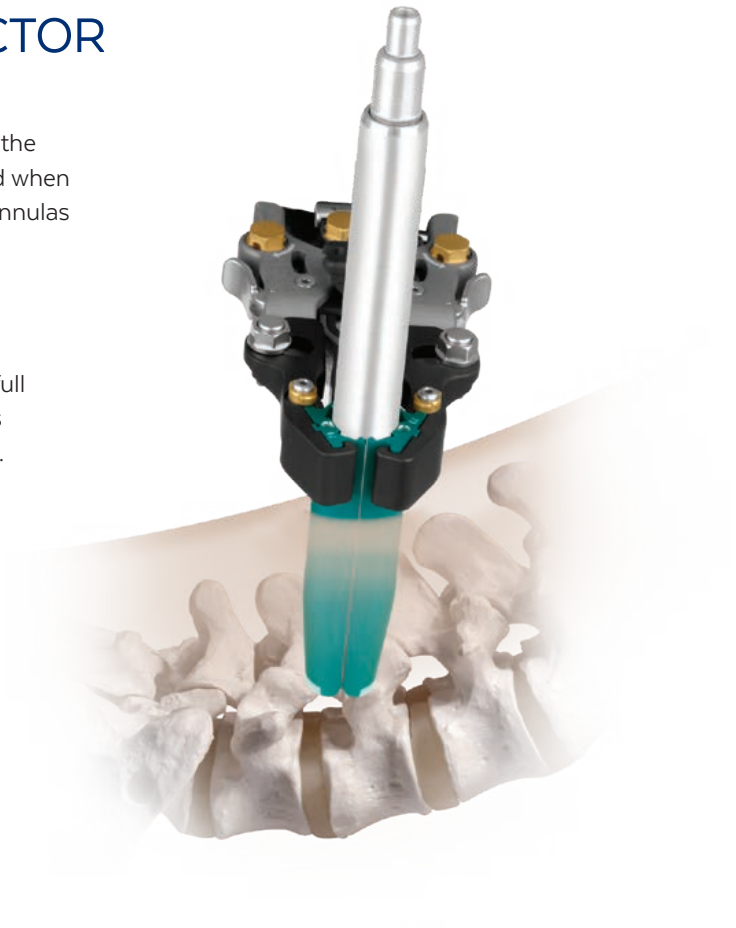


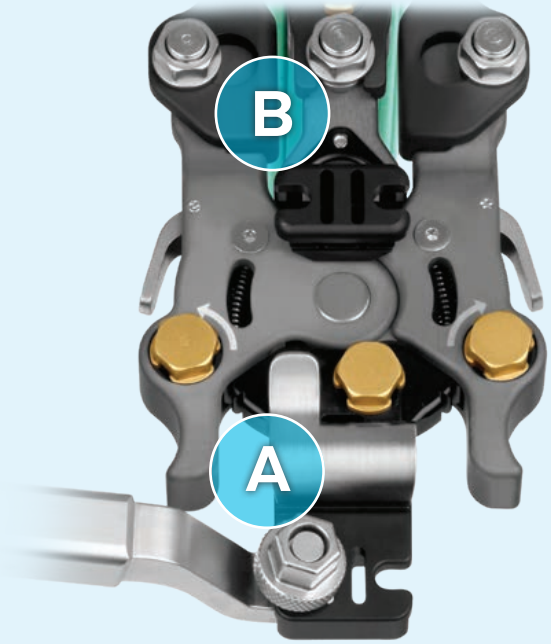
TABLE ARM ATTACHMENT

In order to use MARS™3V, the table arm attachment must be secured. Attach the Table Clamp onto the bed rail attachment. Insert the Articulating Arm Assembly into the Table Clamp and secure. The opposite end of the arm assembly is then attached to the Retractor 3 Blade Frame.

There are two options for attachment positions on the retractor, as shown at right.

Attaching the arm assembly to point **A** maintains retractor position relative to the posterior blade position, and translates the cephalad and caudad blades laterally when the retractor is opened.

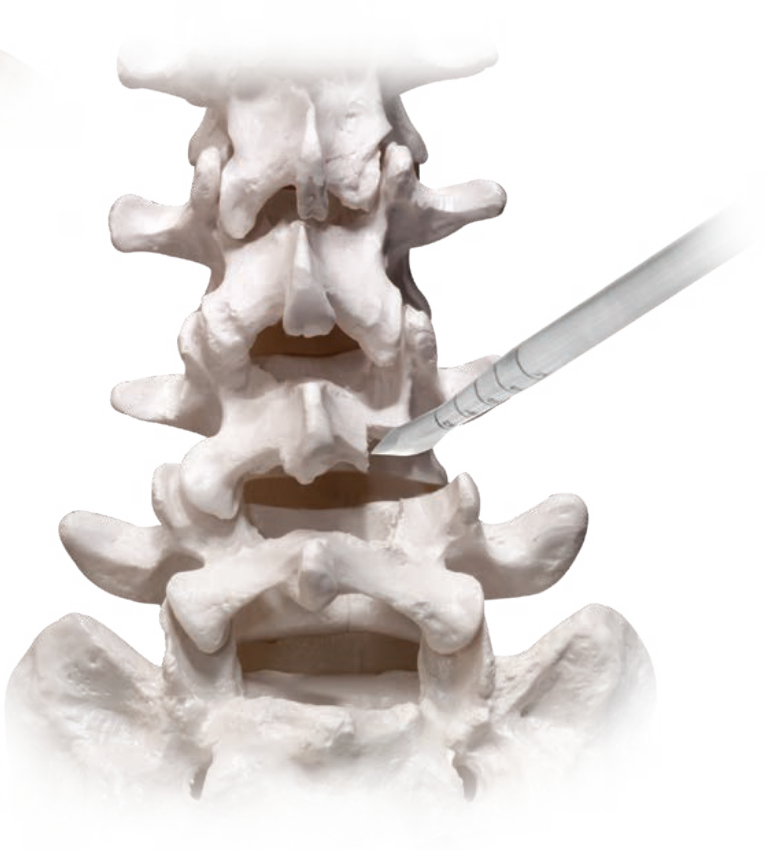
Attaching the arm assembly to point **B** maintains the retractor position relative to the cephalad and caudad blade position, and translates the posterior blade medially.



STEP 3 CREATING TRANSFORAMINAL ACCESS

Use an **Osteotome*** to remove the inferior facet of the cephalad vertebrae and the superior facet of the caudal vertebrae at the appropiate level(s). This creates a working transforaminal access window to the disc.

Approach using Globus MARS™3V Retractor system

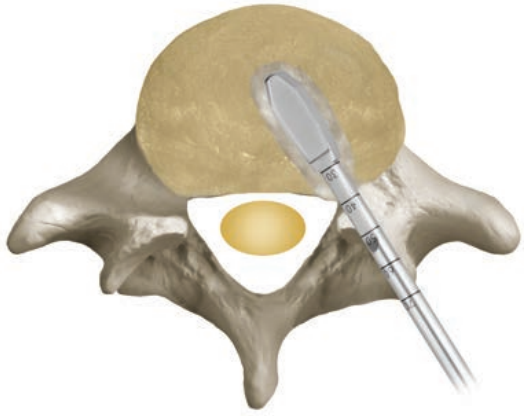


Transforaminal Access

**Available in the Posterior Disc Prep Instruments Set I*

STEP 4 DISCECTOMY/ENDPLATE PREPARATION

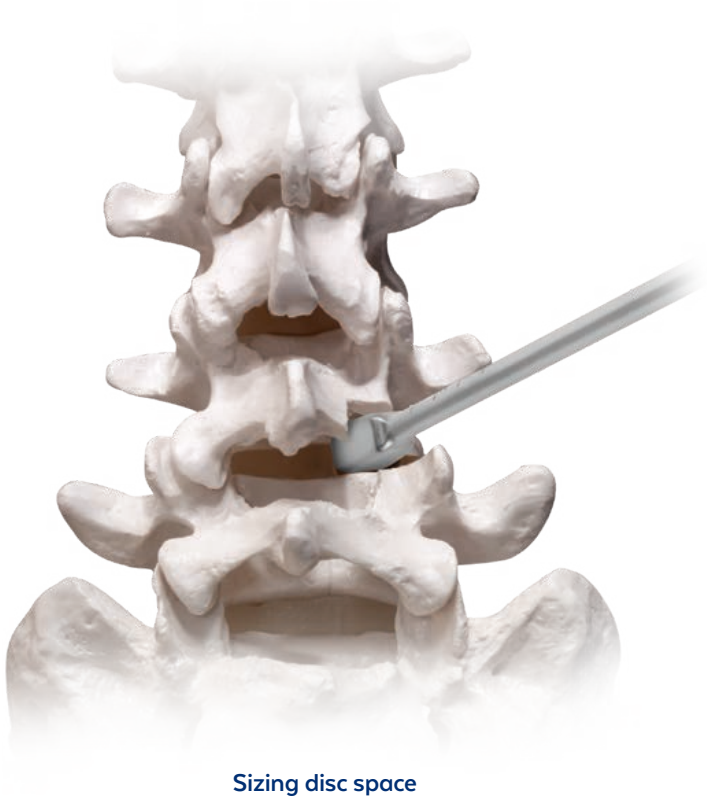
After creating an adequate annular window, remove disc material using Rongeurs, Rasps, Curettes*, and other suitable preparation instruments. **Shavers** may be used to remove superficial layers of the cartilaginous endplates. Insert the smallest Shaver into the disc space for further disc removal and endplate preparation, moving to larger Shavers as needed. Use caution while using the Shavers to avoid damage to the endplate. Careful disc removal and endplate preparation maximizes the potential for a successful fusion.



STEP 5 DISTRACTION AND IMPLANT SIZING

Insert the **Trial**** into the disc using gentle impaction if needed. Determine which height and length best fit the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment. The final implant size may be confirmed using fluoroscopy.

Note: Alternatively, the Shaver/Sizers may be used for distraction and implant sizing. 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.



Sizing disc space

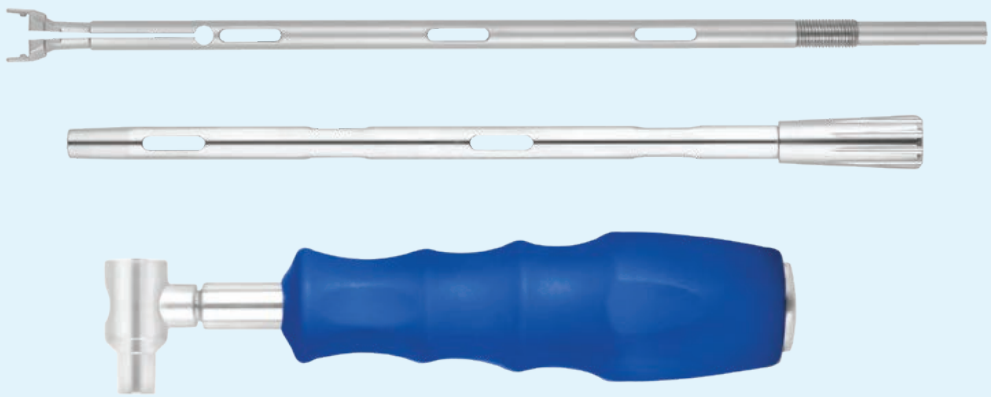
**Available in the Posterior Disc Prep Instrument Set I and II*
***Available in the PRESERVE® Unilateral Instruments Set*

DISTRACTION AND IMPLANT SIZING (CONT'D)

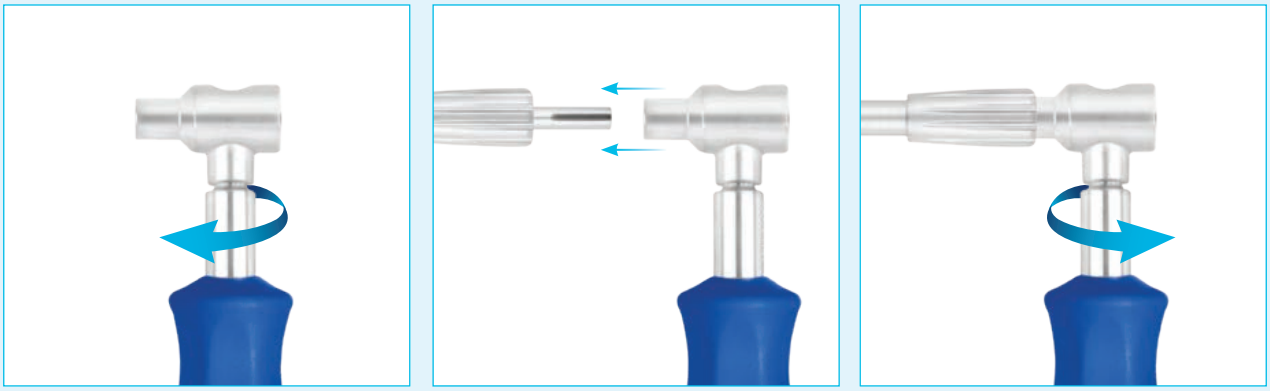
IMPLANT INSERTER ASSEMBLY

Select the proper size **Inserter Fork** that matches the width of the implant. Fully thread the Inserter Fork into the **Inserter Tube**, opposite the knurled knob. Then attach the **Inserter Handle** onto the back of the Inserter Fork. Ensure that the blue handle of the Inserter is in the unlocked position by rotating the handle counterclockwise until it stops. The Inserter Handle may be placed in two orientations based on surgeon preference.

