



COALITION MIS[®]

ACDF System



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

Life moves us 

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

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COALITION MIS[®]

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COALITION MIS[®]

ACDF SYSTEM

COALITION MIS[®] is designed to facilitate simplified implantation with unimpeded visualization of the disc space. The spacer, available in PEEK or titanium, accommodates traditional screws and/or innovative curved anchors delivered inline with the spacer, eliminating the need for angled instruments, particularly at the upper and lower cervical levels where patient anatomy can be challenging.



Inline Integrated Fixation

Innovative instruments facilitate simple implantation even with challenging patient anatomy.

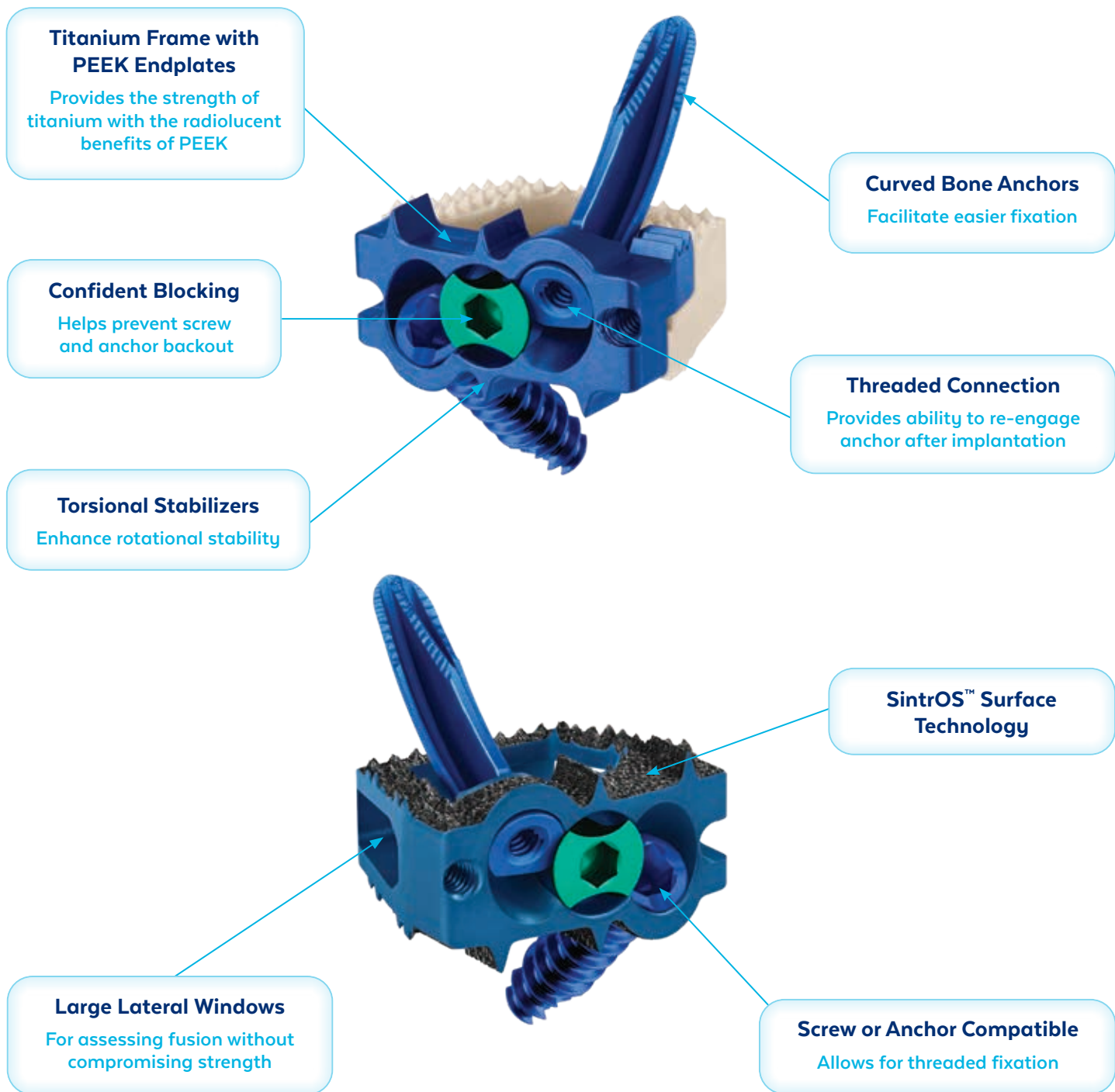
Intraoperative Versatility

Spacer accommodates COALITION MIS[®] anchors and/or screws, providing multiple options to secure it to vertebral bodies.

Biomechanical Stability

Biomechanical cadaveric testing showed no significant difference between two COALITION MIS[®] screw constructs and a 2-level cervical plate and spacer construct.*

* Testing on file.



IMPLANT OVERVIEW

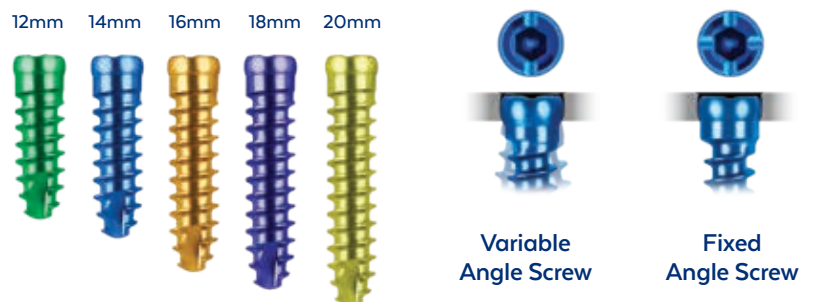
Spacer Options

- PEEK with titanium frame spacer or titanium spacer
- Three axial footprints: 12x14, 14x16, and 15x18mm
- Eight heights: 5, 6, 7, 8, 9, 10, 11, and 12mm
- Three sagittal profiles: 0°, 7°, and 12°



Screw Options

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



Anchor Options

- Five lengths: 11-15mm in 1mm increments
- 3.7mm diameter



INSTRUMENT OVERVIEW

DISTRACTION INSTRUMENTS

The Universal ACDF Instrument Set, 9147.9001 is required.



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	

COALITION MIS® MODULAR TRIALS



Module Handle Inner Shaft Assembly 6147.9002



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



12x14mm		
Height	0°	7°
5mm	6136.0105	6136.0205
6mm	6136.0106	6136.0206
7mm	6136.0107	6136.0207
8mm	6136.0108	6136.0208
9mm	6136.0109	6136.0209
10mm	6136.0110	6136.0210
11mm	6136.0111	6136.0211
12mm	6136.0112	6136.0212

14x16mm		
Height	0°	7°
5mm	6136.0305	6136.0405
6mm	6136.0306	6136.0406
7mm	6136.0307	6136.0407
8mm	6136.0308	6136.0408
9mm	6136.0309	6136.0409
10mm	6136.0310	6136.0410
11mm	6136.0311	6136.0411
12mm	6136.0312	6136.0412

15x18mm		
Height	0°	7°
5mm	6136.0505	6136.0605
6mm	6136.0506	6136.0606
7mm	6136.0507	6136.0607
8mm	6136.0508	6136.0608
9mm	6136.0509	6136.0609
10mm	6136.0510	6136.0610
11mm	6136.0511	6136.0611
12mm	6136.0512	6136.0612

UNIVERSAL ACDF RASPS



12x14mm		
Height	0°	7°
5mm	6147.1025	-
6mm	6147.1026	6147.1126
7mm	6147.1027	6147.1127
8mm	6147.1028	6147.1128
9mm	6147.1029	6147.1129
10mm	6147.1030	6147.1130
11mm	6147.1031	6147.1131
12mm	6147.1032	6147.1132

14x16mm		
Height	0°	7°
5mm	6147.2025	-
6mm	6147.2026	6147.2126
7mm	6147.2027	6147.2127
8mm	6147.2028	6147.2128
9mm	6147.2029	6147.2129
10mm	6147.2030	6147.2130
11mm	6147.2031	6147.2131
12mm	6147.2032	6147.2132

15x18mm		
Height	0°	7°
5mm	6147.3025	-
6mm	6147.3026	6147.3126
7mm	6147.3027	6147.3127
8mm	6147.3028	6147.3128
9mm	6147.3029	6147.3129
10mm	6147.3030	6147.3130
11mm	6147.3031	6147.3131
12mm	6147.3032	6147.3132

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

Awl, Bent with Self-Centering Sleeve 684.404

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



SPACER INSERTION INSTRUMENTS



Double Barrel Anchor Guides

Size	12x14 & 14x16mm	15x18mm
5-6mm	6136.1006	6136.4006
7mm	6136.1007	6136.4007
8mm	6136.1008	6136.4008
9mm	6136.1009	6136.4009
10mm	6136.1010	6136.4010
11mm	6136.1011	6136.4011
12mm	6136.1012	6136.4012



Freehand Inserter

Size	Part No.
Standard, 12x14 and 14x16mm	6136.2020
15x18mm	6136.2030



Impactor 6136.1003



Threaded Rod 6136.1002

SPACER INSERTION INSTRUMENTS (CONT'D)



Mallet 648.003



Set Screw Positioner, 2.0mm Hex, Torque-Limiting (0.3Nm Torque) 650.312



Hex Driver 6136.1004



Anchor Removal Tool 6136.1005



Slide Hammer 6136.8020

SURGICAL TECHNIQUE

COALITION MIS[®]

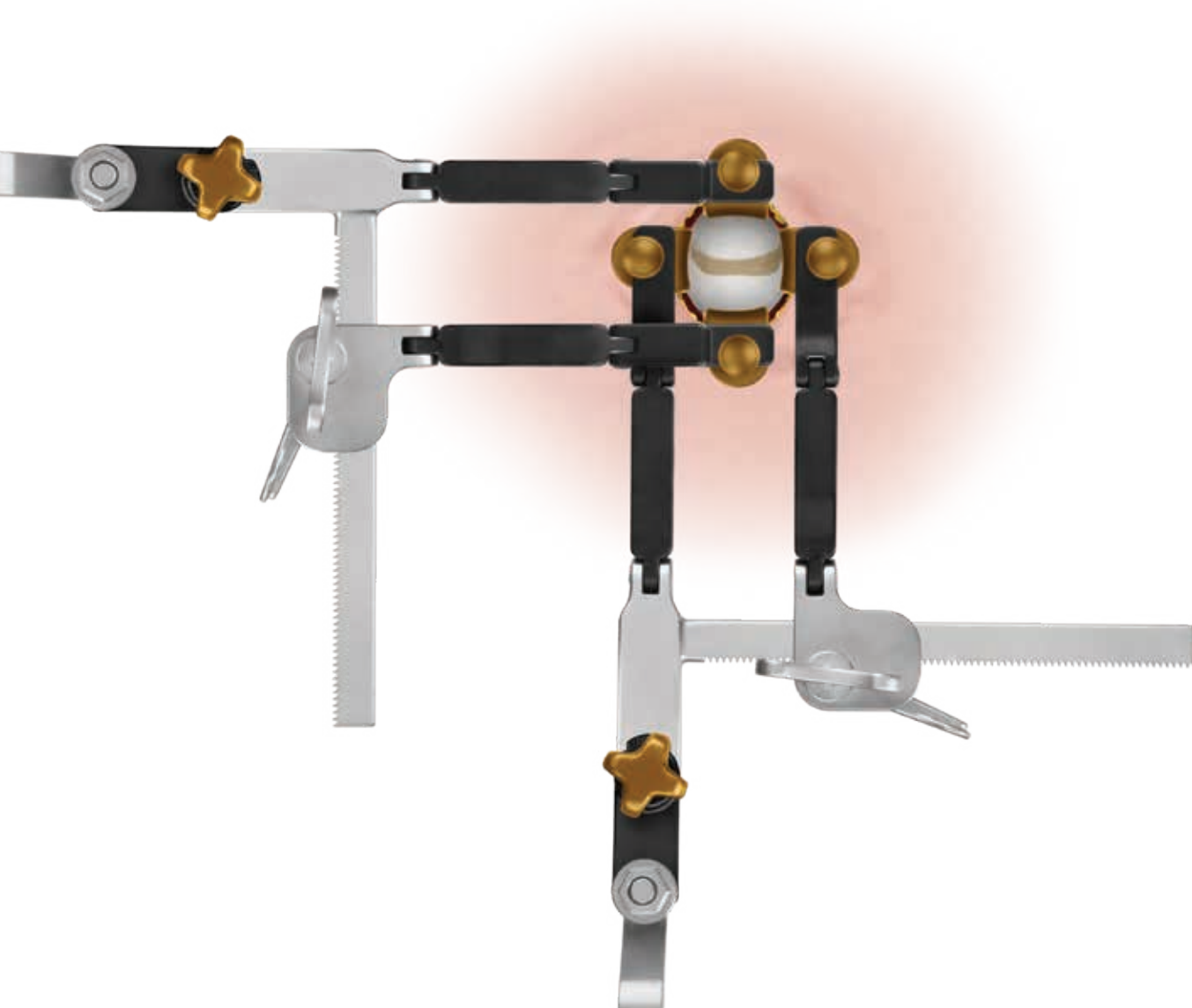
Please refer to the package insert (also printed in the back of this manual) for important information on the device description, indications, contraindications, precautions and potential risks associated with this system.

STEP

1

APPROACH AND DISC PREPARATION

An anterior cervical approach is used to implant the device. 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 distraction methods.

To use the Distractor, determine pin placement 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 screws, anchors, or any 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 by attaching the **Distractor Locking Nuts** and rotating clockwise. 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

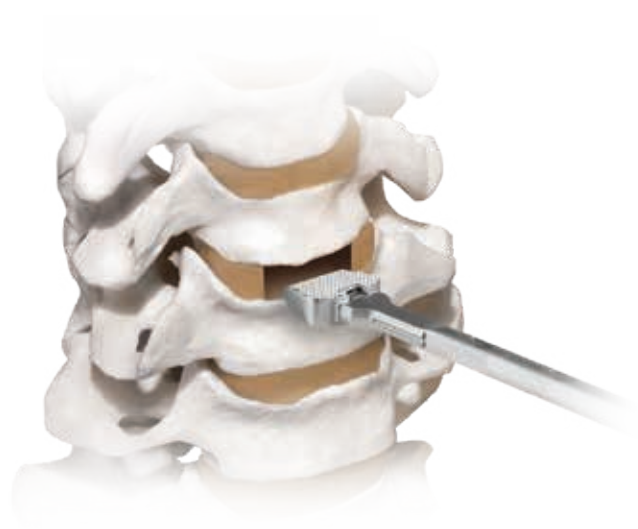
STEP

3

DISCECTOMY/ENDPLATE PREPARATION

Expose the disc space. Remove the superficial layers of the cartilaginous endplates to expose bleeding bone. The lateral walls of the annulus should be preserved to provide peripheral support. Alternatively, **Trial Rasps** match the trial design and can be used to expose bleeding bone. Removal of Distractor Pins is advisable before spacer insertion, but optional if needed to maintain distraction of the disc space.

