REUNION

SACROILIAC JOINT FUSION SYSTEM

ASTURA MEDICAL

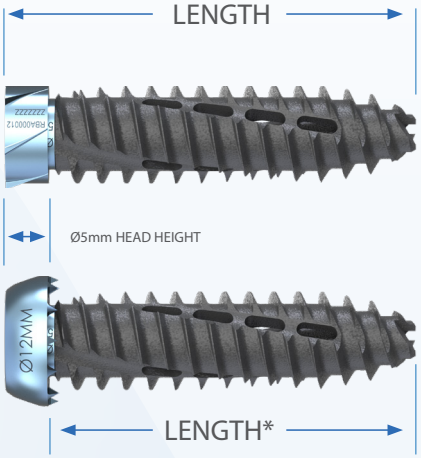
DESIGN RATIONALE

The Astura Sacroiliac (SI) Joint Fusion Set is a comprehensive system designed for a minimally invasive lateral approach to stabilize the SI joint, by providing an environment for joint fusion. The system features a comprehensive set of cannulated and fenestrated screws to promote fusion. The system provides maximum efficiency of screw insertion into pelvic bone, across a variety of patient anatomies, for conditions including Sacroiliac Joint disruptions and Degenerative Sacroiliitis.

SPECIFICATIONS

MODULAR, STANDARD THREAD SCREW OPTIONS

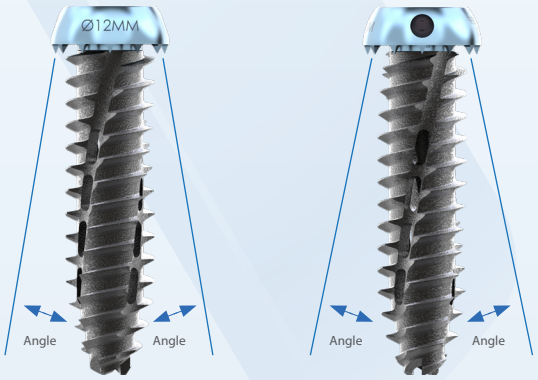
Ø8mm Ø10mm Ø12mm Ø14mm



MODULAR, STANDARD THREAD SCREW HEAD OPTIONS

SCREW TYPE	SCREW LENGTH
MODULAR, STANDARD THREAD	35mm – 80mm* (5mm increments)

***NOTE: If using a Variable Surface Mount Screw Head, subtract 5mm from the given screw length to determine the amount of screw length below the bone surface.**

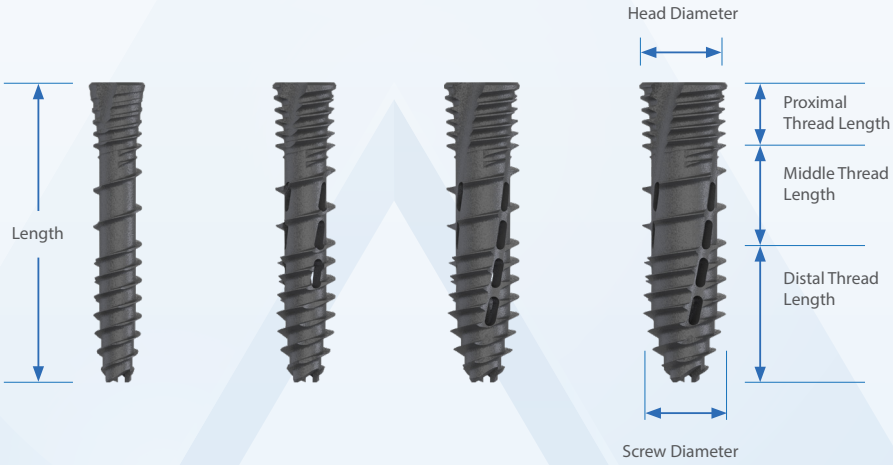


SCREW HEAD	FLUSH MOUNT SCREW HEAD MAX DIAMETER	VARIABLE SURFACE MOUNT SCREW HEAD MAX DIAMETER
Ø8/10mm SCREW HEADS	Ø12.2mm	Ø14mm
Ø12mm SCREW HEADS	Ø13.2mm	Ø16mm
Ø14mm SCREW HEADS	Ø15.2mm	Ø18mm

SCREW DIAMETER	VARIABLE SURFACE MOUNT SCREW HEAD	ANGLE
Ø8mm	Ø8/10mm	9°
Ø10mm	Ø8/10mm	9°
Ø12mm	Ø12mm	9°
Ø14mm	Ø14mm	9°

FIXED, COMPRESSION THERAD SCREW OPTIONS

Ø8mm Ø10mm Ø12mm Ø14mm



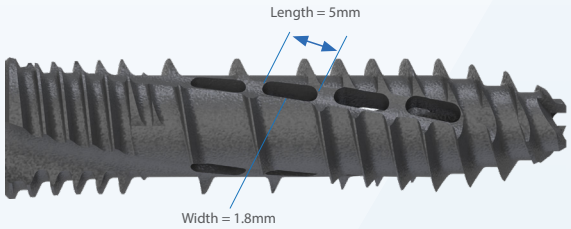
SCREW DIAMETER	HEAD DIAMETER
Ø8mm	9.5mm
Ø10mm	11mm
Ø12mm	13mm
Ø14mm	15mm

SCREW LENGTH (mm)	PROXIMAL THREAD LENGTH (mm)	MIDDLE THREAD LENGTH (mm)	DISTAL THREAD LENGTH (mm)
35	10.5	N/A	24.5
40	12.5	N/A	27.5
45	14.5	N/A	30.5
50	11.0	17.5	21.5
55	12.5	21.0	21.5
60	14.5	24.0	21.5
65	14.0	29.5	21.5
70	15.5	33.0	21.5
75	17.5	36.0	21.5
80	20.0	38.5	21.5

SPECIFICATIONS

SCREW FENNESTRATIONS

The screw fenestration information below is applicable to both the Modular, Standard Thread Screws and the Fixed, Compression Thread Screws.



