CITADEL®

Anterior Lumbar Plate System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

CITADEL®

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Anterior Lumbar Plate System

CITADEL® is an anterior lumbar plate system with a full range of implants and reliable user-friendly instrumention designed to ease the ALIF procedure.

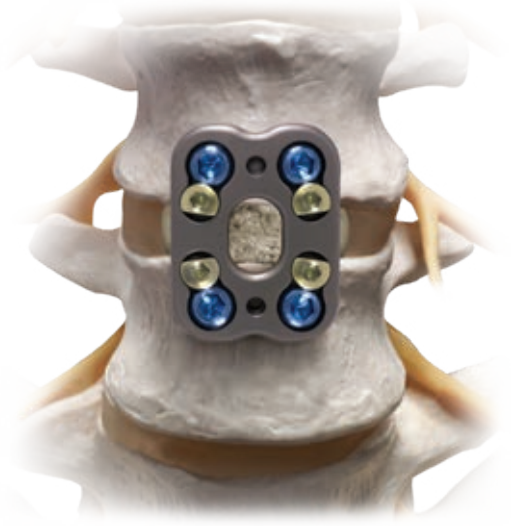
A low profile design and integrated blocking set screw help ensure that the plate maintains a smooth surface to reduce interference with surrounding vessels.

Unlocked

Locked

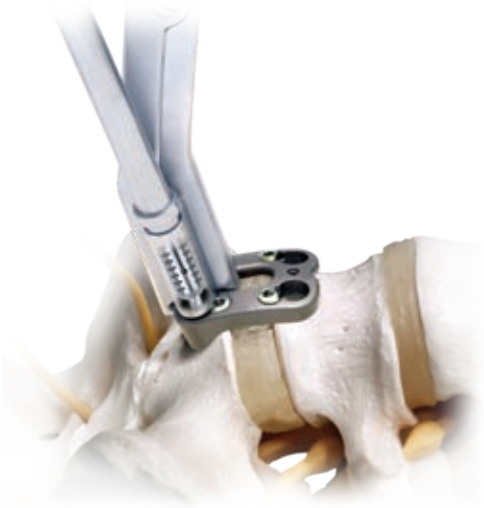
Integrated Screw Locking Mechanism

The abilities to lag bone and integrated blocking set screws help to maintain the plate's low profile



Low Profile

The smooth surface and rounded edges on the plate help to prevent interference with surrounding anatomy



Pre-Set Angle Plate Holder Drill Guide

Facilitates a safe, straightforward ALIF procedure

Unique Sacral Plate Design

Designed to match sacral anatomy

IMPLANT OVERVIEW

CITADEL® Plates

- Low profile, 3.9mm
- Integrated locking set screw to eliminate screw backout
- Large windows for graft visualization
- Narrow width, 26mm

Lumbar Plates

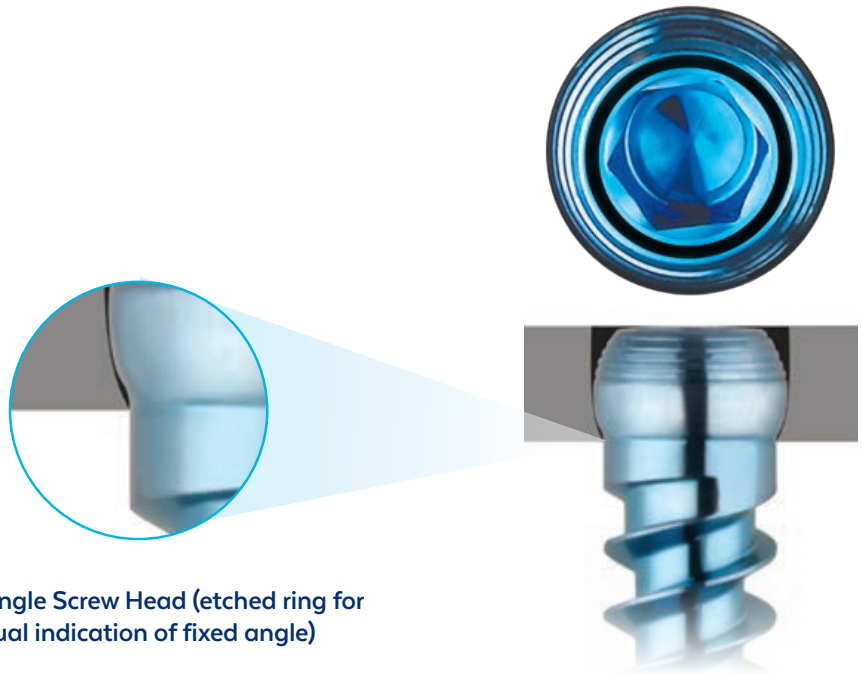
- 1-level and 2-level plates available in multiple lengths:
  - 1-level: 20–38mm in 2mm increments
  - 2-level: 42–60mm in 6mm increments
  - 2-level: 63–99mm in 3mm increments
- Lordotic curvature to match the lumbar anatomy:
  - 1-level plates have a 100mm radius
  - 2-level plates have a 200mm radius

Sacral Plates

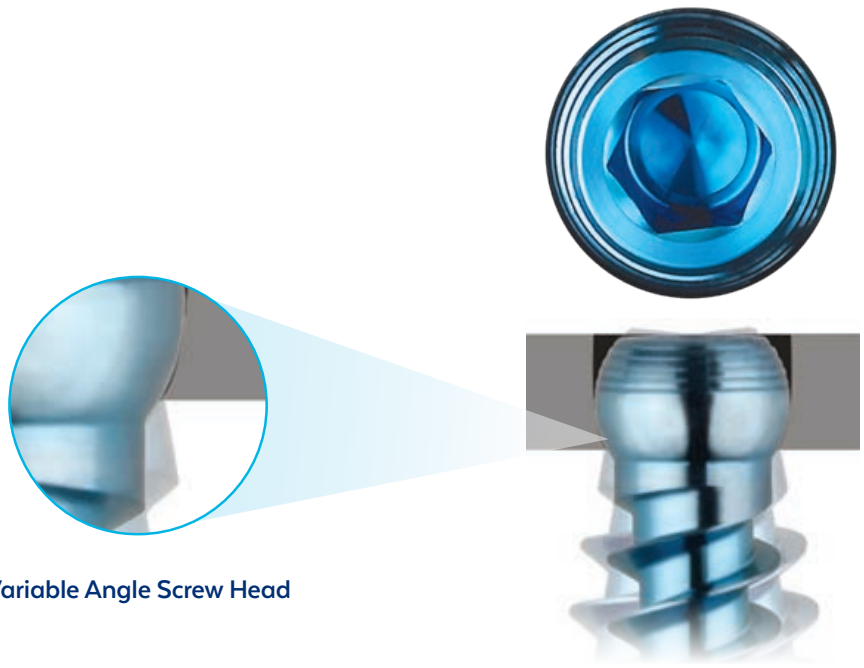
- Unique design to match the natural lumbosacral curvature
- 1-level and 2-level plates available in multiple lengths:
  - 1-level: 20–38mm in 2mm increments
  - 2-level: 42–60mm in 6mm increments
  - 2-level: 63–90mm in 3mm increments
- Universal joint instrumentation for simplified placement
- Lordotic curvature to match the sacral anatomy:
  - 1-level plates have a 75mm radius
  - 2-level plates have a 200mm radius

