# ACUMEN® THORACOLUMBAR PLATE SYSTEM

ANTERIOR FIXATION

## Surgical Technique Guide

CURITEVA®

# Table of Contents

# ACUMEN®
## THORACOLUMBAR PLATE SYSTEM

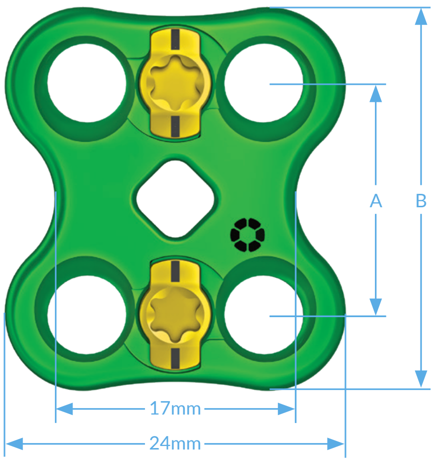


## Disclaimer

The surgical technique shown is for illustrative purposes only. Proper surgical procedure is the responsibility of the medical professional. Please reference the package insert for additional information and system instructions.

# ACUMEN® Thoracolumbar Plate System

The Acumen Thoracolumbar Plate System consists of various styles and sizes of lumbar plates and screws to adapt to the surgeon's needs. The simple and intuitive one-step locking mechanism facilitates complete control by the surgeon during the procedure. All system components are manufactured from biocompatible titanium alloy.



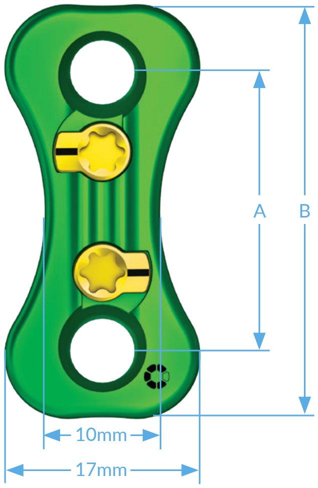

## Four-Hole Plate

**Part Number:** Part Number: C1154-04YY-ZZ
(YY – Length, ZZ – non-standard plate type)
Plate Lengths: 16 - 42mm (2mm increments)

**Offered Curvatures:**

- Standard – 90mm Radius
- Sacral – 45mm Radius

- 17mm width (24mm at screw holes)
- 3.5mm thick
- Center Graft Window for visualization
- Single Cam Lock per level
- Simple and effective, one-step locking mechanism
- Pre-Lordosed design reduces need for contouring

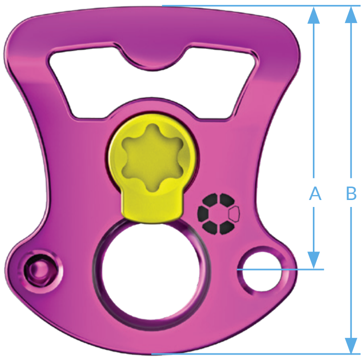



## Two-Hole Plate

**Part Number:** Part Number: C1154-02YY-ZZ
(YY – Length, ZZ – Non-standard plate type)
Plate Lengths: 16 - 42mm (2mm increments)
**Offered Curvatures:**

- Flat – 300mm Radius
- Standard – 90mm Radius
- Sacral – 45mm Radius

- 10mm width (17mm at screw holes)
- 4.0mm thick
- 4.5mm thick extra support ridges
- Single Cam Lock per level for sizes 20 - 42mm
- Simple and effective, one-step locking mechanism
- Pre-Lordosed design reduces need for contouring
- 4 Posterior Spikes for quick interface with vertebral body



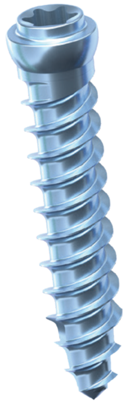

## Buttress Plate

**Part Number:** Part Number:  C1154-01YY
(YY – Length)
Plate Lengths: 20, 24,  and 28mm

- 12mm width (17mm max at graft window and screw holes)
- 3.25mm thick
- Single Cam Lock for simple, effective one-step locking mechanism
- Pre-lordosed design reduces need for contouring
- 2 Posterior spikes for quick interface with vertebral body

## Acumen® Screws

- Ø5.0 and Ø5.5mm in 20 - 35mm lengths (5mm increments)
- Self-Drilling, Self-Tapping, Fixed and Variable Screws
- Increased screw angulation enhance bone purchase
- 5° medial biased at all screw holes
- 10° cephalad/caudal biased at end screw holes (from perpendicular)
- 20° conical screw angulation
- Color-coded screws allow for easy identification



# ACUMEN® Thoracolumbar Plate System


| Four Hole Thoracolumbar Plate, Standard | | | |
|---|---|---|---|
| Catalog # | Description | A | B |
| C1154-0416 | Four Hole, 16mm | 16 | 28 |
| C1154-0418 | Four Hole, 18mm | 18 | 30 |
| C1154-0420 | Four Hole, 20mm | 20 | 32 |
| C1154-0422 | Four Hole, 22mm | 22 | 34 |
| C1154-0424 | Four Hole, 24mm | 24 | 36 |
| C1154-0426 | Four Hole, 26mm | 26 | 38 |
| C1154-0428 | Four Hole, 28mm | 28 | 40 |
| C1154-0430 | Four Hole, 30mm | 30 | 42 |
| C1154-0432 | Four Hole, 32mm | 32 | 44 |
| C1154-0434 | Four Hole, 34mm | 34 | 46 |
| C1154-0436 | Four Hole, 36mm | 36 | 48 |
| C1154-0438 | Four Hole, 38mm | 38 | 50 |
| C1154-0440 | Four Hole, 40mm | 40 | 52 |
| C1154-0442 | Four Hole, 42mm | 42 | 54 |