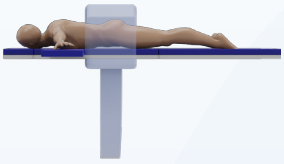
The graft volume analysis includes the volume of the internal cannula, plus the volume of the fenestrations.

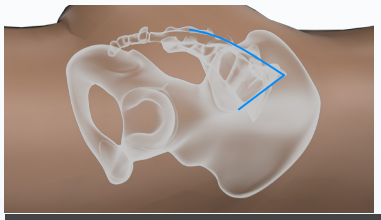
SCREW DIAMETER	SCREW LENGTH (mm)	GRAFT VOLUME (cm3)
Ø8mm	35	0.246
	40	0.317
	45	0.348
	50	0.419
	55	0.490
	60	0.521
	65	0.592
	70	0.664
	75	0.694
	80	0.764
Ø10mm	35	0.271
	40	0.355
	45	0.439
	50	0.522
	55	0.553
	60	0.637
	65	0.720
	70	0.804
	75	0.887
	80	0.919
Ø12mm	35	0.369
	40	0.488
	45	0.607
	50	0.730
	55	0.851
	60	0.907
	65	1.026
	70	1.145
	75	1.267
	80	1.388
Ø14mm	35	0.419
	40	0.563
	45	0.708
	50	0.854
	55	1.001
	60	1.058
	65	1.201
	70	1.345
	75	1.491
	80	1.638

*NOTE: Fenestrations are not available for the Ø8mm Fixed, Compression Thread Screws. Therefore, the graft volume is not applicable

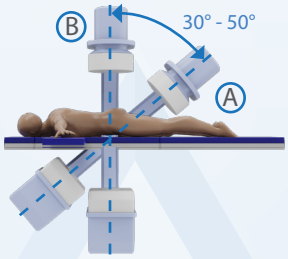
1.0 TARGETING AND STEINMANN PIN INSERTION

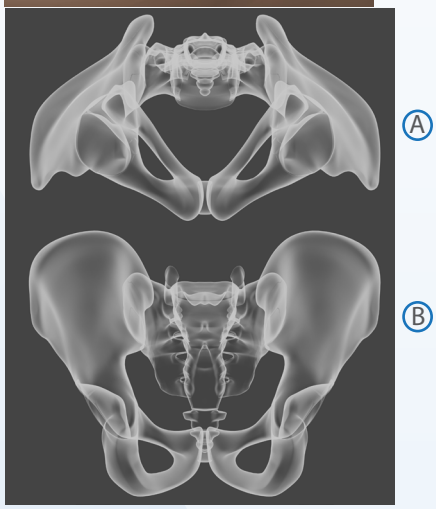
1.1 With the patient in the prone position, achieve a true lateral view through imaging. Mark the posterior sacral wall as reference.





1.1.1 An inlet(A) and outlet (B) view will also need to be established for screw implant placement.

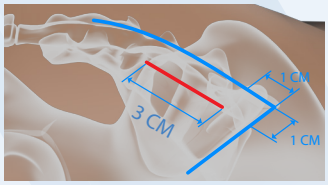




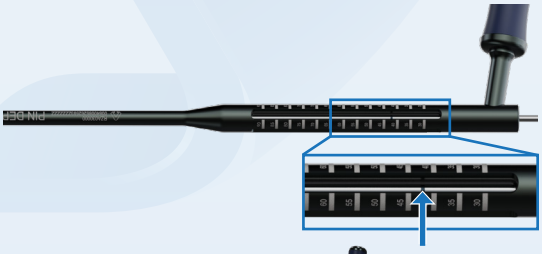
1.2 Starting approximately 1cm from the alar line, and 1 cm from the posterior sacral slope line, make a 3cm incision parallel to the posterior sacral wall reference line, progressing inferiorly.

1.3 The first Steinmann Pin (RZA01XXXX) should be placed 1cm caudal to the ala and 1cm anterior to the posterior wall. The pin may be held and manipulated using the Steinmann Pin Holder (RZA180000) during this process. Avoid advancing the pin to the foramen. The first pin is typically cranial of the S-1 foramen.

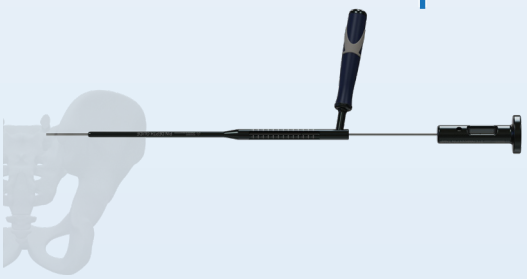
1.4 Once the desired position is located, and the incision is made, advance the Steinmann pin into the iliac bone by gently tapping the pin with a mallet on the proximal end of the pin. The pin may be held and manipulated using the Steinmann Pin Holder (RZA180000) during this process.



1.5 Remove the Pin Holder and place the Depth Guide (RZA030000) over the Steinmann pin and down to the Ilium. Advance the Steinmann pin to the desired depth by aligning the marking on the Steinmann pin, with the Depth Guide depth markings. The pin depth below the Ilium surface, corresponds to the markings on the Depth Guide.

