SUSTAIN®-RT

Insert and Rotate Spacer

SURGICAL TECHNIQUE GUIDE

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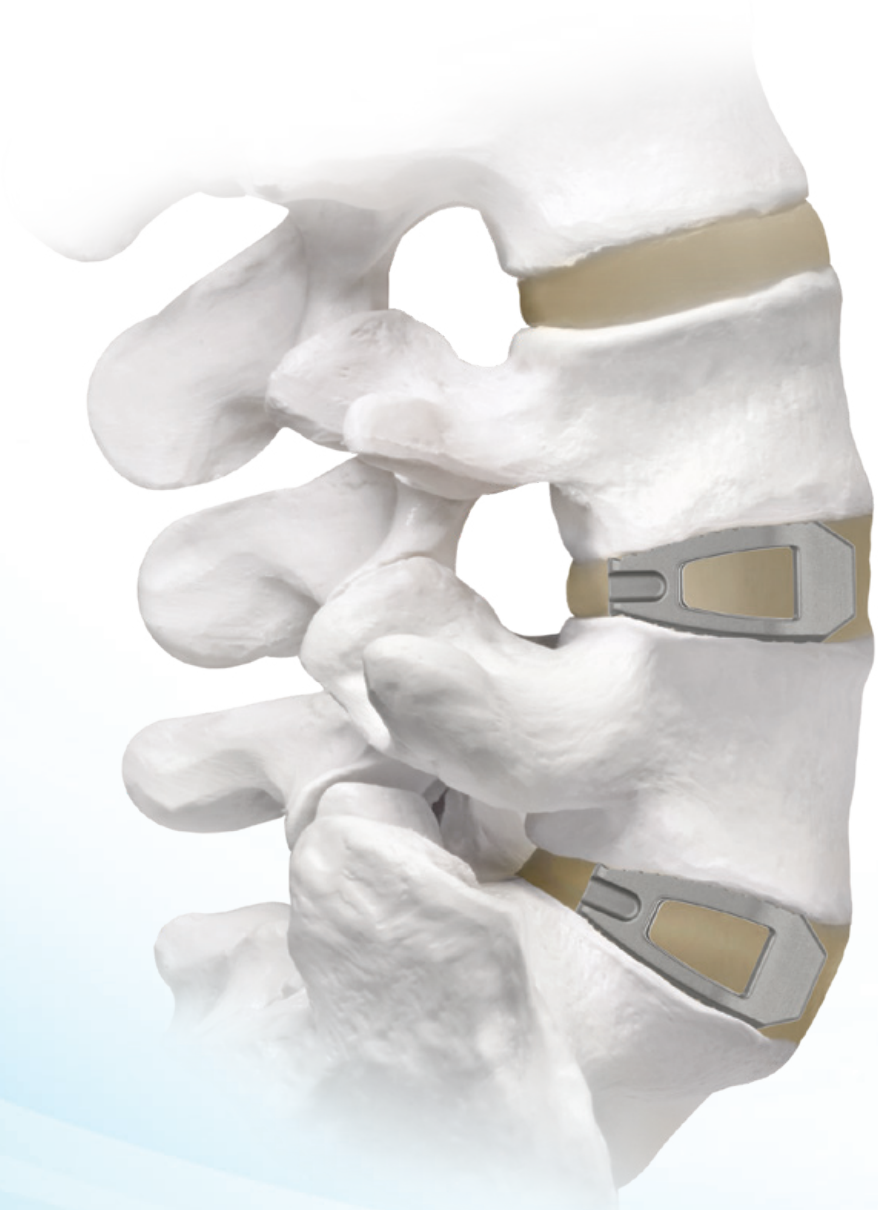
SURGICAL TECHNIQUE GUIDE

SUSTAIN®-RT

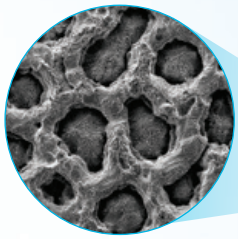
SUSTAIN®-RT

Insert and Rotate Spacer

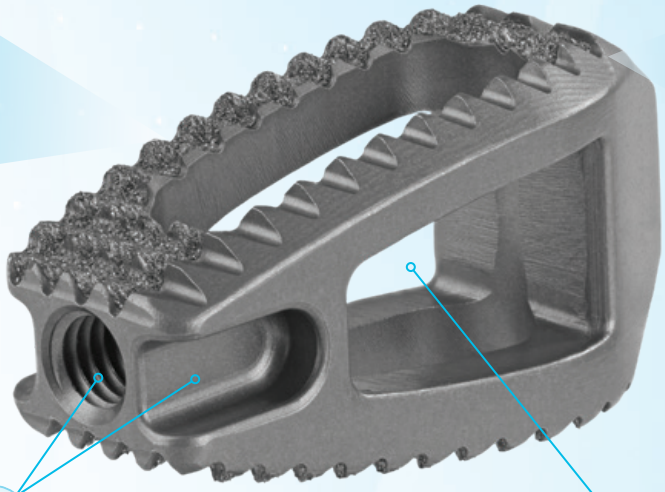
SUSTAIN®-RT is an insert and rotate lumbar interbody fusion device designed to minimize endplate disruption while restoring disc height and lordosis. With a comprehensive offering of heights, lengths, and sagittal profiles in PEEK or titanium, SUSTAIN®-RT accommodates various patient anatomies from either a posterior or transforaminal approach. The bullet nose, beveled edges, and rigid attachment allow for controlled insertion and positioning.

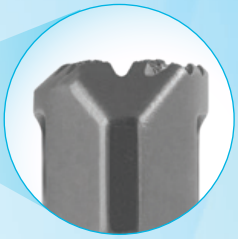


SUSTAIN®-RT (Titanium)



SUSTAIN®-RT titanium endplates feature SintrOS™ technology





Beveled edges designed to minimize endplate disruption during rotation

Fixed-fork and threaded connection allows for rigid attachment

Large, unobstructed graft chamber

SUSTAIN®-RT (PEEK)

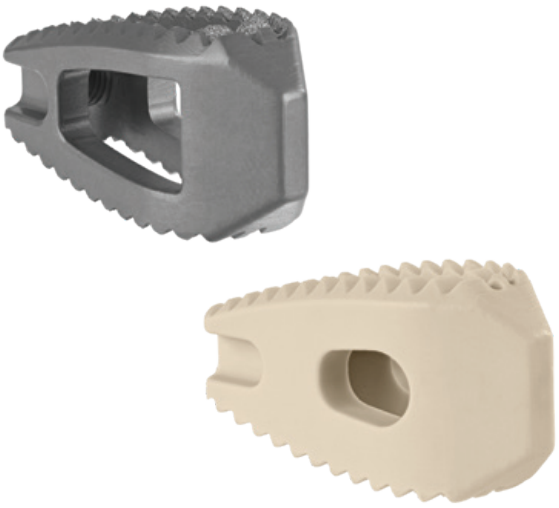
Directional teeth

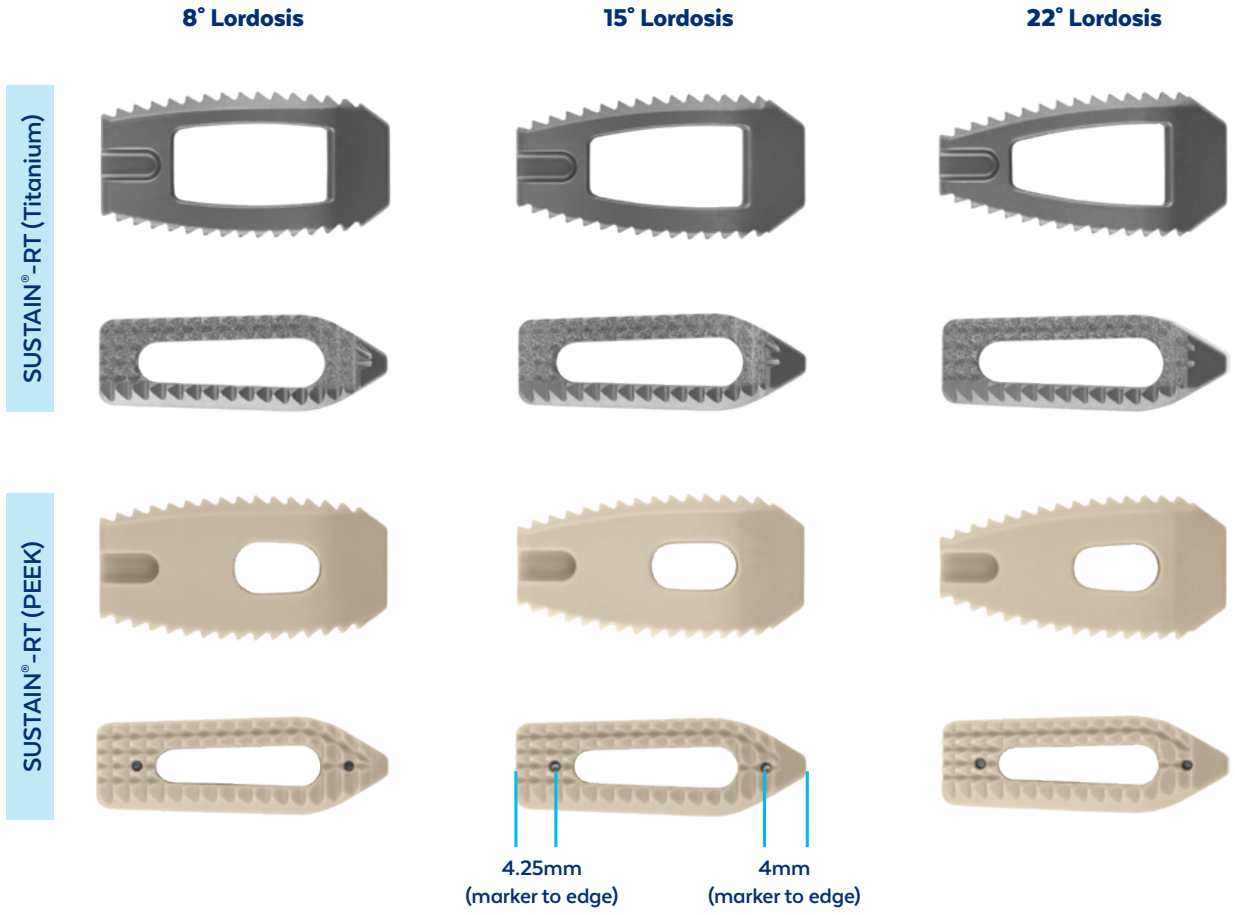
Radiographic markers

Bullet nose designed to help distract disc space for ease of insertion

IMPLANT OVERVIEW

- Offered in commercially pure titanium and PEEK radiolucent polymer
- Titanium spacers feature SintrOS™ laser engraved surface technology
- Fixed-fork and threaded connection allow for rigid attachment
- Beveled edges designed to minimize endplate disruption during rotation
- Directional teeth designed to prevent expulsion
- Radiographic markers in PEEK spacers
- 9-17mm height options in 1mm increments for accurate fit
- Non-rotating spacer available in 6-8mm heights
- 22, 26, and 30mm lengths to accommodate patient anatomy
- 8, 9, and 10mm width options for an ideal fit
- 8°, 15°, and 22° lordotic options





INSTRUMENT OVERVIEW

SHAVERS

Attach to T-Handle 601.800

Height	Part No.
5mm	626.505
6mm	626.506
7mm	626.507
8mm	626.508
9mm	626.509
10mm	626.510
11mm	626.511
12mm	626.512
13mm	626.513
14mm	626.514
15mm	626.515
16mm	626.516
17mm	626.517

DISTRACTORS

Attach to T-Handle 601.800

Height	Part No.
5mm	626.405
6mm	626.406
7mm	626.407
8mm	626.408
9mm	626.409
10mm	626.410
11mm	626.411
12mm	626.412
13mm	626.413
14mm	626.414
15mm	626.415
16mm	626.416
17mm	626.417

**Items in gray are additionally available.*

ENDPLATE SPREADER

Attach to T-Handle 601.800

Endplate Spreader 6145.8800

T-HANDLE

T-Handle 601.800

TRIAL ASSEMBLY INSTRUMENTS

Trials

Part No.	Size
6145.9006	8x22mm, 6mm, 0°
6145.9007	8x22mm, 7mm, 2°
6145.9008	8x22mm, 8mm, 4°
6145.9109	8x22mm, 9mm, 8°
6145.9110	8x22mm, 10mm, 8°
6145.9111	8x22mm, 11mm, 8°
6145.9132	9x22mm, 12mm, 8°
6145.9153	10x22mm, 13mm, 8°
6145.9154	10x22mm, 14mm, 8°
6145.9155	10x22mm, 15mm, 8°
6145.9156	10x22mm, 16mm, 8°
6145.9157	10x22mm, 17mm, 8°

Part No.	Size
6145.9210	8x22mm, 10mm, 15°
6145.9211	8x22mm, 11mm, 15°
6145.9232	9x22mm, 12mm, 15°
6145.9253	10x22mm, 13mm, 15°
6145.9254	10x22mm, 14mm, 15°
6145.9255	10x22mm, 15mm, 15°
6145.9256	10x22mm, 16mm, 15°
6145.9257	10x22mm, 17mm, 15°