| Four Hole Thoracolumbar Plate, Sacral | | | |
|---|---|---|---|
| Catalog # | Description | A | B |
| C1154-0416-S | Four Hole, Sacral, 16mm | 16 | 28 |
| C1154-0418-S | Four Hole, Sacral, 18mm | 18 | 30 |
| C1154-0420-S | Four Hole, Sacral, 20mm | 20 | 32 |
| C1154-0422-S | Four Hole, Sacral, 22mm | 22 | 34 |
| C1154-0424-S | Four Hole, Sacral, 24mm | 24 | 36 |
| C1154-0426-S | Four Hole, Sacral, 26mm | 26 | 38 |
| C1154-0428-S | Four Hole, Sacral, 28mm | 28 | 40 |
| C1154-0430-S | Four Hole, Sacral, 30mm | 30 | 42 |
| C1154-0432-S | Four Hole, Sacral, 32mm | 32 | 44 |
| C1154-0434-S | Four Hole, Sacral, 34mm | 34 | 46 |
| C1154-0436-S | Four Hole, Sacral, 36mm | 36 | 48 |
| C1154-0438-S | Four Hole, Sacral, 38mm | 38 | 50 |
| C1154-0440-S | Four Hole, Sacral, 40mm | 40 | 52 |
| C1154-0442-S | Four Hole, Sacral, 42mm | 42 | 54 |

| Two Hole Thoracolumbar Plate, Standard | | | |
|---|---|---|---|
| Catalog # | Description | A | B |
| C1154-0216 | Two Hole, 16mm | 16 | 28 |
| C1154-0218 | Two Hole, 18mm | 18 | 30 |
| C1154-0220 | Two Hole, 20mm | 20 | 32 |
| C1154-0222 | Two Hole, 22mm | 22 | 34 |
| C1154-0224 | Two Hole, 24mm | 24 | 36 |
| C1154-0226 | Two Hole, 26mm | 26 | 38 |
| C1154-0228 | Two Hole, 28mm | 28 | 40 |
| C1154-0230 | Two Hole, 30mm | 30 | 42 |
| C1154-0232 | Two Hole, 32mm | 32 | 44 |
| C1154-0234 | Two Hole, 34mm | 34 | 46 |
| C1154-0236 | Two Hole, 36mm | 36 | 48 |
| C1154-0238 | Two Hole, 38mm | 38 | 50 |
| C1154-0240 | Two Hole, 40mm | 40 | 52 |
| C1154-0242 | Two Hole, 42mm | 42 | 54 |

| Two Hole Thoracolumbar Plate, Sacral | | | |
|---|---|---|---|
| Catalog # | Description | A | B |
| C1154-0216-S | Two Hole, Sacral, 16mm | 16 | 28 |
| C1154-0218-S | Two Hole, Sacral, 18mm | 18 | 30 |
| C1154-0220-S | Two Hole, Sacral, 20mm | 20 | 32 |
| C1154-0222-S | Two Hole, Sacral, 22mm | 22 | 34 |
| C1154-0224-S | Two Hole, Sacral, 24mm | 24 | 36 |
| C1154-0226-S | Two Hole, Sacral, 26mm | 26 | 38 |
| C1154-0228-S | Two Hole, Sacral, 28mm | 28 | 40 |
| C1154-0230-S | Two Hole, Sacral, 30mm | 30 | 42 |
| C1154-0232-S | Two Hole, Sacral, 32mm | 32 | 44 |
| C1154-0234-S | Two Hole, Sacral, 34mm | 34 | 46 |
| C1154-0236-S | Two Hole, Sacral, 36mm | 36 | 48 |
| C1154-0238-S | Two Hole, Sacral, 38mm | 38 | 50 |
| C1154-0240-S | Two Hole, Sacral, 40mm | 40 | 52 |
| C1154-0242-S | Two Hole, Sacral, 42mm | 42 | 54 |

| Two Hole Thoracolumbar Plate, Sacral, with Ridge | | | |
|---|---|---|---|
| Catalog # | Description | A | B |
| C1154-0216-SR | Two Hole, Sacral, with Ridge, 16mm | 16 | 28 |
| C1154-0218-SR | Two Hole, Sacral, with Ridge, 18mm | 18 | 30 |
| C1154-0220-SR | Two Hole, Sacral, with Ridge, 20mm | 20 | 32 |
| C1154-0222-SR | Two Hole, Sacral, with Ridge, 22mm | 22 | 34 |
| C1154-0224-SR | Two Hole, Sacral, with Ridge, 24mm | 24 | 36 |
| C1154-0226-SR | Two Hole, Sacral, with Ridge, 26mm | 26 | 38 |
| C1154-0228-SR | Two Hole, Sacral, with Ridge, 28mm | 28 | 40 |
| C1154-0230-SR | Two Hole, Sacral, with Ridge, 30mm | 30 | 42 |
| C1154-0232-SR | Two Hole, Sacral, with Ridge, 32mm | 32 | 44 |
| C1154-0234-SR | Two Hole, Sacral, with Ridge, 34mm | 34 | 46 |
| C1154-0236-SR | Two Hole, Sacral, with Ridge, 36mm | 36 | 48 |
| C1154-0238-SR | Two Hole, Sacral, with Ridge, 38mm | 38 | 50 |
| C1154-0240-SR | Two Hole, Sacral, with Ridge, 40mm | 40 | 52 |
| C1154-0242-SR | Two Hole, Sacral, with Ridge, 42mm | 42 | 54 |

| Two Hole Thoracolumbar Plate, Berm Sacral | | | |
|---|---|---|---|
| Catalog # | Description | A | B |
| C1154-0216-BR | Two Hole, Berm Sacral, 16mm | 16 | 28 |
| C1154-0218-BR | Two Hole, Berm Sacral, 18mm | 18 | 30 |
| C1154-0220-BR | Two Hole, Berm Sacral, 20mm | 20 | 32 |
| C1154-0222-BR | Two Hole, Berm Sacral, 22mm | 22 | 34 |
| C1154-0224-BR | Two Hole, Berm Sacral, 24mm | 24 | 36 |
| C1154-0226-BR | Two Hole, Berm Sacral, 26mm | 26 | 38 |
| C1154-0228-BR | Two Hole, Berm Sacral, 28mm | 28 | 40 |
| C1154-0230-BR | Two Hole, Berm Sacral, 30mm | 30 | 42 |
| C1154-0232-BR | Two Hole, Berm Sacral, 32mm | 32 | 44 |
| C1154-0234-BR | Two Hole, Berm Sacral, 34mm | 34 | 46 |
| C1154-0236-BR | Two Hole, Berm Sacral, 36mm | 36 | 48 |
| C1154-0238-BR | Two Hole, Berm Sacral, 38mm | 38 | 50 |
| C1154-0240-BR | Two Hole, Berm Sacral, 40mm | 40 | 52 |
| C1154-0242-BR | Two Hole, Berm Sacral, 42mm | 42 | 54 |

