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VICTORY™

Lumbar Plate System

SURGICAL TECHNIQUE GUIDE

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

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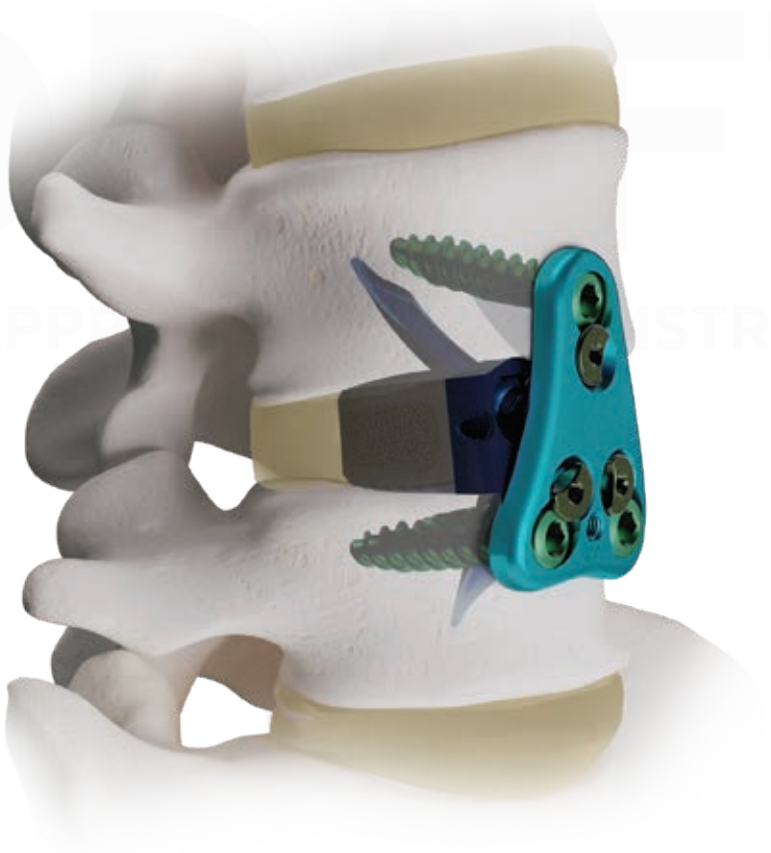
SURGICAL TECHNIQUE GUIDE

VICTORY™

VICTORY™

Lumbar Plate System

The VICTORY™ Lumbar Plate System is designed to provide anterior stabilization to the lumbar and lumbosacral spine. The comprehensive system features configurable screw angulation, a low profile to reduce interference with vascular anatomy, and streamlined instruments for clear visualization.



Comprehensive System Offerings

A diverse range of plate geometry allows surgeons to treat a wide variety of patient anatomies. Intuitive instruments help streamline the procedure, allowing for clear visualization during screw placement.

Low Profile Design

Plates are designed with a maximum thickness of 3.5mm to help reduce interference with surrounding tissue and vasculature.

Configurable Screw Angulation

The lumbar and sacral sides of the plates feature a unique range of screw angulation to facilitate bony purchase from a variety of access angles when an integrated spacer is present. Self-drilling and self-tapping screws are available for versatility in procedures.

Confident Screw Blocking

Designed to help prevent screw backout and provide audible, tactile, and visual confirmation of screw blocking.

IMPLANT OVERVIEW

3-Hole and 4-Hole Plates

- 3.5mm profile
- 26mm maximum width
- Integrated blocking screw designed to help prevent screw backout

Lumbar Plates

- Available in multiple lengths (screw hole to screw hole)
  - 18*, 21, 24, 27, 30, 33, 36*mm
- Available in two configurations
  - 3-Hole Plate
  - 4-Hole Plate
- Lordotic curvatures to accommodate lumbar anatomy
  - 100mm radius

Lumbar Plate

Sacral Plate

Sacral Plates

- Available in multiple lengths (screw hole to screw hole)
  - 18*, 21, 24, 27, 30, 33, 36*mm
- Available in three configurations
  - 3-Hole Plate, Sacral Lip on 1-Hole Side
  - 3-Hole Plate, Sacral Lip on 2-Hole Side
  - 4-Hole Plate
- Lordotic curvatures to accommodate lumbar anatomy
  - 75mm radius

Buttress Plates

- 3.3mm profile
- 15mm maximum width
- Integrated blocking screw designed to help prevent screw backout
- 20mm and 24mm lengths (top to bottom)

*Additionally available

Bone Screws

- Available in multiple lengths
  - 22.5, 25, 27.5, 30, 32.5*, 35*mm
- 6.0mm and 6.5mm diameters
- Self-drilling and self-tapping variable angle screws

Self-Drilling

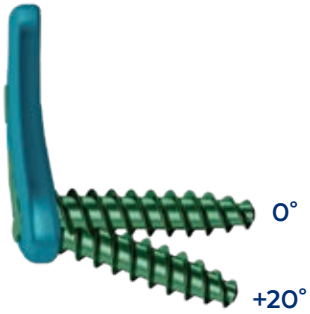
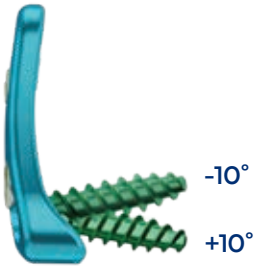
Self-Tapping

Bone Screw, Self-Tapping, 6.0mm

Bone Screw, Self-Drilling, 6.0mm

Bone Screw, Self-Tapping, 6.5mm

Screw Angulation

	Lumbar Plates	Sacral Plates	Buttress Plates
Medial-Lateral			
Cranial-Caudal			

*Additionally available

INSTRUMENT OVERVIEW

SCREW HOLE PREPARATION INSTRUMENTS

VICTORY™ Straight Drill 6236.0009

VICTORY™ Straight Tap 6236.0012

VICTORY™ Angled Drill Bit 6236.0010

VICTORY™ Angled Tap Bit 6236.0011

3.5mm Angled Hex Driver, Short 676.710

Counter-Torque 676.699

Angled Sleeve 676.700

Shaft 676.701

Nut 676.702

VICTORY™ Bent Awl 6236.0007

VICTORY™ Straight Awl 6236.0008

3.5mm Hex Straight Shaft 676.502

QC Handle, Small, with Cap 650.105

VICTORY™ Straight Awl 6236.0008
QC Handle, Small, with Cap 650.105
(Assembled)

3.5mm Hex Straight Shaft 676.502
QC Handle, Small, with Cap 650.105
(Assembled)

PLATE INSTRUMENTS

Buttress Plate Inserter 6236.2000

Awl 6236.2100

Buttress Plate Inserter 6236.2000
Awl 6236.2100
(Assembled)

Plate Holder 6236.1000

Plate Bender 630.324*

Set Screw Positioner, Torque-Limiting 6108.1006

Temporary Pin Driver 6236.5000

Temporary Pin, 18mm 6236.0018

Temporary Pin for Screw Hole, 18mm 6236.5018

*Additionally available

SURGICAL TECHNIQUE

VICTORY™

Please refer to the product insert, also printed at the back of this manual, for information on the intended usage/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

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 level(s). VICTORY™ plate fixation may be used in the lumbosacral spine from L1-S1.

Any interbody fusion techniques should be performed prior to plating. Prepare the disc space and insert bone graft or an interbody fusion device into the disc space.

