



Surgical Technique

## Gallery™ Laminoplasty Spine System

A smart, simple to use system with intuitive design features.

### Smart Plate Design

- Three hole, cobra head design
- Plates with hook or standard plates available

### Multiple Implant Options

- Variety of plate styles and sizes
- Self-tapping and self-drilling screws

### Ergonomic Inserter

- Design incorporates an instant, secure connection between the screws and inserter
- Spin Tight Technology makes screw insertion easy



**BIOMET**<sup>®</sup>  
SPINE

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## Introduction

The Gallery™ Laminoplasty Fixation System provides a simplified approach to instrumented laminoplasty procedures.

The Gallery™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Gallery™ Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

This technique guide describes a surgical technique used by:

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The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient. The contents of this manual are intended to be only a guide and are not intended to set a standard of care.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.



## *Design Features*

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The Design Rationale of the Gallery™ Laminoplasty Fixation System is based on the premise that the laminoplasty procedure should be repeatable and concise. In order to achieve this, the Gallery™ System incorporates specific design features into its implants and instruments to assist in surgery at key points.

## *Implants*

Low Profile plates are easy to bend to fit the contour of the lamina:

### **Standard Double Plates**

Standard double bend plates with screw holes to attach to the lamina, lateral mass, and bone graft.



Standard Plate



Side View of Standard Plate

### **Plates with Hook**

Double bend plates enhanced with a buttress against the lateral mass and a hook against the open lamina to stabilize the lamina in the open position as screws are inserted.



Plate with Hook



Side View of Plate with Hook

## Implants (Continued)

### Screws

Self-drilling and self-tapping bone screws are available in various diameters and lengths to fixate the plates and allografts. The screws are color coded by length.

### Self-Drilling Screws



Self-Drilling Screws 2.4mm Diameter



Self-Drilling Screws 2.8mm Diameter

Gallery™ Self-Drilling Screws	Color
2.4mm x 5.0mm Self-Drilling Screw	Green
2.4mm x 7.0mm Self-Drilling Screw	Gold
2.4mm x 9.0mm Self-Drilling Screw	Light Blue
2.4mm x 11mm Self-Drilling Screw	Dark Magenta
2.8mm x 5.0mm Self-Drilling Screw	Green
2.8mm x 7.0mm Self-Drilling Screw	Gold
2.8mm x 9.0mm Self-Drilling Screw	Light Blue
2.8mm x 11mm Self-Drilling Screw	Dark Magenta

### Self-Tapping Screws



Self-Tapping Screws 2.4mm Diameter



Self-Tapping Screws 2.8mm Diameter

Gallery™ Self-Tapping Screws	Color
2.4mm x 5.0mm Self-Tapping Screw	Green
2.4mm x 7.0mm Self-Tapping Screw	Gold
2.4mm x 9.0mm Self-Tapping Screw	Light Blue
2.4mm x 11mm Self-Tapping Screw	Dark Magenta
2.8mm x 5.0mm Self-Tapping Screw	Green
2.8mm x 7.0mm Self-Tapping Screw	Gold
2.8mm x 9.0mm Self-Tapping Screw	Light Blue
2.8mm x 11mm Self-Tapping Screw	Dark Magenta

*Instruments*



**Drills**



**Plate Bender**



**Awl**



**Quick Connect Handle**



**Trials**



**Screw Driver**



**Plate Holders**

## ***Surgical Technique***

The patient is placed prone, with the neck in neutral alignment. A standard midline approach is used to provide access to the surgical site. The exposure should be just lateral to the lateral mass-laminar junction, with sufficiently more lateral exposure on the open side to accommodate plate placement. Care should be taken to preserve elements of the posterior spine.



### **Step 1: Creating the Open Side**

Once the exposure has been adequately completed, a high speed burr, Kerrison, or similar instrument may be used to drill down through both the dorsal and ventral cortices at the lateral mass/laminar junction.



### **Step 2: Creating the Hinge Side**

The contralateral side is prepared in a similar manner 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, but care must be taken not to break completely through the ventral cortex.





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### Step 3: Opening the Lamina

Once the desired flexibility of the hinge has been achieved, greenstick fractures are created by opening up the laminoplasty using a curette or similar instrument to apply dorsally directed force onto the ventral surface lamina on the open side. Alternatively, gentle manual pressure can be applied to the spinous process. Great care should be taken to prevent the lamina from recoiling back onto the spinal cord where it can cause injury. The ligamentum flavum will be exposed and under tension as the laminoplasty is opened and should be resected over the opening.