| Two Hole Thoracolumbar Plate, Flat | | | |
|---|---|---|---|
| Catalog # | Description | A | B |
| C1154-0216-F | Two Hole, Flat, 16mm | 16 | 28 |
| C1154-0218-F | Two Hole, Flat, 18mm | 18 | 30 |
| C1154-0220-F | Two Hole, Flat, 20mm | 20 | 32 |
| C1154-0222-F | Two Hole, Flat, 22mm | 22 | 34 |
| C1154-0224-F | Two Hole, Flat, 24mm | 24 | 36 |
| C1154-0226-F | Two Hole, Flat, 26mm | 26 | 38 |
| C1154-0228-F | Two Hole, Flat, 28mm | 28 | 40 |
| C1154-0230-F | Two Hole, Flat, 30mm | 30 | 42 |
| C1154-0232-F | Two Hole, Flat, 32mm | 32 | 44 |
| C1154-0234-F | Two Hole, Flat, 34mm | 34 | 46 |
| C1154-0236-F | Two Hole, Flat, 36mm | 36 | 48 |
| C1154-0238-F | Two Hole, Flat, 38mm | 38 | 50 |
| C1154-0240-F | Two Hole, Flat, 40mm | 40 | 52 |
| C1154-0242-F | Two Hole, Flat, 42mm | 42 | 54 |

| Buttress Plate | | | |
|---|---|---|---|
| Catalog # | Description | A | B |
| C1154-0120 | Buttress Plate, 20mm | 20 | 15 |
| C1154-0124 | Buttress Plate, 24mm | 24 | 19 |
| C1154-0128 | Buttress Plate, 28mm | 28 | 23 |

# Implant Guide

## 5.0mm Diameter

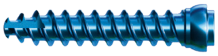
## 5.5mm Diameter

### Fixed

| 5.0mm Self-Drilling Fixed Screws | |
|---|---|
| Catalog # | Description |
| C1154-5020-FSD | 5.0 x 20mm |
| C1154-5025-FSD | 5.0 x 25mm |
| C1154-5030-FSD | 5.0 x 30mm |
| C1154-5035-FSD | 5.0 x 35mm |
| C1154-5040-FSD | 5.0 x 40mm |
| C1154-5045-FSD | 5.0 x 45mm |
| C1154-5050-FSD | 5.0 x 50mm |
| C1154-5055-FSD | 5.0 x 55mm |
| C1154-5060-FSD | 5.0 x 60mm |

| 5.5mm Self-Drilling Fixed Screws | |
|---|---|
| Catalog # | Description |
| C1154-5520-FSD | 5.5 x 20mm |
| C1154-5525-FSD | 5.5 x 25mm |
| C1154-5530-FSD | 5.5 x 30mm |
| C1154-5535-FSD | 5.5 x 35mm |
| C1154-5540-FSD | 5.5 x 40mm |
| C1154-5545-FSD | 5.5 x 45mm |
| C1154-5550-FSD | 5.5 x 50mm |
| C1154-5555-FSD | 5.5 x 55mm |
| C1154-5560-FSD | 5.5 x 60mm |

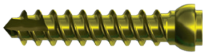
| 5.0mm Self-Tapping Fixed Screws | |
|---|---|
| Catalog # | Description |
| C1154-5020-FST | 5.0 x 20mm |
| C1154-5025-FST | 5.0 x 25mm |
| C1154-5030-FST | 5.0 x 30mm |
| C1154-5035-FST | 5.0 x 35mm |
| C1154-5040-FST | 5.0 x 40mm |
| C1154-5045-FST | 5.0 x 45mm |
| C1154-5050-FST | 5.0 x 50mm |
| C1154-5055-FST | 5.0 x 55mm |
| C1154-5060-FST | 5.0 x 60mm |



| 5.5mm Self-Tapping Fixed Screws | |
|---|---|
| Catalog # | Description |
| C1154-5520-FST | 5.5 x 20mm |
| C1154-5525-FST | 5.5 x 25mm |
| C1154-5530-FST | 5.5 x 30mm |
| C1154-5535-FST | 5.5 x 35mm |
| C1154-5540-FST | 5.5 x 40mm |
| C1154-5545-FST | 5.5 x 45mm |
| C1154-5550-FST | 5.5 x 50mm |
| C1154-5555-FST | 5.5 x 55mm |
| C1154-5560-FST | 5.5 x 60mm |

### Variable

| 5.0mm Self-Drilling Variable Screws | |
|---|---|
| Catalog # | Description |
| C1154-5020-VSD | 5.0 x 20mm |
| C1154-5025-VSD | 5.0 x 25mm |
| C1154-5030-VSD | 5.0 x 30mm |
| C1154-5035-VSD | 5.0 x 35mm |
| C1154-5040-VSD | 5.0 x 40mm |
| C1154-5045-VSD | 5.0 x 45mm |
| C1154-5050-VSD | 5.0 x 50mm |
| C1154-5055-VSD | 5.0 x 55mm |
| C1154-5060-VSD | 5.0 x 60mm |



| 5.5mm Self-Drilling Variable Screws | |
|---|---|
| Catalog # | Description |
| C1154-5520-VSD | 5.5 x 20mm |
| C1154-5525-VSD | 5.5 x 25mm |
| C1154-5530-VSD | 5.5 x 30mm |
| C1154-5535-VSD | 5.5 x 35mm |
| C1154-5540-VSD | 5.5 x 40mm |
| C1154-5545-VSD | 5.5 x 45mm |
| C1154-5550-VSD | 5.5 x 50mm |
| C1154-5555-VSD | 5.5 x 55mm |
| C1154-5560-VSD | 5.5 x 60mm |