Part No.	Size
6145.9332	9x22mm, 12mm, 22°
6145.9353	10x22mm, 13mm, 22°
6145.9354	10x22mm, 14mm, 22°
6145.9355	10x22mm, 15mm, 22°
6145.9356	10x22mm, 16mm, 22°
6145.9357	10x22mm, 17mm, 22°

**Items in gray are additionally available.*

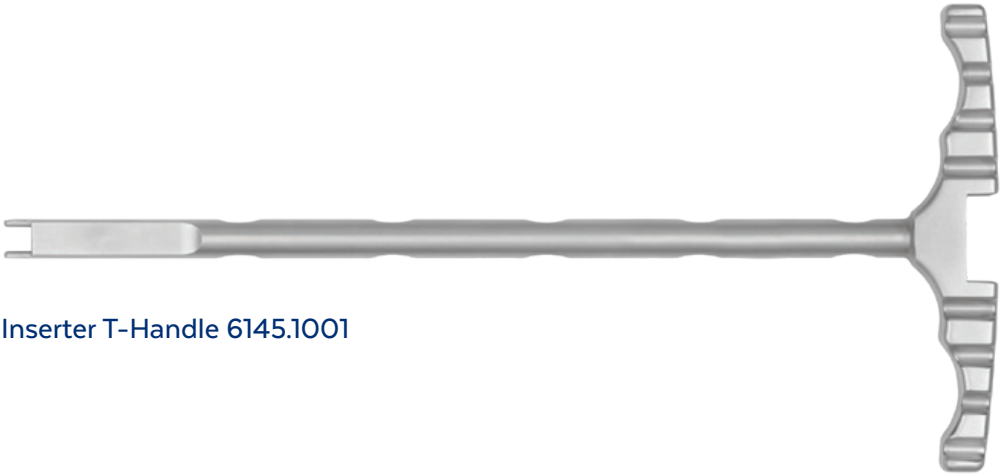
TRIAL ASSEMBLY INSTRUMENTS

Trial Shaft 6145.4100

Trial T-Handle 6145.4101

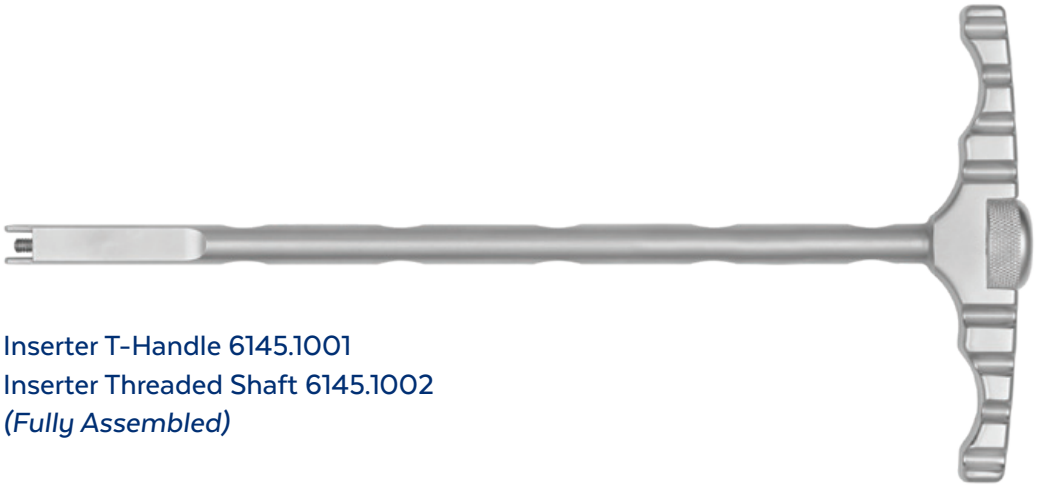
Trial Shaft 6145.4100
Trial T-Handle 6145.4101
(Fully Assembled)

INSERTER ASSEMBLY INSTRUMENTS



Inserter T-Handle 6145.1001

Inserter Threaded Shaft 6145.1002



Inserter T-Handle 6145.1001
Inserter Threaded Shaft 6145.1002
(Fully Assembled)

SURGICAL TECHNIQUE

SUSTAIN®-RT

Refer to the package insert at the back of this guide for information on the indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

A posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF) approach may be used, depending on surgeon preference and patient requirements. A posterior approach is described in this technique.

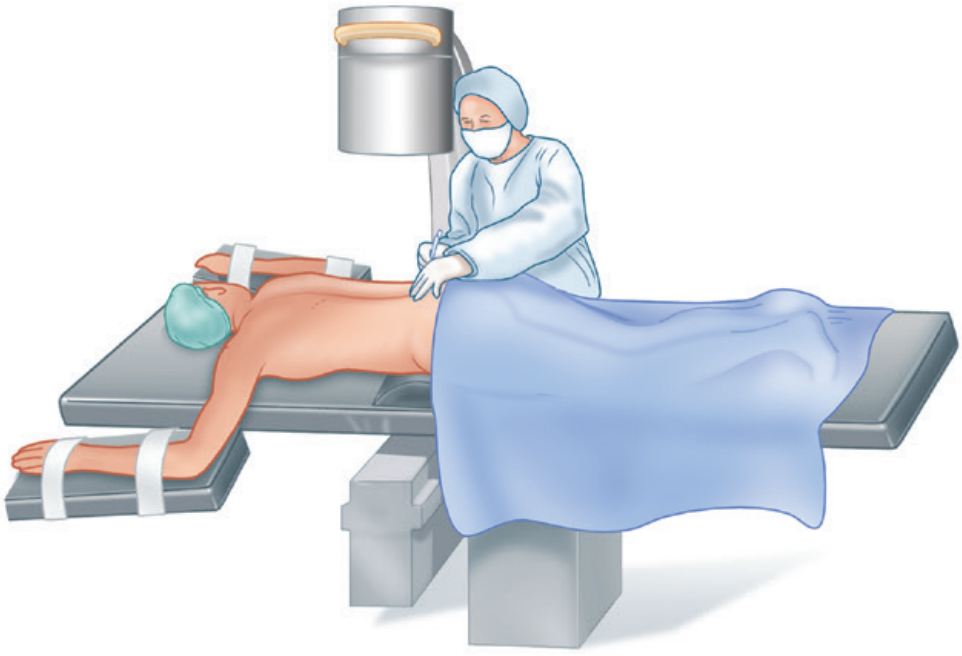
STEP 1 PATIENT POSITIONING AND APPROACH

Place the patient under anesthesia and position prone, preserving the lordosis of the lumbar spine. Lateral C-arm fluoroscopy and other radiographic methods may be used throughout the surgery to ensure correct implant placement.

Carefully clean the operative area and create an incision at the appropriate fusion level(s).

Posterior stabilization, such as CREO®, REVERE®, or REVOLVE®, is required at the appropriate level(s). Please refer to the corresponding technique guide for the selected supplemental fixation system.

The trajectory should be in line with the disc. Finger dissect between the multifidus and longissimus muscles until the facet joint is palpable.

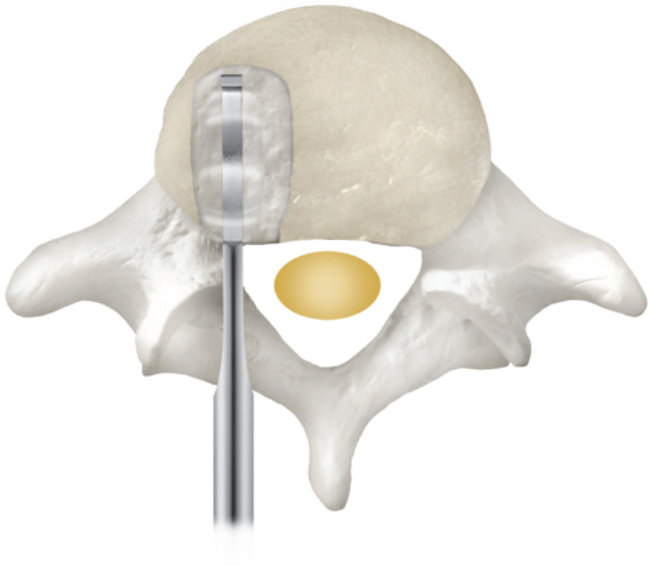


STEP 2 DISCECTOMY/ENDPLATE PREPARATION

Expose the intervertebral disc through a window of approximately 10-12mm on either side of the dura. After creating an adequate annular window, remove disc material using rongeurs, rasps, curettes, or other suitable preparation instruments.* In the event of a collapsed disc space, the **Endplate Spreader** may be inserted between the vertebral bodies to open the disc space.

Remove the cartilaginous endplates with **Shavers**, using caution to maintain bony integrity. Insert the smallest Shaver into the disc space for further disc removal and endplate preparation, moving to larger Shavers as needed. Preserve the anterior and lateral walls of the annulus to provide peripheral support for the implant.

**Available in the Posterior Disc Prep Instruments Set I and II.*

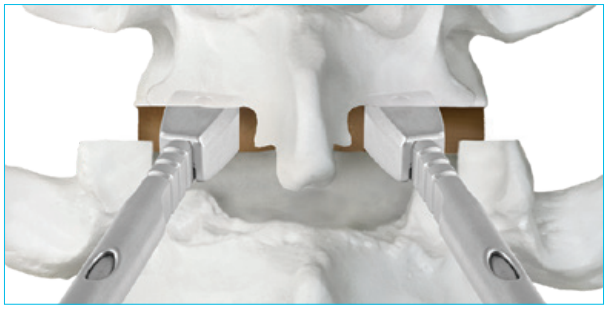


STEP 3 DISTRACTION AND SIZING

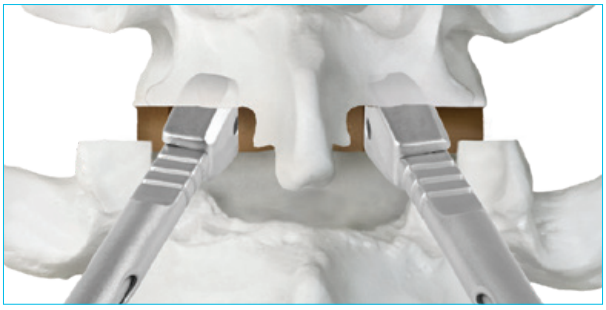
Distraction may be achieved using **Trials** or Shavers by inserting the instrument on its side and rotating into final position. Distraction may also be achieved using pedicle screws.

Trials or Shavers may be used to determine implant size. Attach the desired Trial to the **Trial Shaft** and **T-Handle** assembly as shown on page 12. Insert the Trial with its smallest height in line with the vertebral endplates and rotate clockwise 90° into final position using progressively larger Trials until the desired fit is achieved. Confirm placement using fluoroscopy and tactile feel. Carefully rotate the Trial counterclockwise 90° to remove from the disc space.

Alternatively, Shavers may be used for distraction and sizing. Begin with the smallest Shaver and use progressively larger Shavers until the desired distraction is achieved. Use caution while using Shavers to avoid endplate damage. A secure fit is desirable in order to maintain disc height and stabilize the segment. Confirm placement using fluoroscopy and tactile feel.



Initial Trial insertion

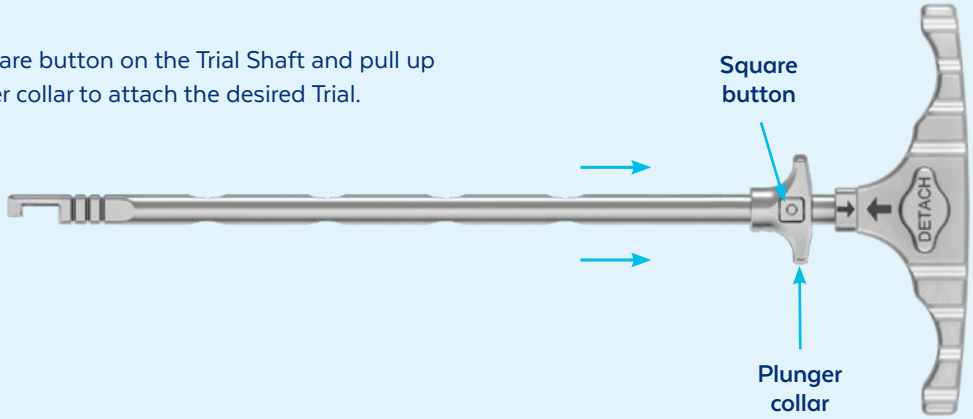


Trials rotated clockwise 90°

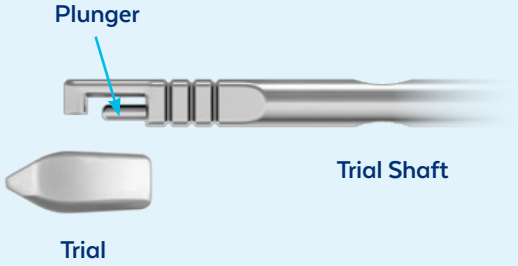
TRIAL ASSEMBLY

Line up the arrows on the T-Handle and Trial Shaft. Press the "DETACH" button on the T-Handle and attach the Trial Shaft.