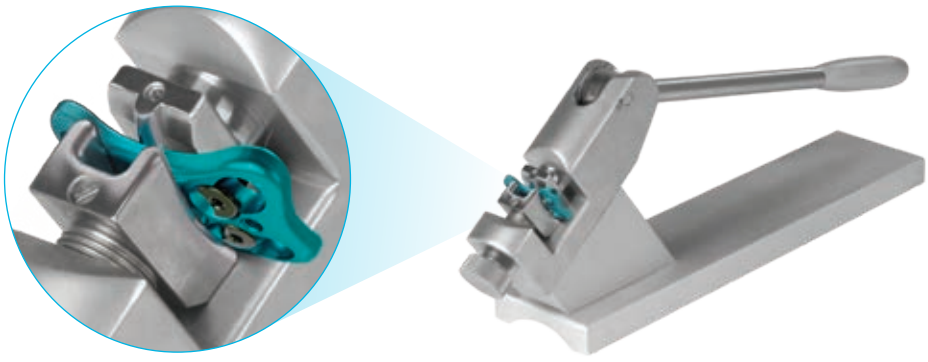
Following graft and/or interbody fusion device placement, prepare the vertebral bodies by removing any anterior osteophytes to allow the plate to sit flush on the vertebral body.

3-Hole and 4-Hole Plates

STEP 2 PLATE SELECTION AND PLACEMENT

All plates are pre-contoured. However, additional contouring may be accomplished using a **Plate Bender**.* The plate should not be bent to decrease lordosis or bent at blocking screw locations. Repeated bending may weaken the plate.

Select the appropriate plate option and size. The etched plate length is the distance between the cephalad and caudal holes (center to center). Plate size can be determined by patient anatomy and type of interbody spacer, if used. For an example of determining plate size based on the interbody spacer used, see “Plate and Spacer Specifications.”



Optional plate bending

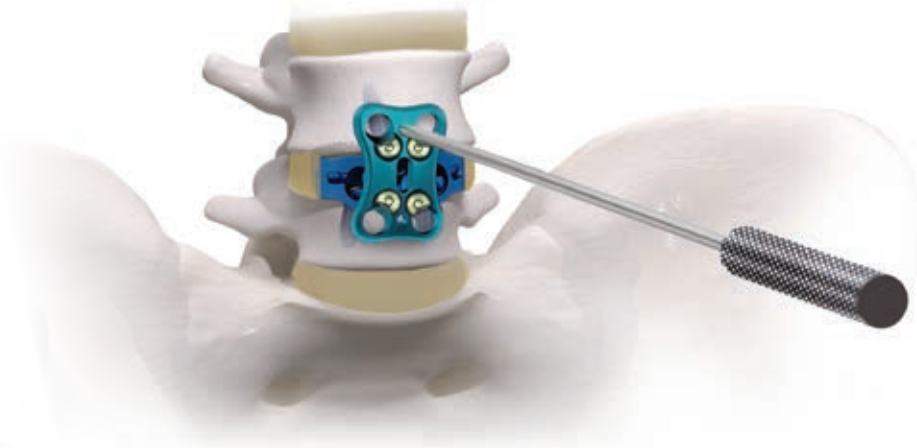
**Additionally available*

PLATE SELECTION AND PLACEMENT (CONT'D)

Thread the **Plate Holder** into the 3-hole and 4-hole plate threaded holes and place the plate onto the vertebral bodies.

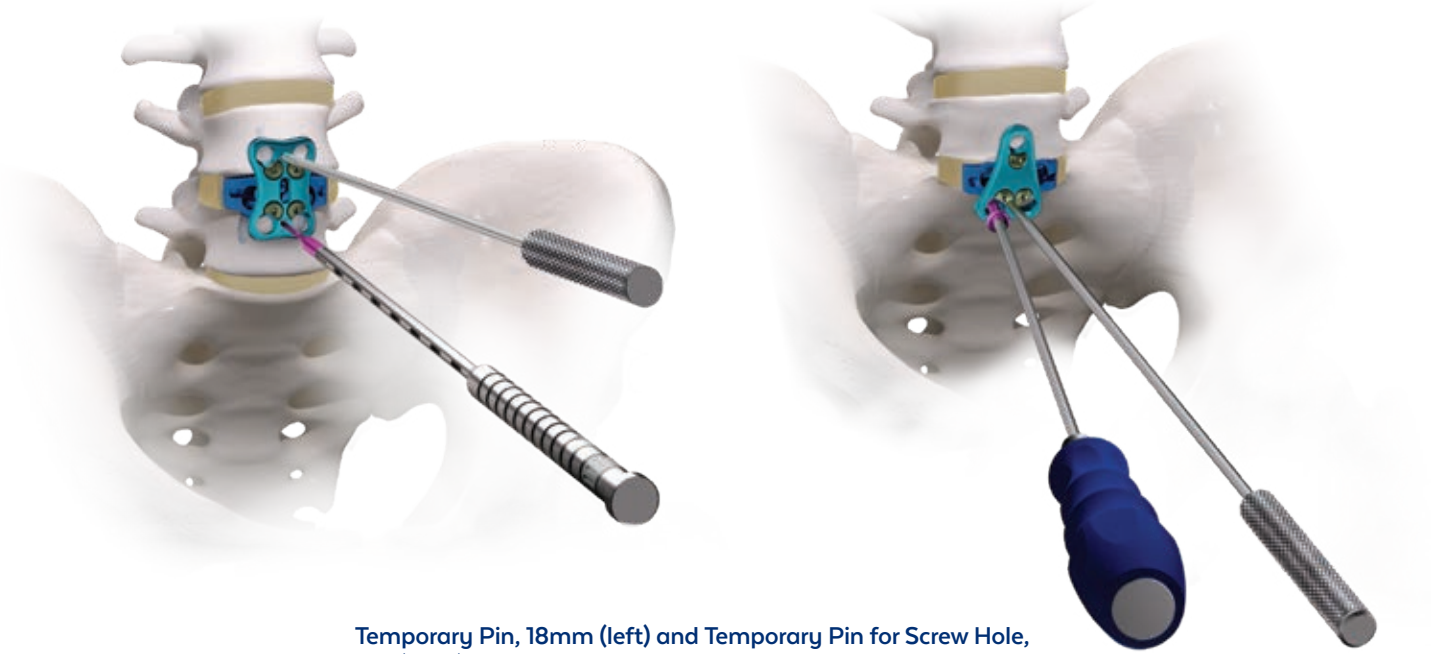
Alternatively, a forceps-style instrument may be used.

Note: Fixation Pins may be used as a means of temporary fixation during subsequent steps. Fixation Pins are designed for single patient use, not for long-term implantation.



Placing plate into position with Plate Holder

Once the plate is in the desired position, a **Temporary Pin, 18mm** may be used to hold the plate in place. Using the **Temporary Pin Driver**, retract the end cap to load the pin. Insert the temporary pin into the threaded pin hole of the plate until fully seated. Remove the driver by retracting the end cap. Alternatively, a **Temporary Pin for Screw Hole, 18mm** may be placed using a **3.5mm Hex Straight Driver**. A **3.5mm Angled Hex Straight Driver, Short** is also available.



Temporary Pin, 18mm (left) and Temporary Pin for Screw Hole, 18mm (right) inserted into plates to provisionally hold them in place

TEMPORARY PIN DRIVER ASSEMBLY

Insert the inner shaft into the outer sleeve.

