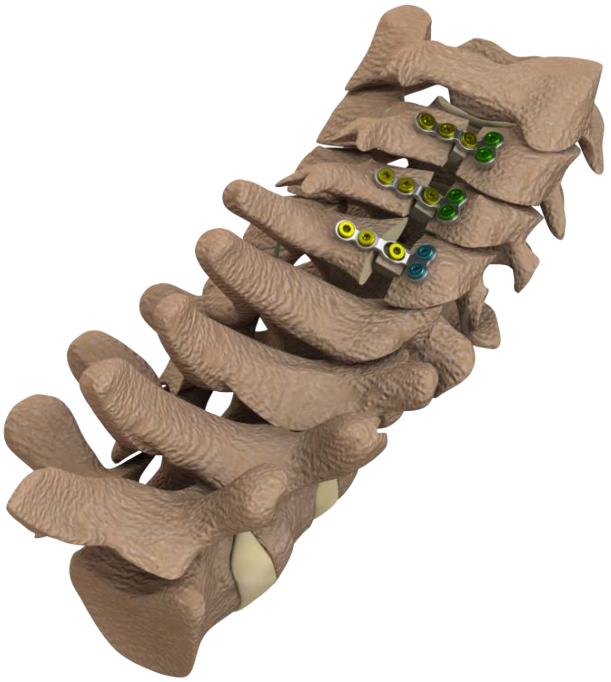
Vy Spine™

VyLam™
Laminoplasty System

Surgical Technique



System Overview

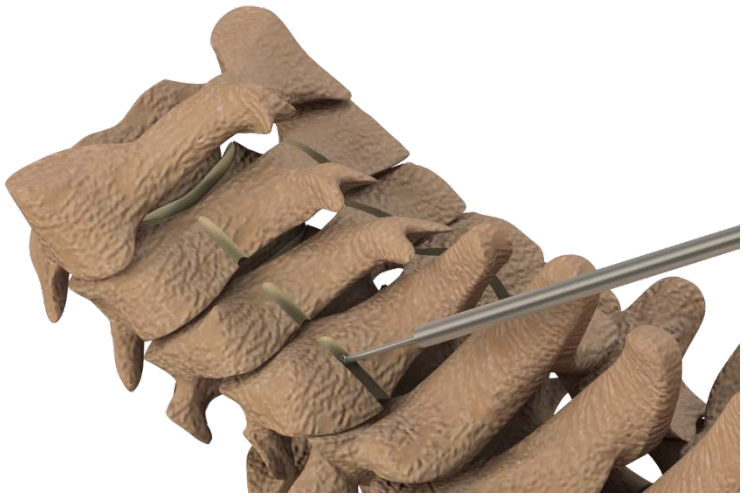
Description:

The Vy Spine™ VyLam™ Laminoplasty System contains plates and screws in a variety of sizes and configurations. The plates are offered in opening sizes ranging from 3 mm to 14 mm, with standard configuration and hook configuration. The screws are offered in lengths ranging from 4 mm to 12 mm, and diameters of 2.0 mm and 2.4 mm, in self-tapping and self-drilling configurations. All the components discussed above are fabricated from Titanium alloy.

Step 1. Perform Laminoplasty

Use the standard midline approach to expose the vertebrae just lateral to the lateral mass-laminar junction.

With a high-speed drill, create the open side by transecting the lamina at the lateral mass-laminar junction. On the contralateral side, create the hinge side by scoring through the dorsal cortex at the lateral mass-laminar junction. If the hinge is too stiff, additional thinning of the ventral cortex can be performed gradually, not to completely break through the ventral cortex.



Step 2. Open the Lamina

With the lamina lifter, carefully apply force on the ventral surface of the open side to expand the opening by hinging on the scoring made previously.

Step 3. Allograft Trial

Insert the trial in the opening between the lamina and the lateral mass to identify the appropriate plate and allograft size. Trials are available in sizes 3mm, 4mm, 6mm, 8mm, 10mm, 12mm, and 14mm.

