GATEWAY®

Thoracolumbar Plate System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

GATEWAY®

Overview 4
Implant Overview 5
Instrument Overview 7
Surgical Technique
1. Approach and Preparation 12
2. REVERE® Screw Insertion 12
Screw Hole Preparation 12
Screw Insertion 13
3. Optional: Staple Insertion 14
4. Optional: Screw Head Distraction 15
5. Plate Placement 15
6. Locking Cap Insertion 16
7. Optional: Plate Distraction 17
8. Construct Compression 18
9. Final Tightening of REVERE® Screws 19
10. Bone Screw Insertion 20
Screw Hole Preparation 20
Screw Insertion 22
11. Locking Set Screw 22
Final Construct 23
GATEWAY® Implants 24
GATEWAY® Instrument Set 26
GATEWAY®/CITADEL® Bone Screw and Instrument Set 28
Important Information 30

GATEWAY®

Thoracolumbar Plate System

Integrated Screw Locking Mechanism

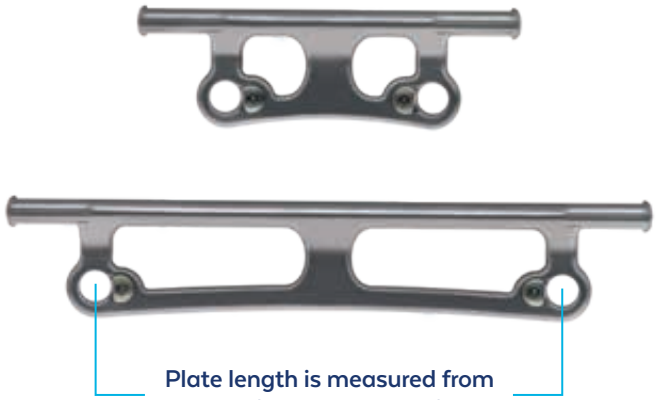
Open Door Access

Non-Threaded Locking Cap

IMPLANT OVERVIEW

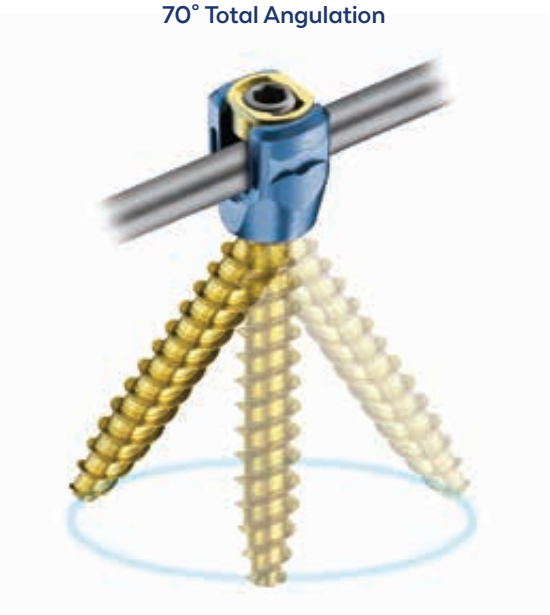
Plates

- Low profile - 4.8mm thick
- Windows provide visualization and access to the vertebral body replacement device
- All plates are 25mm wide
- Available in lengths from 36-100mm



REVERE® Screws

- Available with monoaxial and polyaxial screw heads
- Polyaxial screw heads have 35° of angulation in all directions
- Variety of sizes:
  - 5.0, 5.5, 6.5, 7.5, and 8.5mm diameter screws
  - Lengths from 25-60mm in 5mm increments



REVERE® Locking cap

- Non-threaded design eliminates cross-threading
- 90° rotation of locking cap captures rod portion of plate
- Set screw assembly allows for easy insertion and tightening
- Low torque locking mechanism

Single Hole Staples

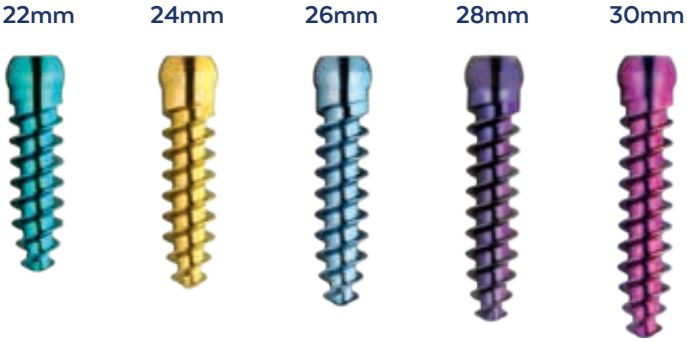
- Available for 5.0, 5.5, 6.5, 7.5, and 8.5mm diameter screws
- Increases resistance to screw toggle
- Color-coded to match corresponding REVERE® screw diameter

Bone Screws

- Lengths from 22-57mm
- 6.5mm diameter, self-tapping screws

- Variable angle and fixed trajectory screws available
- Variable angle screws allow for 10° of angulation

- Fixed angle screws pre-set trajectory
  - 12° posterior
  - 5° cephalad/caudal



Locking Mechanism

- Simple and reliable locking set screw
- Pre-assembled to the plate
- Provides direct visual confirmation of locked bone screw

INSTRUMENT OVERVIEW

PREPARATION INSTRUMENTS

Cortex Awl, 1/4” QC 630.31

Awl Sleeve Retracted

Awl, 1/4” QC 630.317

Drill Bit, 22mm, 1/4” QC 630.400

Tap, 22mm, 1/4” QC 630.405

Quick-Release 1/4”, Ratchet,
T-Handle 630.401

Quick-Release 1/4”, Ratchet,
Straight Handle 630.407

Taps for REVERE® Screws
Tap 5.0mm, 1/4” QC 629.120
Tap 5.5mm, 1/4” QC 629.121
Tap 6.5mm, 1/4” QC 629.122
Tap 7.5mm, 1/4” QC 629.123
Tap 8.5mm, 1/4” QC 629.124*

Screw Placement Guide 629.151

Axial View

**Additionally Available*

PREPARATION INSTRUMENTS (CONT'D)