To lock the assembly, rotate the collar clockwise until finger tight.

To load and unload the pin using a Temporary Pin Driver, retract the endcap proximal to the handle of the pin driver and seat the Temporary Pin, 18mm into the tip of the driver. Insert the temporary pin into the plate threaded pin hole and rotate clockwise until finger tight to secure it.

Retract endcap

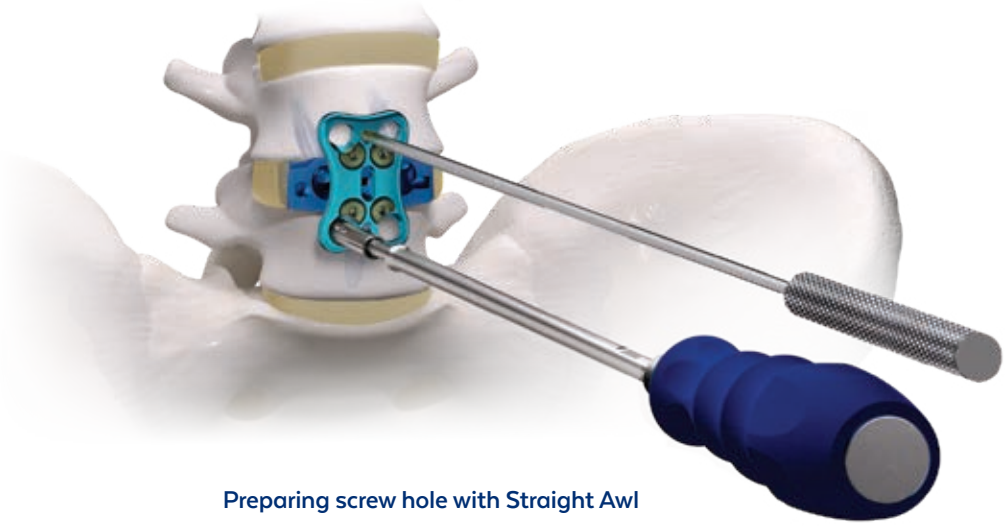
Load/unload

For disassembly instructions for the Temporary Pin Driver, refer to the section titled Temporary Pin Driver Disassembly.

STEP 3 SCREW HOLE PREPARATION

For 3-hole and 4-hole plates, once the plate is in the desired position over the vertebral body, utilize the Straight Awl or Bent Awl to perforate the cortex. The Awl is intended to help ensure the screw trajectory remains within the screw angulation range without the use of a drill guide.

For all VICTORY™ plates, a self-centering drill and tap may be used to further prepare the screw hole. Depending on the angle and position, a straight or angled instrument may be used. For self-tapping screws, drill a pilot hole using the corresponding drill bit. Proceed to screw insertion after preparing the remaining screw holes.



Preparing screw hole with Straight Awl

STEP 4 SCREW INSERTION

Depending on the angle and position of the plate on the vertebral bodies, a straight or angled driver may be used for screw insertion. Load the screw onto the 3.5mm Angled Hex Driver, Short or 3.5mm Hex Straight Driver and insert the screw until it is fully seated within the plate. Repeat for all screw holes.

Inserting screw into screw hole

STEP 5 SCREW BLOCKING

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

Insert the **Set Screw Positioner, Torque-Limiting** into the blocking screw. Rotate the positioner clockwise until the blocking screw is in the blocked position, making sure the hex is fully seated in the screw head. The blocking screw in the blocked position will partially cover the screw head, as shown below. The screws provide audible, tactile, and visual confirmation that they are secured to the plate and blocked.

Note: All blocking screws must be rotated to the blocked position in order to block the construct.

Initial position

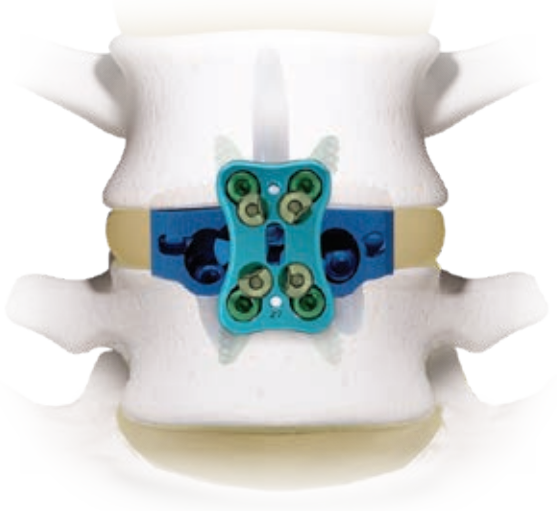
Blocked position

Initial position

Blocked position

FINAL POSITION

Anterior view of 27mm 4-Hole Sacral Plate with HEDRON IA®



Anterior view of 27mm 4-Hole Lumbar Plate with HEDRON IA®

Anterior view of 27mm 3-Hole Lumbar Plate with HEDRON IA®

Anterior view of 27mm 3-Hole Sacral Plate, Sacral Lip on 1-Hole Side with HEDRON IA®

OPTIONAL: IMPLANT REMOVAL

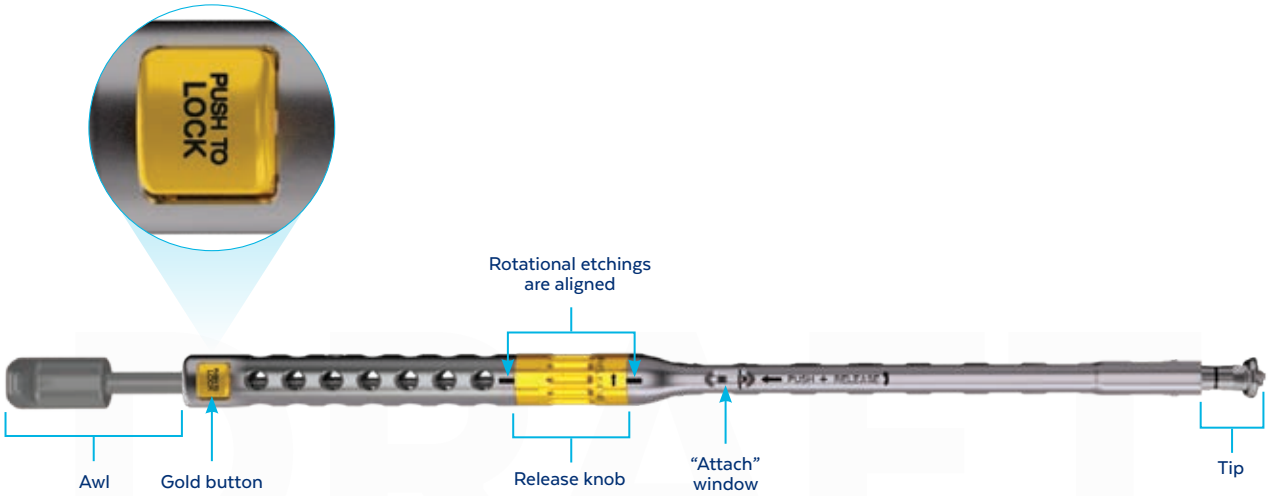
To remove the plates, unlock the blocking screws using the torque-limiting set screw positioner. Loosen and remove the bone screws using the same 3.5mm hex driver used for screw insertion. Once all screws have been removed, the plate may be removed using the Plate Holder, or forceps.

