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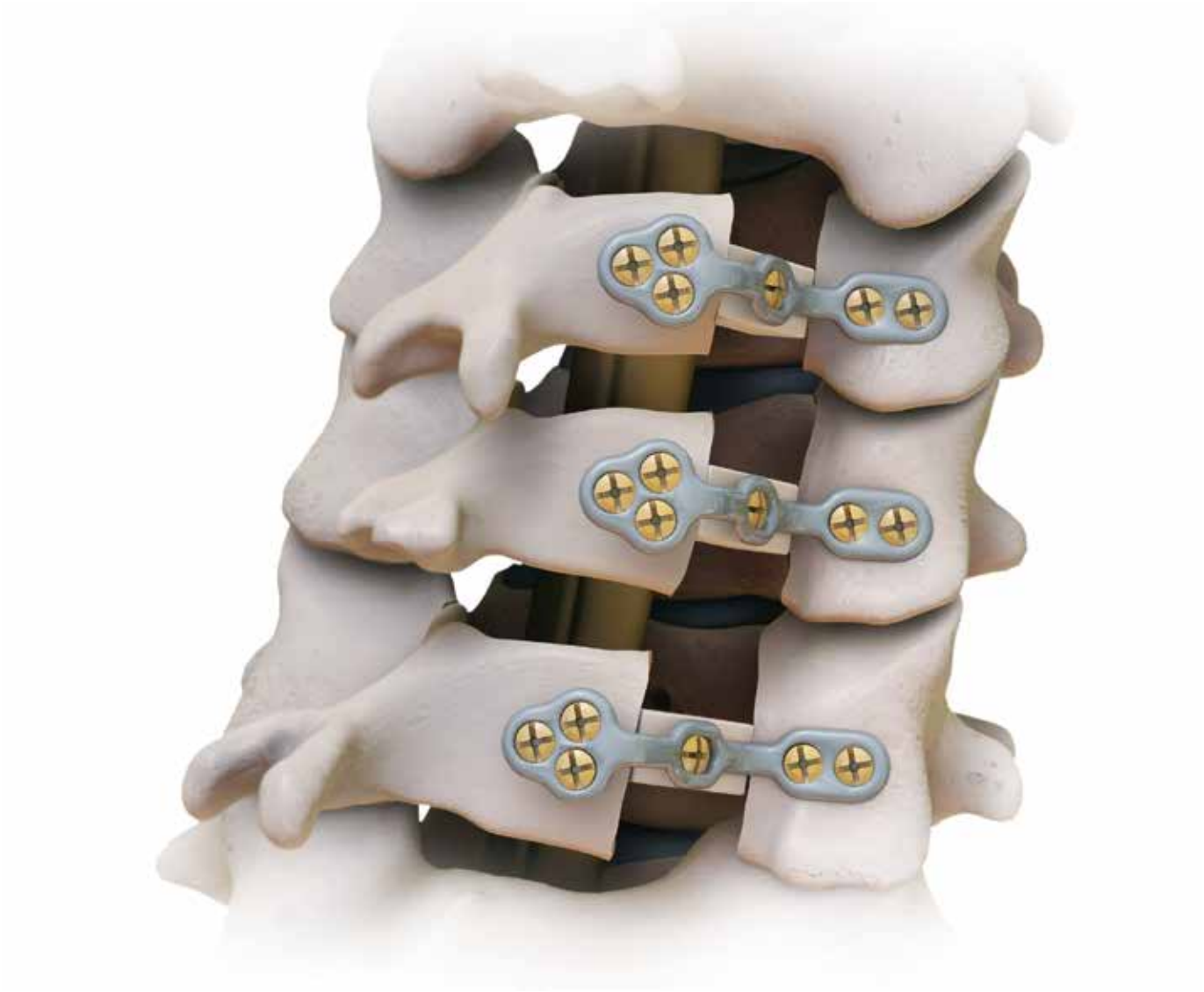

Thoracolumbar Solutions

Gallery™
Laminoplasty Spine System

Surgical Technique Guide

A smart, simple approach to instrumented laminoplasty procedures.