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



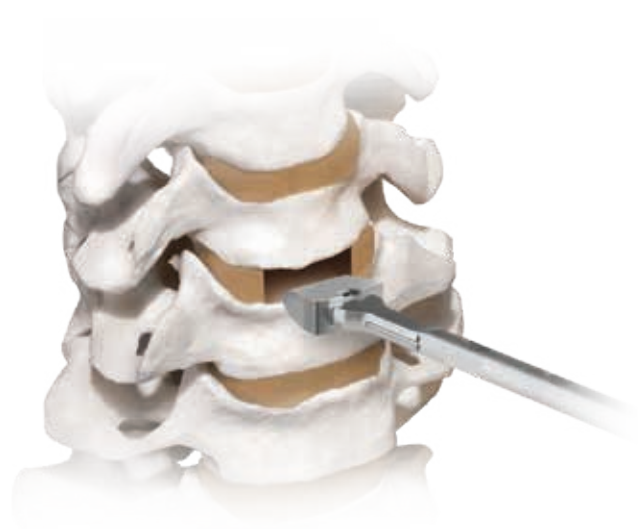
Endplate preparation using Trial Rasp

STEP

4

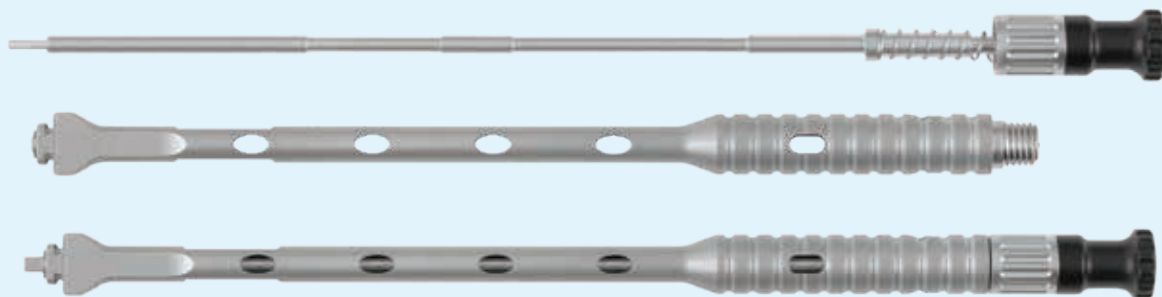
SPACER SIZING

Determine the appropriate spacer profile for the desired segment. 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 to maintain disc height and to stabilize the segment. Confirm using fluoroscopy and tactile feedback.



Trialing for spacer size

USING THE MODULAR TRIAL SYSTEM



The Trial Holder is provided in two parts. To assemble, thread the inner shaft and outer sleeve together with the silver thumb wheel. 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 connection with the holder is secure.



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



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

COALITION MIS® may be used with two anchors (Option A), two screws (Option B), or one screw and one anchor (Option C).

Option A: Anchor Fixation

STEP 5 ANCHOR LOADING

After determining the appropriate sized spacer, choose the corresponding **Double Barrel Anchor Guide**. Select the desired anchor using the anchor sizing chart on page 34. Load the selected anchors into the guide.



LOADING THE ANCHORS

Align the center rib of the anchor with the slot at the distal end of the Double Barrel Anchor Guide.



Push the anchor into the slot with the rounded end of the **Hex Driver** until a tactile and audible click is heard. Repeat for the second anchor. Confirm anchors are fully seated prior to loading the spacer.



STEP 6 SPACER INSERTION

Select an appropriate sized COALITION MIS® spacer and pack with autogenous or allogenic bone graft material. Attach the spacer to the Double Barrel Anchor Guide.

Insert the spacer into the intervertebral space. A **Mallet** may be used to gently position the spacer within the disc space. The anterior face of the spacer should be flush with the anterior portion of the vertebral bodies.



LOADING THE SPACER



To assemble the Double Barrel Anchor Guide, insert the **Threaded Rod** into the small round hole at the proximal end.

Insert the Hex Driver into the same hole to engage the Threaded Rod. Rotate clockwise until the end of the Threaded Rod emerges from the distal end of the guide.



Threaded Rod

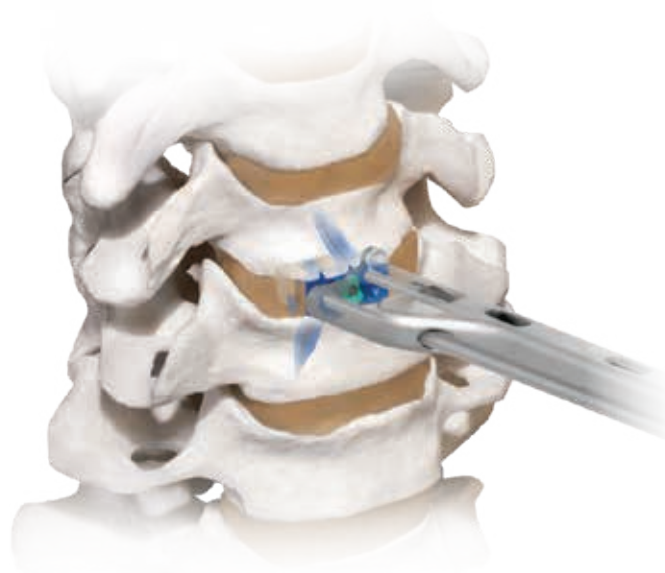
Hook

To attach the spacer, connect the hook on the distal end of the guide into the notch in the spacer. Align the Threaded Rod tip into the threaded hole of the spacer. Using the Hex Driver, rotate the Threaded Rod clockwise to secure the spacer.

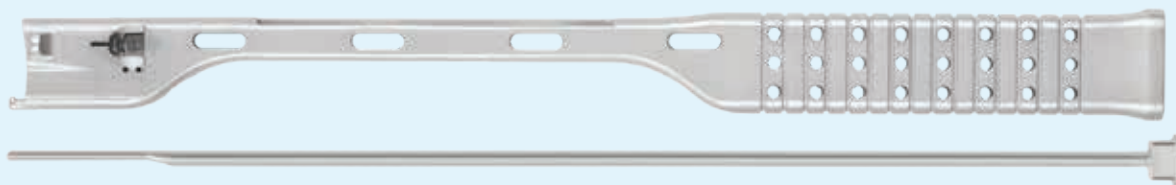


STEP 7 ANCHOR INSERTION

Confirm that the anterior face of the spacer is flush with the anterior portion of the vertebral body. Use the Double Barrel Anchor Guide to insert the anchors, as shown below.



⚙️ USING THE DOUBLE BARREL ANCHOR GUIDE



Insertion

Insert an **Anchor Impactor** into one of the D-shaped holes on the proximal end of the Double Barrel Anchor Guide. Press down to advance the anchor to contact the vertebral endplate. Gently impact with the Mallet to advance the anchor into the vertebral body. Ensure that the rectangular portion of the Impactor is flat against the proximal end of the guide before moving to the second Impactor.

Insert the second Impactor into the opposite hole and advance the anchor into the vertebral body in the same manner as the first anchor.

Do not impact both Impactors simultaneously.

Ensure both Impactors are flush against the proximal end of the guide. Both Impactors should remain in the guide until it is disengaged.

Disengagement

Following anchor insertion, remove the guide. To release the spacer, insert the Threaded Rod and rotate counterclockwise using the Hex Driver, completely disengaging the threads from the spacer. To release, rock the guide gently opposite the direction of the threaded connection.



Inserting first impactor



Inserting second impactor



Disengaging the guide

STEP 8 ANCHOR BLOCKING

Once the anchors are fully seated, insert the **Set Screw Positioner, 2.0mm Hex, 0.3Nm Torque-Limiting** into the blocking set screw and rotate clockwise approximately 90° to the final position (blocked). The positioner provides audible and tactile confirmation that the screw is blocked.

Initial Position



Final Position

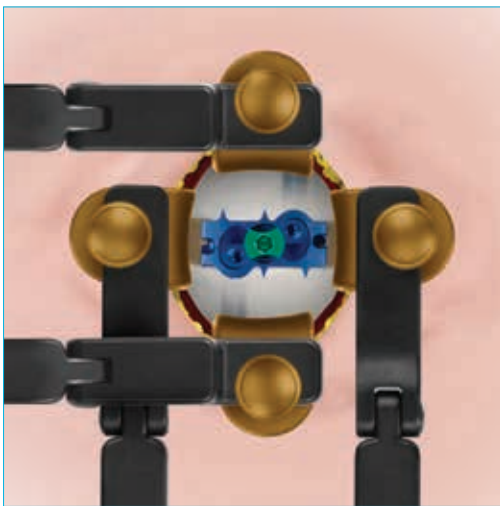


Final blocking with anchors

STEP 9 SUPPLEMENTAL FIXATION

Supplemental fixation (i.e. cervical posterior fixation) is required, in addition to the integrated anchors.

FINAL CONSTRUCT – COALITION MIS® WITH ANCHORS



Final position



Final position – axial view

Note: Construct shown prior to supplemental fixation for clarity.

OPTIONAL: SPACER/ANCHOR REMOVAL

Unblock the locking set screw using the 0.3Nm Torque-Limiting Driver.

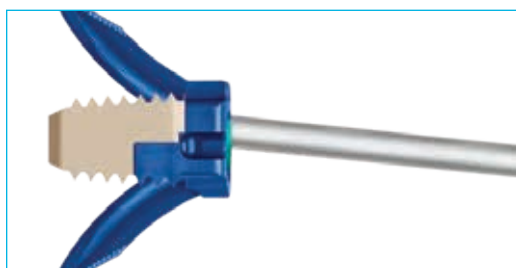
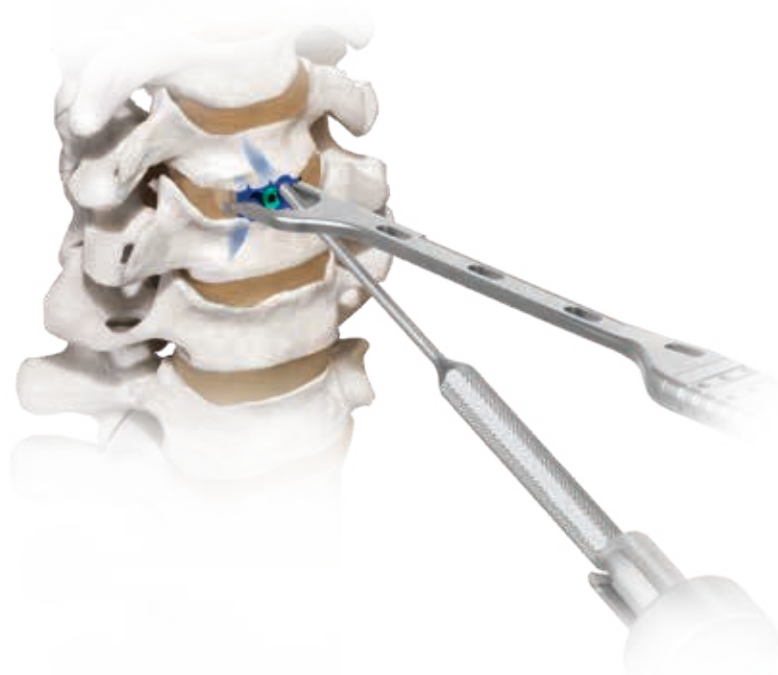


Thread the **Anchor Removal Tool** into the head of the anchor at an approximately 25° angle until fully seated.

The **Freehand Insertor** may be used to help grip the spacer while removing anchors. Attach prior to Anchor Removal Tool connection.



Pull the removal tool to remove the anchor. If needed, attach the **Slide Hammer** to the removal tool to aid in anchor removal.



 **INCORRECT**



 **CORRECT**

Remove the spacer using the Freehand Inserter, forceps, or other manual surgical instruments.

In the event of a fracture, follow the steps above, including a partial corpectomy if necessary.



Option B: Screw Fixation

STEP 5 SPACER INSERTION

Select an appropriate size COALITION MIS® spacer and pack with autogenous or allogenic bone graft material. Attach the spacer to the Freehand Inserter.

Insert the spacer into the intervertebral disc space. The anterior face of the spacer should be flush with the anterior portion of the vertebral bodies. A Mallet may be used to gently position the spacer within the disc space.



⚙️ USING THE FREEHAND INSERTER

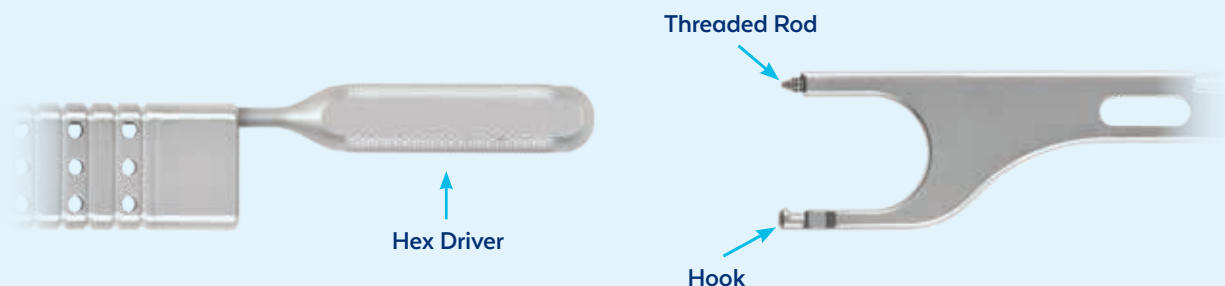


The **Freehand Inserter, Standard** accommodates 12x14mm and 14x16mm footprints. The **15x18 Freehand Inserter** is used for 15x18mm spacers. To assemble the inserter, insert the **Threaded Rod** into the hole at the proximal end of the inserter.



USING THE FREEHAND INSERTER (CONT'D)

Insert the **Hex Driver** into the hole at the proximal end of the inserter. Engage the Threaded Rod and rotate clockwise until the end of the rod emerges from the distal end of the inserter.



To attach the spacer, connect the hook on the distal end of the inserter into the notch in the spacer. Align the Threaded Rod tip into the threaded hole in the spacer. Using the Hex Driver, rotate the Threaded Rod clockwise to secure the spacer.



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.

Insert 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.



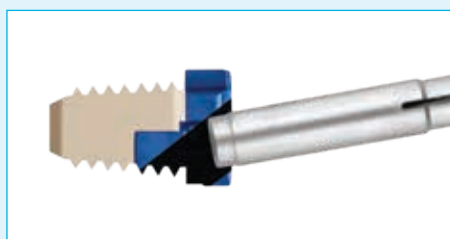
Freehand Inserter



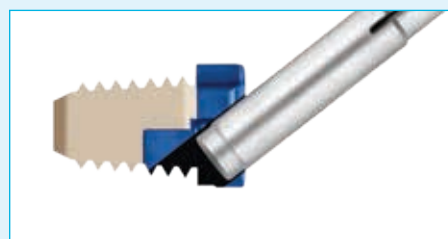
Awl with Self-Centering Sleeve

Aligning the Self-Centering Sleeve

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



INCORRECT



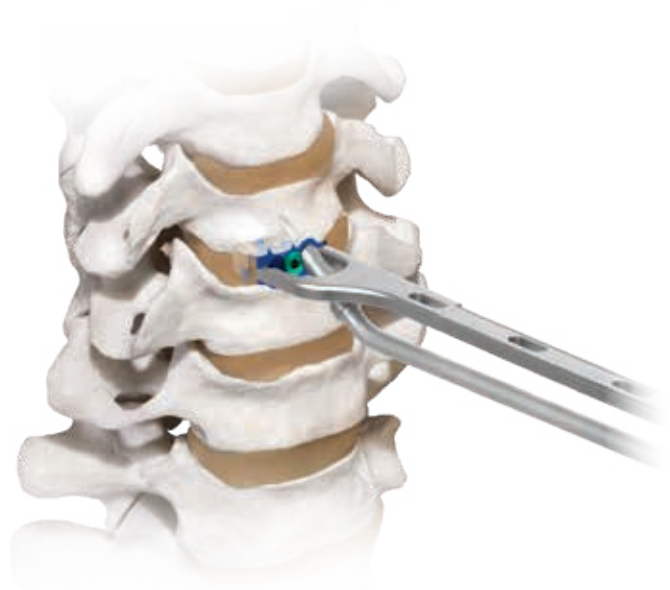
CORRECT

STEP

6

SCREW HOLE PREPARATION

Insert 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. Fixed angle screws are used with self-centering instruments, while variable angle screws can be inserted freehand.