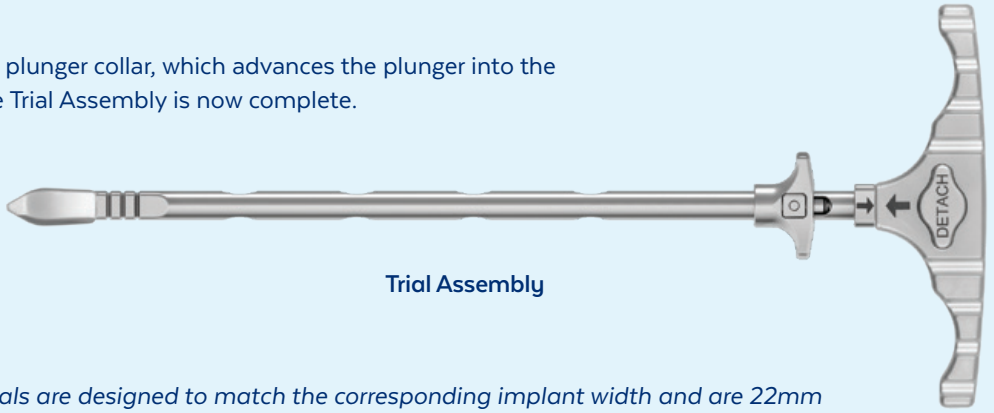
Press the square button on the Trial Shaft and pull up on the plunger collar to attach the desired Trial.



Place the distal end of the Trial Shaft into the desired Trial.



Release the plunger collar, which advances the plunger into the Trial tip. The Trial Assembly is now complete.



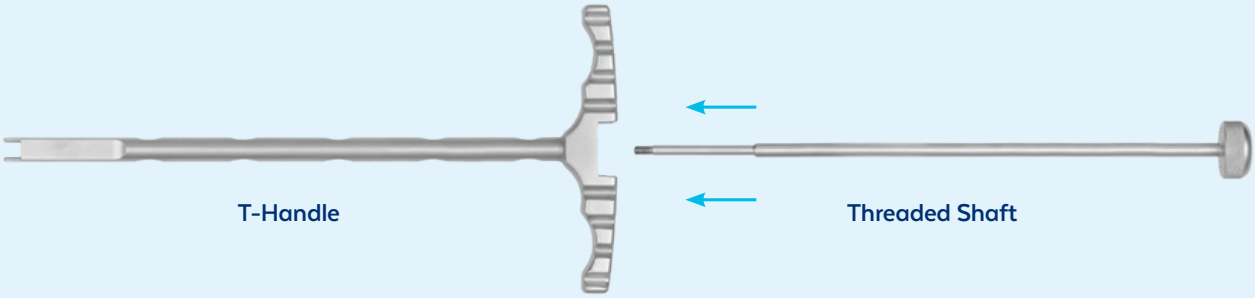
Note: All Trials are designed to match the corresponding implant width and are 22mm in length. Notches on the Trial Shaft indicate 26, 30, and 34mm lengths.

STEP 4 INSERTION

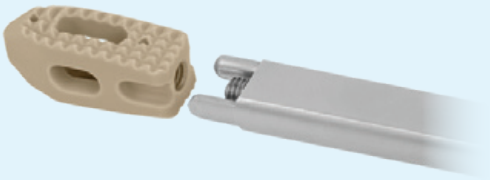
Select an appropriately sized implant. Assemble the inserter and attach the implant as shown below.

ASSEMBLING THE INSERTER AND ATTACHING THE IMPLANT

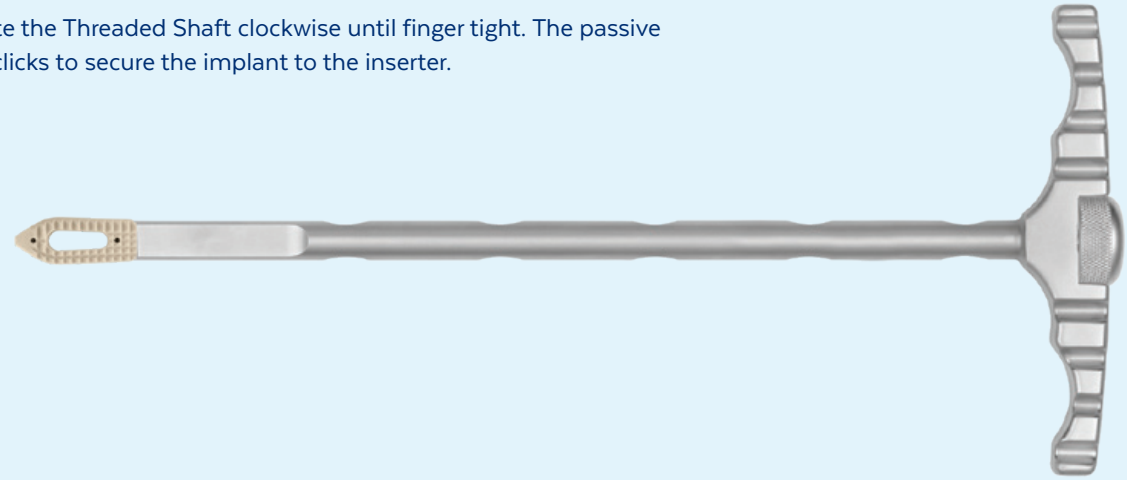
Insert the **Threaded Shaft** into the Inserter **T-Handle**.



Place the forks of the Inserter into the slots on the posterior side of the desired implant.



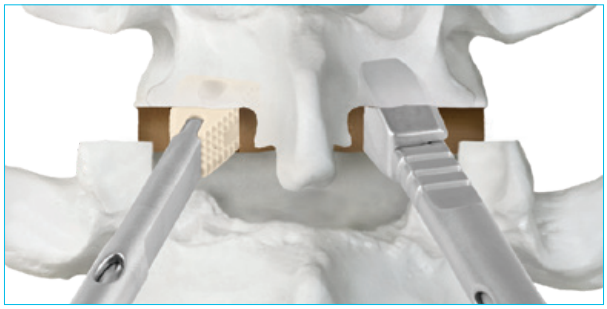
Rotate the Threaded Shaft clockwise until finger tight. The passive lock clicks to secure the implant to the inserter.



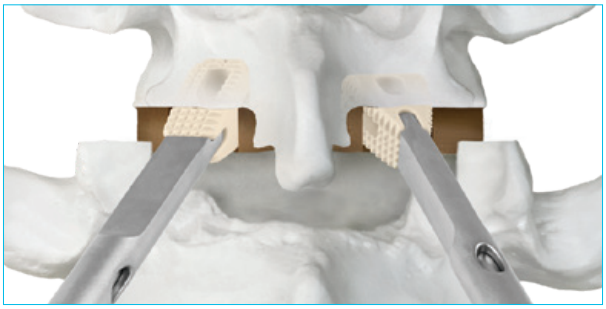
INSERTION (CONT'D)

Fill the graft chamber with allograft or autogenous bone graft comprised of cancellous or corticocancellous bone. Insert the implant with its smallest height in line with the vertebral endplates to the desired depth within the disc space and rotate clockwise 90° into position. The implant should be recessed a few millimeters into the disc space. Gently impact until it reaches the desired position.

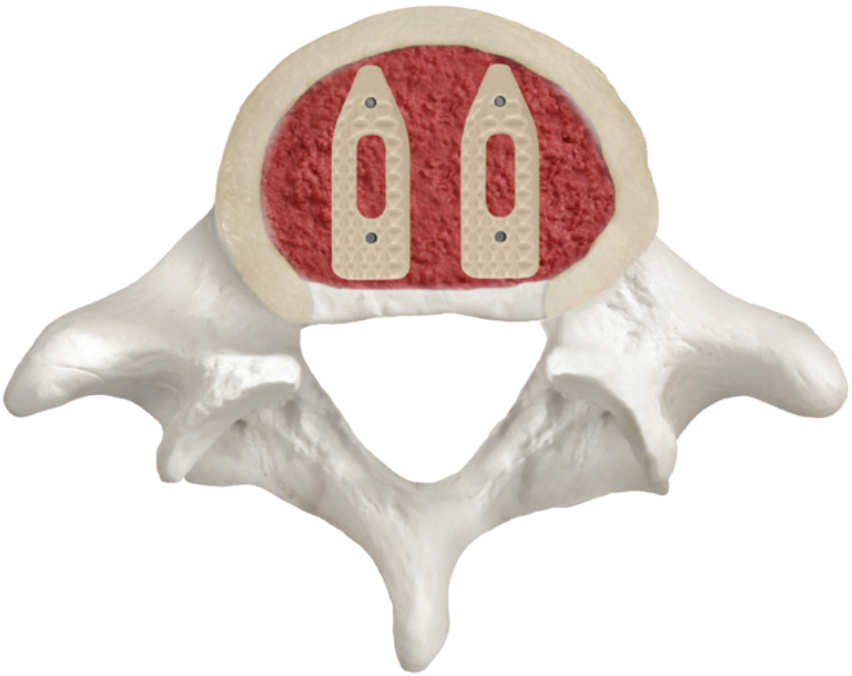
Place bone graft around the implant(s). If necessary, apply compression to help restore sagittal alignment and resist posterior migration.



Initial insertion



Left implant rotated clockwise 90°



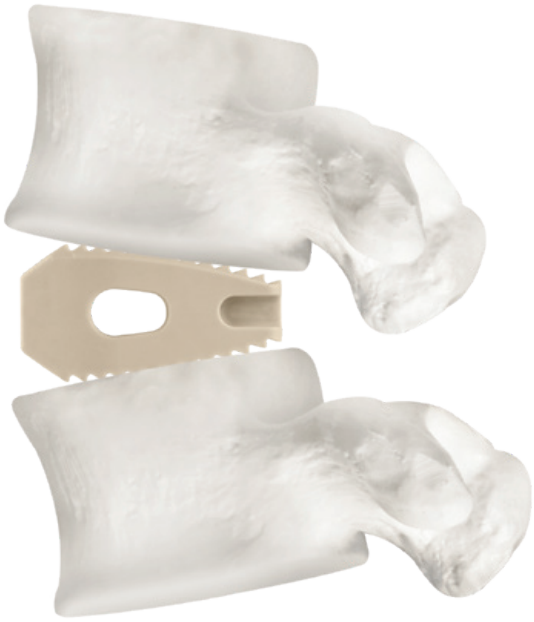
PLIF final position

SUPPLEMENTAL FIXATION

Supplemental fixation such as CREO®, REVERE®, or REVOLVE® is required at all interbody level(s). Please refer to the corresponding surgical technique guides for additional instructions.

FINAL CONSTRUCT

AP view



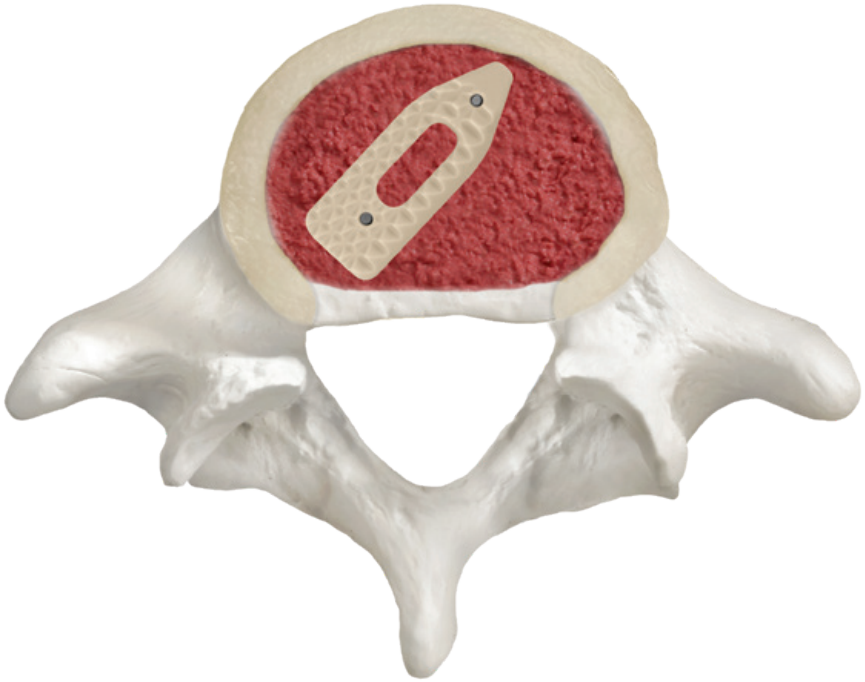
Lateral view

OPTIONAL: SHORT IMPLANTS

Certain shorter heights, 6, 7, and 8mm, are not intended to be rotated into position because the advantage of rotation is not needed. To insert shorter height implants, attach the appropriately sized implant to the Inserter Assembly. Gently impact on the Inserter Assembly until the implant is in the desired position. Using fluoroscopy, ensure the implant is recessed into the disc space.