TABLE OF CONTENTS

Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

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.

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.

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.

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.

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.

SURGICAL TECHNIQUE

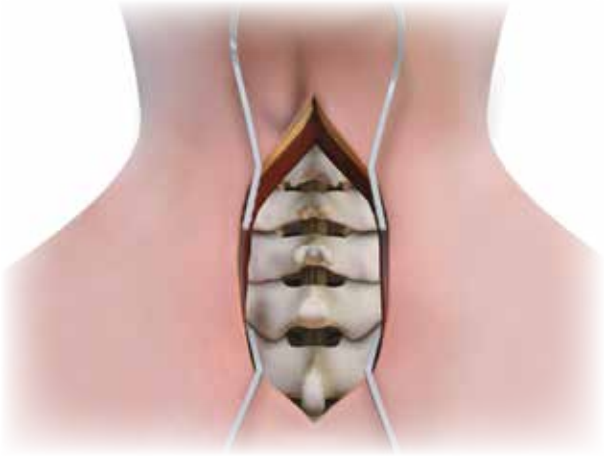

Figure 1
Exposure

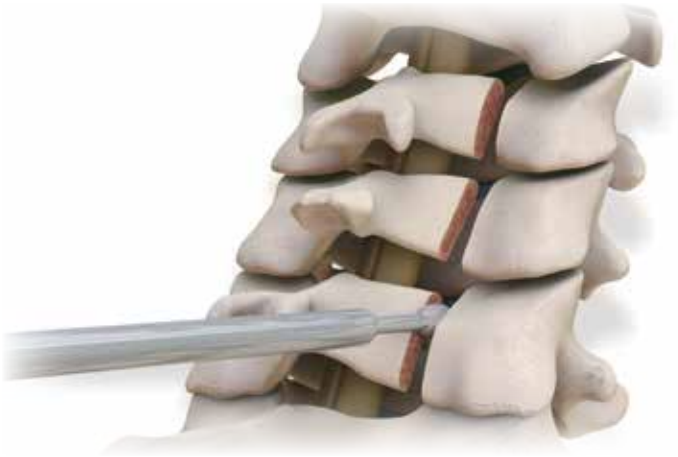

Figure 2
Creating the open side

STEP 1

The patient is placed prone, with the neck in neutral alignment. A standard midline approach is used to provide access to the surgical site (Figure 1). 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 2

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 (Figure 2).

Figure 3
Hinge side

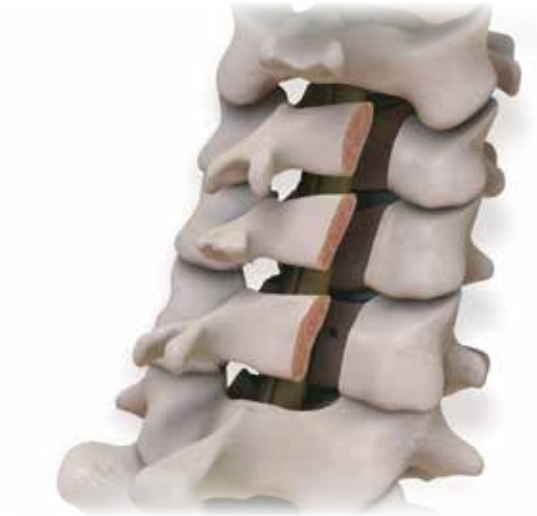

Figure 4
Opening the lamina

STEP 3

Creating the Hinge Side

- The contralateral side is prepared in a similar manner through the dorsal cortex at the lateral mass/laminar junction (Figure 3).
- 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.

STEP 4

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 (Figure 4).

