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REVEL™-S

Expandable Stand-Alone ACDF Spacer

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

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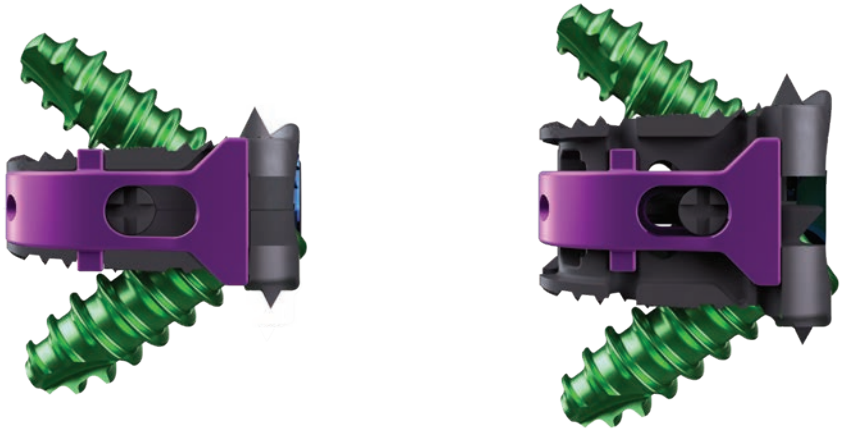
REVEL™-S

Expandable Stand-Alone ACDF Spacer

REVEL™-S is an all-titanium, expandable stand-alone ACDF spacer designed to restore segmental height and cervical lordosis while reducing impaction forces and providing controlled, continuous expansion.



REVEL™-S is designed for:

Controlled Expansion

REVEL™-S continuously expands up to 3mm to help maximize indirect decompression and allows for up to 12° of lordosis.

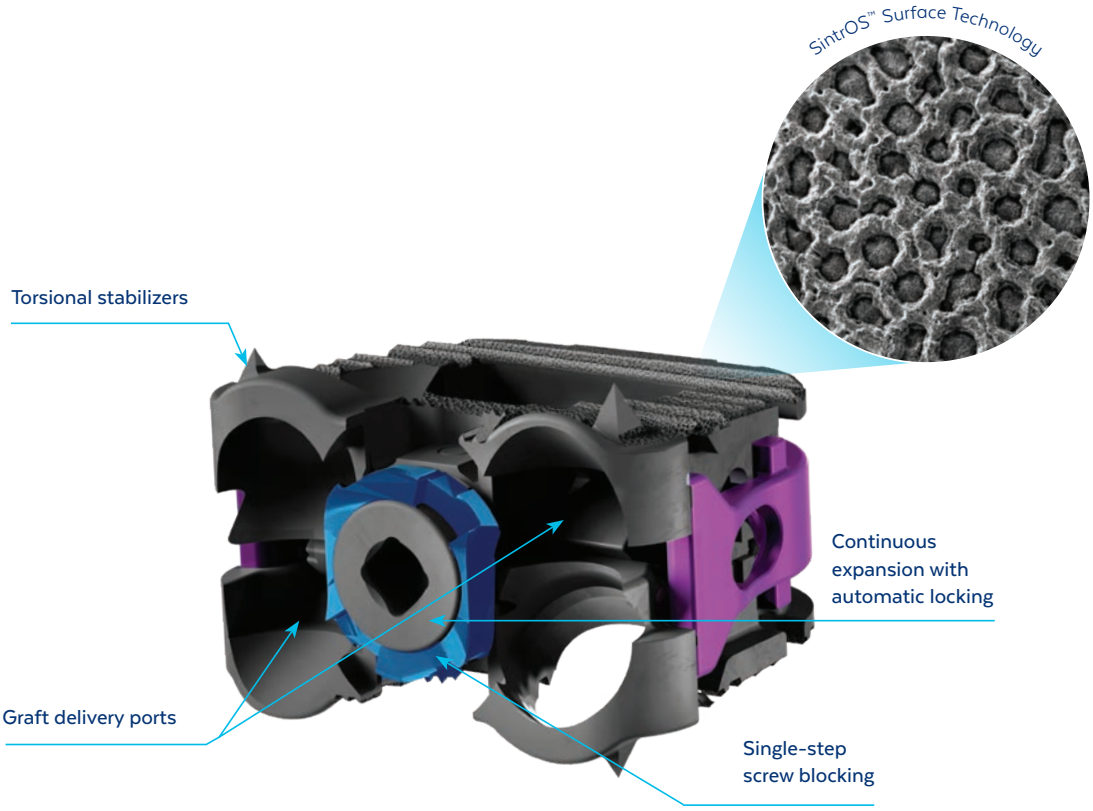
Minimized Impaction

Inserted at a contracted height to ease insertion and reduce impaction, to help preserve endplate integrity.

Maximized Fusion Potential

Endplates are treated with SintrOS™ laser etched surface technology designed to encourage cellular activity at the bone interface* coupled with post-expansion delivery of bone graft.

Cell study data on file

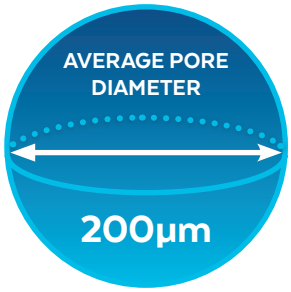


SintrOS™ titanium laser-etched surface technology features a biomimetic texture designed to encourage cellular activity at the bone interface.[1]

BONE INSPIRED

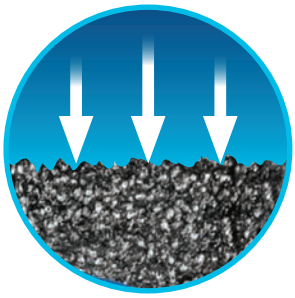
Pore structure is designed to mimic osteoclast resorption pits in bone.

CONTROLLED PORE SIZE



Pore diameter ranges from 100µm to 300µm.

ENCOURAGES CELLULAR ACTIVITY



Small pores (<300µm) have been shown to support initial surface adhesion in *in vitro* testing.[2]

1. *Cell study data on file*
2. Torres-Sanchez et al. *Material Science and Engineering.* 2017 Mar; 219-228.

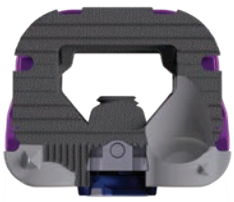
IMPLANT OVERVIEW

Spacer Options

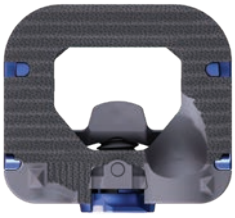
- All-titanium spacer
- Three axial footprints: 12x14, 14x16, 15x18mm
- Height ranges from 5-10mm
  - 5-8mm, 6-9mm, 7-10mm
- Sagittal profiles: 0°, 7°, 12°
- SintrOS™ Surface Technology
  - 5-8mm; available with roughened texture

Features

- Minimized need for trialing due to expansion capabilities
- Implant inserted at a contracted height
- Controlled continuous expansion up to 3mm
- Automatic expansion locking
- Streamlined instrumentation
- Integrated fixation
- SintrOS™ Surface Technology



12x14mm

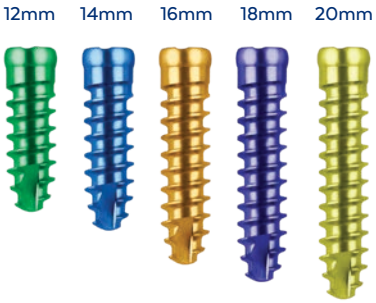


14x16mm

15x18mm

Screw Options

- Fixed and variable angle screws (±4°)
- Five screw lengths: 12, 14, 16, 18, 20mm
- Two screw diameters: 3.6mm, 4.2mm
- Self-drilling and self-tapping



Variable Angle Screw

Fixed Angle Screw

Items in gray are additionally available.

INSTRUMENT OVERVIEW

DISTRACTION INSTRUMENTS

The Universal ACDF Instrument Set, 9147.9001 is required.

Distractor, Left 601.020

Distractor, Right 601.021

Distractor Locking Nuts 665.606

Distractor Pin Driver 665.608

Distractor Pins

Height	Part No.	
12mm	665.612	
14mm	665.614	
16mm	665.616	
18mm	665.618	

REVEL™ MODULAR TRIALS

Module Handle Inner Shaft Assembly 6147.9002

Trial Holder, Modular Trial/Rasp Heads - Outer Sleeve 6147.9001

12x14mm		
Height	0°	7°
5mm	6131.0005	6131.0105
6mm	6131.0006	6131.0106
7mm	6131.0007	6131.0107
8mm	6131.0008	6131.0108
9mm	6131.0009	6131.0109
10mm	6131.0010	6131.0110

14x16mm		
Height	0°	7°
5mm	6131.1005	-
6mm	6131.1006	6131.1106
7mm	6131.1007	6131.1107
8mm	6131.1008	6131.1108
9mm	6131.1009	6131.1109
10mm	6131.1010	6131.1110

15x18mm		
Height	0°	7°
5mm	6131.2005	-
6mm	6131.2006	6131.2106
7mm	6131.2007	6131.2107
8mm	6131.2008	6131.2108
9mm	6131.2009	6131.2109
10mm	6131.2010	6131.2110

IMPLANT INSERTION INSTRUMENTS

Thumb Wheel 6131.6001.02

Outer Sleeve 6131.6001.03

Inner Shaft 6131.6001.01

Midline Holder 6131.6001 (Assembled)

Size	Part No.
5-8mm	6131.6105
6-9mm	6131.6106
7-10mm	6131.6107

Midline Tips

Expansion Driver, Torque-Limiting, 1Nm 6131.6002

Blocking Positioner, 6131.6102

Torque-Limiting, Quick-Connect Handle, 0.3Nm 697.312

BONE PACKING INSTRUMENTS

Bone Packing Pusher, 6131.6005

Bone Packing Funnel, 6131.6004

Bone Packing Funnel Tip, 6131.6006

Assembled Bone Funnel and Bone Funnel Tip

STRAIGHT INSTRUMENTS

Quick-Connect Handle, Swivel 636.450

Awl, Straight with Self-Centering Sleeve 684.403

Tap Straight, 684.004

Awl with Retractable Sleeve 684.006

Drills, Straight with Self-Centering Sleeve

Lengths	Part No.
12mm	684.422
14mm	684.424
16mm	684.426
18mm	684.428
20mm	684.430

Screwdriver, 2.5mm Hex, Self-Retaining, with Cap 684.305

ANGLED INSTRUMENTS

Awl, Bent with Self-Centering Sleeve 684.404

Angled Driver (Sleeve) Body 684.415

Backing Nut 684.416

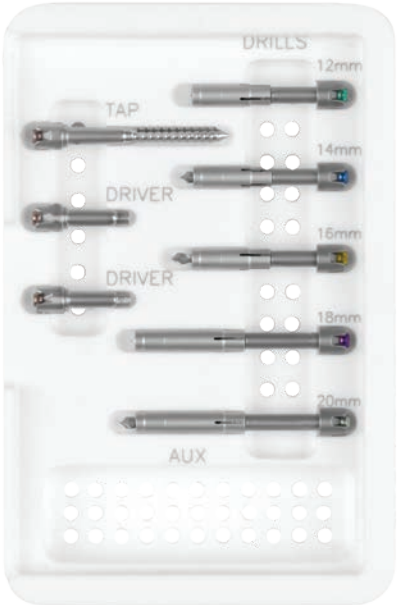
Counter-Torque 684.421

Angled Driver Shaft 684.417

Angled Driver Assembly
Angled Drill, 14mm with Self-Centering Sleeve 684.434
Angled Driver Body 684.415
Backing Nut 684.416
Angled Driver Shaft 684.417

Angled Tap, Driver, and Drills

Instrument	Part No.
Angled Tap	684.419
Angled Driver	684.418
Angled Driver	684.418
Angled Drill, 12mm	684.432
Angled Drill, 14mm	684.434
Angled Drill, 16mm	684.436
Angled Drill, 18mm	684.438
Angled Drill, 20mm	684.440