| 5.0mm Self-Tapping Variable Screws | |
|---|---|
| Catalog # | Description |
| C1154-5020-VST | 5.0 x 20mm |
| C1154-5025-VST | 5.0 x 25mm |
| C1154-5030-VST | 5.0 x 30mm |
| C1154-5035-VST | 5.0 x 35mm |
| C1154-5040-VST | 5.0 x 40mm |
| C1154-5045-VST | 5.0 x 45mm |
| C1154-5050-VST | 5.0 x 50mm |
| C1154-5055-VST | 5.0 x 55mm |
| C1154-5060-VST | 5.0 x 60mm |

| 5.5mm Self-Tapping Variable Screws | |
|---|---|
| Catalog # | Description |
| C1154-5520-VST | 5.5 x 20mm |
| C1154-5525-VST | 5.5 x 25mm |
| C1154-5530-VST | 5.5 x 30mm |
| C1154-5535-VST | 5.5 x 35mm |
| C1154-5540-VST | 5.5 x 40mm |
| C1154-5545-VST | 5.5 x 45mm |
| C1154-5550-VST | 5.5 x 50mm |
| C1154-5555-VST | 5.5 x 55mm |
| C1154-5560-VST | 5.5 x 60mm |

| | |
|---|---|
| C1155-700 | Self-Retaining Lumbar Screw Driver |

| | |
|---|---|
| C1155-600 | 4.5mm Tap |


| | |
|---|---|
| C1155-510 | 3.0 x 15mm Self-Centering Drill |


| | |
|---|---|
| C1155-410 | 3.0 x 15mm Self-Centering Awl |

| | |
|---|---|
| C1155-400-15 | 3.0 x 15mm Awl |

| | |
|---|---|
| C1155-500-20 | 3.0mm x 20mm Drill |
| C1155-500-25 | 3.0mm x 25mm Drill |
| C1155-500-30 | 3.0mm x 30mm Drill |
| C1155-500-35 | 3.0mm x 35mm Drill |
| C1155-500-40 | 3.0mm x 40mm Drill |


| | |
|---|---|
| C1155-100 | Vise Plate Inserter, Two-Hole |


| | |
|---|---|
| C1155-101 | Vise Plate Inserter, Four-Hole |

| | |
|---|---|
| C1155-800 | Variable Angle Drill Guide |

| | |
|---|---|
| C1155-810 | Fixed Angle Drill Guide |

| | |
|---|---|
| C1155-150 | Buttress Plate Inserter |

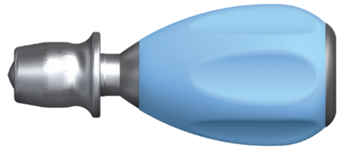
C1155-1000 Ratcheting Axial Handle

C1155-1005 Ratcheting Axial Handle, Push Lock

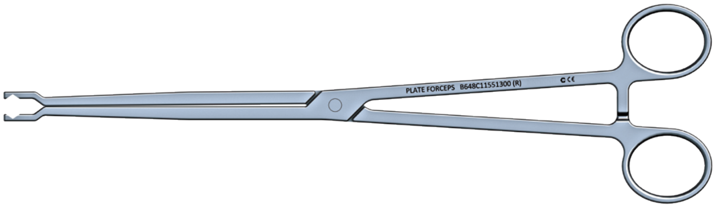
C1155-1010 Fixed Axial Handle

C1155-120 Plate Holder

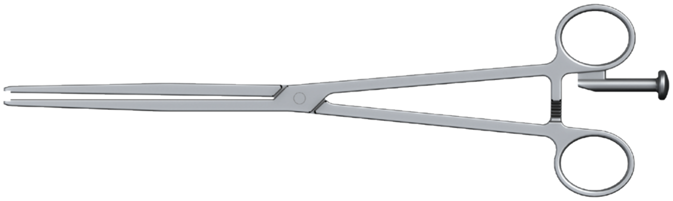
C1155-1015 Fixed Axial Handle, Push Lock



C1155-1020 Fixed Palm Handle, ¼ SQ, Impact Cap



C1155-130 Plate Forceps



C1155-300 Temporary Fixation Pin Inserter

C1155-311 3.0 x 15mm Temporary Fixation Screw

C1155-321 3.0 x 15mm Temporary Fixation Pin

# ACUMEN® Thoracolumbar Plate

## Surgical Technique

# ACUMEN® Two-Hole and Four Hole
# Surgical Technique

## Step 1: Surgical Approach

Standard anterior exposure techniques should be utilized to expose the spinal segment(s) to be fused. A properly-sized plate should span the distance between the caudal and cephalad vertebrae. The surgeon should obtain an anterior exposure to the spine according to preference of incision, approach angle and side (left or right). Care should be taken to protect the vasculature structures. **(Figure 1)**

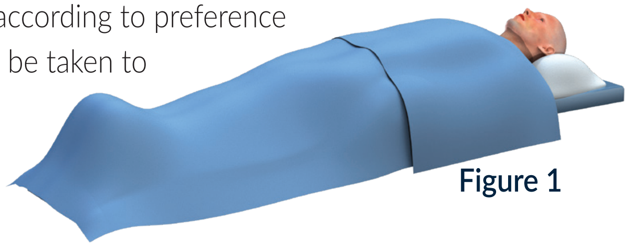


Figure 1

## Step 2: Exposure of Spine

A multitude of retractors exist to provide adequate exposure during dissection, performing disc preparation and implanting the prosthesis. Depending on dissection preference, the surgeon should expose the midline of the intervertebral disc above and below the diseased level. Fluoroscopy should be used to verify position. Distractors, whether a spreader or distraction pins can be used to help with gentle distraction of the disc space.

## Step 3: Plate Insertion

Determine the appropriate size plate. Securely grab the plate with the appropriate Vise Plate Inserter (C1155-100 / C1155-101) or Plate Holder (C1155-120) using the outer edges of the plate. Insert the plate into the correct position and at the correct location of the vertebral bodies. Optionally, one can temporarily hold the plate in place by grabbing the Temporary Fixation Pin with the Temporary Pin Inserter and tapping gently into the preferred bone screw hole. **(Figure 3)**

Temporary Fixation Screws (C1155-311) or Temporary Fixation Pins (C1155-321) may be placed in any of the screw holes to provide short-term stability during screw placement. The Temporary Fixation Screws can be inserted and extracted with the Self-Retaining Lumbar Screw Driver (C1155-700). The Temporary Fixation Pins can be inserted with the Temporary Fixation Pin Inserter and tapping gently into the preferred screw hole. Ensure that the Temporary Fixation Screws and Temporary Fixation Pins are removed before completing the procedure.