Figure 5
Trial insertion

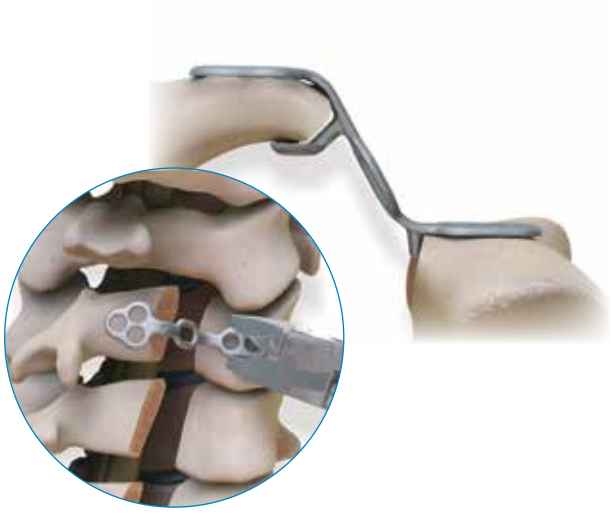

Figure 6
Plate trialing

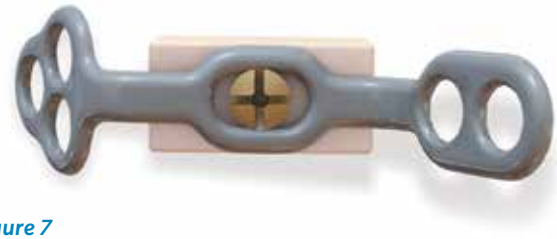

Figure 7
Allograft attachment

STEP 5

Allograft Trialing

- Trials are available in 8-16 mm heights in 2.0 mm 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 (Figure 5).

STEP 6

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 (Figure 6).
- Both self-drilling and self-tapping screws are available to fixate the allograft to the plate. Attach the quick connect handle to the screwdriver shaft.
- Seat the tip of the screw inserter in the cruciate of the desired 2.4 mm 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 (Figure 7).

Figure 8
Plate and graft placement

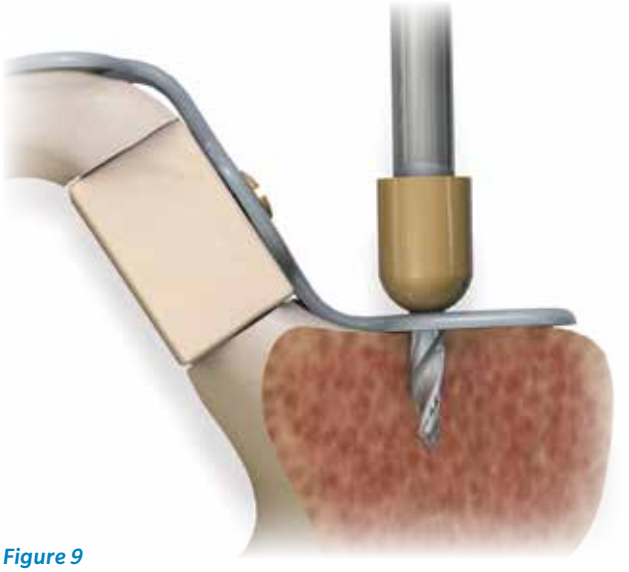

Figure 9
Screw hole preparation

STEP 7

Plate and Graft Placement

- Attach the plate holder to the graft and plate assembly and introduce the implant to the surgical site (Figure 8).
- 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 2.0 mm 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 (Figure 9).
- 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.