Bone Screws

- Lengths from 22–57mm
- 6.5mm diameter, self-tapping screws
- Variable angle and fixed angle screws available
  - Variable angle screws allow for 10° angulation
  - Fixed angle screw trajectory is perpendicular to the plate curvature



Fixed Angle Screw Head (etched ring for visual indication of fixed angle)



Variable Angle Screw Head

INSTRUMENT OVERVIEW

SCREW PREPARATION INSTRUMENTS

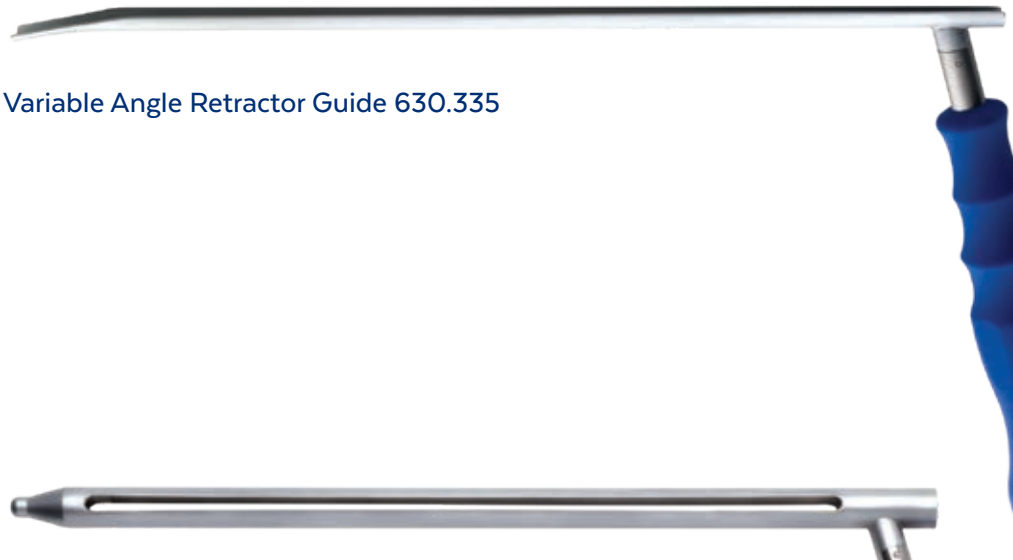
Cortex Awl, 1/4” QC 630.316

Awl, 1/4” QC 630.317

Plate Holder DTS Guide, Double Barrel 630.332

Plate Holder DTS Guide, Left 630.333

Plate Holder DTS Guide, Right 630.334



Variable Angle Retractor Guide 630.335

Drill Guide, Freehand 630.336

Drill Bit, 22mm, 1/4” QC 630.400

Tap, 22mm, 1/4” QC 630.405

HANDLES

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

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

PLATE INSTRUMENTS

Plate Holder Forceps 630.322

Plate Bender 630.324

Temporary Pin Driver, Internal Grip 630.005

Temporary Pin Driver, External Grip 630.006

Temporary Pin for Screw Holes 630.016

Temporary Pin, 22mm 630.018

Temporary Pin, 16mm 630.020

SCREW INSTRUMENTS

Screwdriver, 3.5mm Hex, Self-Retaining 630.410

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

LOCKING INSTRUMENTS

Set Screw Positioner, Ball Hex 630.501

SACRAL INSTRUMENTS

Awl, 1/4” QC, U-Joint 630.493

Drill Bit, 22mm 1/4” QC, U-Joint 630.494

Screwdriver, 3.5mm Hex, 1/4” QC, U-Joint 630.495

Tap, 22mm, 1/4” QC, U-Joint 630.496

CITADEL®

STEP 1 APPROACH AND PREPARATION

The patient is placed under anesthesia and positioned supine. The operative area is carefully cleaned and an incision is made at the appropriate fusion level(s). CITADEL® plate fixation may be used in the lumbosacral spine from L1-S1. Please refer to the product insert for complete description, contraindications, indications, warnings and precautions.

Prepare the disc space and insert bone graft or interbody fusion device into the disc space. Refer to the PRESERVE® ALIF Surgical Technique Guide for a recommended technique. Following graft placement, prepare the vertebral bodies by removing any anterior osteophytes to allow the plate to sit flush on the vertebral body.

For the purposes of this technique guide, an L5-S1 construct is shown.

STEP 2 PLATE BENDING AND PLACEMENT

Choose the appropriate plate size. The etched plate length represents the distance from the center of the cephalad holes to the center of the caudal holes. It is recommended that screws are placed close to the vertebral endplates for optimal purchase.

All plates are pre-contoured. However, additional contouring may be accomplished using the Plate Bender. Insert the plate into the bender with the top of the plate facing down.

Note: The plate should not be bent at set screw hole locations; nor should it be bent to decrease lordosis. Repeated bending may weaken the plate.

Use the Plate Holder Forceps and place the plate onto the vertebral bodies. Alternatively, one of the three Plate Holder DTS Guides may be used to hold the plate for placement.

