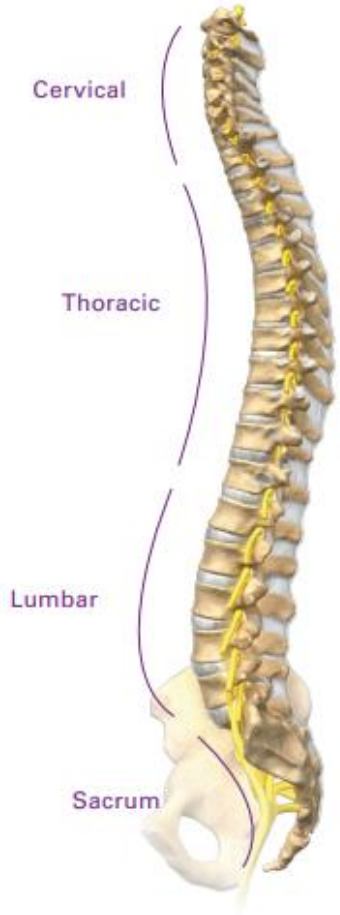
AttraX Putty Patient Information Leaflet

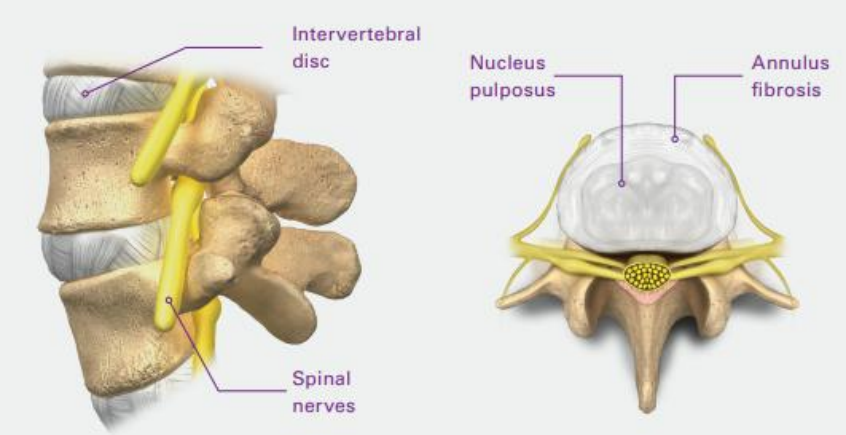
Device Name: Bone matrix implant, synthetic

Model: NuVasive AttraX Putty

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.



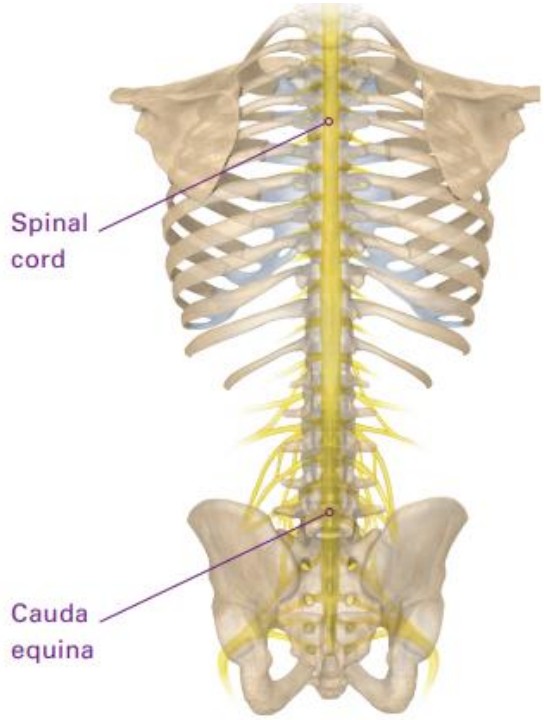
Vertebrae are connected by several joints, which allow you to bend, twist, and carry loads. The main joint between the two vertebrae is called an intervertebral disc. The disc is made of two parts, a tough and fibrous outer layer (annulus fibrosis) and a soft, gelatinous center (nucleus pulposus). These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

AttraX Putty is a calcium phosphate resorbable and micro-structured bone void filler for the repair of bony defects.

AttraX Putty is intended to be used in spinal fusion procedures and may be combined with autogenous bone, blood, platelet rich plasma and/or bone marrow. AttraX Putty is to be used in conjunction with internal or external fixation devices.

Warnings, Cautions and Precaution:

PREOPERATIVE WARNINGS

- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the device.
- Devices should be inspected for damage prior to implantation.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POSTOPERATIVE WARNINGS

- Post-operative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

Contraindications

Use of AttraX Putty synthetic bone void filler is CONTRAINDICATED in the presence of one or more of the following clinical situations:

- To treat conditions in which general bone grafting is not advisable
- In conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware (e.g., defect site stabilization is not possible)
- In cases of significant vascular impairment proximal to the graft site
- In cases of severe metabolic or systemic bone disorders that affect bone or wound healing
- In cases of acute and chronic infections in the operated area (soft tissue infections; inflamed, bacterial bone diseases; osteomyelitis)
- When intraoperative soft tissue coverage is not planned or possible
- When in direct contact with the articular space
- In cases of treatment with pharmaceuticals interfering with the calcium metabolism

Despite the presence of some of the listed circumstances, the use of AttraX Putty may be the best solution for rectifying bone defects. The patient must be duly informed of the possible effects of complicating circumstances on the anticipated success of using AttraX Putty.

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