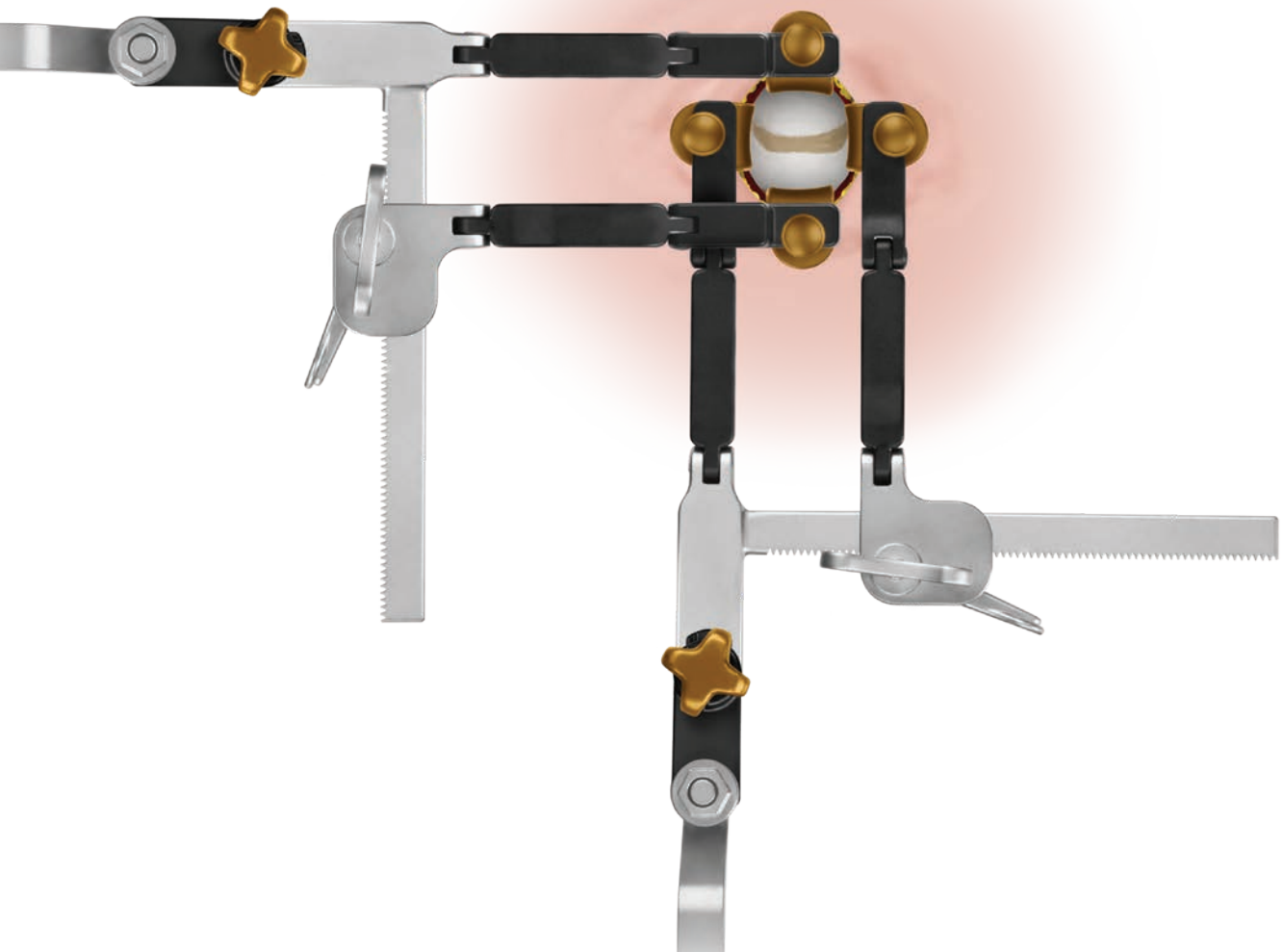
SURGICAL TECHNIQUE

REVEL™-S

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

STEP 1 SURGICAL APPROACH

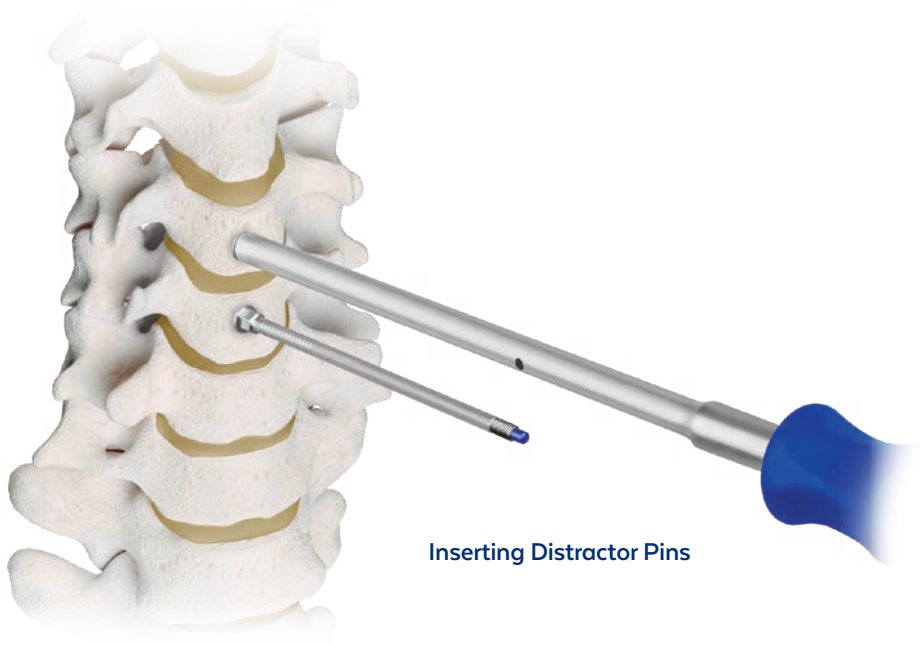
An anterior cervical approach is used to implant REVEL™-S. The patient is placed under anesthesia and positioned supine with support of the posterior cervical spine to maintain cervical lordosis. The operative area is carefully cleaned and an incision is made at the appropriate fusion level. Traditional cervical retractors may be used.



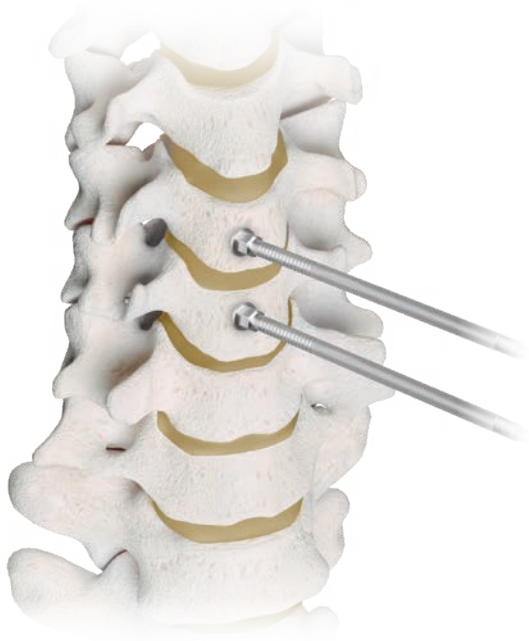
STEP 2 DISTRACTION

Distraction may be accomplished using the **Distractor** available in this system or other standard methods.

To use the Distractor, determine placement of the distractor pins within the vertebral bodies. Select the appropriate pin length and place the **Distractor Pins** into adjacent vertebral bodies using the **Distractor Pin Driver**. Care should be taken when placing pins to avoid interference with any subsequently placed screws or supplemental fixation.



Inserting Distractor Pins



Distractor Pins inserted

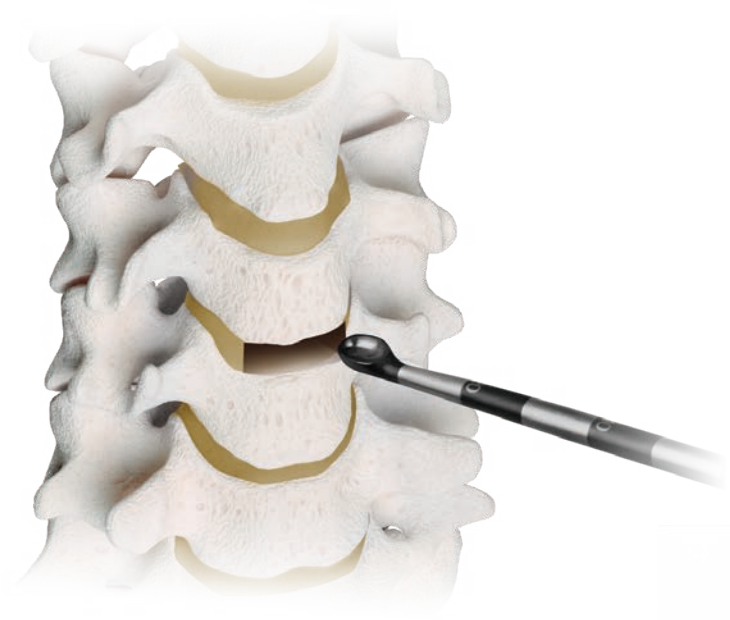
Place the Distractor, right or left as desired, over pins until seated. Once seated, secure the Distractor in place by attaching the **Distractor Locking Nuts** and rotating clockwise until secured. Rotate the ratchet handle to distract to the desired amount, being careful not to over-distract the segment. Distraction may be used throughout the technique to provide visualization and access to the disc and osseous structures.

Distracting disc space using Distractor

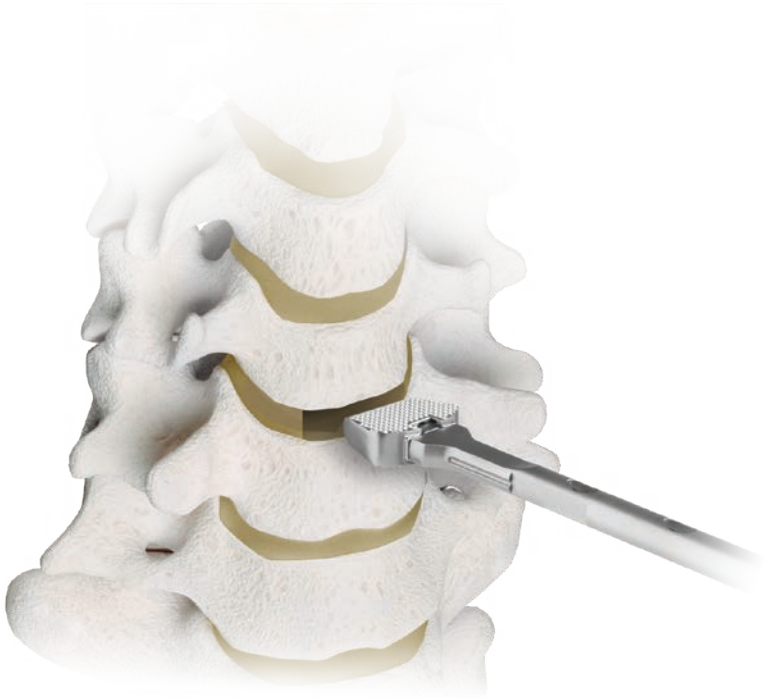
STEP 3 DISCECTOMY/ENDPLATE PREPARATION

Expose the disc space. Leaving the lateral annulus intact, remove the intervertebral disc and the osteophytes, using rongeurs, curettes, rasps and other instruments as needed. Remove the superficial layers of the cartilaginous endplates to expose bleeding bone; trial spacer rasps may be used for this purpose. The lateral walls of the annulus should be preserved to provide peripheral support for the implant and bone graft material. Distraction pins may be removed before insertion of the implant but are optional if needed to maintain distraction of the disc space.

Note: Excessive endplate preparation may weaken the vertebral endplates and may result in subsidence.



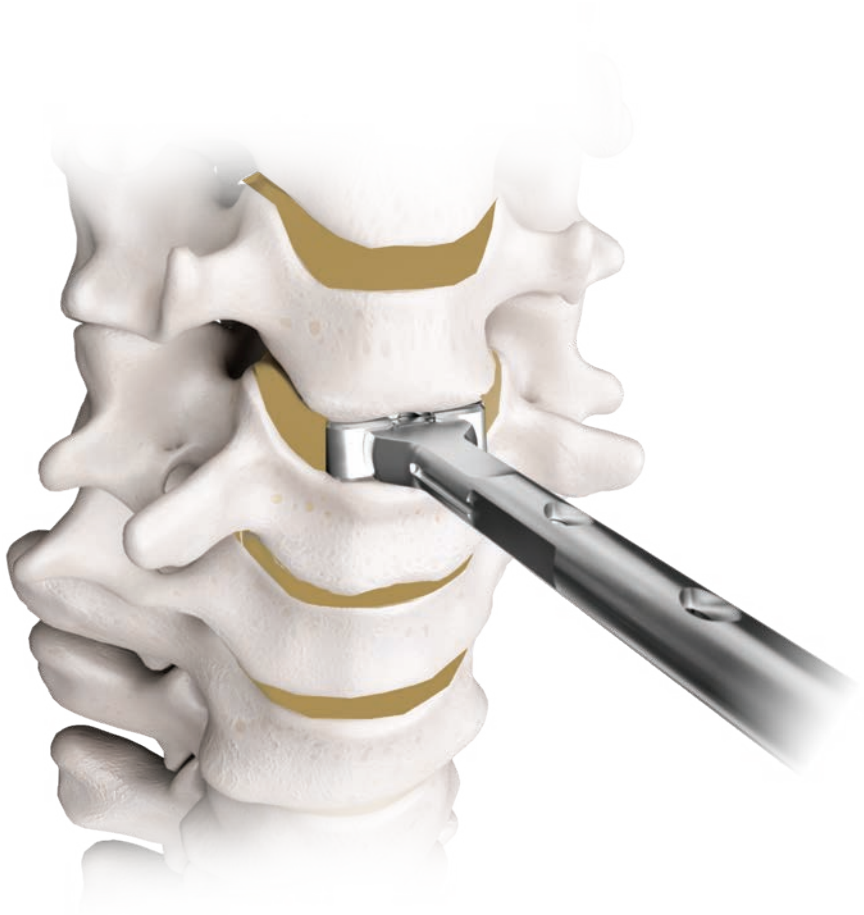
Endplate preparation using Box Curette



Endplate preparation using Trial Rasp

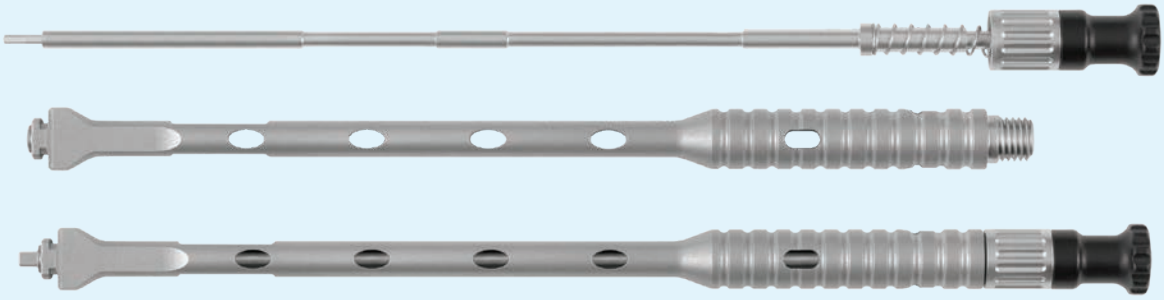
STEP 4 SPACER SIZING

Determine the most suitable spacer profile for the desired segment. Refer to the section titled “Using the Modular Trial System” for detailed instructions on use of the modular trials. Insert the smallest **Modular Trial Head** into the disc space first, moving to larger trials as needed. Determine which trial best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment. Confirm using fluoroscopy and tactile feedback. After the size has been determined, proceed to implant insertion.