Buttress Plates

STEP 2 PLATE SELECTION AND PLACEMENT

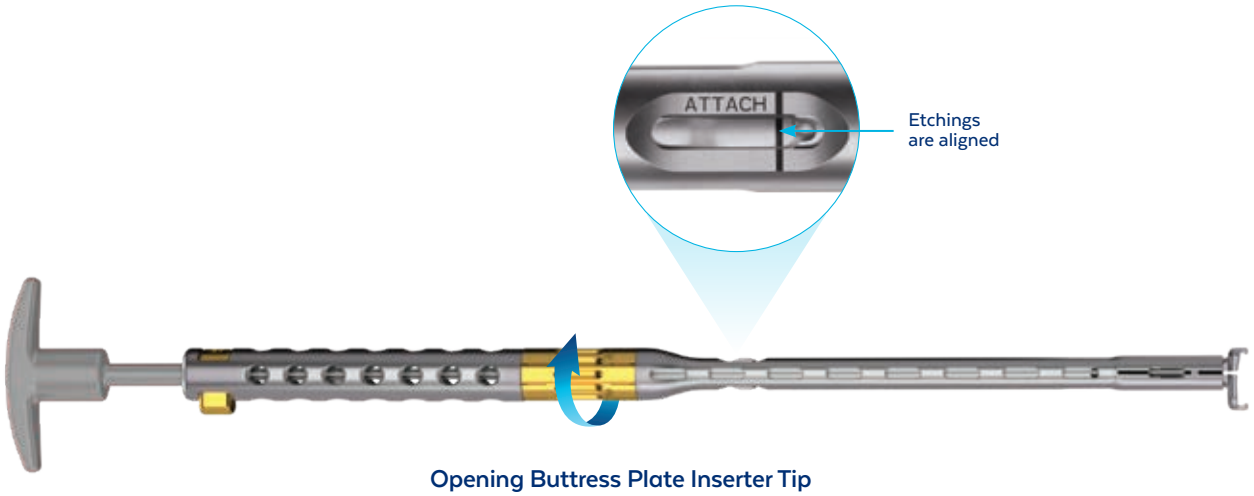
Select the appropriate plate size. The etched plate length is the distance from the top of the plate to the bottom of the plate. Plate size can be determined by patient anatomy and type of interbody spacer used.

For assembly instructions for the Buttress Plate Inserter (with Awl insertion), refer to the section titled Buttress Plate Inserter Assembly. Instructions for disassembly are listed in the section titled Buttress Plate Inserter Disassembly.



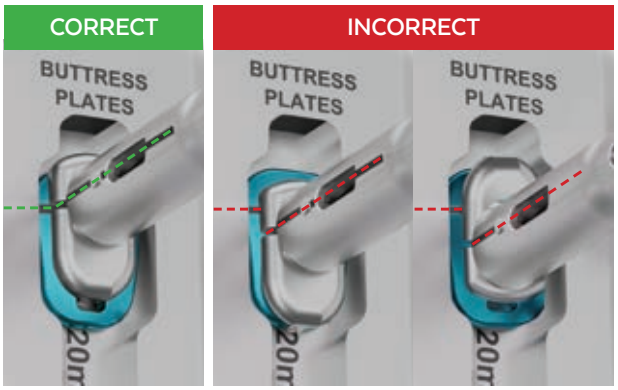
Assembled Buttress Plate Inserter

Once the **Buttress Plate** has been selected, open the Buttress Plate Inserter Tip by rotating the release knob counterclockwise until the line etching on the Buttress Plate Inserter Tip aligns with the etchings on the Buttress Plate Inserter within the "attach" window.



Opening Buttress Plate Inserter Tip

Hold the Buttress Plate Inserter (with Awl) over the selected Buttress Plate in the screw module so that the laser etched lines on the inserter and plate are aligned. Push down on the Buttress Plate Inserter to align prongs to the attachment points (divots) on the backside of the plate.



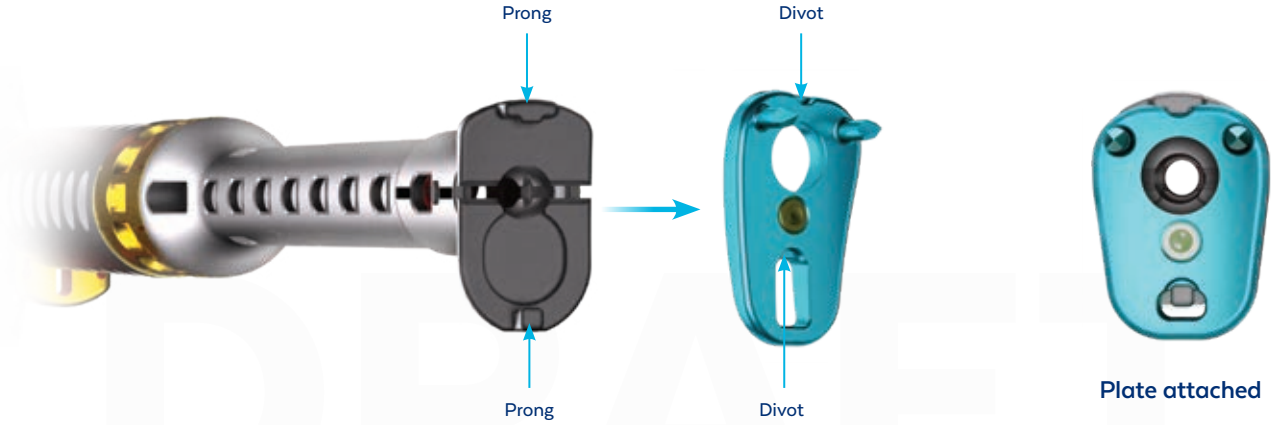
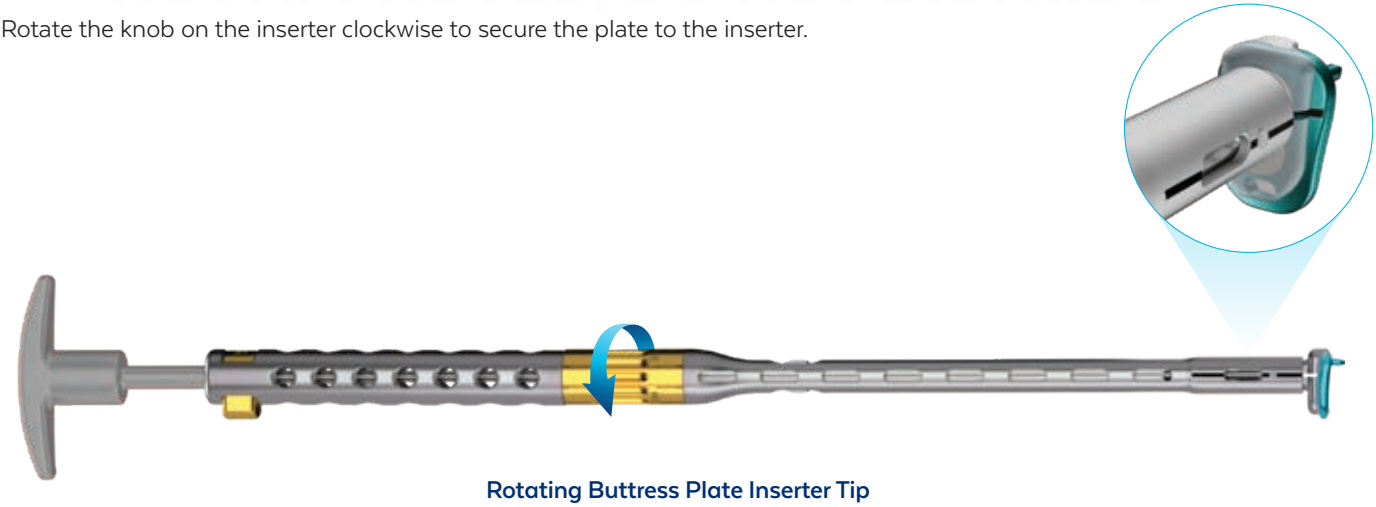


Plate attached

Rotate the knob on the inserter clockwise to secure the plate to the inserter.