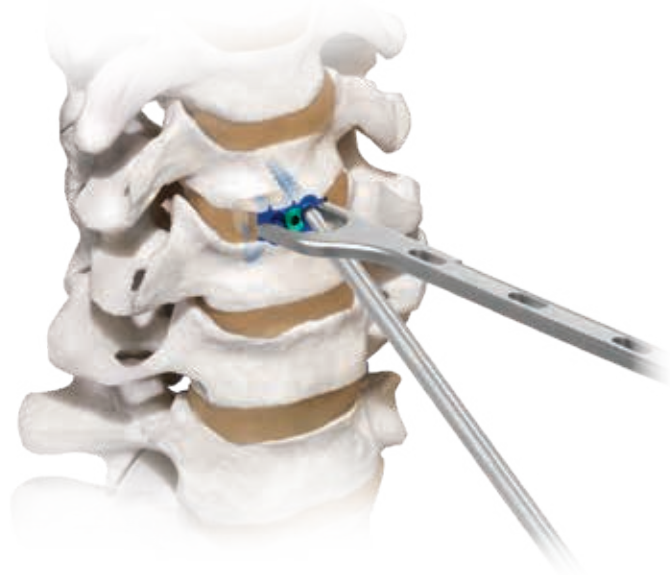
STEP

7

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 desired screw size using the screw sizing chart on page 35. Load the screw onto the driver and insert the screw. The spacer lags to the bone during screw insertion. Repeat for the second screw.



Disengaging the Inserter

Remove the Freehand Inserter after spacer and screw insertion. To release the spacer, rotate the Threaded Rod counterclockwise using the Hex Driver, while simultaneously withdrawing the Freehand Inserter. Rock the inserter gently medial/lateral to release.



ASSEMBLING THE ANGLED INSTRUMENTS

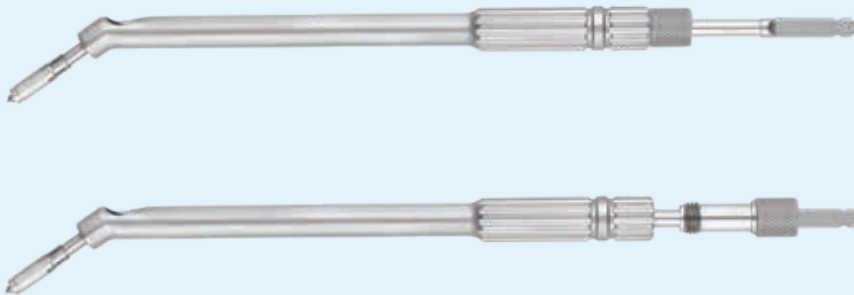
1. Select the appropriate Angled Driver, Angled Drill or Angled Tap for assembly with the body and shaft.
2. Hold the **Angled Driver Body** pointed downward with the cutout facing upward. Insert the selected tip into the cutout on the distal end of the driver body.



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.



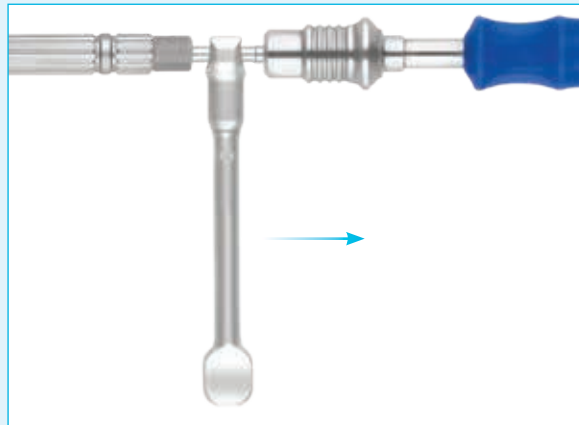
5. Attach a **Quick-Connect Handle, Swivel**. The driver is now ready for use.



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.

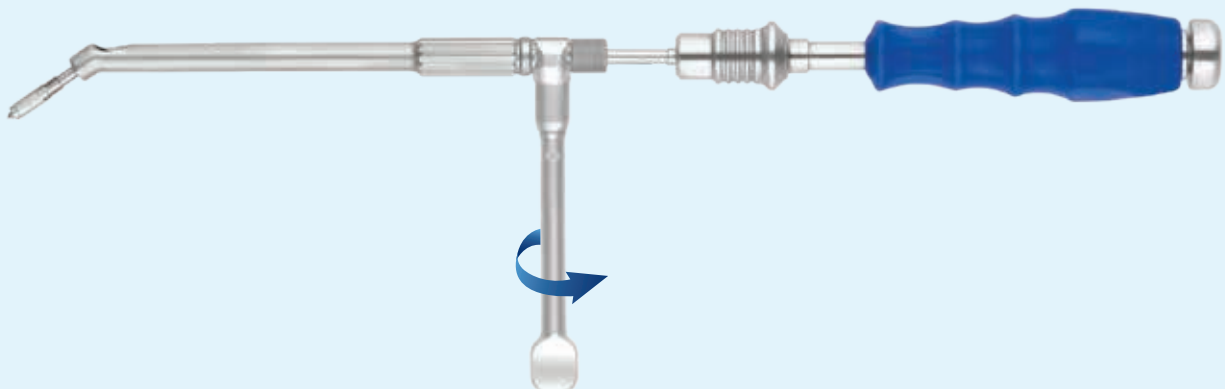


Attaching Counter-Torque



Counter-Torque in final position

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



STEP

8

SCREW BLOCKING

Once the screws are fully seated, insert the **Set Screw Positioner, 2.0mm Hex, 0.3Nm Torque-Limiting** into the blocking set screw and rotate clockwise approximately 90° to the final position (blocked). The positioner provides audible and tactile confirmation that the screw is blocked.

Initial Position

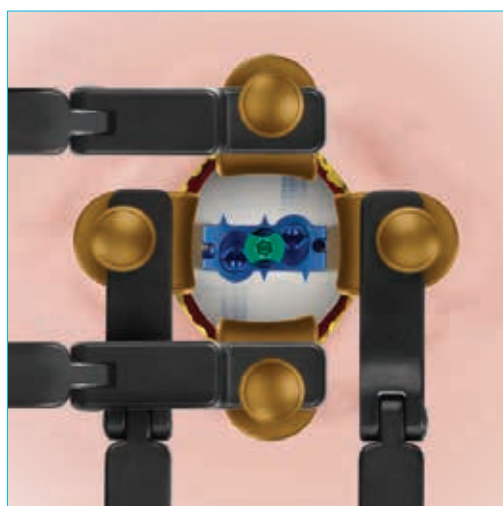


Final Position



Final blocking with screws

FINAL CONSTRUCT



Final position



Final position - axial view

OPTIONAL TECHNIQUE: 2-LEVEL INSERTION

To implant a second spacer at an adjacent level, repeat steps 2-8 as described in this technique guide.

Final 2-Level Construct



OPTIONAL: SPACER/SCREW REMOVAL

Unlock the set screws using the 0.3Nm Torque-Limiting Driver.



For screw removal, use the 2.5mm Hex Driver.

Remove the spacer using the Freehand Inserter, forceps, or other manual surgical instruments.

In the event of a fracture, follow the steps above, including a partial corpectomy if necessary.



Option C: Anchor and Screw Hybrid Fixation

If a hybrid screw and anchor construct is desired, follow technique steps 1-4 for disc preparation and spacer insertion.

Continue with Option A: Anchor Fixation steps 5-7.

Remove the Double Barrel Anchor Guide.

Complete steps 6-8 in Option B: Screw Fixation for screw insertion and final blocking.

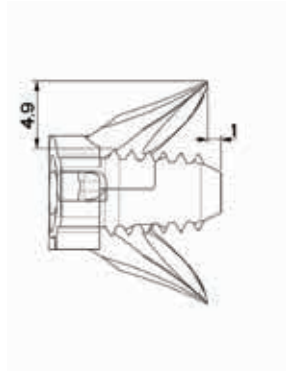
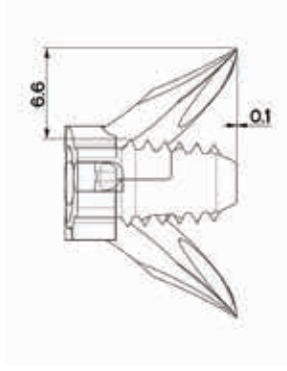
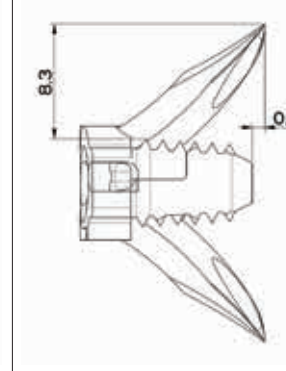
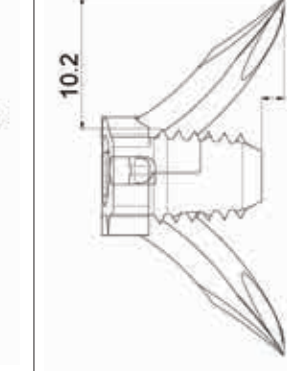
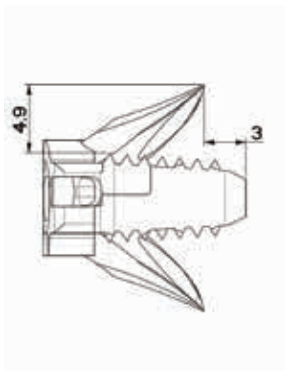
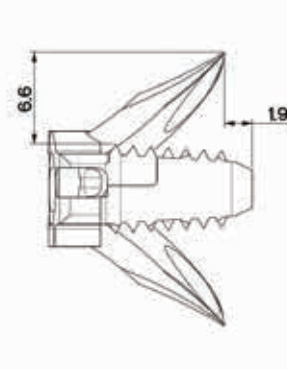
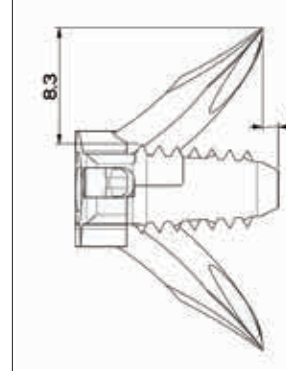
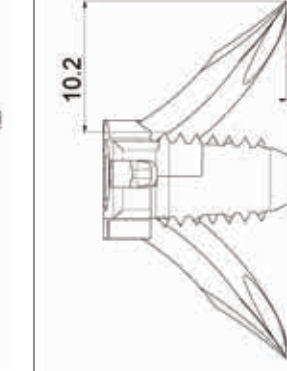
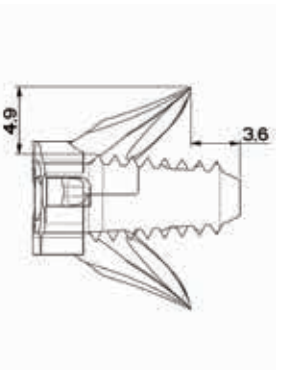
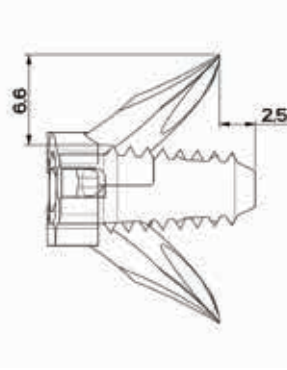
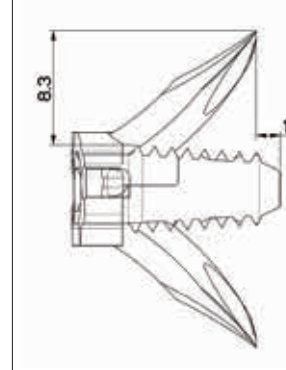
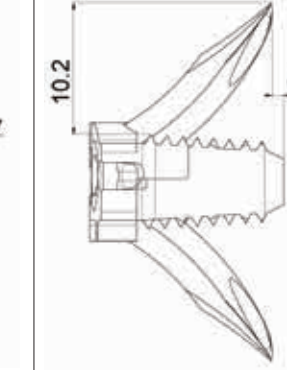
FINAL CONSTRUCT



Note: Construct shown prior to supplemental fixation for clarity.

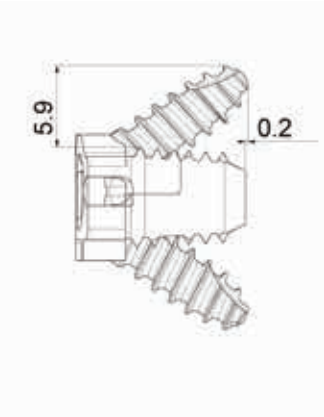
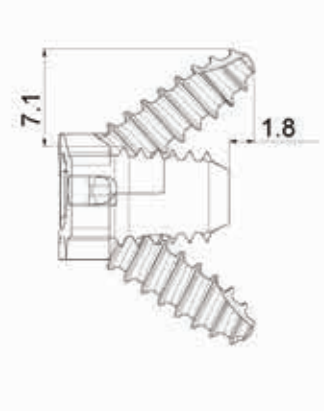
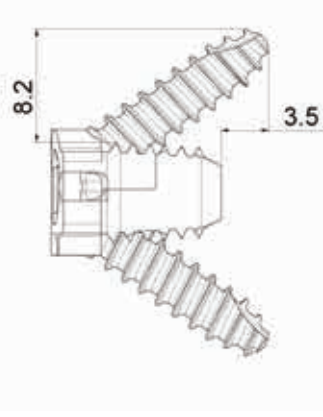
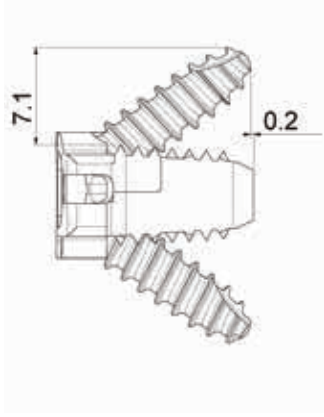
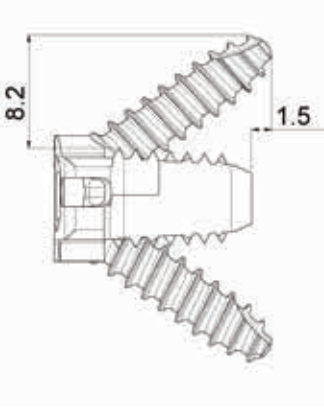
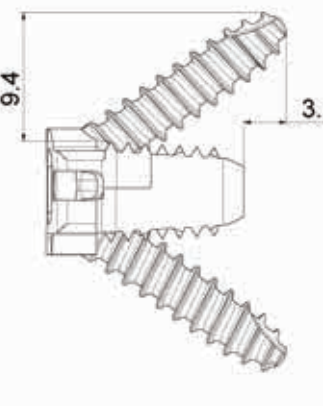
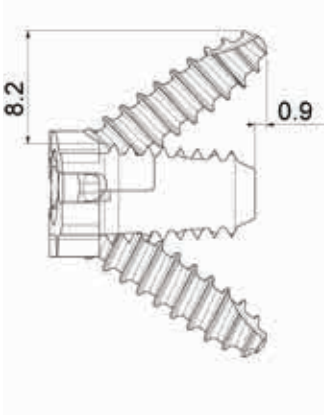
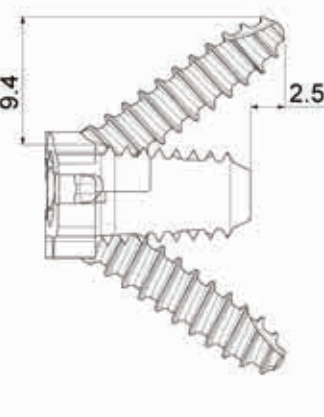
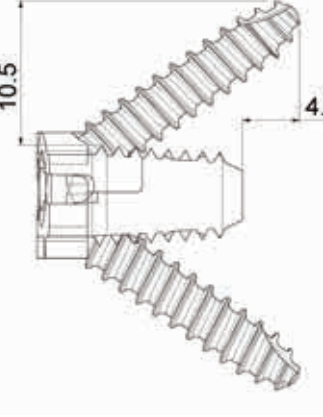
ADDITIONAL SPECIFICATIONS