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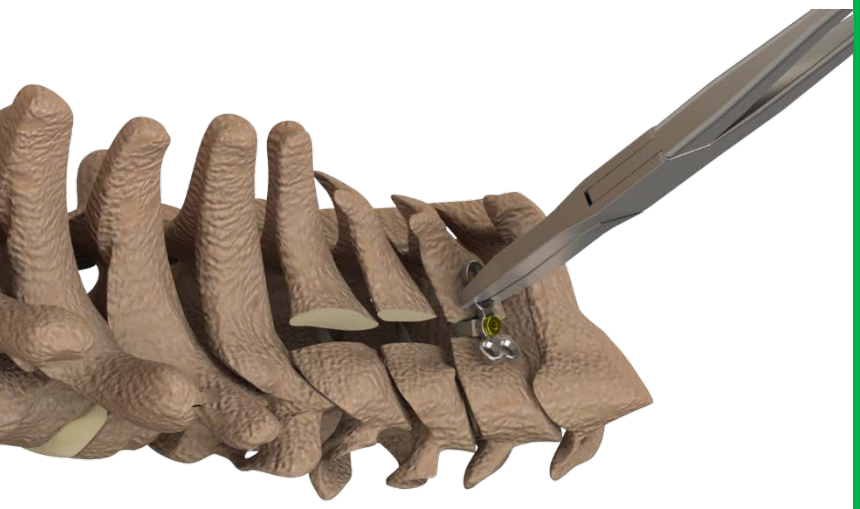
Step 4. Select Plate

Select plate size and design, and with the plate holder, place the plate on the expanded lamina to ensure the best anatomical fit. Plates are available in sizes 3mm, 4mm, 6mm, 8mm, 10mm, 12mm, and 14mm, with options of either standard or hook design.

Step 5. Attach Allograft to Plate

Fix the allograft to the plate with a 2.0mm diameter screw through the center screw site.



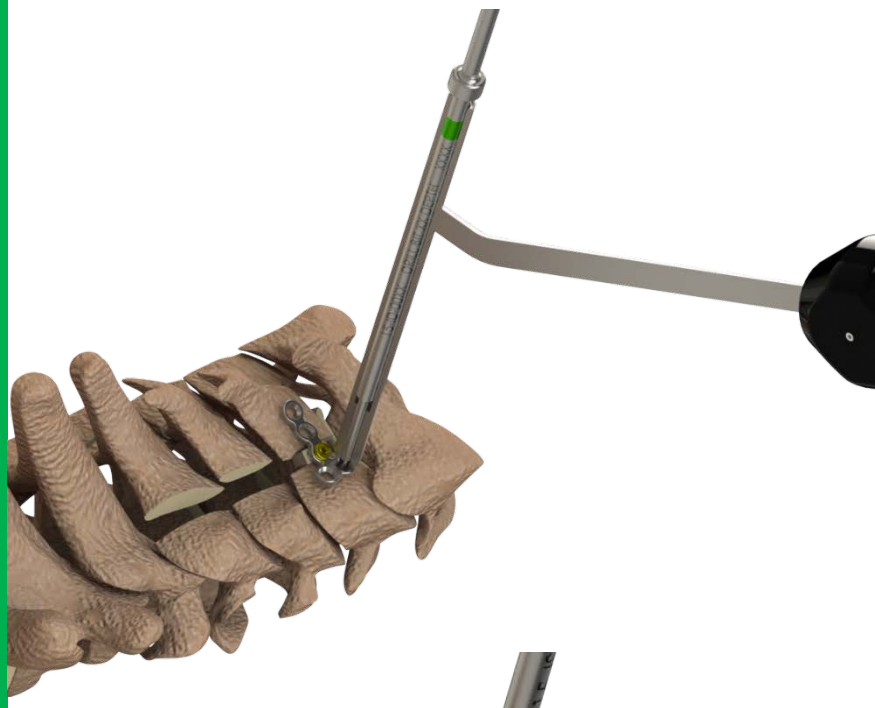
Step 6. Place Plate and Graft

With the plate holder, securely place graft and plate at the surgical site. For hook plates, fix the hook end to the elevated edge of the opened lamina. If necessary, the plate bender may be used to contour the plate for better fit in both standard and hook configurations.