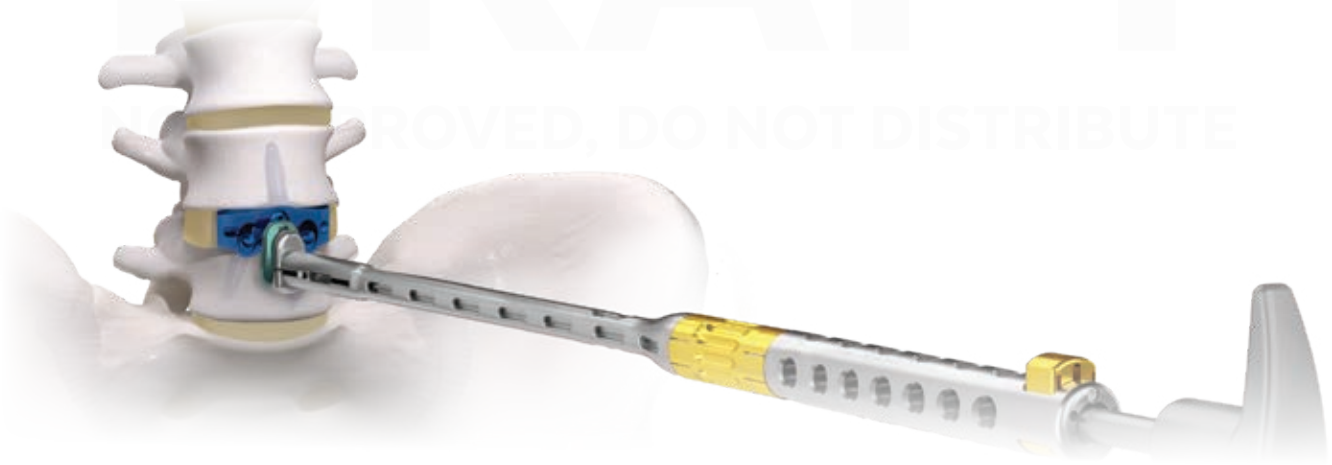
Rotating Buttress Plate Inserter Tip clockwise to secure Buttress Plate

PLATE SELECTION AND PLACEMENT (CONT'D)

Ensure that the Awl remains in the "lock" position, as described in the section titled Buttress Plate Inserter Assembly, prior to positioning on the vertebral body.

Awl in "lock" position

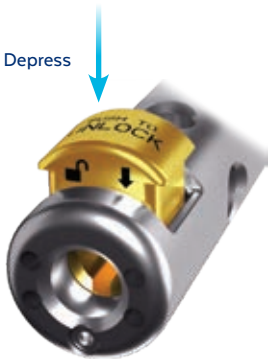
Position the Buttress Plate over the desired location on the vertebral body. Use light impaction to seat the spikes of the Buttress Plate into the vertebral body, ensuring the plate sits flush on the vertebral body. Alternatively, a forceps-style instrument may be used.



Placing and seating Buttress Plate into vertebral body using Buttress Plate Inserter

STEP 3 SCREW HOLE PREPARATION

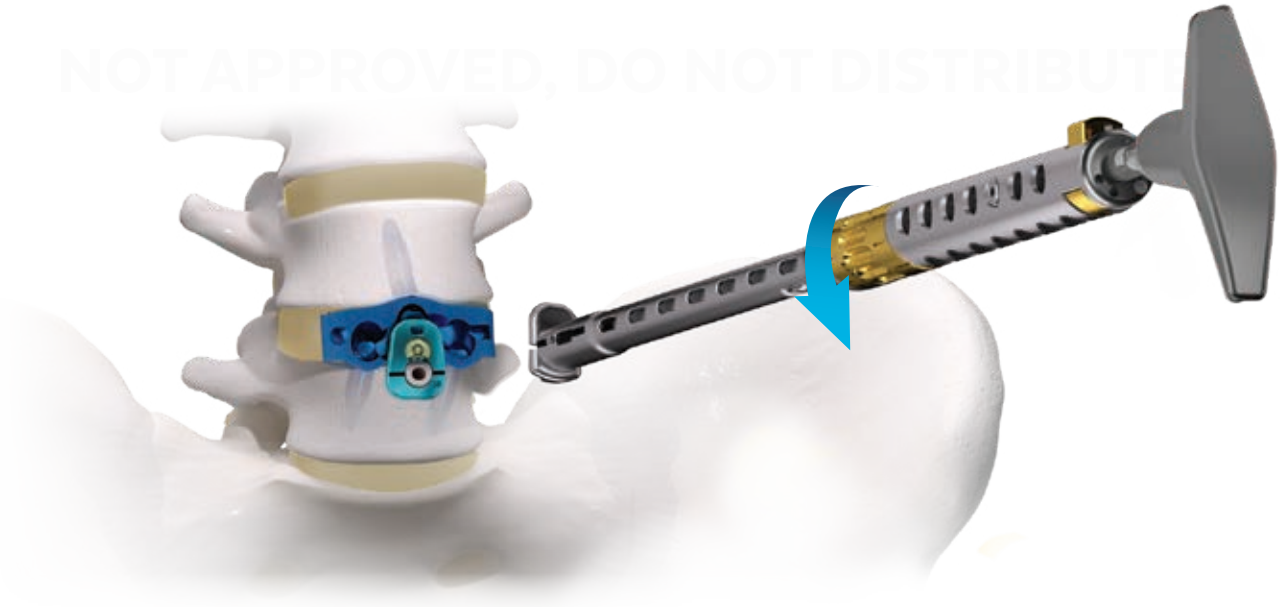
Once the plate is impacted into its desired position, depress the button on the Buttress Plate Inserter into the “unlock” position. Insert the Awl to perforate the cortex for a 0° trajectory. For an angled trajectory, the Buttress Plate Inserter is removed and the Bent Awl or Straight Awl from the VICTORY™ instrument set is used to perforate the cortex.



Unlocking Awl

Inserting Awl to perforate cortex and create screw hole

Hold the Buttress Plate Inserter in position and pull the Awl to remove it from the bone. Rotate the release knob counterclockwise until finger tight to achieve maximum width to release the Buttress Plate. The Buttress Plate Inserter can now be gently removed from the access site.



Removing Awl and Buttress Plate Inserter

For self-tapping screws, the corresponding drill may be used to further prepare the screw hole. Depending on the angle and position, a straight or angled instrument may be used. Proceed to screw insertion after all screw holes have been prepared.

STEP 4 SCREW INSERTION

Load the selected screw onto the 3.5mm Hex Straight Driver and insert the screw until it is fully seated within the plate. Depending on the angle and position, a straight or angled driver may be used.