Anchor Sizing Chart

	11mm	12mm	13mm	14mm
12x14mm				
14x16mm				
15x18mm				

ADDITIONAL SPECIFICATIONS

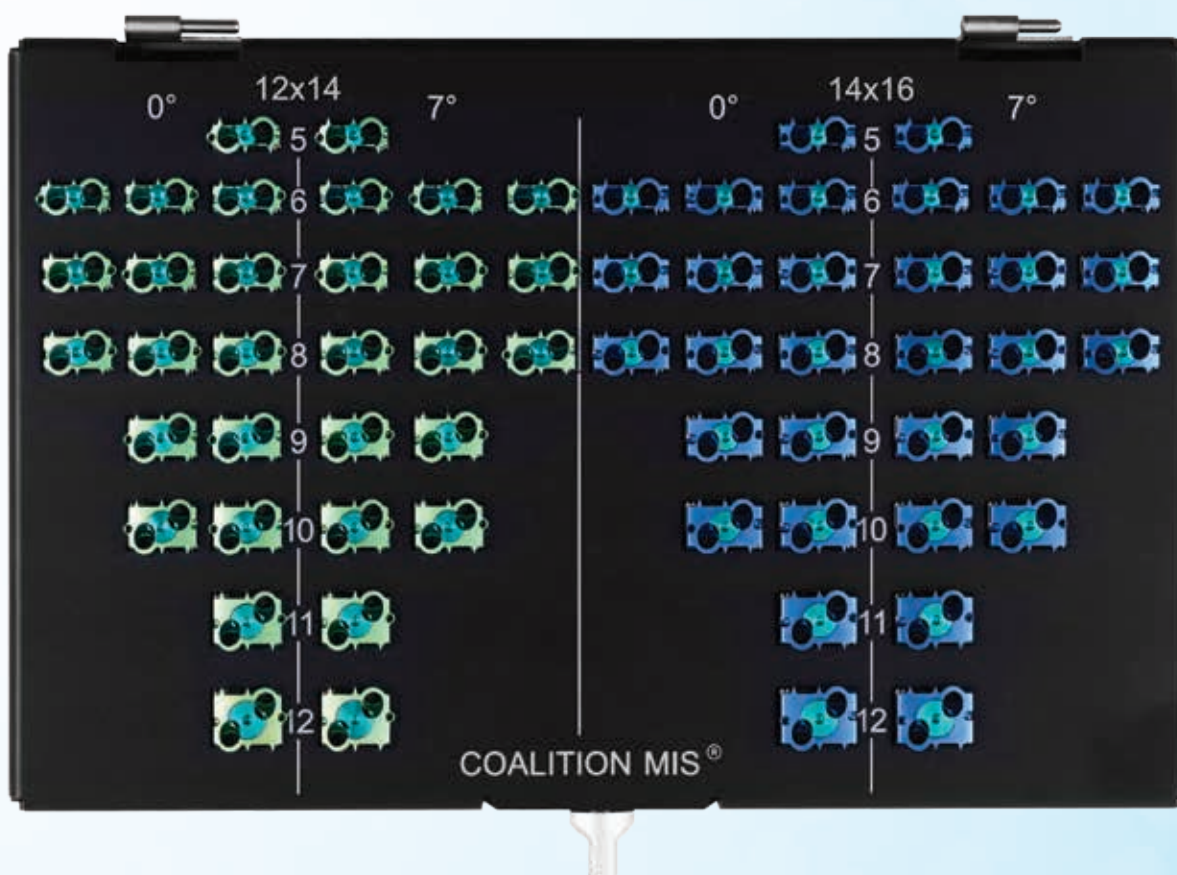
Screw Sizing Chart

12x14mm	 12mm Screw	 14mm Screw	 16mm Screw
14x16mm	 14mm Screw	 16mm Screw	 18mm Screw
15x18mm	 16mm Screw	 18mm Screw	 20mm Screw

COALITION MIS® 12x14mm and 14x16mm SPACER SET 9136.9002

Part No.	Spacers	Qty
3136.1005	COALITION MIS® 12x14mm, 0°, 5mm	1
3136.1006	COALITION MIS® 12x14mm, 0°, 6mm	3
3136.1007	COALITION MIS® 12x14mm, 0°, 7mm	3
3136.1008	COALITION MIS® 12x14mm, 0°, 8mm	3
3136.1009	COALITION MIS® 12x14mm, 0°, 9mm	2
3136.1010	COALITION MIS® 12x14mm, 0°, 10mm	2
3136.1011	COALITION MIS® 12x14mm, 0°, 11mm	1
3136.1012	COALITION MIS® 12x14mm, 0°, 12mm	1
3136.1105	COALITION MIS® 12x14mm, 7°, 5mm	1
3136.1106	COALITION MIS® 12x14mm, 7°, 6mm	3
3136.1107	COALITION MIS® 12x14mm, 7°, 7mm	3
3136.1108	COALITION MIS® 12x14mm, 7°, 8mm	3
3136.1109	COALITION MIS® 12x14mm, 7°, 9mm	2
3136.1110	COALITION MIS® 12x14mm, 7°, 10mm	2
3136.1111	COALITION MIS® 12x14mm, 7°, 11mm	1
3136.1112	COALITION MIS® 12x14mm, 7°, 12mm	1
3136.2005	COALITION MIS® 14x16mm, 0°, 5mm	1
3136.2006	COALITION MIS® 14x16mm, 0°, 6mm	3
3136.2007	COALITION MIS® 14x16mm, 0°, 7mm	3
3136.2008	COALITION MIS® 14x16mm, 0°, 8mm	3
3136.2009	COALITION MIS® 14x16mm, 0°, 9mm	2
3136.2010	COALITION MIS® 14x16mm, 0°, 10mm	2
3136.2011	COALITION MIS® 14x16mm, 0°, 11mm	1
3136.2012	COALITION MIS® 14x16mm, 0°, 12mm	1
3136.2105	COALITION MIS® 14x16mm, 7°, 5mm	1
3136.2106	COALITION MIS® 14x16mm, 7°, 6mm	3
3136.2107	COALITION MIS® 14x16mm, 7°, 7mm	3
3136.2108	COALITION MIS® 14x16mm, 7°, 8mm	3
3136.2109	COALITION MIS® 14x16mm, 7°, 9mm	2
3136.2110	COALITION MIS® 14x16mm, 7°, 10mm	2
3136.2111	COALITION MIS® 14x16mm, 7°, 11mm	1
3136.2112	COALITION MIS® 14x16mm, 7°, 12mm	1
9136.0002	COALITION MIS® 12x14/14x16 Spacer Module	

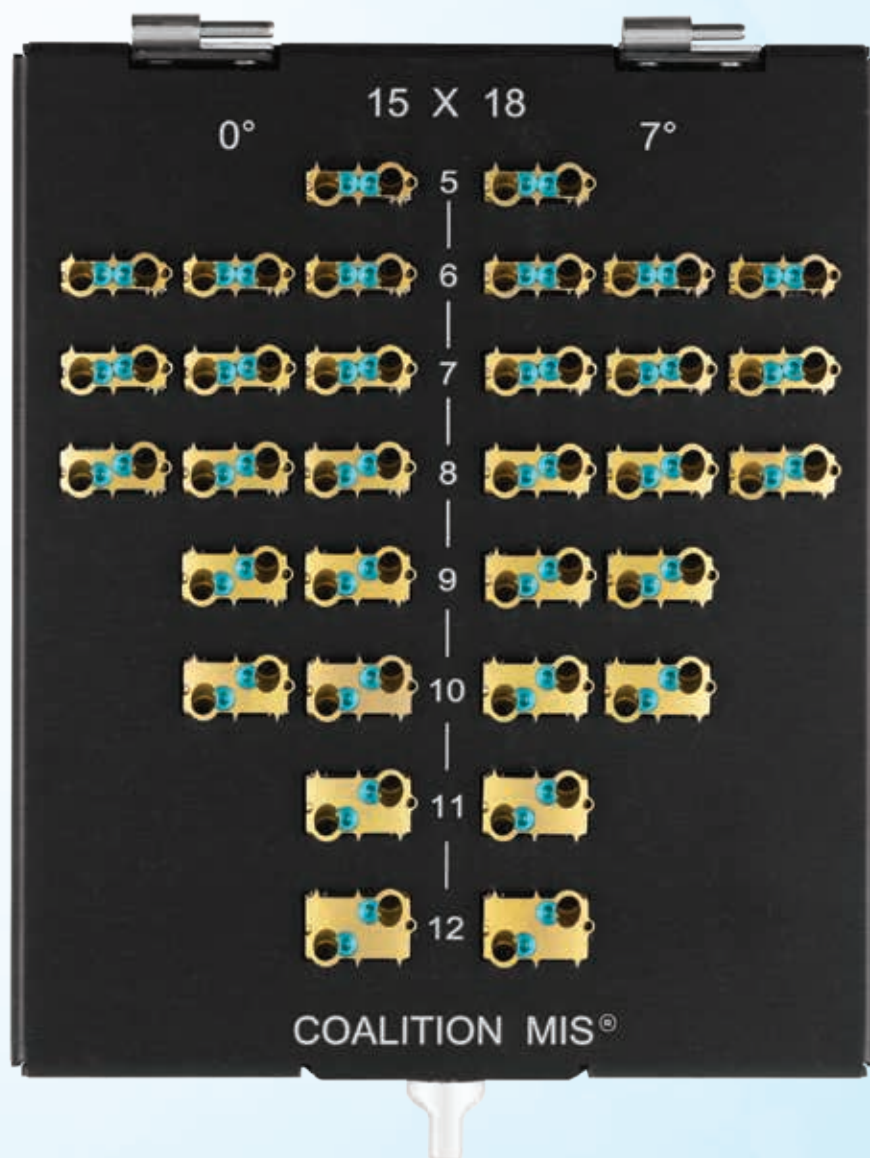
COALITION MIS® 12x14mm and 14x16mm SPACER SET 9136.9002



COALITION MIS® 15x18mm SPACER SET 9136.9003

Part No.	Spacers	Qty
3136.4005	COALITION MIS® Spacer, 15x18mm, 0°, 5mm	1
3136.4006	COALITION MIS® Spacer, 15x18mm, 0°, 6mm	3
3136.4007	COALITION MIS® Spacer, 15x18mm, 0°, 7mm	3
3136.4008	COALITION MIS® Spacer, 15x18mm, 0°, 8mm	3
3136.4009	COALITION MIS® Spacer, 15x18mm, 0°, 9mm	2
3136.4010	COALITION MIS® Spacer, 15x18mm, 0°, 10mm	2
3136.4011	COALITION MIS® Spacer, 15x18mm, 0°, 11mm	1
3136.4012	COALITION MIS® Spacer, 15x18mm, 0°, 12mm	1
3136.4105	COALITION MIS® Spacer, 15x18mm, 7°, 5mm	1
3136.4106	COALITION MIS® Spacer, 15x18mm, 7°, 6mm	3
3136.4107	COALITION MIS® Spacer, 15x18mm, 7°, 7mm	3
3136.4108	COALITION MIS® Spacer, 15x18mm, 7°, 8mm	3
3136.4109	COALITION MIS® Spacer, 15x18mm, 7°, 9mm	2
3136.4110	COALITION MIS® Spacer, 15x18mm, 7°, 10mm	2
3136.4111	COALITION MIS® Spacer, 15x18mm, 7°, 11mm	1
3136.4112	COALITION MIS® Spacer, 15x18mm, 7°, 12mm	1
9136.0003	COALITION MIS® 15x18mm Spacer Module	