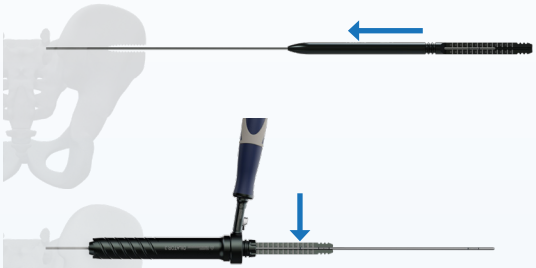


1.6 (Optional): Attach the Steinmann Pin Tamp (RZA170000) to the proximal end of the Steinmann pin and mallet the tamp surface to assist the pin advancement to the proper depth.



2.0 ACCESS AND SCREW PREPARATION

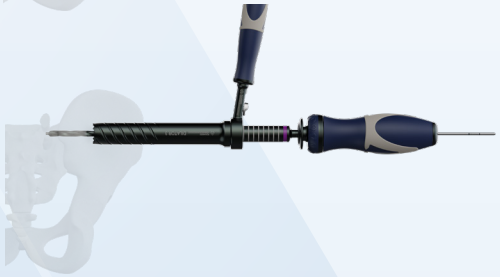
2.1 Remove all instruments leaving only the Steinmann pin. Ensure the pin does not retract upon instrument removal.



2.2 Insert Dilator 1 (RZA040001) to the Ilium and verify the lasermarked line on the Steinmann pin corresponds to the desired depth on the dilator depth markings. Insert Dilator 2 (RZA040002) to the Ilium. Attach the Dilator 3 Handle (RZA050000) to Dilator 3 (RZA040003) then insert to the Ilium.

2.3 Remove Dilator 1(Highlighted Pink) and Dilator 2 (Highlighted Blue).

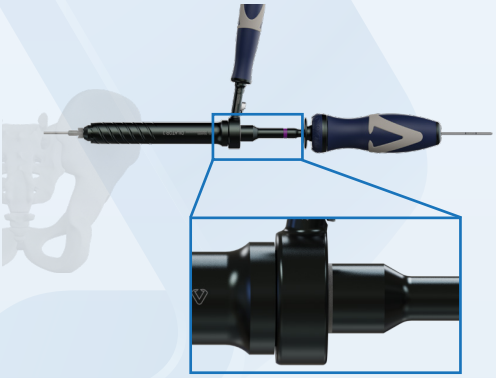
2.4 Select the drill size (RZA06XXXX) that corresponds to the desired screw diameter. Attach the Axial Ratcheting Handle (EAECNZBBZ) or T-Handle (EBECNZBBZ) to the drill.



NOTE: The drill epoxy line colors match the screw colors, which are color coordinated by diameter.

NOTE: If using a larger screw diameter (Ø12 or Ø14), it is recommended to start with the smallest drill, and step up the drill sizes until the desired hole size is achieved for the selected screw.

2.5 Advance the drill to align the desired depth marking to the proximal end of Dilator 3.

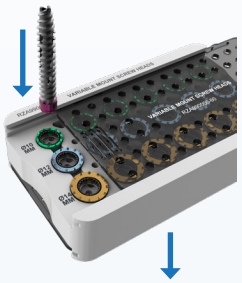


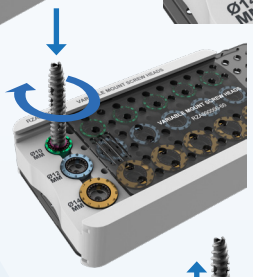
NOTE: The counterbore tool (RZA08XXXX) attached to the Axial Ratcheting Handle (EAECNZBBZ) or T-Handle (EBECNZBBZ) will be required for screws with the Flush Mount Screw Head. A single lasermarked line on the tool aligns with the proximal end of Dilator 3 when correct depth is achieved.

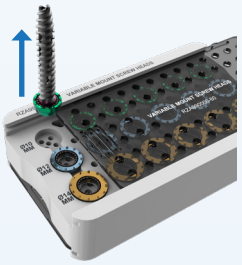
2.6 (Optional): To tap the hole, advance the tap (RZA07XXXX) attached to the Axial Ratcheting Handle (EAECNZBBZ) or T-Handle (EBECNZBBZ) and align the desired depth marking to the proximal end of Dilator 3. The tap epoxy line colors match the screw colors, which are color coordinated by diameter. Advance the tap to align the desired depth marking to the proximal end of Dilator 3.

3.0 (Optional): JOINT PREPARATION

3.1 Use a curette (RZA160000) for joint disruption by placing into the drilled hole until the tim reaches the joint. Then, rotate the curette 360° around the guidewire, inside of the joint to maximize the joint disruption.







4.0 SCREW ASSEMBLY AND INSERTION

4.1 Select the desired screw diameter and length.

NOTE: If using a Variable Mount Screw Head, the overall length, once implanted, will be 5mm shorter than the overall screw length.

4.2 If using the standard thread screws (RAX00XXXX) identify the corresponding Variable Mount Screw Head (RBB0000XX) or Flush Mount Screw Head (RBA0000XX) to the applicable screw diameter.