Figure 10
Screw insertion

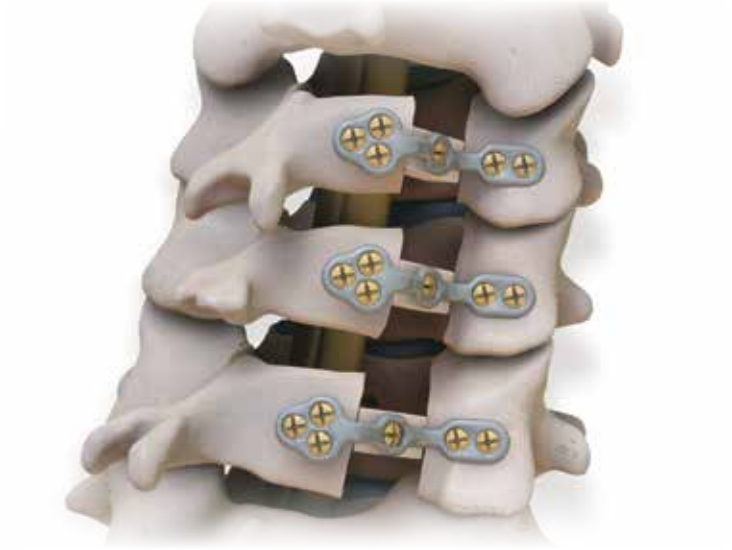

Figure 11
Final construct

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 screwdriver 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 (Figure 10). 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 (Figure 11).

REMOVING THE GALLERY IMPLANT

Removal Instructions

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

KIT CONTENTS

Gallery Implants and Instruments
Kit Number: 14-523000

DESCRIPTION	PART NUMBER
8.0 mm Standard Plate	14-523208
10 mm Standard Plate	14-523210
12 mm Standard Plate	14-523212
14 mm Standard Plate	14-523214
16 mm Standard Plate	14-523216
8.0 mm Plate with Hook	14-523228
10 mm Plate with Hook	14-523230
12 mm Plate with Hook	14-523232
14 mm Plate with Hook	14-523234
16 mm Plate with Hook	14-523236
ø2.4 mm x 5.0 mm Self-tapping Screw	14-523080
ø2.4 mm x 7.0 mm Self-tapping Screw	14-523081
ø2.4 mm x 9.0 mm Self-tapping Screw	14-523082
ø2.4 mm x 11 mm Self-tapping Screw	14-523083
ø2.8 mm x 5.0 mm Self-tapping Screw	14-523085
ø2.8 mm x 7.0 mm Self-tapping Screw	14-523086
ø2.8 mm x 9.0 mm Self-tapping Screw	14-523087
ø2.8 mm x 11 mm Self-tapping Screw	14-523088
ø2.4 mm x 5.0 mm Self-drilling Screw	14-523095
ø2.4 mm x 7.0 mm Self-drilling Screw	14-523096
ø2.4 mm x 9.0 mm Self-drilling Screw	14-523097
ø2.4 mm x 11 mm Self-drilling Screw	14-523098
ø2.8 mm x 5.0 mm Self-drilling Screw	14-523100
ø2.8 mm x 7.0 mm Self-drilling Screw	14-523101
ø2.8 mm x 9.0 mm Self-drilling Screw	14-523102
ø2.8 mm x 11 mm Self-drilling Screw	14-523103
ø2.4 mm x 5.0 mm Drill*	14-523035
ø2.4 mm x 7.0 mm Drill*	14-523037
ø2.4 mm x 9.0 mm Drill*	14-523039
ø2.4 mm x 11 mm Drill*	14-523041
Awl	14-523056
Plate Holder, 25°	14-523024
Plate Holder, 60°	14-523026
Plate Bender	14-523070
8.0 mm Trial	14-523008
10 mm Trial	14-523010
12 mm Trial	14-523012
14 mm Trial	14-523014
16 mm Trial	14-523016
Quick Connect Handle	14-523020
Screwdriver	14-523060

GALLERY IMPLANTS

Standard Plate *Side View of Standard Plate*

Plate with Hook *Side View of Plate with Hook*

Standard Plate	PART NUMBER
8.0 mm Standard Plate	14-523208
10 mm Standard Plate	14-523210
12 mm Standard Plate	14-523212
14 mm Standard Plate	14-523214
16 mm Standard Plate	14-523216

Plates with Hook	PART NUMBER
8.0 mm Plate with Hook	14-523228
10 mm Plate with Hook	14-523230
12 mm Plate with Hook	14-523232
14 mm Plate with Hook	14-523234
16 mm Plate with Hook	14-523236

Self-drilling Screws

ø2.4mm Self-drilling Screws	PART NUMBER
ø2.4 mm x 5.0 mm Self-drilling Screw, Green	14-523095
ø2.4 mm x 7.0 mm Self-drilling Screw, Gold	14-523096
ø2.4 mm x 9.0 mm Self-drilling Screw, Lt Blue	14-523097
ø2.4 mm x 11 mm Self-drilling Screw, Dk Magenta	14-523098

