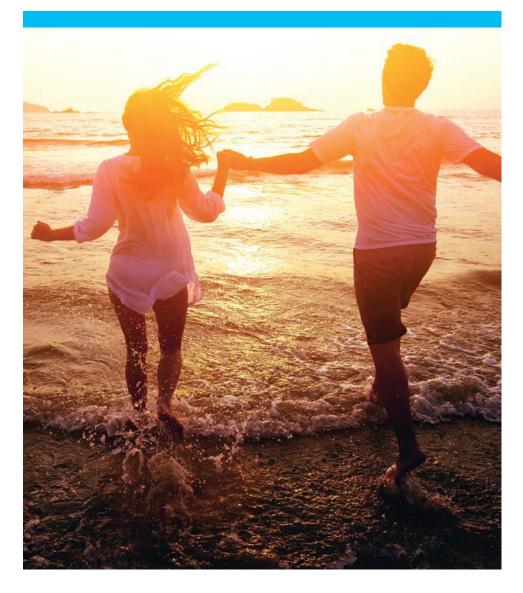
### PATIENT INFORMATION



# POSTERIOR CERVICAL

FIXATIO





Outside the US Only

# Posterior Cervical Fixation

### Patient Information

This brochure will help you understand more about:

- Anatomy of the spine
- Common conditions of the cervical spine
- Posterior cervical fixation surgery

The decision to receive medical treatment is individualized to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment, or outcome, as surgical techniques vary and complications can occur. It is important to discuss the viability of this procedure with your physician to decide whether this treatment option is right for you.

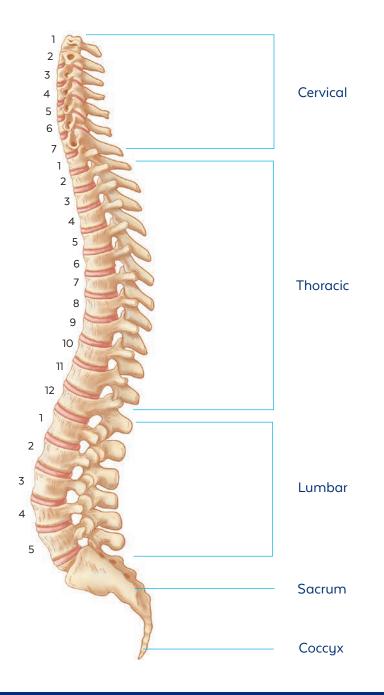
This brochure is intended to be an educational resource only and is not meant to be a warranty or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results and other important medical information that pertains to this procedure.



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# Anatomy of the Spine

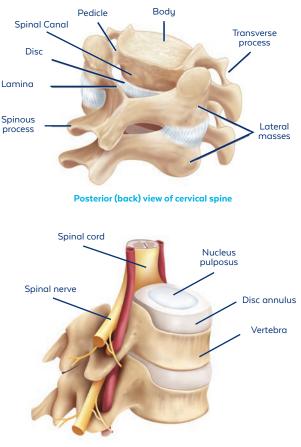


The spine is composed of vertebrae (bones) and is divided into three main parts:

- Cervical (7 vertebrae)
- Thoracic (12 vertebrae)
- Lumbar (5 vertebrae)

The vertebrae bear the weight of the upper body and provide points of attachment for muscles and ligaments. They also protect the spinal canal (the cavity that runs through each vertebra and contains the spinal cord) and provide exit points for spinal nerves.

The individual vertebrae are separated by intervertebral discs that act as cushions or shock absorbers between the vertebral bodies.



Anterior (front) view of cervical spine

### Conditions of the Cervical Spine

In the normal spine, intervertebral discs act as a cushion between vertebrae. Age, genetics, injury, and daily wear and tear can contribute to damage and deterioration in your spine. As a result, someone may experience one or more of the following conditions in their neck.

#### **Degenerative Disc Disease**

Over time, the discs in your neck can lose flexibility, elasticity, and height. When this happens, this discs' shock-absorbing characteristics can be reduced, which can lead to abnormal motion or alignment and instability of the spine.

#### **Herniated Disc**

Degeneration can cause cracks and tears in the outer layer of the disc where material inside the disc can be forced out, causing the disc to bulge or herniate (protrusion), break open (extrusion), or break into pieces (sequestration), putting pressure on a nerve root or the spinal cord.