Rotate the blue handle clockwise to lock the Inserter Handle onto the Inserter Fork.



Inserter Fork, Inserter Tube, and Inserter Handle



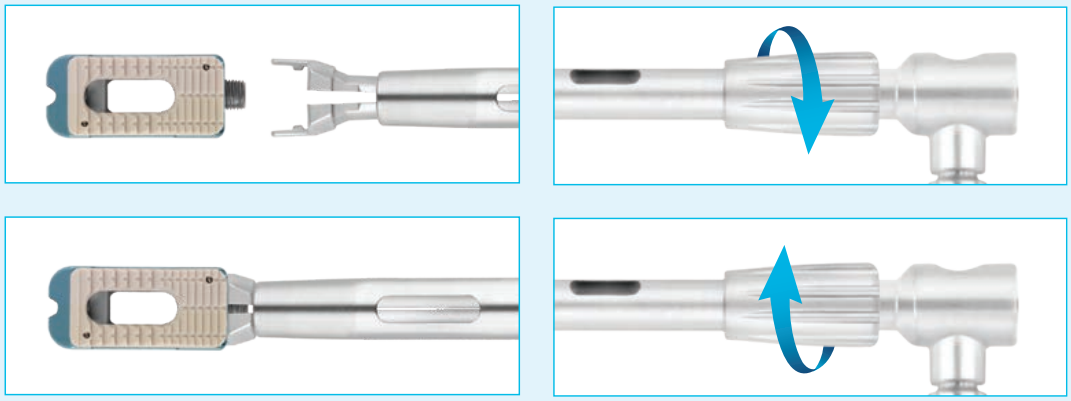
Attaching Inserter Handle to Inserter Tube

STEP 6 IMPLANT INSERTION

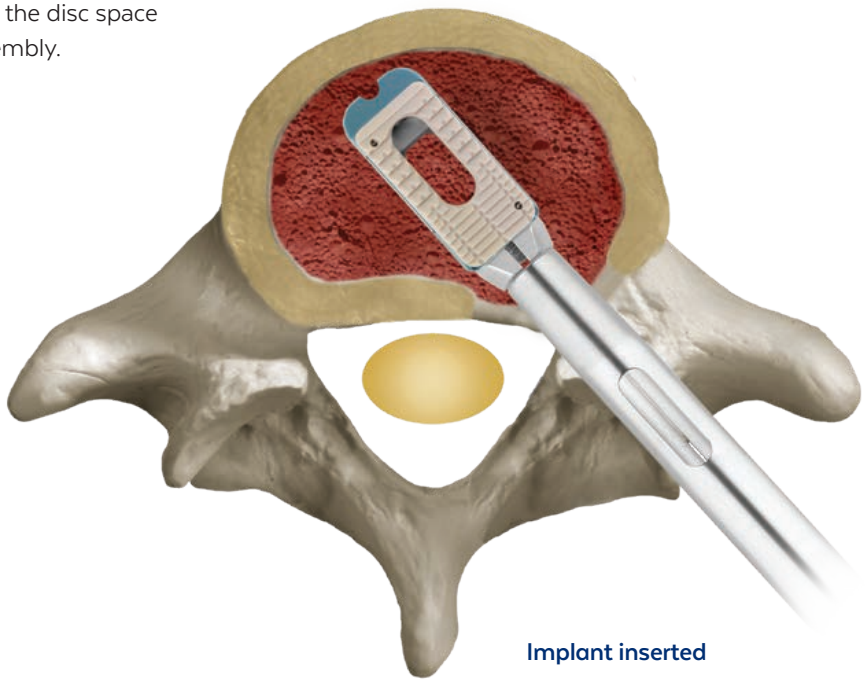
Select an appropriately sized implant and pack autogenous bone graft material both in and around the implant. Graft should be packed into the disc space before and after implant insertion. Packing autogenous graft in and the around the device will help to promote fusion.

IMPLANT ATTACHMENT

With the Inserter Tube fully threaded counterclockwise, attach the implant by placing the implant between the tips of the Inserter Fork and rotate the Inserter Tube clockwise until the implant is secure.



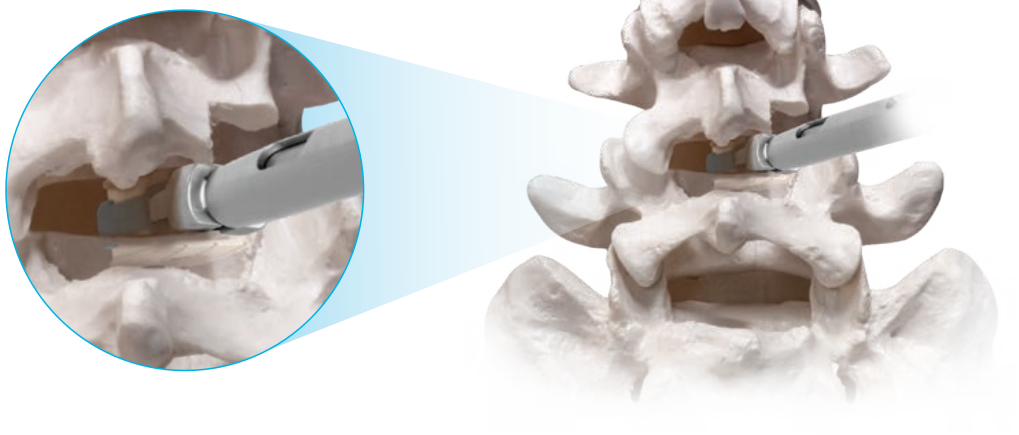
Insert the implant into the disc space using the Inserter Assembly.



Implant inserted

STEP 7 IMPLANT EXPANSION

Rotate the 2.5mm Torque-Limiting Driver clockwise to expand the implant to the appropriate height.



Determining Implant Height

The 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 until the desired fit is achieved.

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

Use arrow on back end of driver to count revolutions

The 7mm, 0°–10° and the 8mm, 0°–12° wedge shaped implants expand to variable lordotic positions. Implants with 7mm starting heights provide up to 10° of lordosis and implants with 8mm starting heights provide up to 12° of lordosis.

For the variable lordotic implants, full expansion is achieved by 6 revolutions of the set screw. At full expansion, the anterior height is approximately 10mm for the 7mm, 0°–10° implants and 11mm for the 8mm, 0°–12° implants.

If inserting two CALIBER® implants, count the number of revolutions of the set screw and/or confirm implant heights using fluoroscopy to ensure that both implants are expanded to the same height.

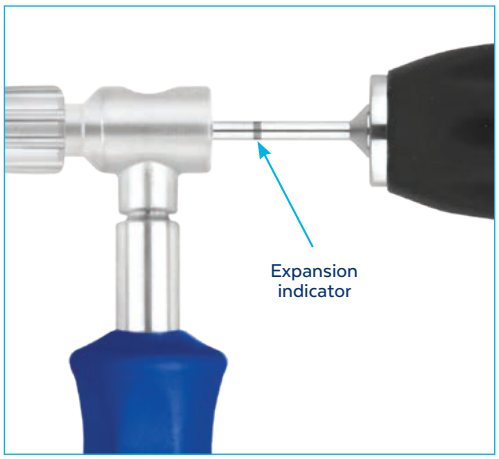
Set Screw Revolutions Required											
Expansion Ranges	Final Height (mm)										
	7	8	9	10	11	12	13	14	15	16	17
7–10mm	0	1.5	3	MAX	-	-	-	-	-	-	-
8–12mm	-	0	1.5	3	4.5	MAX	-	-	-	-	-
9–13mm	-	-	0	1.5	3	4.5	MAX	-	-	-	-
10–15mm	-	-	-	0	1.25	2.50	3.75	5	MAX	-	-
11–15mm	-	-	-	-	0	1.5	3	4.5	MAX	-	-
12–17mm	-	-	-	-	-	0	1.25	2.5	3.75	5	MAX
7mm, 0–10°	0	2	4	MAX	-	-	-	-	-	-	-
8mm, 0–12°	-	0	2	4	MAX	-	-	-	-	-	-

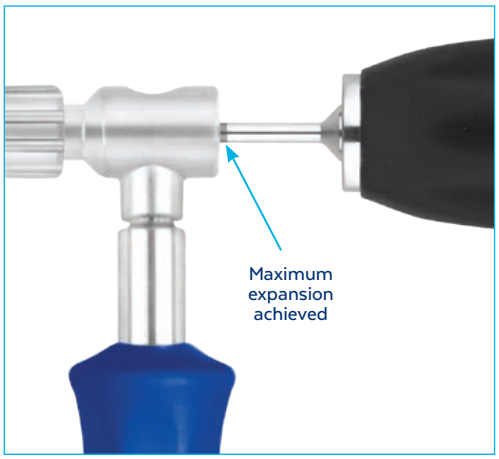
The 2.5mm Torque-Limiting Driver is designed to allow the user to identify when either of the following conditions has occurred:

- The implant has reached its maximum height expansion OR the implant is exerting the maximum allowable output of 864N of distraction force on the vertebral endplates.

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

The maximum expansion of an implant can be visually verified by observing the location of the etched ring on the 2.5mm Torque-Limiting Driver relative to the Inserter Handle. Maximum expansion is achieved when the etched ring is flush with the Inserter Handle.





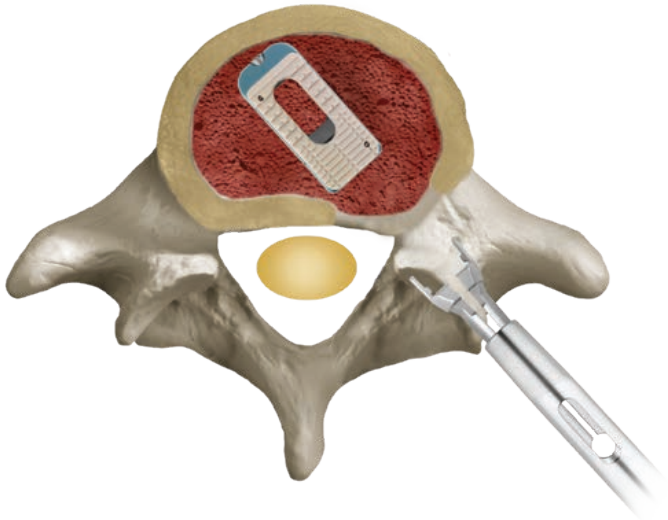
2.5mm Torque-Limiting Driver (Assembled)

STEP 8 FINAL POSITIONING AND RADIOGRAPHIC CONFIRMATION

Using fluoroscopy, verify the position before disengaging. Once the desired position is achieved, disengage the Inserter from the implant by first removing the 2.5mm Torque-Limiting Driver. Then rotate the Inserter Tube counterclockwise until disengaged.

Alternatively, the **Spanner Wrench** can be used to loosen the Inserter Tube if it is difficult to rotate.

If repositioning is needed the implant must be fully contracted before repositioning the implant.



RADIOGRAPHIC POSITIONING

Lateral view

Anterior/posterior view

IMPLANT REMOVAL

For implant removal, the implant height may be reduced by inserting a hex driver into the set screw and rotating counterclockwise. Forceps or other manual surgical instruments may then be used to grasp and extract the implant. Alternatively, the implant may be rotated 90° and subsequently extracted using forceps or other manual surgical instruments.

SUPPLEMENTAL FIXATION

In addition to the described interbody fusion technique, posterior stabilization, such as REVERE® or REVOLVE®, must be used at the appropriate level(s).

REVOLVE® is a posterior stabilization system designed for 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

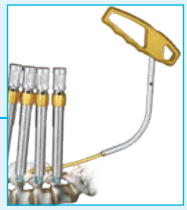
The system adapts to surgeon needs, with capabilities for trauma, tumor, and deformity applications.

