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 _____

Centurion Posterior Occipital Cervico-Thoracic (POCT) System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the Centurion POCT 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

Centurion® Posterior Occipital Cervico-Thoracic (POCT) System.

The Centurion POCT System is a temporary, multiple component system comprised of a variety of non-sterile, single use components made of titanium alloy or cobalt chrome alloy that allow the surgeon to build a spinal implant construct in the region of the spine from the occiput to T3. The system consists of an assortment of rods, set screws, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, and bone screws. The specific implants used in your case are provided in the table above.

What is the device for?

The Centurion POCT System temporary internal fixation devices used in your recent spinal surgery are metallic implants that attach to the bone and aid in the healing of bone grafts. These implants are used to provide immobilization and stabilization of the craniocervical junction, the cervical spine (C1 to C7), or the thoracic spine (T1 to T3), and have been shown to be valuable aids to surgeons in the treatment of bony fusions. The fusion of two or more adjacent vertebrae in the spine is also known as spondylodesis.

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

The Centurion POCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 to T3):

1. Traumatic spinal fractures and/or traumatic dislocations;
2. Instability or deformity;
3. Failed previous fusions (e.g., pseudoarthrosis);
4. Tumors involving the cervical/thoracic spine;
5. Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.
6. The system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The Centurion POCT System can also be linked to the Orthofix Spinal Fixation System using the Axial or Parallel Rod Connector.

Special operating instructions for the use of the device

There are no special operating instructions for the patient.

Intended performance of the device

The Centurion POCT System is intended to immobilize and stabilize segments of the spine in the craniocervical junction, cervical region (C1 to C7), and thoracic region (T1 to T3). This stabilization aids the healing of bone grafts and helps facilitate the fusion of vertebrae in the stabilized anatomy.

Side Effects

All of the possible side effects associated with spinal fusion surgery are possible. A listing of possible side effects includes, but is not limited to:

- Device component fracture.
- Loss of fixation.
- Non-union.
- Fracture of the vertebra.
- Neurological injury.
- Vascular or visceral injury.
- Early or late loosening of any or all of the components.
- Disassembly and/or bending of any or all components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Hemorrhage.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

Risks that can remain despite preventive measures

Refer to Side Effects.

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

These devices do not have the capabilities of living bone. Intact living bone is self-repairing, flexible and occasionally breaks and/or degrades. The anatomy of the human body places a size limitation on any artificial fixation device used in surgery. The maximum size limitation increases the chances of the mechanical complications of loosening, bending or breaking of the devices. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation devices. Exposure of the patient or device to mechanical vibrations that may loosen the device construct should be avoided. Any of these complications could result in the need for additional surgery. Accordingly, it is very important that you follow the recommendations of your physician.

Safety information regarding MRI (Magnetic Resonance Imaging):

The Centurion POCT 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 Centurion POCT 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

- Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation devices. Any of these complications could result in the need for additional surgery. Accordingly, it is very important that you follow the recommendations of your physician. Use braces as instructed. By following these instructions, you can increase your chances of a successful result and reduce your risk of injury and/or additional surgery.
- 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.
- To allow the maximum potential for a successful surgical result, the patient or device should not be exposed to mechanical vibration that may loosen the device construct.
- 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. 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. If the device is not removed following completion of its intended use, complication may occur as follows:
    a. Corrosion, with localized tissue reaction or pain.
    b. Migration of implant position resulting in injury.
    c. Risk of injury from postoperative trauma.
    d. Bending, loosening and/or breakage, which could make removal impractical or difficult.
    e. Pain, discomfort or abnormal sensations due to the presence of the device.
    f. Possible increased risk of infection.
    g. Bone loss caused by stress shielding.

  Adequate postoperative management to avoid fracture, re-fracture, or other complications should follow implant removal.

- 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: device component fracture, loss of fixation, non-union, vascular or visceral injury, early or late loosening of any or all of the components, disassembly and/or bending of any or all the

components, pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain, post-operative change in spinal curvature, loss of correction, height, and/or reduction, infection, vertebral body fracture at, above, or below the level of surgery, neurological injury, infection, pain, discomfort, or abnormal sensations due to the presence of the device, and cessation of any potential growth of the operated portion of the spine.

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. If the device is not removed following completion of its intended use, complication may occur as follows:

a) Corrosion, with localized tissue reaction or pain.
b) Migration of implant position resulting in injury.
c) Risk of injury from postoperative trauma.
d) Bending, loosening and/or breakage, which could make removal impractical or
e) difficult.
f) Pain, discomfort or abnormal sensations due to the presence of the device.
g) Possible increased risk of infection.
h) Bone loss caused by stress shielding.

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

Centurion POCT System implants are made of 6AL-4V ELI Titanium Alloy per ASTM F136 and Cobalt Chrome per ASTM F1537.

Any residues from production that could put the patient at risk

Centurion POCT 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 Centurion POCT 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 Centurion POCT 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.)