Distributor Name -

Distributor Address -

Phone Number:

Fax:

Distributor Email Address:

After Hours Phone Number:

Operation Date:

Instruments /Procedure

Implant System:

Manufactured by:
Orthofix
3451 Plano Parkway
Lewisville, TX 75056
www.orthofix.com

Surgeon:

Hospital:

Patient:

Implant Label

Catalog Number	Lot#	Item Name	Single Use Item	QTY	HOSP IN	HOSP OUT

CSSD Count _____ Date _____

NewBridge® Laminoplasty Fixation System

Interlaminal Fixation Appliance

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the Newbridge® Laminoplasty Fixation System were implanted in your body. Because of this, you must be aware of the following information.

GENERAL INFORMATION

Name and model of the device

Newbridge® Laminoplasty Fixation System.

The NewBridge Laminoplasty Fixation System is a device comprised of non-sterile, single use, titanium and titanium alloy components. The specially shaped plates, made of commercially pure (CP) titanium conforming to ASTM F67, are designed to fit the anatomy of a dorsally elevated lamina. The plates have screw holes on both ends, which allow for attachment to the vertebral body, and a screw hole in the center for attachment to the allograft.

The screws, made of titanium alloy (Ti6Al4V ELI, per ASTM F136), are available in a variety of lengths and diameters in order to meet individual anatomical requirements.

The NewBridge Laminoplasty Fixation System must always be used with an allograft.

What is the device for?

The NewBridge Laminoplasty Fixation System devices used in your recent spinal surgery are metallic implants that attach to the bone and aid in the healing of bone grafts after a laminoplasty has been performed.

Kind of patient on whom the device is intended to be used

Patients with congenital or acquired stenosis involving multiple levels from C3 to T3. Candidates for laminoplasty should not have significant instability or kyphosis. The NewBridge Laminoplasty Fixation System is contraindicated for use in patients with loss of anterior column support resulting from tumor, trauma, or infection.

Special operating instructions for the use of the device

There are no special operating instructions for the patient.

Intended performance of the device

The NewBridge Laminoplasty Fixation System is indicated for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The system holds or buttresses the allograft in place in order to prevent expulsion of the allograft or impingement of the spinal cord.

Side Effects

Potential adverse events include, but are not limited to:

1. Failure of the device to provide adequate mechanical stability.
2. Loss of fixation of the implant.
3. Device component failure.
4. Migration or bending of the device.
5. Immunogenic response to the implant materials.
6. Nerve damage that may occur as a result of surgical trauma.

Note: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, permanent pain and/or deformity.

Risks that can remain despite preventive measures

Refer to Side Effects.

Warnings about risks that may arise from the use of the device

The safety and effectiveness of the NewBridge Laminoplasty Fixation System has not been established when implanted in the anterior spinal column.

Safety information regarding MRI (Magnetic Resonance Imaging):

The NewBridge Laminoplasty Fixation 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 Newbridge Laminoplasty Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions and other measures to be taken by the patient or a health professional

- Potential risks identified with the use of the devices in this system, which may require additional surgery, include: failure of the device to provide adequate mechanical stability, loss of fixation of the implant, device component failure, migration or bending of the device, immunogenic response to the implant materials, and nerve damage that may occur as a result of surgical trauma.
- As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, permanent pain and/or deformity.
- The NewBridge Laminoplasty Fixation System, as with other metallic orthopedic appliances, is contraindicated for use in patients with active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection. The device is also contraindicated for use in patients with known or suspected metal allergies.
- The safety and effectiveness of the NewBridge Laminoplasty Fixation System has not been established when implanted in the anterior spinal column.
- Any adverse or unexpected effects should be reported to your primary surgeon.

Regular exams, checks and/or care of the device

The requirement for routine follow-up after implantation is determined by your primary surgeon. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components.

Symptoms that could indicate that the device is not functioning as it should

Some symptoms may indicate that the device is not functioning as it should. These include, but are not limited to: failure of the device to provide adequate mechanical stability, loss of fixation of the implant, device component failure, migration or bending of the device, immunogenic response to the implant materials, and nerve damage that may occur as a result of surgical trauma.

These symptoms and any other adverse or unexpected effects should be reported to your primary surgeon for assessment.

What to do if you suspect the device is malfunctioning

If you have any of the symptoms described above, contact your primary surgeon. If he/she is not available, contact a trained surgeon. Please seek medical assessment if a surgeon is not available.

Expected lifecycle of the device, what influences it, and precautions to take

These implants are temporary internal fixation devices. Internal fixation devices are designed to assist in the stabilization of the operative site during the normal healing process. The duration of treatment required is dependent on a variety of factors, and should be determined by your primary surgeon. Adherence to the instructions provided in the section titled, “Precautions and other measures to be taken by the patient or a health professional” will increase the likelihood of successful results and reduce your risk of injury and/or the need for additional surgery. After healing occurs, these devices serve no functional purpose and should be removed. In most cases removal is indicated because the implants are not intended to transfer or support forces developed during normal activities.

Other cases in which the patient should contact a health professional in relation to the device

Refer to Symptoms

Materials and substances included in the device

Newbridge Laminoplasty Fixation System implants are made of 6AL-4V ELI Titanium Alloy per ASTM F136 and commercially pure titanium conforming to ASTM F67.

Any residues from production that could put the patient at risk

Newbridge Laminoplasty Fixation System implants have been evaluated for the presence of manufacturing residuals that could pose a risk to the patient. These evaluations determined that there are no residual materials present at toxic levels on finished devices. It is known that the production process may introduce residues, contaminants, and additives with potential toxicity. All Newbridge Laminoplasty Fixation System implants undergo validated cleaning processes at multiple points in the manufacturing process to reduce the presence of residual materials below the level of concern.

Important note:

Please report any serious problem with the Newbridge Laminoplasty Fixation System. You must contact Orthofix and the Therapeutic Goods Administration.

Orthofix

3451 Plano Parkway, Lewisville, TX 75056, USA
Tel: 1-214-937-3199 or 1-888-298-5700
Email: complaints@orthofix.com

Therapeutic Goods Administration:

https://www.tga.gov.au

(Please click on “Consumers”, then click on button “Report a problem or side effect” and then follow the instructions reported in “I want to report a problem with a medical device (adverse event)” section.)