REVOLVE® ENHANCES EVERY STEP OF A MIS PROCEDURE

Tap and awl in one step

Precise rod measurement

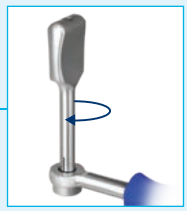
Single handed rod manipulation



Built-in reduction sleeves

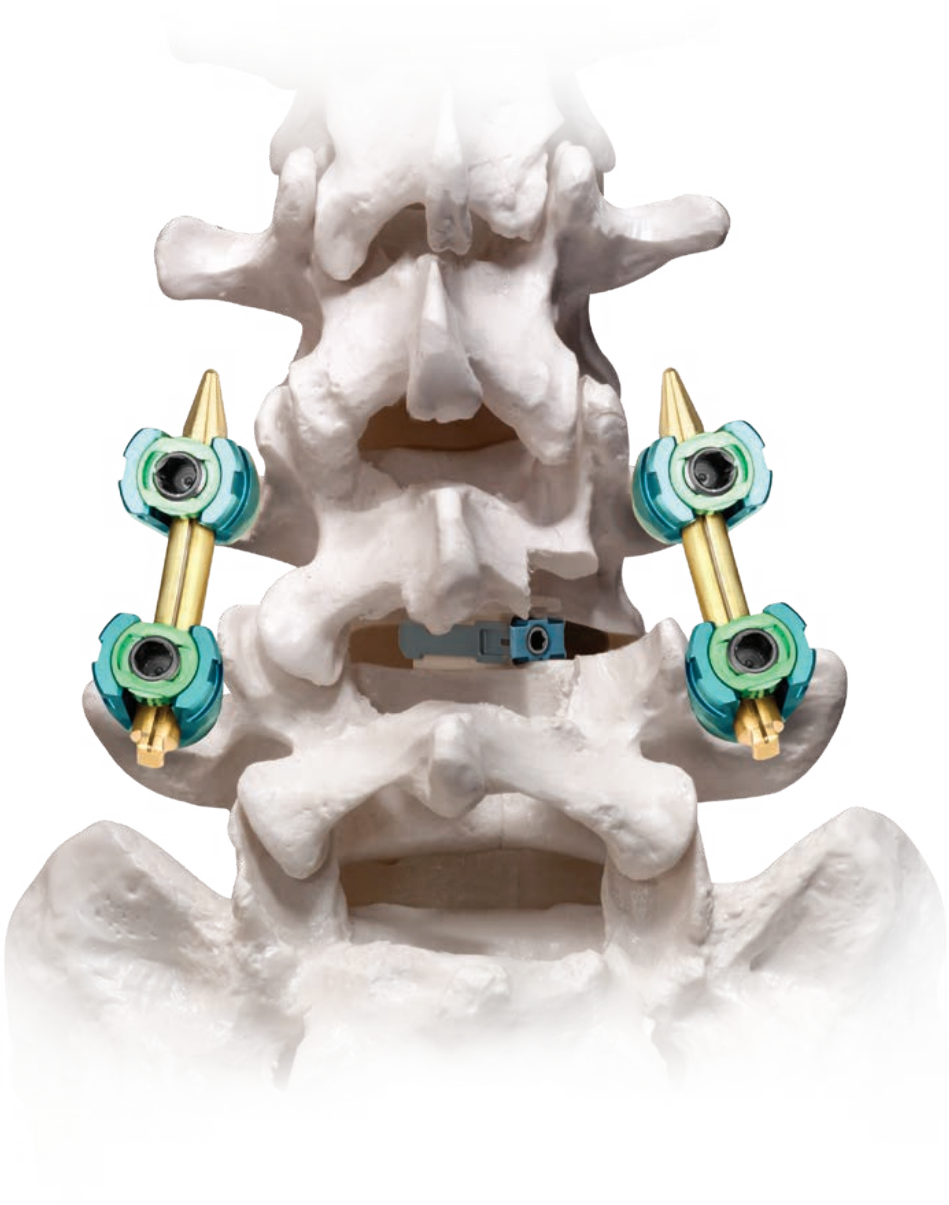
Fulcrum style compressor/ distractor follows anatomical curves

Simple locking cap mechanism requires only two finger 90° turn

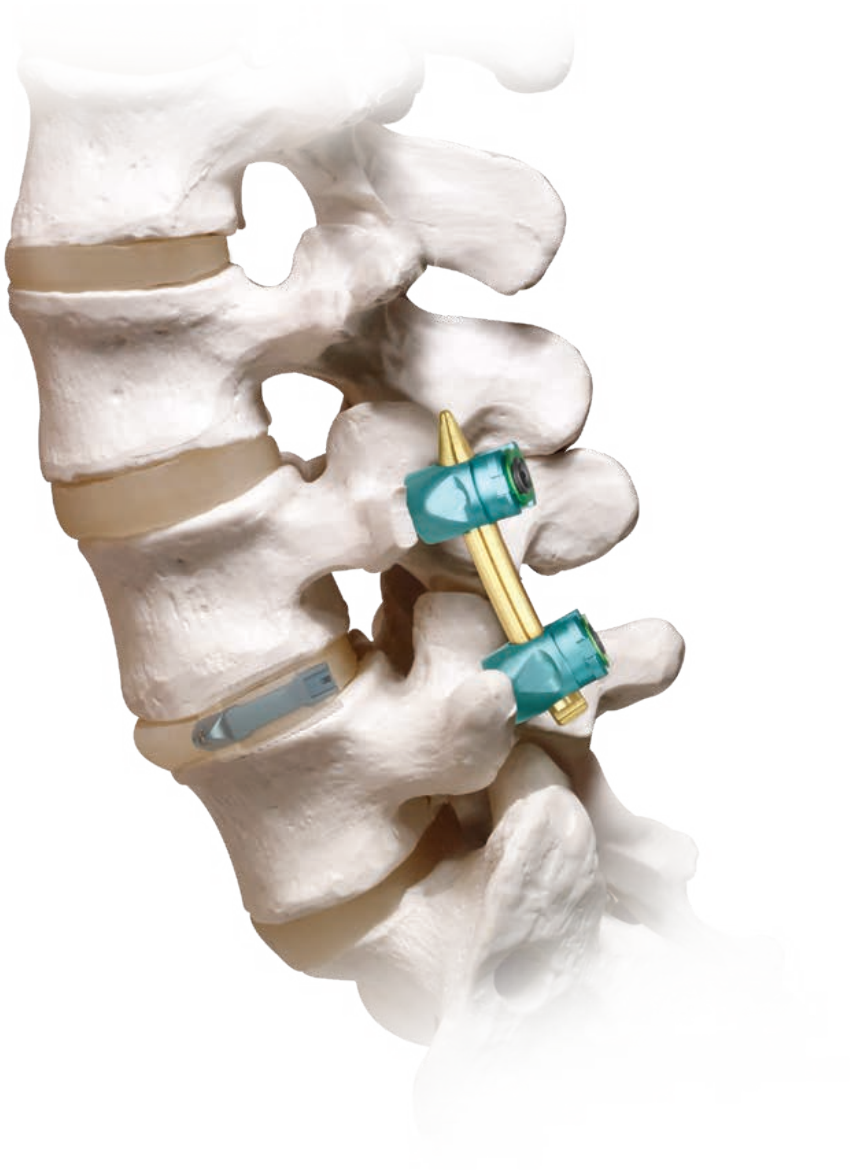


Final tightening

FINAL CONSTRUCT (POSTERIOR VIEW)



FINAL CONSTRUCT (LATERAL VIEW)



CALIBER®
IMPLANT SETS

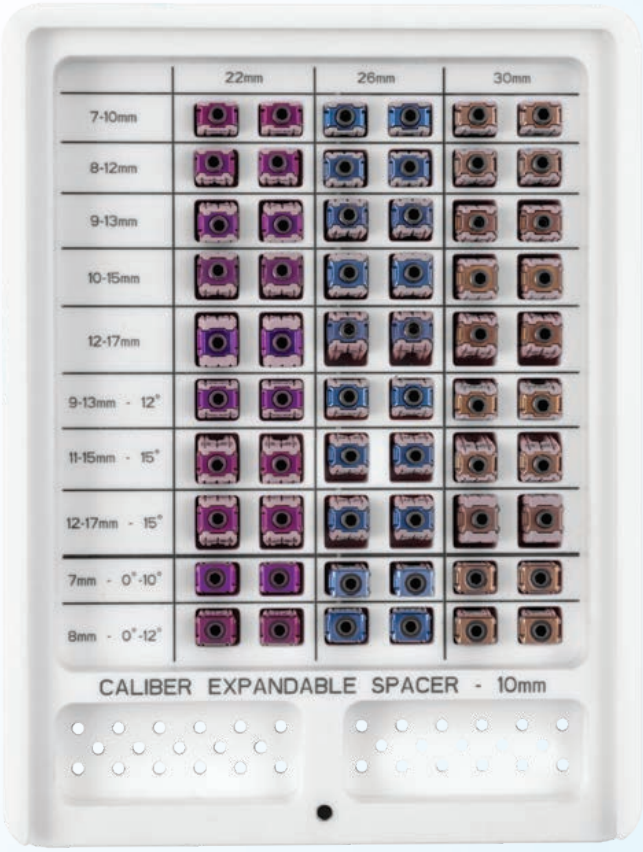
CALIBER® Implant Set 994.020

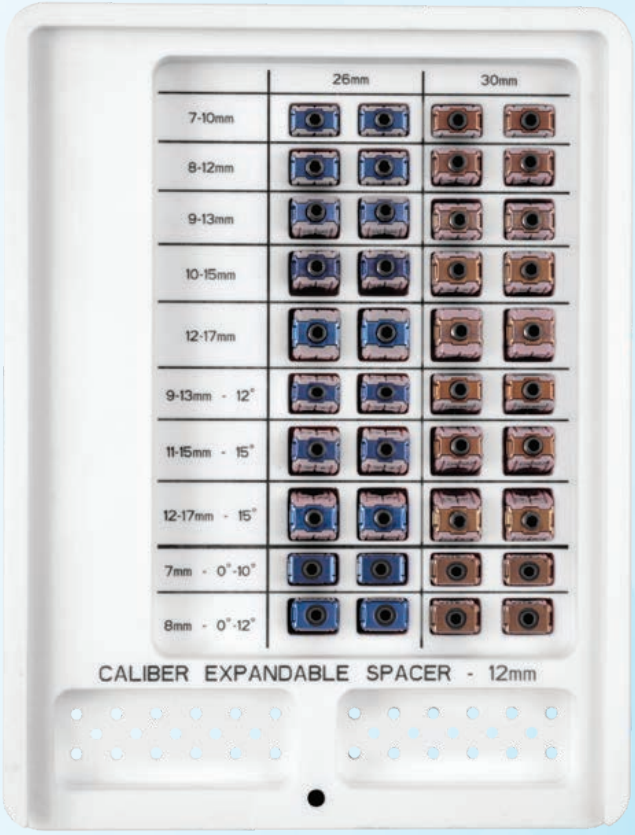
Part No.	Description	Qty
194.510	CALIBER® Spacer 10x22mm, 7–10mm	2
194.511	CALIBER® Spacer 10x26mm, 7–10mm	2
194.512	CALIBER® Spacer 10x30mm, 7–10mm	2
194.122	CALIBER® Spacer 10x22mm, 8–12mm	2
194.126	CALIBER® Spacer 10x26mm, 8–12mm	2
194.130	CALIBER® Spacer 10x30mm, 8–12mm	2
194.422	CALIBER® Spacer 10x22mm, 9–13mm	2
194.426	CALIBER® Spacer 10x26mm, 9–13mm	2
194.430	CALIBER® Spacer 10x30mm, 9–13mm	2
194.222	CALIBER® Spacer 10x22mm, 10–15mm	2
194.226	CALIBER® Spacer 10x26mm, 10–15mm	2
194.230	CALIBER® Spacer 10x30mm, 10–15mm	2
194.322	CALIBER® Spacer 10x22mm, 12–17mm	2
194.326	CALIBER® Spacer 10x26mm, 12–17mm	2
194.330	CALIBER® Spacer 10x30mm, 12–17mm	2
194.610	CALIBER® Spacer 10x22mm, 9–13mm, 12°	2
194.611	CALIBER® Spacer 10x26mm, 9–13mm, 12°	2
194.612	CALIBER® Spacer 10x30mm, 9–13mm, 12°	2
194.822	CALIBER® Spacer 10x22mm, 11–15mm, 15°	2
194.826	CALIBER® Spacer 10x26mm, 11–15mm, 15°	2
194.830	CALIBER® Spacer 10x30mm, 11–15mm, 15°	2
194.922	CALIBER® Spacer 10x22mm, 12–17mm, 15°	2
194.926	CALIBER® Spacer 10x26mm, 12–17mm, 15°	2
194.930	CALIBER® Spacer 10x30mm, 12–17mm, 15°	2
194.272	CALIBER® Spacer 10x22mm, 7mm, 0–10°	2
194.273	CALIBER® Spacer 10x26mm, 7mm, 0–10°	2
194.274	CALIBER® Spacer 10x30mm, 7mm, 0–10°	2
194.282	CALIBER® Spacer 10x22mm, 8mm, 0–12°	2
194.283	CALIBER® Spacer 10x26mm, 8mm, 0–12°	2
194.284	CALIBER® Spacer 10x30mm, 8mm, 0–12°	2
994.002	CALIBER® 10mm Implant Module	

