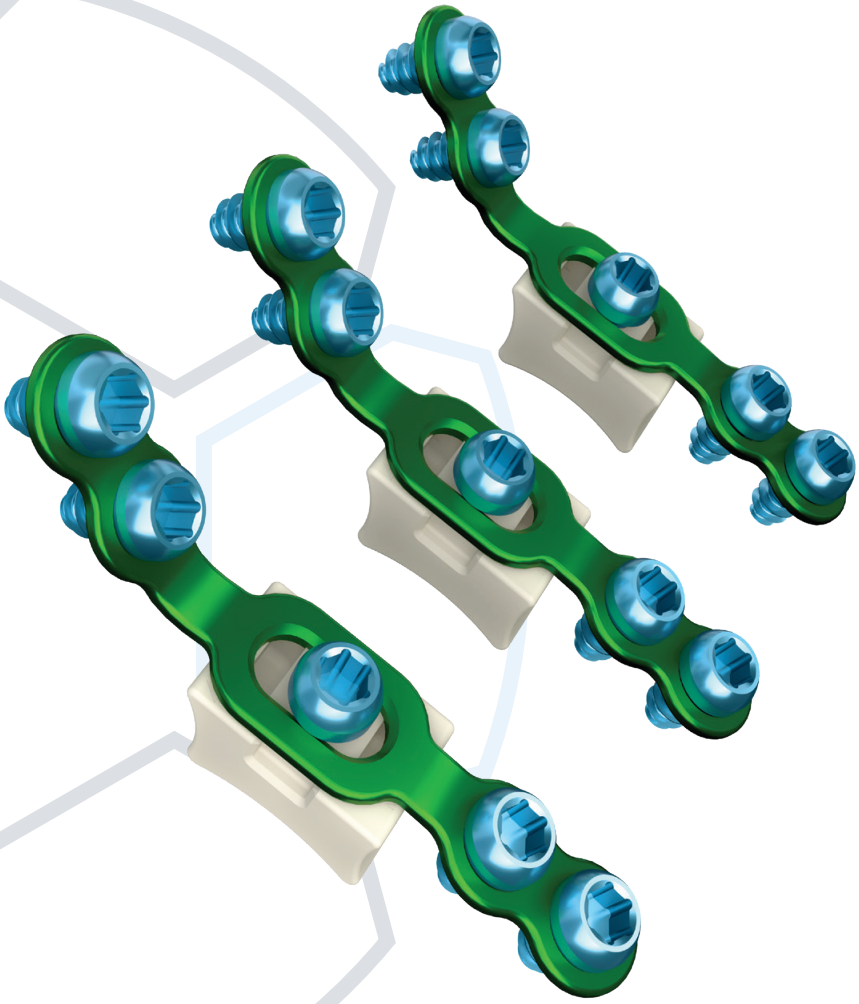
PROWESS®

LAMINOPLASTY SYSTEM



Surgical Technique Guide

CURITEVA®

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PROWESS®
LAMINOPLASTY SYSTEM

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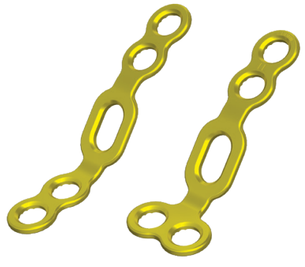
Disclaimer

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.

Features and Benefits

PROWESS® LAMINOPLASTY SYSTEM

The Curiteva PROWESS System provides a comprehensive solution for Laminoplasty procedures and consists of streamlined instrumentation and a variety of plate and spacer options for intraoperative adaptability. The instrumentation are intuitive and maintain secure connections to the implants. The implants are offered in a range of sizes and are color coded for easy visual identification.