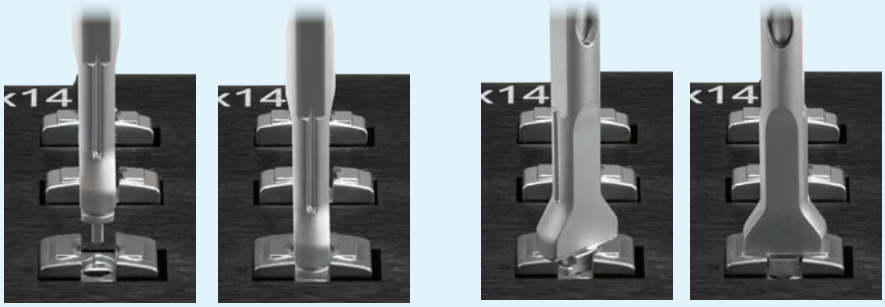


Trialing for spacer size

USING THE MODULAR TRIAL SYSTEM



The Trial Holder is provided in two parts (inner shaft and outer sleeve). To assemble, thread the inner shaft and outer sleeve together by turning the silver thumb wheel clockwise. To load a Modular Trial or Rasp Head on the Trial Holder, insert the tip of the holder into the notch in the appropriate trial or rasp head and rotate clockwise 90°, as shown below.



Trial Holder inserted into Modular Trial *Trial Holder rotated 90° to fully load*

Loading Modular Trial Onto Trial Holder

Confirm that the trial or rasp head is fully engaged with the holder and that the black knob is in the lock position.

To remove the trial or rasp head from the holder, pull the black knob on the distal end of the holder and rotate counterclockwise to the “UNLOCK” position.

To reconnect or connect to a different trial or rasp head, insert the tip of the trial holder into a new head, and rotate clockwise 90°. Rotate the black knob clockwise until it is back in the “LOCK” position.

STEP 5 IMPLANT INSERTION

ASSEMBLING THE MIDLINE HOLDER

To assemble the **Midline Holder**, slide the **Thumb Wheel** into the **Outer Sleeve** as shown below.

Thumb Wheel Outer Sleeve

Inner Shaft

Slide the **Inner Shaft** through the Thumb Wheel and the Outer Sleeve assembly while rotating the Thumb Wheel counterclockwise until the Inner Shaft cannot be advanced any farther. The midline implant holder is ready to accept the **Midline Tip**.

Assembled Midline Holder

Thread the midline tip clockwise into the distal portion of the midline holder until it cannot be advanced any farther.

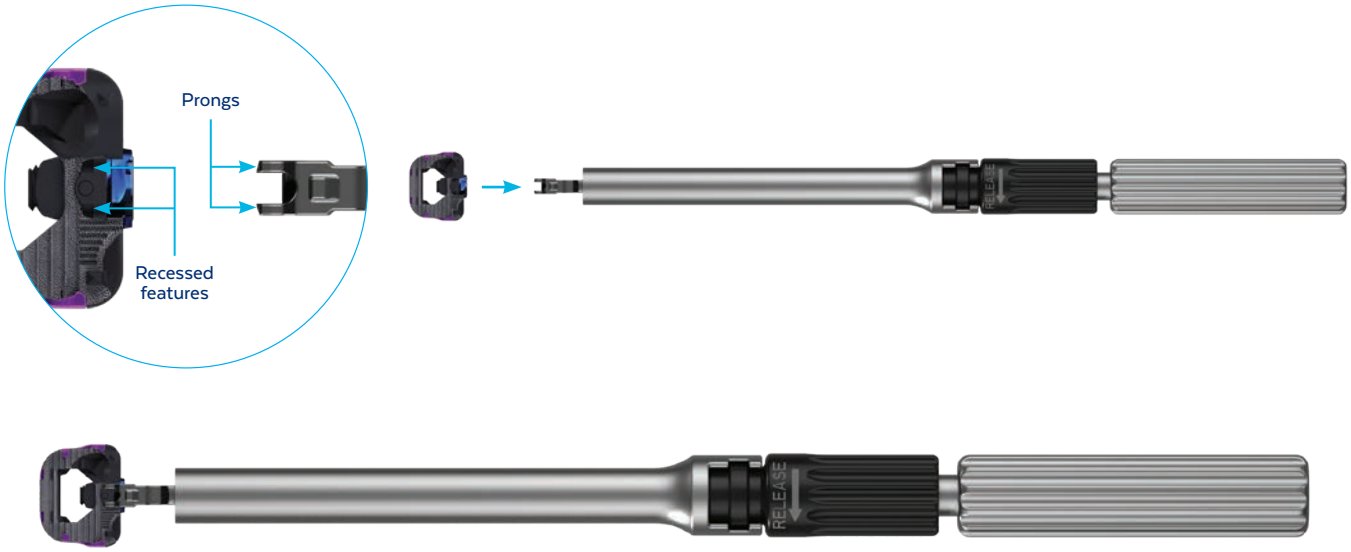
Midline Tip

Assembled Midline Holder with Midline Tip

IMPLANT INSERTION (CONT'D)

Select an appropriately sized implant and pack with autograft bone and/or allogenic bone graft composed of cortical, cancellous, and/or corticocancellous bone. The Midline Holder is used to insert the implant into the intervertebral space.

In order to attach the implant to the tip of the Midline Holder, insert the prongs of the midline tip into the recess features on the selected implant. Rotate the thumb wheel clockwise until the Outer Sleeve stops and the implant is secured onto the Midline Holder.



Implant loaded onto Midline Holder

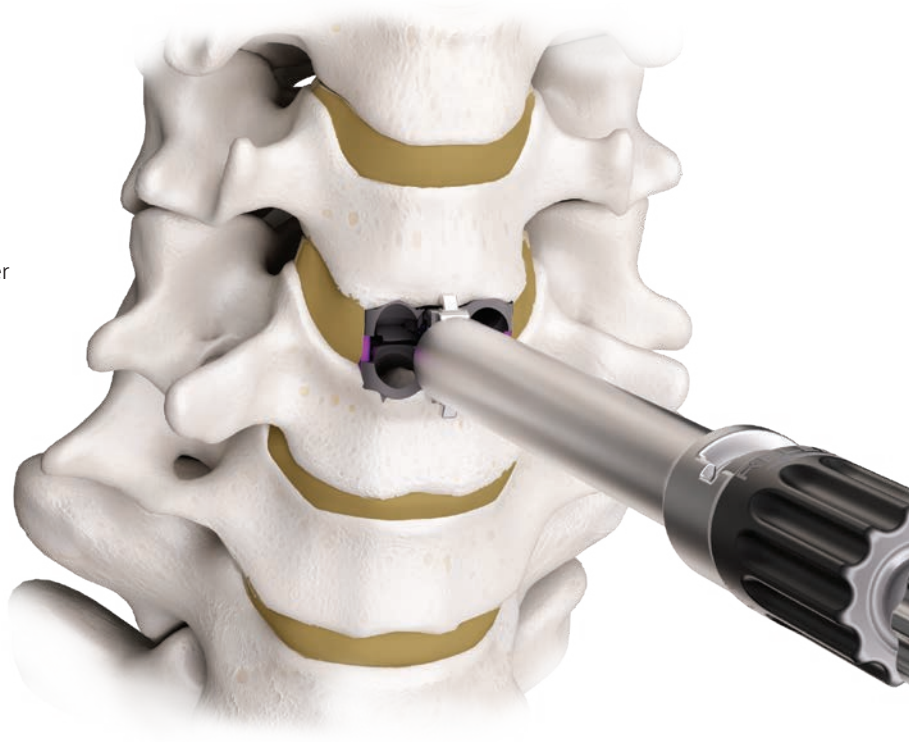
Insert the implant into the disc space. The implant should be flush or slightly recessed. Confirm placement using fluoroscopy.

Implant insertion

STEP 6 EXPANSION

Insert the **Expansion Driver, Torque-Limiting, 1Nm** into the shaft of the Midline Holder. Ensure the square tip of the driver is seated in the actuator screw and rotate clockwise until the desired height is achieved. Use fluoroscopy and tactile feedback to confirm proper placement and expansion.

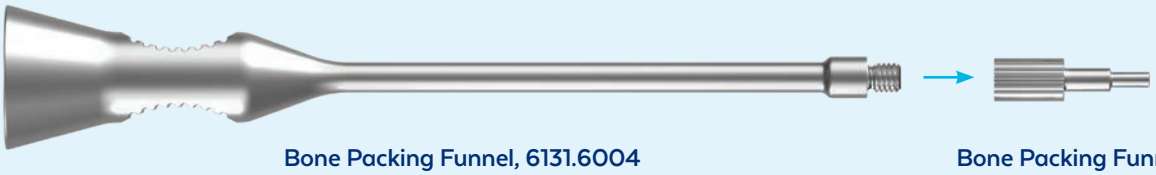
1 rotation = 0.4mm



Implant expansion

ASSEMBLING THE BONE PACKING FUNNEL

Thread the **Bone Packing Funnel Tip** clockwise to the distal end of the **Bone Packing Funnel**.



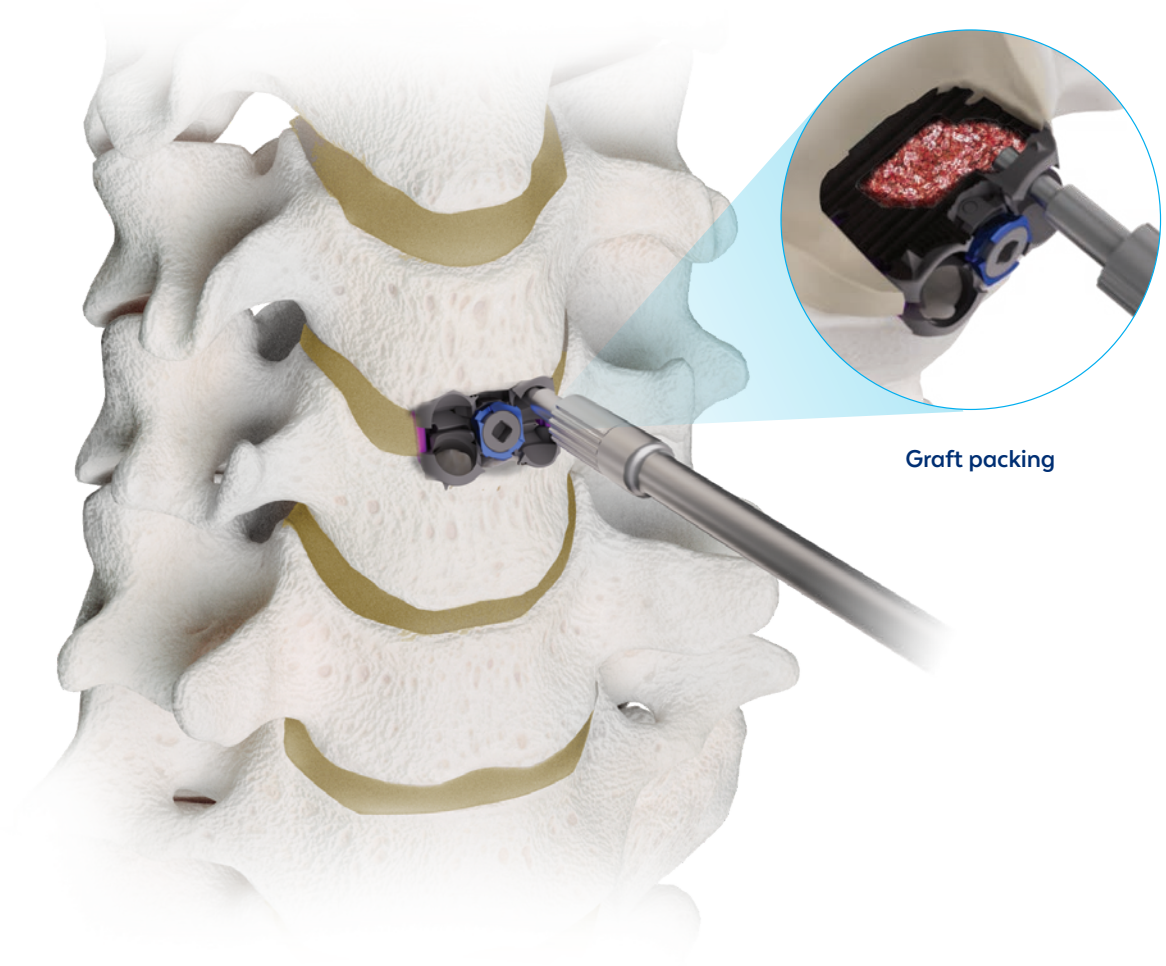
Bone Packing Funnel, 6131.6004

Bone Packing Funnel Tip, 6131.6006

Assembled Bone Packing Funnel

STEP 7 EXPANSION GRAFT DELIVERY

Once expansion is complete, remove the holder by rotating counterclockwise on the thumb wheel. Additional autograft bone and/or allogenic bone graft composed of cortical, cancellous, and/or corticocancellous bone may be inserted through the fixation holes using the Bone Packing Funnel and Pusher if needed.