ø2.8mm Self-drilling Screws	PART NUMBER
ø2.8 mm x 5.0 mm Self-drilling Screw, Green	14-523100
ø2.8 mm x 7.0 mm Self-drilling Screw, Gold	14-523101
ø2.8 mm x 9.0 mm Self-drilling Screw, Lt Blue	14-523102
ø2.8 mm x 11 mm Self-drilling Screw, Dk Magenta	14-523103

Self-tapping Screws

ø2.4mm Self-tapping Screws	PART NUMBER
ø2.4 mm x 5.0 mm Self-tapping Screw, Green	14-523080
ø2.4 mm x 7.0 mm Self-tapping Screw, Gold	14-523081
ø2.4 mm x 9.0 mm Self-tapping Screw, Lt Blue	14-523082
ø2.4 mm x 11 mm Self-tapping Screw, Dk Magenta	14-523083

ø2.8mm Self-tapping Screws	PART NUMBER
ø2.8 mm x 5.0 mm Self-tapping Screw, Green	14-523085
ø2.8 mm x 7.0 mm Self-tapping Screw, Gold	14-523086
ø2.8 mm x 9.0 mm Self-tapping Screw, Lt Blue	14-523087
ø2.8 mm x 11 mm Self-tapping Screw, Dk Magenta	14-523088

GALLERY INSTRUMENTS

Drills	PART NUMBER
ø2.4 mm x 5.0 mm Drill*	14-523035
ø2.4 mm x 7.0 mm Drill*	14-523037
ø2.4 mm x 9.0 mm Drill*	14-523039
ø2.4 mm x 11.0 mm Drill*	14-523041

Awl	PART NUMBER
	14-523056

Trials	PART NUMBER
8.0 mm Trial	14-523008
10 mm Trial	14-523010
12 mm Trial	14-523012
14 mm Trial	14-523014
16 mm Trial	14-523016

**Single use only item.*

Plate Holder	PART NUMBER
Plate Holder, 25°	14-523024
Plate Holder, 60°	14-523026

Plate Bender	PART NUMBER
	14-523070

Quick Connect Handle	PART NUMBER
	14-523020

Screwdriver	PART NUMBER
	14-523060

IMPORTANT INFORMATION ON THE GALLERY LAMINOPLASTY FIXATION SYSTEM

Device Description

The Gallery Laminoplasty Fixation System is a plate and screw system fabricated from titanium alloy (Ti-6Al-4V ELI) and CP Titanium. Various instruments are available to facilitate implantation of the device. The aims of the Gallery Laminoplasty Fixation System are to maintain an expanded spinal canal, secure stability of the lamina, and help preserve the protective function of the spine after a laminoplasty has been performed. The Gallery Laminoplasty Fixation System plates are available in different designs, sizes, and bends to allow for different patient anatomy. Plate lengths correspond with allograft lengths.

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:

- For screw attachment or fixation to the posterior elements of the lumbar spine
- For single-level 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 site.

Other Standard Contraindications Include:

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

Warnings

- This device is not approved for screw attachments to the posterior elements of the lumbar spine.
- Allograft must always be used with the Gallery Laminoplasty Fixation System plates.
- 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.
- 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.
- 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.
- 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.

IMPORTANT INFORMATION *(continued)*

Precautions

- Single Use Only. Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.
- Handling of Implants. Titanium implants are to be handled with care. If contouring of the plate is required, avoid sharp bends and reverse or repetitive bends. Avoid notching or scratching of the device, which could produce internal stresses and lead to early breakage. Avoid bending across the screw holes.
- Implant Removal After Healing. After healing is complete, the implant may be removed since it is no longer necessary. Implants that are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone, particularly in young, active patients. Implant removal should be followed by adequate postoperative management.
- Adequate Patient Instructions. A patient must be instructed on the limitations of the metallic implant, and should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.

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.
- Zimmer 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.

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.*

CE 0086

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