Prowess Spacer Plates

Part Number: C1054-1XX-N/C1054-1XX-SS
(XX - Length, N – Inline, SS – Side-by-Side

- 4-12mm lengths (in 2mm increments) that work with various Spacers
- 2.8mm across neck, 5.7mm across center graft window
- Color-coded plates allow for easy identification
- Double-bend design, low-profile to allow further contouring
- Anterior ridges resist slippage and increase torsional stability
- Accepts Ø2.3 x 4mm Self-Tapping Bone Screw for assembly

Prowess Hook Plates

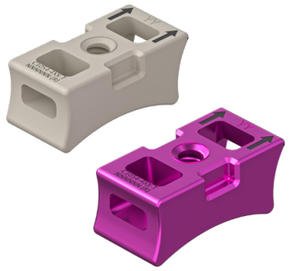
Part Number: C1054-2XX-N/C1054-2XX-SS
(XX - Length, N – Inline, SS – Side-by-Side

- 4-12mm lengths (in 2mm increments) that work with various Spacers
- 2.8mm across neck
- Color-coded plates allow for easy identification
- Double-bend design, low-profile to allow further contouring
- Anterior ridges resist slippage and increase torsional stability

Prowess Hinge Plates

Part Number: C1054-3-N/C1054-3-SS
(N – Inline, SS – Side-by-Side

- 2.8mm across neck
- Singe-bend design, low-profile to allow further contouring
- Anterior ridges resist slippage and increase torsional stability



Prowess Spacers

Part Number: C1054-4XX-T/C1054-4XX-P
(XX - Length, T – Titanium, P – PEEK

- Titanium or PEEK construction
- 6mm wide, and 4mm minimum height from posterior face to anterior curve
- Implant Inserter grip features
- Medial, lateral, and anterior anatomical curvatures
- Graft cavities on all sizes
- Accepts Ø2.3 x 4mm Self-Tapping Bone Screw for assembly
- Titanium Spacers are color-coded for easy identification

Prowess Screws

Part Number: C1054-DDLL-XX
(DD – Diameter, LL – Length, XX – Screw Type)

- Ø2.3 and Ø2.7 in 4-12mm lengths (in 2mm increments)
- Self-Drilling and Self-Tapping
- Color-coded screws allow for easy identification
- Works with self-retaining Screw Driver
- Same Ø2.3 x 4mm Self-Tapping bone screw assembles Spacer to Spacer Plate

PROWESS® LAMINOPLASTY SYSTEM

Spacer Plates, Inline Holes		
Catalog Number	**Description**	**Color**
C1054-104-N	4mm Spacer Plate, Inline	Light Blue
C1054-106-N	6mm Spacer Plate, Inline	Yellow
C1054-108-N	8mm Spacer Plate, Inline	Green
C1054-110-N	10mm Spacer Plate, Inline	Pink
C1054-112-N	12mm Spacer Plate, Inline	Seafoam

Spacer Plates, Side-by-Side Holes		
Catalog Number	**Description**	**Color**
C1054-104-SS	4mm Spacer Plate, Side-by-Side	Light Blue
C1054-106-SS	6mm Spacer Plate, Side-by-Side	Yellow
C1054-108-SS	8mm Spacer Plate, Side-by-Side	Green
C1054-110-SS	10mm Spacer Plate, Side-by-Side	Pink
C1054-112-SS	12mm Spacer Plate, Side-by-Side	Seafoam

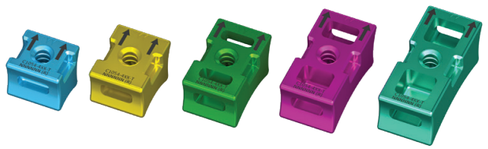
Hook Plates, Inline Holes		
Catalog Number	**Description**	**Color**
C1054-204-N	4mm Hook Plate, Inline*	Light Blue
C1054-206-N	6mm Hook Plate, Inline*	Yellow
C1054-208-N	8mm Hook Plate, Inline*	Green
C1054-210-N	10mm Hook Plate, Inline*	Pink
C1054-212-N	12mm Hook Plate, Inline*	Seafoam

Hook Plates, Side-by-Side Holes		
Catalog Number	**Description**	**Color**
C1054-204-SS	4mm Hook Plate, Side-by-Side*	Light Blue
C1054-206-SS	6mm Hook Plate, Side-by-Side*	Yellow
C1054-208-SS	8mm Hook Plate, Side-by-Side*	Green
C1054-210-SS	10mm Hook Plate, Side-by-Side*	Pink
C1054-212-SS	12mm Hook Plate, Side-by-Side*	Seafoam

Hinge Plates		
Catalog Number	**Description**	**Color**
C1054-3-N	Hinge Plate, Inline	Bronze
C1054-3-SS	Hinge Plate, Side-By-Side	Bronze

