

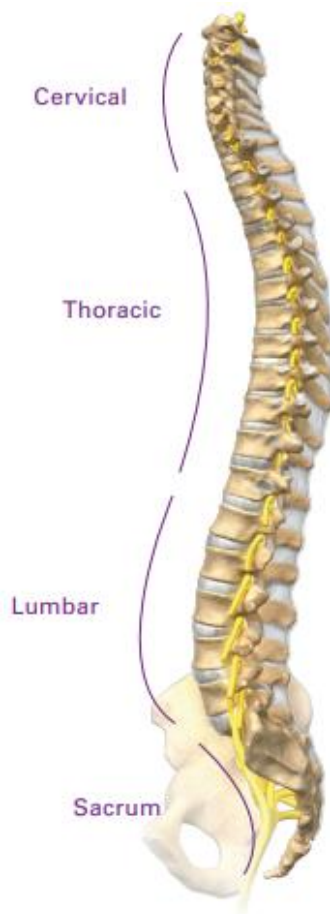
Monolith Corpectomy System Patient Information Leaflet

Device Name: Non-sterile Vertebral Body Replacement Implant

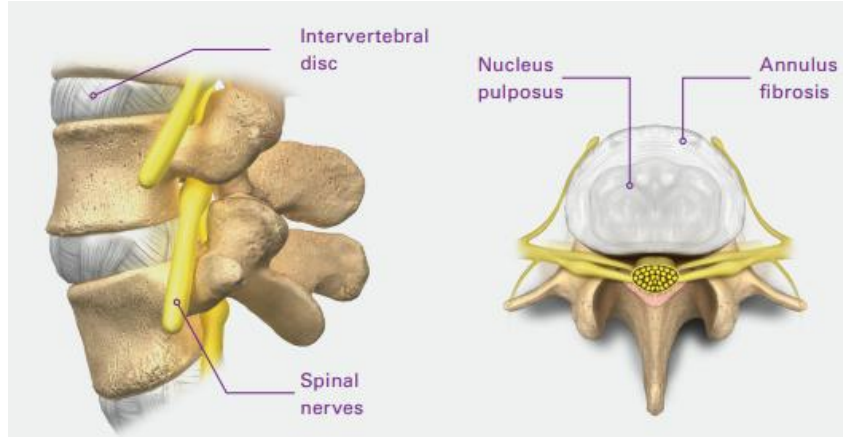
Model: NuVasive Monolith Corpectomy System

Anatomy of Spine:

The human spine is made up of 24 bones or vertebrae in the cervical (neck) spine, thoracic (chest) spine and lumbar (lower back) spine plus the sacral bones.



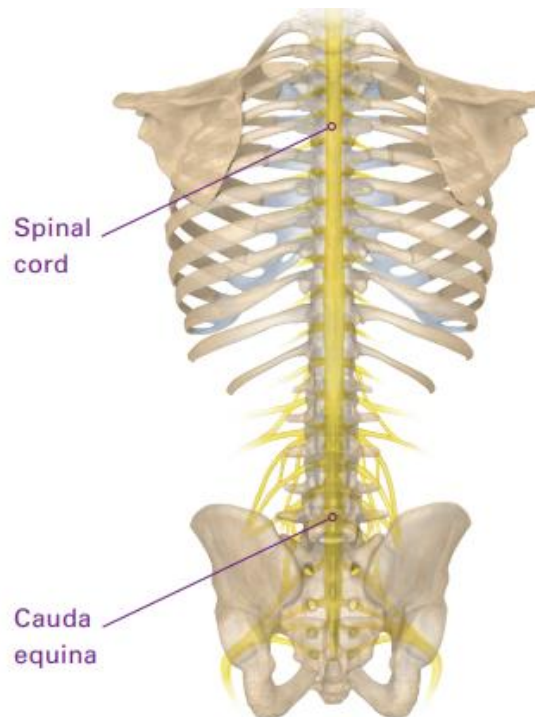
Vertebrae are connected by several joints, which allow you to bend, twist, and carry loads. The main joint between the two vertebrae is called an intervertebral disc. The disc is made of two parts, a tough and fibrous outer layer (annulus fibrosis) and a soft, gelatinous center (nucleus pulposus). These two parts work in conjunction to allow the spine to move, and also provide shock absorption.