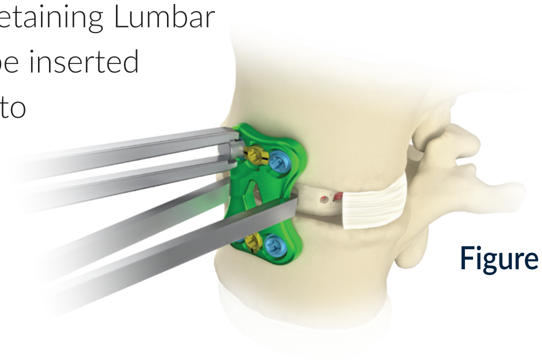


Figure 3

**Note:** Temporary Fixation Screws seat 15mm into the bone.

# Step 4: Holes Preparation

### Option 1: Fixed Angle Drill Guide

The Fixed Angle Drill Guide (C1155-810) provides a fixed angle of introduction for Awl, Drills, and Tap. This single barrel instrument should be fully seated in the screw socket with the small pilot diameter on the distal tip of the Drill Guide engaging the screw hole to ensure proper angulation. **(Figure 4a)**

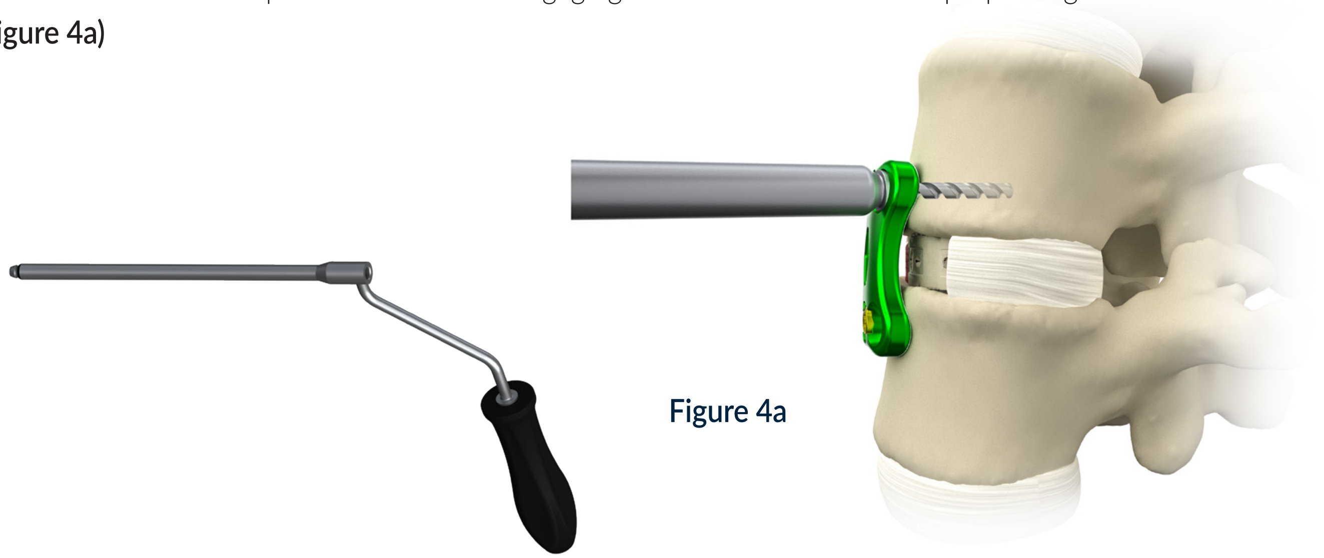


Figure 4a

### Option 2: Variable Angle Drill Guide

The Variable Angle Drill Guide (C1155-800) allows for freehand angle selection within the conical limitations of the screw pockets (20° conical) for Awl, Drills, and Tap. This single barrel instrument should be fully seated in the screw socket to ensure proper angulation. **(Figure 4b)**

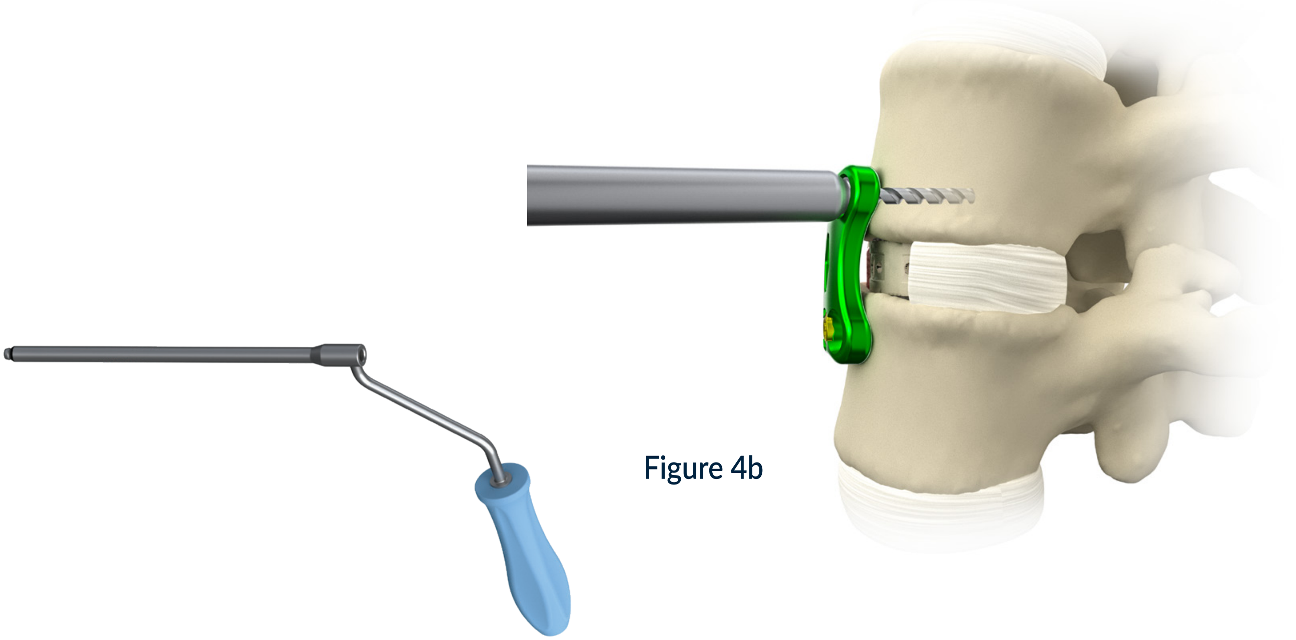


Figure 4b

A 3.0mm diameter pilot hole can be created using Awl or Drills. The Awl generates a 15mm deep pilot hole and the Drills generate 20-40mm pilot holes. The Awl and Drills should be advanced until they stop on the Drill Guide to achieve the specified depth.