STEP 3 SCREW HOLE PREPARATION

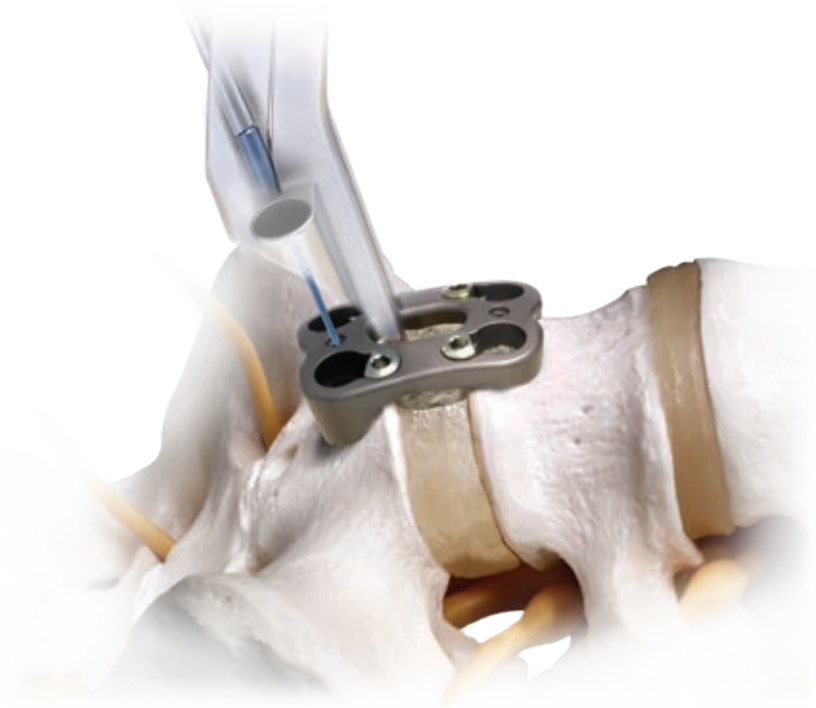
Once the plate is inserted, temporary pins may be used to hold the plate in position. There are two temporary pin options.

The **Temporary Pins** can be placed through the small pin hole in the center of the plate, medial to the screw holes. The **Temporary Pin Drivers** are used to place these pins. To load and unload the pin using the **Temporary Pin Driver, Internal Grip**, retract the sleeve below the handle of the pin driver, as shown below. The temporary pin can be inserted through the DTS guides using this instrument.

To load and unload the pin using the **Temporary Pin Driver, External Grip**, slide the sleeve back and forth over the pin head. This instrument cannot be inserted through the DTS guides.

Alternatively, the **Temporary Pin for Screw Holes** may be inserted using a 3.5mm hex driver. These pins are inserted into the screw hole.

Retracting sleeve on Temporary Pin Driver, Internal Grip



Temporary Pin inserted into plate through Double Barrel DTS Guide

Option A: Pre-Set Angulation

Three **Plate Holder Drill-Tap-Screw (DTS) Guide** options are available to securely hold the plate while preparing the screw holes and inserting the screws. These DTS guides provide a pre-set angle and should always be used when inserting fixed angle screws.

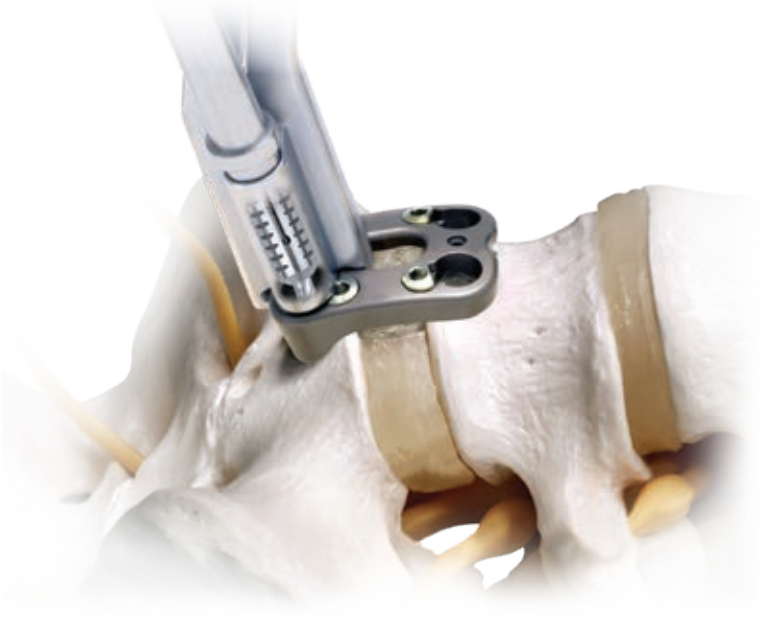
Secure the DTS guide of choice (double, left or right barrel) to the plate. The front of the guide should be oriented with the outside of the plate, as shown at right.

Note: Screws longer than 30mm should not be inserted through the pre-set angle drill guides as they will interfere medially.

Prepare a pilot screw hole using the **Awl, 1/4" QC**. Connect the awl to either the **Quick-Release 1/4" Ratchet T-Handle or Straight Handle** and insert into the screw hole. When inserting the **Drill Bit, 22mm, 1/4" QC** or Awl, 1/4" QC through the DTS guide, move the positioning sleeve to the forward position to ensure the instrument is centered through the guide. Connect the Drill Bit, 22mm, 1/4" QC to one of the **Quick-Release Ratchet Handles.** Drill to the stop.

Note: When connecting instruments to the Quick-Release 1/4" Ratchet Handles, the instrument shaft should be inserted into the handle so that the black etch line is no longer visible.

Screws are self-tapping, but the holes may be tapped through the DTS guide using the **Tap 22mm, 1/4" QC** and quick-release handle assembly. Both the fixed angle or variable angle screws may be inserted through the DTS guides.



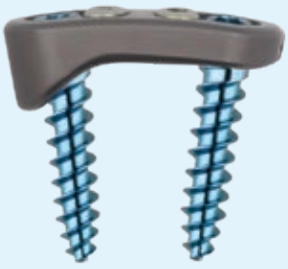
Drilling through Plate Holder DTS Guide, Double Barrel

Correct orientation of Plate Holder DTS Guides on CITADEL® Plate

PLATE HOLDER DTS GUIDES

The Plate Holder DTS Guides provide pre-set screw angulation for drilling, tapping and inserting screws.