COALITION MIS® 15x18mm SPACER SET 9136.9003



COALITION MIS® TITANIUM

12x14mm and 14x16mm

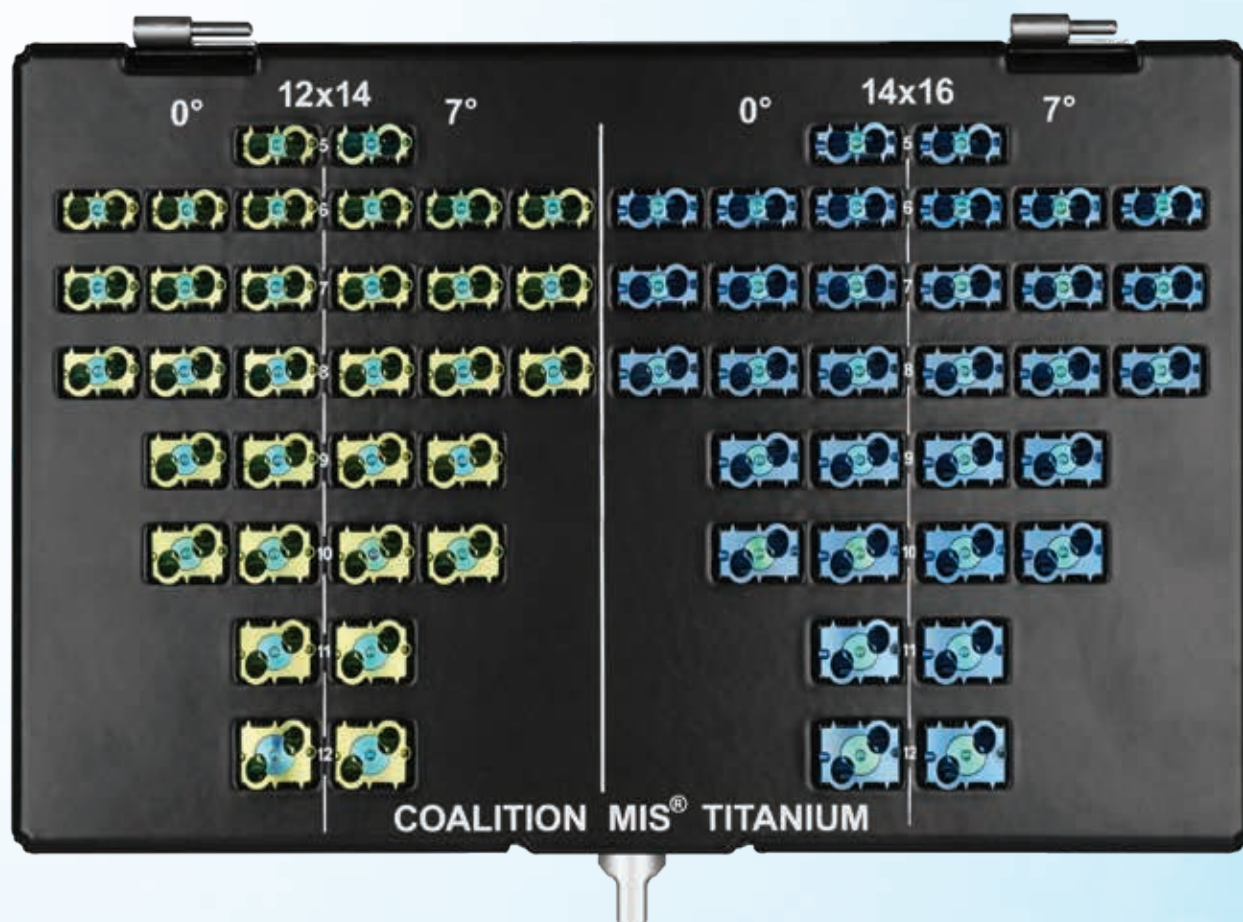
SPACER SET 9136.9007

Part No.	Spacers	Qty
1136.2405	COALITION MIS® Spacer, Ti 12x14, 0°, 5mm	1
1136.2406	COALITION MIS® Spacer, Ti 12x14, 0°, 6mm	1
1136.2407	COALITION MIS® Spacer, Ti 12x14, 0°, 7mm	1
1136.2408	COALITION MIS® Spacer, Ti 12x14, 0°, 8mm	1
1136.2409	COALITION MIS® Spacer, Ti 12x14, 0°, 9mm	1
1136.2410	COALITION MIS® Spacer, Ti 12x14, 0°, 10mm	0
1136.2411	COALITION MIS® Spacer, Ti 12x14, 0°, 11mm	0
1136.2412	COALITION MIS® Spacer, Ti 12x14, 0°, 12mm	0
1136.2475	COALITION MIS® Spacer, Ti 12x14, 7°, 5mm	1
1136.2476	COALITION MIS® Spacer, Ti 12x14, 7°, 6mm	2
1136.2477	COALITION MIS® Spacer, Ti 12x14, 7°, 7mm	2
1136.2478	COALITION MIS® Spacer, Ti 12x14, 7°, 8mm	2
1136.2479	COALITION MIS® Spacer, Ti 12x14, 7°, 9mm	2
1136.2480	COALITION MIS® Spacer, Ti 12x14, 7°, 10mm	0
1136.2481	COALITION MIS® Spacer, Ti 12x14, 7°, 11mm	0
1136.2482	COALITION MIS® Spacer, Ti 12x14, 7°, 12mm	0
1136.4405	COALITION MIS® Spacer, Ti 14x16, 0°, 5mm	1
1136.4406	COALITION MIS® Spacer, Ti 14x16, 0°, 6mm	1
1136.4407	COALITION MIS® Spacer, Ti 14x16, 0°, 7mm	1
1136.4408	COALITION MIS® Spacer, Ti 14x16, 0°, 8mm	1
1136.4409	COALITION MIS® Spacer, Ti 14x16, 0°, 9mm	1
1136.4410	COALITION MIS® Spacer, Ti 14x16, 0°, 10mm	0
1136.4411	COALITION MIS® Spacer, Ti 14x16, 0°, 11mm	0
1136.4412	COALITION MIS® Spacer, Ti 14x16, 0°, 12mm	0
1136.4675	COALITION MIS® Spacer, Ti 14x16, 7°, 5mm	1
1136.4676	COALITION MIS® Spacer, Ti 14x16, 7°, 6mm	2
1136.4677	COALITION MIS® Spacer, Ti 14x16, 7°, 7mm	2
1136.4678	COALITION MIS® Spacer, Ti 14x16, 7°, 8mm	2
1136.4679	COALITION MIS® Spacer, Ti 14x16, 7°, 9mm	2
1136.4680	COALITION MIS® Spacer, Ti 14x16, 7°, 10mm	0
1136.4681	COALITION MIS® Spacer, Ti 14x16, 7°, 11mm	0
1136.4682	COALITION MIS® Spacer, Ti 14x16, 7°, 12mm	0
9136.0007	COALITION MIS® Titanium 12x14 and 14x16 Implant Module	

COALITION MIS[®] TITANIUM

12x14mm and 14x16mm

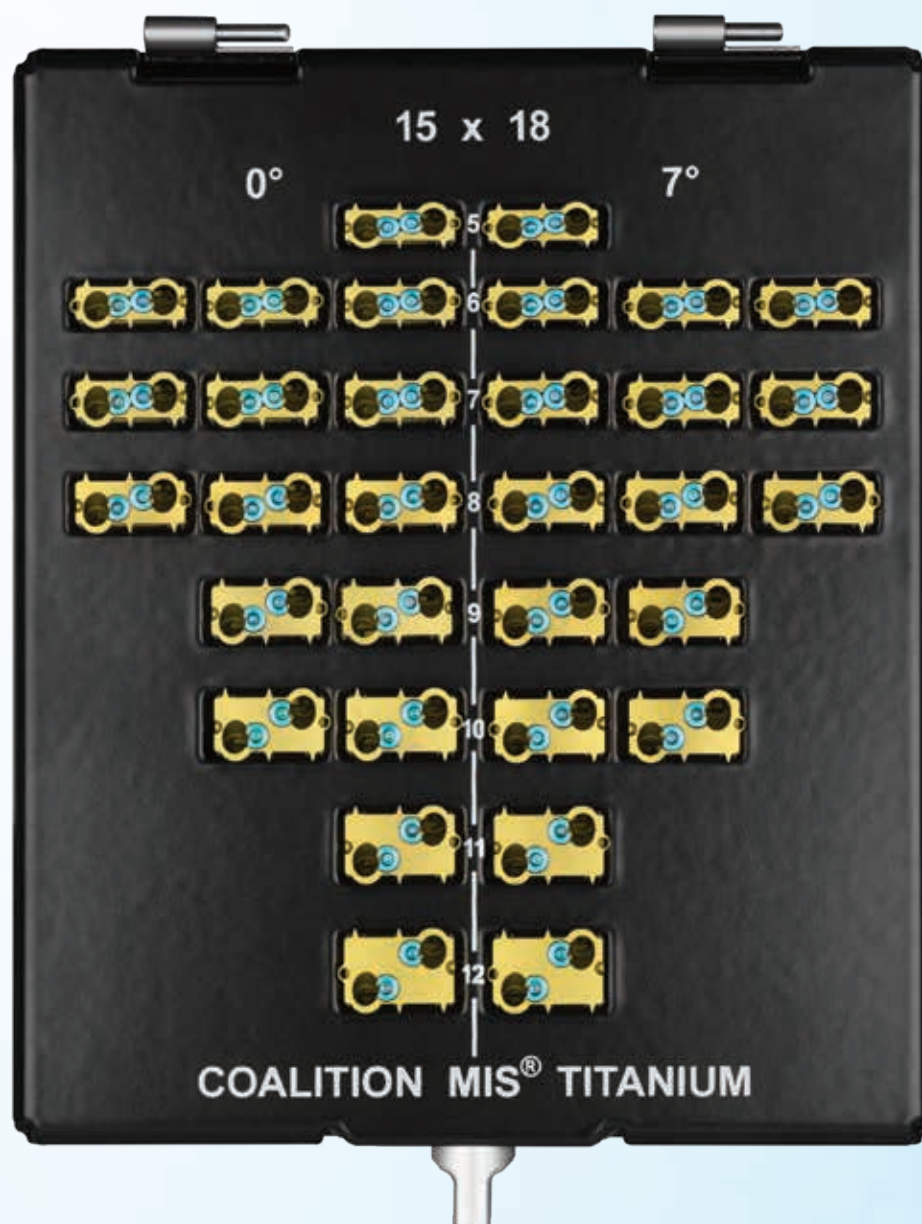
SPACER SET 9136.9007



COALITION MIS® TITANIUM 15x18mm SPACER SET 9136.9008

Part No.	Spacers	Qty
1136.5805	COALITION MIS® Spacer, Ti 15x18, 0°, 5mm	1
1136.5806	COALITION MIS® Spacer, Ti 15x18, 0°, 6mm	3
1136.5807	COALITION MIS® Spacer, Ti 15x18, 0°, 7mm	3
1136.5808	COALITION MIS® Spacer, Ti 15x18, 0°, 8mm	3
1136.5809	COALITION MIS® Spacer, Ti 15x18, 0°, 9mm	2
1136.5810	COALITION MIS® Spacer, Ti 15x18, 0°, 10mm	2
1136.5811	COALITION MIS® Spacer, Ti 15x18, 0°, 11mm	1
1136.5812	COALITION MIS® Spacer, Ti 15x18, 0°, 12mm	1
1136.5875	COALITION MIS® Spacer, Ti 15x18, 7°, 5mm	1
1136.5876	COALITION MIS® Spacer, Ti 15x18, 7°, 6mm	3
1136.5877	COALITION MIS® Spacer, Ti 15x18, 7°, 7mm	3
1136.5878	COALITION MIS® Spacer, Ti 15x18, 7°, 8mm	3
1136.5879	COALITION MIS® Spacer, Ti 15x18, 7°, 9mm	2
1136.5880	COALITION MIS® Spacer, Ti 15x18, 7°, 10mm	2
1136.5881	COALITION MIS® Spacer, Ti 15x18, 7°, 11mm	1
1136.5882	COALITION MIS® Spacer, Ti 15x18, 7°, 12mm	1
9136.0008	COALITION MIS® Titanium 15x18 Implant Module	

COALITION MIS[®] TITANIUM 15x18mm SPACER SET 9136.9008



COALITION MIS[®]

ANCHOR SET 9136.9005

Part No.	Anchors	Qty
1136.2011	COALITION MIS [®] Anchor, 11mm	6
1136.2012	COALITION MIS [®] Anchor, 12mm	6
1136.2013	COALITION MIS [®] Anchor, 13mm	6
9136.0005	COALITION MIS [®] Anchor Module	

COALITION MIS[®]

ANCHOR SET 9136.9005



COALITION MIS®

STANDARD INSTRUMENT SET 9136.9001

Instruments		Qty
1	6136.1006 Double Barrel Anchor Guide, Standard, 5-6mm	1
2	6136.1007 Double Barrel Anchor Guide, Standard, 7mm	1
3	6136.1008 Double Barrel Anchor Guide, Standard, 8mm	1
4	6136.1009 Double Barrel Anchor Guide, Standard, 9mm	1
5	6136.1010 Double Barrel Anchor Guide, Standard, 10mm	1
6	6136.1011 Double Barrel Anchor Guide, Standard, 11mm	1
7	6136.1012 Double Barrel Anchor Guide, Standard, 12mm	1
8	6136.1004 Hex Driver	3
9	6136.1002 Threaded Rod	8
10	6136.1003 Impactor	4
11	648.003 Mallet	1
12	6136.1005 Anchor Removal Tool	4
13	6136.8020 Slide Hammer	1
14	650.312 Set Screw Positioner, 2.0mm Hex, Torque Limiting	1
15	6147.9001 Trial Holder, Modular Trial/Rasp Heads - Outer Sleeve	2
16	6147.9002 Module Handle Inner Shaft Assembly	2
17	6136.2020 Freehand Inserter, Standard	1
	9136.0001 COALITION MIS® Instruments Graphic Case	

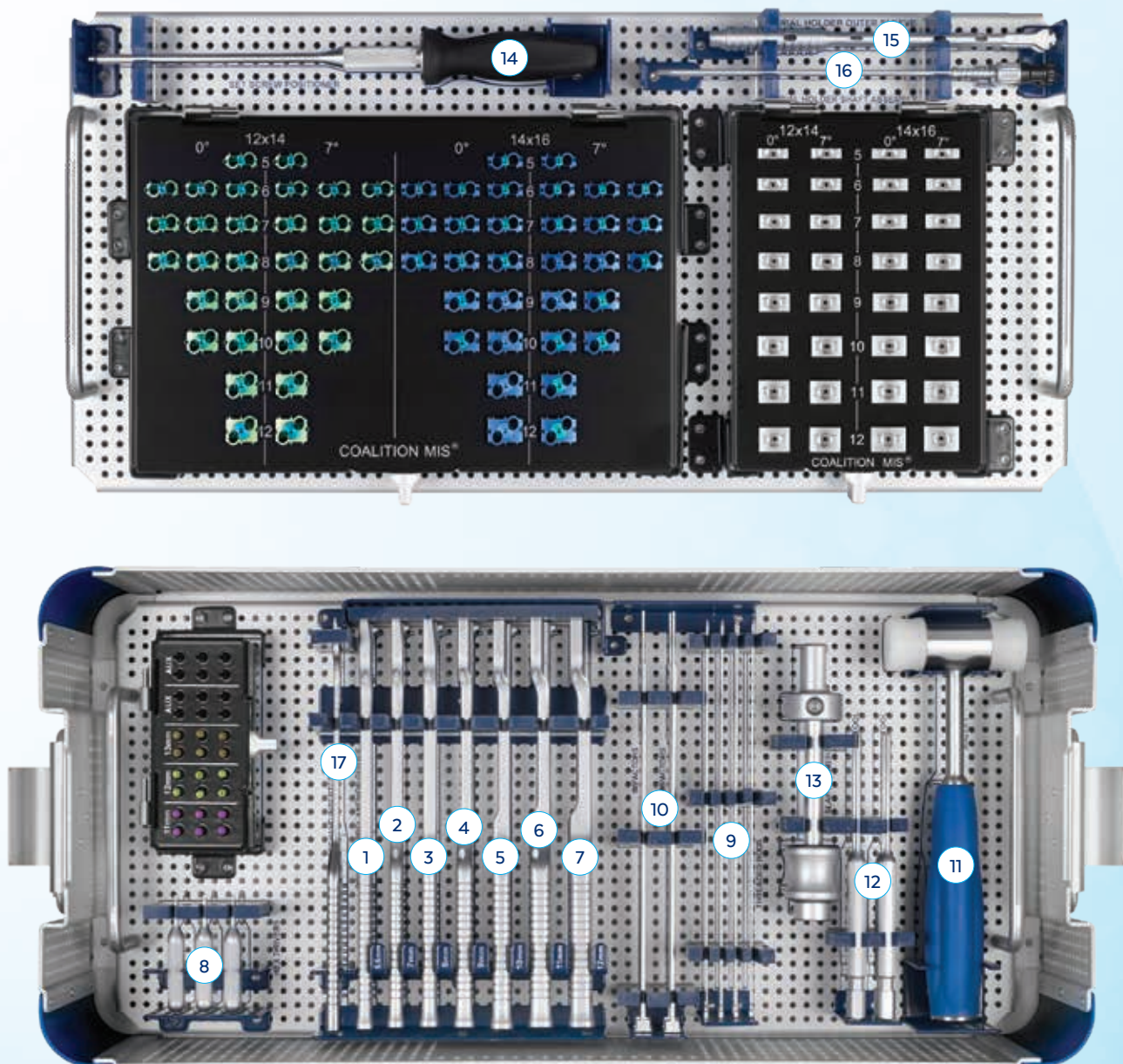
COALITION MIS® 15x18mm

INSTRUMENT SET 9136.9023

Instruments		Qty
	66136.4006 Double Barrel Anchor Guide, 15x18mm, 6mm	1
	6136.4007 Double Barrel Anchor Guide, 15x18mm, 7mm	1
	6136.4008 Double Barrel Anchor Guide, 15x18mm, 8mm	1
	6136.4009 Double Barrel Anchor Guide, 15x18mm, 9mm	1
	6136.4010 Double Barrel Anchor Guide, 15x18mm, 10mm	1
	6136.4011 Double Barrel Anchor Guide, 15x18mm, 11mm	1
	6136.4012 Double Barrel Anchor Guide, 15x18mm, 12mm	1
	6136.2030 15x18 Freehand Inserter	1
	9136.0023 COALITION MIS® 15x18mm Instrument Graphic Case	