OPTIONAL: TRANSFORAMINAL APPROACH

SUSTAIN®-RT may be implanted through a transforaminal approach using the same insert and rotate technique. The final position of the spacer for a TLIF technique is shown at right. Please refer to the SUSTAIN®-O Technique Guide (GMTGD115) for more information.



TLIF final position

OPTIONAL: REMOVAL/REVISION

For revision or removal, position the Inserter Assembly onto the implant and rethread. Rotate the implant counterclockwise 90° and carefully remove from the disc space. If desired, use the Inserter Assembly with the **Slide Hammer** for removal. Forceps or other manual surgical instruments may also be used to grasp and extract the implant.

SUSTAIN®-RT PEEK 22mm
IMPLANT SET 9145.9101

Part No.	Description	Qty
3145.4006	8x22mm, 6mm, 0°	2
3145.4007	8x22mm, 7mm, 2°	2
3145.4008	8x22mm, 8mm, 4°	2
3145.4109	8x22mm, 9mm, 8°	2
3145.4110	8x22mm, 10mm, 8°	2
3145.4111	8x22mm, 11mm, 8°	2
3145.4132	9x22mm, 12mm, 8°	2
3145.4153	10x22mm, 13mm, 8°	2
3145.4154	10x22mm, 14mm, 8°	2
3145.4155	10x22mm, 15mm, 8°	2
3145.4156	10x22mm, 16mm, 8°	
3145.4157	10x22mm, 17mm, 8°	
3145.4210	8x22mm, 10mm, 15°	2
3145.4211	8x22mm, 11mm, 15°	2
3145.4232	9x22mm, 12mm, 15°	2
3145.4253	10x22mm, 13mm, 15°	2
3145.4254	10x22mm, 14mm, 15°	2
3145.4255	10x22mm, 15mm, 15°	2
3145.4256	10x22mm, 16mm, 15°	
3145.4257	10x22mm, 17mm, 15°	
3145.4332	9x22mm, 12mm, 21°	2
3145.4353	10x22mm, 13mm, 22°	2
3145.4354	10x22mm, 14mm, 22°	2
3145.4355	10x22mm, 15mm, 22°	2
3145.4356	10x22mm, 16mm, 22°	
3145.4357	10x22mm, 17mm, 22°	
9145.0101	SUSTAIN®-RT PEEK 22mm Implant Module	

*Additionally available

SUSTAIN®-RT PEEK 26mm
IMPLANT SET 9145.9102

Part No.	Description	Qty
3145.5006	8x26mm, 6mm, 0°	2
3145.5007	8x26mm, 7mm, 2°	2
3145.5008	8x26mm, 8mm, 4°	2
3145.5109	8x26mm, 9mm, 6°	2
3145.5110	8x26mm, 10mm, 8°	2
3145.5111	8x26mm, 11mm, 8°	2
3145.5132	9x26mm, 12mm, 8°	2
3145.5153	10x26mm, 13mm, 8°	2
3145.5154	10x26mm, 14mm, 8°	2
3145.5155	10x26mm, 15mm, 8°	2
3145.5156	10x26mm, 16mm, 8°	
3145.5157	10x26mm, 17mm, 8°	
3145.5211	8x26mm, 11mm, 13°	2
3145.5232	9x26mm, 12mm, 15°	2
3145.5253	10x26mm, 13mm, 15°	2
3145.5254	10x26mm, 14mm, 15°	2
3145.5255	10x26mm, 15mm, 15°	2
3145.5256	10x26mm, 16mm, 15°	
3145.5257	10x26mm, 17mm, 15°	
3145.5353	10x26mm, 13mm, 19°	2
3145.5354	10x26mm, 14mm, 21°	2
3145.5355	10x26mm, 15mm, 22°	2
3145.5356	10x26mm, 16mm, 22°	
3145.5357	10x26mm, 17mm, 22°	
9145.0102	SUSTAIN®-RT PEEK 26mm Implant Module	

*Additionally available

SUSTAIN®-RT PEEK 30mm
IMPLANT SET 9145.9103

Part No.	Description	Qty
3145.6006	8x30mm, 6mm, 0°	2
3145.6007	8x30mm, 7mm, 2°	2
3145.6008	8x30mm, 8mm, 4°	2
3145.6109	8x30mm, 9mm, 6°	2
3145.6110	8x30mm, 10mm, 8°	2
3145.6111	8x30mm, 11mm, 8°	2
3145.6132	9x30mm, 12mm, 8°	2
3145.6153	10x30mm, 13mm, 8°	2
3145.6154	10x30mm, 14mm, 8°	2
3145.6155	10x30mm, 15mm, 8°	2
3145.6156	10x30mm, 16mm, 8°	
3145.6157	10x30mm, 17mm, 8°	
3145.6232	9x30mm, 12mm, 13°	2
3145.6253	10x30mm, 13mm, 15°	2
3145.6254	10x30mm, 14mm, 15°	2
3145.6255	10x30mm, 15mm, 15°	2
3145.6256	10x30mm, 16mm, 15°	
3145.6257	10x30mm, 17mm, 15°	
3145.6355	10x30mm, 15mm, 20°	2
3145.6356	10x30mm, 16mm, 22°	
3145.6357	10x30mm, 17mm, 22°	
9145.0103	SUSTAIN®-RT PEEK 30mm Implant Module	

*Additionally available

SUSTAIN®-RT Ti 22mm
IMPLANT SET 9145.9105

Part No.	Description	Qty
1145.4006	8x22mm, 6mm, 0°	2
1145.4007	8x22mm, 7mm, 2°	2
1145.4008	8x22mm, 8mm, 4°	2
1145.4109	8x22mm, 9mm, 8°	2
1145.4110	8x22mm, 10mm, 8°	2
1145.4111	8x22mm, 11mm, 8°	2
1145.4132	9x22mm, 12mm, 8°	2
1145.4153	10x22mm, 13mm, 8°	2
1145.4154	10x22mm, 14mm, 8°	2
1145.4155	10x22mm, 15mm, 8°	2
1145.4156	10x22mm, 16mm, 8°	
1145.4157	10x22mm, 17mm, 8°	
1145.4210	8x22mm, 10mm, 15°	2
1145.4211	8x22mm, 11mm, 15°	2
1145.4232	9x22mm, 12mm, 15°	2
1145.4253	10x22mm, 13mm, 15°	2
1145.4254	10x22mm, 14mm, 15°	2
1145.4255	10x22mm, 15mm, 15°	2
1145.4256	10x22mm, 16mm, 15°	
1145.4257	10x22mm, 17mm, 15°	
1145.4332	9x22mm, 12mm, 21°	2
1145.4353	10x22mm, 13mm, 22°	2
1145.4354	10x22mm, 14mm, 22°	2
1145.4355	10x22mm, 15mm, 22°	2
1145.4356	10x22mm, 16mm, 22°	
1145.4357	10x22mm, 17mm, 22°	
9145.0105	SUSTAIN®-RT Titanium 22mm Implant Module	

*Additionally available

SUSTAIN®-RT Ti 26mm
IMPLANT SET 9145.9106

Part No.	Description	Qty
1145.5006	8x26mm, 6mm, 0°	2
1145.5007	8x26mm, 7mm, 2°	2
1145.5008	8x26mm, 8mm, 4°	2
1145.5109	8x26mm, 9mm, 6°	2
1145.5110	8x26mm, 10mm, 8°	2
1145.5111	8x26mm, 11mm, 8°	2
1145.5132	9x26mm, 12mm, 8°	2
1145.5153	10x26mm, 13mm, 8°	2
1145.5154	10x26mm, 14mm, 8°	2
1145.5155	10x26mm, 15mm, 8°	2
1145.5156	10x26mm, 16mm, 8°	
1145.5157	10x26mm, 17mm, 8°	
1145.5211	8x26mm, 11mm, 13°	2
1145.5232	9x26mm, 12mm, 15°	2
1145.5253	10x26mm, 13mm, 15°	2
1145.5254	10x26mm, 14mm, 15°	2
1145.5255	10x26mm, 15mm, 15°	2
1145.5256	10x26mm, 16mm, 15°	
1145.5257	10x26mm, 17mm, 15°	
1145.5353	10x26mm, 13mm, 19°	2
1145.5354	10x26mm, 14mm, 21°	2
1145.5355	10x26mm, 15mm, 22°	2
1145.5356	10x26mm, 16mm, 22°	
1145.5357	10x26mm, 17mm, 22°	
9145.0106	SUSTAIN®-RT Titanium 26mm Implant Module	

*Additionally available

SUSTAIN®-RT Ti 30mm
IMPLANT SET 9145.9107

Part No.	Description	Qty
1145.6006	8x30mm, 6mm, 0°	2
1145.6007	8x30mm, 7mm, 2°	2
1145.6008	8x30mm, 8mm, 4°	2
1145.6109	8x30mm, 9mm, 6°	2
1145.6110	8x30mm, 10mm, 8°	2
1145.6111	8x30mm, 11mm, 8°	2
1145.6132	9x30mm, 12mm, 8°	2
1145.6153	10x30mm, 13mm, 8°	2
1145.6154	10x30mm, 14mm, 8°	2
1145.6155	10x30mm, 15mm, 8°	2
1145.6156	10x30mm, 16mm, 8°	
1145.6157	10x30mm, 17mm, 8°	
1145.6232	9x30mm, 12mm, 13°	2
1145.6253	10x30mm, 13mm, 15°	2
1145.6254	10x30mm, 14mm, 15°	2
1145.6255	10x30mm, 15mm, 15°	2
1145.6256	10x30mm, 16mm, 15°	
1145.6257	10x30mm, 17mm, 15°	
1145.6355	10x30mm, 15mm, 20°	2
1145.6356	10x30mm, 16mm, 22°	
1145.6357	10x30mm, 17mm, 22°	
9145.0107	SUSTAIN®-RT Titanium 30mm Implant Module	