Axial Plane



Sagittal Plane (Normal Angle to Plate)

SCREW HOLE PREPARATION (CONT'D)

Option B: Variable Angulation

Perforate the cortex of the vertebral body using an awl. Attach the **Cortex Awl, 1/4" QC** to the Quick-Release 1/4" Ratchet T-Handle or Straight Handle. The cortex awl can be used to create a freehand trajectory. Alternately, the Awl, 1/4" QC and Quick-Release Ratcheting Handle assembly can be inserted through the **Drill Guide, Freehand** to begin a pilot hole.

When inserting the Awl, 1/4" QC or Drill Bit, 22mm, 1/4" QC through the Drill Guide, move the positioning sleeve to the back position to be fully inserted.

Place the Drill Guide into the desired plate hole. This guide permits full angulation of the drill through the plate. Attach the Drill Bit, 22mm, 1/4" QC to a Quick-Release Ratcheting Handle, and insert into the drill guide. Drill to the stop. *NOTE: Care should be taken to prevent interference in medial angulation.*

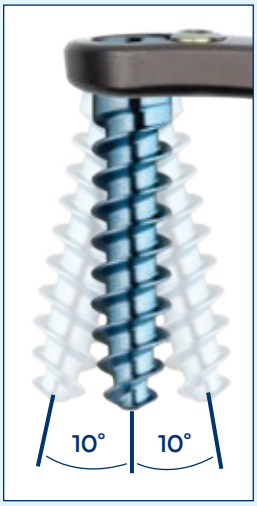
The screws are self-tapping, but the holes may be tapped if needed using the Tap 22mm, 1/4" QC and a Quick-Release Ratcheting Handle.

Note: Fixed angle screws must not be used in conjunction with the Drill Guide, Freehand. Fixed angle screws are inserted through the trajectory provided by the Plate Holder DTS Guides, as described on page 13.

Drilling through Drill Guide, Freehand

DRILL GUIDE, FREEHAND

Provides screw angulation of ±10° in all directions for drilling screw pilot holes.

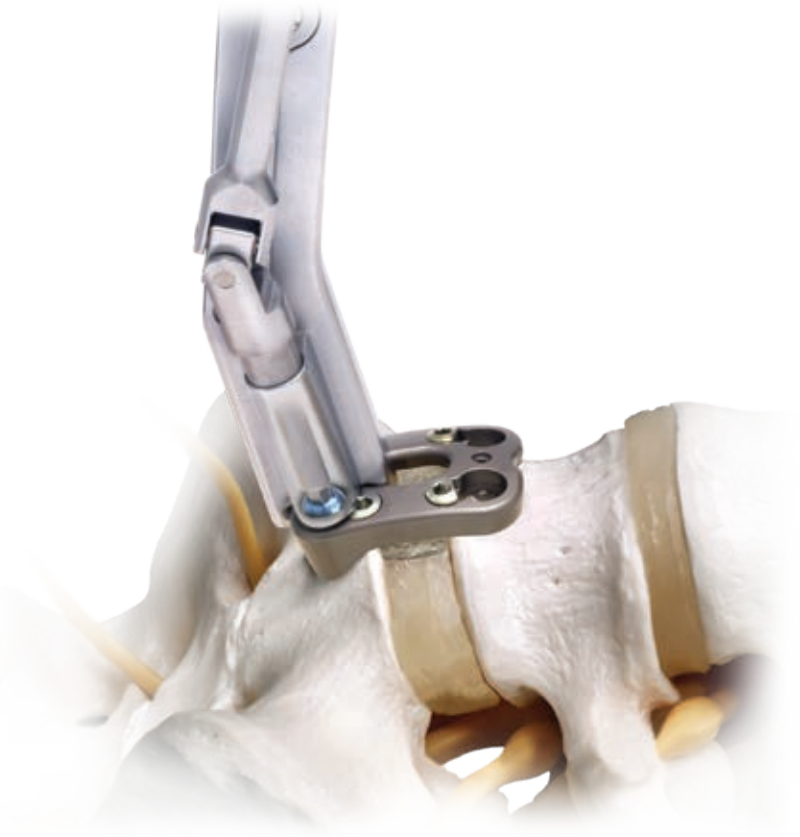


Note: Care should be taken to prevent interference in medial angulation.

STEP 4 OPTIONAL: SACRAL INSTRUMENTS

The CITADEL® fixation system includes sacral plates for use at the lumbosacral junction. Due to the unique insertion angle needed for these plates, specialized universal joint instruments are provided to aid in accessing the plate.

The **Awl, 1/4" QC, U-Joint** and **Drill Bit, 22mm, 1/4" QC, U-Joint** can be used with all drill guides provided. The **Tap, 22mm, 1/4" QC, U-Joint** can be used with the Plate Holder DTS Guides. Insert universal joint instruments through either the Drill Guide, Freehand or Plate Holder DTS Guides, as described in Step 3, ensuring the sleeve is positioned correctly. A universal joint screwdriver is also provided and can be used for screw insertion through the Plate Holder DTS Guides.

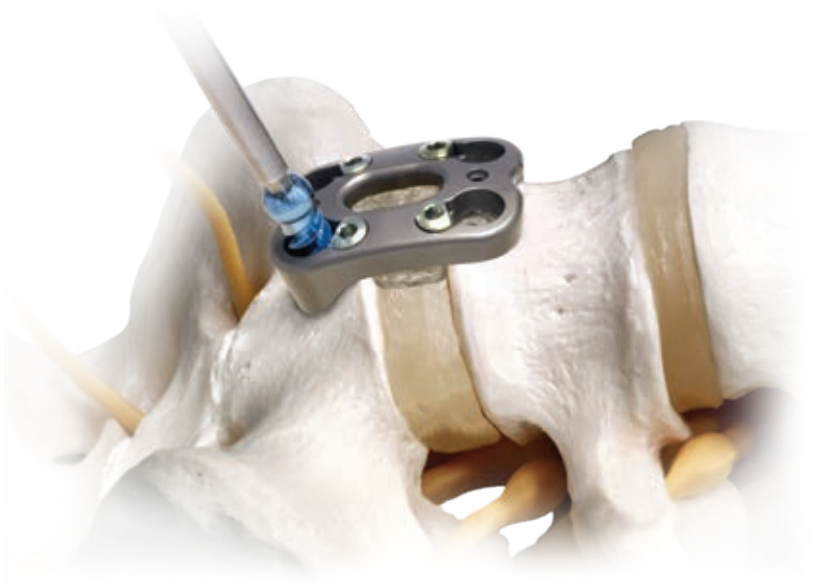


Inserting screw with Screwdriver, 3.5mm Hex. 1/4" QC, U-Joint

STEP 5 SCREW INSERTION

Screws are available in variable angle or fixed angle designs, from 22–57mm in length. Select the desired screw and use the **Screwdriver, 3.5mm Hex, Self-Retaining** to remove it from the screw module. Remove temporary pins prior to insertion. Insert the screw into the plate. Repeat for all screw holes.