Inserting screw into screw hole

STEP 5 SCREW BLOCKING

Once the screw is fully seated within the plate, the blocking screw can be rotated into place.

Insert the Set Screw Positioner, Torque-Limiting into the blocking screw. Rotate the positioner clockwise until the blocking screw is in the blocked position, making sure the hex is fully seated in the screw head. The blocking screw in the blocked position will partially cover the screw head, as shown below. The screws provide audible, tactile, and visual confirmation that they are secured to the plate and blocked.

Note: All blocking screws must be rotated to the blocked position in order to block the construct.

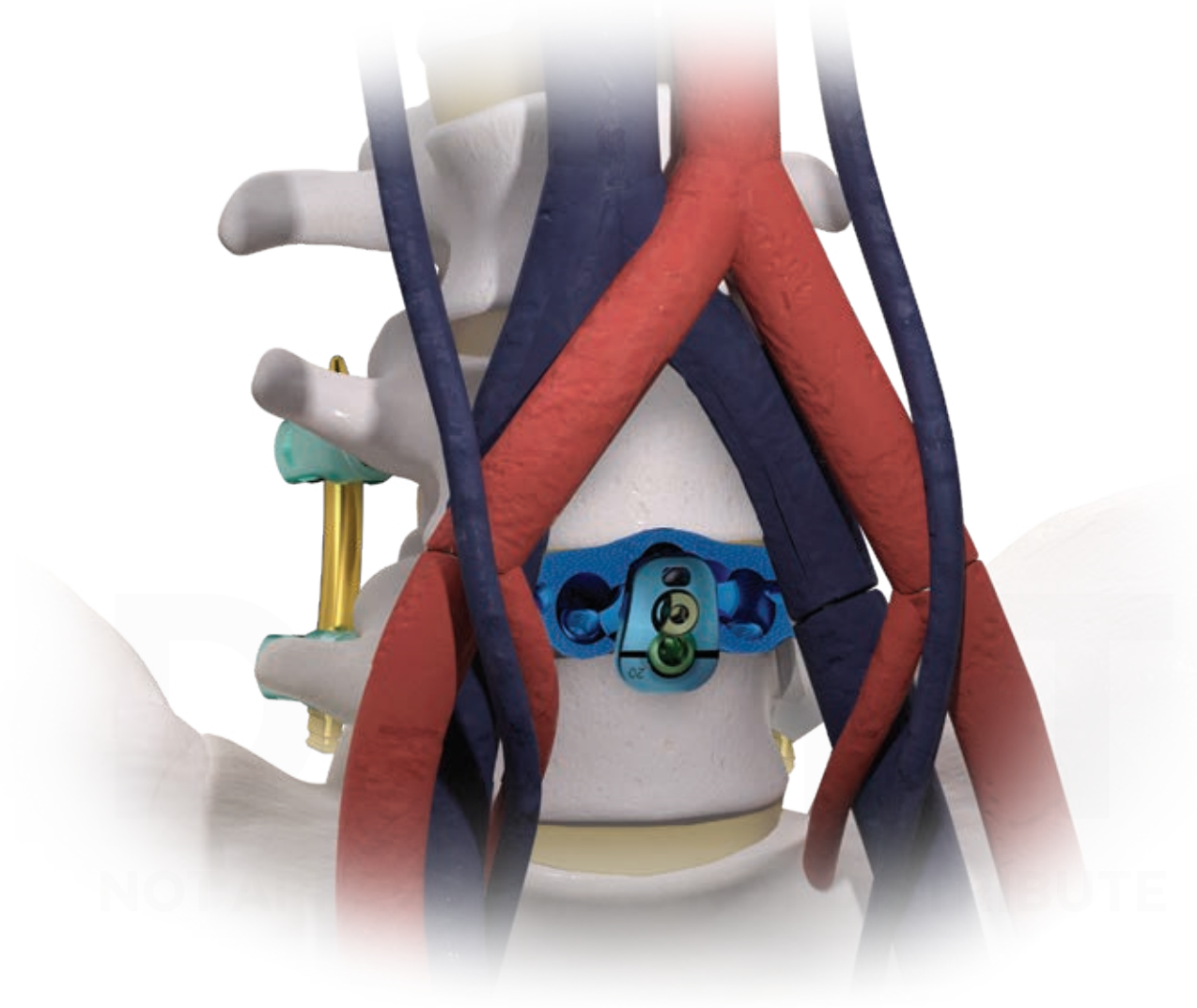
Initial position

Blocked position

Initial position

Blocked position

FINAL POSITION



Anterior view of 20mm Buttress Plate with HEDRON IA® and CREO MIS®

(Supplemental fixation is required; the device is not intended for load bearing applications.)

OPTIONAL: IMPLANT REMOVAL

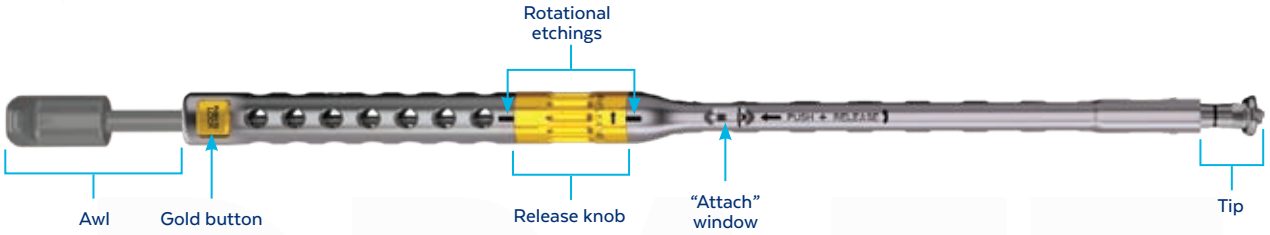
To remove the plates, unlock the blocking screw using the torque-limiting set screw positioner. Loosen and remove the bone screw using the same 3.5mm hex driver used for screw insertion. Once the screw has been removed, the plate may be removed using the Buttress Plate Inserter, or forceps.

BUTTRESS PLATE INSERTER ASSEMBLY

Buttress Plate Inserter

Buttress Plate Inserter Tip

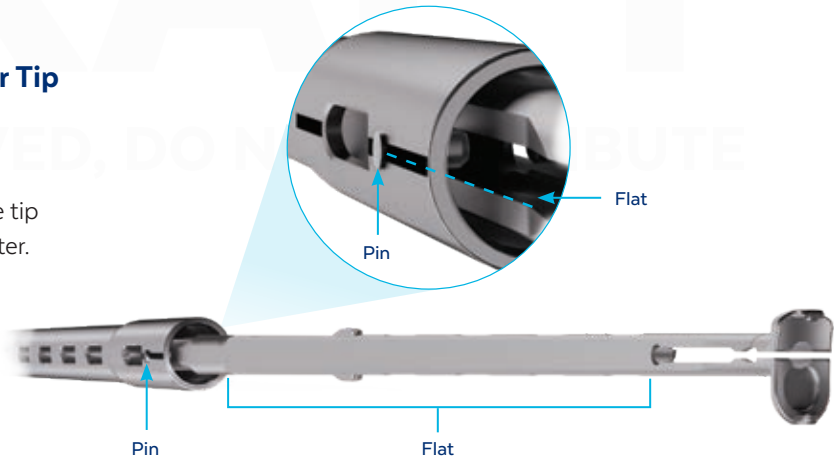
Awl



Assembled Buttress Plate Inserter

Assemble the Buttress Plate Inserter Tip and Buttress Plate Inserter

Insert the Buttress Plate Inserter Tip into the Buttress Plate Inserter, aligning the flats on the tip with the pins inside of the Buttress Plate Inserter.