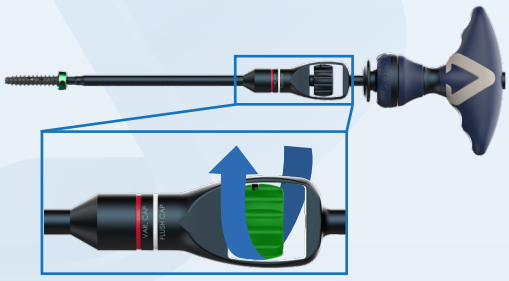
NOTE: The screw head and screw match in color. The green Ø8/10mm screw head size will be used for the magenta Ø8mm diameter screw as well as the green Ø10mm screw.

4.3 With the screw head in the caddy, verify the pin ratcheting teeth are facing up, as shown. Insert the screw shank into the screw head. Rotate the screw shank as needed to allow for proper alignment with the screw head. Minimal insertion force is required for assembly. An audible click can be heard when fully seated. The head will not be able to be removed from the screw, once attached.

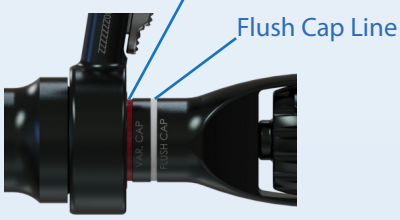
4.4 To ensure the head is fully seated, pull head away from shank, then manually rotate the screw and head to ensure the ratcheting mechanism is functional. Audible clicks can be heard as the screw rotates.

4.5 (Optional) Load a Steinmann Pin through the screw. Pack the screw fenestrations with graft material.

4.6 Attach an Axial Ratcheting Handle (EAECNZBBZ) or T-Handle (EBECNZBBZ) handle to the screwdriver (RZA09X000) then align the hexalobe feature to the screw. Rotate the proximal knob on the driver clockwise, to thread the screwdriver onto the screw's internal threads, until resistance is felt.



4.7 Once the screw is securely attached, place the screw and driver over the Steinmann pin and through Dilator 3. Advance the screw in a clockwise motion with downward force, until fully seated through the Sacroiliac Joint. The epoxy marked line(s) on the driver should be flush with proximal end of Dilator 3 to denote the screw is fully inserted (red epoxy line for the Variable Mount Screw Head and white epoxy line for the Flush Mount Screw Head).



5.0 ADDITIONAL SCREW PLACEMENT

5.1 Remove Dilator 3.

5.2 Attach the Implant Locator Guide Handle (RZA11000X) to the Fixed ImplantLocator Guide (RZA12XXXX) or the Variable Implant Locator Guide (RZA100000).

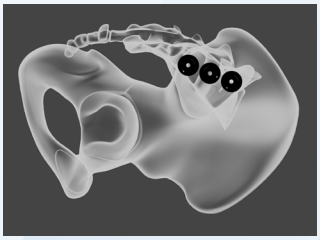
5.3 Place the guide over the first Steinmann pin down to the implant.

5.4 Insert a second Steinmann pin through the guide.

5.5 Repeat the process steps to insert a second and third screw implant.

5.5.1 The screws should align parallel the sacral slope line established. The second implant typically aligns with the S-1 foramen in the outlet fluoroscopy view. The third implant is typically between the S-1 and S-2 neuro foramen on the outlet fluoroscopy view. The screws are typically parallel in the inlet view.

5.5.2 Verify the screw placement in the lateral (A), outlet (B), and inlet (C) views as shown.



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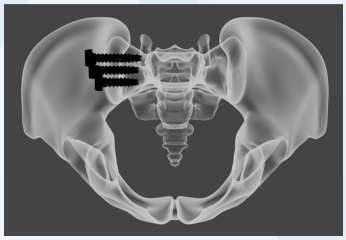

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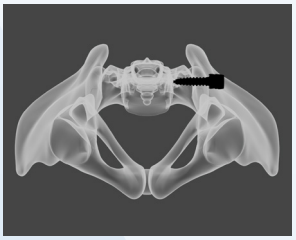

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6.0 GRAFT DELIVERY (Optional)

6.1 Attach the Graft Funnel (RZA130000) to the Graft Tube (RZA140000). Locate the screw implant with the Graft Tube by aligning the distal tip within the screw hex.

6.2 Remove the Steinmann pin.

6.3 Load the Graft Funnel with graft material

6.4 Pack the graft material into the screw's cannula using the Graft Tamp (RZA150000).

6.5 Repeat the process steps for adding bone material for each screw implant.

7.0 IMPLANT REMOVAL

7.1 Attach a ratcheting T-handle to the screwdriver (RZA09X000)

7.2 Attach the screwdriver to the screw implant by aligning the hexalobe feature and then rotate the proximal knob on the driver clockwise, to thread the screwdriver onto the screw's internal threads, until resistance is felt. Once securely attached, rotate the handle counterclockwise with upward force until the screw implant is fully removed from the patient.

REUNION MODULAR SCREW OFFERING

MODULAR, SRANDARD THREAD, ASTURABOND FINISH, Ø8MM

Part Number	Description	Qty
RA0000835	Modular, Standard Thread, Asturabond Finish, Ø8mm X 35mm	6/OPT
RA0000840	Modular, Standard Thread, Asturabond Finish Ø8mm X 40mm	6/OPT
RA0000845	Modular, Standard Thread, Asturabond Finish, Ø8mm X 45mm	6/OPT
RA0000850	Modular, Standard Thread, Asturabond Finish, Ø8mm X 50mm	6/OPT
RA0000855	Modular, Standard Thread, Asturabond Finish, Ø8mm X 55mm	6/OPT
RA0000860	Modular, Standard Thread, Asturabond Finish, Ø8mm X 60mm	6/OPT
RA0000865	Modular, Standard Thread, Asturabond Finish, Ø8mm X 65mm	6/OPT
RA0000870	Modular, Standard Thread, Asturabond Finish, Ø8mm X 70mm	6/OPT
RA0000875	Modular, Standard Thread, Asturabond Finish, Ø8mm X 75mm	6/OPT
RA0000880	Modular, Standard Thread, Asturabond Finish, Ø8mm X 80mm	6/OPT