Step 7. Drill Screw Hole

This step is only required if self-tapping screws are being used to secure the plate to the bone.

Place the drill guide tip into the hole in the plate. The awl may be used to start the screw hole by inserting into the drill guide and pressing firmly until the stop contacts the top of the drill guide.
Drills are color-coded to match screw lengths. Insert the appropriate drill into the drill guide and turn clockwise until the stop contacts the top of the drill guide.



Step 8. Screw

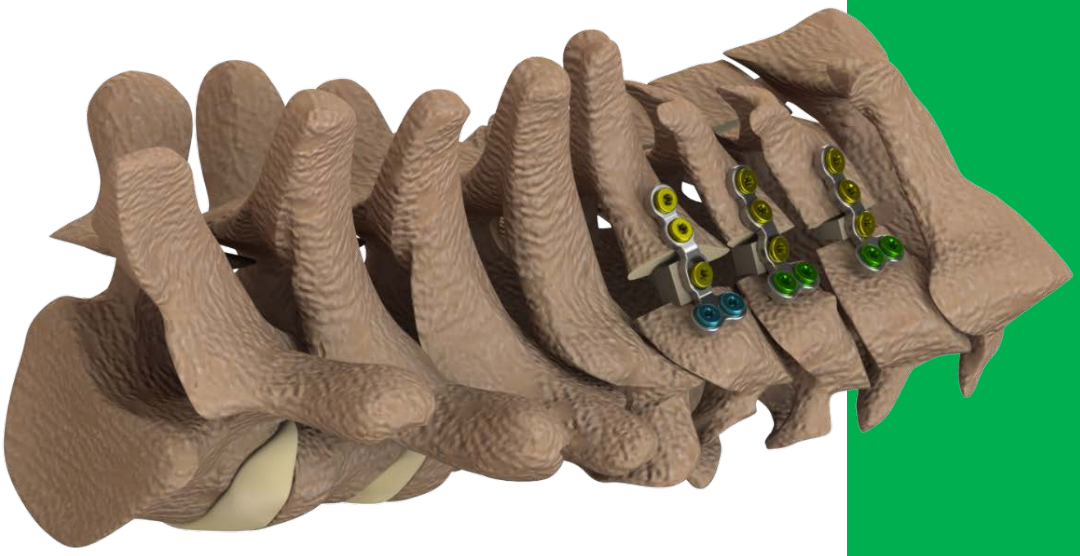
With the screwdriver, insert appropriate length 2.0 mm diameter screw through the hole in the plate. Turn until the screw is fully seated in the plate. Emergency 2.4 mm diameter screws are provided should they be required.

Step 9. Insert Remaining Screws

Repeat steps 7 and 8 with the remaining screws. Two screws are typically placed on each end of the plate for sufficient fixation.

Step 10. Complete Construct

Repeat steps 1 through 9 at all levels.



Removal of Implants

1. Should removal of VyLam™ implants be required, begin by removing the VyLam™ Laminoplasty Screws by using the screwdriver, turning screws counterclockwise to back screws out.
2. Using the plate holder, remove all plates and allograft.

VyLam™ Ordering Information

Standard Plate

Part Number	Product Size
15-LP-4503-TI-N	3 mm
15-LP-4504-TI-N	4 mm
15-LP-4506-TI-N	6 mm
15-LP-4508-TI-N	8 mm
15-LP-4510-TI-N	10 mm
15-LP-4512-TI-N	12 mm
15-LP-4514-TI-N	14 mm

Standard Plate

Standard Plate Side View

Hook Plate

Part Number	Product Size
15-LPH-4503-TI-N	3 mm
15-LPH-4504-TI-N	4 mm
15-LPH-4506-TI-N	6 mm
15-LPH-4508-TI-N	8 mm
15-LPH-4510-TI-N	10 mm
15-LPH-4512-TI-N	12 mm
15-LPH-4514-TI-N	14 mm

