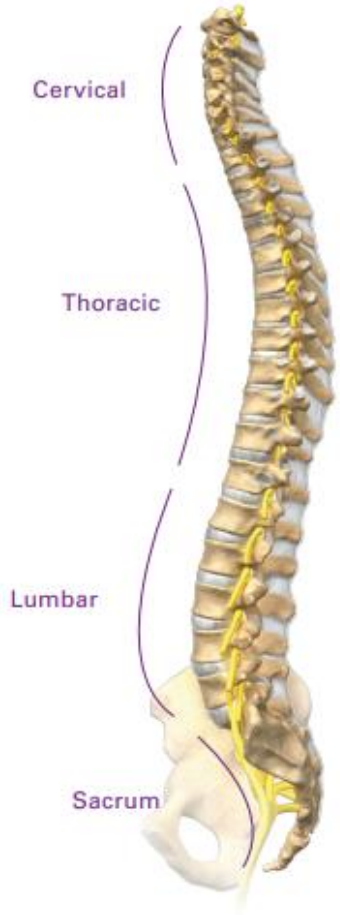
Coroent Thoracolumbar System Patient Information Leaflet

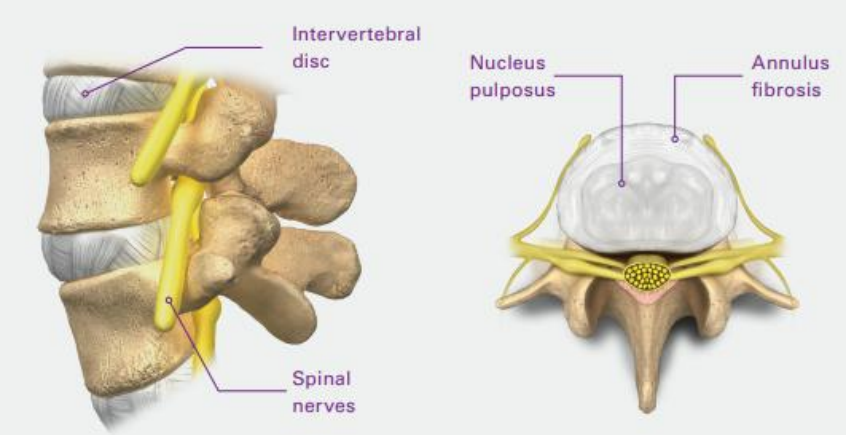
Device Name: Sterile and Non-sterile Thoracolumbar Spinal Fusion Cage

Model: NuVasive Coroent Thoracolumbar 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.



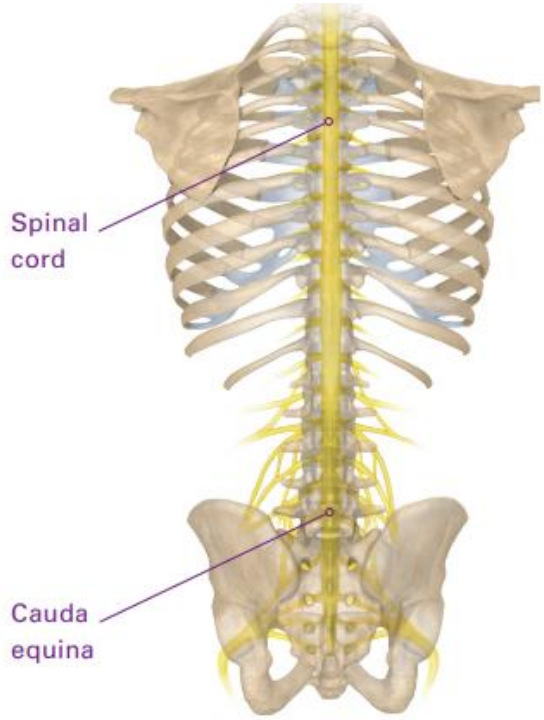
Vertebrae are connected by several joints, which allow you to bend, twist, and carry loads. The main joint between the two vertebrae is called an intervertebral disc. The disc is made of two parts, a tough and fibrous outer layer (annulus fibrosis) and a soft, gelatinous center (nucleus pulposus). These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

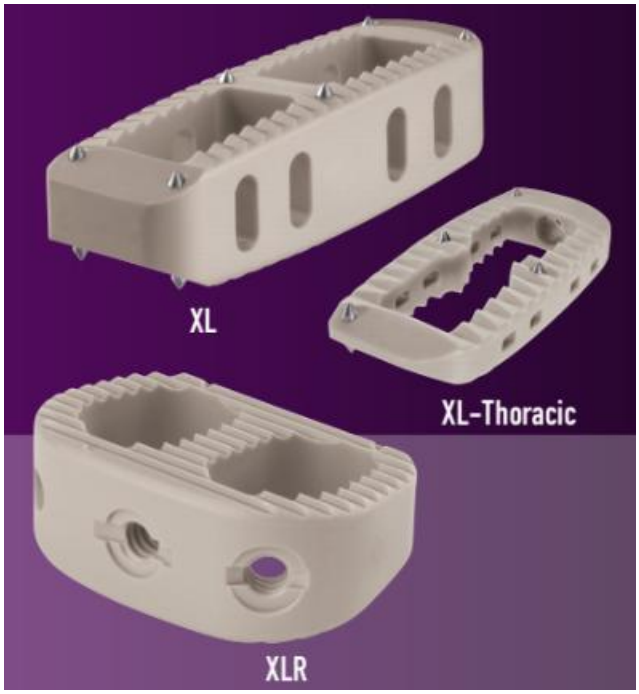
The NuVasive Coroent Thoracolumbar System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Coroent Thoracolumbar (XL platform) implants are intended for use in interbody fusions in the thoracic spine, from T1 to T12, and at the thoracolumbar junction (T12-L1), and the Coroent Thoracolumbar System (XL and L platforms) implants are intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive Coroent Thoracolumbar System (XL and L platforms) can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

The Coroent Ti-C System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. The System is intended to be used with supplemental internal spinal fixation systems for use in the lumbar spine.

The Coroent Thoracolumbar Non-Interfixated implants are manufactured of either PEEK-Optima (Polyether-ether-ketone) or Titanium. PEEK implants include radiographic markers made of Titanium (Ti) or Tantalum (Ta). Coroent Thoracolumbar Interfixated implants are made of PEEK-Optima, with a canted coil locking mechanism manufactured from Nickel-CobaltChromium-Molybdenum alloy and screws made of titanium alloy

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 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.

Coroent Thoracolumbar 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
- With prior fusion at the level(s) to be treated.

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 Coroent Thoracolumbar System implants can he scanned in a magnetic resonance system (MRI) with the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial field gradient of 2,575 G/cm (25.8 T/m).
- Whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode) or less.

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:

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