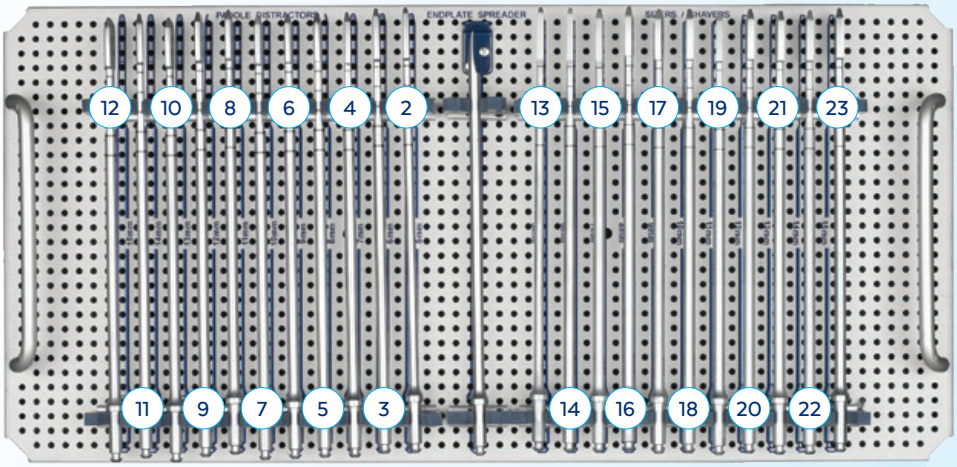
Additionally available

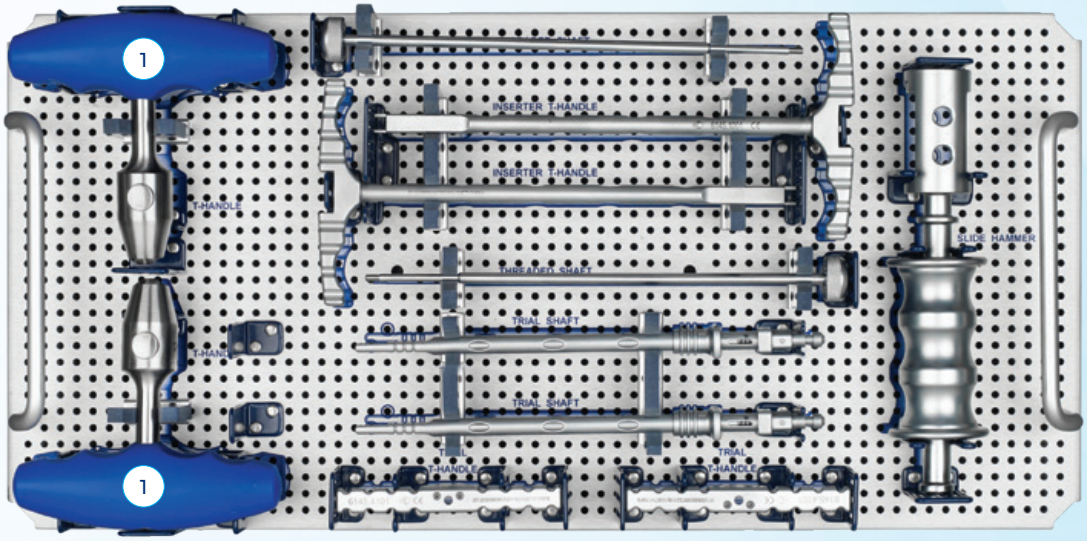
SUSTAIN®-RT
INSTRUMENT SET 9145.9100

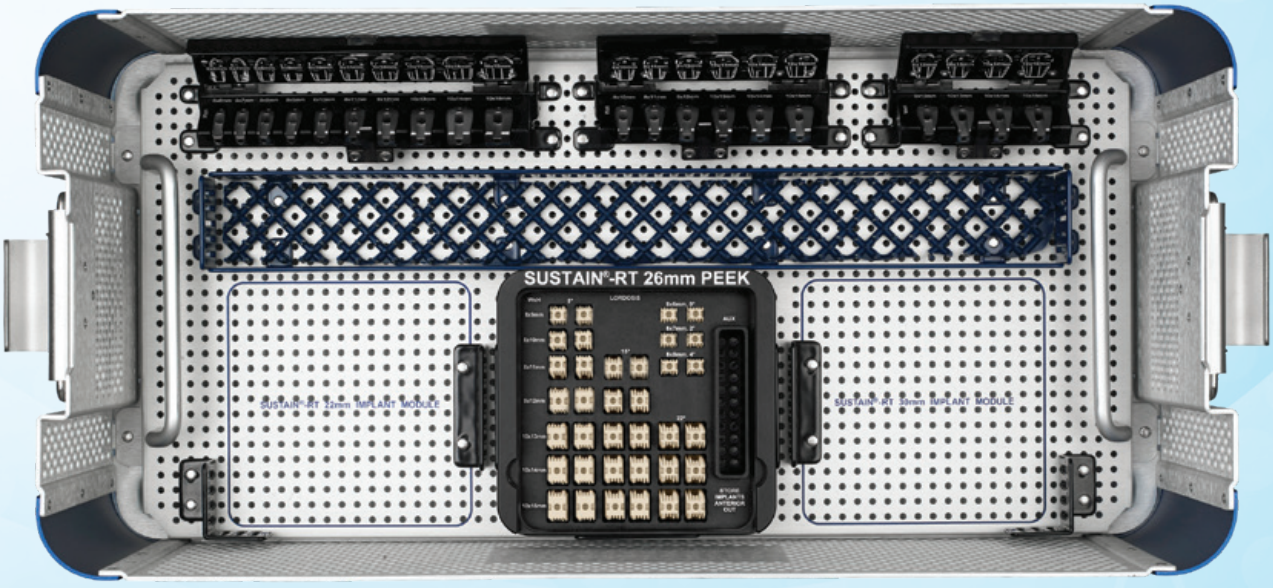
	Instrument		Qty
1	601.800	T-Handle	2
2	626.405	Paddle Distractor, 5mm	1
3	626.406	Paddle Distractor, 6mm	1
4	626.407	Paddle Distractor, 7mm	1
5	626.408	Paddle Distractor, 8mm	1
6	626.409	Paddle Distractor, 9mm	1
7	626.410	Paddle Distractor, 10mm	1
8	626.411	Paddle Distractor, 11mm	1
9	626.412	Paddle Distractor, 12mm	1
10	626.413	Paddle Distractor, 13mm	1
11	626.414	Paddle Distractor, 14mm	1
12	626.415	Paddle Distractor, 15mm	1
	626.416	Paddle Distractor, 16mm	
	626.417	Paddle Distractor, 17mm	
13	626.505	Sizer/Shaver, 5mm	1
14	626.506	Sizer/Shaver, 6mm	1
15	626.507	Sizer/Shaver, 7mm	1
16	626.508	Sizer/Shaver, 8mm	1
17	626.509	Sizer/Shaver, 9mm	1
18	626.510	Sizer/Shaver, 10mm	1
19	626.511	Sizer/Shaver, 11mm	1
20	626.512	Sizer/Shaver, 12mm	1
21	626.513	Sizer/Shaver, 13mm	1
22	626.514	Sizer/Shaver, 14mm	1
23	626.515	Sizer/Shaver, 15mm	1
	626.516	Sizer/Shaver, 16mm	
	626.517	Sizer/Shaver, 17mm	

*Additionally available

SUSTAIN®-RT
INSTRUMENT SET 9145.9100





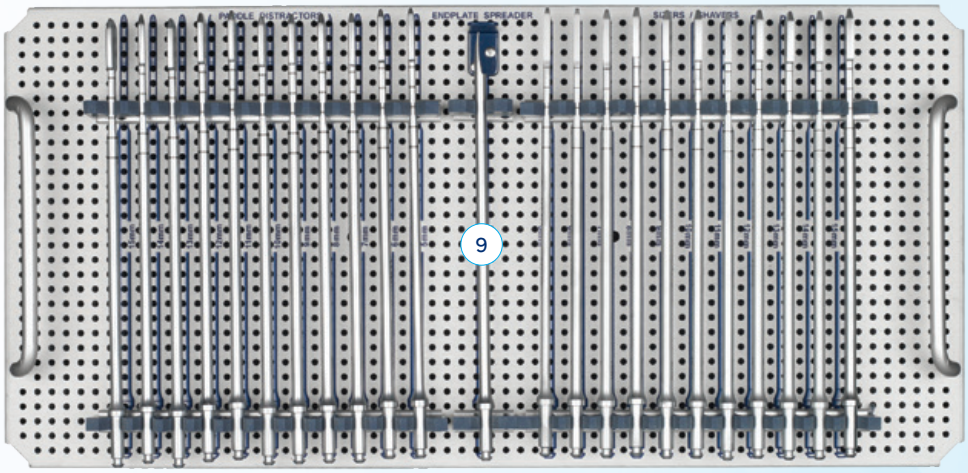


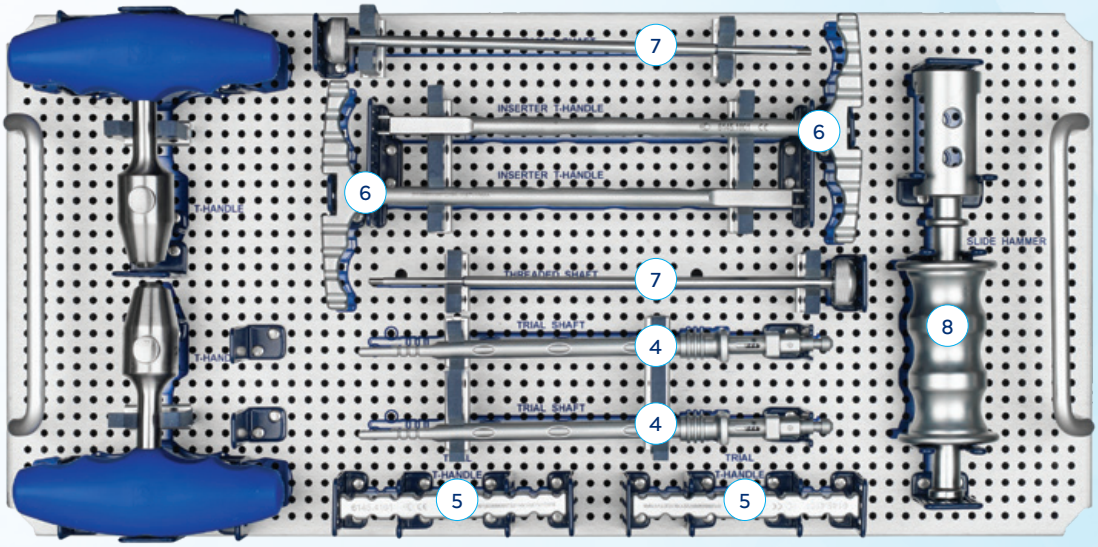
SUSTAIN®-RT
INSTRUMENT SET 9145.9100 (CONT'D)

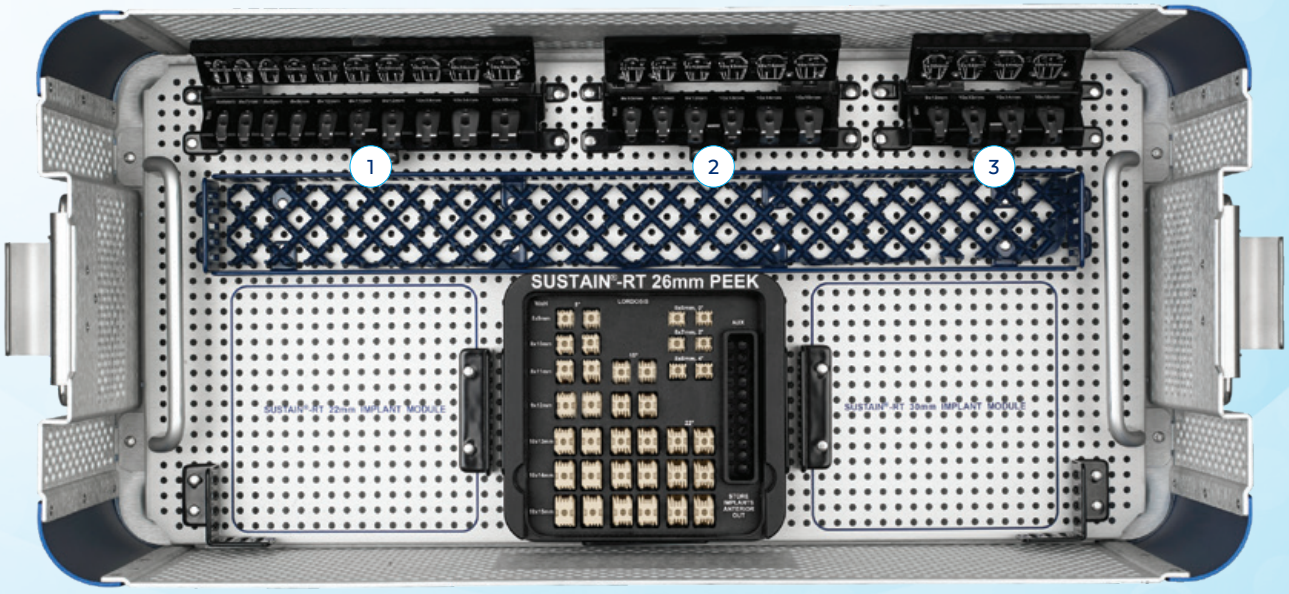
	Instrument		Qty
1	6145.9006	Trial, 8x22mm, 6mm, 0°	1
	6145.9007	Trial, 8x22mm, 7mm, 2°	1
	6145.9008	Trial, 8x22mm, 8mm, 4°	1
	6145.9109	Trial, 8x22mm, 9mm, 8°	1
	6145.9110	Trial, 8x22mm, 10mm, 8°	1
	6145.9111	Trial, 8x22mm, 11mm, 8°	1
	6145.9132	Trial, 9x22mm, 12mm, 8°	1
	6145.9153	Trial, 10x22mm, 13mm, 8°	1
	6145.9154	Trial, 10x22mm, 14mm, 8°	1
	6145.9155	Trial, 10x22mm, 15mm, 8°	1
	6145.9156	Trial, 10x22mm, 16mm, 8°	
	6145.9157	Trial, 10x22mm, 17mm, 8°	
2	6145.9210	Trial, 8x22mm, 10mm, 15°	1
	6145.9211	Trial, 8x22mm, 11mm, 15°	1
	6145.9232	Trial, 9x22mm, 12mm, 15°	1
	6145.9253	Trial, 10x22mm, 13mm, 15°	1
	6145.9254	Trial, 10x22mm, 14mm, 15°	1
	6145.9255	Trial, 10x22mm, 15mm, 15°	1
	6145.9256	Trial, 10x22mm, 16mm, 15°	
	6145.9257	Trial, 10x22mm, 17mm, 15°	
3	6145.9332	Trial, 9x22mm, 12mm, 22°	1
	6145.9353	Trial, 10x22mm, 13mm, 22°	1
	6145.9354	Trial, 10x22mm, 14mm, 22°	1
	6145.9355	Trial, 10x22mm, 15mm, 22°	1
	6145.9356	Trial, 10x22mm, 16mm, 22°	
	6145.9357	Trial, 10x22mm, 17mm, 22°	
4	6145.4100	Trial Shaft	2
5	6145.4101	Trial T-Handle	2
6	6145.1001	Inserter T-Handle	2
7	6145.1002	Inserter Threaded Shaft	2
	6145.1003	Inserter T-Handle, Long	
	6145.1004	Inserter Threaded Shaft, Long	
8	6145.8010	Slide Hammer	1
9	6145.8800	Endplate Spreader	1
	9145.0100	SUSTAIN®-RT Instrument Graphic Case	

*Additionally available

SUSTAIN®-RT
INSTRUMENT SET 9145.9100 (CONT'D)