### Step 4: Allograft Trialing

Trials are available in 8-16mm heights in 2.0mm increments. Insert the tip of the allograft trial between the cut edges of the lamina and lateral mass to identify the proper allograft and plate size. Repeat for all levels.



## *Surgical Technique (Continued)*

### **Step 5: Plate Selection**

Utilizing the plate holder, trial the preferred plate design and size by holding it against the expanded lamina to ensure it is the desired size.



Both self-drilling and self-tapping screws are available to fixate the allograft to the plate. Attach the quick connect handle to the screw driver shaft. Seat the tip of the screw inserter in the cruciate of the desired 2.4mm diameter screw while in the caddy. Press down firmly on the end of the handle to seat the screw on the driver. Place the screw through the hole in the center section of the plate and into the allograft and tighten until the screw is fully seated against the plate.



### **Step 6 and 7: Plate and Graft Placement**

Attach the plate holder to the graft and plate assembly and introduce the implant to the surgical site. If using a plate with a hook, place the graft and plate such that the buttress and hook are fixated to the medial edges of the lateral mass and elevated edge of the opened lamina, respectively. At this point, the plate should be well-contoured against the bone. If necessary, the plate benders may be used to provide additional contour so that the plates fit properly.



### Step 8: Screw hole preparation (optional)

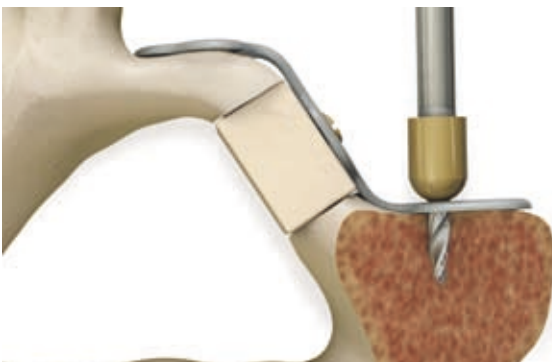
This step is only required if self-tapping screws are being used to fixate the plate to the allograft laminae and/or lateral masses.

The standard awl may be used to break the cortex of the bone prior to insertion of the screw. The awl, when fully seated in the plate, extends 2.0mm into the bone. Attach the awl to the quick connect handle. Center the tip of the awl in the hole in the plate and press down firmly on the handle until the stop contacts the plate.

Alternatively, drills are available in lengths corresponding to the lengths of the screws. The drills are color-coded to the screws according to the following table. The drills will create a hole consistent with the minor diameter of the primary screws.

Screw/Drill Length	Color
5.0mm	Green
7.0mm	Gold
9.0mm	Light Blue
11mm	Dark Magenta

Attach the appropriate drill to the quick connect handle. Center the tip of the drill in the hole in the plate and turn clockwise until the colored hard stop contacts the plate.



### Step 9: Screw Placement

Choose the desired length and diameter screw to fixate the plate to the lateral mass and lamina. Seat the tip of the screw driver in the cruciate of the desired screw while in the caddy. Press down firmly on the end of the handle to seat the screw on the inserter. Place the screw through the hole in the plate and turn until the screw is fully seated against the plate. Repeat for all desired screw holes. Typically, two screws are placed on each end of the plate, as necessary to achieve adequate fixation. Repeat at all levels.



## ***Implant Removal***

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### **Removal instructions**

Utilize the screw driver to turn the screws counterclockwise to back screws out. Use the plate holder to remove all plates and allograft spacers.

## Ordering Information

### Implant and Instrument Kit and Components

(Catalog # 14-523000)