### Myelopathy

Myelopathy is a condition that can result from compression on the spinal cord.

### **Spinal Stenosis**

Spinal stenosis is the narrowing of areas in the spine that cover and protect the nerve roots and the spinal cord. This can be caused by herniated discs, osteophytes (bony projections), or ligaments compressing the spinal cord.

### Trauma

Traumatic events such as car accidents, sports injuries, and other serious incidents can cause injury to the spine, including fractures and dislocations.

#### **Spinal Instability**

Spinal instability is a condition that occurs when stabilizing structures of the spine become compromised by disease, age, or damage. Several factors can lead to spinal instability, including degeneration or trauma.

#### Pseudarthrosis

Pseudarthrosis refers to failed previous fusion.

#### **Spinal Deformity**

Spinal deformity is an abnormal curvature to the spine. The type of deformity depends on the curvature.

- Scoliosis abnormal sideways curve
- Kyphosis abnormal outwards curve that may create the appearance of a hunch back
- Lordosis abnormal inward curve

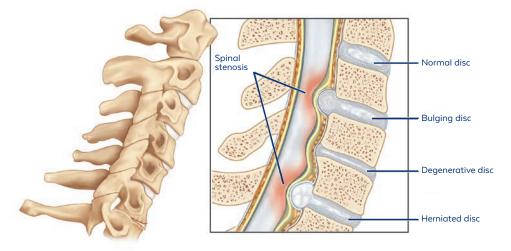
Symptoms of these conditions include:

- Loss of motion and dexterity, gait imbalance, and incontinence
- Tingling or numbness in the arms or hands
- Radiating pain, weakness, and/or numbness in the shoulders, arm, and/or neck

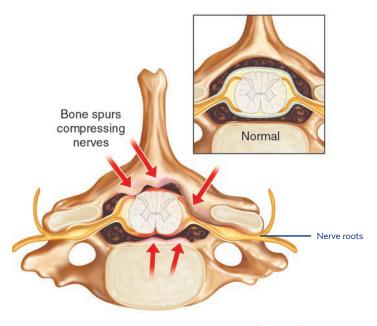
These symptoms may be treated with non-surgical methods for as long as possible. These treatments include rest, ice or heat, weight control, exercise, physical therapy, epidural injections for pain management, and medication.

If these non-surgical treatments do not bring relief after a period of time, surgical treatments may be recommended to take pressure off the nerves that are causing pain by restoring alignment of the spine and/or the space between the vertebrae.

# Conditions of the Cervical Spine (Cont'd)



Narrowing of cervical spine canal due to disc herniation (spinal stenosis)



Narrowing of cervical spine canal due to osteophyte (bone spur)

### What is Posterior Cervical Fixation?

The goal of posterior cervical fixation is to stabilize the spine and help relieve pressure on the spinal cord and the nerve roots, often by removing some or all of the bone causing compression. Posterior cervical fixation can also be used to support fusion (joining of two bones), to prevent motion.



### How is Posterior Cervical Fixation Performed?

During surgery, the patient lies face down. A vertical incision(surgical cut) is made in the posterior (back) of the neck, usually along the midline (middle of the neck). The incision size depends on the number of vertebrae being treated.

The soft tissues and muscles of the neck are gently separated and lifted off the spine to access to the surgical site.

Surgical instruments are used to remove all or part of the bone surrounding the spinal canal and decompress (relieve pressure on) the nerve structures. This may include the removal of the lamina (a thin part of the bone that encloses the back of the spinal canal) as well as the removal of bone spurs where nerve roots exit the spinal canal, depending on the source of the compression.

### Screw and Rod Fixation

Screws and rods are used to hold the spinal column in place while fusion may occur. The surgeon uses medical imaging (such as X-rays) to determine the screw location. The screws are inserted into the left and right sides of the vertebrae to be treated. A rod connects the screws to stabilize the spine on each side. Caps secure each rod to the screws. Bone graft may be added along the sides of the vertebrae to help with fusion.

Bone graft may be harvested from the patient's own bone or may come from donated tissue. Once the surgery is complete, the surgeon closes the incision and moves the patient into recovery.

Over time, the vertebrae can grow together through fusion. Complete fusion varies among patients and can take a few months to a year.