Alternatively, the **Screwdriver Shaft, 3.5mm Hex, 1/4" QC**, may be used in conjunction with a Ratcheting 1/4" Quick-Connect Handle.



STEP 6 LOCKING THE CONSTRUCT

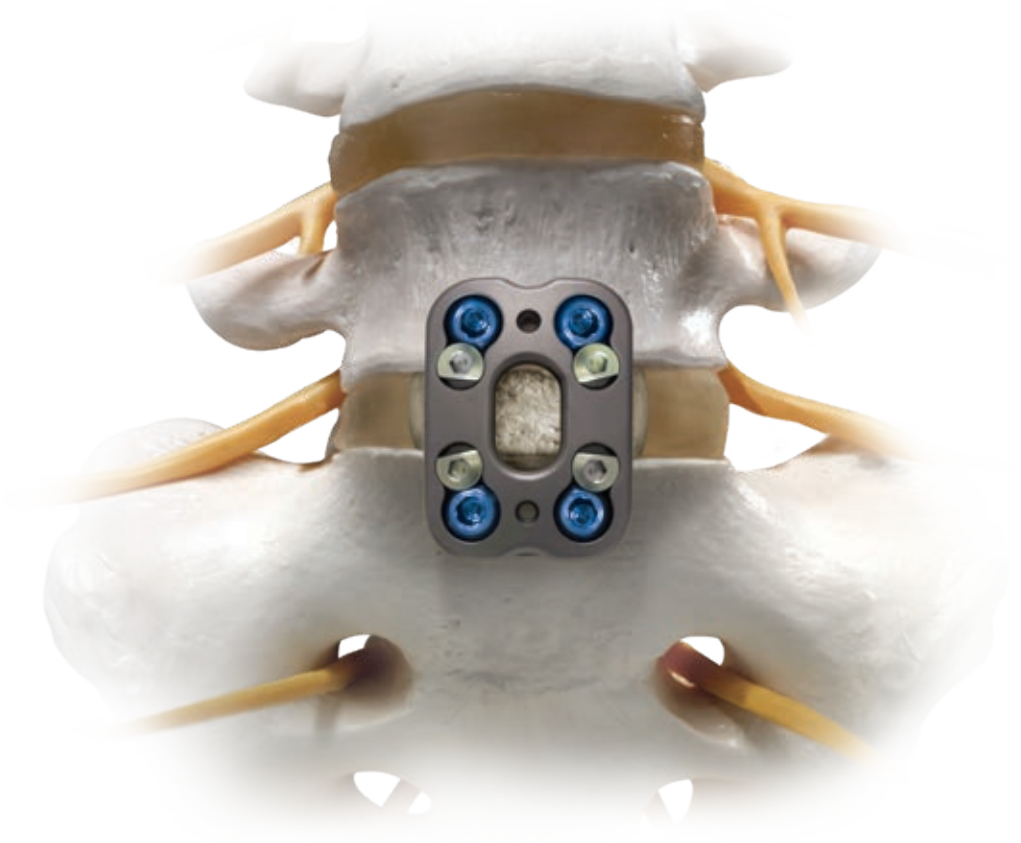
Once all screws are fully seated within the plate, the locking set screw can be rotated into place.

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

Initial Position

Locked Position

FINAL CONSTRUCT



CITADEL®
IMPLANT SET 930.902

Plates (Qty 1 Each)

1-Level Lumbar

Part No.	Length
130.120	20mm
130.122	22mm
130.124	24mm
130.126	26mm
130.128	28mm
130.130	30mm
130.132	32mm
130.134	34mm
130.136	36mm
130.138	38mm

1-Level Sacral

Part No.	Length
130.220	20mm
130.222	22mm
130.224	24mm
130.226	26mm
130.228	28mm
130.230	30mm
130.232	32mm
130.234	34mm
130.236	36mm
130.238	38mm