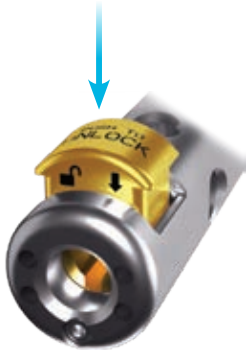


Align the rotational etchings and hold in this position. Gently push the Buttress Plate Inserter Tip while rotating the release knob clockwise to guide it into place. The two parts are assembled when the button snaps into the "attach" window, and the line etching on the Buttress Plate Inserter Tip aligns with the etchings on the Buttress Plate Inserter.

Assemble the Awl and Buttress Plate Inserter

Hold the Buttress Plate Inserter and press the gold button into the “unlock” position.

Locate the retaining set screw on the Buttress Plate Inserter and loosen it. Rotate counterclockwise with the Set Screw Positioner, Torque-Limiting.



Press button

Loosen retaining screw

Insert the Awl into the Buttress Plate Inserter until the handle of the Awl contacts the back of the inserter handle. While holding in this position, tighten the retaining set screw by rotating it clockwise with the Set Screw Positioner, Torque-Limiting until finger tight.

Press the gold button into the “lock” position to finalize the assembly.

Holding Awl fully depressed while tightening retaining screw

Pressing button to lock position

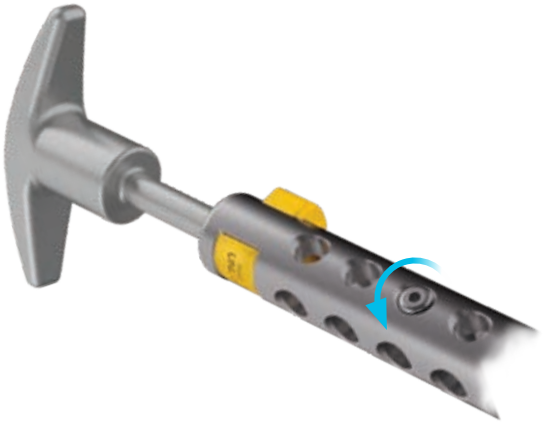
BUTTRESS PLATE INSERTER DISASSEMBLY

Remove the Awl for Buttress Inserter from the Buttress Inserter

Locate the retaining set screw on the Buttress Inserter and rotate counterclockwise with the Set Screw Positioner, Torque-Limiting.

Press the gold button into the “unlock” position.

The Awl for Buttress Plate is removed by pulling it out of the back of the Buttress Inserter.



Remove the Buttress Inserter Tip From the Buttress Inserter

After disassembly of the Buttress Inserter, rotate the release knob counterclockwise while pressing the button on the Buttress Inserter Tip.

Continue to rotate until the Buttress Inserter Tip can be pulled out of the front of the Buttress Inserter. When the Buttress Inserter Tip is disengaged and can be removed, the release knob will freely spin and the etch on the Buttress Inserter Tip will be visible.

TEMPORARY PIN DRIVER DISASSEMBLY

To unlock the assembly, rotate the collar counterclockwise.

Remove the inner shaft from the outer sleeve.

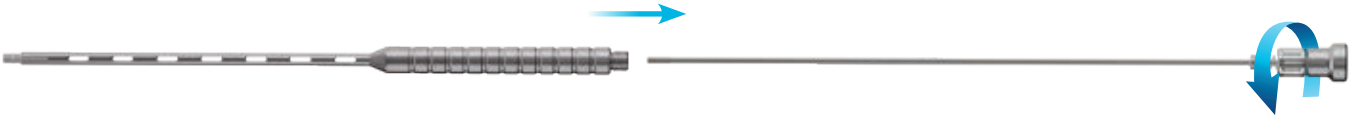


PLATE AND SPACER SPECIFICATIONS

The specifications are applicable to HEDRON IA®, HEDRON A®, INDEPENDENCE®, INDEPENDENCE MIS®, and CONTINENTAL®.

The height pairings are independent of the spacer angle.

	INDEPENDENCE MIS® Spacer, 26x34mm, 8°, 11mm VICTORY™ Lumbar Tri Plate, 18mm	HEDRON IA® Spacer, 26x34, 17mm, 15° VICTORY™ Lumbar Tri Plate, 36mm
Front View		
Oblique View		

Spacer Height	Plate Length	
11mm	18mm*	21mm
13mm	21mm	24mm
15mm	24mm	27mm
17mm	27mm	30mm
19mm	30mm	33mm
21mm	33mm	36mm*

*Additionally available

VICTORY™ BUTTRESS PLATE
IMPLANT AND INSTRUMENT SET 9236.9001

Part No.	Description	Qty
650.105	QC Handle, Small, with Cap	1
676.502	3.5mm Hex Straight Driver	1
6108.1006	Set Screw Positioner, Torque-Limiting	1
6236.2000	Buttress Plate Inserter	1
6236.2100	Awl	1
9236.0003	Screw Module	1
1236.0020	VICTORY™ Buttress Plate, 20mm	2
1236.0024	VICTORY™ Buttress Plate, 24mm	2
1236.3022	Self-Tapping Screw, Variable Angle, 6.0, 22.5mm	2
1236.3025	Self-Tapping Screw, Variable Angle, 6.0, 25mm	2
1236.3027	Self-Tapping Screw, Variable Angle, 6.0, 27.5mm	2
1236.3030	Self-Tapping Screw, Variable Angle, 6.0, 30mm	2
1236.3032	Self-Tapping Screw, Variable Angle, 6.0, 32.5mm	0
1236.3035	Self-Tapping Screw, Variable Angle, 6.0, 35mm	0
1236.3125	Self-Drilling Screw, Variable Angle, 6.0, 25mm	2
1236.3127	Self-Drilling Screw, Variable Angle, 6.0, 27.5mm	2
1236.3130	Self-Drilling Screw, Variable Angle, 6.0, 30mm	2
1236.3132	Self-Drilling Screw, Variable Angle, 6.0, 32.5mm	0
1236.3135	Self-Drilling Screw, Variable Angle, 6.0, 35mm	0
1236.4022	Self-Tapping Screw, Variable Angle, 6.5, 22.5mm	1
1236.4025	Self-Tapping Screw, Variable Angle, 6.5, 25mm	1
1236.4027	Self-Tapping Screw, Variable Angle, 6.5, 27.5mm	1
1236.4030	Self-Tapping Screw, Variable Angle, 6.5, 30mm	1
1236.4032	Self-Tapping Screw, Variable Angle, 6.5, 32.5mm	0
1236.4035	Self-Tapping Screw, Variable Angle, 6.5, 35mm	0
9236.0001	Buttress Plate Graphic Case	

Items in gray are additionally available.