MODULAR, SRANDARD THREAD, ASTURABOND FINISH, Ø10MM

Part Number	Description	Qty
RA0001035	Modular, Standard Thread, Asturabond Finish, Ø10mm X 35mm	6/OPT
RA0001040	Modular, Standard Thread, Asturabond Finish, Ø10mm X 40mm	6/OPT
RA0001045	Modular, Standard Thread, Asturabond Finish, Ø10mm X 45mm	6/OPT
RA0001050	Modular, Standard Thread, Asturabond Finish, Ø10mm X 50mm	6/OPT
RA0001055	Modular, Standard Thread, Asturabond Finish Ø10mm X 55mm	6/OPT
RA0001060	Modular, Standard Thread, Asturabond Finish, Ø10mm X 60mm	6/OPT
RA0001065	Modular, Standard Thread, Asturabond Finish, Ø10mm X 65mm	6/OPT
RA0001070	Modular, Standard Thread, Asturabond Finish Ø10mm X 70mm	6/OPT
RA0001075	Modular, Standard Thread, Asturabond Finish, Ø10mm X 75mm	6/OPT
RA0001080	Modular, Standard Thread, Asturabond Finish, Ø10mm X 80mm	6/OPT

MODULAR, SRANDARD THREAD, ASTURABOND FINISH, Ø12MM

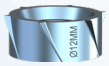
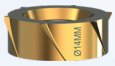
Part Number	Description	Qty
RA0001235	Modular, Standard Thread, Asturabond Finish, Ø12mm X 35mm	6/OPT
RA0001240	Modular, Standard Thread, Asturabond Finish, Ø12mm X 40mm	6/OPT
RA0001245	Modular, Standard Thread, Asturabond Finish, Ø12mm X 45mm	6/OPT
RA0001250	Modular, Standard Thread, Asturabond Finish, Ø12mm X 50mm	6/OPT
RA0001255	Modular, Standard Thread, Asturabond Finish, Ø12mm X 55mm	6/OPT
RA0001260	Modular, Standard Thread, Asturabond Finish, Ø12mm X 60mm	6/OPT
RA0001265	Modular, Standard Thread, Asturabond Finish, Ø12mm X 65mm	6/OPT
RA0001270	Modular, Standard Thread, Asturabond Finish, Ø12mm X 70mm	6/OPT
RA0001275	Modular, Standard Thread, Asturabond Finish, Ø12mm X 75mm	6/OPT
RA0001280	Modular, Standard Thread, Asturabond Finish, Ø12mm X 80mm	6/OPT

MODULAR, SRANDARD THREAD, ASTURABOND FINISH, Ø14MM

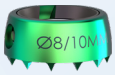
Part Number	Description	Qty
RA0001435	Modular, Standard Thread, Asturabond Finish, Ø14mm X 35mm	6/OPT
RA0001440	Modular, Standard Thread, Asturabond Finish, Ø14mm X 40mm	6/OPT
RA0001445	Modular, Standard Thread, Asturabond Finish, Ø14mm X 45mm	6/OPT
RA0001450	Modular, Standard Thread, Asturabond Finish, Ø14mm X 50mm	6/OPT
RA0001455	Modular, Standard Thread, Asturabond Finish, Ø14mm X 55mm	6/OPT
RA0001460	Modular, Standard Thread, Asturabond Finish, Ø14mm X 60mm	6/OPT
RA0001465	Modular, Standard Thread, Asturabond Finish, Ø14mm X 65mm	6/OPT
RA0001470	Modular, Standard Thread, Asturabond Finish, Ø14mm X 70mm	6/OPT
RA0001475	Modular, Standard Thread, Asturabond Finish, Ø14mm X 75mm	6/OPT
RA0001480	Modular, Standard Thread, Asturabond Finish, Ø14mm X 80mm	6/OPT

REUNION MODULAR SCREW HEAD OFFERING

MODULAR, SRANDARD THREAD, FLUSH MOUNT SCREW HEADS

Part Number	Description	Qty	
RBA000010	Flush Mount Screw Head, Anti-Rotation, Ø8/10mm	6	
RBA000012	Flush Mount Screw Head, Anti-Rotation, Ø12mm	6	
RBA000014	Flush Mount Screw Head, Anti-Rotation, Ø14mm	6	

MODULAR, SRANDARD THREAD, VARIABLE SURFACE MOUNT SCREW HEADS

Part Number	Description	Qty	
RBB000010	Variable Mount Screw Head, Anti-Rotation, Ø8/10mm	6	
RBB000012	Variable Mount Screw Head, Anti-Rotation, Ø12mm	6	
RBB000014	Variable Mount Screw Head, Anti-Rotation, Ø14mm	6	

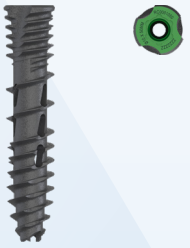
REUNION COMPRESSION SCREW OFFERING

FIXED, COMPRESSION THREAD, ASTURABOND FINISH, Ø8MM

Part Number	Description	Qty
RC0000835	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 35mm	6/OPT
RC0000840	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 40mm	6/OPT
RC0000845	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 45mm	6/OPT
RC0000850	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 50mm	6/OPT
RC0000855	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 55mm	6/OPT
RC0000860	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 60mm	6/OPT
RC0000865	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 65mm	6/OPT
RC0000870	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 70mm	6/OPT
RC0000875	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 75mm	6/OPT
RC0000880	Fixed, Compression Thread, Asturabond Finish, Ø8mm X 80mm	6/OPT