Depth Gauge, Large 631.011

Clamping Plate Holder 629.154

Locking Cap Guide, Long 629.156

Locking Cap Driver, Long 629.157

Drill Guide, Freehand 630.336

Rocker Arm 629.160

Rocker Arm Drill Guide, Superior 629.161

Rocker Arm Drill Guide, Inferior 629.162

SCREW INSERTION INSTRUMENTS

Screwdriver, 3.5mm Hex, Self-Retaining 630.410

Screwdriver Shaft, 3.5mm Hex, 1/4” QC, Self-Retaining 630.414

Monoaxial Screwdriver, 1/4” QC, Long 629.415

UNIVERSAL JOINT INSTRUMENTS

Screwdriver, 3.5mm Hex, Self-Retaining 630.410

Screwdriver Shaft, 3.5mm Hex, 1/4” QC, Self-Retaining 630.414

Monoaxial Screwdriver, 1/4” QC, Long 629.415

Monoaxial Screwdriver, 1/4” QC, Long 629.415

COMPRESSION/DISTRACTION INSTRUMENTS

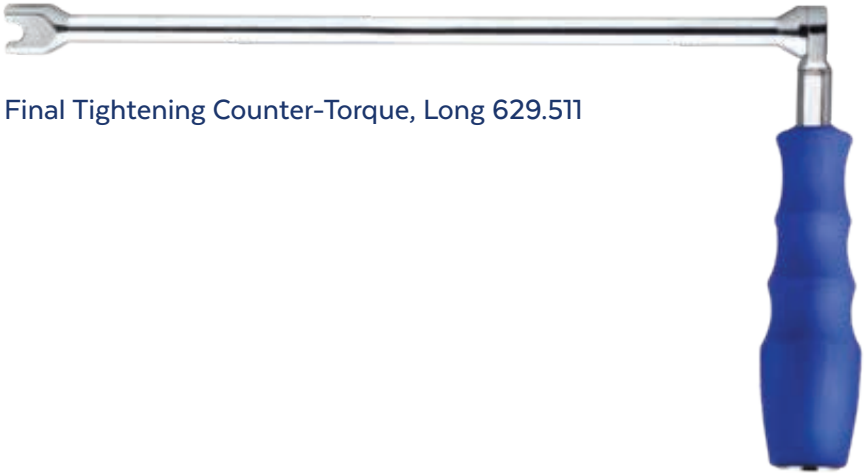
Plate Distractor 629.500

Screw Head Distractor 629.501

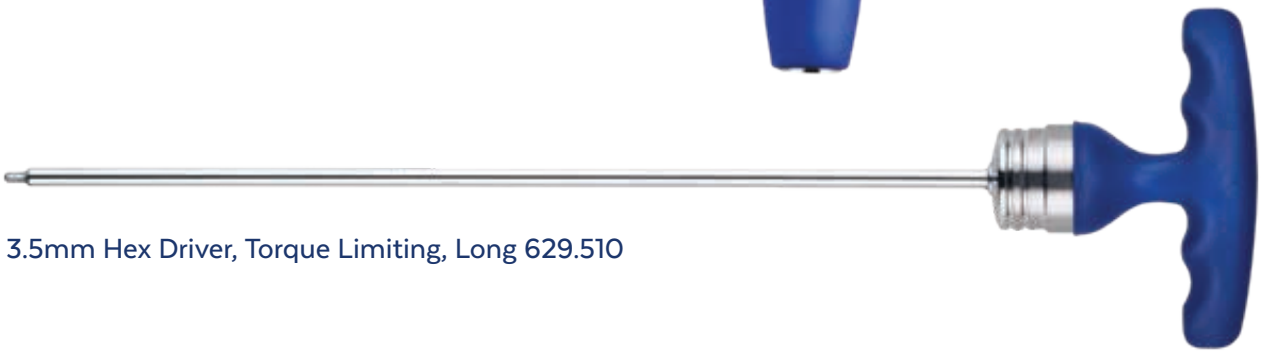
Parallel Compressor 624.503

LOCKING INSTRUMENTS

Set Screw Positioner, Ball Hex 630.501



Final Tightening Counter-Torque, Long 629.511



3.5mm Hex Driver, Torque Limiting, Long 629.510

STAPLE INSTRUMENTS

Single Staple Holder 629.108

Hammer 603.977

SURGICAL TECHNIQUE

GATEWAY®

STEP 1 APPROACH AND PREPARATION

The patient is placed under general anesthesia and positioned in a true lateral position. It is important to maintain patient position throughout the procedure. In general, a left-sided approach is used for the thoracolumbar junction, while a right-sided approach is more common for the upper thoracic spine. The operative area is carefully cleaned and an incision is made at the appropriate fusion level(s). GATEWAY® Plate fixation may be used in the thoracolumbar spine between T1-L5. Please refer to the product insert for complete description, indications, and warnings.

Perform a corpectomy (if needed) and remove the adjacent discs. Distraction can be performed at this point using a vertebral body spreader, or later in the procedure with either the Screw Head Distractor or the Plate Distractor.

STEP 2 REVERE® SCREW INSERTION

Screw Hole Preparation

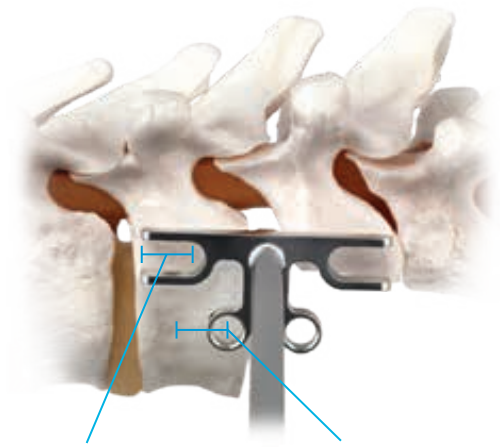
Proper REVERE® Screw placement is crucial to insertion of the GATEWAY® Plate. To determine REVERE® Screw location, the Screw Placement Guide can be used. Hold the guide so that the U-shaped slots are closest to the posterior elements, as shown at left. Press the bottom keel of the guide firmly against the endplate of the vertebral body where the screw will be placed.

The circular hole on the Screw Placement Guide represents the bone screw hole location in the plate. The U-shaped slot represents the location for the REVERE® Screw. Connect the Cortex Awl, 1/4" QC to one of the 1/4" Quick-Release Ratcheting Handles and insert through this slot to perforate the vertebral body cortex.

Please note that this guide indicates the REVERE® Screw insertion point closest to the corpectomy site, which still permits the bone screw to be inserted into the vertebral body. The REVERE® Screw can be inserted beyond the opening of the slot if desired.

Repeat to determine screw location for the vertebral body on the opposite side of the corpectomy site.

Screw Placement Guide positioned against vertebral body endplate



Use the Depth Gauge, Large to measure the width of the vertebral bodies superior and inferior to the corpectomy site. This measurement is used to determine appropriate screw length for bicortical fixation.