VICTORY™
INSTRUMENT AND SCREW SET 9236.9004

Part No.	Description	Qty
650.105	QC Handle, Small, with Cap	2
676.502	3.5mm Hex Straight Driver	1
676.699	Counter-Torque	1
676.700	Angled Sleeve	1
676.701	Shaft	1
676.702	Nut	1
676.710	3.5mm Angled Hex Driver, Short	1
6236.0007	Bent Awl	1
6236.0008	Straight Awl	1
6236.0009	Straight Drill	1
6236.0010	Angled Drill Bit	1
6236.0011	Angled Tap Bit	1
6236.0012	Straight Tap	1
6236.0018	Temporary Pin, 18mm	2
6236.1000	Plate Holder	1
6236.5000	Temporary Pin Driver	1
6236.5018	Temporary Pin for Screw Hole, 18mm	1
6108.1006	Set Screw Positioner, Torque-Limiting	1
9236.0003	Screw Module	1
1236.3022	6.0mm Bone Screw, Self-Tapping, 22.5mm	8
1236.3025	6.0mm Bone Screw, Self-Tapping, 25mm	8
1236.3027	6.0mm Bone Screw, Self-Tapping, 27.5mm	8
1236.3030	6.0mm Bone Screw, Self-Tapping, 30mm	4
1236.3032	6.0mm Bone Screw, Self-Tapping, 32.5mm	0
1236.3035	6.0mm Bone Screw, Self-Tapping, 35mm	0
1236.3125	6.0mm Bone Screw, Self-Drilling, 25mm	8
1236.3127	6.0mm Bone Screw, Self-Drilling, 27.5mm	8
1236.3130	6.0mm Bone Screw, Self-Drilling, 30mm	4
1236.3132	6.0mm Bone Screw, Self-Drilling, 32.5mm	0
1236.3135	6.0mm Bone Screw, Self-Drilling, 35mm	0
1236.4022	6.5mm Bone Screw, Self-Drilling, 22.5mm	4
1236.4025	6.5mm Bone Screw, Self-Drilling, 25mm	4
1236.4027	6.5mm Bone Screw, Self-Drilling, 27.5mm	4
1236.4030	6.5mm Bone Screw, Self-Drilling, 30mm	4
1236.4032	6.5mm Bone Screw, Self-Drilling, 32.5mm	0
1236.4035	6.5mm Bone Screw, Self-Drilling, 35mm	0
9236.0004	VICTORY™ Graphic Case	

Items in gray are additionally available.

VICTORY™ 3-HOLE PLATE
IMPLANT SET 9236.9006

Part No.	Description	Qty
1236.5018	VICTORY™ Lumbar Tri Plate, 18mm	0
1236.5021	VICTORY™ Lumbar Tri Plate, 21mm	1
1236.5024	VICTORY™ Lumbar Tri Plate, 24mm	1
1236.5027	VICTORY™ Lumbar Tri Plate, 27mm	1
1236.5030	VICTORY™ Lumbar Tri Plate, 30mm	1
1236.5033	VICTORY™ Lumbar Tri Plate, 33mm	1
1236.5036	VICTORY™ Lumbar Tri Plate, 36mm	0
1236.6018	VICTORY™ Sacral (2-Screw Side) Tri Plate, 18mm	0
1236.6021	VICTORY™ Sacral (2-Screw Side) Tri Plate, 21mm	1
1236.6024	VICTORY™ Sacral (2-Screw Side) Tri Plate, 24mm	1
1236.6027	VICTORY™ Sacral (2-Screw Side) Tri Plate, 27mm	1
1236.6030	VICTORY™ Sacral (2-Screw Side) Tri Plate, 30mm	1
1236.6033	VICTORY™ Sacral (2-Screw Side) Tri Plate, 33mm	1
1236.6036	VICTORY™ Sacral (2-Screw Side) Tri Plate, 36mm	0
1236.7018	VICTORY™ Sacral (1-Screw Side) Tri Plate, 18mm	0
1236.7021	VICTORY™ Sacral (1-Screw Side) Tri Plate, 21mm	1
1236.7024	VICTORY™ Sacral (1-Screw Side) Tri Plate, 24mm	1
1236.7027	VICTORY™ Sacral (1-Screw Side) Tri Plate, 27mm	1
1236.7030	VICTORY™ Sacral (1-Screw Side) Tri Plate, 30mm	1
1236.7033	VICTORY™ Sacral (1-Screw Side) Tri Plate, 33mm	1
1236.7036	VICTORY™ Sacral (1-Screw Side) Tri Plate, 36mm	0
9236.9006	VICTORY™ 3-Hole Plate Module	

Items in gray are additionally available.

VICTORY™ 4-HOLE PLATE
IMPLANT SET 9236.9005

Part No.	Description	Qty
1236.1018	VICTORY™ Lumbar Plate, 18mm	0
1236.1021	VICTORY™ Lumbar Plate, 21mm	1
1236.1024	VICTORY™ Lumbar Plate, 24mm	1
1236.1027	VICTORY™ Lumbar Plate, 27mm	1
1236.1030	VICTORY™ Lumbar Plate, 30mm	1
1236.1033	VICTORY™ Lumbar Plate, 33mm	1
1236.1036	VICTORY™ Lumbar Plate, 36mm	0
1236.2018	VICTORY™ Sacral Plate, 18mm	0
1236.2021	VICTORY™ Sacral Plate, 21mm	1
1236.2024	VICTORY™ Sacral Plate, 24mm	1
1236.2027	VICTORY™ Sacral Plate, 27mm	1
1236.2030	VICTORY™ Sacral Plate, 30mm	1
1236.2033	VICTORY™ Sacral Plate, 33mm	1
1236.2036	VICTORY™ Sacral Plate, 36mm	0
9236.9005	VICTORY™ 4-Hole Plate Module	

Items in gray are additionally available.

IMPORTANT INFORMATION ON THE VICTORY™ LUMBAR PLATE SYSTEM

DESCRIPTION

The VICTORY™ Lumbar Plate System consists of one-level lumbar and sacral plates, buttress plates, and variable angle bone screws for fixation to the anterior, anterolateral or lateral portion of the vertebral bodies of the lumbar and lumbosacral spine (L1-S1). The implants are manufactured from titanium alloy, as specified in ASTM F136 or F1295.

INDICATIONS

The VICTORY™ Lumbar Plate System is indicated for use through an anterior, lateral or anterolateral surgical approach above the bifurcation of the great vessels, or through an anterior surgical approach below the bifurcation of the great vessels 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.

The VICTORY™ Buttress Plate is intended to stabilize allograft or autograft at one level (L1-S1), aiding in spinal fusion and to provide temporary stabilization and augment development of a spinal fusion. The device is not intended for load bearing applications.

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.

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Possible adverse effects that may occur include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; loss of fixation; vertebral fracture; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

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.

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

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 implant size and screw diameter and length.

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

CONTRAINDICATIONS

Use of this system is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Severe osteoporosis, which may prevent adequate fixation.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Any condition not described in the indications for use.

MRI SAFETY INFORMATION

MR

MRI Safety Information

A person implanted with the VICTORY™ Lumbar Plate System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	VICTORY™ Lumbar Plate System
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

PACKAGING

The 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 implants and instruments may be 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 (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

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

CLEANING

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

Cleaning and disinfecting 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 and instrument trays and cases after use or exposure to soil, and prior to sterilization:

IMPORTANT INFORMATION ON THE VICTORY™ LUMBAR PLATE SYSTEM

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 provided sterile or nonsterile. Instruments are provided nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile devices 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 should be discarded. Sterile implants meet pyrogen limit specifications.

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

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

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

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

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

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

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

SYMBOL TRANSLATION			
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		

DI225A Rev A

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08.24 Rev C