**Available by request*

Implant Guide



Titanium Spacers		
Catalog Number	**Description**	**Color**
C1054-404-T	4mm Titanium Spacer*	Light Blue
C1054-406-T	6mm Titanium Spacer*	Yellow
C1054-408-T	8mm Titanium Spacer*	Green
C1054-410-T	10mm Titanium Spacer*	Pink
C1054-412-T	12mm Titanium Spacer*	Seafoam

PEEK Spacer		
Catalog Number	**Description**	**Color**
C1054-404-P	4mm PEEK Spacer	PEEK
C1054-406-P	6mm PEEK Spacer	PEEK
C1054-408-P	8mm PEEK Spacer	PEEK
C1054-410-P	10mm PEEK Spacer	PEEK
C1054-412-P	12mm PEEK Spacer	PEEK

Ø 2.3mm Self-Drilling Screws		
Catalog Number	**Description**	**Color**
C1054-2304-SD	Ø 2.3 x 4mm, Self-Drilling	Light Blue
C1054-2306-SD	Ø 2.3 x 6mm, Self-Drilling	Yellow
C1054-2308-SD	Ø 2.3 x 8mm, Self-Drilling	Green
C1054-2310-SD	Ø 2.3 x 10mm, Self-Drilling	Pink
C1054-2312-SD	Ø 2.3 x 12mm, Self-Drilling	Seafoam

Ø 2.3mm Self-Tapping Screws		
Catalog Number	**Description**	**Color**
C1054-2304-ST	Ø 2.3 x 4mm, Self-Tapping	Light Blue
C1054-2306-ST	Ø 2.3 x 6mm, Self-Tapping*	Yellow
C1054-2308-ST	Ø 2.3 x 8mm, Self-Tapping*	Green
C1054-2310-ST	Ø 2.3 x 10mm, Self-Tapping*	Pink
C1054-2312-ST	Ø 2.3 x 12mm, Self-Tapping*	Seafoam

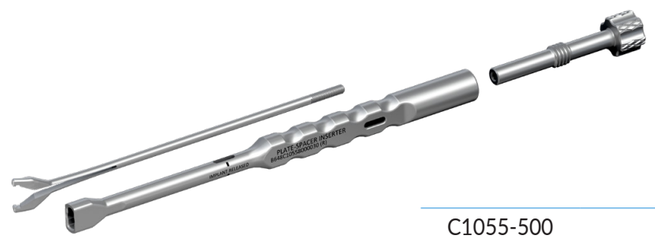
Ø 2.7mm Self-Drilling Screws		
Catalog Number	**Description**	**Color**
C1054-2704-SD	Ø 2.7 x 4mm, Self-Drilling*	Light Blue
C1054-2706-SD	Ø 2.7 x 6mm, Self-Drilling*	Yellow
C1054-2708-SD	Ø 2.7 x 8mm, Self-Drilling*	Green
C1054-2710-SD	Ø 2.7 x 10mm, Self-Drilling*	Pink
C1054-2712-SD	Ø 2.7 x 12mm, Self-Drilling*	Seafoam

Ø 2.7mm Self-Tapping Screws		
Catalog Number	**Description**	**Color**
C1054-2704-ST	Ø 2.7 x 4mm, Self-Tapping	Light Blue
C1054-2706-ST	Ø 2.7 x 6mm, Self-Tapping	Yellow
C1054-2708-ST	Ø 2.7 x 8mm, Self-Tapping	Green
C1054-2710-ST	Ø 2.7 x 10mm, Self-Tapping	Pink
C1054-2712-ST	Ø 2.7 x 12mm, Self-Tapping	Seafoam