STEP 8 SCREW PREPARATION

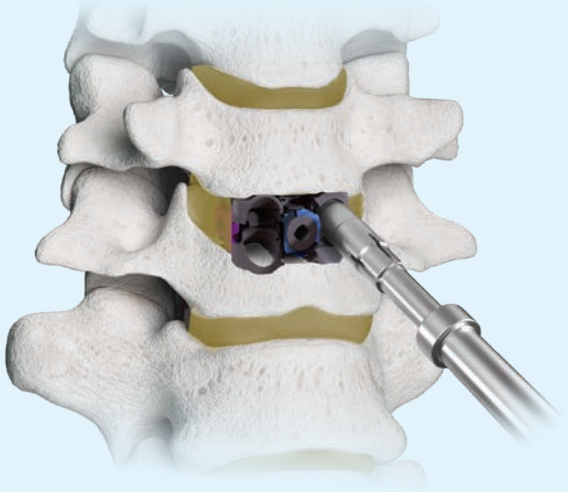
Universal ACDF Set (9147.9001) is required.

USING SELF-CENTERING INSTRUMENTS

Self-centering awls (bent and straight) and drills are available for screw trajectories up to 35° cephalad/caudal.

Insert the spacer into the disc space.

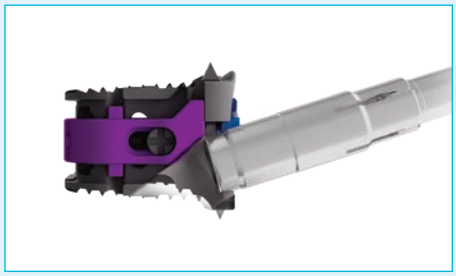
After the spacer is inserted into the disc space, use an **Awl with Self-Centering Sleeve** to break the cortex. A **Self-Centering Drill and Tap** may be used to further prepare the screw hole. Depending on the angle and position, a straight or angled instrument may be used.



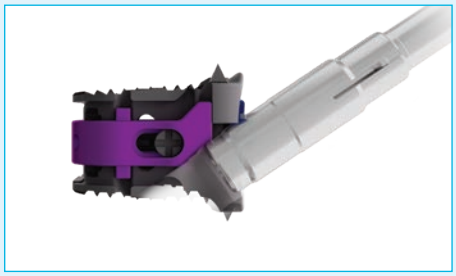
Awl insertion

Aligning the Self-Centering Sleeve

The **Self-Centering Sleeve** helps to ensure proper screw trajectory without the use of a drill guide. The sleeve must be properly engaged with the screw hole on the implant before advancing a screw hole preparation instrument. Proceed to screw insertion prior to preparing the remaining screw hole.



INCORRECT



CORRECT

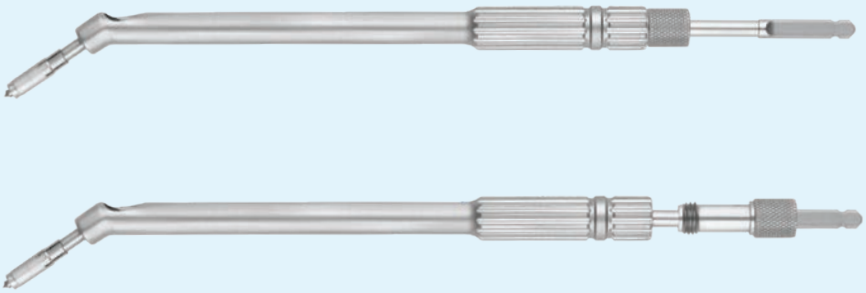
ASSEMBLING THE ANGLED INSTRUMENTS

1. Select the appropriate Angled Driver, Angled Drill, or Angled Tap for assembly with the **Angled Driver Body** and **Angled Driver Shaft**.

2. Hold the Angled Driver Body pointed downward with the cutout facing upward. Insert the selected tip into the cutout on the distal end of the driver body.

3. Insert the Angled Driver Shaft into the driver body until the gears on the shaft mesh with the gears on the selected tip.

4. Place the **Backing Nut** over the shaft. Rotate the threads clockwise until the nut sits flush with the driver body.

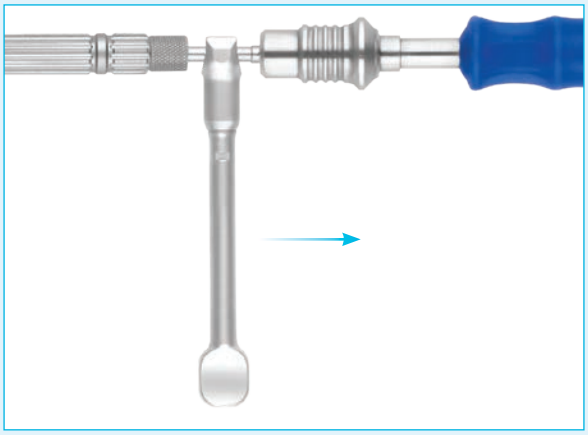


5. Attach a **Quick-Connect Handle, Swivel**. The driver is now ready for use.

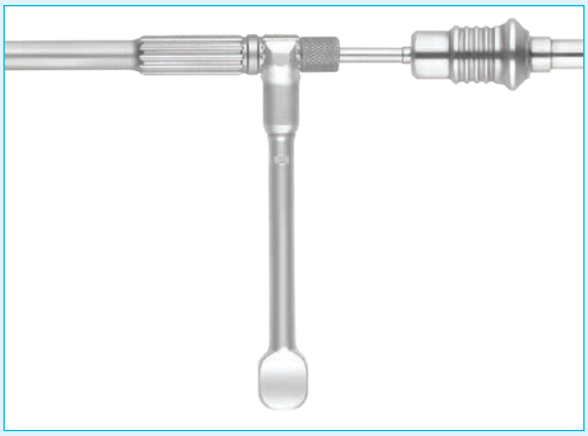
ASSEMBLING THE ANGLED INSTRUMENTS (CONT'D)

6. For additional control, a **Counter-Torque** handle may be attached to the Angled Instruments.

   Starting from the top, slide the Counter-Torque from the smooth portion of the Angled Driver Body to the knurled portion until fully seated.

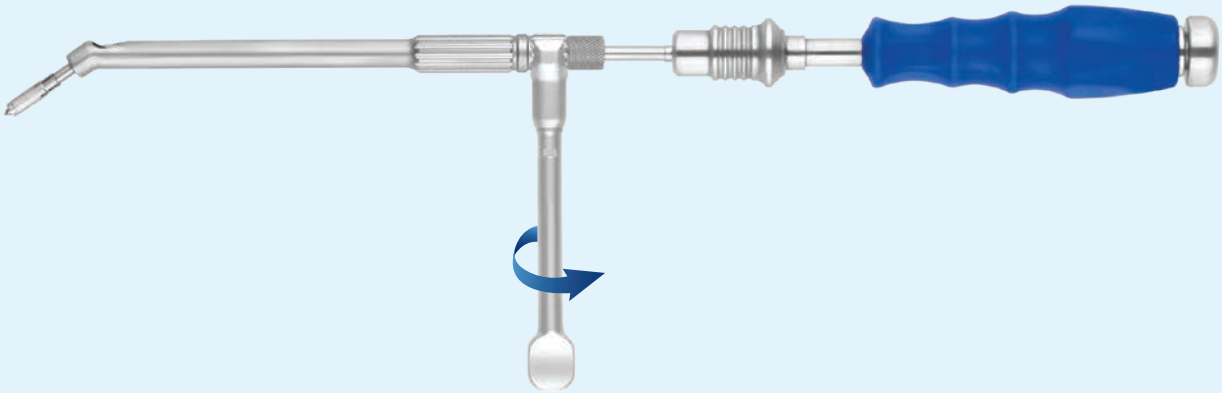


Attaching Counter-Torque



Counter-Torque in final position

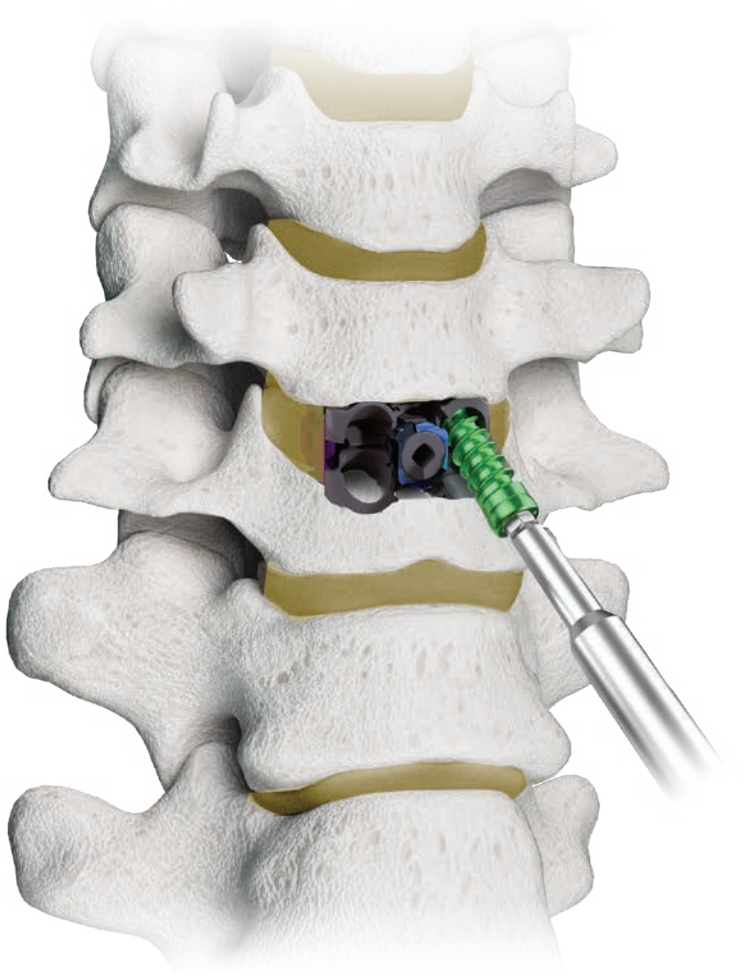
7. Rotate the Counter-Torque clockwise to final tighten.



STEP 9 SCREW INSERTION

Depending on the angle and position of the spacer, a **Straight** or **Angled Driver** may be used. If drilling is preferred, determine the desired drill depth and select the appropriate fixed length drill. Insert the drill into the screw hole and drill to the stop.

Select the appropriate length screw, load onto the driver, and insert the screw. Repeat for the second screw.



Screw insertion

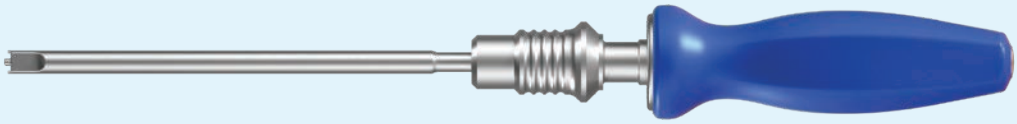
STEP 10 SCREW BLOCKING

ASSEMBLING THE BLOCKING POSITIONER

Attach the Blocking Positioner to the Torque-Limiting, Quick-Connect Handle. The Blocking Positioner is now ready to use.