Each vertebra has an opening (vertebral foramen) through which a tubular nervous structure travels. Beginning at the base of the brain to the upper lumbar spine, this structure is called the spinal cord.

Below the spinal cord, in the lumbar spine, the nerves that exit the spinal cord continue to travel through the vertebral foramen as a bundle known as the cauda equina.

At each level of the spine, spinal nerves exit the bony spine then extend throughout the body.



What causes pain?

There are several possible causes of spine problems. The most frequent symptoms are caused by either instability or by disc, bone, or ligaments putting pressure on (compressing) the nerve roots, spinal cord, or cauda equina.

What are treatment options?

Many symptoms can be treated without surgery including rest, heat, ice, medication, injections, and physical therapy.

If symptoms do not improve with conservative treatment, physicians may recommend spinal surgery. Surgery is reserved for those who do not gain relief from non-operative forms of treatment, patients whose symptoms are increasing or worsening, and/or patients that present with a spinal condition which indicates the need for surgery. It is important to speak with a physician about the best option.

The surgical option

Interbody fusion is a surgical technique that attempts to re-stabilize the spine. The purpose of spinal fusion implants is to provide short-term stability until new bone growth takes place. Spinal fusion typically occurs within 12 months of surgery. A component of an interbody fusion procedure is fixation. The NuVasive Monolith Corpectomy System is a vertebral body replacement device indicated for use in the cervical spine (C3-C7 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The NuVasive Monolith Corpectomy System is intended to be used with supplemental fixation for use in the cervical spine. These implants are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The NuVasive Monolith Corpectomy 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, with bone graft used at the surgeon's discretion.

Monolith Corpectomy System implants are made from PEEK-Optima LT-1 (Polyether-etherketone) and Tantalum (Ta). These materials were selected for their stability, corrosion resistance and strong mechanical properties. Long-term clinical experience of the use of these materials has shown that an acceptable level of biological response can be expected, if the materials are used in appropriate applications.





Warnings, Cautions and Precaution:

As with any surgical procedure, complications may occur following the implantation of this device. These can include but are not limited to implant bending, breakage, failure, loosening, movement/migration, bone fracture, and allergic reaction to implant material.

Other general complications associated with any spinal surgical procedure include non-union or delayed union, vertebrae fracture, pain, neurological injury, vascular injury, infection, bursitis, dural leak, paralysis, and death.

Limiting postoperative activity should reduce the risk of bent, broken or loose implant components. To ensure the earliest possible detection of device dysfunction, the devices must be checked by a surgeon periodically postoperatively, using appropriate radiographic techniques.

Monolith Corpectomy System should not be used in patients:

- With infections, local to the operative site
- With signs of local inflammation
- With known sensitivity to the materials implanted
- Who are unwilling to restrict activities or follow medical advice
- With inadequate bone stock or quality
- With physical or medical conditions that would prohibit beneficial surgical outcome

This list above does not include all possible contraindications, complications, warnings, or precautions. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

MRI Safety Information:

A patient with this device can be scanned in an MR system with the following conditions:

1. Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
2. Maximum spatial gradient field of 19 T/m (1900 G/cm).
3. Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode).

Consult your surgeon for further information related to magnetic field interference from magnetic resonance imaging devices.

Incident Reporting:

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the Therapeutic Goods Administration.



Name and Address of Manufacturer:

NuVasive, Inc.,
7475 Lusk Boulevard
San Diego, CA 92121
USA
(858) 909-1800
www.nuvasive.com

Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609
Australia
1800 141 144
www.tga.gov.au/medical-devices-ivds