Catalog #	Description	Qty
14-523080	2.4mm x 5.0mm Self-Tapping Screw	16
14-523081	2.4mm x 7.0mm Self-Tapping Screw	16
14-523082	2.4mm x 9.0mm Self-Tapping Screw	8
14-523083	2.4mm x 11mm Self-Tapping Screw	8
14-523085	2.8mm x 5.0mm Self-Tapping Screw	6
14-523086	2.8mm x 7.0mm Self-Tapping Screw	6
14-523087	2.8mm x 9.0mm Self-Tapping Screw	6
14-523088	2.8mm x 11mm Self-Tapping Screw	6
14-523095	2.4mm x 5.0mm Self-Drilling Screw	16
14-523096	2.4mm x 7.0mm Self-Drilling Screw	16
14-523097	2.4mm x 9.0mm Self-Drilling Screw	8
14-523098	2.4mm x 11mm Self-Drilling Screw	8
14-523100	2.8mm x 5.0mm Self-Drilling Screw	6
14-523101	2.8mm x 7.0mm Self-Drilling Screw	6
14-523102	2.8mm x 9.0mm Self-Drilling Screw	6
14-523103	2.8mm x 11mm Self-Drilling Screw	6
14-523208	8.0mm Standard Plate	6
14-523210	10mm Standard Plate	6
14-523212	12mm Standard Plate	6
14-523214	14mm Standard Plate	6
14-523216	16mm Standard Plate	6
14-523228	8.0mm Plate with Hook	6
14-523230	10mm Plate with Hook	6
14-523232	12mm Plate with Hook	6
14-523234	14mm Plate with Hook	6
14-523236	16mm Plate with Hook	6

### Implant and Instrument Kit and Components

(Catalog # 14-523000) (Continued)

Catalog #	Description	Qty
14-523008	8.0mm Trial	1
14-523010	10mm Trial	1
14-523012	12mm Trial	1
14-523014	14mm Trial	1
14-523016	16mm Trial	1
14-523020	Quick Connect Handle	2
14-523024	25° Plate Holder	1
14-523026	60° Plate Holder	1
14-523035	2.4mm x 5.0mm Drill*	2
14-523037	2.4mm x 7.0mm Drill*	2
14-523039	2.4mm x 9.0mm Drill*	2
14-523041	2.4mm x 11mm Drill*	2
14-523056	2.0mm Standard Awl	1
14-523060	Screw Driver	2
14-523070	Plate Bender	2

\* Single Use Only Item

## Indications for Use

The Gallery™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Gallery™ Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

### Contraindications

The Gallery™ Laminoplasty Fixation System is not to be used:

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

### Other standard contraindications include:

1. Spinal infection or inflammation
2. Morbid obesity
3. Mental illness, alcoholism, or drug abuse
4. Pregnancy
5. Metal sensitivity/foreign body sensitivity
6. Patients with inadequate tissue coverage over the operative site
7. Open wounds local to the operative area
8. Rapid joint disease, bone absorption, osteopenia and/or osteoporosis.

Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or intolerance.

### Warnings

1. This device is not approved for screw attachments to the posterior elements of the lumbar spine.
2. Allograft must always be used with the Gallery™ Laminoplasty Fixation System plates.
3. Selection of Implants. Selection of proper size, shape and design of the implant increase 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 and Loading. These devices are not designed to withstand the unsupported stress of full weight bearing and/or load bearing, and cannot withstand activity levels and/or loads equal to those placed on normal healthy bones. If healing is delayed or does not occur, the implant could eventually 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, which could enhance fatigue fracture of the implants. Therefore, only use like or compatible metals with implants that are in contact with each other.
6. The Gallery™ Laminoplasty Fixation System has not been evaluated for safety and compatibility in the MR environment. The Gallery™ Laminoplasty Fixation System has not been tested for heating or migration in the MR environment.

### For further information on:

Precautions

Adverse Effects

Please refer to Gallery™ Laminoplasty Fixation System package insert.

## ***Sterilization***

Components provided nonsterile must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

### **U.S. Sterilization Parameters:**

Cycle: High Vacuum

Temperature: 270°F/132°C

Time: 4 minutes

Drying Time: 30 minutes

**NOTE:** Allow for cooling

### **Sterilization Parameters For Use Outside of the U.S.:**

Cycle: Pre-vacuum Steam

Temperature: 275°F/135°C

Time: 3 minutes

Drying Time: 30 minutes

**NOTE:** Allow for cooling

FDA cleared sterilization wraps should be used to maintain sterility after processing.

Biomet does not recommend stacking of trays during the sterilization process.

Individuals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

Any sterile packed products are sterilized by exposure to a minimum dose of 25-kGy gamma radiation. These components are for single use only and cannot be reused. Do not use if package has been compromised.

## ***Further Information***

For further information, please contact the Customer Service Department at:

Biomet Spine

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Parsippany, NJ 07054

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[www.biomet.com](http://www.biomet.com)











At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

### **Gallery™ Laminoplasty Spine System**

A smart, simple to use system with intuitive design features.

To learn more about this product, contact your local Biomet Sales Representative today.

**BIOMET®**

SPINE & BONE HEALING  
TECHNOLOGIES

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