COALITION MIS[®]

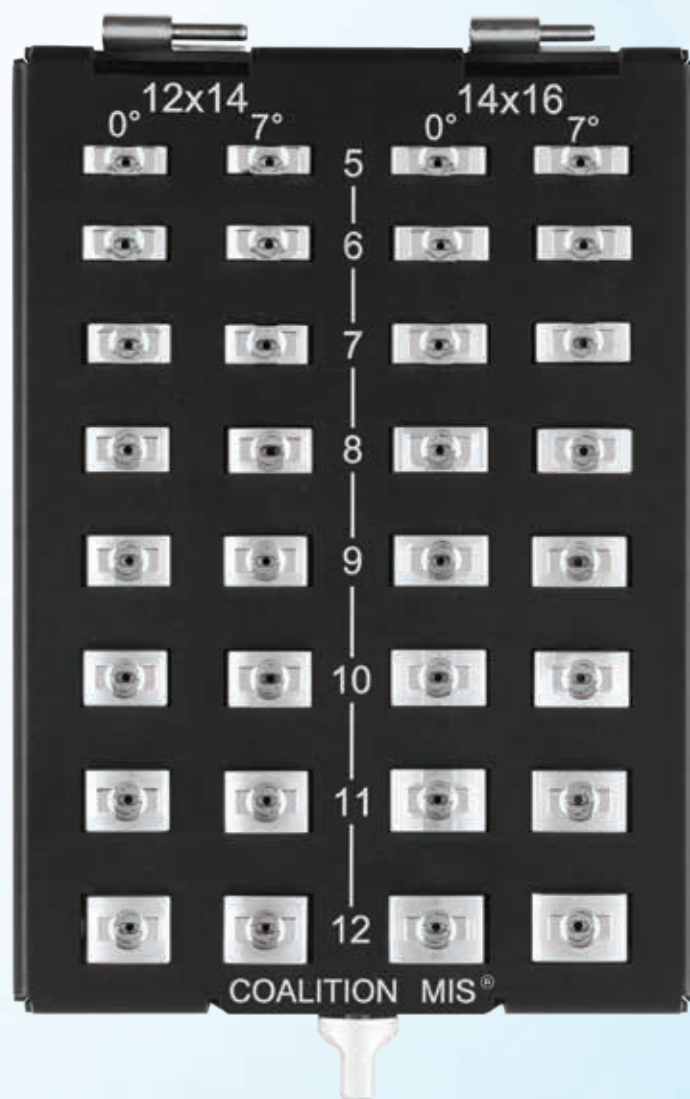
STANDARD INSTRUMENT SET 9136.9001



COALITION MIS® 12x14mm and 14x16mm TRIAL SET 9136.9012

Part No.	Trials	Qty
6136.0105	Modular Trial Head, 12x14mm, 0°, 5mm	1
6136.0106	Modular Trial Head, 12x14mm, 0°, 6mm	1
6136.0107	Modular Trial Head, 12x14mm, 0°, 7mm	1
6136.0108	Modular Trial Head, 12x14mm, 0°, 8mm	1
6136.0109	Modular Trial Head, 12x14mm, 0°, 9mm	1
6136.0110	Modular Trial Head, 12x14mm, 0°, 10mm	1
6136.0111	Modular Trial Head, 12x14mm, 0°, 11mm	1
6136.0112	Modular Trial Head, 12x14mm, 0°, 12mm	1
6136.0205	Modular Trial Head, 12x14mm, 7°, 5mm	1
6136.0206	Modular Trial Head, 12x14mm, 7°, 6mm	1
6136.0207	Modular Trial Head, 12x14mm, 7°, 7mm	1
6136.0208	Modular Trial Head, 12x14mm, 7°, 8mm	1
6136.0209	Modular Trial Head, 12x14mm, 7°, 9mm	1
6136.0210	Modular Trial Head, 12x14mm, 7°, 10mm	1
6136.0211	Modular Trial Head, 12x14mm, 7°, 11mm	1
6136.0212	Modular Trial Head, 12x14mm, 7°, 12mm	1
6136.0305	Modular Trial Head, 14x16mm, 0°, 5mm	1
6136.0306	Modular Trial Head, 14x16mm, 0°, 6mm	1
6136.0307	Modular Trial Head, 14x16mm, 0°, 7mm	1
6136.0308	Modular Trial Head, 14x16mm, 0°, 8mm	1
6136.0309	Modular Trial Head, 14x16mm, 0°, 9mm	1
6136.0310	Modular Trial Head, 14x16mm, 0°, 10mm	1
6136.0311	Modular Trial Head, 14x16mm, 0°, 11mm	1
6136.0312	Modular Trial Head, 14x16mm, 0°, 12mm	1
6136.0405	Modular Trial Head, 14x16mm, 7°, 5mm	1
6136.0406	Modular Trial Head, 14x16mm, 7°, 6mm	1
6136.0407	Modular Trial Head, 14x16mm, 7°, 7mm	1
6136.0408	Modular Trial Head, 14x16mm, 7°, 8mm	1
6136.0409	Modular Trial Head, 14x16mm, 7°, 9mm	1
6136.0410	Modular Trial Head, 14x16mm, 7°, 10mm	1
6136.0411	Modular Trial Head, 14x16mm, 7°, 11mm	1
6136.0412	Modular Trial Head, 14x16mm, 7°, 12mm	1
9136.0012	12x14mm/14x16mm Trial Head Module	

COALITION MIS® 12x14mm and 14x16mm TRIAL SET 9136.9012



COALITION MIS® 15x18mm

TRIAL SET 9136.9013

Part No.	Trials	Qty
6136.0505	Modular Trial Head, 15x18mm, 0°, 5mm	1
6136.0506	Modular Trial Head, 15x18mm, 0°, 6mm	1
6136.0507	Modular Trial Head, 15x18mm, 0°, 7mm	1
6136.0508	Modular Trial Head, 15x18mm, 0°, 8mm	1
6136.0509	Modular Trial Head, 15x18mm, 0°, 9mm	1
6136.0510	Modular Trial Head, 15x18mm, 0°, 10mm	1
6136.0511	Modular Trial Head, 15x18mm, 0°, 11mm	1
6136.0512	Modular Trial Head, 15x18mm, 0°, 12mm	1
6136.0605	Modular Trial Head, 15x18mm, 7°, 5mm	1
6136.0606	Modular Trial Head, 15x18mm, 7°, 6mm	1
6136.0607	Modular Trial Head, 15x18mm, 7°, 7mm	1
6136.0608	Modular Trial Head, 15x18mm, 7°, 8mm	1
6136.0609	Modular Trial Head, 15x18mm, 7°, 9mm	1
6136.0610	Modular Trial Head, 15x18mm, 7°, 10mm	1
6136.0611	Modular Trial Head, 15x18mm, 7°, 11mm	1
6136.0612	Modular Trial Head, 15x18mm, 7°, 12mm	1
9136.0013	15x18 Modular Trial Module	

COALITION MIS® 15x18mm TRIAL SET 9136.9013



COALITION MIS® 12° SPACER SET 9136.9004

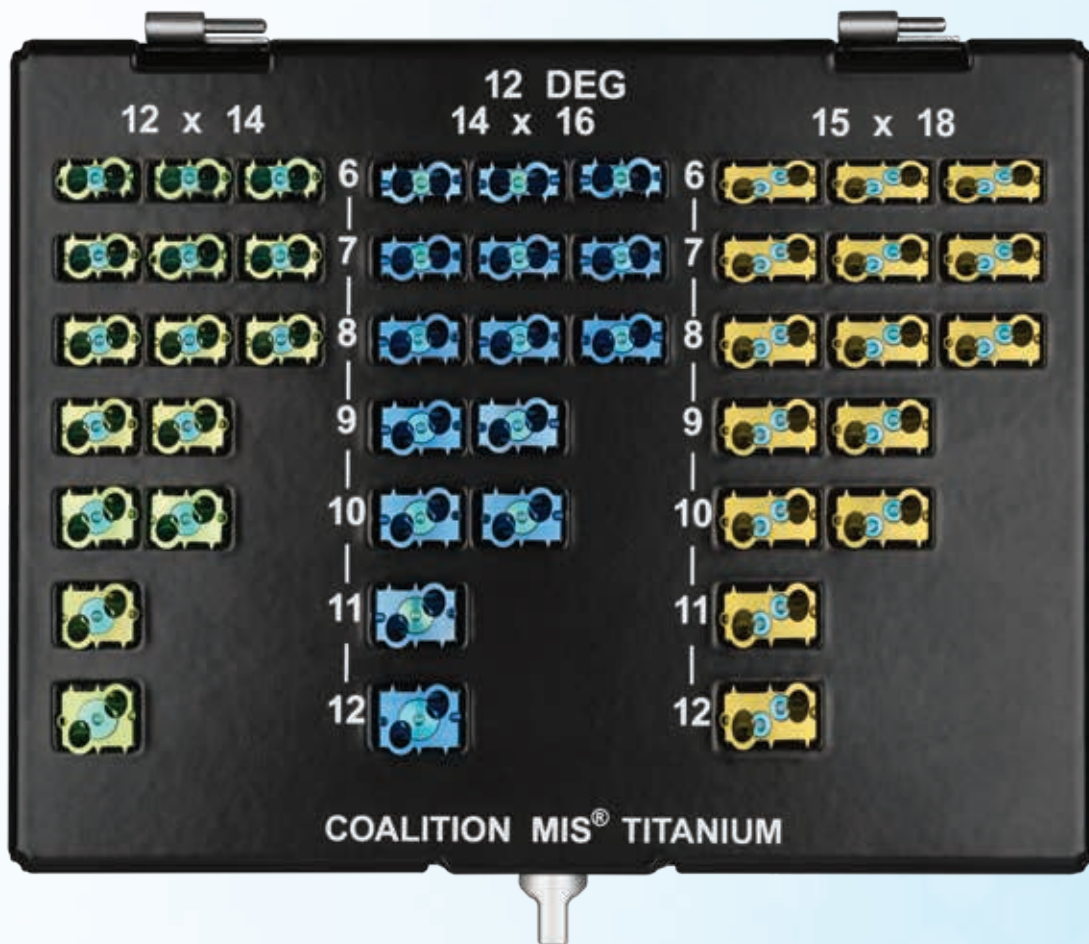
Part No.	Spacers	Qty
3136.1606	COALITION MIS® Spacer, 12x14mm, 12°, 6mm	3
3136.1607	COALITION MIS® Spacer, 12x14mm, 12°, 7mm	3
3136.1608	COALITION MIS® Spacer, 12x14mm, 12°, 8mm	3
3136.1609	COALITION MIS® Spacer, 12x14mm, 12°, 9mm	2
3136.1610	COALITION MIS® Spacer, 12x14mm, 12°, 10mm	2
3136.1611	COALITION MIS® Spacer, 12x14mm, 12°, 11mm	1
3136.1612	COALITION MIS® Spacer, 12x14mm, 12°, 12mm	1
3136.2606	COALITION MIS® Spacer, 14x16mm, 12°, 6mm	3
3136.2607	COALITION MIS® Spacer, 14x16mm, 12°, 7mm	3
3136.2608	COALITION MIS® Spacer, 14x16mm, 12°, 8mm	3
3136.2609	COALITION MIS® Spacer, 14x16mm, 12°, 9mm	2
3136.2610	COALITION MIS® Spacer, 14x16mm, 12°, 10mm	2
3136.2611	COALITION MIS® Spacer, 14x16mm, 12°, 11mm	1
3136.2612	COALITION MIS® Spacer, 14x16mm, 12°, 12mm	1
3136.4606	COALITION MIS® Spacer, 15x18mm, 12°, 6mm	3
3136.4607	COALITION MIS® Spacer, 15x18mm, 12°, 7mm	3
3136.4608	COALITION MIS® Spacer, 15x18mm, 12°, 8mm	3
3136.4609	COALITION MIS® Spacer, 15x18mm, 12°, 9mm	2
3136.4610	COALITION MIS® Spacer, 15x18mm, 12°, 10mm	2
3136.4611	COALITION MIS® Spacer, 15x18mm, 12°, 11mm	1
3136.4612	COALITION MIS® Spacer, 15x18mm, 12°, 12mm	1
9136.0004	COALITION MIS® 12° Spacer Module	

COALITION MIS® 12° SPACER SET 9136.9004



COALITION MIS® TITANIUM 12° SPACER SET 9136.9009

Part No.	Spacers	Qty
1136.2496	COALITION MIS® Spacer, Ti 12x14, 12°, 6mm	3
1136.2497	COALITION MIS® Spacer, Ti 12x14, 12°, 7mm	3
1136.2498	COALITION MIS® Spacer, Ti 12x14, 12°, 8mm	3
1136.2499	COALITION MIS® Spacer, Ti 12x14, 12°, 9mm	2
1136.2500	COALITION MIS® Spacer, Ti 12x14, 12°, 10mm	2
1136.2501	COALITION MIS® Spacer, Ti 12x14, 12°, 11mm	1
1136.2502	COALITION MIS® Spacer, Ti 12x14, 12°, 12mm	1
1136.4696	COALITION MIS® Spacer, Ti 14x16, 12°, 6mm	3
1136.4697	COALITION MIS® Spacer, Ti 14x16, 12°, 7mm	3
1136.4698	COALITION MIS® Spacer, Ti 14x16, 12°, 8mm	3
1136.4699	COALITION MIS® Spacer, Ti 14x16, 12°, 9mm	2
1136.4700	COALITION MIS® Spacer, Ti 14x16, 12°, 10mm	2
1136.4701	COALITION MIS® Spacer, Ti 14x16, 12°, 11mm	1
1136.4702	COALITION MIS® Spacer, Ti 14x16, 12°, 12mm	1
1136.5896	COALITION MIS® Spacer, Ti 15x18, 12°, 6mm	3
1136.5897	COALITION MIS® Spacer, Ti 15x18, 12°, 7mm	3
1136.5898	COALITION MIS® Spacer, Ti 15x18, 12°, 8mm	3
1136.5899	COALITION MIS® Spacer, Ti 15x18, 12°, 9mm	2
1136.5900	COALITION MIS® Spacer, Ti 15x18, 12°, 10mm	2
1136.5901	COALITION MIS® Spacer, Ti 15x18, 12°, 11mm	1
1136.5902	COALITION MIS® Spacer, Ti 15x18, 12°, 12mm	1
9136.0008	COALITION MIS® Titanium 12° Implant Module	