Blocking Positioner

Torque-Limiting, Quick-Connect Handle, 0.3Nm 697.312



Blocking Positioner assembled with Torque-Limiting, Quick-Connect Handle, 0.3Nm

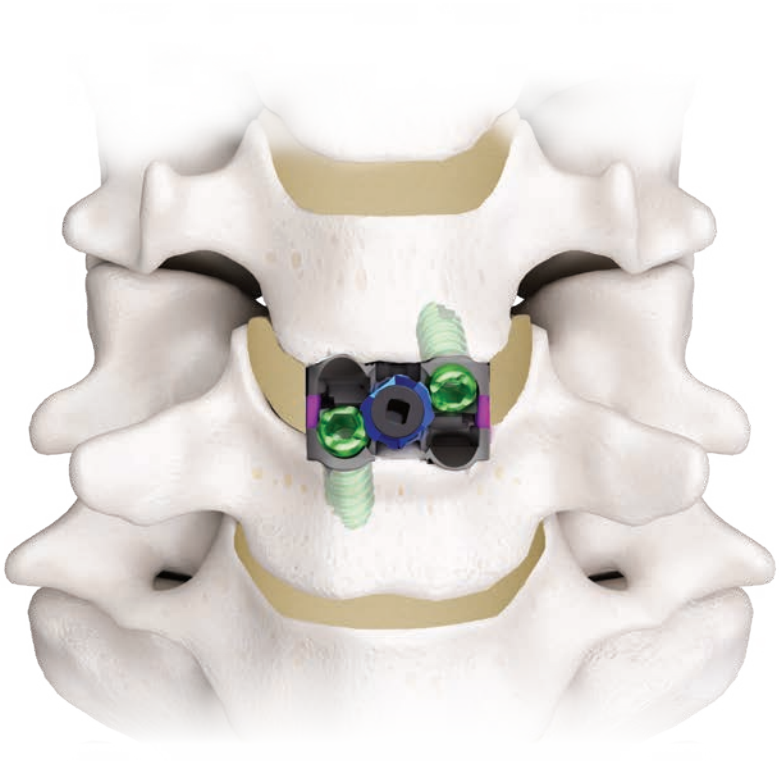
Once the screws are fully seated, use the **0.3Nm Torque-Limiting, Blocking Positioner** to secure the **Blocking Ring**.

Note: Hyperlordotic (≥20°) devices must be used with supplemental fixation, in addition to the two bone screws.

Initial position
Blocking Ring unblocked

Final position
Blocking Ring blocked

FINAL CONSTRUCT



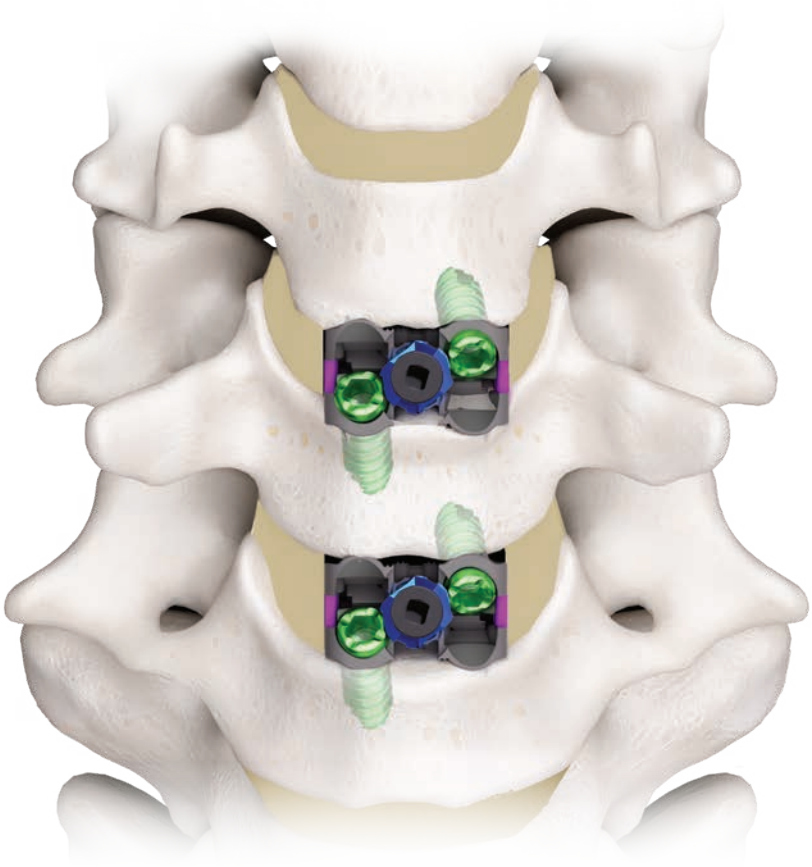
Anterior view

Axial view

OPTIONAL TECHNIQUE: 2-LEVEL INSERTION

To implant a second spacer at an adjacent level, repeat steps 2-10.

Final Two-Level Construct

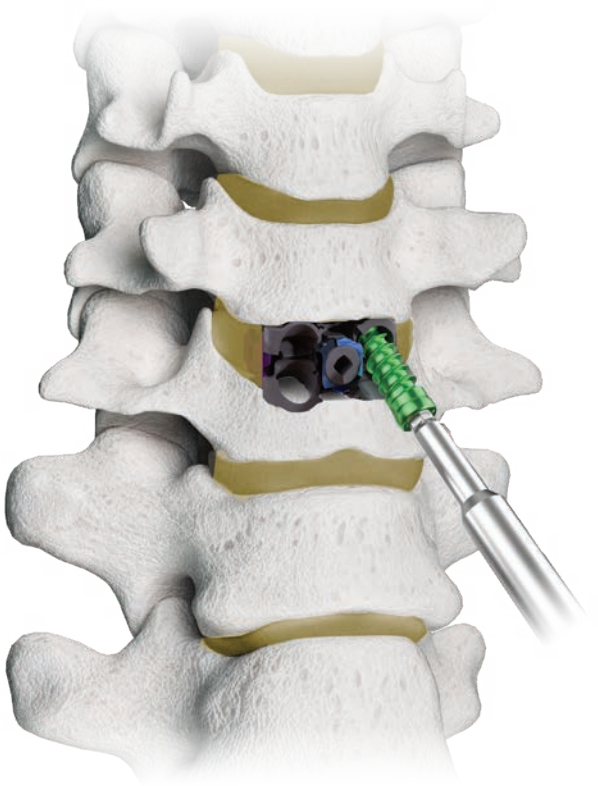


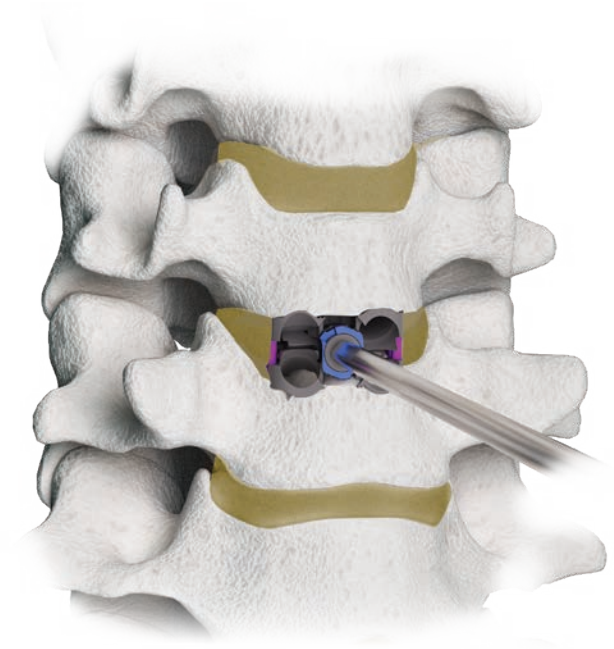
Coronal/AP view

OPTIONAL: IMPLANT OR SCREW REMOVAL

For screw removal, rotate the blocking ring 90° counterclockwise. Remove the screws using a screwdriver.

Initial position
Blocking set screw unlocked

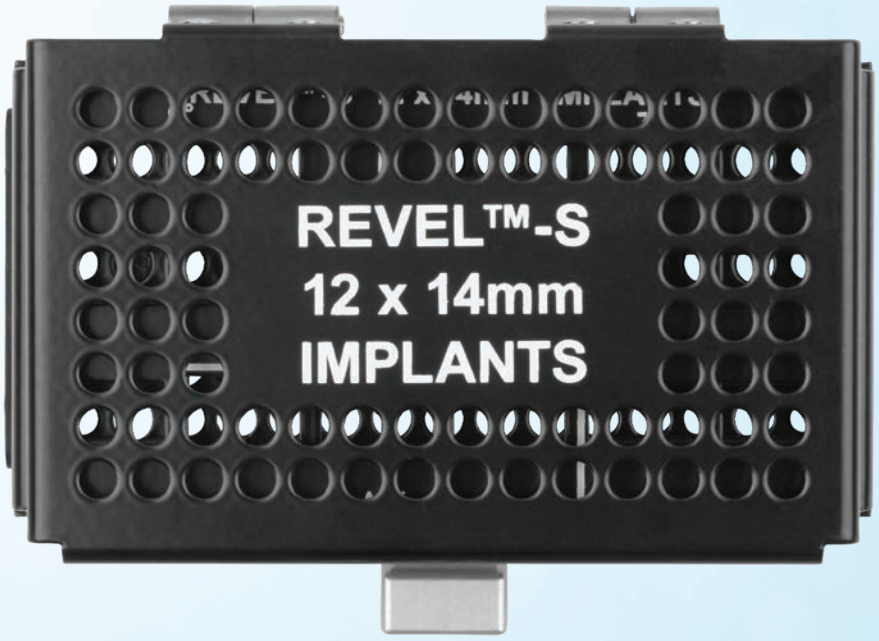




For implant removal, insert the Expansion Driver, Torque-Limiting, 1Nm, and rotate the actuator screw counterclockwise until the implant is fully collapsed. The implant may be removed using the Midline Holder with Midline Tip, forceps, or other manual surgical instruments. In the event of a fracture, follow removal steps, including a partial corpectomy if necessary.

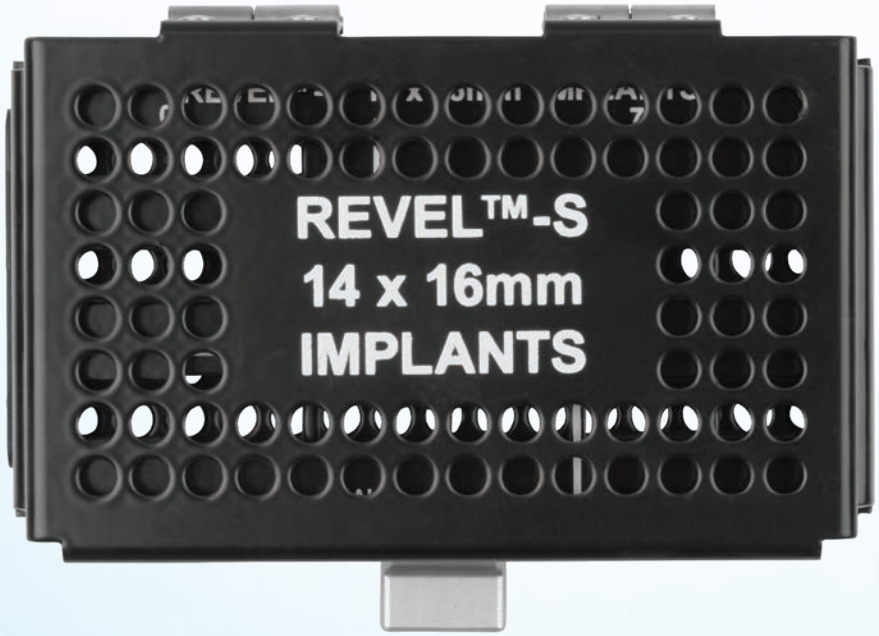
REVEL™-S 12x14mm
IMPLANT SET 9131.9102

Part No.	Description	Qty
1131.0005	REVEL™-S, 12x14mm, 0°, 5-8mm	2
1131.0006	REVEL™-S, 12x14mm, 0°, 6-9mm	2
1131.0007	REVEL™-S, 12x14mm, 0°, 7-10mm	1
1131.0105	REVEL™-S, 12x14mm, 7°, 5-8mm	3
1131.0106	REVEL™-S, 12x14mm, 7°, 6-9mm	3
1131.0107	REVEL™-S, 12x14mm, 7°, 7-10mm	2
9131.0102	REVEL™-S 12x14mm Implant Module	



REVEL™-S 14x16mm
IMPLANT SET 9131.9103

Part No.	Description	Qty
1131.1005	REVEL™-S, 14x16mm, 0°, 5-8mm	2
1131.1006	REVEL™-S, 14x16mm, 0°, 6-9mm	2
1131.1007	REVEL™-S, 14x16mm, 0°, 7-10mm	1
1131.1106	REVEL™-S, 14x16mm, 7°, 6-9mm	3
1131.1107	REVEL™-S, 14x16mm, 7°, 7-10mm	2
9131.0103	REVEL™-S 14x16mm Implant Module	