REVERE® screws are self-tapping; however, screw holes may be tapped if desired. Insert the Tap (629.120-124) of desired diameter into either the Quick-Release 1/4", Ratchet, T-Handle or Straight Handle. Tap to the desired depth.

Note: Taps with gold tips are for REVERE® Screw hole preparation only.

Determining REVERE® screw length using Depth Gauge

Screw Insertion

REVERE® Screws are available with polyaxial or monoaxial screw heads. Polyaxial screws provide 35° of screw angulation in all directions for additional flexibility.

Monoaxial Screws

Attach the Monoaxial Screwdriver, 1/4" QC, Long shaft to a 1/4" Quick-Release Ratcheting Handle. Determine the appropriate screw size and load the screw from the module. After loading the screw, verify size by checking the length and diameter markings on the screw head, in addition to using the gauges provided on the Locking Cap Module. Insert the screws as shown at right.

Inserting a monoaxial screw

Polyaxial Screws

Polyaxial screws should be inserted in the same manner as described above using the Screwdriver, 3.5mm Hex, Self-Retaining. The Screwdriver Shaft, 3.5mm, 1/4" QC, Self-Retaining and 1/4" Quick-Release Ratcheting Handle assembly may also be used to insert the polyaxial screws. The screw heads can be oriented to better receive the plate using the Screw Head Positioner (624.402), as described at right.

USING THE SCREW HEAD POSITIONER

The Screw Head Positioner can be used to orient the polyaxial screw head after insertion. Insert the positioner into the head of the screw, and rotate to the desired position.

Positioning screw using Screw Head Positioner

STEP 3 OPTIONAL: STAPLE INSERTION

For additional resistance to screw toggle, Single Staples are provided. These staples can be used in conjunction with either monoaxial or polyaxial REVERE® screws. Staple sizes are color-coded to correspond to the REVERE® screw diameters as shown below.

Load the staple from the module onto the Single Staple Holder. Place the staple onto the desired screw location on vertebral body. The center spike of the staple holder is located where the REVERE® screw will be inserted. Use the Screw Placement Guide to determine the desired screw location. Impact upon the Single Staple Holder with the Hammer to seat the staple.

Placing a staple on vertebral body

Hammer impacting Single Staple Holder

Insert the appropriate REVERE® screw through the staple as described in Step 2, page 13.

Inserting REVERE® screw through Single Staples

STEP 4 OPTIONAL: SCREW HEAD DISTRACTION

Insert the tips of the Screw Head Distractor under the screw heads as shown below. Compress the handles until the desired amount of distraction is achieved. Alternately, the Plate Distractor may be used as described in Step 7, page 17.

Vertebral bodies distracted and XPand®-R inserted

Insert the desired vertebral body replacement device. The XPand®-R Corpectomy Spacer is shown here. After removing the Screw Head Distractor, additional distraction can be achieved by further opening the XPand®-R Corpectomy Spacer. Refer to the XPand®-R Surgical Technique Guide for recommended technique.

The thumb wheel bar on the Screw Head Distractor is etched to assist in determining approximate plate size.

STEP 5 PLATE PLACEMENT

Using the Clamping Plate Holder, remove the desired GATEWAY® plate from the plate module. Place over the vertebrae and confirm appropriate plate length. Insert the rod portion of the plate into the REVERE® screw heads.

STEP 6 LOCKING CAP INSERTION

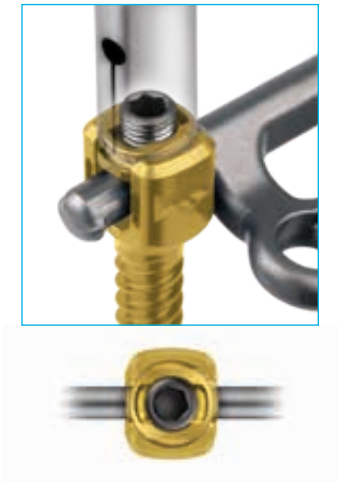
Locking Caps can be inserted with the plate in the open or closed position. To insert a Locking Cap, load the Locking Cap Driver, Long as described at right and insert through the Locking Cap Guide, Long. Install the locking cap as described below.

Locking Cap insertion through Locking Cap Guide

Locking Cap Insertion

With a loaded Locking Cap Driver, insert the Locking Cap into the screw head and rotate clockwise 90° to capture the rod.

Note: Locking Cap insertion requires minimal effort. If the Locking Cap is difficult to rotate, the rod portion of the plate may not be seated properly.



Locking Cap INSERTED

Locking Cap ENGAGED

Remove the Locking Cap Driver and Locking Cap Guide. The plate is now captured by the screw and cap, but the construct is not completely locked until final tightening.

LOADING CAP DRIVER

Align the tabs on the Cap Driver with the indentations on the Locking Cap within the implant module. Push the Cap Driver down over the Locking Cap until fully seated.

Ensure that the cap is properly seated in the driver before insertion.

Cap Driver aligned

Cap Driver loaded

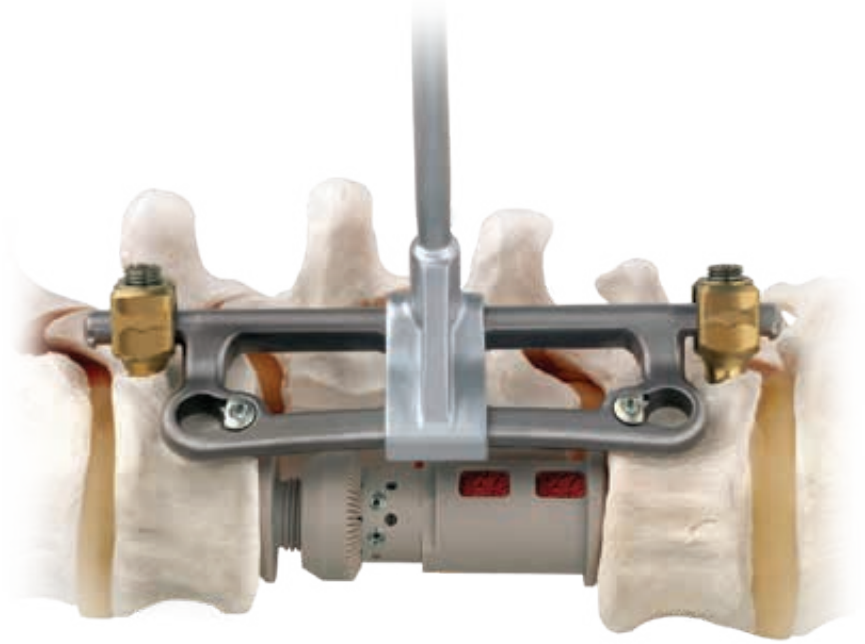
STEP 7 OPTIONAL: PLATE DISTRACTION

Once the plate is seated in the REVERE® screws, additional distraction can be performed if needed. With the plate in the open position, insert the Plate Distractor so that one leg of the distractor is on the rod between the screw head and plate and the other leg is against the middle bar of the plate (see image below). Compress the handles of the distractor until desired distraction is achieved. To maintain distraction, provisionally tighten the set screw within the Locking Cap using a 3.5mm Hex Driver.