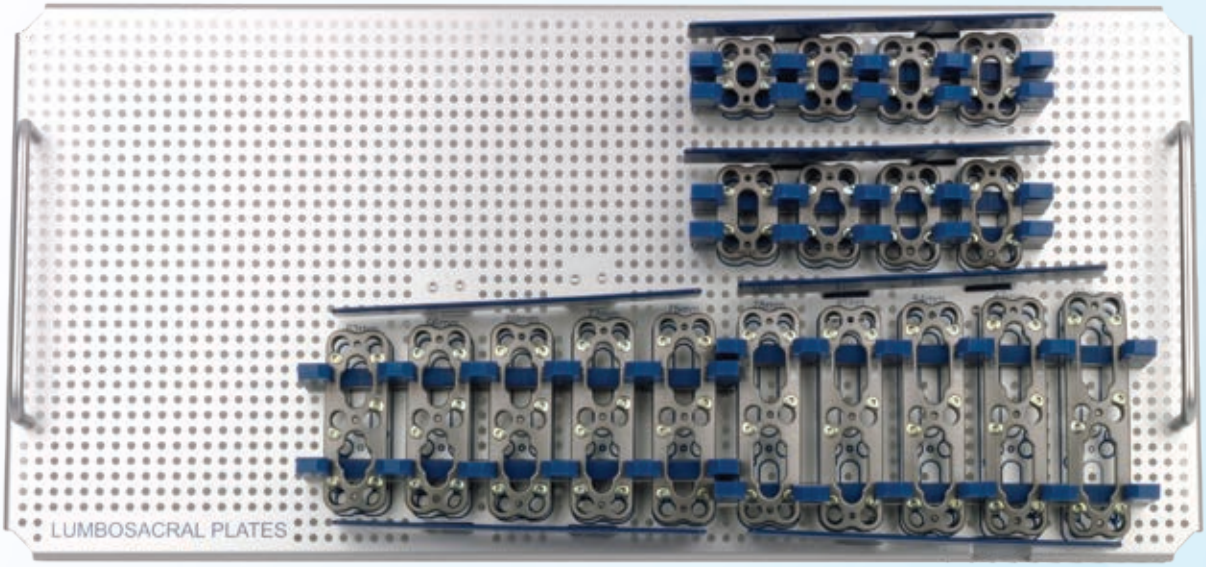
2-Level Lumbar

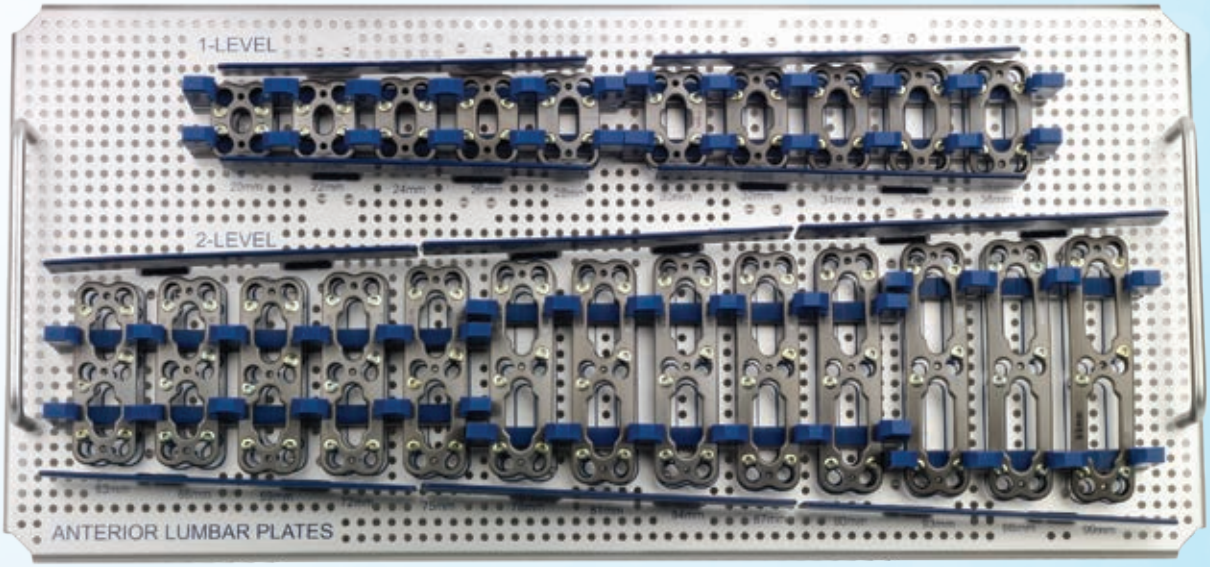
Part No.	Length
130.142	42mm
130.148	48mm
130.154	54mm
130.160	60mm
130.163	63mm
130.166	66mm
130.169	69mm
130.172	72mm
130.175	75mm
130.178	78mm
130.181	81mm
130.184	84mm
130.187	87mm
130.190	90mm
130.193	93mm
130.196	96mm
130.199	99mm

2-Level Asymmetric Graft Window

Part No.	Length
130.263	63mm
130.266	66mm
130.269	69mm
130.272	72mm
130.275	75mm
130.278	78mm
130.281	81mm
130.284	84mm
130.287	87mm
130.290	90mm
130.542	42mm
130.548	48mm
130.554	54mm
130.560	60mm
130.566	66mm
130.572	72mm
130.578	78mm
130.584	84mm

CITADEL®
IMPLANT SET 930.902





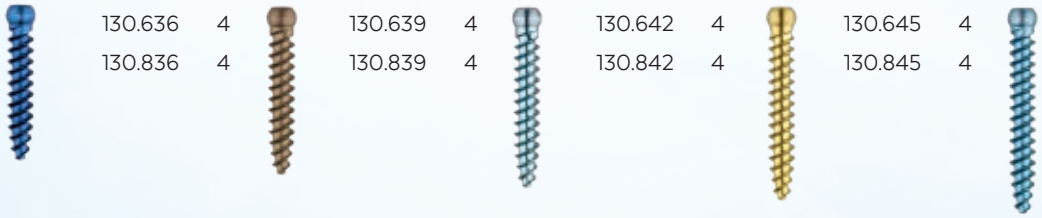
GATEWAY®/CITADEL®
BONE SCREW INSTRUMENT SET 929.906

	Part No.	Description	Qty
1	630.316	Cortex Awl, 1/4" QC	1
2	630.317	Awl, 1/4" QC	1
3	630.336	Drill Guide, Freehand	1
4	630.400	Drill Bit, 22mm, 1/4" QC	2
5	630.401	Quick-Release 1/4", Ratchet, T-Handle	1
6	630.405	Tap, 22mm, 1/4" OC	2
7	630.407	Quick-Release 1/4", Ratchet, Straight Handle	1
8	630.410	Screwdriver, 3.5mm Hex, Self-Retaining	2
9	630.414	Screwdriver Shaft, 3.5mm Hex, 1/4" QC, Self-Retaining	1
10	630.493	Awl, 1/4" QC, U-Joint	1
11	630.494	Drill Bit, 22mm, 1/4" QC, U-Joint	1
12	630.495	Screwdriver, 3.5mm Hex, 1/4" QC, U-Joint	1
13	630.496	Tap, 22mm, 1/4" QC, U-Joint	1
14	630.501	Set Screw Positioner, Ball Hex	1
	929.006	GATEWAY®/CITADEL® Bone Screw Instrument Graphic Case	