FIXED, COMPRESSION THREAD, ASTURABOND FINISH, Ø10MM

Part Number	Description	Qty
RC0001035	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 40mm	6/OPT
RC0001040	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 45mm	6/OPT
RC0001045	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 50mm	6/OPT
RC0001050	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 55mm	6/OPT
RC0001055	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 60mm	6/OPT
RC0001060	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 65mm	6/OPT
RC0001065	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 70mm	6/OPT
RC0001070	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 75mm	6/OPT
RC0001075	Fixed, Compression Thread, Asturabond Finish, Ø10mm X 80mm	6/OPT
RC0001080	Modular, Standard Thread, Asturabond Finish, Ø10mm X 80mm	6/OPT



FIXED, COMPRESSION THREAD, ASTURABOND FINISH, Ø12MM

Part Number	Description	Qty
RC0001235	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 35mm	6/OPT
RC0001240	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 40mm	6/OPT
RC0001245	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 45mm	6/OPT
RC0001250	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 50mm	6/OPT
RC0001255	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 55mm	6/OPT
RC0001260	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 60mm	6/OPT
RC0001265	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 65mm	6/OPT
RC0001270	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 70mm	6/OPT
RC0001275	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 75mm	6/OPT
RC0001280	Fixed, Compression Thread, Asturabond Finish, Ø12mm X 80mm	6/OPT

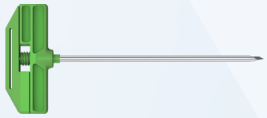
FIXED, COMPRESSION THREAD, ASTURABOND FINISH, Ø14MM

Part Number	Description	Qty
RC0001435	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 35mm	6/OPT
RC0001440	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 40mm	6/OPT
RC0001445	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 45mm	6/OPT
RC0001450	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 50mm	6/OPT
RC0001455	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 55mm	6/OPT
RC0001460	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 60mm	6/OPT
RC0001465	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 65mm	6/OPT
RC0001470	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 70mm	6/OPT
RC0001475	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 75mm	6/OPT
RC0001480	Fixed, Compression Thread, Asturabond Finish, Ø14mm X 80mm	6/OPT

REUNION INSTRUMENTATION OFFERING

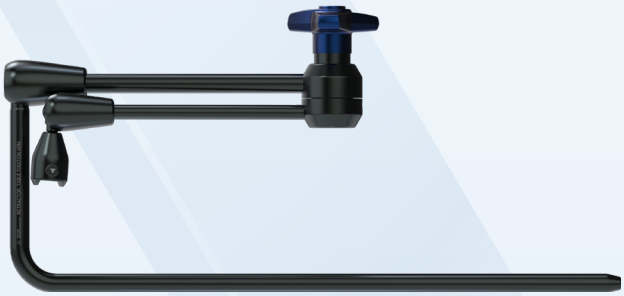
Part Number	Description	Qty
EBECNZBBZ	T-Handle, L, 1/4" Sq Ratchet 2.0	1
EAECNZBBZ	Axial, L, 1/4" Sq Ratchet 2.0	1
EJZCMBBZZ	External 1/4 Sq W/Trinkle	1
RAN-815NRT-BEV	Targeting Needle	1/OPT
RZA010300	Steinmann Pin, Sharp Tip, Ø2.4mm X 300mm, Stainless Steel	6/OPT
RZA010450	SteinmannPin, Sharp Tip, Ø2.4mm X 450mm, Stainless Steel	6/OPT
RZA010600	Steinmann Pin, Sharp Tip, Ø2.mm X 600mm, Stainless Steel	6/OPT
RZA011300	Steinmann Pin, Blunt Tip, Ø2.4mm X 300mm, Stainless Steel	6/OPT
RZA011450	Steinmann Pin, Blunt Tip, Ø2.4mm X 450mm, Stainless Steel	6/OPT
RZA011600	Steinmann Pin, Blunt Tip, Ø2.4mm X 600mm, Stainless Steel	6/OPT
RZA012300	Steinmann Pin, Threaded Tip, Ø2.4mm X 300mm, Stainless Steel	6
RZA012450	Steinmann Pin, Threaded Tip, Ø2.4mm X 450mm, Stainless Steel	6
RZA012600	Steinmann Pin, Threaded Tip, Ø2.4mm X 600mm, Stainless Steel	6/OPT
RZA017001	Steinmann Pin, Extended, Sharp Tip, Ø2.4mm X 650mm	6/OPT
RZA017002	Steinmann Pin, Extended, Threaded Tip, Ø2.4mm X 650mm	6/OPT
RZA017003	Steinmann Pin, Extended, Blunt Tip, Ø2.4mm X 650mm	6/OPT
RZA030000	Steinmann Pin Depth Guide	1
RZA040001	Dilator 1	1
RZA040002	Dilator 2	1
RZA040003	Dilator 3	1
RZA050000	Dilator 3 Handle	1






REUNION INSTRUMENTATION OFFERING

Part Number	Description	Qty	
RZA160000	Joint Prep Tool	1/OPT	
RZA170000	Steinmann Pin Tamp	1	
RZA180000	Steinmann Pin Holder	1	
RZA190000	Fusion Screwdriver, Knob Driver	1	
RZA200000	Dilator 3 Tamp	1/OPT	
KZH010000	Reunion, Table Fixation Arm	1/OPT	
RZB020000	Dilator 3 Table Arm Connector	1/OPT	
5.750-N-VE	Baitella Universal Radial Clamp	1/OPT	