Provisionally tightening set screw to maintain distraction

OPTIONAL: PLATE DISTRACTION (CONT'D)

Insert the vertebral body replacement (VBR) device of choice; the XPand®-R Corpectomey Spacer is shown here. Loosen the set screws in the locking caps using a 3.5mm Hex Driver. Use the Rocker Arm as shown below to close the GATEWAY® Plate over the VBR device.



STEP 8 CONSTRUCT COMPRESSION

The Parallel Compressor can be used to compress the construct. Place the tips of the compressor on the plate as shown below and compress the handles. Final tighten the Locking Caps as described in Step 9, page 19.

STEP 9 FINAL TIGHTENING REVERE® SCREWS

Final tightening of the Locking Cap Set Screws is necessary to secure the construct and is accomplished using the Torque-Limiting 3.5mm Hex Driver, Long and Final Tightening Counter-Torque, Long.

Insert the 3.5mm Hex, Torque-Limiting Screwdriver, Long into the Final Tightening Counter-Torque, Long. Fully engage the 3.5mm hex into the set screw and position the Final Tightening Counter-Torque over the screw head, ensuring the sleeve is fully seated on the head and cap. Rotate the Hex Driver until it reaches its torque limit. Repeat for all locking caps.

Inserting Final Tightening Instrument and Torque-Limiting Screwdriver

Tightening set screw

Before final tightening

After final tightening

STEP 10 BONE SCREW INSERTION

Screw Hole Preparation

Prepare the pilot screw holes on the anterior portion of the plate. Use the Cortex Awl, 1/4" QC and 1/4" Quick-Release Ratcheting Handle assembly to perforate the cortex of the vertebral body. Push down on the awl to allow the sleeve to retract and the tip to break the vertebral body cortex.

Alternately, the Awl, 1/4" QC can be connected to a 1/4" Quick-Release Ratcheting Handle and inserted through either of the Rocker Arm Drill Guides, or the Drill Guide, Freehand.

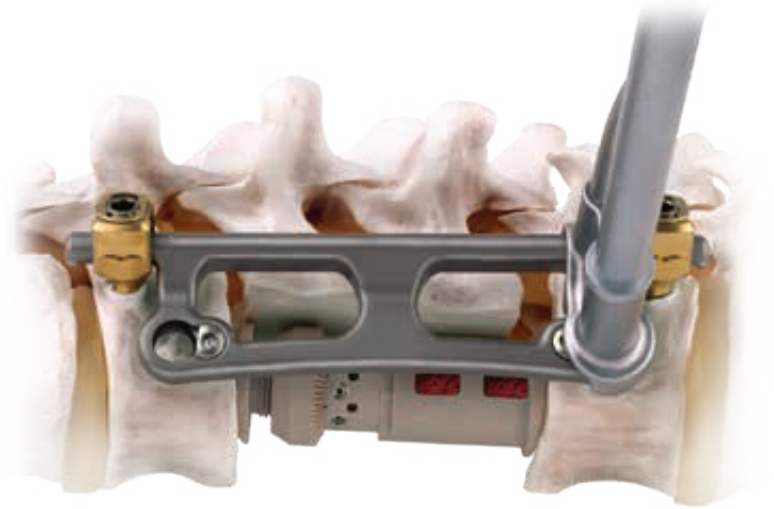
Option A: Rocker Arm Drill Guides - Fixed Angulation

The Rocker Arm Drill Guide, Superior and Rocker Arm Drill Guide, Inferior provide pre-set angulation for screw insertion. Place the appropriate drill guide onto the corresponding plate hole. Attach the Drill Bit, 22mm, 1/4" QC to a 1/4" Quick-Release Ratcheting Handle, and insert through the drill guide. Drill until it reaches the stop.

The screws are self-tapping; however, the vertebral body may be tapped if desired. Attach the Tap, 22mm, 1/4" QC to a 1/4" Quick-Release Ratcheting Handle, and tap through the drill guide. To avoid stripping the screw hole, stop rotating the tap when its shoulder contacts the barrel of the drill guide.

Screws may also be inserted through the Rocker Arm Drill Guides. See page 22 for screw insertion.

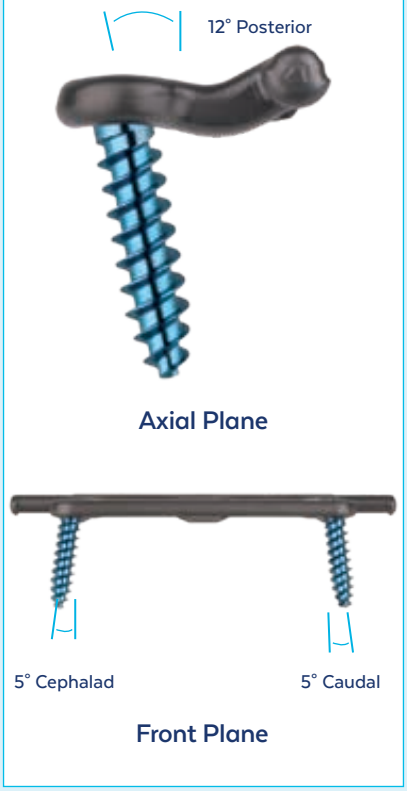
Note: The Fixed Angle Screws should always be inserted through the Rocker Arm Drill Guides.