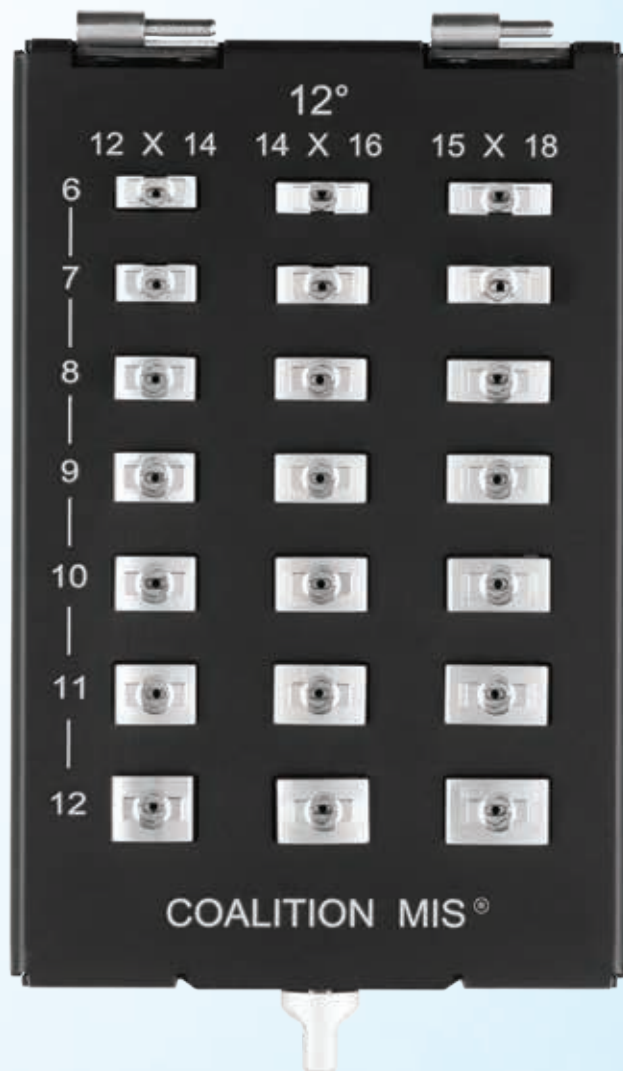


COALITION MIS® 12°

INSTRUMENT SET 9136.9014

Part No.	Instruments	Qty
6136.0226	Modular Trial Head, 12x14mm, 12°, 6mm	1
6136.0227	Modular Trial Head, 12x14mm, 12°, 7mm	1
6136.0228	Modular Trial Head, 12x14mm, 12°, 8mm	1
6136.0229	Modular Trial Head, 12x14mm, 12°, 9mm	1
6136.0230	Modular Trial Head, 12x14mm, 12°, 10mm	1
6136.0231	Modular Trial Head, 12x14mm, 12°, 11mm	1
6136.0232	Modular Trial Head, 12x14mm, 12°, 12mm	1
6136.0426	Modular Trial Head, 14x16mm, 12°, 6mm	1
6136.0427	Modular Trial Head, 14x16mm, 12°, 7mm	1
6136.0428	Modular Trial Head, 14x16mm, 12°, 8mm	1
6136.0429	Modular Trial Head, 14x16mm, 12°, 9mm	1
6136.0430	Modular Trial Head, 14x16mm, 12°, 10mm	1
6136.0431	Modular Trial Head, 14x16mm, 12°, 11mm	1
6136.0432	Modular Trial Head, 14x16mm, 12°, 12mm	1
6136.0626	Modular Trial Head, 15x18mm, 12°, 6mm	1
6136.0627	Modular Trial Head, 15x18mm, 12°, 7mm	1
6136.0628	Modular Trial Head, 15x18mm, 12°, 8mm	1
6136.0629	Modular Trial Head, 15x18mm, 12°, 9mm	1
6136.0630	Modular Trial Head, 15x18mm, 12°, 10mm	1
6136.0631	Modular Trial Head, 15x18mm, 12°, 11mm	1
6136.0632	Modular Trial Head, 15x18mm, 12°, 12mm	1
9136.0014	COALITION MIS® 12° Modular Trial Module	

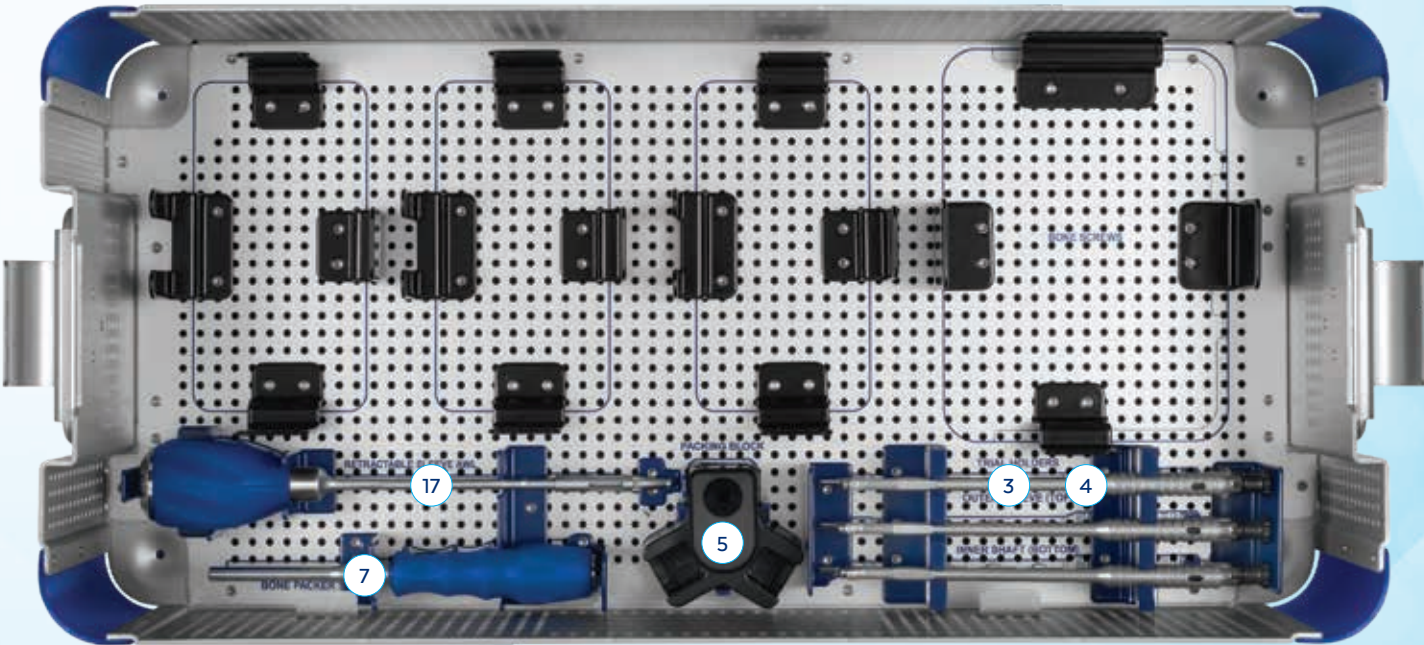
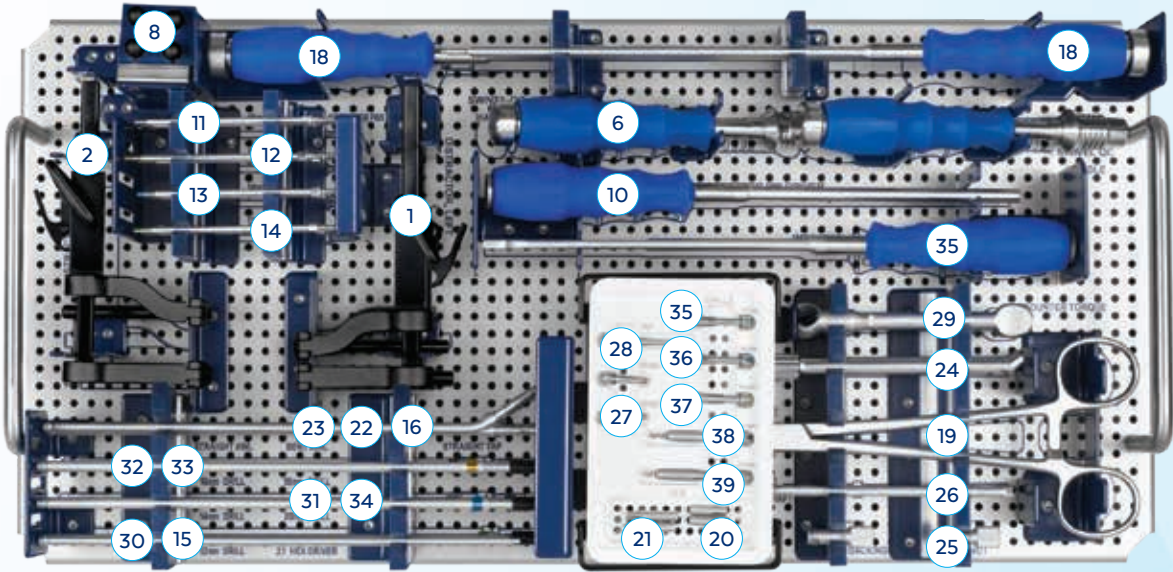
COALITION MIS® 12° INSTRUMENT SET 9136.9014



UNIVERSAL ACDF INSTRUMENT SET 9147.9001

Instruments	Qty	Instruments	Qty
1 601.020 Distractor, Left	1	29 684.421 Counter-Torque, Angled Instrument	2
2 601.021 Distractor, Right	1	30 684.422 Straight Drill with Self-Centering Sleeve, 12mm	1
3 6147.9001 Trial Holder, Modular Trial/Rasp Heads - Outer Sleeve	3	31 684.424 Straight Drill with Self-Centering Sleeve, 14mm	1
4 6147.9002 Trial Holder, Modular Trial/Rasp Heads - Inner Shaft Assembly	3	684.425 Angled Driver Tip, Short	0
5 6147.9003 Packing Block	1	32 684.426 Straight Drill with Self-Centering Sleeve, 16mm	1
6 636.450 Quick-Connect Handle, Swivel	2	33 684.428 Straight Drill with Self-Centering Sleeve, 18mm	1
7 665.504 Bone Packer	1	34 684.430 Straight Drill with Self-Centering Sleeve, 20mm	1
8 665.606 Distractor Locking Nuts	4	35 684.432 Angled Drill Tip with Self-Centering Sleeve, 12mm	1
9 665.607 Impactor	1	36 684.434 Angled Drill Tip with Self-Centering Sleeve, 14mm	1
10 665.608 Distractor Pin Driver	1	37 684.436 Angled Drill Tip with Self-Centering Sleeve, 16mm	1
665.610 Distractor Pin, 10mm	0	38 684.438 Angled Drill Tip with Self-Centering Sleeve, 18mm	1
11 665.612 Distractor Pin, 12mm	2	39 684.440 Angled Drill Tip with Self-Centering Sleeve, 20mm	1
12 665.614 Distractor Pin, 14mm	2	9147.0001 Universal ACDF Instrument Graphic Case	
13 665.616 Distractor Pin, 16mm	2	984.004 COALITION® Module, Angled Instruments	
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	0		
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		

UNIVERSAL ACDF INSTRUMENT SET 9147.9001



UNIVERSAL ACDF 12x14mm RASP SET 9147.9003

Part No.	Rasps	Qty
6147.1025	Modular Rasp, 12x14mm, 0°, 5mm	1
6147.1026	Modular Rasp, 12x14mm, 0°, 6mm	1
6147.1027	Modular Rasp, 12x14mm, 0°, 7mm	1
6147.1028	Modular Rasp, 12x14mm, 0°, 8mm	1
6147.1029	Modular Rasp, 12x14mm, 0°, 9mm	1
6147.1030	Modular Rasp, 12x14mm, 0°, 10mm	1
6147.1031	Modular Rasp, 12x14mm, 0°, 11mm	1
6147.1032	Modular Rasp, 12x14mm, 0°, 12mm	1
6147.1126	Modular Rasp, 12x14mm, 7°, 6mm	1
6147.1127	Modular Rasp, 12x14mm, 7°, 7mm	1
6147.1128	Modular Rasp, 12x14mm, 7°, 8mm	1
6147.1129	Modular Rasp, 12x14mm, 7°, 9mm	1
6147.1130	Modular Rasp, 12x14mm, 7°, 10mm	1
6147.1131	Modular Rasp, 12x14mm, 7°, 11mm	1
6147.1132	Modular Rasp, 12x14mm, 7°, 12mm	1
9147.0003	12x14mm Universal Rasps	

UNIVERSAL ACDF 14x16mm RASP SET 9147.9004

Part No.	Rasps	Qty
6147.2025	Modular Rasp, 14x16mm, 0°, 5mm	1
6147.2026	Modular Rasp, 14x16mm, 0°, 6mm	1
6147.2027	Modular Rasp, 14x16mm, 0°, 7mm	1
6147.2028	Modular Rasp, 14x16mm, 0°, 8mm	1
6147.2029	Modular Rasp, 14x16mm, 0°, 9mm	1
6147.2030	Modular Rasp, 14x16mm, 0°, 10mm	1
6147.2031	Modular Rasp, 14x16mm, 0°, 11mm	1
6147.2032	Modular Rasp, 14x16mm, 0°, 12mm	1
6147.2126	Modular Rasp, 14x16mm, 7°, 6mm	1
6147.2127	Modular Rasp, 14x16mm, 7°, 7mm	1
6147.2128	Modular Rasp, 14x16mm, 7°, 8mm	1
6147.2129	Modular Rasp, 14x16mm, 7°, 9mm	1
6147.2130	Modular Rasp, 14x16mm, 7°, 10mm	1
6147.2131	Modular Rasp, 14x16mm, 7°, 11mm	1
6147.2132	Modular Rasp, 14x16mm, 7°, 12mm	1
9147.0004	14x16mm Universal Rasps	

UNIVERSAL ACDF 12x14mm RASP SET 9147.9003



UNIVERSAL ACDF 14x16mm RASP SET 9147.9004



UNIVERSAL ACDF 15x18mm

RASP SET 9147.9005

Part No.	Rasps	Qty
6147.3025	Modular Rasp, 15x18mm, 0°, 5mm	1
6147.3026	Modular Rasp, 15x18mm, 0°, 6mm	1
6147.3027	Modular Rasp, 15x18mm, 0°, 7mm	1
6147.3028	Modular Rasp, 15x18mm, 0°, 8mm	1
6147.3029	Modular Rasp, 15x18mm, 0°, 9mm	1
6147.3030	Modular Rasp, 15x18mm, 0°, 10mm	1
6147.3031	Modular Rasp, 15x18mm, 0°, 11mm	1
6147.3032	Modular Rasp, 15x18mm, 0°, 12mm	1
6147.3126	Modular Rasp, 15x18mm, 7°, 6mm	1
6147.3127	Modular Rasp, 15x18mm, 7°, 7mm	1
6147.3128	Modular Rasp, 15x18mm, 7°, 8mm	1
6147.3129	Modular Rasp, 15x18mm, 7°, 9mm	1
6147.3130	Modular Rasp, 15x18mm, 7°, 10mm	1
6147.3131	Modular Rasp, 15x18mm, 7°, 11mm	1
6147.3132	Modular Rasp, 15x18mm, 7°, 12mm	1
9147.0005	15x18mm Universal Rasps	