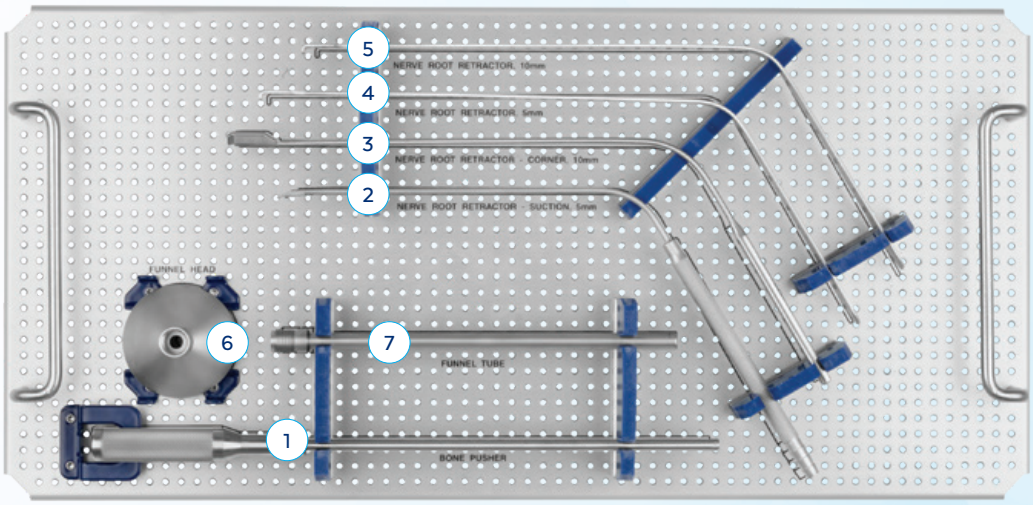


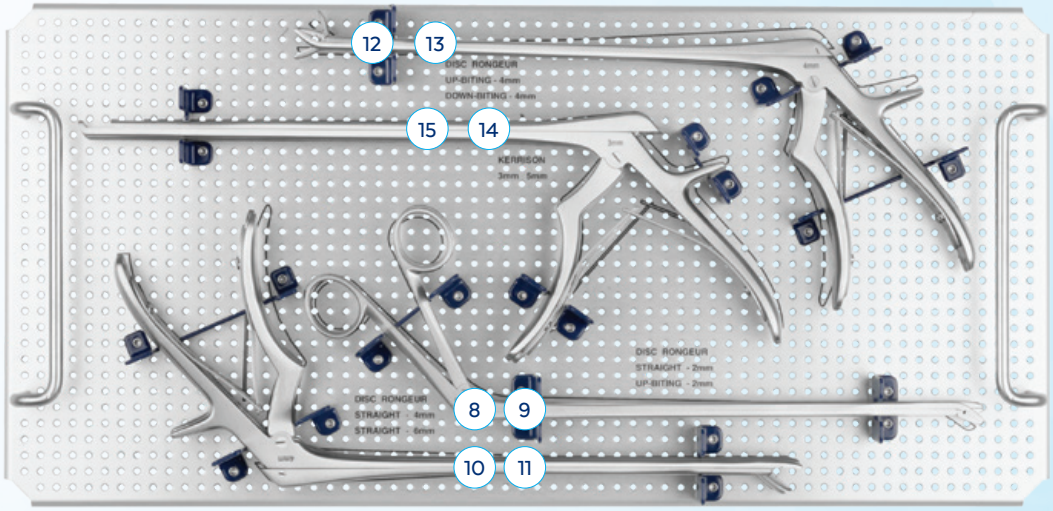


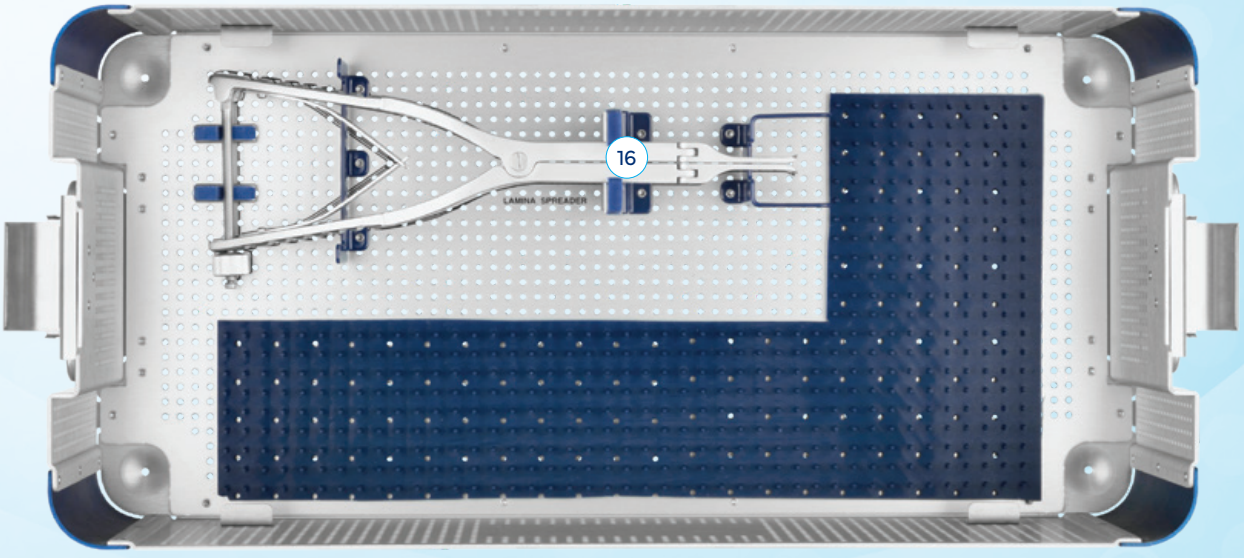
POSTERIOR DISC PREP
INSTRUMENT I SET 926.901

	Instrument		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	

POSTERIOR DISC PREP
INSTRUMENT I SET 926.901



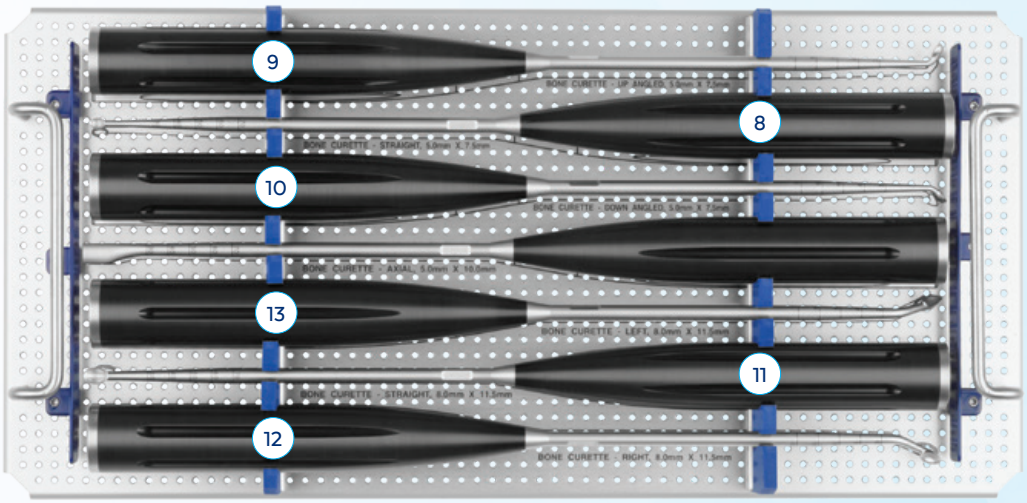


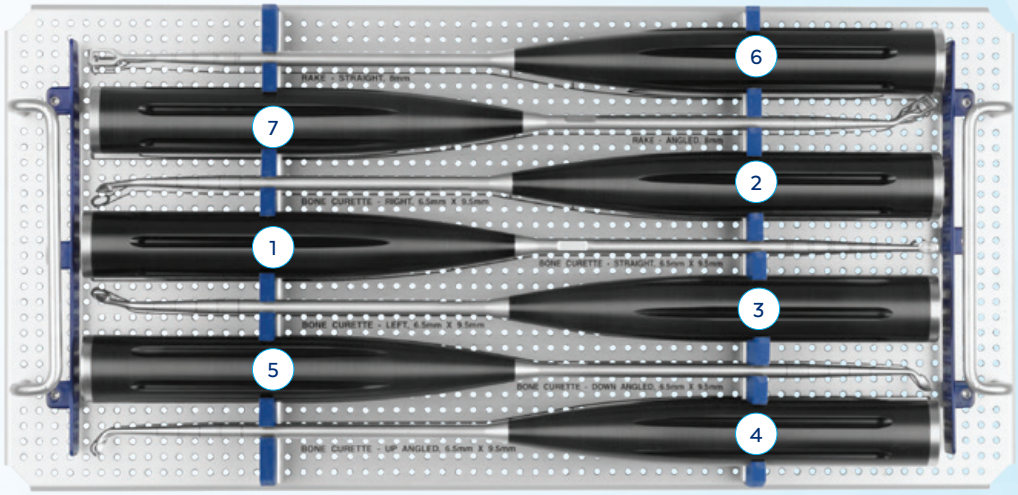


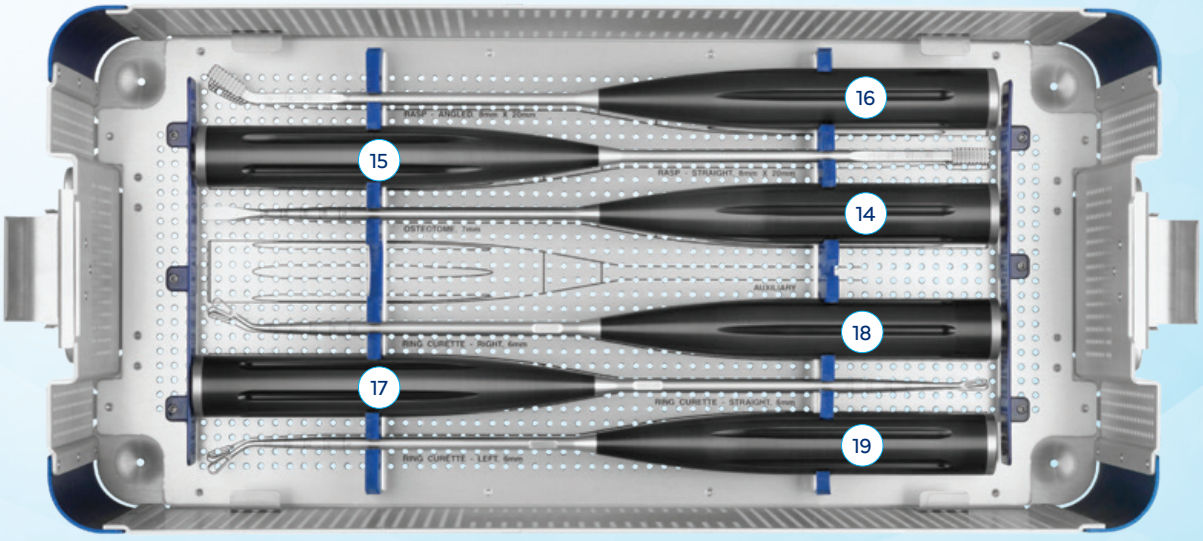
POSTERIOR DISC PREP
INSTRUMENT II SET 926.902

	Instrument		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 II	

POSTERIOR DISC PREP
INSTRUMENT II SET 926.902







MARS™ 3V RETRACTOR
INSTRUMENT SET 998.901

	Instruments		Qty
1	623.003	K-Wire Gripper	1
2	698.100	Retractor 3 Blade Frame	1
3	632.102	Retractor 2 Blade Frame	1
4	632.150	10mm Socket Driver	1
5	698.250	Hook and Latch Driver	1
6	675.403	Flouro Modulator	1
7	675.404	Incision Locator	1
8	675.513	8” Suction	1
9	675.800	Radiolucent Initial Dilator Holder	1
10	698.205	Cannula A	1
11	698.210	Cannula B	1
12	698.215	Cannula C	1
13	698.220	Cannula D	1
14	698.230	Frame Handle	1
15	698.240	Shim Tool, CC	1
16	698.260	Docking Pin Tool	1
17	698.330	Disc Shim Tool	1
18	698.350	Docking Pin Sleeve	4

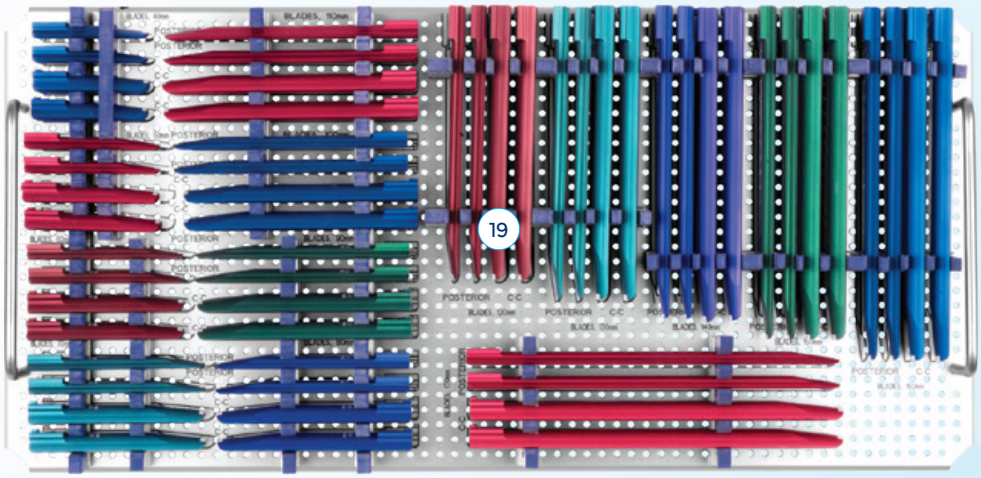
19	Retractor Blades		Qty
	698.450	Blade, Posterior, 40mm	2
	698.452	Blade, Posterior, 50mm	2
	698.454	Blade, Posterior, 60mm	2
	698.456	Blade, Posterior, 70mm	2
	698.458	Blade, Posterior, 80mm	2
	698.460	Blade, Posterior, 90mm	2
	698.462	Blade, Posterior, 100mm	2
	698.464	Blade, Posterior, 110mm	2
	698.466	Blade, Posterior, 120mm	2
	698.468	Blade, Posterior, 130mm	2
	698.470	Blade, Posterior, 140mm	2
	698.472	Blade, Posterior, 150mm	2
	698.474	Blade, Posterior, 160mm	2