Hook Plate

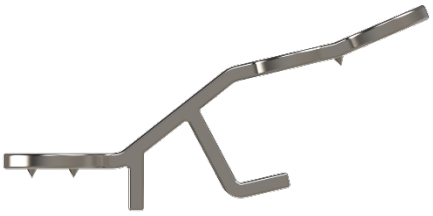
Hook Plate Side View

VyLam™ Ordering Information

Double Hook Plate

Part Number	Product Size
15-LPHD-4503-TI-N*	3 mm
15-LPHD-4504-TI-N*	4 mm
15-LPHD-4506-TI-N	6 mm
15-LPHD-4508-TI-N	8 mm
15-LPHD-4510-TI-N	10 mm
15-LPHD-4512-TI-N	12 mm
15-LPHD-4514-TI-N	14 mm

Double Hook Plate

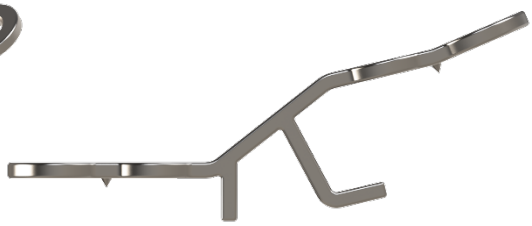


Double Hook Plate Side View

Inline Double Hook Plate

Part Number	Product Size
15-LPHDI-4503-TI-N*	3 mm
15-LPHDI-4504-TI-N*	4 mm
15-LPHDI-4506-TI-N	6 mm
15-LPHDI-4508-TI-N	8 mm
15-LPHDI-4510-TI-N	10 mm
15-LPHDI-4512-TI-N	12 mm
15-LPHDI-4514-TI-N	14 mm

Inline Double Hook Plate



Inline Double Hook Plate Side View

Support Hinge Plate

Part Number
15-LPS-001-TI-N

Support Hinge Plate

Support Hinge Plate Side View

*Note: 3mm and 4mm double hook and double hook inline plates are available upon request.

VyLam™ Ordering Information

Screw Self-Drilling

Part Number	Product Size	Color
15-LSD-2004-TI-N	Ø2.0x4	Gold
15-LSD-2006-TI-N	Ø2.0x6	Green
15-LSD-2008-TI-N	Ø2.0x8	Blue
15-LSD-2010-TI-N	Ø2.0x10	Violet
15-LSD-2012-TI-N	Ø2.0x12	Magenta

Part Number	Product Size	Color
15-LSD-2404-TI-N	Ø2.4x4	Gold
15-LSD-2406-TI-N	Ø2.4x6	Green
15-LSD-2408-TI-N	Ø2.4x8	Blue
15-LSD-2410-TI-N	Ø2.4x10	Violet
15-LSD-2412-TI-N	Ø2.4x12	Magenta

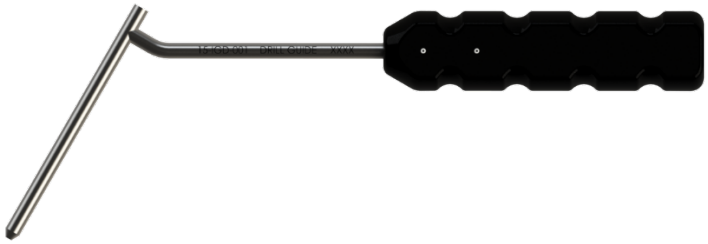
VyLam™ Ordering Information

Screw Self-Tapping

Part Number	Product Size	Color	Part Number	Product Size	Color
15-LST-2004-TI-N	Ø2.0x4	Gold	15-LST-2404-TI-N	Ø2.4x4	Gold
15-LST-2006-TI-N	Ø2.0x6	Green	15-LST-2406-TI-N	Ø2.4x6	Green
15-LST-2008-TI-N	Ø2.0x8	Blue	15-LST-2408-TI-N	Ø2.4x8	Blue
15-LST-2010-TI-N	Ø2.0x10	Violet	15-LST-2410-TI-N	Ø2.4x10	Violet
15-LST-2012-TI-N	Ø2.0x12	Magenta	15-LST-2412-TI-N	Ø2.4x12	Magenta