Using Rocker Arm, Inferior to prepare screw pilot hole

ROCKER ARM DRILL GUIDES

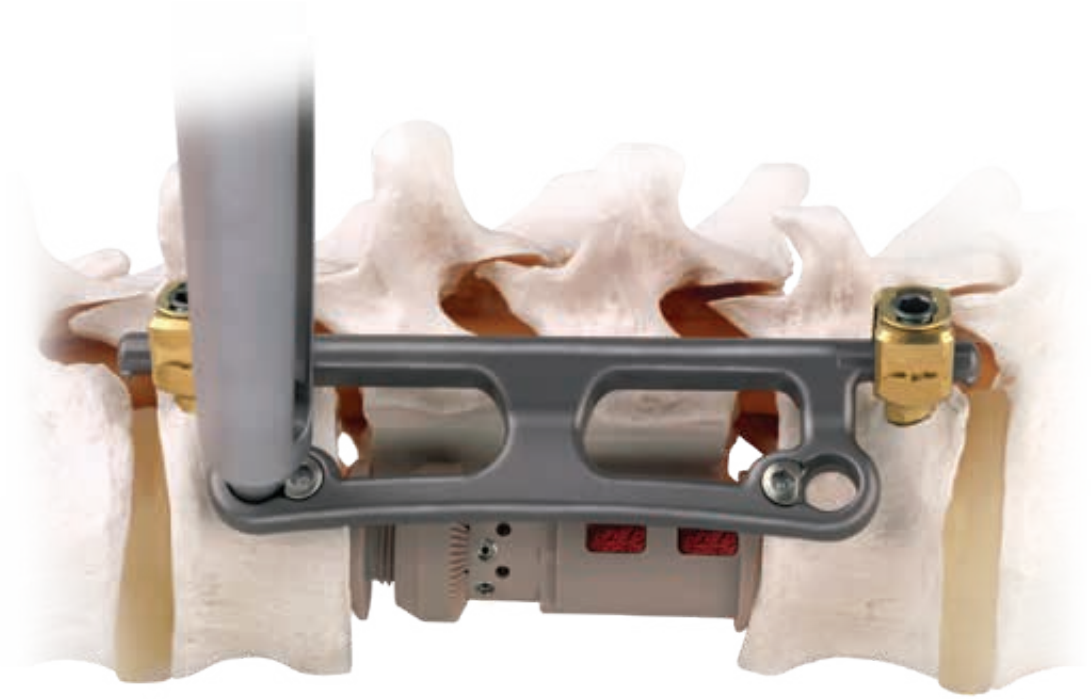
Provide pre-set screw angulation for awling, drilling, tapping, and screw insertion.



Option B: Drill Guide, Freehand

The Drill Guide, Freehand permits full angulation of the drill guide through the plate. This drill guide should only be used to create a trajectory for Variable Angle Screws.

Place the drill guide into the plate hole. Attach the Drill Bit, 22mm, 1/4" QC to a 1/4" Quick-Release Ratcheting Handle, and insert through the drill guide. Drill until it reaches the stop.



Using Drill Guide, Freehand to prepare screw pilot hole

UNIVERSAL JOINT INSTRUMENTS

A series of universal joint tools are provided as alternatives for added flexibility. The Awl, 1/4" QC, U-Joint and Drill Bit, 22mm, 1/4" QC, U-Joint can be used through all the drill guides provided. The Tap, 1/4" QC, U-Joint can be used through the Rocker Arm Drill Guides. Insert Universal Joint Instruments through either the Rocker Arm Guide or Freehand Drill Guide in the same manner as described above. A Universal Joint Screwdriver is also provided and can be used for screw insertion through the Rocker Arm Drill Guides.

BONE SCREW INSERTION (CONT'D)

Bone Screw Insertion

Bone screws are available in variable angle and fixed angle options. Lengths range from 22-30mm in 2mm increments, and 33-57mm in 3mm increments.

Note: Screw lengths indicate the length of bone engagement.

Before bone screw insertion, verify that the flat of the Locking Set Screw is oriented to permit the bone screw to pass through the plate hole. See initial position of Locking Set Screw below.

Select the appropriate screw length. Use the Screwdriver, 3.5mm Hex, Self-Retaining to load the screw out of the screw module. Alternately, the Screwdriver Shaft, 3.5mm Hex, 1/4" QC, Self-Retaining may be used in conjunction with a 1/4" Quick-Release Ratcheting Handle to insert the screws. Before insertion, confirm screw length using the gauges provided on the screw module. As the screws are inserted, the plate will lag to the bone as shown at right.

Inserting Bone Screw

SCREW LAGS PLATE TO BONE

As screw is inserted, plate lags to bone

Plate in final position on bone surface

STEP 11 LOCKING SET SCREW

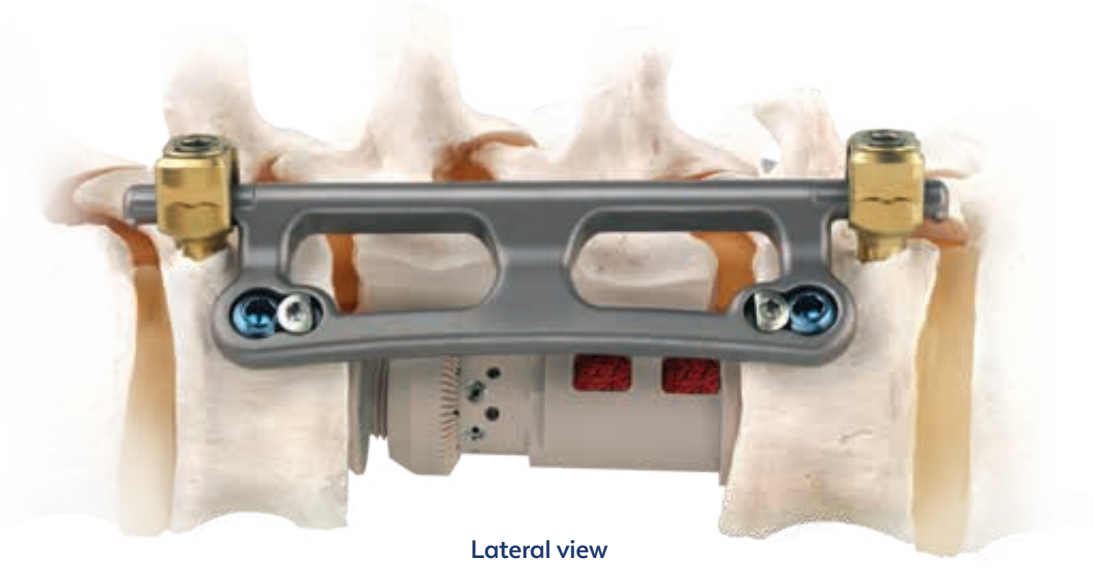
Insert the Set Screw Positioner, Ball Hex into the set screw, making sure the hex is fully seated in the screw head, and rotate clockwise until two-finger tight. As shown below, the flat on the locking set screw should be facing approximately 180° away from the screw head when locked.

