How can intervertebral discs degenerate?

Intervertebral discs can deteriorate through normal aging and injury, causing dehydration, flattening, and loss of natural cushioning. Just like the way grapes lose water over time and turn into raisins, your intervertebral discs undergo a similar dehydration process. This process leaves your discs vulnerable to motion stress, strains your spinal nerves, and can result in lower back pain.

VIA® Disc Allograft

This brochure is designed to inform you about VIA Disc allograft product and procedure. It is not meant to replace personal conversations with your physician or other members of your healthcare team. The information is intended to answer some of your questions and serve as a guide for you to ask appropriate questions about the product and the procedure.

Risks with Allograft Products Like VIA Disc and the Associated Procedure

Careful donor screening, laboratory testing, and tissue processing, including sterilization via electron-beam irradiation of the disc tissue, have been used to minimize the risk of transmission of relevant diseases to the patient. Tissue donors are thoroughly screened and tested to meet or exceed safety standards mandated by the FDA and AATB. As with any processed human donor tissue, VIA Disc cannot be guaranteed to be free of all pathogens. **CONTRAINDICATIONS:** VIA® Disc is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, or Bacitracin or polyampholytes. **ADVERSE EVENTS:** Possible adverse events may include: Immunologic response – since parts of VIA Disc are taken from another person's bone marrow, your body may see the cells as foreign or not "belonging" to you and may develop a type of antibody (a substance naturally produced in your body) to try and get rid of them. These antibodies may or may not be harmful. If you might be receiving an organ transplant in the future, your physician will discuss these risks further with you. Transmission of disease of unknown cause and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants, pain and/or inflammation/swelling near the injection area in your spine or back, hematoma – a collection of blood at the site of the injection, epidural bleedings – a collection of blood in the potential space between the dura (covering of the spinal cord) and the bone, along the spinal canal (hollow passage through the back bones through which the spinal cord runs), infections (for example, at the injection site, in the spinal disc or bone in your spine and/or meningitis), neurological deterioration, such as loss of feeling or tingling or weakness, as serious as paralysis of the legs or lower body, sexual dysfunction, cerebrospinal fluid fistula (CSF), a spinal fluid leak, relapsing herniation, herniated disc material at the same level as the procedure, bladder (urination) or bowel dysfunction, vertebral end plate inflammation, or damage to endplates can occur with disc and/or endplate degeneration.

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VIA® Disc Allograft

VIA Disc is intended for use as an allograft to supplement degenerated intervertebral discs.

What is VIA Disc?

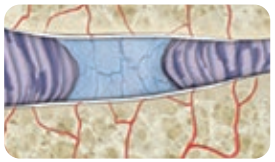
VIA Disc is intended for use as an allograft to supplement degenerated intervertebral discs. An allograft is tissue recovered from a human cadaveric donor that is transferred to a human recipient. Allograft transplantation has long been accepted as an effective option to treat a wide variety of orthopaedic and spine-related issues.

VIA Disc consists of two key allograft components:

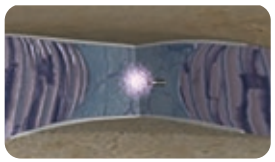
1. **Intervertebral disc tissue particulate**
2. **Spine-derived cells**

Both will be injected with saline into your intervertebral disc during a non-surgical spinal procedure.

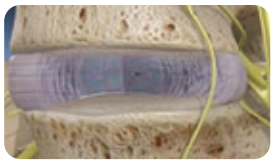
How Does VIA Disc Work?

1. 

Age-related wear and tear of the intervertebral disc can cause loss of hydration and degeneration.

2. 

VIA Disc is injected into the degenerated intervertebral disc through a 22G spine needle.

3. 

After injection, VIA Disc supplements the degenerated intervertebral disc.

What to Expect with VIA Disc?

Pre-Procedure

The disc tissue particulate component and cell component of VIA Disc are mixed together with saline for injection into your intervertebral disc.

Intravenous antibiotics may be given before the VIA Disc injection to reduce risk of infection.

Procedure

The VIA Disc procedure is performed under strict sterile conditions.

The VIA Disc procedure can be done under local anesthesia or moderate sedation may be recommended by your physician. An injection into the pain-generating intervertebral disc can be painful.

During the procedure, your physician will use fluoroscopy (a computer tomography scan that continues to take images during the procedure so that the physician can see where the needle is going).

A needle is inserted through the skin and muscle and into the center of the spinal disc. VIA Disc will be slowly injected into the center of the spinal disc. The injection procedure generally takes about 20 to 30 minutes.

Post-Procedure

You may experience pain and soreness after the procedure, which is normal. This pain may be due to increased pressure within your intervertebral disc.

It is important to follow your physician's instructions after the procedure. You may be instructed to keep your activity to the normal activities of daily life and limit physical or strenuous activity for 72 hours post-procedure.

Your physician may prescribe certain pain medications (e.g. analgesics, steroid dose pack, muscle relaxants). Patients may experience moderate to severe pain after an injection into an intervertebral disc, and oral medications may be needed promptly to treat this post-injection pain and discomfort. An ice pack may be given to place over the injection site in the event of post-injection site discomfort. Your physician may suggest a back brace, or recommend physical therapy to make you feel more comfortable following your procedure.

A follow-up appointment will typically be scheduled two to four weeks after the procedure to monitor your pain and comfort. Additional follow-up appointments may be scheduled at the discretion of your physician to assess your condition.

It is important that you consult with your physician for medical advice, including any questions you may have regarding the VIA Disc product or the associated procedure.