A 4.5mm Tap (C1155-600) is also provided and can be used with each of the guide options. The shaft of the tap is depth marked to the top of the Drill Guides.

### Option 3: Variable Angle, Self-Centering Awl and Drill

The Self-Centering Awl (C1155-410) has a variable tip geometry that allows for freehand angle selection within the conical limitations of the screw pockets (20° conical). The Self-Centering Drill (C1155-510) may be used in a similar fashion. Fully seat the instrument in the screw socket and advance the handle forward until fully seated with the laser marked depth line (15mm). The handle may be advanced by pushing or with the aid of a mallet. **(Figure 4c)**

**CAUTION:** Over-angulation of the drilled hole beyond the prescribed insertion angles may result in failure of the screw to engage the plate and/or locking mechanism.

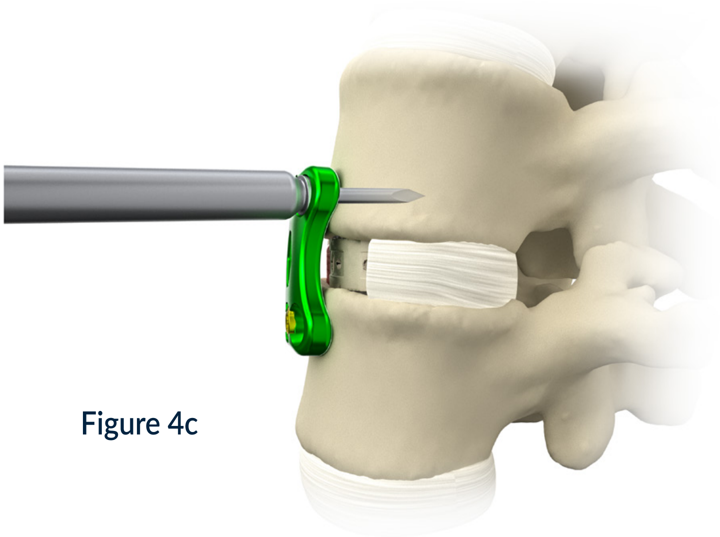


Figure 4c

## Step 5: Screw Insertion

The lumbar screws are offered in various diameters, lengths, and styles. Please refer to the Implant Guide for more details.

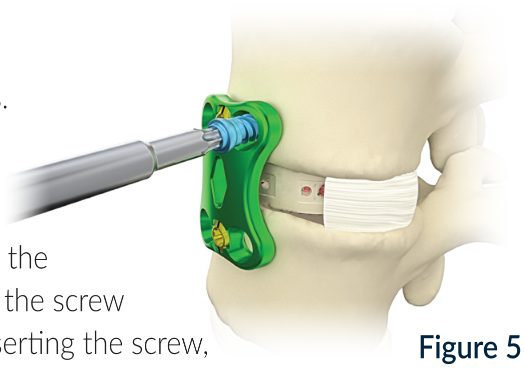


Figure 5

Once the desired screws have been selected, the Self-Retaining Lumbar Screw Driver (C1155-700) is used to properly insert them into the vertebral body. The Screw Driver has a self-retaining spring tip to hold the screw during insertion. Load the screw onto the Screw Driver and prior to inserting the screw, confirm that the Screw Driver is fully engaged with the hexalobular screw socket. Screws should be advanced until they are firmly seated inside the screw socket in the plate. Screws must be fully seated to allow the cam locks to be properly engaged.

**CAUTION:** Over-torquing the screws during insertion may result in plate damage, stripping of bone, or compromise of the screw/plate interface.

**CAUTION:** Following plate and screw placement, confirm appropriate construct positioning fluoroscopically prior to final screw locking.

**CAUTION:** Failure to fully seat the screw in the screw socket may inhibit the cam lock from functioning properly by not rotating to the locked position, or by causing damage to the cam lock due to direct interference with the screw. **(Figure 5)**

## Step 6: Securement of Screws

Each screw is locked by rotating the adjacent cam lock clockwise one-quarter turn using the same Screw Driver that is used to insert the screws. It is not recommended to rotate the cam lock more than two times. **(Figure 6)**

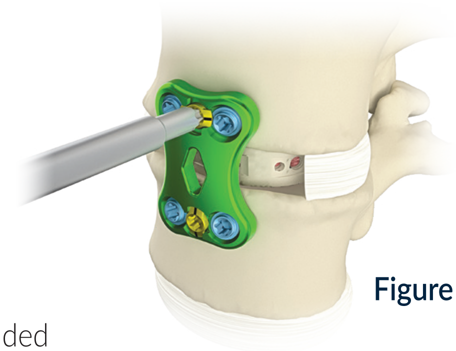


Figure 6

**Note:** The laser marked line on the cam blocker will intersect with the intended screw hole in the locked position. The laser marked lines on teh cam blocker will be horizontal for Four-Hole Plates and vertical for Two-Hole Plates when secured.