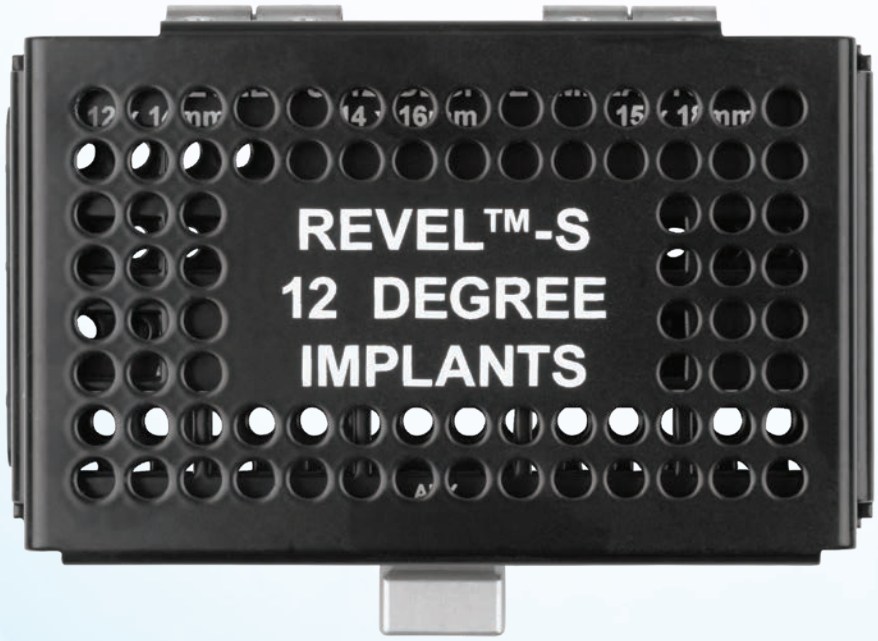


REVEL™-S 15x18mm
IMPLANT SET 9131.9104

Part No.	Description	Qty
1131.2005	REVEL™-S, 15x18mm, 0°, 5-8mm	2
1131.2006	REVEL™-S, 15x18mm, 0°, 6-9mm	2
1131.2007	REVEL™-S, 15x18mm, 0°, 7-10mm	1
1131.2106	REVEL™-S, 15x18mm, 7°, 6-9mm	3
1131.2107	REVEL™-S, 15x18mm, 7°, 7-10mm	2
9131.0104	REVEL™-S 15x18mm Implant Module	

REVEL™-S 12°
IMPLANT SET 9131.9108

Part No.	Description	Qty
1131.0206	REVEL™-S, 12x14mm, 12°, 6-9mm	2
1131.0207	REVEL™-S, 12x14mm, 12°, 7-10mm	2
1131.1207	REVEL™-S, 14x16mm, 12°, 7-10mm	2
1131.2207	REVEL™-S, 15x18mm, 12°, 7-10mm	2
9131.0108	REVEL™-S 12° Implant Module	



TRIAL MODULES

12x14 Trial Module 9131.9001

Part No.	Description	Qty
6131.0005	Modular Trial, 12x14mm, 0°, 5mm	1
6131.0006	Modular Trial, 12x14mm, 0°, 6mm	1
6131.0007	Modular Trial, 12x14mm, 0°, 7mm	1
6131.0009	Modular Trial, 12x14mm, 0°, 9mm	1
6131.0010	Modular Trial, 12x14mm, 0°, 10mm	1
6131.0105	Modular Trial, 12x14mm, 7°, 5mm	1
6131.0106	Modular Trial, 12x14mm, 7°, 6mm	1
6131.0107	Modular Trial, 12x14mm, 7°, 7mm	1
6131.0109	Modular Trial, 12x14mm, 7°, 9mm	1
6131.0110	Modular Trial, 12x14mm, 7°, 10mm	1
9131.0001	REVEL™ 12x14mm Trial Module	

14x16 Trial Module 9131.9002

Part No.	Description	Qty
6131.1005	Modular Trial, 14x16mm, 0°, 5mm	1
6131.1006	Modular Trial, 14x16mm, 0°, 6mm	1
6131.1007	Modular Trial, 14x16mm, 0°, 7mm	1
6131.1009	Modular Trial, 14x16mm, 0°, 9mm	1
6131.1010	Modular Trial, 14x16mm, 0°, 10mm	1
6131.1106	Modular Trial, 14x16mm, 7°, 6mm	1
6131.1107	Modular Trial, 14x16mm, 7°, 7mm	1
6131.1109	Modular Trial, 14x16mm, 7°, 9mm	1
6131.1110	Modular Trial, 14x16mm, 7°, 10mm	1
9131.0002	REVEL™ 14x16 Trial Module	

15x18 Trial Module 9131.9003

Part No.	Description	Qty
6131.2005	Modular Trial, 15x18mm, 0°, 5mm	1
6131.2006	Modular Trial, 15x18mm, 0°, 6mm	1
6131.2007	Modular Trial, 15x18mm, 0°, 7mm	1
6131.2009	Modular Trial, 15x18mm, 0°, 9mm	1
6131.2010	Modular Trial, 15x18mm, 0°, 10mm	1
6131.2106	Modular Trial, 15x18mm, 7°, 6mm	1
6131.2107	Modular Trial, 15x18mm, 7°, 7mm	1
6131.2109	Modular Trial, 15x18mm, 7°, 9mm	1
6131.2110	Modular Trial, 15x18mm, 7°, 10mm	1
9131.0003	REVEL™ 15x18mm Trial Module	

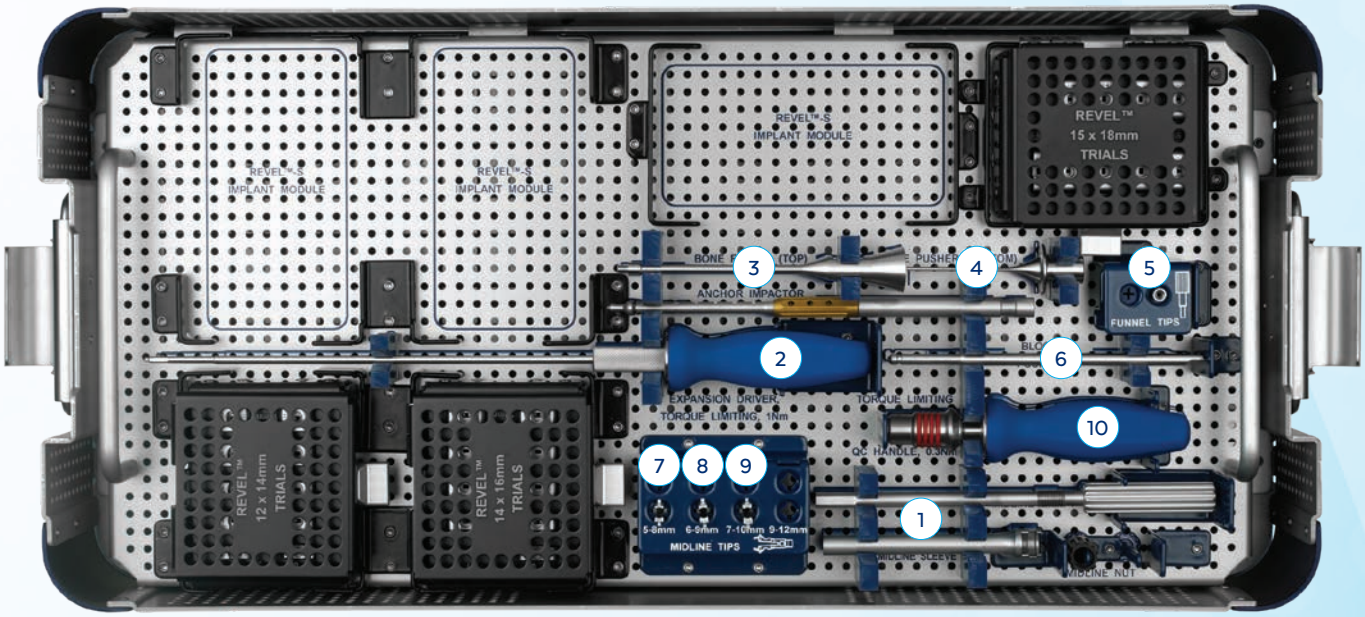
12° Trial Module 9131.9008

Part No.	Description	Qty
6131.0206	Modular Trial, 12x14mm, 12°, 6mm	1
6131.0207	Modular Trial, 12x14mm, 12°, 7mm	1
6131.0209	Modular Trial, 12x14mm, 12°, 9mm	1
6131.0210	Modular Trial, 12x14mm, 12°, 10mm	1
6131.1207	Modular Trial, 14x16mm, 12°, 7mm	1
6131.1209	Modular Trial, 14x16mm, 12°, 9mm	1
6131.1210	Modular Trial, 14x16mm, 12°, 10mm	1
6131.2207	Modular Trial, 15x18mm, 12°, 7mm	1
6131.2209	Modular Trial, 15x18mm, 12°, 9mm	1
6131.2210	Modular Trial, 15x18mm, 12°, 10mm	1
9131.0008	REVEL™ 12° Trial Module	

REVEL™-S
INSTRUMENT SET 9131.9101

	Part No.	Description	Qty
1	6131.6001	Midline Holder	2
2	6131.6002	Expansion Driver, Torque-Limiting, 1Nm	1
3	6131.6004	Bone Packing Funnel - 2mm	1
4	6131.6005	Bone Packing Pusher - 2mm	1
5	6131.6006	Bone Packing Funnel Tip - 2mm	2
6	6131.6102	Blocking Positioner, Torque-Limiting, 0.15Nm	1
7	6131.6105	Midline Tip, 5-8mm	2
8	6131.6106	Midline Tip, 6-9mm	2
9	6131.6107	Midline Tip, 7-10mm	2
10	697.3120	Torque-Limiting Quick-Connect Handle, 0.3Nm	1
	9131.0101	REVEL™-S Graphic Case	