Bone Screws

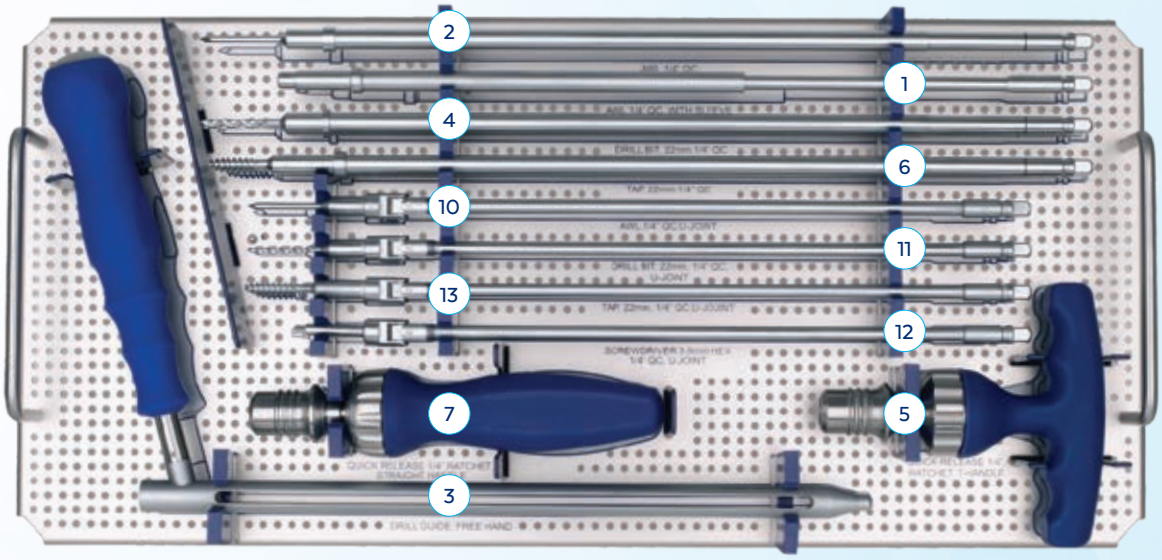
	22mm	Qty	24mm	Qty	26mm	Qty	28mm	Qty	30mm	Qty
Variable Angle	130.622	8	130.624	10	130.626	10	130.628	8	130.630	8
Fixed Angle	130.822	8	130.824	10	130.826	10	130.828	8	130.830	8

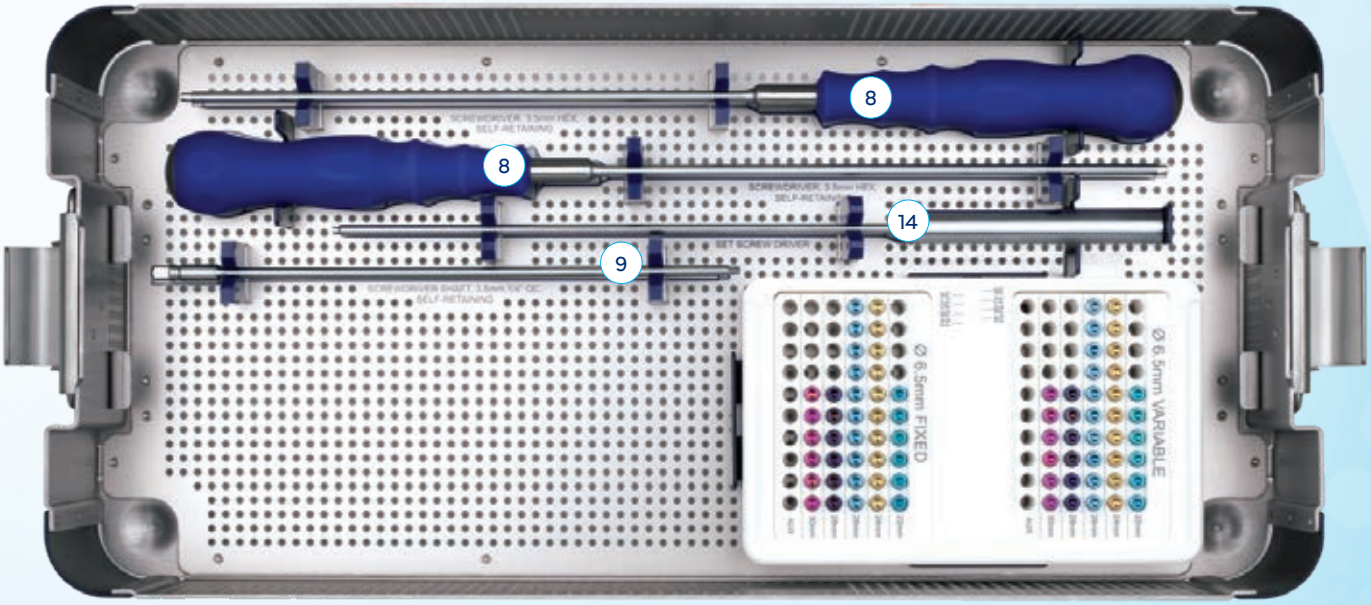
	33mm	Qty	36mm	Qty	39mm	Qty	42mm	Qty	45mm	Qty
Variable Angle	130.633	4	130.636	4	130.639	4	130.642	4	130.645	4
Fixed Angle	130.833	4	130.836	4	130.839	4	130.842	4	130.845	4



	48mm	Qty	51mm	Qty	54mm	Qty	57mm	Qty
Variable Angle	130.648	4	130.651	4	130.654	4	130.657	4
Fixed Angle	130.848	4	130.851	4	130.854	4	130.857	4