CALIBER® Implant Set 994.030

Part No.	Description	Qty
594.511	CALIBER® Spacer 12x26mm, 7–10mm	2
594.512	CALIBER® Spacer 12x30mm, 7–10mm	2
594.126	CALIBER® Spacer 12x26mm, 8–12mm	2
594.130	CALIBER® Spacer 12x30mm, 8–12mm	2
594.426	CALIBER® Spacer 12x26mm, 9–13mm	2
594.430	CALIBER® Spacer 12x30mm, 9–13mm	2
594.226	CALIBER® Spacer 12x26mm, 10–15mm	2
594.230	CALIBER® Spacer 12x30mm, 10–15mm	2
594.326	CALIBER® Spacer 12x26mm, 12–17mm	2
594.330	CALIBER® Spacer 12x30mm, 12–17mm	2
594.611	CALIBER® Spacer 12x26mm, 9–13mm, 12°	2
594.612	CALIBER® Spacer 12x30mm, 9–13mm, 12°	2
594.826	CALIBER® Spacer 12x26mm, 11–15mm, 15°	2
594.830	CALIBER® Spacer 12x30mm, 11–15mm, 15°	2
594.926	CALIBER® Spacer 12x26mm, 12–17mm, 15°	2
594.930	CALIBER® Spacer 12x30mm, 12–17mm, 15°	2
594.273	CALIBER® Spacer 12x26mm, 7mm, 0–10°	2
594.274	CALIBER® Spacer 12x30mm, 7mm, 0–10°	2
594.283	CALIBER® Spacer 12x26mm, 8mm, 0–12°	2
594.284	CALIBER® Spacer 12x30mm, 8mm, 0–12°	2
994.003	CALIBER® 12mm Implant Module	

CALIBER®
IMPLANT SETS





CALIBER®
IMPLANT SET 994.020

Size	Part No.	Width (mm)	Length (mm)	Height (mm)	Axial Opening (mm^2)	Graft Volume (cc^3)	Tooth Height (mm)
10x22mm	194.510	10	22	7–10	22.7	.16–.23	.30–.80
	194.122	10	22	8–12	22.7	.18–.27	.50–.80
	194.422	10	22	9–13	22.7	.20–.30	.50–.80
	194.222	10	22	10–15	22.7	.23–.35	.50–.80
	194.322	10	22	12–17	22.7	.27–.39	.50–.80
	194.610	10	22	9–13	22.7	.20–.30	.30–.80
	194.822	10	22	11–15	22.7	.25–.34	.50–.80
	194.922	10	22	12–17	22.7	.27–.39	.50–.80
	194.272	10	22	7	25.4	.18–.22	.50–.80
	194.282	10	22	8	25.4	.20–.25	.80

Size	Part No.	Width (mm)	Length (mm)	Height (mm)	Axial Opening (mm^2)	Graft Volume (cc^3)	Tooth Height (mm)
10x26mm	194.511	10	26	7–10	33.6	.24–.34	.30–.80
	194.126	10	26	8–12	33.6	.27–.40	.50–.80
	194.426	10	26	9–13	33.6	.30–.44	.50–.80
	194.226	10	26	10–15	33.6	.34–.50	.50–.80
	194.326	10	26	12–17	33.6	.40–.57	.50–.80
	194.611	10	26	9–13	33.6	.30–.44	.30–.80
	194.826	10	26	11–15	33.6	.37–.50	.50–.80
	194.926	10	26	12–17	33.6	.40–.57	.50–.80
	194.273	10	26	7	41.4	.29–.35	.50–.80
	194.283	10	26	8	41.4	.33–.41	.80

Size	Part No.	Width (mm)	Length (mm)	Height (mm)	Axial Opening (mm^2)	Graft Volume (cc^3)	Tooth Height (mm)
10x30mm	194.512	10	30	7–10	37.6	.26–.38	.30–.80
	194.130	10	30	8–12	37.6	.30–.45	.50–.80
	194.430	10	30	9–13	37.6	.34–49	.50–.80
	194.230	10	30	10–15	37.6	.38–.57	.50–.80
	194.330	10	30	12–17	37.6	.45–.64	.50–.80
	194.612	10	30	9–13	37.6	.34–.49	.30–.80
	194.830	10	30	11–15	37.6	.41–.56	.50–.80
	194.930	10	30	12–17	37.6	.45–.64	.50–.80
	194.274	10	30	7	57.4	.40–.49	.50–.80
	194.284	10	30	8	57.4	.46–.57	.80

CALIBER®
IMPLANT SET 994.030

Size	Part No.	Width (mm)	Length (mm)	Height (mm)	Axial Opening (mm^2)	Graft Volume (cc^3)	Tooth Height (mm)
12x26mm	594.511	12	26	7–10	56.5	.40–.57	.30–.80
	594.126	12	26	8–12	56.5	.45–.68	.50–.80
	594.426	12	26	9–13	56.5	.51–.73	.50–.80
	594.226	12	26	10–15	56.5	.57–.85	.50–.80
	594.326	12	26	12–17	56.5	.68–.96	.50–.80
	594.611	12	26	9–13	56.5	.51–.73	.30–.80
	594.826	12	26	11–15	56.5	.62–.85	.50–.80
	594.926	12	26	12–17	56.5	.68–.96	.50–.80
	594.273	12	26	7	59.5	.42–.51	.50–.80
	594.283	12	26	8	59.5	.48–.60	.80

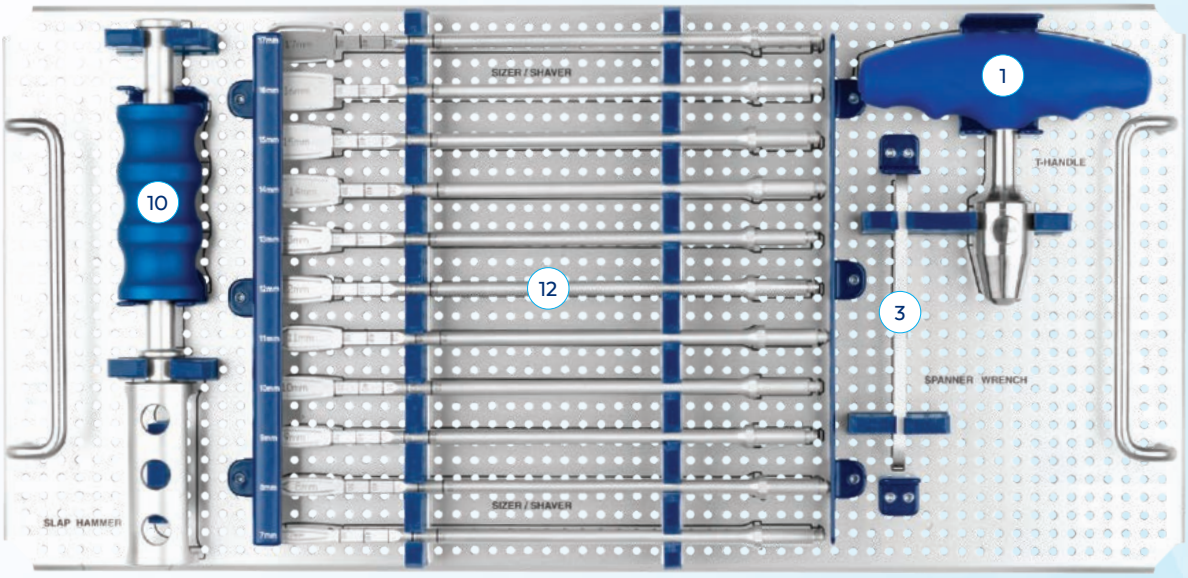
Size	Part No.	Width (mm)	Length (mm)	Height (mm)	Axial Opening (mm^2)	Graft Volume (cc^3)	Tooth Height (mm)
12x30mm	594.512	12	30	7–10	61.4	.43–.61	.30–.80
	594.130	12	30	8–12	61.4	.49–.74	.50–.80
	594.430	12	30	9–13	61.4	.55–.80	.50–.80
	594.230	12	30	10–15	61.4	.61–.92	.50–.80
	594.330	12	30	12–17	61.4	.74–1.0	.50–.80
	594.612	12	30	9–13	61.4	.55–.80	.30–.80
	594.830	12	30	11–15	61.4	.68–.92	.50–.80
	594.930	12	30	12–17	61.4	.74–1.0	.50–.80
	594.274	12	30	7	83.5	.58–.71	.50–.80
	594.284	12	30	8	83.5	.67–.84	.80

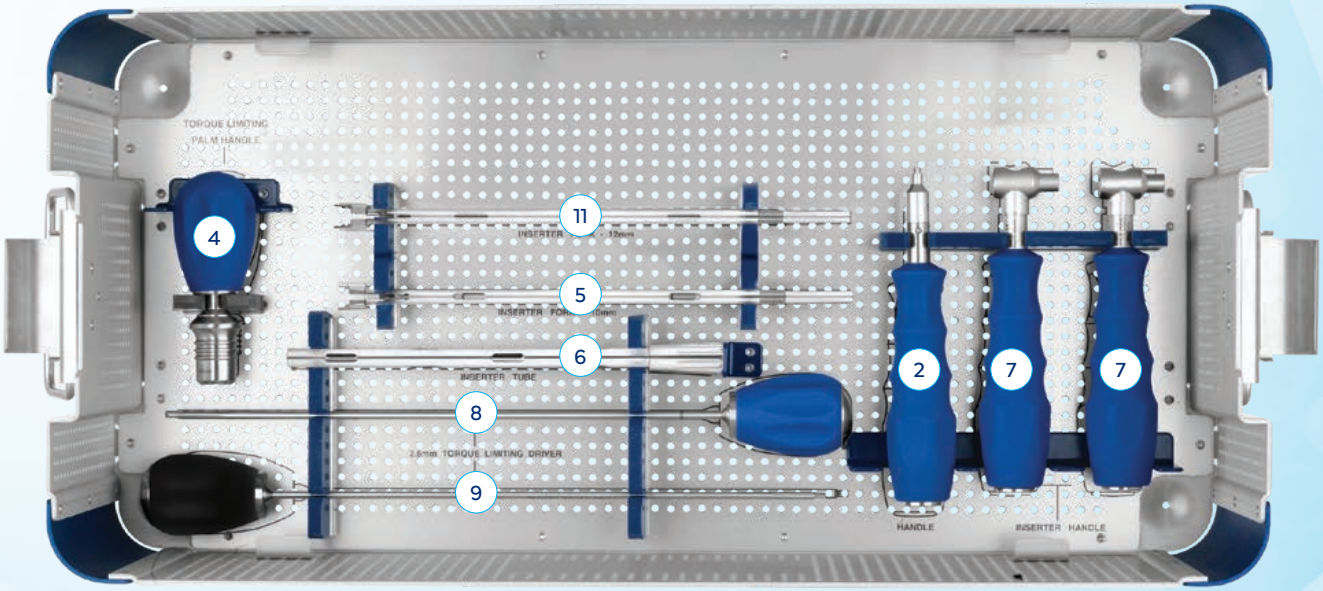
CALIBER®
INSTRUMENT SET 994.010

	Part No.	Description	Qty
1	601.800	T-Handle	2
2	673.003	MIS Handle	1
3	687.509	Spanner Wrench	1
4	694.002	Torque-Limiting Palm Handle	1
5	694.003	Inserter Fork, 10mm	2
6	694.004	Inserter Tube	2
7	694.005	Inserter Handle	2
8	694.006	2.5mm Torque-Limiting Driver	1
9	694.016	2.5mm Torque-Limiting Driver, 2.0N	1
10	694.008	Slap Hammer	1
11	694.013	Inserter Fork, 12mm	2