UNIVERSAL ACDF 15x18mm
RASP SET 9147.9005



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

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

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

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

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

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

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 Fixed, Self-Drilling

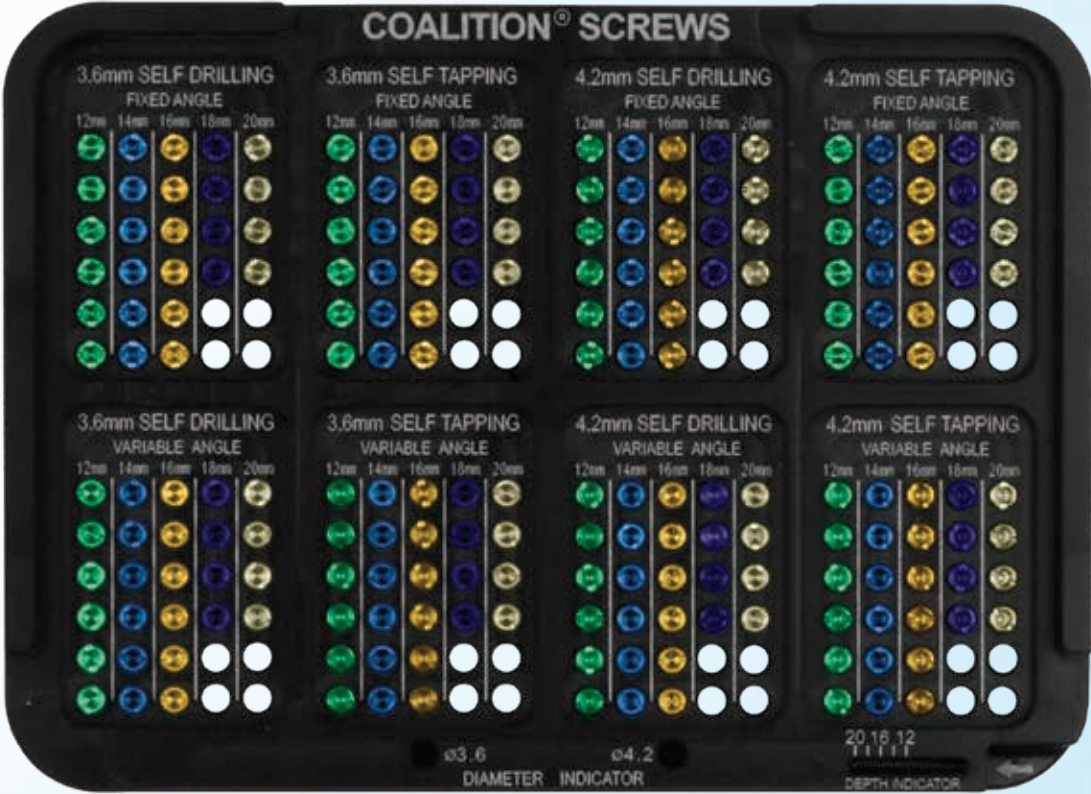
Qty

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 ACD F

SCREW SET 9147.9008

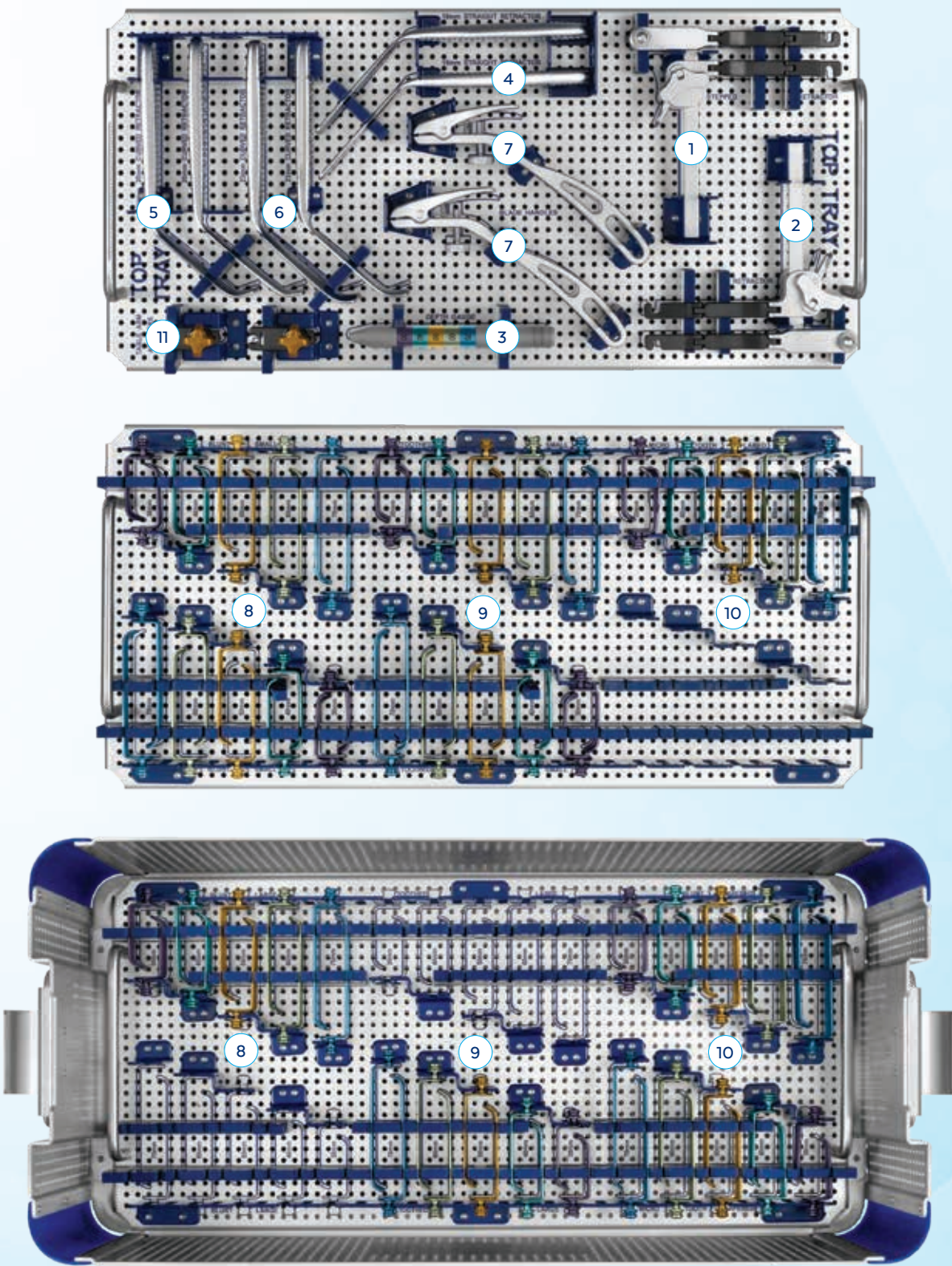


MARS™ ACDF

RETRACTOR SET 9138.9001

Instruments			Qty	Toothed Blades (Cont'd)			Qty
1	6138.0103	Retractor Frame, Offset	1	6138.1231	30mm Blade, Toothed - Large		2
2	6138.0101	Retractor Frame, Left	1	6138.1241	40mm Blade, Toothed - Large		2
3	6138.0203	Depth Gauge	1	6138.1251	50mm Blade, Toothed - Large		2
4	6138.0218	Handheld Retractor, Straight - 18mm	2	6138.1261	60mm Blade, Toothed - Large		2
5	6138.0220	Handheld Retractor, Curved - 20mm	2	6138.1271	70mm Blade, Toothed - Large		2
6	6138.0223	Handheld Retractor, Curved - 23mm	2				
7	6138.0230	Blade Handle, Interchangeable	2				
8	Blunted Blades		Qty	10	Micro Tooth Blades		Qty
	6138.1030	30mm Blade, Blunt - Small	4		6138.1330	30mm Blade, Micro Tooth - Tapered	2
	6138.1040	40mm Blade, Blunt - Small	4		6138.1340	40mm Blade, Micro Tooth - Tapered	2
	6138.1050	50mm Blade, Blunt - Small	4		6138.1350	50mm Blade, Micro Tooth - Tapered	2
	6138.1060	60mm Blade, Blunt - Small	4		6138.1360	60mm Blade, Micro Tooth - Tapered	2
	6138.1070	70mm Blade, Blunt - Small	4		6138.1370	70mm Blade, Micro Tooth - Tapered	2
	6138.1031	30mm Blade, Blunt - Large	2		6138.1430	30mm Blade, Micro Tooth - Flared	2
	6138.1041	40mm Blade, Blunt - Large	2		6138.1440	40mm Blade, Micro Tooth - Flared	2
	6138.1051	50mm Blade, Blunt - Large	2		6138.1450	50mm Blade, Micro Tooth - Flared	2
	6138.1061	60mm Blade, Blunt - Large	2		6138.1460	60mm Blade, Micro Tooth - Flared	2
	6138.1071	70mm Blade, Blunt - Large	2		6138.1470	70mm Blade, Micro Tooth - Flared	2
	6138.1130	30mm Blade, Blunt - Tapered	2	11	6133.0790	Table Arm Adaptor	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		9138.0001	ACDF Graphic Case	
	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				

MARS™ ACDF
RETRACTOR SET 9138.9001



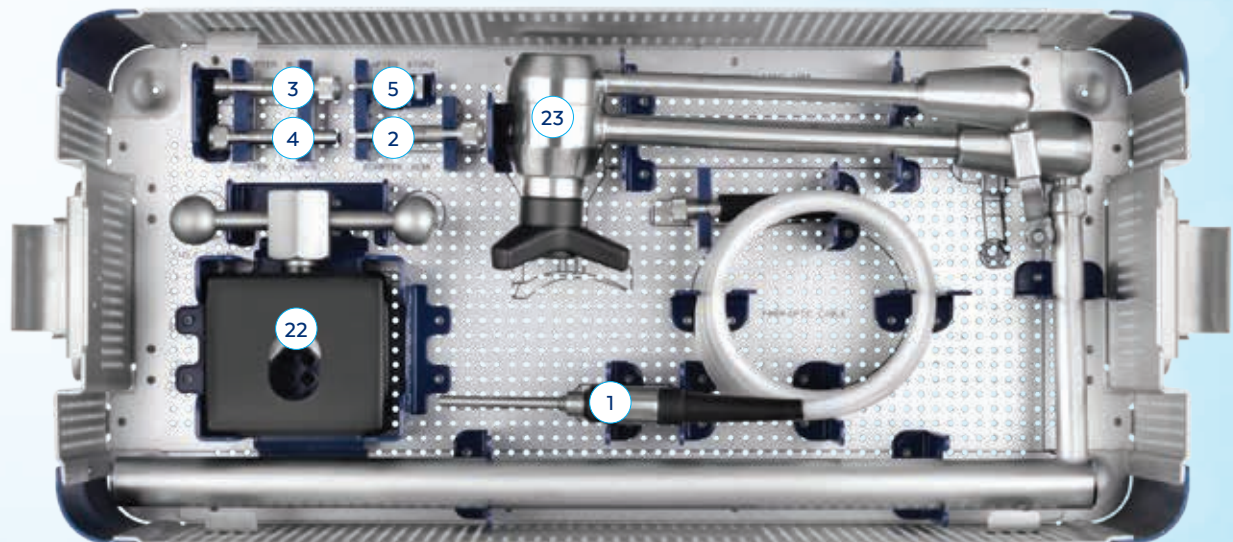
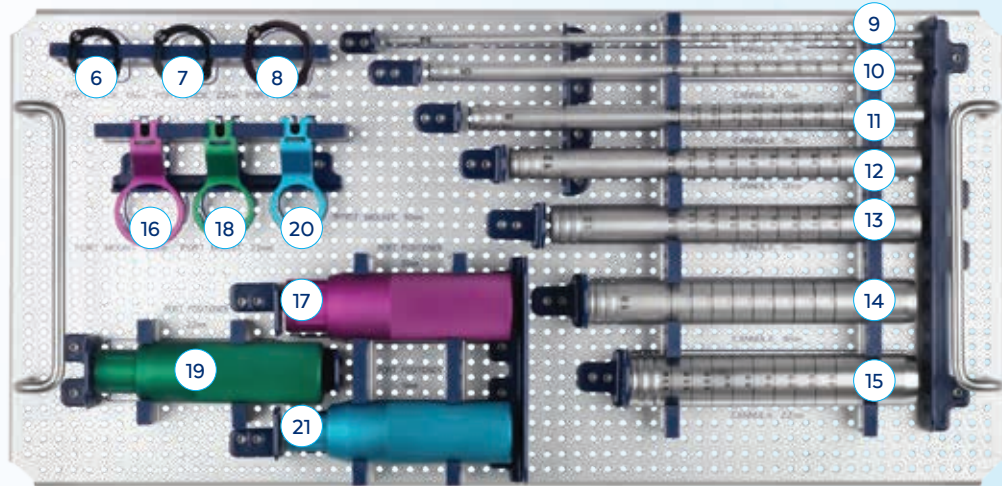
MARS™

INSTRUMENT II SET 932.902

	Instruments	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 THE COALITION® SPACERS

DESCRIPTION

COALITION® Spacers (including COALITION MIS®, and COALITION AGX®) are cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. COALITION® Spacers are inserted through an anterior cervical approach, and 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 aid in expulsion resistance. The COALITION AGX® Plate is an anterior cervical fixation device that is available in various lengths and widths to fit the anatomical needs of a wide variety of patients. Screws are inserted through the anterior titanium portion of the implants into adjacent vertebral bodies for bony fixation. The COALITION MIS® Spacer may also be used with anchors inserted through the anterior titanium portion of the implant into adjacent vertebral bodies.

COALITION® Spacers are made from radiolucent PEEK polymer and titanium alloy, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. COALITION® Spacers are additionally available in an all-titanium alloy version. COALITION® PEEK spacers are available with commercially pure titanium plasma spray (TPS) coating, as specified in ASTM F67 and F1580. COALITION AGX® Plates are made from titanium alloy, as specified in ASTM F136, F1295, and F1472. The screws and anchors are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

INDICATIONS

All COALITION® Spacers 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 cancellous, cortical and/or corticocancellous bone. All COALITION® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

The COALITION® Spacer and COALITION AGX® Plate and Spacer assembly are stand-alone integrated interbody fusion devices intended for use at one or two levels of the cervical spine (C2-T1) and used with two titanium alloy screws which accompany the implant.

The COALITION MIS® Spacer is an integrated interbody fusion device intended to be used with two titanium alloy screws and/or anchors which accompany the implants. When used with screws, COALITION MIS® Spacers are stand-alone interbody fusion devices intended for use at one or two levels of the cervical spine (C2-T1). When used with anchors, COALITION MIS® Spacers are intended for use at one level of the cervical spine (C2-T1) with additional supplemental fixation such as posterior cervical screw fixation.

COALITION AGX® 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 (C2-T1). When used with the COALITION AGX® Plate, the plate-spacer assembly takes on the indications for use of the COALITION AGX® Spacer, with the COALITION AGX® Plate acting as the supplemental fixation.

The COALITION AGX® Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

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.

The COALITION AGX® Plates are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Plate contouring is not recommended due to the plate's translational components.

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

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

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

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

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

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

PRECAUTIONS

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

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

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

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

MRI SAFETY INFORMATION



The COALITION® 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 COALITION® 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 localized to the site of the proposed implantation, or when the patient has a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
2. Signs of local inflammation.
3. Prior fusion at the level(s) to be treated.
4. Severe osteoporosis, which may prevent adequate fixation.
5. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
6. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
7. Any patient not willing to cooperate with postoperative 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. 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:

IMPORTANT INFORMATION ON THE COALITION® SPACERS

- 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 products from the packaging using aseptic technique.

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

HANDLING AND USE

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

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidentally 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 products 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 can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

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

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.

7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile products are packaged in a heat-sealed 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 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 in² 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			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		

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