REUNION INSTRUMENTATION OFFERING

Part Number	Description	Qty
RZA110001	Implant Locator Guide Handle, Short	1
RZA110002	Implant Locator Guide Handle, Long	1
RZA120102	Fixed Implant Locator Guide, Ø8/10mm, 2 Pins	1
RZA120103	Fixed Implant Locator Guide, Ø8/10mm, 3 Pins	1
RZA120142	Fixed Implant Locator Guide, Ø12/14mm, 2 Pins	1
RZA120143	Fixed Implant Locator Guide, Ø12/14mm, 3 Pins	1
RZA121103	Fixed Implant Locator Guide, Left Offset, Ø8/10mm 3 Pins	1/OPT
RZA121143	Fixed Implant Locator Guide, Left Offset, Ø12/14mm 3 Pins	1/OPT
RZA122103	Fixed Implant Locator Guide, Right Offset, Ø8/10mm, 3 Pins	1/OPT
RZA122143	Fixed Implant Locator Guide, Right Offset, Ø12/14mm, 3 Pins	1/OPT
RZA130000	Graft Funnel	1
RZA140000	Graft Tube	1
RZA150000	Graft Funnel Tamp	1

REUNION INSTRUMENTATION OFFERING

Part Number	Description	Qty	
RZA060060	SI Screw Drill, Standard, Ø6mm	1	
RZA060070	SI Screw Drill, Standard, Ø7mm	1	
RZA060090	SI Screw Drill, Standard, Ø9mm	1	
RZA060110	SI Screw Drill, Standard, Ø11mm	1	
RZA070007	SI Screw Tap, Standard, Ø7mm	1	
RZA070008	SI Screw Tap, Standard, Ø8mm	1	
RZA070010	SI Screw Tap, Standard, Ø10mm	1	
RZA070012	SI Screw Tap, Standard, Ø12mm	1	
RZA070014	SI Screw Tap, Standard, Ø14mm	1	
RZA080008	Flush Screw Counterbore, Standard, Ø8mm Screw	1	
RZA080010	Flush Screw Counterbore, Standard, Ø10mm Screw	1	
RZA080012	Flush Screw Counterbore, Standard, Ø12mm Screw	1	
RZA080014	Flush Screw Counterbore, Standard, Ø14mm Screw	1	
RZA090000	SI Screwdriver, Standard	2	
RZA100000	Variable Implant Locator Guide	1	
RZA100000-03-10	Variable Implant Locator Guide Tube, Ø8/10mm	3	
RZA100000-03-12	Variable Implant Locator Guide Tube, Ø12mm	3	
RZA100000-03-14	Variable Implant Locator Guide Tube, Ø14mm	3	

REUNION NAVIGATED INSTRUMENTATION OFFERING

Part Number	Description	Qty	
RZA061060	SI Screw Drill, Navigated, Ø6mm	1/OPT	
RZA061070	SI Screw Drill, Navigated, Ø7mm	1/OPT	
RZA061090	SI Screw Drill, Navigated, Ø9mm	1/OPT	
RZA061110	SI Screw Drill, Navigated, Ø11mm	1/OPT	
RZA071007	SI Screw Tap, Navigated, Ø7mm	1/OPT	
RZA071008	SI Screw Tap, Navigated, Ø8mm	1/OPT	
RZA071010	SI Screw Tap, Navigated, Ø10mm	1/OPT	
RZA071012	SI Screw Tap, Navigated, Ø12mm	1/OPT	
RZA071014	SI Screw Tap, Navigated, Ø14mm	1/OPT	
RZA081008	Flush Screw Counterbore, Navigated, Ø8mm Screw	1/OPT	
RZA081010	Flush Screw Counterbore, Navigated, Ø10mm Screw	1/OPT	
RZA081012	Flush Screw Counterbore, Navigated, Ø12mm Screw	1/OPT	
RZA081014	Flush Screw Counterbore, Navigated, Ø14mm Screw	1/OPT	
RZA091000	SI Screwdriver, Navigated	2/OPT	

REUNION
SACROILIAC JOINT FUSION SYSTEM

INSTRUCTIONS FOR USE

1.0 IMPORTANT NOTE TO OPERATING SURGEON: REUNION spinal implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

2.0 DESCRIPTION: The REUNION SACROILIAC JOINT FUSION system are implants developed to promote joint fusion and provide fixation across the sacroiliac joint. The screws are a modular design which allows for interchangeability of the secondary fixation method, via a screw head. The screw and screw head components contain an interlocking component which allows for intraoperative assembly prior to implantation. The screw components are available in a range of diameters and lengths. The screw heads are offered in two fixation types, with sizes to suit the individual pathology and anatomical conditions of the patient. The implant screws are cannulated and fenestrated to allow placement of autogenous bone graft, as well as promote growth across the implant.

3.0 MATERIALS: TI-6AL-4V ELI (ASTM F136), Nitinol #1 (ASTM F2063).

4.0 CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

All implants are intended for single use only. The REUNION SYSTEM must not be reused under any circumstances. These instructions for use are designed to assist in use of the REUNION SYSTEM and are not a reference for surgical techniques.