**Available by request*

Instrument Guide

C1055-800 Plate-Spacer Inserter



C1055-500 Screw Driver

C155-1000 Handle

C1055-410 4mm Flat End Bone Awl*

C1055-200 Plate Bender

C1055-810 Implant Pickups

C1055-210 Plate Cutter

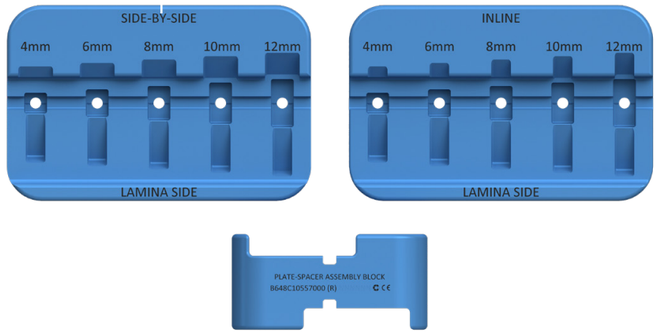
C1055-811 Angled Implant Pickups

C1055-100 Lamina Elevator*

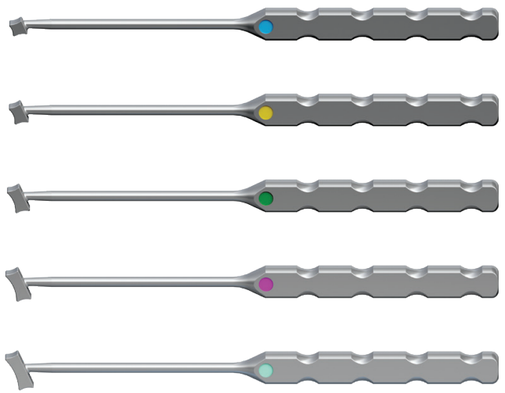
C1055-110 Lamina Lifter

**Available by request*

C1055-700	Plate-Spacer Assembly Block



Drill Bit		Ring Color
C1055-300-04	4mm Drill	Light Blue
C1055-300-06	6mm Drill	Yellow
C1055-300-08	8mm Drill	Green
C1055-300-10	10mm Drill	Magenta
C1055-300-12	12mm Drill	Seafoam



Trial		Dot Color
C1055-300-600	4mm Spacer Trial	Light Blue
C1055-300-601	6mm Spacer Trial	Yellow
C1055-300-602	8mm Spacer Trial	Green
C1055-300-603	10mm Spacer Trial	Magenta
C1055-300-604	12mm Spacer Trial	Seafoam

PROWESS®
Surgical Technique

Disclaimer

Each surgical step applies to all material types but the illustrations only show PEEK.

Step 1: Surgical Approach

The patient is positioned prone with the neck in slight flexion, and held in place with Mayfield pins. A standard midline approach should be used to expose the laminae at the desired levels. **(Figure 1)**

CAUTION: Care should be taken to preserve the facet capsules, soft tissue attachments to the facet joints, the spinous processes, and the interspinous ligaments.

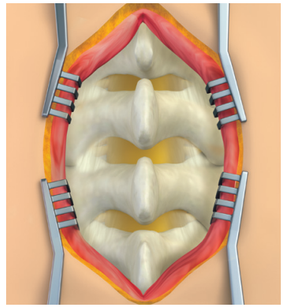


Figure 1

Step 2: Prepare the Open Side

Prepare a trough, 1-2mm wide using a highspeed burr, kerrison, or similar instrument to cut through both the dorsal and ventral cortices at the lateral edge of the lamina, medial edge of the lateral mass. **(Figure 2)**

CAUTION: Avoid contact with the underlying dura and make note of the thickness of the lamina for preparation of the hinge side.

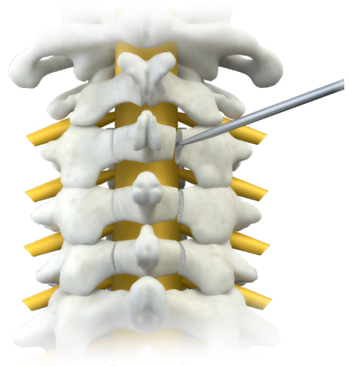


Figure 2

Step 3: Prepare the Hinge Side

On the contralateral side use a highspeed burr to cut a half-thickness trough at the lateral edge of the lamina, medial edge of the lateral mass. **(Figure 3)**

CAUTION: Care should be taken not to completely break through the ventral cortex.

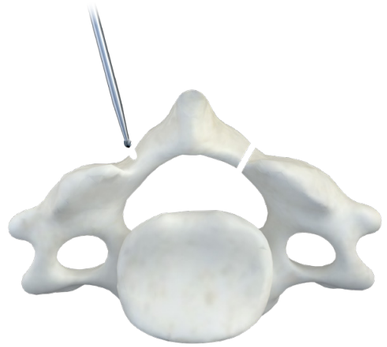


Figure 3

Step 4: Elevation

Use the Lamina Lifter, or Lamina Elevator, **(Figure 4)** lift each lamina up partially and away from the spinal canal. Release the lateral open side of the ligamentum flavum with the lifter or rongeur. If more than one level, elevate the multiple laminae as a unit.