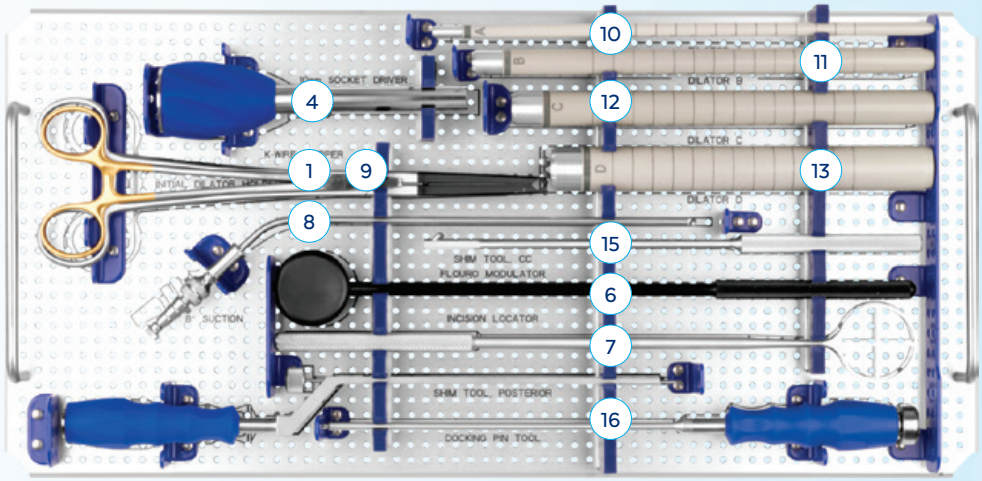
Retractor Blades		Qty
698.476	Blade, Posterior, 170mm	2
698.510	Blade, CC, 40mm	2
698.512	Blade, CC, 50mm	2
698.514	Blade, CC, 60mm	2
698.516	Blade, CC, 70mm	2
698.518	Blade, CC, 80mm	2
698.520	Blade, CC, 90mm	2
698.522	Blade, CC, 100mm	2
698.524	Blade, CC, 110mm	2
698.526	Blade, CC, 120mm	2
698.528	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

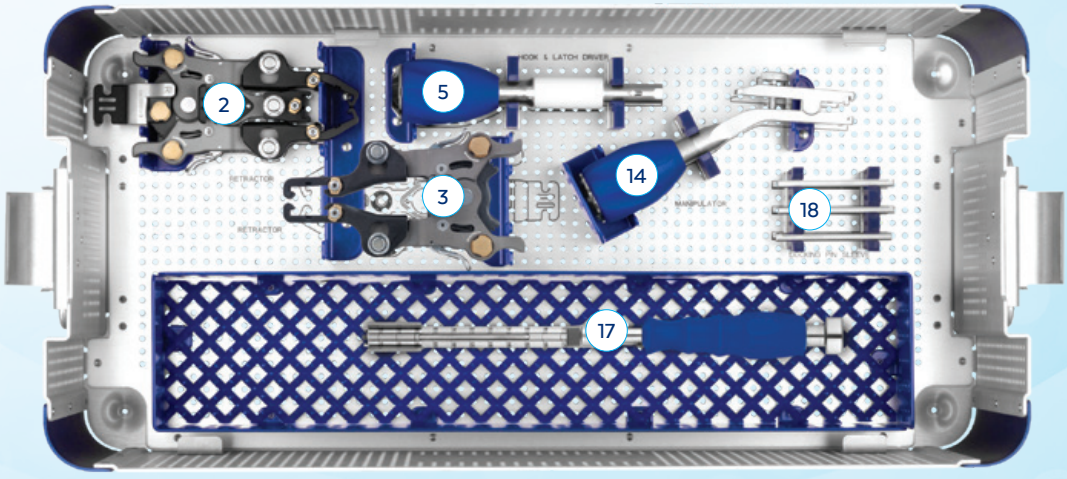
Disposables		Qty
632.678S	Bipolar Forceps, 10” Bayo, 1.0mm Tip	1
698.600S	MARS™ 3V Disposable Kit	1
698.300S	Lengthening Shim	2
698.305S	Widening Shim	2
698.310S	Docking Pin, 10mm	2
698.315S	Docking Pin, 20mm	2
698.325S	Disc Shim, Aluminum	1
698.326S	Disc Shim, Stainless Steel	

*Additionally available

MARS™ 3V RETRACTOR
INSTRUMENT SET 998.901



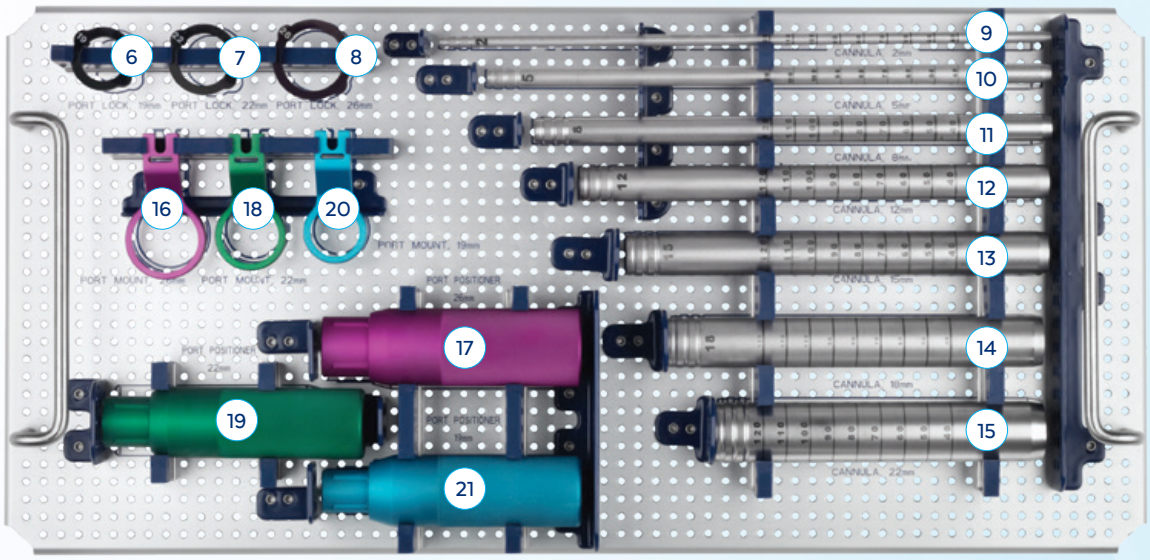


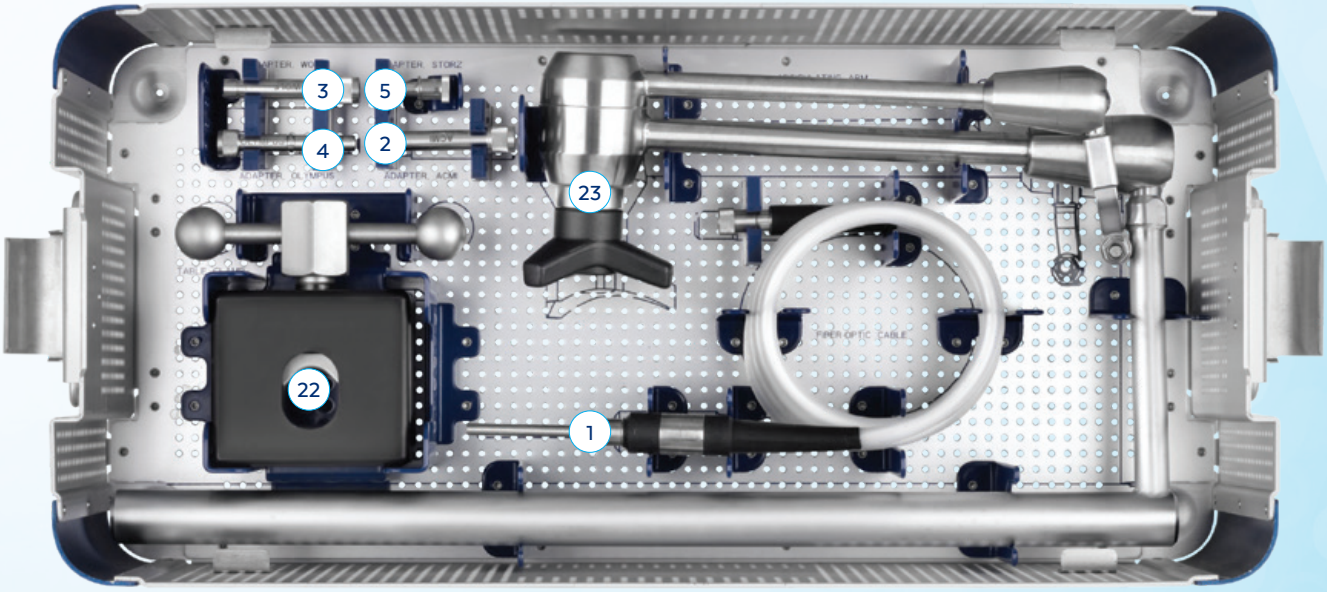


MARS™
INSTRUMENT II SET 932.902

	Instrument		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
	632.310S	Light Cable	1
6	632.390	Port Lock, 19mm	1
7	632.391	Port Lock, 22mm	1
8	632.392	Port Lock, 26mm	1
9	632.401	2mm Cannula	1
10	632.402	5mm Cannula	1
11	632.403	8mm Cannula	1
12	632.404	12mm Cannula	1
13	632.405	15mm Cannula	1
14	632.406	18mm Cannula	1
15	632.407	22mm Cannula	1
16	632.408	26mm Port Mount	1
17	632.409	26mm Port Positioner	1
18	632.410	22mm Port Mount	1
19	632.411	22mm Port Positioner	1
20	632.412	19mm Port Mount	1
21	632.413	19mm Port Positioner	1
22	632.500	Table Clamp	1
23	632.750	Articulating Arm Assembly	1
	932.002	MARS™ Instrument II Graphic Case	

MARS™
INSTRUMENT II SET 932.902



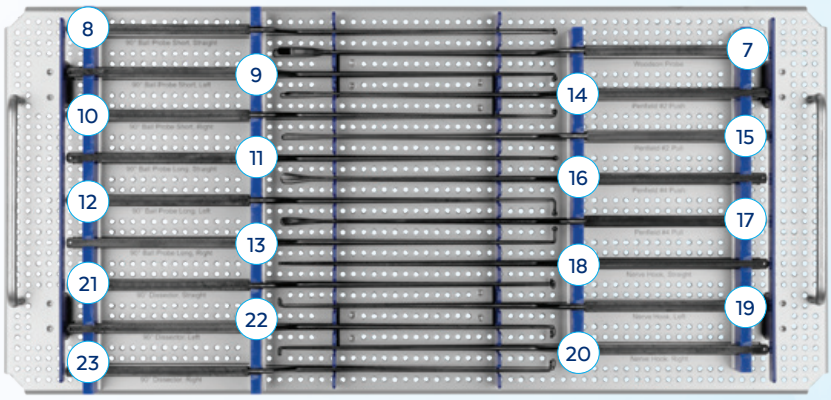


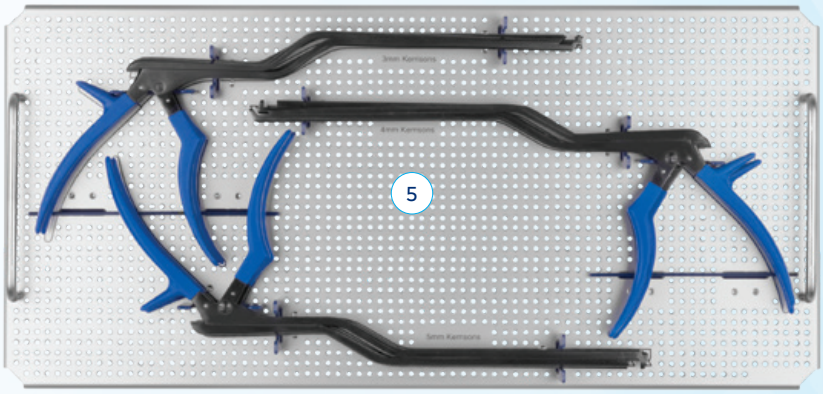
MARS™
INSTRUMENT III SET 932.903

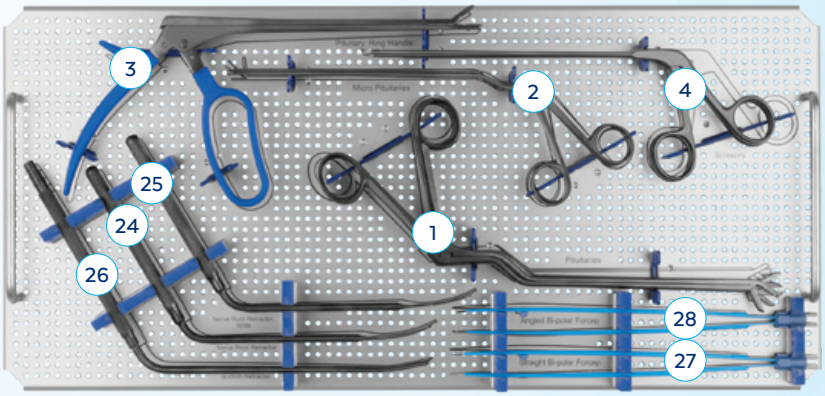
	Instruments		Qty
1	632.600	Pituitary, 2mm Bayoneted	1
	632.601	Pituitary, 2mm, Down-Biting, Bayoneted	1
	632.602	Pituitary, 2mm, Up-Biting, Bayoneted	1
	632.605	Pituitary, 4mm, Up-Biting, Bayoneted	1
2	632.610	Micro Pituitary, 2mm, Up-Biting, Bayoneted	1
	632.611	Micro Pituitary, 2mm, Bayoneted	1
3	632.615	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
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