## Step 7: Implant Removal (optional)

Use the Screw Driver to unlock each cam lock by rotating counterclockwise one-quarter turn to uncover the screw socket. After cam locks have been rotated, each screw can be removed using the Screw Driver. **(Figure 7)**

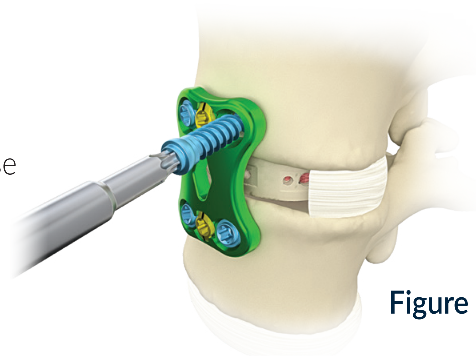


Figure 7

# ACUMEN® Buttress Plate
# Surgical Technique

## Step 1: Plate Insertion

Determine the appropriate size plate. Attach the selected Buttress Plate to the Buttress Plate Inserter (C1155-150) by aligning the pin in the hole. Twist the thumb wheel clockwise to thread the post on the Plate Inserter into the threaded hole in the plate. Position the plate so that the fixation spikes and bone screw hole are located over the vertebral body. Temporarily attach the plate to the vertebral body by impacting the fixation spikes into the bone. **(Figure 1)**

**Note:** Fixation spikes only requires light tapping with a mallet on the top of the Buttress Plate Inserter.

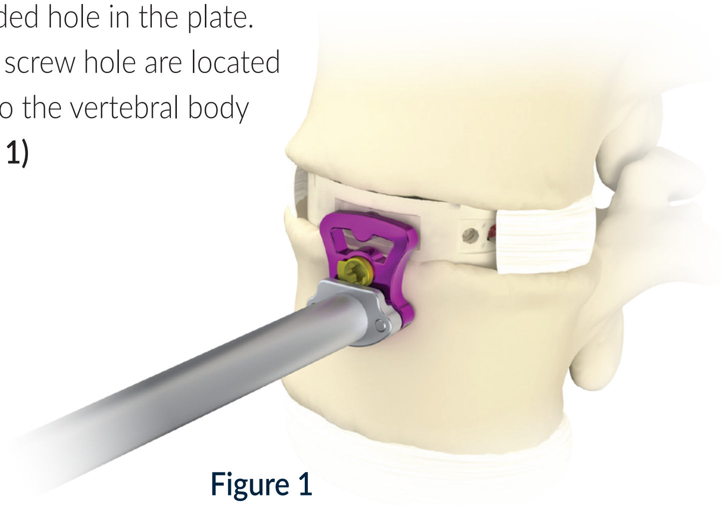


Figure 1

## Step 2: Holes Preparation

Attach the Fixed Axial Handle (C1155-1010) to the 3.0 x 15mm Awl (C1155-400-15) and insert the awl through the cannulated shaft of the Buttress Plate Inserter. To create the pilot hole for the bone screw, advance the awl down the shaft of the inserter until the stop on the awl meets the proximal end of the plate inserter. Once the pilot hole has been created, remove the awl from the inserter. (**Figure 2)**

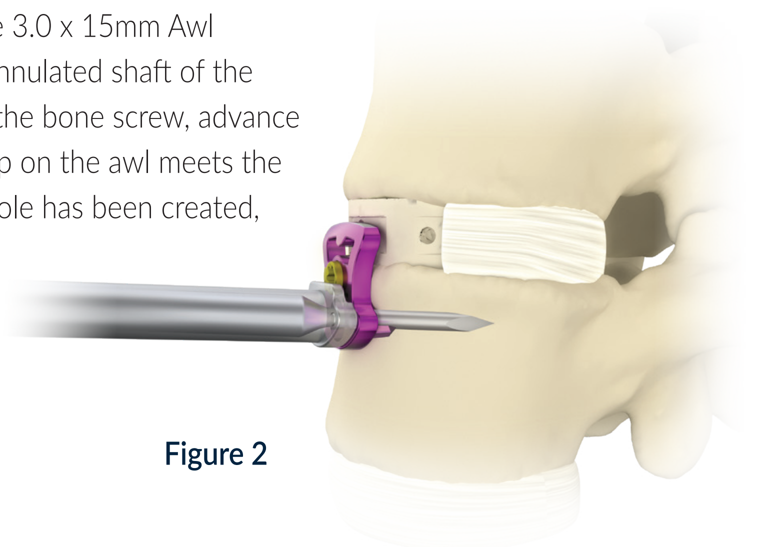


Figure 2

## Step 3: Screw Insertion

Once the desired screw has been selected, the Self-Retaining Lumbar Screw Driver (C1155-700) is used to properly insert them into the vertebral body. The Screw Driver has a self-retaining spring tip to hold the screw during insertion. Load the screw onto the Screw Driver and prior to inserting the screw, confirm that the Screw Driver is fully engaged with the hexalobular screw socket. Screw and Screw Driver should be advanced through the cannulated shaft of the Buttress Plate Inserter. The screw should be advanced until it is firmly seated inside the screw socket in the plate. The screw must be fully seated to allow the cam lock to be properly engaged. **(Figure 3)**

**CAUTION:** Over-torquing the screws during insertion may result in plate damage, stripping of bone, or compromise of the screw/plate interface.

**CAUTION:** Failure to fully seat the screw in the screw socket may inhibit the cam lock from functioning properly by not rotating to the locked position, or by causing damage to the cam lock due to direct interference with the screw.

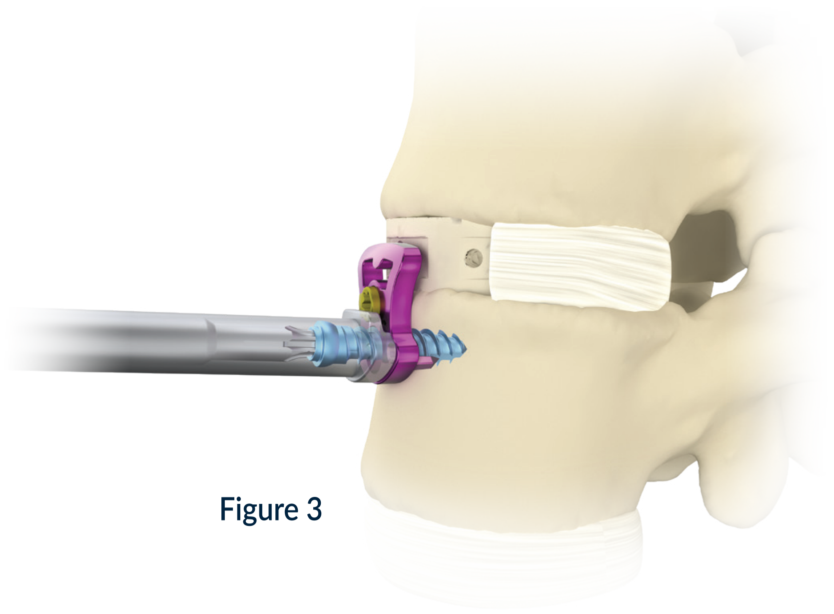


**Figure 3**

## Step 4: Securement of Screw

Rotate the thumb wheel on the Buttress Plate Inserter counter-clockwise until unthreaded from the plate and remove the inserter. The screw is locked by rotating the cam lock clockwise one-quarter turn using the same Screw Driver that is used to insert the screws.

