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 _____

NGage® Surgical Mesh System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the NGage® Surgical Mesh 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

NGage® Surgical Mesh System.

The NGage Surgical Mesh System is a diamond pattern, surgical mesh device. The body is manufactured from commercially pure (CP) titanium conforming to ASTM F67, the end rings, the standard ring, and the screws are manufactured from titanium alloy that conforms to ASTM F136. Because of the construction, the angle and the length of the mesh can be reduced incrementally to adjust it to individual anatomical conditions. The system is sold non-sterile.

What is the device for?

The NGage Surgical Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

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

The NGage Surgical Mesh System is intended to restore biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period in skeletally mature patients with fracture or tumor of the vertebral body.

Special operating instructions for the use of the device

There are no special operating instructions for the patient.

Intended performance of the device

The NGage Surgical Mesh System is indicated for use in the thoraco-lumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The NGage Surgical Mesh System is also indicated for treating fractures of the thoracic and lumbar spine.

The NGage Surgical Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. It is recommended to pack bone graft material inside the mesh cage prior to implantation.

The NGage Surgical Mesh System is intended for use with supplemental fixation. As an example, the supplemental fixation system that may be used with the system is the Orthofix Spinal Fixation System.

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. Loss of bony alignment.
6. Non-union.
7. Fracture of bony structures.
8. Resorption without incorporation of any bone graft utilized.
9. Immunogenic response to the implant materials.

Note: As with any 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, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, and permanent pain and/or deformity. Rarely, some complications may be fatal.

Risks that can remain despite preventive measures

Refer to Side Effects.

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

The size and shape of human bones present limiting restrictions on the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing. Use caution to limit weight bearing and body stress on the device to secure bone healing.

Safety information regarding MRI (Magnetic Resonance Imaging):

The NGage Surgical Mesh 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 NGage Surgical Mesh 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, loss of bony alignment, non-union, fracture of bony structures, resorption without incorporation of any bony graft utilized, and immunogenic response to the implant materials.
- As with any 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, spinal cord or

peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, and permanent pain and/or deformity. Rarely, some complications may be fatal.

- The NGage Surgical Mesh 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.
- 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, loss of bony alignment, non-union, fracture of bony structures, resorption without incorporation of any bony graft utilized, and immunogenic response to the implant materials.

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

The functional lifetime of the NGage Surgical Mesh System implants is defined as two years or until fusion is expected to occur. 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.

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

NGage Surgical Mesh System implants are made of 6AL-4V ELI Titanium Alloy per ASTM F136.

Any residues from production that could put the patient at risk

NGage Surgical Mesh 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 NGage Surgical Mesh 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 NGage Surgical Mesh 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.)