	12 Shavers		Qty
	668.507	Sizer/Shaver, 7mm	1
	668.508	Sizer/Shaver, 8mm	1
	668.509	Sizer/Shaver, 9mm	1
	668.510	Sizer/Shaver, 10mm	1
	668.511	Sizer/Shaver, 11mm	1
	668.512	Sizer/Shaver, 12mm	1
	668.513	Sizer/Shaver, 13mm	1
	668.514	Sizer/Shaver, 14mm	1
	668.515	Sizer/Shaver, 15mm	1
	668.516	Sizer/Shaver, 16mm	1
	668.517	Sizer/Shaver, 17mm	1

CALIBER®
INSTRUMENT SET 994.010





MARS™ 3V RETRACTOR
INSTRUMENT SET 998.901

	Part. No	Description	Qty
1	623.003	K-Wire Gripper	1
2	698.100	Retractor 3 Blade Frame	1
3	632.150	10mm Socket Driver	1
4	698.250	Hook & Latch Driver	1
5	675.403	Flouro Modulator	1
6	675.404	Incision Locator	1
7	675.513	8” Suction	1
8	675.800	Radiolucent Initial Dilator Holder	1
9	675.901	Shim Tool, Lateral	1
10	698.230	Frame Handle	1
11	698.240	Shim Tool, CC	1
12	698.260	Docking Pin Tool	1
13	698.350	Docking Pin Sleeve	4

14	Retractor Blades		Qty
	698.410	Blade, Posterior, 40mm	2
	698.412	Blade, Posterior, 50mm	2
	698.414	Blade, Posterior, 60mm	2
	698.416	Blade, Posterior, 70mm	2
	698.418	Blade, Posterior, 80mm	2
	698.420	Blade, Posterior, 90mm	2
	698.422	Blade, Posterior, 100mm	2
	698.424	Blade, Posterior, 110mm	2
	698.426	Blade, Posterior, 120mm	2
	698.428	Blade, Posterior, 130mm	2
	698.430	Blade, Posterior, 140mm	2
	698.432	Blade, Posterior, 150mm	2
	698.434	Blade, Posterior, 160mm	2
	698.436	Blade, Posterior, 170mm	2

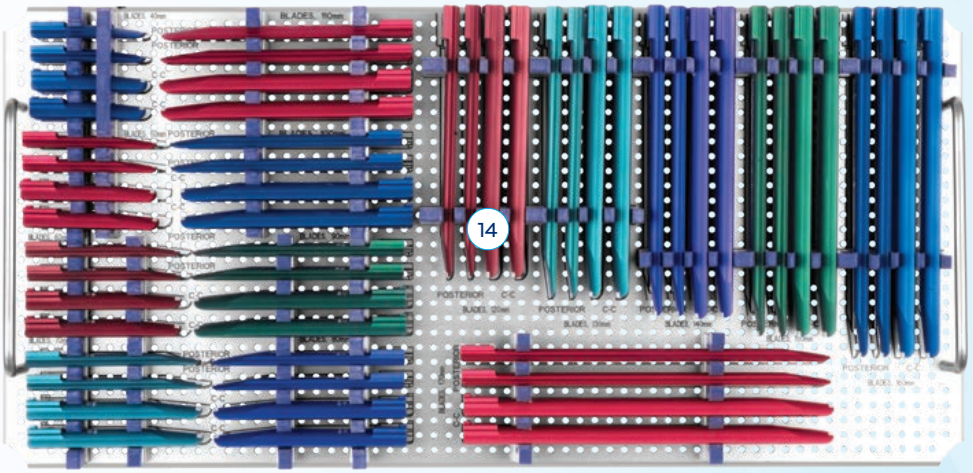
Retractor Blades (Cont’d)		Qty
698.510	Blade, CC, 40mm	2
698.512	Blade, CC, 50mm	2
698.514	Blade, CC, 60mm	2
698.516	Blade, CC, 70mm	2
698.518	Blade, CC, 80mm	2
698.520	Blade, CC, 90mm	2
698.522	Blade, CC, 100mm	2
698.524	Blade, CC, 110mm	2
698.526	Blade, CC, 120mm	2
698.528	Blade, CC, 130mm	2
698.530	Blade, CC, 140mm	2
698.532	Blade, CC, 150mm	2
698.534	Blade, CC, 160mm	2
698.536	Blade, CC, 170mm	2

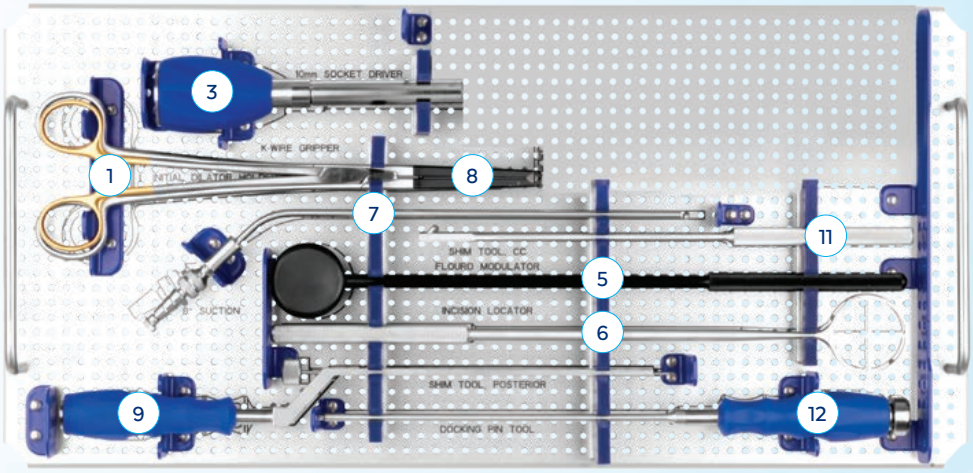
Disposables		Qty
698.600S	MARS™ 3V Disposable Kit	1
698.300S	Lengthening Shim	2
698.305S	Widening Shim	2
698.310S	Docking Pin, 10mm	2
698.315S	Docking Pin, 20mm	2
632.678S	Bi-Polar Forceps, 10” Bayo, 1.0mm Tip	1

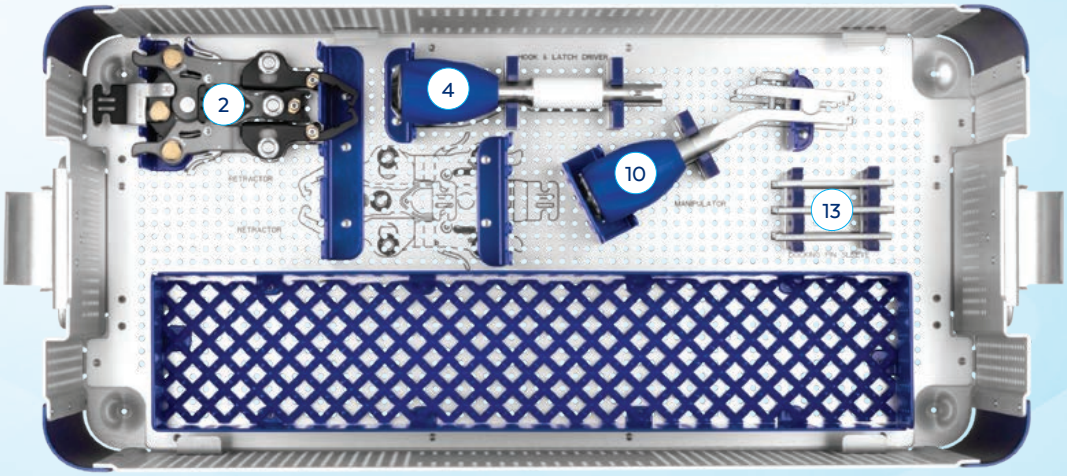
Additionally Available

675.399S	K-Wires
675.725S	MIS Illumination System
698.320S	Disc Shim
999.098	MARS™ 3V Usage Fee

MARS™ 3V RETRACTOR
INSTRUMENT SET 998.901



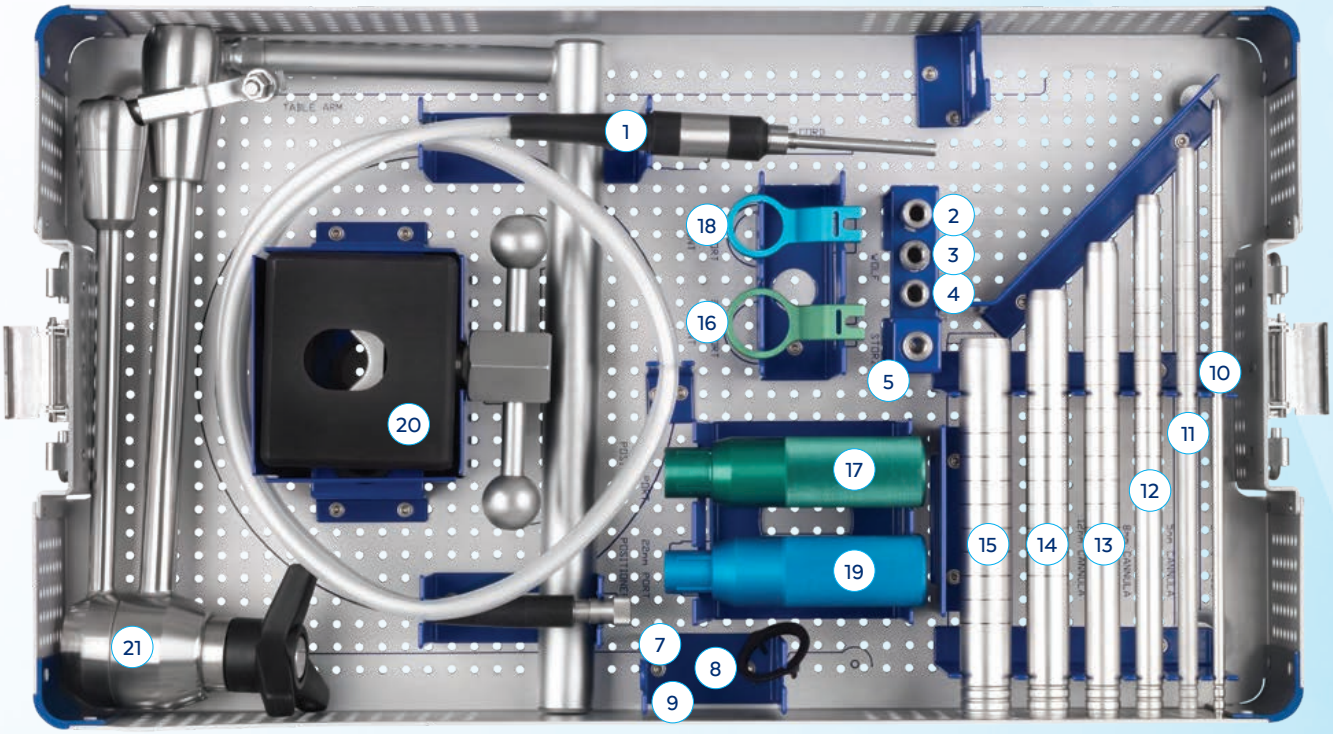




MARS™
INSTRUMENTS II SET 932.902

	Part No.	Description	Qty
1	632.300	Fiber-Optic Cord	1
2	632.305	Adapter, ACMI	1
3	632.306	Adapter, Wolf	1
4	632.307	Adapter, Olympus	1
5	632.308	Adapter, Storz	1
6	632.310S	Light Cable	1
7	632.390	Port Lock, 19mm	1
8	632.391	Port Lock, 22mm	1
9	632.392	Port Lock, 26mm	1
10	632.401	2mm Cannula	1
11	632.402	5mm Cannula	1
12	632.403	8mm Cannula	1
13	632.404	12mm Cannula	1
14	632.405	15mm Cannula	1
15	632.406	18mm Cannula	1
16	632.410	22mm Port Mount	1
17	632.411	22mm Port Positioner	1
18	632.412	19mm Port Mount	1
19	632.413	19mm Port Positioner	1
20	632.500	Table Clamp	1
21	632.750	Articulating Arm Assembly	1
	932.002	MARS™ Graphic Case, Retractor II	