REVEL™-S
INSTRUMENT SET 9131.9101



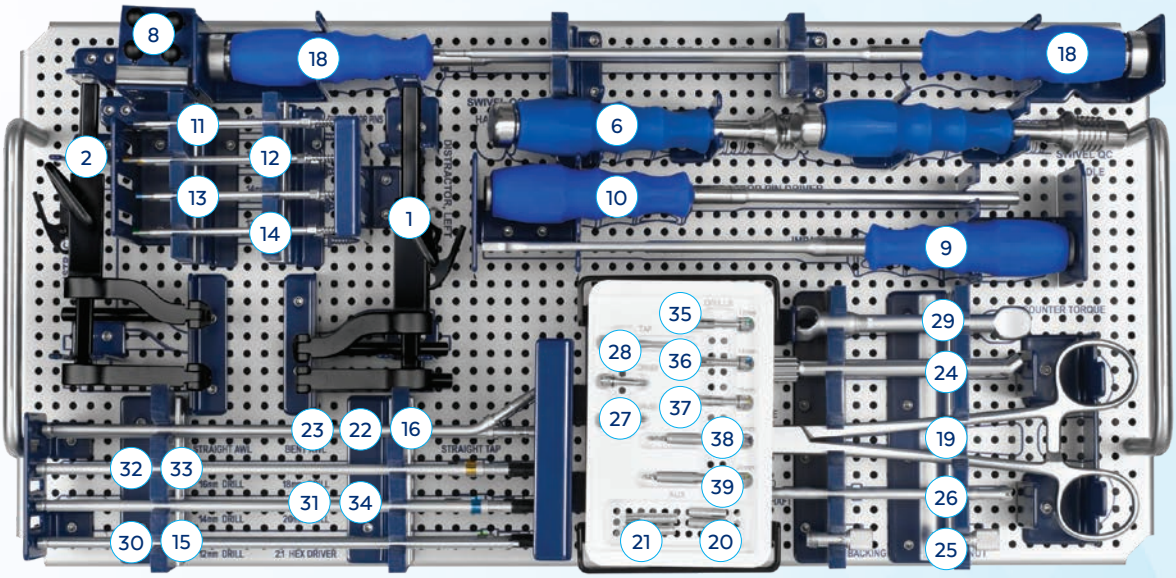
UNIVERSAL ACDF
INSTRUMENT SET 9147.9001

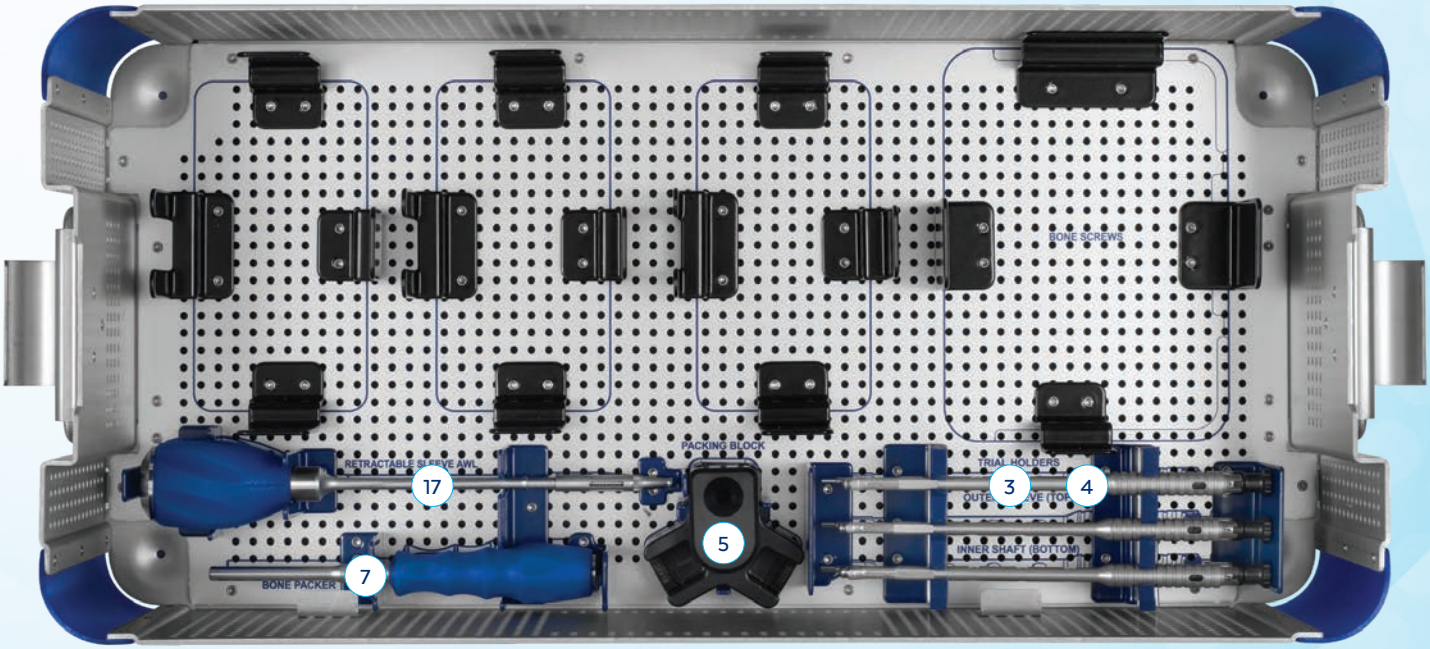
	Part No.	Description	Qty
1	601.020	Distractor, Left	1
2	601.021	Distractor, Right	1
3	6147.9001	Trial Holder, Modular Trial/Rasp Heads - Outer Sleeve	3
4	6147.9002	Trial Holder, Modular Trial/Rasp Heads - Inner Shaft Assembly	3
5	6147.9003	Packing Block	1
6	636.450	Quick-Connect Handle, Swivel	2
7	665.504	Bone Packer	1
8	665.606	Distractor Locking Nuts	4
9	665.607	Impactor	1
10	665.608	Distractor Pin Driver	1
	665.610	Distractor Pin, 10mm	
11	665.612	Distractor Pin, 12mm	2
12	665.614	Distractor Pin, 14mm	2
13	665.616	Distractor Pin, 16mm	2
14	665.618	Distractor Pin, 18mm	2
15	671.313	VIP® Screwdriver, 2.1mm Hex, QC	1
16	684.004	Tap, Straight	1
17	684.006	Awl with Retractable Sleeve	1
18	684.305	Screwdriver, 2.5mm Hex, Self-Retaining, with Cap	2
19	684.309	Drill Sleeve Adjuster	1
20	684.401	Self-Centering Sleeve - Short	2
21	684.402	Self-Centering Sleeve - Long	2
22	684.403	Awl with Self-Centering Sleeve, Straight	1
23	684.404	Awl with Self-Centering Sleeve, Bent	1
	684.405	Sleeved Driver	
24	684.415	Angled Sleeve	2
25	684.416	Angled Sleeve with Backing Nut	2
26	684.417	Angled Driving Shaft	2
27	684.418	Hex Driver Assembly	2
28	684.419	Angled Tap Tip	1
29	684.421	Counter-Torque, Angled Instrument	2

	Part No.	Description	Qty
30	684.422	Straight Drill with Self-Centering Sleeve, 12mm	1
31	684.424	Straight Drill with Self-Centering Sleeve, 14mm	1
	684.425	Angled Driver Tip, Short	
32	684.426	Straight Drill with Self-Centering Sleeve, 16mm	1
33	684.428	Straight Drill with Self-Centering Sleeve, 18mm	1
34	684.430	Straight Drill with Self-Centering Sleeve, 20mm	1
35	684.432	Angled Drill Tip with Self-Centering Sleeve, 12mm	1
36	684.434	Angled Drill Tip with Self-Centering Sleeve, 14mm	1
37	684.436	Angled Drill Tip with Self-Centering Sleeve, 16mm	1
38	684.438	Angled Drill Tip with Self-Centering Sleeve, 18mm	1
39	684.440	Angled Drill Tip with Self-Centering Sleeve, 20mm	1
	9147.0001	Universal ACDF Instrument Graphic Case	
	984.004	COALITION® Module, Angled Instruments	

Items in gray are additionally available.

UNIVERSAL ACDF
INSTRUMENT SET 9147.9001





UNIVERSAL ACDF
SCREW SET 9147.9008

4.2mm Variable, Self-Tapping		Qty
184.012	4.2mm Bone Screw, Variable, Self-Tapping, 12mm	6
184.014	4.2mm Bone Screw, Variable, Self-Tapping, 14mm	6
184.016	4.2mm Bone Screw, Variable, Self-Tapping, 16mm	6
184.018	4.2mm Bone Screw, Variable, Self-Tapping, 18mm	4
184.020	4.2mm Bone Screw, Variable, Self-Tapping, 20mm	4

4.2mm Fixed, Self-Tapping		Qty
184.032	4.2mm Bone Screw, Fixed, Self-Tapping, 12mm	6
184.034	4.2mm Bone Screw, Fixed, Self-Tapping, 14mm	6
184.036	4.2mm Bone Screw, Fixed, Self-Tapping, 16mm	6
184.038	4.2mm Bone Screw, Fixed, Self-Tapping, 18mm	4
184.040	4.2mm Bone Screw, Fixed, Self-Tapping, 20mm	4

4.2mm Variable, Self-Drilling		Qty
184.052	4.2mm Bone Screw, Variable, Self-Drilling, 12mm	6
184.054	4.2mm Bone Screw, Variable, Self-Drilling, 14mm	6
184.056	4.2mm Bone Screw, Variable, Self-Drilling, 16mm	6
184.058	4.2mm Bone Screw, Variable, Self-Drilling, 18mm	4
184.060	4.2mm Bone Screw, Variable, Self-Drilling, 20mm	4

4.2mm Fixed, Self-Drilling		Qty
184.072	4.2mm Bone Screw, Fixed, Self-Drilling, 12mm	6
184.074	4.2mm Bone Screw, Fixed, Self-Drilling, 14mm	6
184.076	4.2mm Bone Screw, Fixed, Self-Drilling, 16mm	6
184.078	4.2mm Bone Screw, Fixed, Self-Drilling, 18mm	4
184.080	4.2mm Bone Screw, Fixed, Self-Drilling, 20mm	4

3.6mm Variable, Self-Tapping		Qty
184.112	3.6mm Bone Screw, Variable, Self-Tapping, 12mm	6
184.114	3.6mm Bone Screw, Variable, Self-Tapping, 14mm	6
184.116	3.6mm Bone Screw, Variable, Self-Tapping, 16mm	6
184.118	3.6mm Bone Screw, Variable, Self-Tapping, 18mm	4
184.120	3.6mm Bone Screw, Variable, Self-Tapping, 20mm	4

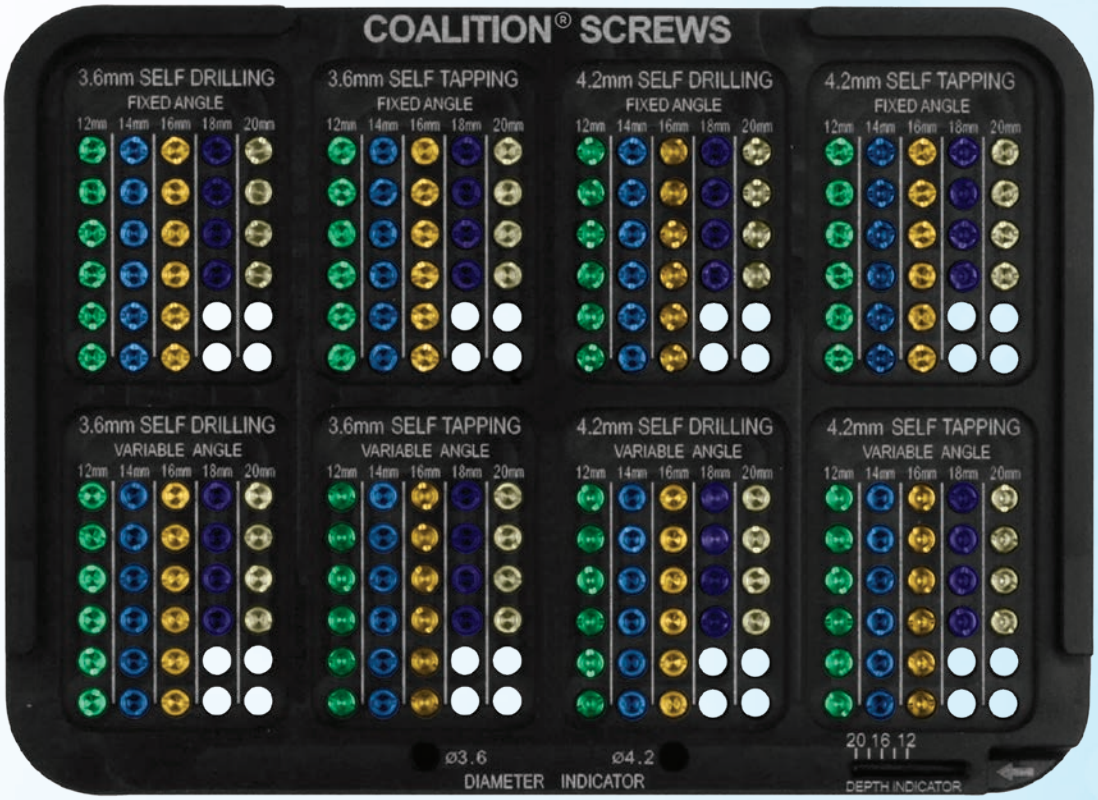
3.6mm Fixed, Self-Tapping		Qty
184.132	3.6mm Bone Screw, Fixed, Self-Tapping, 12mm	6
184.134	3.6mm Bone Screw, Fixed, Self-Tapping, 14mm	6
184.136	3.6mm Bone Screw, Fixed, Self-Tapping, 16mm	6
184.138	3.6mm Bone Screw, Fixed, Self-Tapping, 18mm	4
184.140	3.6mm Bone Screw, Fixed, Self-Tapping, 20mm	4

3.6mm Variable, Self-Drilling		Qty
184.152	3.6mm Bone Screw, Variable, Self-Drilling, 12mm	6
184.154	3.6mm Bone Screw, Variable, Self-Drilling, 14mm	6
184.156	3.6mm Bone Screw, Variable, Self-Drilling, 16mm	6
184.158	3.6mm Bone Screw, Variable, Self-Drilling, 18mm	4
184.160	3.6mm Bone Screw, Variable, Self-Drilling, 20mm	4

3.6mm Fixed, Self-Drilling		Qty
184.172	3.6mm Bone Screw, Fixed, Self-Drilling, 12mm	6
184.174	3.6mm Bone Screw, Fixed, Self-Drilling, 14mm	6
184.176	3.6mm Bone Screw, Fixed, Self-Drilling, 16mm	6
184.178	3.6mm Bone Screw, Fixed, Self-Drilling, 18mm	4
184.180	3.6mm Bone Screw, Fixed, Self-Drilling, 20mm	4

9147.0008	Screw Module, Universal ACDF	

UNIVERSAL ACDF
SCREW SET 9147.9008



MARS™ ACDF
RETRACTOR SET 9138.9001

	Part No.	Description	Qty
1	6138.0103	Retractor Frame, Offset	1
2	6138.0101	Retractor Frame, Left	1
3	6138.0203	Depth Gauge	1
4	6138.0218	Handheld Retractor, Straight - 18mm	2
5	6138.0220	Handheld Retractor, Curved - 20mm	2
6	6138.0223	Handheld Retractor, Curved - 23mm	2
7	6138.0230	Blade Handle, Interchangeable	2

8	Blunted Blades		Qty
	6138.1030	30mm Blade, Blunt - Small	4
	6138.1040	40mm Blade, Blunt - Small	4
	6138.1050	50mm Blade, Blunt - Small	4
	6138.1060	60mm Blade, Blunt - Small	4
	6138.1070	70mm Blade, Blunt - Small	4
	6138.1031	30mm Blade, Blunt - Large	2
	6138.1041	40mm Blade, Blunt - Large	2
	6138.1051	50mm Blade, Blunt - Large	2
	6138.1061	60mm Blade, Blunt - Large	2
	6138.1071	70mm Blade, Blunt - Large	2
	6138.1130	30mm Blade, Blunt - Tapered	2
	6138.1140	40mm Blade, Blunt - Tapered	2
	6138.1150	50mm Blade, Blunt - Tapered	2
	6138.1160	60mm Blade, Blunt - Tapered	2
	6138.1170	70mm Blade, Blunt - Tapered	2