Note: Lack of laminar movement may indicate that deeper scoring is required at the hinge site.

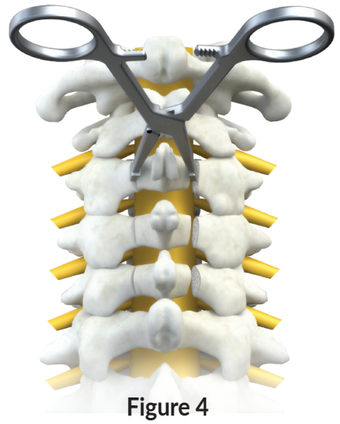


Figure 4

Step 5: Trialing

Insert the tip of the trial between the cut, open edges of the expanded lamina and lateral mass to identify the proper size of plate and/or plate spacer. **(Figure 5)** Be sure there is adequate decompression at each level. Repeat for all levels.

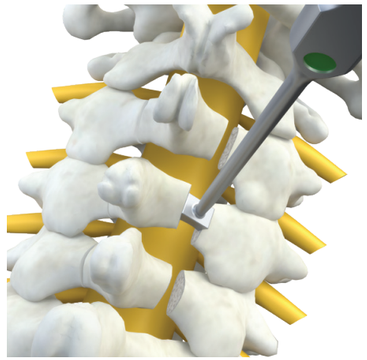


Figure 5

Step 6: Plate Selection

Use the Implant Pickups to trial the preferred plate design and size by holding it against the expanded lamina to ensure it is the desired size. **(Figure 6)** If necessary, the Plate Benders may be used to provide additional contour so that the plates fit properly.

CAUTION: Prowess plates should be bent in one direction only. Plates are not intended to be bent and then reversed.

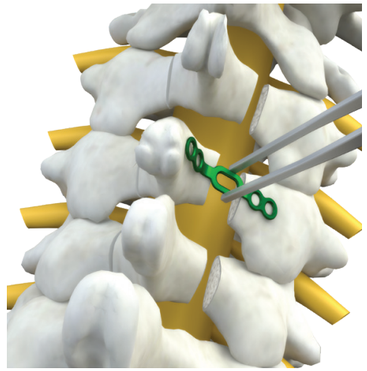


Figure 6

Step 7a: Spacer-First Placement
(Option #1)

Attach the Inserter to the Spacer and introduce the implant to the surgical site. **(Figure 7a)** Introduce the Spacer Plate to the appropriate level with the center slot over the pilot hole on the Spacer. The Spacer and Spacer Plate are affixed together using the 4mm Self-Tapping Screw.

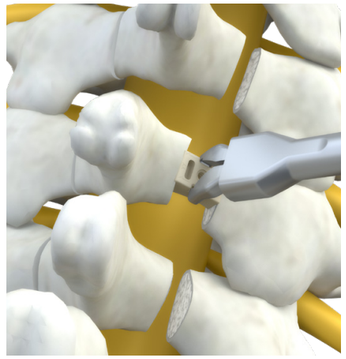


Figure 7a

Step 7b: Spacer Plate Assembly Placement
(Option #2)

Alternatively, assemble the Spacer and Spacer Plate together in the Assembly Block using the 4mm Self-Tapping screw. **(Figure 7b)** Attach the Inserter to the Plate assembly and introduce the implant to the surgical site.

Note: The Pickups can be used in place of the Inserter for this step.