MARS™
INSTRUMENTS II SET 932.902

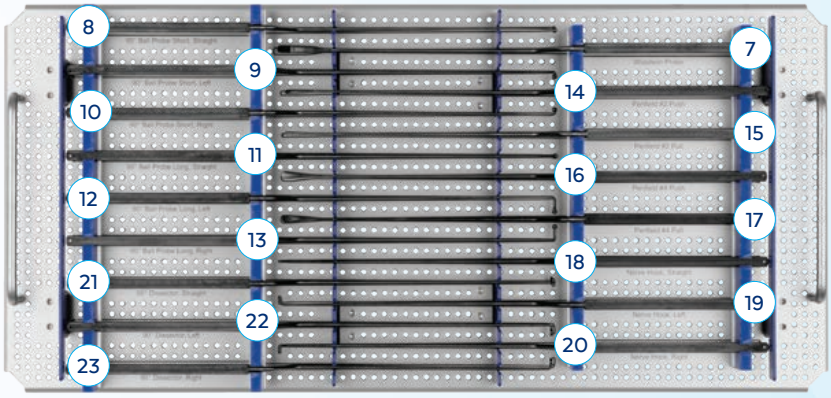


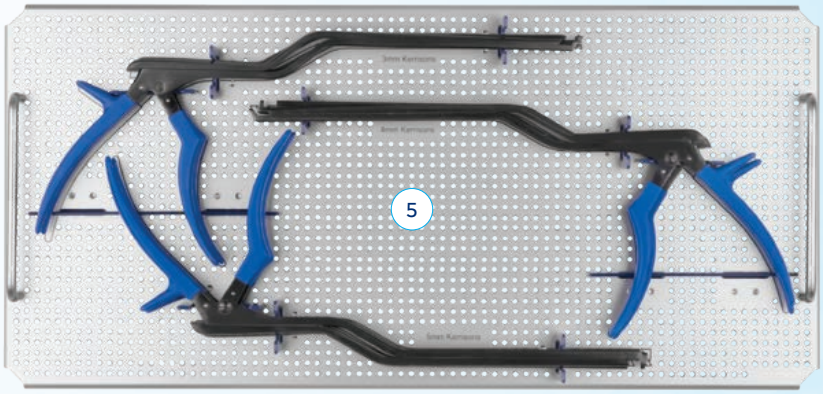
MARS™
INSTRUMENT III SET 932.903

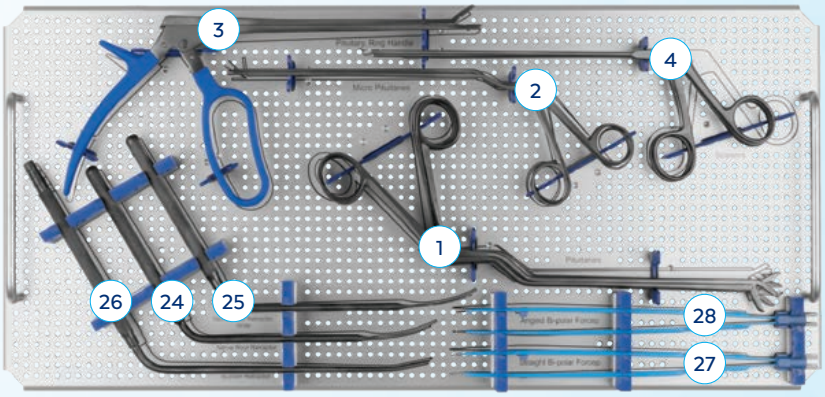
	Part No.	Description	Qty
1	632.600	Pituitary, 2mm Bayoneted	1
	632.601	Pituitary, 2mm, Down-Biting, Bayoneted	1
	632.602	Pituitary, 2mm, Up-Biting, Bayoneted	1
	632.605	Pituitary, 4mm, Up-Biting, Bayoneted	1
2	632.610	Micro Pituitary, 2mm, Up-Biting, Bayoneted	1
	632.611	Micro Pituitary, 2mm, Bayoneted	1
3	632.615	Pituitary, Ring Handle, 2mm	1
4	632.616	Scissors, Straight	1
	632.618	Scissors, Curved Left	1
	632.619	Scissors, Curved Right	1
5	632.620	Kerrison 40°, 3mm, Bayoneted	1
	632.621	Kerrison 90°, 3mm, Bayoneted	1
	632.622	Kerrison 40°, 4mm, Bayoneted	1
	632.623	Kerrison 90°, 4mm, Bayoneted	1
	632.624	Kerrison 40°, 5mm, Bayoneted	1
	632.625	Kerrison 90°, 5mm, Bayoneted	1
6	632.630	Bone Curette Straight, 5.2 Cup, Bayoneted	1
	632.631	Bone Curette Straight, 3.6 Cup, Bayoneted	1
	632.632	Bone Curette Angled, 5.2 Cup, Bayoneted	1
	632.633	Bone Curette Angled, 3.6 Cup, Bayoneted	1
	632.634	Bone Curette Reverse Angled, 5.2 Cup, Bayoneted	1
	632.635	Bone Curette Reverse Angled, 3.6 Cup, Bayoneted	1

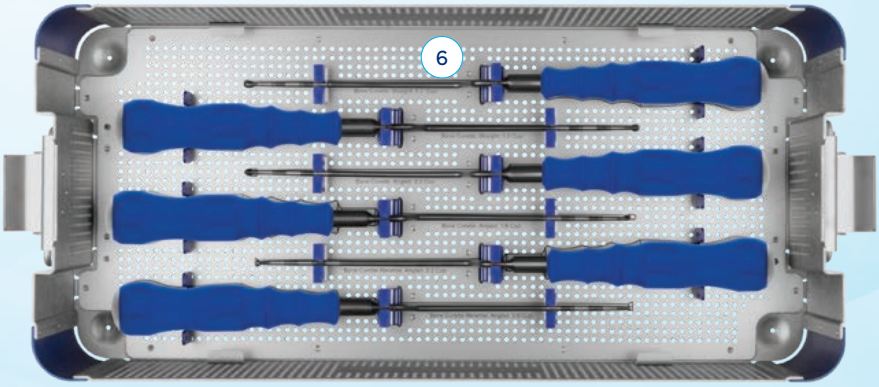
	Part No.	Description	Qty
7	632.640	Woodson Probe	1
8	632.641	90° Ball Probe Short, Straight, Bayoneted	1
9	632.642	90° Ball Probe Short, Left, Bayoneted	1
10	632.643	90° Ball Probe Short, Right, Bayoneted	1
11	632.644	90° Ball Probe Long, Straight, Bayoneted	1
12	632.645	90° Ball Probe Long, Left, Bayoneted	1
13	632.646	90° Ball Probe Long, Right, Bayoneted	1
14	632.650	Penfield #2 Push, Bayoneted	1
15	632.651	Penfield #2 Pull, Bayoneted	1
16	632.652	Penfield #4 Push, Bayoneted	1
17	632.653	Penfield #4 Pull, Bayoneted	1
18	632.655	Nerve Hook, Straight, Bayoneted	1
19	632.656	Nerve Hook, Left, Bayoneted	1
20	632.657	Nerve Hook, Right, Bayoneted	1
21	632.660	90° Dissector, Straight, Bayoneted	1
22	632.661	90° Dissector, Left, Bayoneted	1
23	632.662	90° Dissector, Right, Bayoneted	1
24	632.673	Nerve Root Retractor	1
25	632.674	Nerve Root Retractor, Wide	1
26	632.675	Suction Retractor	1
27	632.676	Bi-Polar Forcep, Straight, Bayoneted, US Connection	1
28	632.677	Bi-Polar Forcep, Angled, Bayoneted, US Connection	1
	932.003	MARS™ Instrument Graphic Case	1

MARS™
INSTRUMENT III SET 932.903





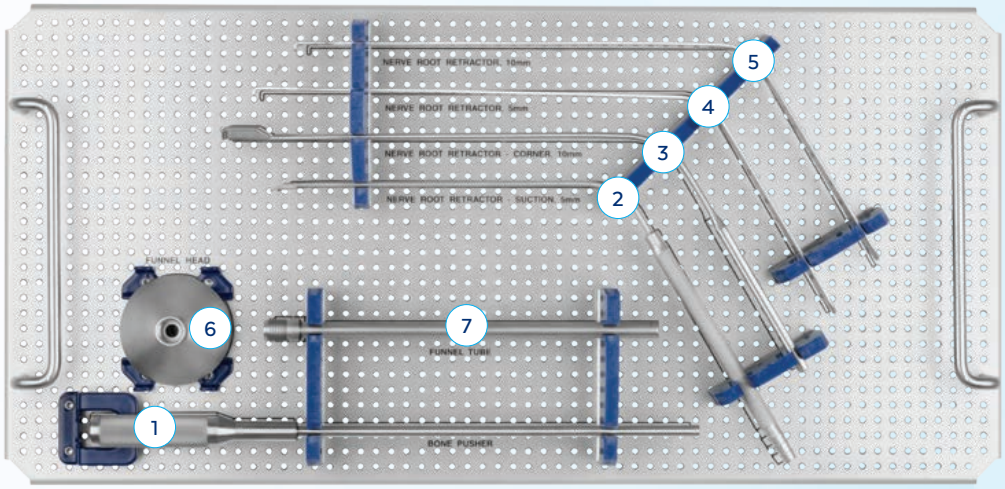


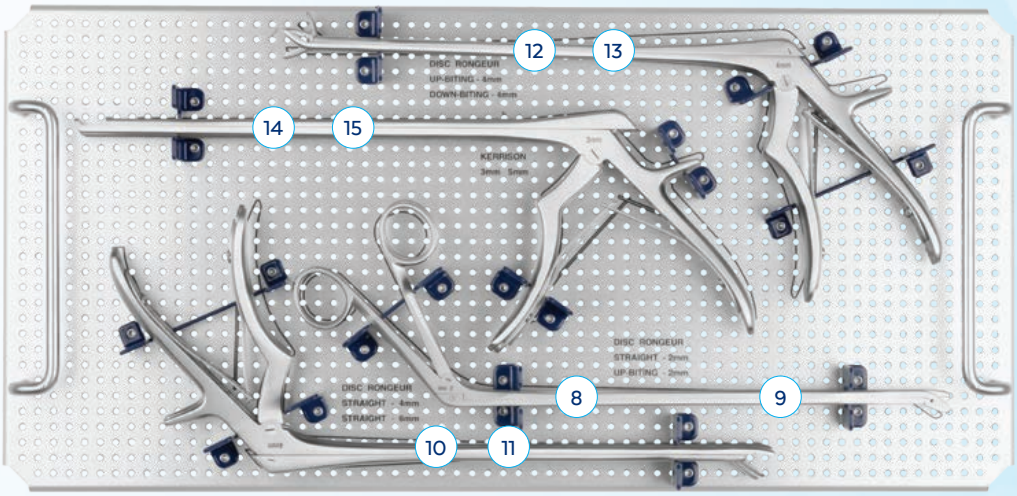


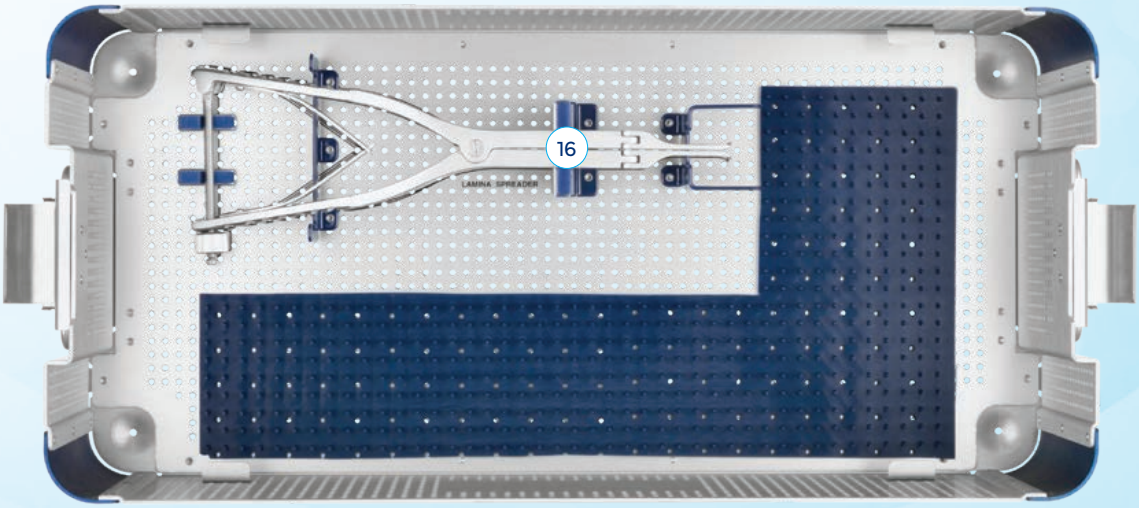
POSTERIOR DISC PREP
INSTRUMENTS I SET 926.901

