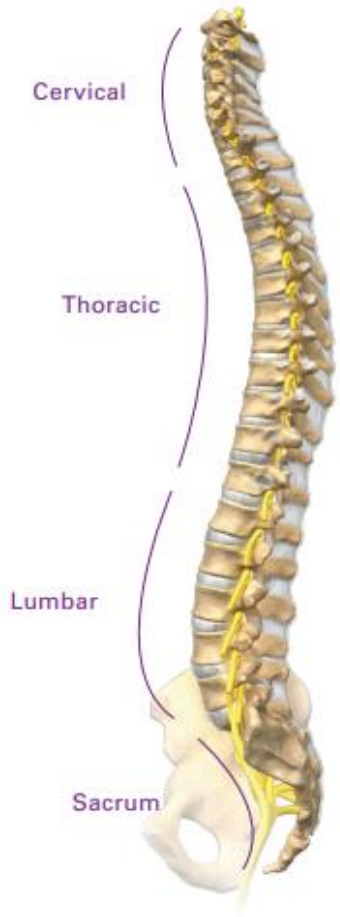
VersaTie System Patient Information Leaflet

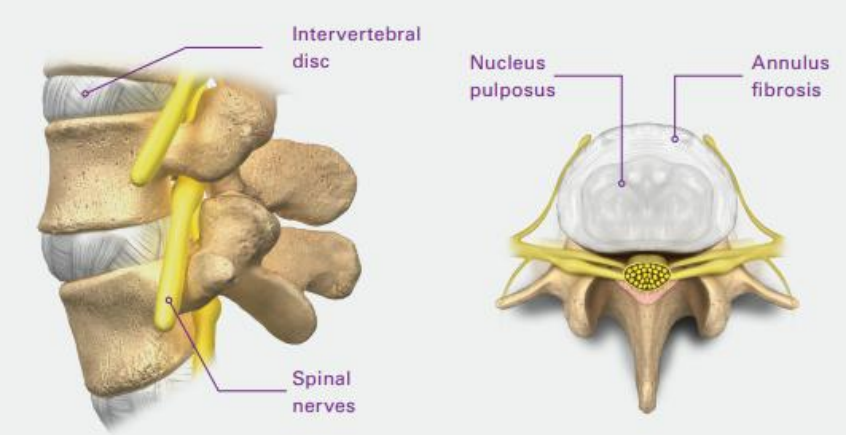
Device Name: Sterile and Non-sterile Temporary Orthopedic Stabilization

Model: NuVasive VersaTie 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.



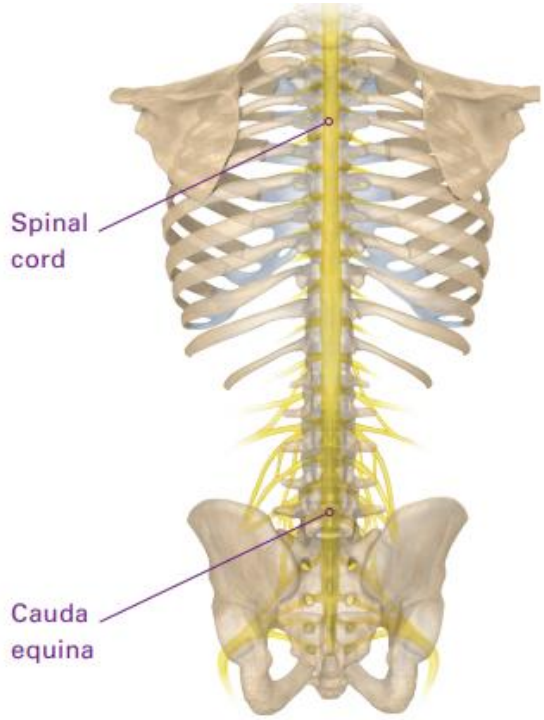
Vertebrae are connected by several joints, which allow you to bend, twist, and carry loads. The main joint between the two vertebrae is called an intervertebral disc. The disc is made of two parts, a tough and fibrous outer layer (annulus fibrosis) and a soft, gelatinous center (nucleus pulposus). These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

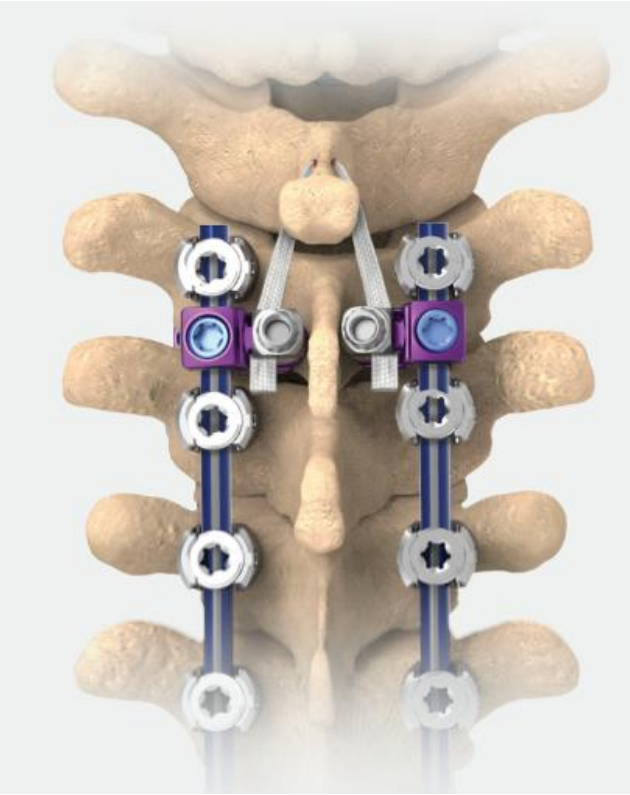
The surgical option
Interbody fusion is a surgical technique that attempts to re-stabilize the spine. The purpose of spinal fusion implants is to provide short-term stability until new bone growth takes place. Spinal fusion typically occurs within 12 months of surgery. A component of an interbody fusion procedure is fixation.

The VersaTie System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques.
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and spondylolisthesis.
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The VersaTie System may also be used in conjunction with other medical implants made of titanium alloy or cobalt chromium alloy whenever “wiring” may help secure the attachment of the other implants.

The VersaTie implants are manufactured from braided polyester (polyethyleneterephthalate – PET) band with commercially pure titanium or stainless steel removable tips, The VersaTie clamps are manufactured from 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.

VersaTie System should not be used in patients:

- With severe segmental instability
- 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:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T)
- Maximum spatial gradient field less than or equal to 1,000 Gauss (G)/cm (10.0T/m).
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
    - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
    - 1.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

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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