Note: To avoid stripping the locking set screw, insert the Set Screw Positioner, Ball Hex at a perpendicular position and maintain that position as the locking set screw is rotated.

Initial Position

Locked Position

FINAL CONSTRUCT

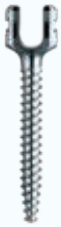
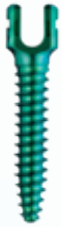


Lateral view

Anterior view

GATEWAY® IMPLANTS

GATEWAY® Monoaxial Screws 929.902

Length	 5.0mm Diameter	Qty	 5.5mm Diameter	Qty	 6.5mm Diameter	Qty	 7.5mm Diameter	Qty	 8.5mm Diameter	Qty
25mm	124.851	0	124.251	0	124.261	0	124.271	0	124.281	0
30mm	124.852	4	124.252	4	124.262	4	124.272	0	124.282	0
35mm	124.853	4	124.253	4	124.263	4	124.273	4	124.283	0
40mm	124.854	4	124.254	4	124.264	4	124.274	4	124.284	0
45mm	124.855	4	124.255	4	124.265	4	124.275	4	124.285	0
50mm	124.856	0	124.256	4	124.266	4	124.276	4	124.286	0
55mm	124.857	0	124.257	0	124.267	4	124.277	4	124.287	0
60mm			124.258	0	124.268	0	124.278	0	124.288	0

GATEWAY® Polyaxial Screws 929.903

Length	 5.0mm Diameter	Qty	 5.5mm Diameter	Qty	 6.5mm Diameter	Qty	 7.5mm Diameter	Qty	 8.5mm Diameter	Qty
25mm	124.051	0	124.451	0	124.461	0	124.471	0	124.481	0
30mm	124.052	4	124.452	4	124.462	4	124.472	0	124.482	0
35mm	124.053	4	124.453	4	124.463	4	124.473	4	124.483	0
40mm	124.054	4	124.454	4	124.464	4	124.474	4	124.484	0
45mm	124.055	4	124.455	4	124.465	4	124.475	4	124.485	0
50mm	124.056	0	124.456	4	124.466	4	124.476	4	124.486	0
55mm			124.457	0	124.467	4	124.477	4	124.487	0
60mm					124.468	0	124.478	0	124.488	0

Bone Screws (Part of the GATEWAY®/CITADEL® Bone Screw Instrument Set 929.906)

Length	 Variable Angle	Qty	 Fixed Angle	Qty
22mm	130.622	8	130.822	8
24mm	130.624	10	130.824	10
26mm	130.626	10	130.826	10
28mm	130.628	8	130.828	8
30mm	130.630	8	130.830	8
33mm	130.633	4	130.833	4
36mm	130.636	4	130.836	4
39mm	130.639	4	130.839	4
42mm	130.642	4	130.842	4
45mm	130.645	4	130.845	4
48mm	130.648	4	130.848	4
51mm	130.651	4	130.851	4
54mm	130.654	4	130.854	4
57mm	130.657	4	130.857	4

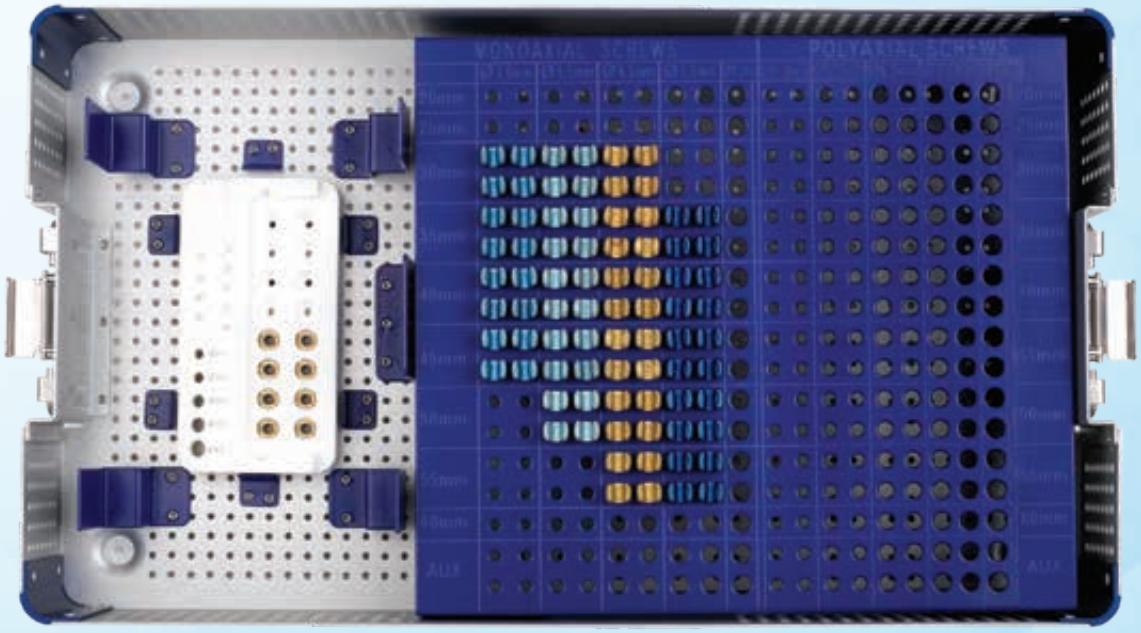
GATEWAY® Implant Set (with monoaxial screw 929.902, with polyaxial screws 929.903)

GATEWAY® Plates (Qty 1 each)	
129.436	Thoracolumbar Plate, 36mm
129.438	Thoracolumbar Plate, 38mm
129.440	Thoracolumbar Plate, 40mm
129.442	Thoracolumbar Plate, 42mm
129.444	Thoracolumbar Plate, 44mm
129.448	Thoracolumbar Plate, 48mm
129.452	Thoracolumbar Plate, 52mm
129.456	Thoracolumbar Plate, 56mm
129.460	Thoracolumbar Plate, 60mm
129.464	Thoracolumbar Plate, 64mm
129.468	Thoracolumbar Plate, 68mm
129.472	Thoracolumbar Plate, 72mm
129.476	Thoracolumbar Plate, 76mm
129.480	Thoracolumbar Plate, 80mm
129.484	Thoracolumbar Plate, 84mm
129.488	Thoracolumbar Plate, 88mm
129.492	Thoracolumbar Plate, 92mm
129.496	Thoracolumbar Plate, 96mm
129.500	Thoracolumbar Plate, 100mm

Staples		Qty
129.650	Single Staple, 5.0mm	2
129.655	Single Staple, 5.5mm	2
129.665	Single Staple, 6.5mm	2
129.675	Single Staple, 7.5mm	2
129.685	Single Staple, 8.5mm	0
124.000	REVERE® Locking Cap	8
929.002	GATEWAY® System Implant Graphic Case	1
929.004	GATEWAY® Plate and Staple Module	1
929.005	GATEWAY® Locking Cap Module	1

Items in gray are additionally available.