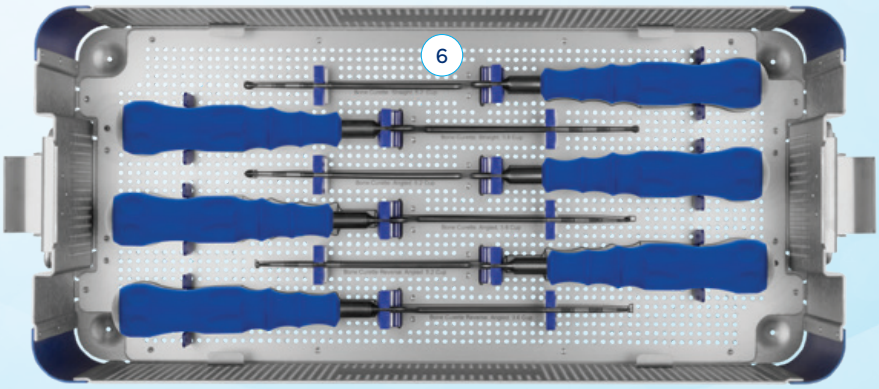
	Instruments		Qty
16	632.652	Penfield #4 Push, Bayoneted	1
17	632.653	Penfield #4 Pull, Bayoneted	1
18	632.655	Nerve Hook, Straight, Bayoneted	1
19	632.656	Nerve Hook, Left, Bayoneted	1
20	632.657	Nerve Hook, Right, Bayoneted	1
21	632.660	90° Dissector, Straight, Bayoneted	1
22	632.661	90° Dissector, 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 III	

MARS™
INSTRUMENT III SET 932.903









MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901

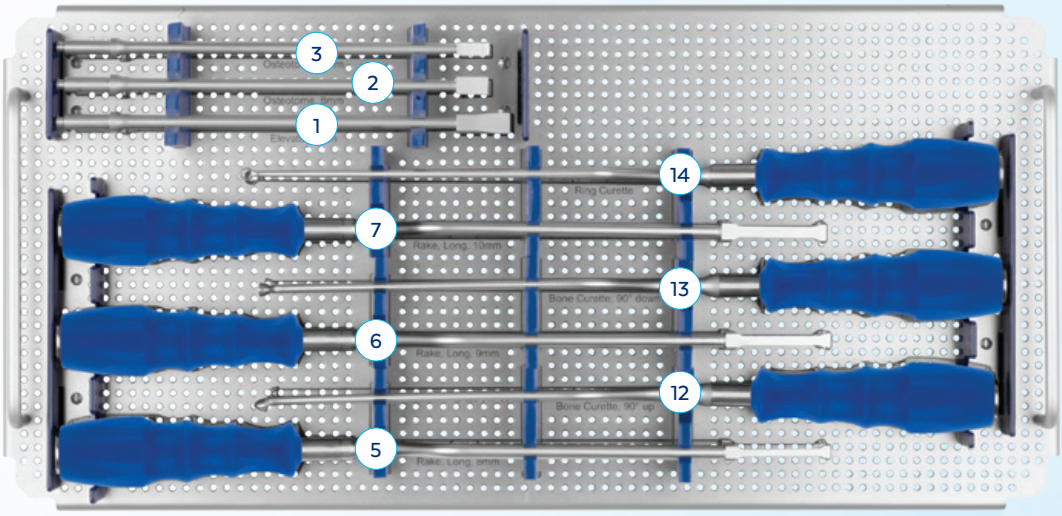
	Instrument		Qty
1	679.005	Elevator 6mm	1
2	679.007	Osteotome, 8mm QR	1
3	679.008	Osteotome, 6mm QR	1
4	679.010	L-Handle	1
5	679.011	Rake, Long 8mm, Bayoneted	1
6	679.012	Rake, Long 9mm, Bayoneted	1
7	679.013	Rake, Long 10mm, Bayoneted	1
8	679.015	Bone Funnel	1
9	679.016	Bone Funnel Clamp	1
10	679.017	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
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	

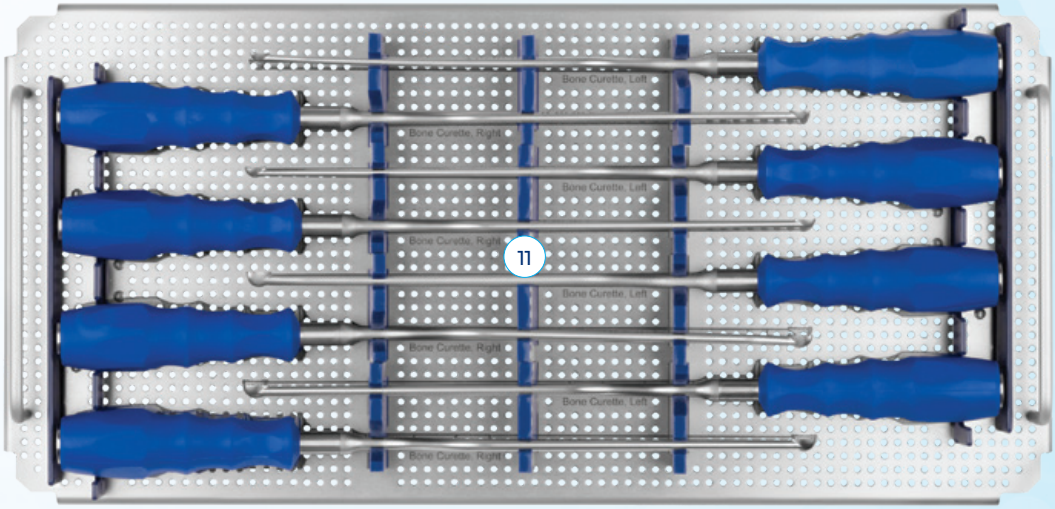
Additionally Available

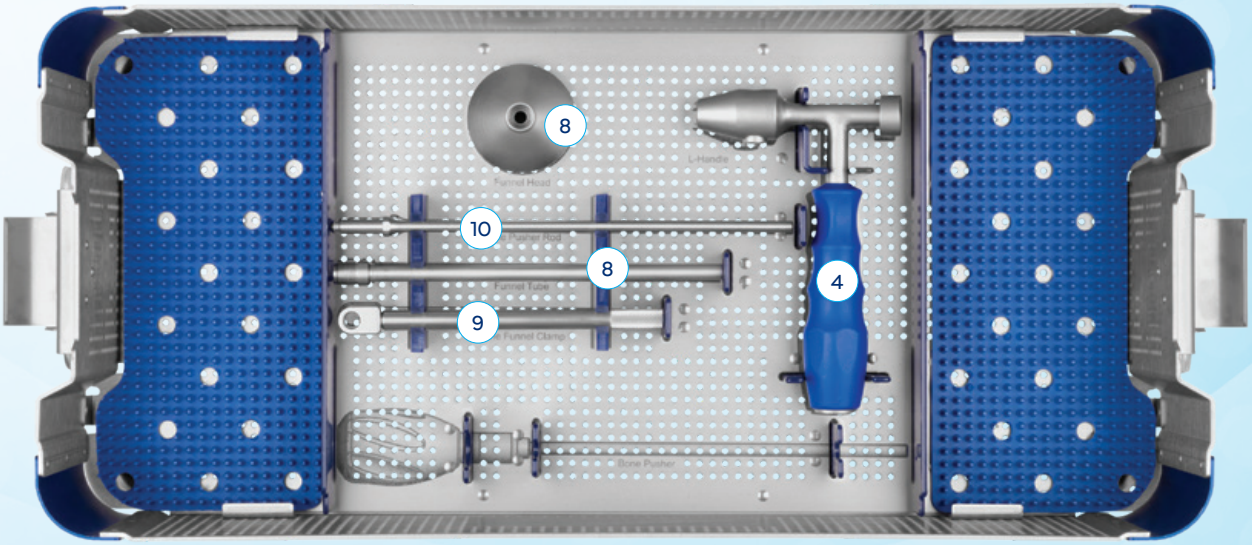
673.018	Push Rod, Bone Funnel
679.021	Bone Curette, Angled, 10.7 Serrated Cup
679.022	Bone Curette, Straight, 10.7 Serrated Cup
679.023	Bone Curette, Angled, 10.7 Serrated Cup
679.024	Bone Curette, Straight, 10.7 Serrated Cup
679.061	Bone Curette, 10.0 Rectangle Cup, 75° Up
679.062	Bone Curette, 10.0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

Additionally available

MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901







IMPORTANT INFORMATION ON SUSTAIN® SPACERS

DESCRIPTION

SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR, and SUSTAIN®-RT) are devices that can be used as intervertebral fusion devices or as vertebral body replacement devices. When used as interbody fusion devices, each of the spacers provides a different shape to accommodate various surgical approaches to the spine. SUSTAIN® Small, SUSTAIN®-IR, and SUSTAIN®-RT Spacers are inserted using a posterior or transforaminal approach. SUSTAIN® Arch Spacers are inserted using a transforaminal or lateral approach. SUSTAIN® Large Spacers are inserted using an anterior, anterolateral, or lateral approach. SUSTAIN® Oblique and SUSTAIN® G Spacers are inserted using a posterior, transforaminal, or lateral approach. These spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. Each spacer has an axial hole to allow grafting material to be packed inside the spacer.

These spacers are used to provide structural stability in skeletally mature individuals following discectomy, corpectomy, or vertebrectomy (including partial). All approaches may be used in the lumbar spine; only the anterior, anterolateral, or lateral approach may be used in the thoracic spine. An anterior approach is used in the cervical spine.

The SUSTAIN® Spacers are made from commercially pure titanium or titanium alloy as specified in ASTM F67, F136, and F1295. SUSTAIN® Radiolucent (SUSTAIN® R) and SUSTAIN® R TPS Spacers are made from radiolucent PEEK polymer with titanium alloy or tantalum markers as specified in ASTM F136, F560, F1295, and F2026. SUSTAIN® R TPS Spacers, SUSTAIN®-IR TPS Spacers and SUSTAIN®-RT TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDICATIONS

When used as thoracolumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR and SUSTAIN®-RT) are indicated 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. SUSTAIN® Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. 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). All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

When used as cervical intervertebral body fusion devices, SUSTAIN® Spacers including SUSTAIN® R are intended for one or more levels of the cervical spine C2-T1 in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six 6 weeks of non-operative treatment. All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

SUSTAIN® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. These devices are intended to be used with supplemental fixation, such as the ASSURE®, PROVIDENCE®, or XTEND® Anterior Cervical Plate Systems.

When used as vertebral body replacement devices, SUSTAIN® Spacers (including SUSTAIN® and SUSTAIN® R TPS) are intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with bone grafting material. SUSTAIN® Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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 involved level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

These warnings do not include all adverse effects that could occur with surgery in general, but are important consideration 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 these 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 may appear 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 SUSTAIN® 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 SUSTAIN® 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 SUSTAIN® 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 risk 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 instructions.
8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Pregnancy.
11. Any other condition that 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, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.
12. Any case not needing a fusion.
13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
15. Spondylolisthesis unable to be reduced to Grade 1.
16. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
17. Any case that requires the mixing of metals from two different components or systems.
18. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
19. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

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
- 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 implants 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.

IMPORTANT INFORMATION ON SUSTAIN® SPACERS

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, double pouch or 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	Rx ONLY	PRESCRIPTION USE ONLY

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NOTES

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Audubon, PA 19403
www.globusmedical.com

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

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