	Part No.	Description	Qty
1	626.210	Push Rod Assembly, Bone Funnel	1
2	626.215	Nerve Retractor, 5mm, Suction	1
3	626.220	Nerve Retractor, Corner	1
4	603.061	Nerve Root Retractor, Fine, 5mm	1
5	603.062	Nerve Root Retractor, Medium, 10mm	1
6	679.015	Bone Funnel	1
7	679.015	Bone Funnel - Tube	1
8	626.235	Disc Rongeur, 250x2mm, Straight	1
9	626.236	Disc Rongeur, 250x2mm, Up Biting	1
10	626.240	Disc Rongeur, 250x4mm, Straight	1
11	626.241	Disc Rongeur, 250x6mm, Straight	1
12	626.242	Disc Rongeur, 250x4mm, Up Biting	1
13	626.243	Disc Rongeur, 250x4mm, Down Biting	1
14	626.250	Kerrison, 250x3mm, Straight	1
15	626.252	Kerrison, 250x5mm, Straight	1
16	626.260	Lamina Spreader, Hinged	1
	926.102	Graphic Case 1	

POSTERIOR DISC PREP
INSTRUMENTS I SET 926.901



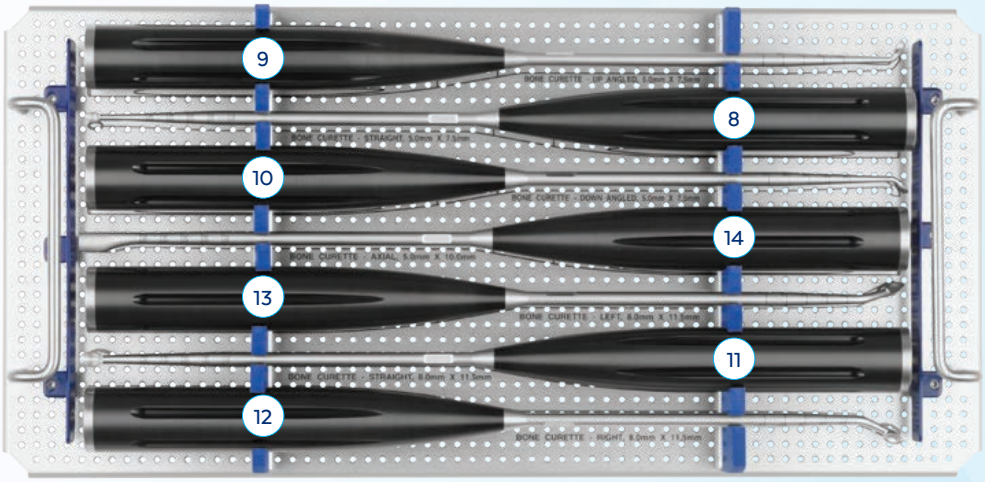


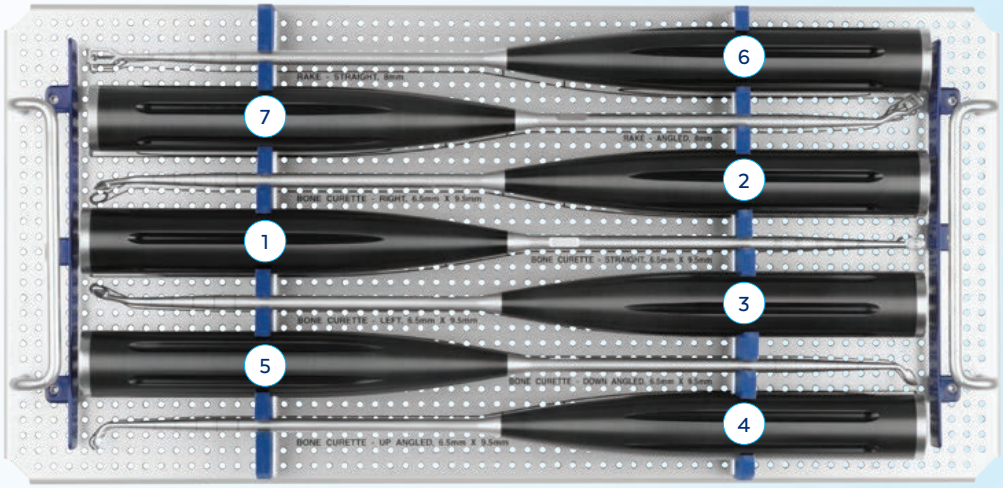


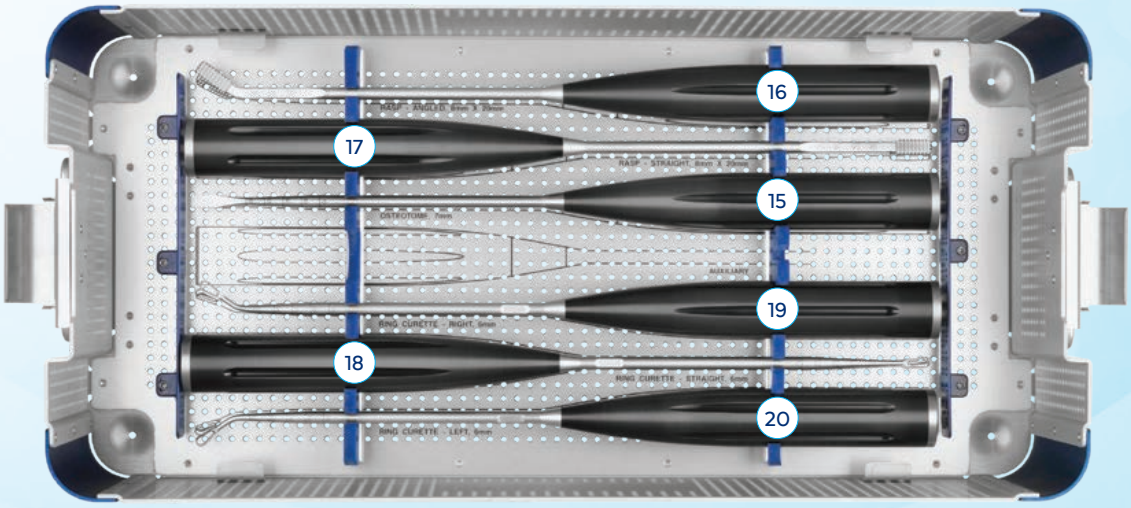
POSTERIOR DISC PREP
INSTRUMENTS II SET 926.902

	Part No.	Description	Qty
1	626.150	Bone Curette, 6.5x9.5mm, Straight	1
2	626.151	Bone Curette, 6.5x9.5mm, Right	1
3	626.152	Bone Curette, 6.5x9.5mm, Left	1
4	626.153	Bone Curette, 6.5x9.5mm, Up Pushing	1
5	626.154	Bone Curette, 6.5x9.5mm, Down Pushing	1
6	626.190	Rake, 8mm, Straight	1
7	626.191	Rake, 8mm, Angled	1
8	626.140	Bone Curette, 5.0x7.5mm, Straight	1
9	626.143	Bone Curette, 5.0x7.5mm, Up Pushing	1
10	626.144	Bone Curette, 5.0x7.5mm, Down Pushing	1
11	626.160	Bone Curette, 8.0x11.5mm, Straight	1
12	626.161	Bone Curette, 8.0x11.5mm, Right	1
13	626.162	Bone Curette, 8.0x11.5mm, Left	1
14	626.170	Bone Curette, 5.0x10mm, Axial	1
15	626.180	Osteotome, 7mm	1
16	626.185	Rasp, 8x20mm, Knurled, Straight	1
17	626.186	Rasp, 8x20mm, Knurled, Angled	1
18	626.200	Ring Curette, 6mm, Straight	1
19	626.201	Ring Curette, 6mm, Angled Right	1
20	626.202	Ring Curette, 6mm, Angled Left	1
	926.101	Graphic Case 2	

POSTERIOR DISC PREP
INSTRUMENTS II SET 926.902







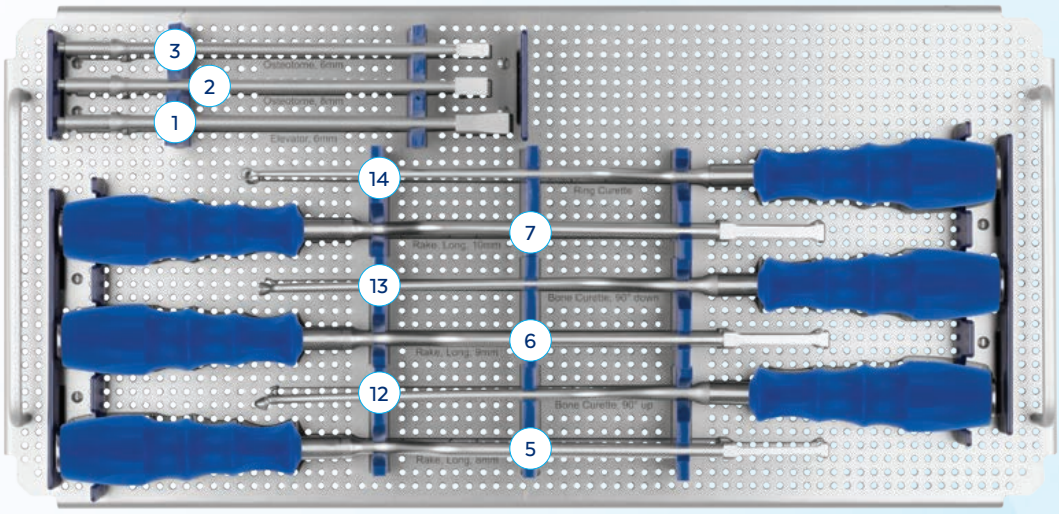
MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901

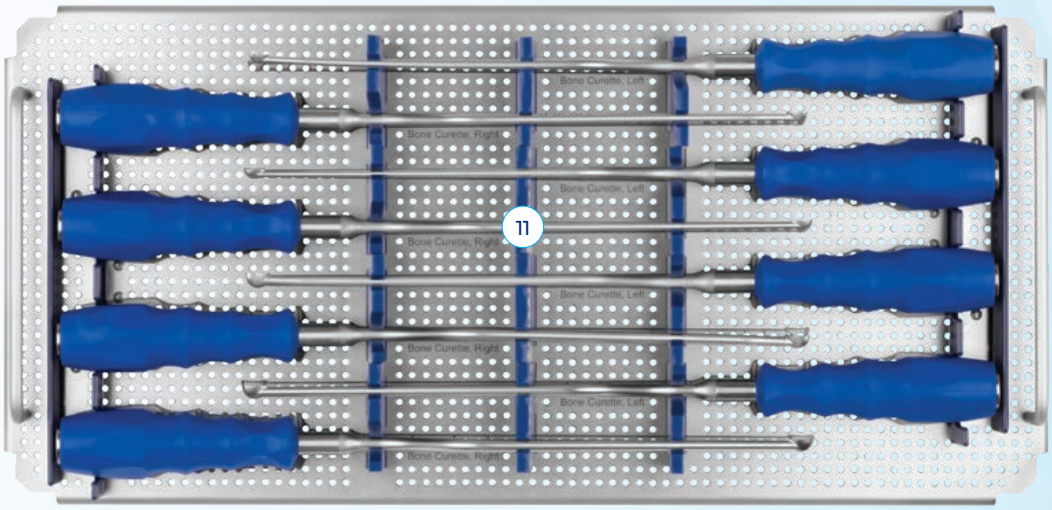
	Part No.	Description	Qty
1	679.005	Elevator 6mm	1
2	679.007	Osteotome, 8mm QR	1
3	679.008	Osteotome, 6mm QR	1
4	679.010	L-Handle	1
5	679.011	Rake, Long 8mm, Bayoneted	1
6	679.012	Rake, Long 9mm, Bayoneted	1
7	679.013	Rake, Long 10mm, Bayoneted	1
8	679.015	Bone Funnel	1
9	679.016	Bone Funnel Clamp	1
10	679.017	Bone Pusher Rod	1
11	679.025	Bone Curette, 10.0 Serrated Cup	1
	679.026	Bone Curette, Straight, 10.0 Serrated Cup	1
	679.027	Bone Curette, Angled, 10.0 Serrated Cup	1
	679.028	Bone Curette, Straight, 10.0 Serrated Cup	1
	679.031	Bone Curette, Angled, 12.0 Serrated Cup, Bayoneted, LH	1
	679.032	Bone Curette, Straight, 12.0 Serrated Cup, Bayoneted, LH	1
	679.033	Bone Curette, Angled, 12.0 Serrated Cup, Bayoneted, RH	1
	679.034	Bone Curette, Straight, 12.0 Serrated Cup, Bayoneted, RH	1
	679.041	Bone Curette, 10.7 Serrated Cup, 90° Up	1
12	679.041	Bone Curette, 10.7 Serrated Cup, 90° Up	1
13	679.042	Bone Curette, 10.7 Serrated Cup, 90° Down	1
14	679.051	Ring Curette, 6mm	1
	979.001	MIS Discectomy Instruments Graphic Case	