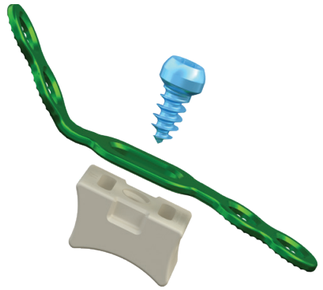


Figure 7b

Step 7c: Plate-Only Placement
(Option #3)

Use the Implant Pickups to hold the Hook Plate and introduce the implant to the surgical site. Place the plate such that the buttress and hook is fixated to the medial edges of the lateral mass and elevated edge of the opened lamina, respectively. **(Figure 7c)**

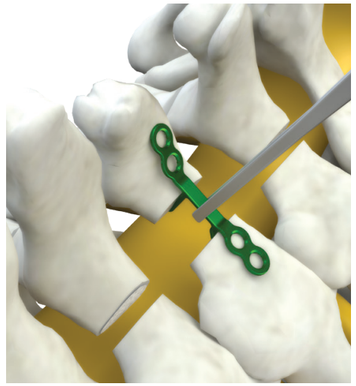


Figure 7c

Step 8: Screw Hole Preparation (Optional)

Drills are available in lengths corresponding to the lengths of the screws. The drills will create a hole consistent with the minor diameter of the primary screws.

Attach axial handle to drill bit connection end and align the drill with the center of the desired screw hole and drill until the instrument's depth stop reaches the plate. **(Figure 8)**

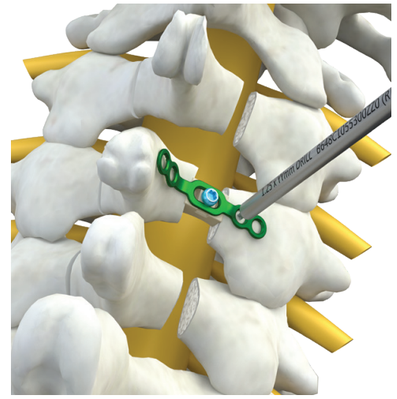


Figure 8

Step 9: Screw Placement

Load screw onto the self-retaining Screw Driver and through the screw holes on the plate onto the lamina or lateral mass at the predetermined hole location. **(Figure 9)** Repeat for all screw holes or pilot holes.

CAUTION: Be mindful of screw length and trajectory to avoid compromising underlying anatomy.

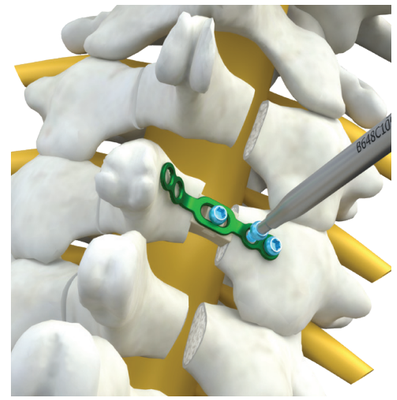


Figure 9

Step 10: Implant Removal (Optional)

Use the screw driver to turn the screws counterclockwise to back screws out. **(Figure 10)** Revision screws are provided if needed. Use the Implant Pickups to remove all plates and plate spacers as necessary.

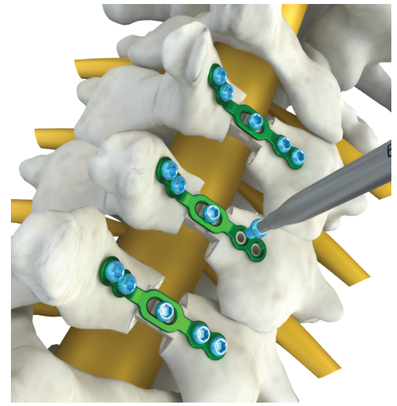


Figure 10

Description:

The Prowess Laminoplasty System is an internal fixation device for spinal surgery that consists of various configurations of plates and screws. The implant configurations are available in different types and sizes so that adaptations can be made to take into account pathology and individual patient anatomy. The plates come preformed with holes to receive bone screws. Screws are used to attach the plates to bone. System plate configurations may be used with allograft or autograft material. A hinge plate is provided when additional stabilization is necessary.

All system components are manufactured from Titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136, or PEEK (Polyetheretherketone) as described by ASTM F2026.

Indications for Use:

The Prowess Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Prowess Laminoplasty System is used to hold or buttress the allograft or autograft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

Contraindications:

Contraindications for the Prowess Laminoplasty System are similar 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.
- 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, and/or the amount of mechanical fixation.
- 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. Stainless steel and titanium components must NOT be used together.

Do not use components of the Prowess Laminoplasty System with components from any other manufacturer.
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 Prowess Laminoplasty 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 Prowess Laminoplasty System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Prowess Laminoplasty System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

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 or in cases that develop into a non-union will 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.

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 corporate sales 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 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 in adequate 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

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