GATEWAY® IMPLANTS



GATEWAY®
INSTRUMENT SET 929.901

	Preparation Instruments		Qty
1	631.011	Depth Gauge, Large	1
2	629.120	Tap, 5.0mm, 1/4" QC	1
3	629.121	Tap, 5.5mm, 1/4" QC	1
4	629.122	Tap, 6.5mm, 1/4" QC	1
5	629.123	Tap, 7.5mm, 1/4" QC	1
6	629.151	Screw Placement Guide	1
7	629.154	Clamping Plate Holder	1
8	629.156	Locking Cap Guide, Long	1
9	629.157	Locking Cap Driver, Long	1
10	629.160	Rocker Arm	1
11	629.161	Rocker Arm Drill Guide, Superior	1
12	629.162	Rocker Arm Drill Guide, Inferior	1

	Staple Insertion Instruments		Qty
13	629.108	Single Staple Holder	1
14	603.977	Hammer	1

	Screw Insertion		Qty
15	629.415	Monoaxial Screwdriver, 1/4" QC, Long	2

	Compression/Distraction		Qty
16	629.500	Plate Distractor	1
17	629.501	Screw Head Distractor	1
18	624.503	Parallel Compressor	1

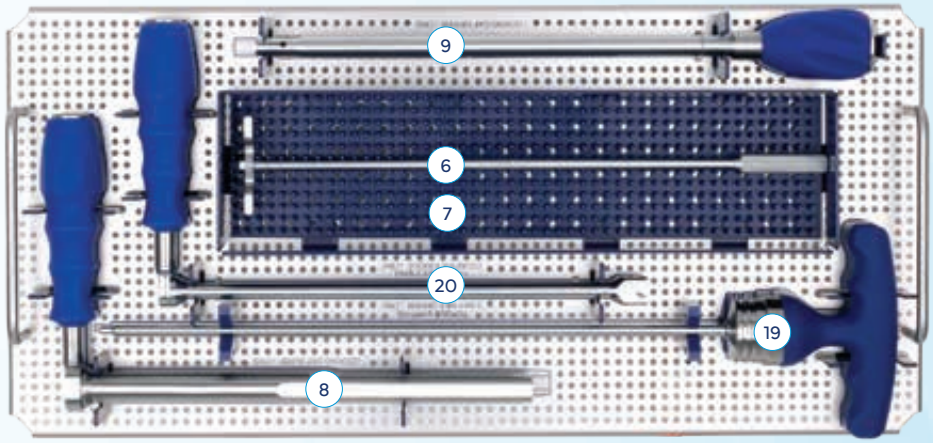
	Screw Locking Instruments		Qty
19	629.510	3.5mm Hex Driver, Torque Limiting, Long	1
20	629.511	Final Tightening Counter-Torque, Long	1

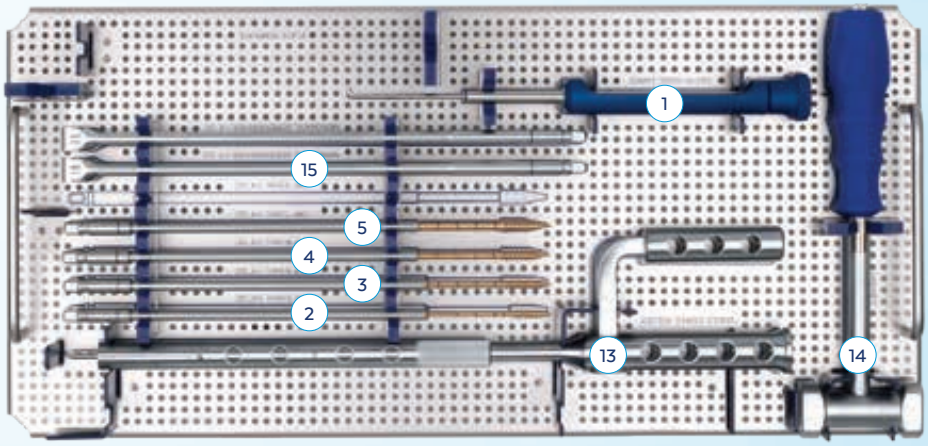
	929.001	GATEWAY® System Instrument Graphic Case

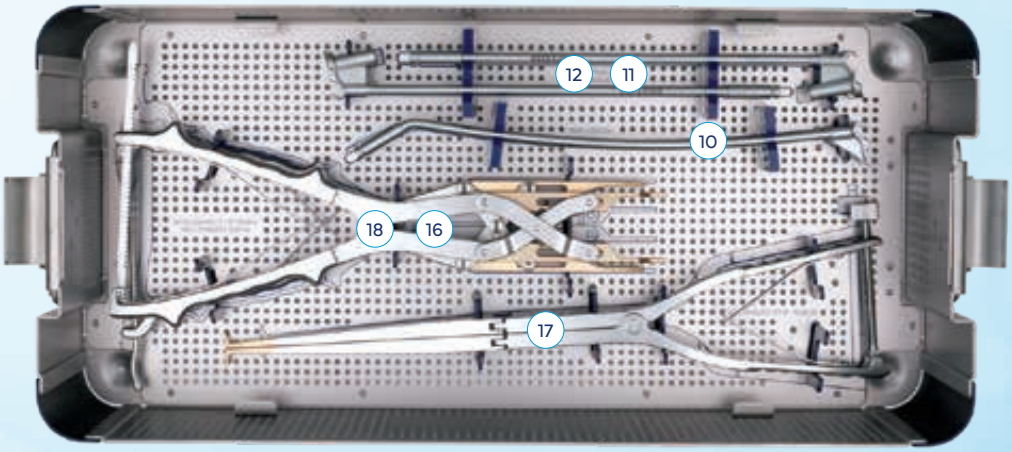
Additionally Available Instruments

629.124	Tap, 8.5mm, 1/4" QC
630.403	Quick-Release 1/4", Palm Handle
629.409	Ball Handle, Quick-Connect
630.503	Set Screw Positioner, Torque Limiting, 1.5Nm