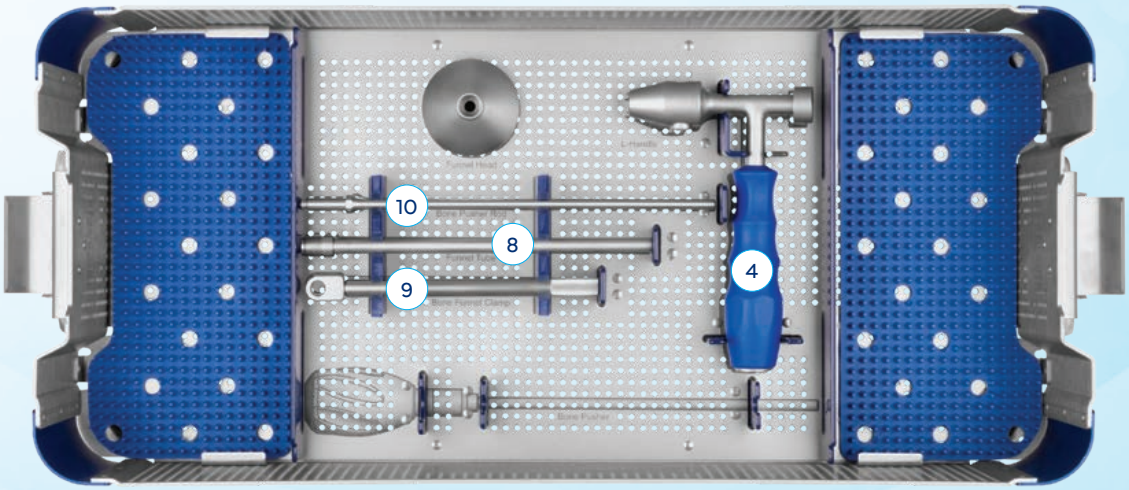
Additionally Available

673.018	Push Rod, Bone Funnel
679.021	Bone Curette, Angled, 10.7 Serrated Cup
679.022	Bone Curette, Straight, 10.7 Serrated Cup
679.023	Bone Curette, Angled, 10.7 Serrated Cup
679.024	Bone Curette, Straight, 10.7 Serrated Cup
679.061	Bone Curette, 10.0 Rectangle Cup, 75° Up
679.062	Bone Curette, 10.0 Rectangle Cup, 75° Down
679.063	Bone Curette, 12.0 Rectangle Cup, 75° Up
913.001	MIS Lumbar Discectomy Graphic Case

MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901





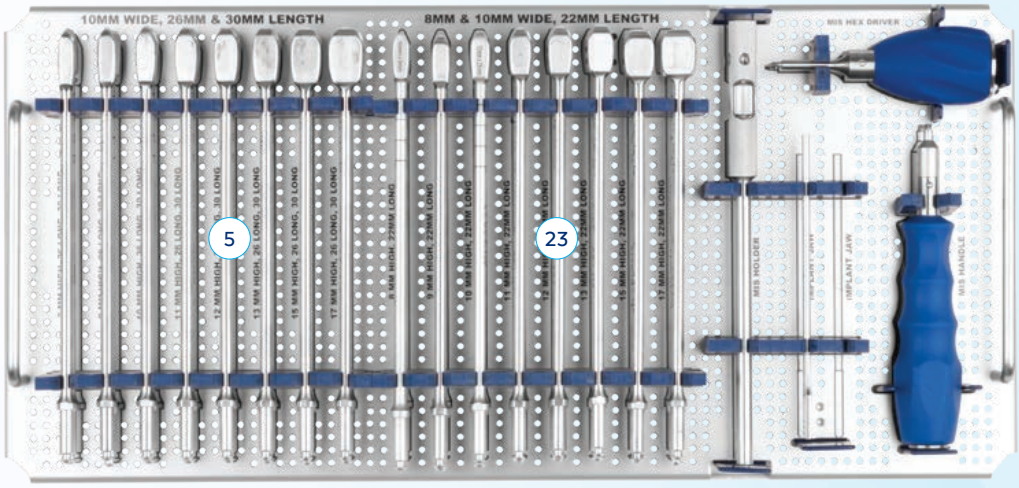


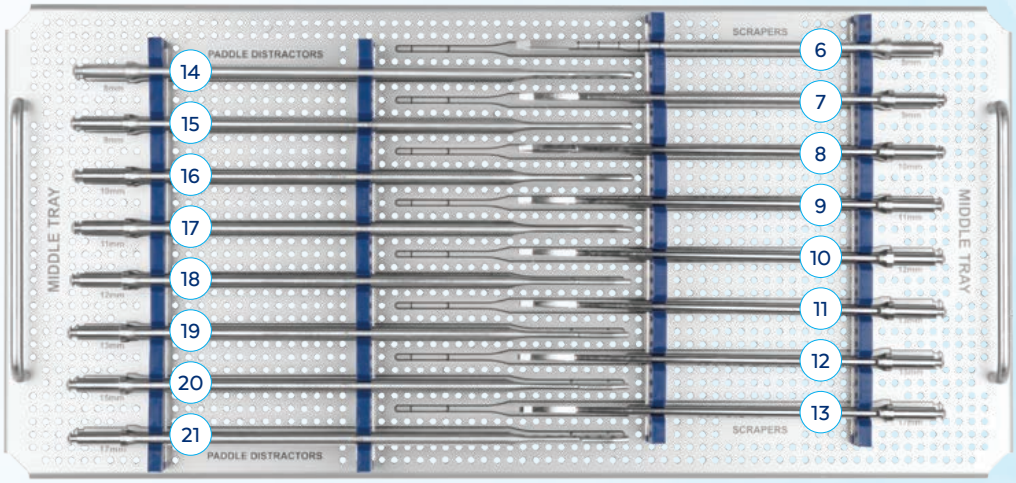
PRESERVE® POSTERIOR UNILATERAL INSTRUMENT SET 904.907

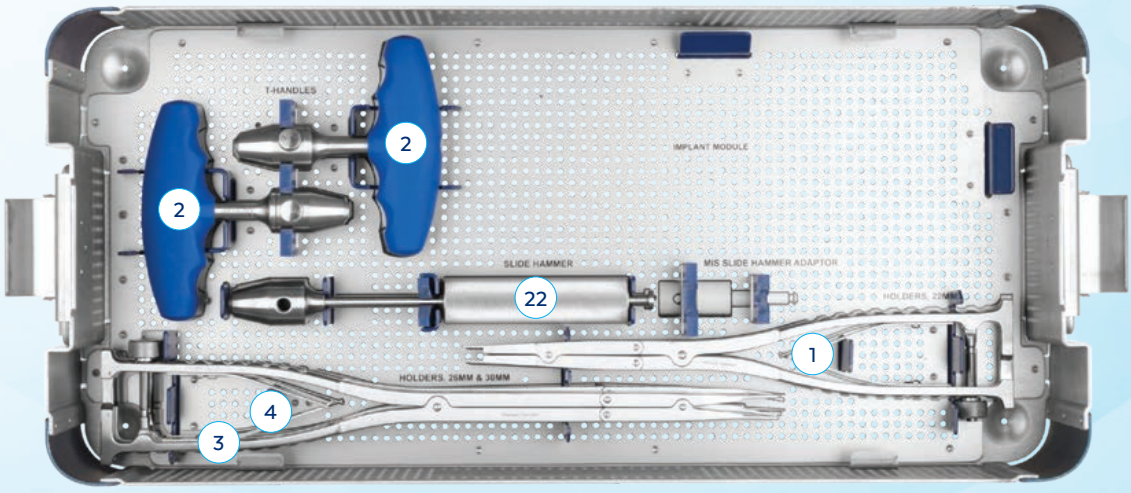
	Part No.	Description	Qty
1	601.001	Implant Holder	1
2	601.800	T-Handle	2
3	604.001	Holder, Straight	1
4	604.002	Holder, Angled	1
5	604.108	Trial, SUSTAIN®-R Oblique, 26mm length, 8mm	1
	604.109	Trial, SUSTAIN®-R Oblique, 26mm length, 9mm	1
	604.110	Trial, SUSTAIN®-R Oblique, 26mm length, 10mm	1
	604.111	Trial, SUSTAIN®-R Oblique, 26mm length, 11mm	1
	604.112	Trial, SUSTAIN®-R Oblique, 26mm length, 12mm	1
	604.113	Trial, SUSTAIN®-R Oblique, 26mm length, 13mm	1
	604.115	Trial, SUSTAIN®-R Oblique, 26mm length, 15mm	1
	604.117	Trial, SUSTAIN®-R Oblique, 26mm length, 17mm	1
	604.208	Trial, SUSTAIN®-R Oblique, 30mm length, 8mm	1
	604.209	Trial, SUSTAIN®-R Oblique, 30mm length, 9mm	1
	604.210	Trial, SUSTAIN®-R Oblique, 30mm length, 10mm	1
	604.211	Trial, SUSTAIN®-R Oblique, 30mm length, 11mm	1
	604.212	Trial, SUSTAIN®-R Oblique, 30mm length, 12mm	1
	604.213	Trial, SUSTAIN®-R Oblique, 30mm length, 13mm	1
	604.215	Trial, SUSTAIN®-R Oblique, 30mm length, 15mm	1
	604.217	Trial, SUSTAIN®-R Oblique, 30mm length, 17mm	1
6	604.308	Scraper, Oblique, 8mm	1
7	604.309	Scraper, Oblique, 9mm	1
8	604.310	Scraper, Oblique, 10mm	1
9	604.311	Scraper, Oblique, 11mm	1
10	604.312	Scraper, Oblique, 12mm	1
11	604.313	Scraper, Oblique, 13mm	1
12	604.315	Scraper, Oblique, 15mm	1

	Part No.	Description	Qty
13	604.317	Scraper, Oblique, 17mm	1
14	604.808	Paddle Distractor, 8mm	1
15	604.809	Paddle Distractor, 9mm	1
16	604.810	Paddle Distractor, 10mm	1
17	604.811	Paddle Distractor, 11mm	1
18	604.812	Paddle Distractor, 12mm	1
19	604.813	Paddle Distractor, 13mm	1
20	604.815	Paddle Distractor, 15mm	1
21	604.817	Paddle Distractor, 17mm	1
22	673.017	Slide Hammer, Quick-Disconnect	1
23	673.108	Trial Shaft, 8mm x 22mm wide, 8mm, SUSTAIN® Oblique, Small	1
	673.109	Trial Shaft, 8mm wide, 9mm, SUSTAIN® Oblique, Small	1
	673.110	Trial Shaft, 8mm wide, 10mm, SUSTAIN® Oblique, Small	1
	673.111	Trial Shaft, 8mm x 22mm wide, 11mm, SUSTAIN® Oblique, Small	1
	673.112	Trial Shaft, 8mm x 22mm wide, 12mm, SUSTAIN® Oblique, Small	1
	673.113	Trial Shaft, 8mm x 22mm wide, 13mm, SUSTAIN® Oblique, Small	1
	673.115	Trial Shaft, 8mm x 22mm wide, 15mm, SUSTAIN® Oblique, Small	1
	673.117	Trial Shaft, 8mm x 22mm wide, 17mm, SUSTAIN® Oblique, Small	1
	673.208	Trial Shaft, 10mm x 22mm wide, 8mm, SUSTAIN® Oblique, Small	1
	673.209	Trial Shaft, 10mm x 22mm wide, 9mm, SUSTAIN® Oblique, Small	1
	673.210	Trial Shaft, 10mm x 22mm wide, 10mm, SUSTAIN® Oblique, Small	1
	673.211	Trial Shaft, 10mm x 22mm wide, 11mm, SUSTAIN® Oblique, Small	1
	673.212	Trial Shaft, 10mm x 22mm wide, 12mm, SUSTAIN® Oblique, Small	1
	673.213	Trial Shaft, 10mm x 22mm wide, 13mm, SUSTAIN® Oblique, Small	1
	673.215	Trial Shaft, 10mm x 22mm wide, 15mm, SUSTAIN® Oblique, Small	1
	673.217	Trial Shaft, 10mm x 22mm wide, 17mm, SUSTAIN® Oblique, Small	1
	904.009	PRESERVE® Posterior Unilateral Instruments	

PRESERVE® POSTERIOR UNILATERAL
INSTRUMENT SET 904.907







IMPORTANT INFORMATION ON CALIBER® LUMBAR SPACERS

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

IMPORTANT INFORMATION ON CALIBER® LUMBAR SPACERS

- Change in spinal curvature, loss of correction, height and/or reduction
- 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

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