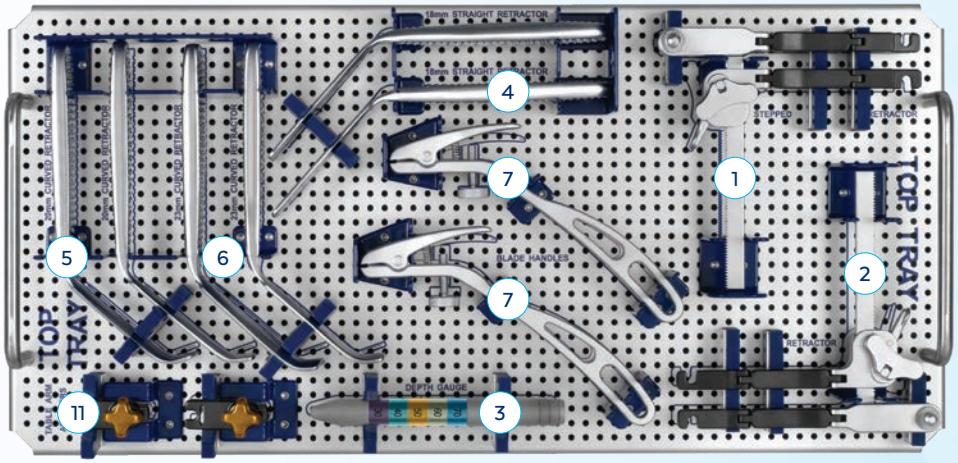
9	Toothed Blades		Qty
	6138.1230	30mm Blade, Toothed - Small	4
	6138.1240	40mm Blade, Toothed - Small	4
	6138.1250	50mm Blade, Toothed - Small	4
	6138.1260	60mm Blade, Toothed - Small	4
	6138.1270	70mm Blade, Toothed - Small	4

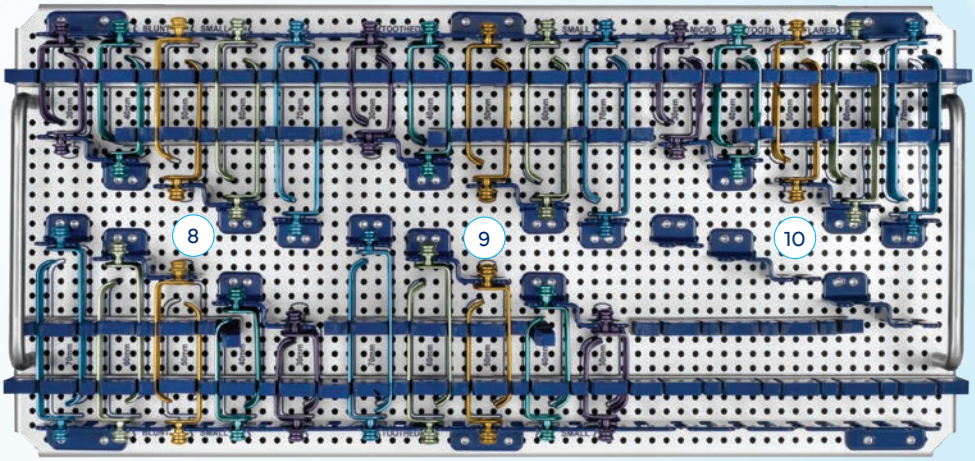
	Toothed Blades (Cont'd)		Qty
	6138.1231	30mm Blade, Toothed - Large	2
	6138.1241	40mm Blade, Toothed - Large	2
	6138.1251	50mm Blade, Toothed - Large	2
	6138.1261	60mm Blade, Toothed - Large	2
	6138.1271	70mm Blade, Toothed - Large	2

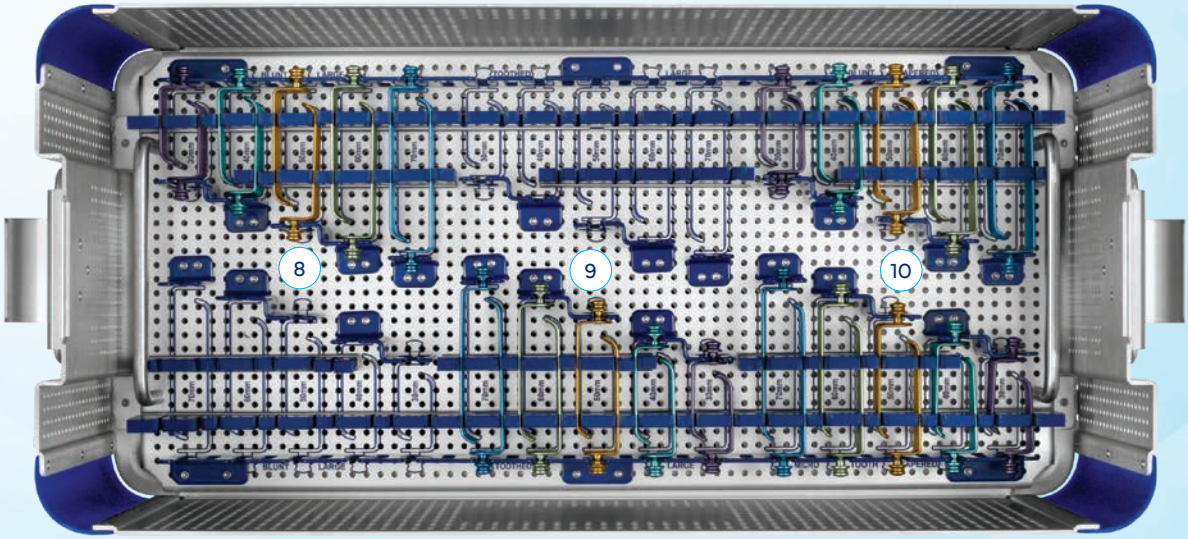
10	Micro Tooth Blades		Qty
	6138.1330	30mm Blade, Micro Tooth - Tapered	2
	6138.1340	40mm Blade, Micro Tooth - Tapered	2
	6138.1350	50mm Blade, Micro Tooth - Tapered	2
	6138.1360	60mm Blade, Micro Tooth - Tapered	2
	6138.1370	70mm Blade, Micro Tooth - Tapered	2
	6138.1430	30mm Blade, Micro Tooth - Flared	2
	6138.1440	40mm Blade, Micro Tooth - Flared	2
	6138.1450	50mm Blade, Micro Tooth - Flared	2
	6138.1460	60mm Blade, Micro Tooth - Flared	2
	6138.1470	70mm Blade, Micro Tooth - Flared	2
11	6133.0790	Table Arm Adaptor	2

	9138.0001	ACDF Graphic Case

MARS™ ACDF
RETRACTOR SET 9138.9001



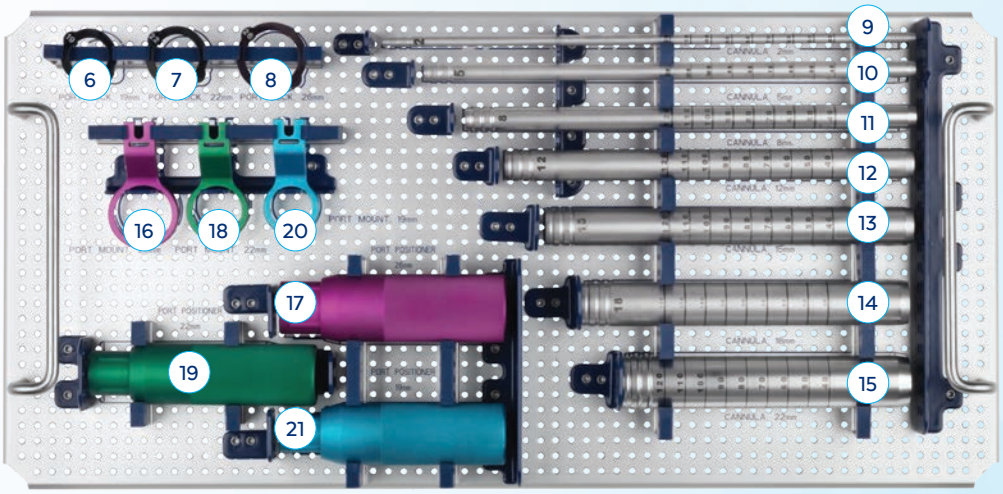


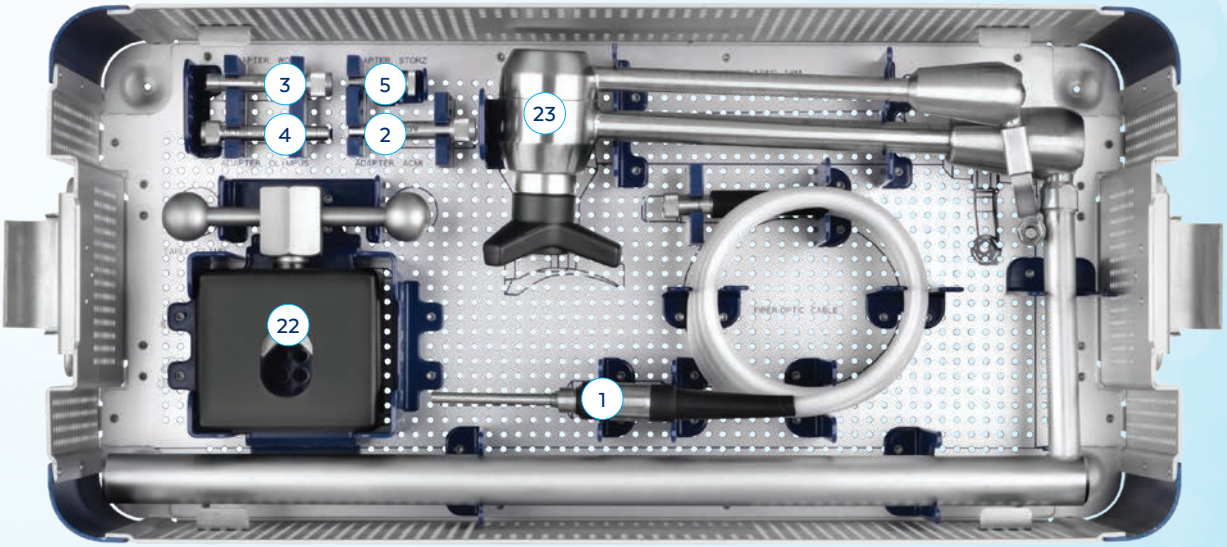


MARS™
INSTRUMENT II SET 932.902

	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	632.407	22mm Cannula	1
17	632.408	26mm Port Mount	1
18	632.409	26mm Port Positioner	1
19	632.410	22mm Port Mount	1
20	632.411	22mm Port Positioner	1
21	632.412	19mm Port Mount	1
22	632.413	19mm Port Positioner	1
23	632.500	Table Clamp	1
24	632.750	Articulating Arm Assembly	1
	932.002	MARS™ Instrument II Graphic Case	

MARS™
INSTRUMENT II SET 932.902





IMPORTANT INFORMATION ON ON REVEL™ SPACERS

DESCRIPTION

REVEL™ Spacers are expandable, anterior cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The devices are available in various height ranges and footprints 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.

REVEL™ Spacers are manufactured from titanium alloy, as specified in ASTM F136, F1295, and F1472. The screws and anchors for use with the REVEL™-S Spacer are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

INDICATIONS

REVEL™ Spacers (REVEL™ and REVEL™-S) are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two contiguous levels, depending on the system. DDD is defined as discogenic 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) weeks of non-operative treatment. Hyperlordotic implants (≥20°) must be used with supplemental fixation in addition to the two screws or anchors. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cortical, cancellous, and/or corticocancellous bone.

The REVEL™ Spacer is an interbody fusion device intended to be used with supplemental fixation, such as anterior cervical plates or posterior cervical screw fixation, for one or two levels of the cervical spine.

The REVEL™-S Spacer is an integrated interbody fusion device intended to be used with two titanium alloy screws and/or anchors which accompany the implant. When used with two screws, the REVEL™-S Spacer is a stand-alone interbody fusion device intended for use at one or two levels of the cervical spine. When used with any anchors, the REVEL™-S Spacer is intended for use at one level of the cervical spine with additional supplemental fixation such as posterior cervical screw fixation.

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.

Components of this system should not be used with components of any other system or manufacturer.

The components of this system are manufactured from titanium alloy. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical, and functional reasons.

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

These warnings do not include all adverse effects which 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

MR

The REVEL™ 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 REVEL™ 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 these implants is contraindicated in patients with the following conditions:

1. Active systemic infection, infection or inflammation localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity 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. Pregnancy.
11. 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.
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. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
16. Any case that requires the mixing of metals from two different components or systems.
17. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
18. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

- Loosening, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- Nerve damage, including loss of neurological function (sensory and/or motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome
- Dural tears, cerebral spinal fluid leakage
- Fracture of vertebrae
- Foreign body reaction (allergic) to components or debris
- Vascular or visceral injury
- Change in spinal curvature, loss of correction, height and/or reduction

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- 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

Implants 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, discoloration, pitting, 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

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. 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 may be supplied sterile or nonsterile. Instruments are provided nonsterile.

Sterile implants 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 on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants 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

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 (USA) 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		

DI192A Rev B

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