GATEWAY® /CITADEL®
BONE SCREW INSTRUMENT SET 929.906





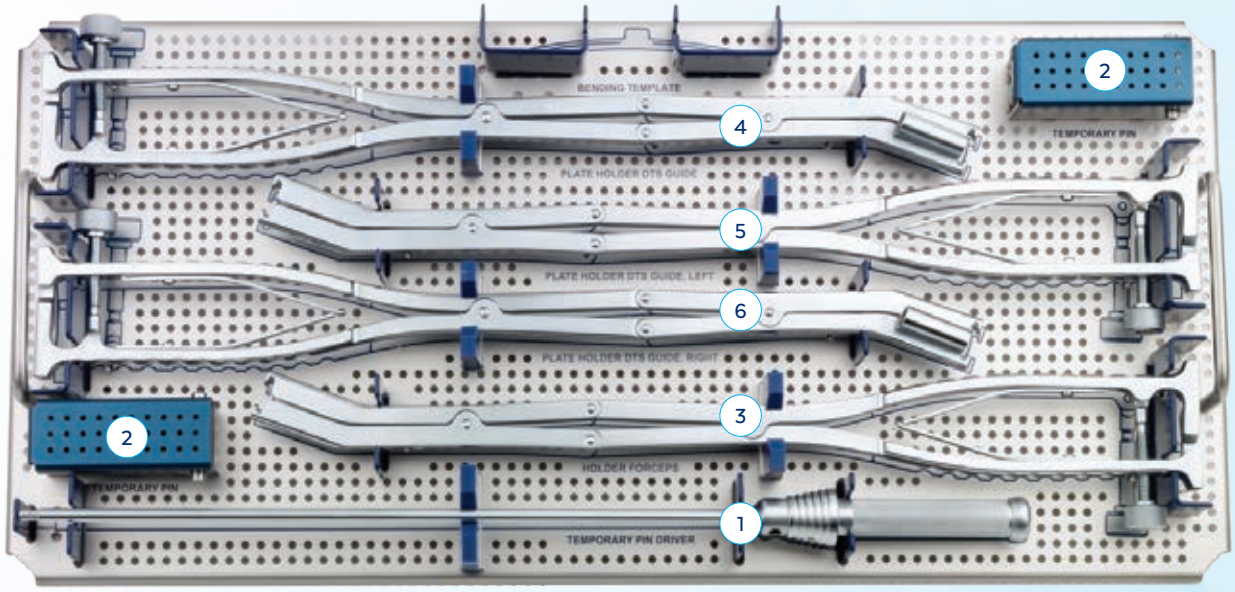
CITADEL®
INSTRUMENT SET 930.901

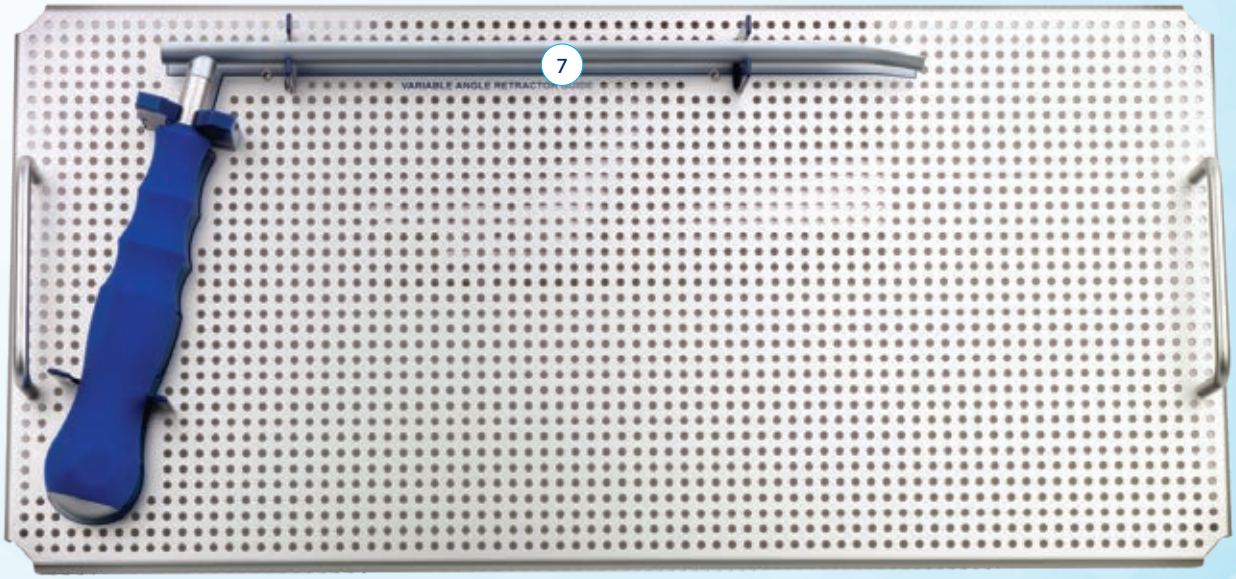
	Part No.	Description	Qty
1	630.005	Temporary Pin Driver, Internal Grip	1
2	630.018	Temporary Pin, 22mm	6
3	630.322	Plate Holder Forceps	1
	630.324	Plate Bender	1
4	630.332	Plate Holder DTS Guide, Double Barrel	1
5	630.333	Plate Holder DTS Guide, Left	1
6	630.334	Plate Holder DTS Guide, Right	1
7	630.335	Variable Angle Retractor Guide	1
	930.001	CITADEL® Instrument Graphic Case	

Additionally Available

630.006	Temporary Pin Driver, External Grip
630.009	Slap Hammer, Quick-Connect
630.016	Temporary Pin for Screw Holes
630.020	Temporary Pin, 16mm
630.163	Bending Template
630.320	Slap Hammer
630.411	Screwdriver, 3.5mm Ball Hex
630.403	Quick-Release 1/4" Palm Handle
630.503	Set Screw Positioner, Torque-Limiting, 1.5Nm

CITADEL®
INSTRUMENT SET 930.901





IMPORTANT INFORMATION ON THE CITADEL® ANTERIOR LUMBAR PLATE

DESCRIPTION

The CITADEL® Anterior Lumbar Plate System consists of plates of various lengths to be used with variable or fixed bone screws for fixation to the anterior or anterolateral aspect of the vertebral bodies of the lumbar and lumbosacral spine (L1-S1). CITADEL® implants are composed of titanium alloy, as specified in ASTM F136, F1295.

INDICATIONS

The CITADEL® Anterior Lumbar Plate System is intended for use by an anterior or anterolateral approach in the treatment of lumbar and lumbosacral (L1-S1) 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), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

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.

WARNINGS

One of the following 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 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.

PRECAUTIONS

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 list of potential risks. References to fracture systems in the above insert apply to non-spinal systems which are intended for reconstruction rather than spinal fixation.

MRI SAFETY INFORMATION

Non-Clinical testing has demonstrated the CITADEL® Anterior Lumbar Plate Systems 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 2 W/kg (Normal Operating Mode)
- Quadrature Body Coil only

Under the scan conditions defined above, the CITADEL® Anterior Lumbar Plate Systems are expected to produce a maximum temperature rise of less than or equal to 3.5°C after 15 minutes of continuous scanning.

The image artifact is not expected to extend beyond 55mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

PACKAGING

These implants may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

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

HANDLING AND USE

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

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants may be available sterile or nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

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

IMPORTANT INFORMATION ON THE CITADEL® ANTERIOR LUMBAR PLATE

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

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes
Steam	Pre-vacuum	134°C (273°F)	3 Minutes	30 Minutes

Do not stack trays during sterilization. These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

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

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CE 0297

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