GATEWAY®
INSTRUMENT SET 929.901







GATEWAY®/CITADEL®
BONE SCREW AND INSTRUMENT SET 929.906

		Preparation Instruments	Qty
1	630.316	Cortex Awl, 1/4" QC	1
2	630.317	Awl, 1/4" QC	1
3	630.401	Quick-Release 1/4", Ratchet, T-Handle	1
4	630.407	Quick-Release 1/4", Ratchet, Straight Handle	1
5	630.336	Drill Guide, Freehand	1
6	630.400	Drill Bit, 22mm, 1/4" QC	2
7	630.405	Tap, 22mm, 1/4" QC	2

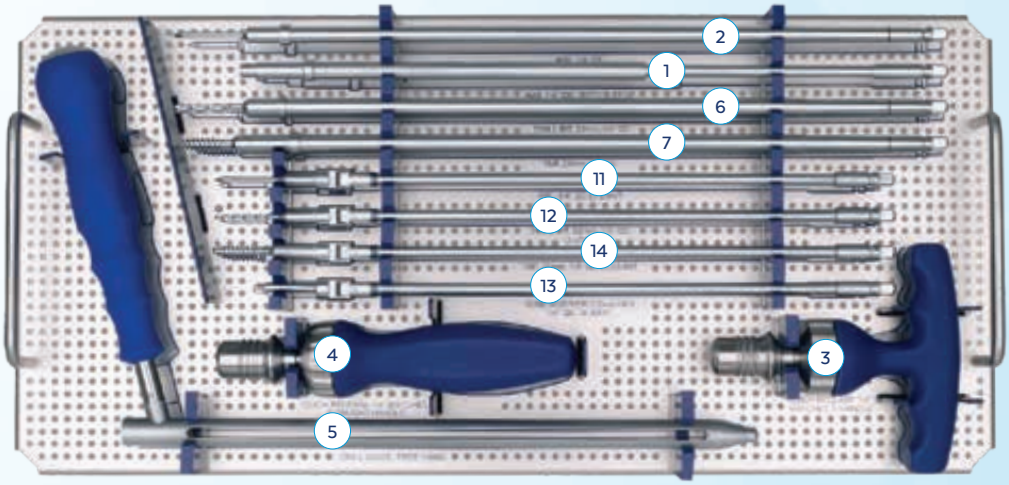
		Screw Insertion	Qty
8	630.410	Screwdriver, 3.5mm Hex, Self-Retaining	2
9	630.414	Screwdriver Shaft, 3.5mm Hex, 1/4" QC, Self-Retaining	1

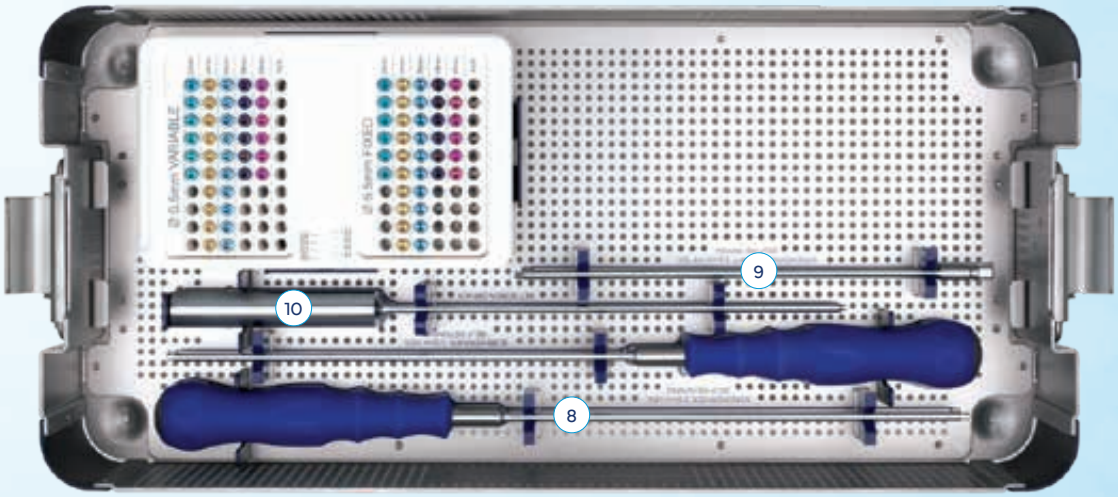
		Screw Locking Instruments	Qty
10	630.501	Set Screw Positioner, Ball Hex	1

		Universal Joint Instruments	Qty
11	630.493	Awl, 1/4" QC, U-Joint	1
12	630.494	Drill Bit, 22mm, 1/4" QC, U-Joint	1
13	630.495	Screwdriver, 3.5mm Hex, 1/4" QC, U-Joint	1
14	630.496	Tap, 22mm, 1/4" QC, U-Joint	1

	929.006	GATEWAY®/CITADEL® Bone Screw & Instrument Graphic Case

GATEWAY® /CITADEL®
BONE SCREW AND INSTRUMENT SET 929.906





IMPORTANT INFORMATION ON THE GATEWAY® THORACOLUMBAR PLATE

DESCRIPTION

The GATEWAY® Thoracolumbar Plate System consists of plates of various lengths to be used with polyaxial or monoaxial REVERE® screws and variable or fixed bone screws. Polyaxial or monoaxial REVERE® screws attach to the rod portion of the plate and variable or fixed bone screws are inserted through the plate, for fixation of GATEWAY® plates to the vertebral bodies of the thoracolumbar spine (T1-L5). REVERE® locking caps are used to connect polyaxial or monoaxial screws to the rod portion of the plate. Optional staples may be used for additional fixation of polyaxial or monoaxial screws to vertebral bodies. GATEWAY® implants are composed of titanium alloy, as specified in ASTM F136, F1295.

INDICATIONS

The GATEWAY® Thoracolumbar Plate System is intended for use in the treatment of thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

WARNINGS

The components of this system are manufactured from titanium alloy. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical, and functional reasons.

PRECAUTION

The implantation of screw and plate systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length.

ATTENTION

See Warnings, Precautions and Potential Adverse Events sections of the insert entitled "Suggestions Concerning Orthopaedic Metallic Internal Fixation Devices" for a complete list of potential risks.

CONTRAINDICATIONS

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

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

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

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

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

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

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

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.

IMPORTANT INFORMATION ON THE GATEWAY® THORACOLUMBAR PLATE

- 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 Law (USA) Restricts this Device to Sale by or on the order of a Physician.

REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY	Rx ONLY	PRESCRIPTION USE ONLY

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Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

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