### **Occipital Fixation**

In some instances, a surgeon may need to treat instability between the occiput (base of the skull) and neck by using a plate and screws to extend the construct. The plate is held onto the skull while screws are inserted through the plate and into the occipital bone. Two rods are used to connect the occipital plate to the screws in the cervical spine. Caps secure each rod to the screws. Once the surgery is complete, the surgeon closes the incision and moves the patient to recovery. Occipital fixation can result in a limited range of motion for the head and neck.







Globus Medical offers a variety of implants for posterior cervical fixation.

#### Implant Type

Occipito-Cervico-Thoracic Spinal Systems (screws, rods, caps, and connectors)

#### Implant Name\*

ELLIPSE<sup>®</sup>/CAPITOL<sup>®</sup> PROTEX<sup>®</sup> CT QUARTEX<sup>®</sup>

#### Spine Conditions\*\*

Degenerative disc disease, spondylolisthesis, fracture, dislocation, spinal stenosis, spinal instability, spinal tumor, pseudarthrosis



Visit Globus Medical's website at https://www.globusmedical.com/international/ \*These products may not be available in your region.

\*\*See definitions starting on page 6.

These implants are composed of titanium or titanium alloys, stainless steel, and/or cobalt chromium molybdenum alloy. These materials are biocompatible and have a history of clinical use. If you have an allergy to any of these materials, please consult your physician.

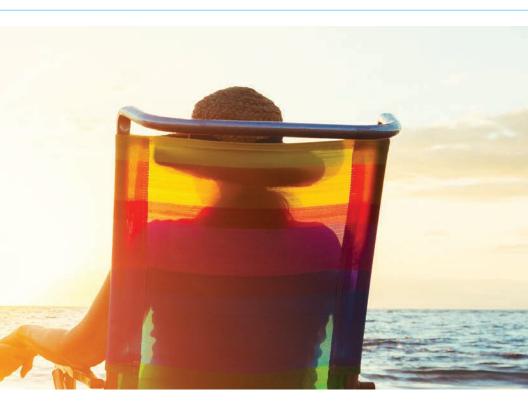


### Frequently Asked Questions

### What should I expect with my recovery?

Many patients notice improvement of some or all of their symptoms, and pain may diminish a few weeks after surgery. However, recovery time varies among patients.

Typically, it is the surgeon's goal for the patient to eventually return to their preoperative activities. A positive attitude, reasonable expectations, and compliance with your doctor's post-surgery instructions may all contribute to a satisfactory outcome.



### How long will my implant last?

The device lifetime for these implants is one year, in which it is expected that the devices will achieve their intended purpose (stabilize and support fusion) and maintain performance until fusion occurs. After fusion occurs, the devices are made to survive the life of the patient. These devices can be removed after fusion occurs; however, this is determined by the surgeon and patient.

### Can I have an MRI after the devices are implanted?

The occipito-cervico-thoracic spinal systems have not been evaluated for safety and compatibility in the MR environment. These devices have not been tested for heating or migration in the MR environment.

### Contraindications and Adverse Effects

You may be contraindicated (not suitable) for this procedure if you have an infection, congenital abnormality, rheumatoid arthritis, osteoporosis, diabetes, or cancer, or are obese, pregnant, or mentally ill. In addition, a patient whose mental or physical impairment may place an undue stress on the implant during healing may be at a higher risk of implant failure.

As with any surgical procedure, complications or adverse effects may occur following the placement of these devices. These can include but are not limited to early or late implant bending, device fracture or failure, loss of fixation or subsidence, breakage, loosening, movement/ migration, bone fracture, and allergic reaction to implant materials.

Other adverse effects that may be associated with spinal surgery procedures include pseudarthrosis, pain, secondary surgery, decrease in bone density, discomfort or abnormal sensations, organ damage, nerve damage, cardiovascular system compromise, incisional complications, bone grafting complications, presence of blood clots in veins and lungs, sexual dysfunction, impotence, scar formation, paralysis, and death

If you experience any of the above adverse effects, please contact a healthcare professional. This list does not include all possible contraindications and adverse effects. Please consult your surgeon for additional information on this topic and how it applies to your particular medical condition. If you experience a serious adverse effect in relation to the implanted device, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for convenience.

Region	Authority	Website
All	Globus Medical	https://www.globusmedical.com/ international/about/contact/
Australia	Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	https://www.medsafe.govt.nz/
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk/government/ organisations/medicines-and-healthcare- products-regulatory-agency
Other	Report to your local health authority per local guidelines	

About Globus Medical: Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.



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