5.0 INDICATIONS: The REUNION SI Joint System is indicated for skeletally mature patients for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

6.0 CONTRAINDICATIONS

6.1 Acute or chronic infectious diseases of any etiology and localization
6.2 Signs of local inflammation
6.3 Fever or leukocytosis
6.4 Morbid obesity
6.5 Pregnancy
6.6 Metal/polymer sensitivity/allergies to the implant materials
6.7 Mental illness, alcoholism, drug abuse
6.8 Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery
6.9 Grossly distorted anatomy due to congenital abnormalities
6.10 Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
6.11 Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6.12 Any case not needing a bone graft and fusion or where fracture healing is not required
6.13 Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
6.14 Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis.
6.15 Any case not described in the Indications.
6.16 Any patient unwilling to cooperate with the post-operative instructions.
6.17 Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
6.18 Symptomatic cardiac disease.
6.19 Systemic or terminal illness.
6.20 Prior fusion at the level to be treated.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

7.0 POSSIBLE ADVERSE EVENTS:

7.1 A listing of possible adverse events includes, but is not limited to:

7.1.1 Bending or fracture of implant. Loosening of the implant.
7.1.2 Implant material sensitivity, or allergic reaction to a foreign body.
7.1.3 Infection, early or late.
7.1.4 Decrease in bone density due to stress shielding?.
7.1.5 Pain, discomfort, or abnormal sensations due to the presence of the device.
7.1.6 Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments.
7.1.7 Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
7.1.8 Dural tears.
7.1.9 Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
7.1.10 Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
7.1.11 Loss of bowel and/or bladder control or other types of urological system compromise.
7.1.12 Scar formation possibly causing neurological compromise around nerves and/or pain.
7.1.13 Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
7.1.14 Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
14. Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
7.1.15 Graft donor site complications including pain, fracture, or wound healing problems.
7.1.16 Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
7.1.17 Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
7.1.18 Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
7.1.19 Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
7.1.20 Change in mental status.
7.1.21 Non-union (or pseudarthrosis). Delayed union. Mal-union.
7.1.22 Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
7.1.23 Inability to perform the activities of daily living.
7.1.24 Paralysis.
7.1.25 Death.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

8.0 WARNINGS AND PRECAUTIONS: The REUNION system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the REUNION system is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the REUNION system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.

The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. The physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.

The REUNION SI Joint System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of REUNION SI Joint System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

9.0 IMPLANT SELECTION: The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be responsible for additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon must be thoroughly trained with the surgical procedure, instrumentation and implant characteristics prior to performing surgery. The use of dissimilar materials (e.g., titanium and stainless steel) should not be used together because of the

risk of galvanic corrosion. REUNION system components should not be used with components from other manufacturers.

10.0 PREOPERATIVE:

10.1 Only patients that meet the criteria described in the indications should be selected.

10.2 Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

10.3 Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

10.4 The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

10.5 The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.

10.6 Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The REUNION system components are not to be combined with the components from another manufacturer

10.7 All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

10.8 All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.

10.9 A surgical technique manual may be obtained from REUNION system from any of its representatives.

11.0 INTRAOPERATIVE

11.1 Any instruction manual should be carefully followed.

11.2 At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.

11.3 The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.

11.4 Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.

11.5 Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.

11.6 Before closing the soft tissues, all of the devices should be securely seated.

11.7 Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

12.0 POSTOPERATIVE: The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

12.1 Detailed instructions on the use and limitations of the device should be given to the patient. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

12.2 To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

12.3 The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

12.4 If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

12.5 Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.

12.6 Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved REUNION system components should ever be reused under any circumstances.

13.0 PACKAGING: Packages for each of the components should be intact upon receipt. All sets and components should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to ASTURA MEDICAL.

14.0 CLEANING AND DECONTAMINATION: Instruments of the REUNION system are supplied clean and NOT STERILE, and must be sterilized prior to use.

15.0 CLEANING: All instruments must first be cleaned before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. Rinse the instruments under running tap water for a minimum of 1 minute. An enzymatic cleaner bath (soak) or a solution of water and neutral pH detergent are effective in removing organic material from instruments. Use distilled water if possible. Instruments should be fully submerged for at least ten (10) minutes.

Instruments must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Confirm that all cannulated and modular instruments are fully disassembled. Ensure that all cannulas are flushed until cleaning solution runs clear and that all instruments are completely immersed. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Rinse instruments under running water for at least one (1) minute to remove solutions. Once instruments are cleaned and disassembled place instruments in an ultrasonic cleaner with warm enzymatic detergent for a minimum of fifteen (15) minutes. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Rinse instruments under running water for at least one (1) minute to remove solutions.

Instruments should never be exposed to cleaning agents containing any peroxides.

Users should periodically inspect instruments for corrosion, discoloration, etc., and properly dispose of instruments that show signs of wear and tear.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

16.0 STERILIZATION: Moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline ST79:2006 according to the following validated cycle parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	270°F(132°C)	4 minutes	30 minutes

Wrap tray with a towel placed between tray and FDA cleared wrap.

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods. No claims of pyrogenicity are made. Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to ASTURA MEDICAL.

This gravity displacement sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

17.0 PRODUCT COMPLAINTS: Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify ASTURA MEDICAL or its representative. Further, if any of the implanted REUNION system component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately.

If any REUNION system product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or ASTURA MEDICAL must be notified immediately by telephone, fax or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help ASTURA MEDICAL understand the cause of the complaint.

If further information is needed or required, please contact using the company information listed below.

18.0 COMPANY INFORMATION

Astura Medical
4949 W Royal Ln.
Irving, TX 75063
Phone: (469) 501-5530
Email: info@asturamedical.com


ASTURA
MEDICAL