VyLam™ Ordering Information

Instrumentation Options

Part Number	Description	
15-IA-001	Awl	
15-ID-0004	Drill Bits, 4 mm	
15-ID-0006	Drill Bits, 6 mm	
15-ID-0008	Drill Bits, 8 mm	
15-ID-0010	Drill Bits, 10 mm	
15-ID-0012	Drill Bits, 12 mm	
15-IDF-0004	Freehand Drill Bits, 4 mm	
15-IDF-0006	Freehand Drill Bits, 6 mm	
15-IDF-0008	Freehand Drill Bits, 8 mm	
15-IGD-001	Drill Guide	
15-IL-001	Lamina Lifter	
15-IPB-001	Plate Bender	
15-IPH-001	Plate Holder	

15-IPH-003	Angled Plate Holder	
15-IS-001	Screwdriver	
15-ITG-4503	Graft Trial, 3 mm	
15-ITG-4504	Graft Trial, 4 mm	
15-ITG-4506	Graft Trial, 6 mm	
15-ITG-4508	Graft Trial, 8 mm	
15-ITG-4510	Graft Trial, 10 mm	
15-ITG-4512	Graft Trial, 12 mm	
15-ITG-4514	Graft Trial, 14 mm	

VyLam™ Ordering Information

INDICATIONS:

The Vy Spine™ VyLam™ Laminoplasty System is indicated for use in laminoplasty of the lower cervical and upper thoracic spine (C3 to T3) in skeletally mature patients. The system devices are designed for use with allogenic bone graft in order to prevent the allograft from expulsion or impinging on the spinal cord. One device may be used per vertebra.

CONTRAINDICATIONS:

The Vy Spine™ VyLam™ Laminoplasty System is not to be used:

- For screw attachments to the posterior elements of the lumbar spine
- For single- or two-level spondylosis without developmental spinal canal stenosis
- Under any direct load bearing conditions
- In the presence of focal anterior compression
- In the presence of isolated radiculopathy
- In the presence of loss of anterior column support resulting from tumor, trauma, or infection

WARNINGS AND PRECAUTIONS:

The following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient before surgery.

WARNINGS

1. FOR LOWER CERVICAL AND UPPER THORACIC SPINE ONLY. These devices are not approved for screw attachments to the posterior elements of the lumbar spine.
2. ALLOGRAFT. Allograft must always be used with the VyLam™ Laminoplasty System.
3. IMPLANT SELECTION. Proper implant size selection increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants.
4. IMPLANT STRENGTH. The implants are intended for obtaining and maintaining the alignment until normal healing occurs. These devices are not designed to withstand full weight or load bearing from activity levels equal to those placed on normal healthy bones. If healing is delayed or does not occur, the implant may break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant.
5. CORROSION. Contact of dissimilar metals accelerates the corrosion process, and hence shorten the longevity of the implants. Therefore, only use like or compatible metals with implants that are in contact with each other.

PRECAUTIONS

1. SINGLE USE ONLY. Implants should never be reused. Though an implant may appear undamaged, stress from previous implantation may have caused internal defects that can compromise device performance and service life.
2. HANDLING. Handle titanium implants with care. Should plate contouring be required, avoid sharp or reverse bending, notching, or scratching, as they may lead to early breakage. Bending across screw holes should also be avoided.
3. IMPLANT REMOVAL AFTER HEALING. After its intended used and healing, the implant may be removed. If implants are not removed, complications such as implant bending, loosening, breakage, migration, corrosion, pain, discomfort, or stress shielding of bone may occur, particularly in young, active patients. The surgeon should carefully weigh these risks versus the risks of implant removal surgery when deciding whether to remove the implant.
4. ADEQUATE PATIENT INSTRUCTIONS. Patient must be made aware of the limitations of the implants, and should be instructed to limit and restrict weight or load bearing physical activities until complete healing.

FOR ADDITIONAL INFORMATION INCLUDING CLEANING AND STERILIZATION, PLEASE REFER TO THE PACKAGE INSERT

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