**CAUTION:** It is not recommended to rotate the cam lock more than two times. **(Figure 4)**

**Note:** The laser marked line on the cam blocker will be in a vertical orientation when secured.

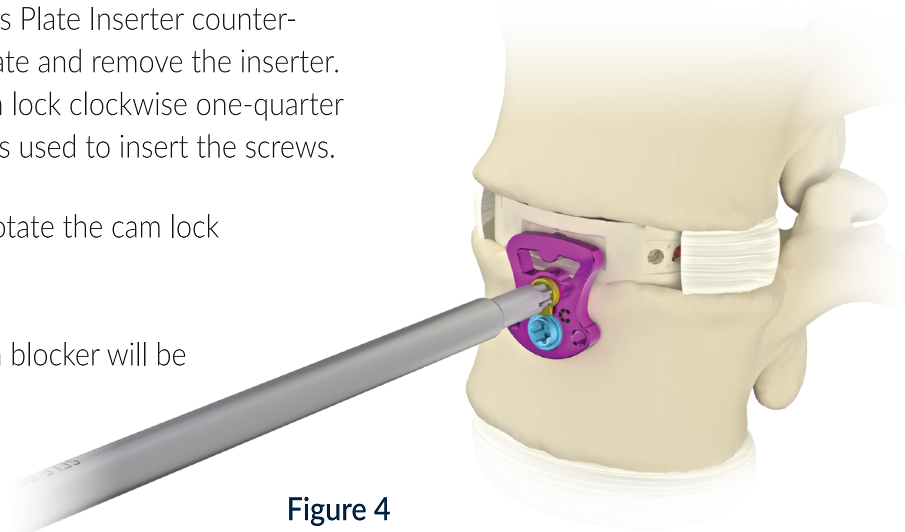


Figure 4

## Step 5: Implant Removal

Use the Screw Driver to unlock the cam lock by rotating counterclockwise one-quarter turn to uncover the screw socket. After the cam lock has been rotated, the screw can be removed using the Screw Driver. **(Figure 5)**

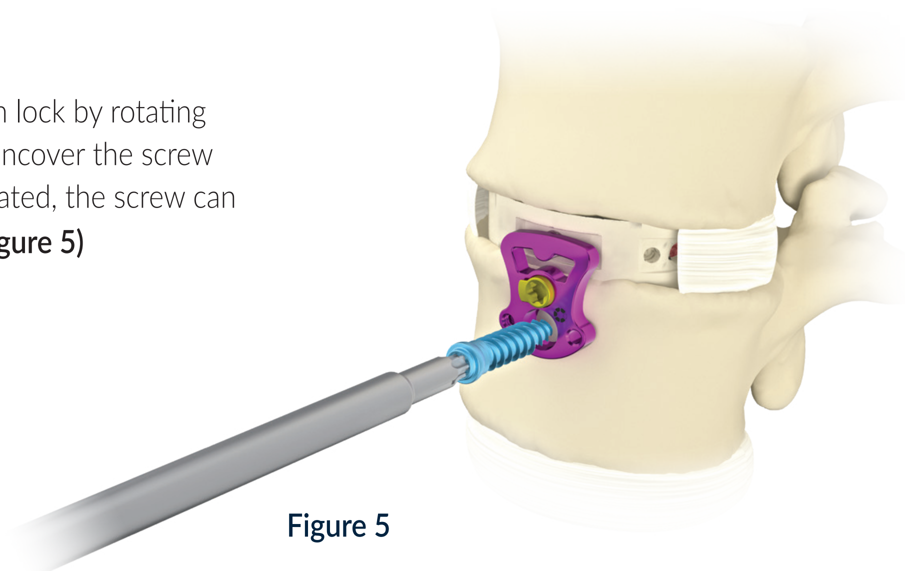


Figure 5

## Indications for Use:

The Acumen Thoracolumbar Plate System Two Hole and Four Hole Plates are intended for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability, or via the anterior surgical approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability in skeletally mature patients 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 a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

The Acumen Thoracolumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

## Contraindications:

Contraindications for the Acumen Thoracolumbar Plate System are comparable to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post- operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems, or in any case requiring the mixing of metals from different components.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.

## Cautions, Precautions and Warnings:

### Cautions:

Mixing of dissimilar metals can accelerate the corrosion process. Do NOT use titanium and/or cobalt chromium with stainless steel in the same implant construct.

Do not use components of the Acumen Thoracolumbar Plate System with components from any other manufacturer unless indicated.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with other objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic implants, none of the Acumen Thoracolumbar Plate System components should ever be reused under any circumstances.

### Precautions:

The implantation of properly selected and placed system implants and components should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Acumen Thoracolumbar Plate System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Acumen Thoracolumbar Plate System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

## Warnings:

The safety and effectiveness of spinal fixation systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. The safety and effectiveness of these devices for any other conditions are unknown.

This device system is not intended to be the sole means of spinal support. Its use without a bone graft, for instance, or in cases that develop into a non-union may not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

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

The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through Curiteva customer support representatives.

## Possible Adverse Effects:

Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects, including but not limited to:

- Early or late loosening of any or all of the components
- Disassembly, bending, and/or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone at, above, and/or below the level of surgery
- Non-union (pseudarthrosis), mal-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Neurovascular compromise including paralysis or other types of serious injuries
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death

Toll Free: 877.9CURITEVA
Phone: 256.213.1057
www.curiteva.com
customersupport@curiteva.com

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