WHAT IS AN INTERVERTEBRAL DISC?

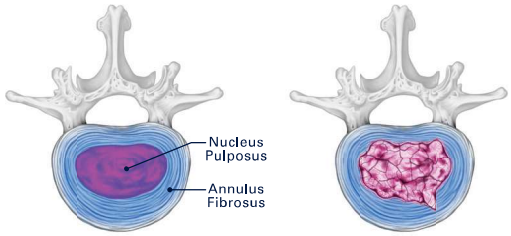
The spine is made up of a series of small bones called vertebrae. Between each vertebra are **intervertebral discs (IVD)** that act as a cushion against impact and provide flexibility to support the body's ability to bend, twist, and rotate.

Each IVD consists of three regions: the annulus fibrosus (AF), the **nucleus pulposus (NP)**, and the cartilaginous endplates.

The AF is a fibrous outer ring which functions as the primary load-bearing component of the IVD.

Within the AF lies the gel-like NP, which is composed of mostly water and performs the **mechanical function** of absorption and redistribution of stresses on the spine.

The endplates provide a layer of protection between the vertebrae and allow for the supply of nutrients to the discs.



Healthy Disc *Degenerated Disc*

HOW CAN INTERVERTEBRAL DISCS DEGENERATE?

Intervertebral discs can deteriorate through normal aging and injury, causing dehydration, flattening, and **loss of natural cushioning**. The nucleus pulposus is generally where the degenerative cascade of the intervertebral disc begins, making it especially prone to dehydration.

Just like 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.

FROM THE DISC. FOR THE DISC.

VIADISC® NP

VIA DISC NP ALLOGRAFT

VIA Disc NP is intended for use as an allograft to supplement nucleus pulposus tissue loss in degenerated intervertebral discs.

VIVEX BIOLOGICS

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Risks with Allograft Products like VIA Disc NP 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 applicable diseases to the patient. Tissue donors are thoroughly screened and tested to meet or exceed safety standards mandated by the FDA and AATB. VIA DISC NP may be exposed to Gentamicin or Vancomycin, trace amounts may remain. As with any processed human donor tissue, VIA Disc NP cannot be guaranteed to be free of all pathogens. ADVERSE EVENTS: Possible adverse events may include: 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.

MKG-IVP-12 Rev. 03

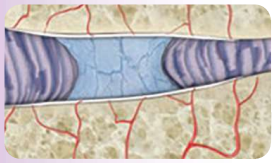
WHAT IS VIA DISC NP?

VIA Disc NP is intended for use as an allograft to supplement nucleus pulposus tissue loss in degenerated intervertebral discs. An **allograft** is tissue recovered from a human donor that is transferred to a human recipient.

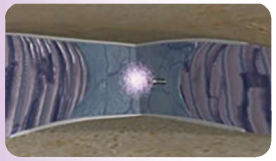
VIA Disc NP consists of dehydrated nucleus pulposus particulate derived from the intervertebral disc region of the donor.

The nucleus pulposus particulate is mixed together with saline and delivered into your intervertebral disc during a non-surgical spinal procedure.

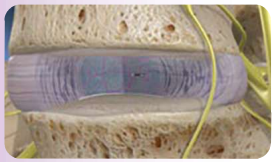
HOW DOES VIA DISC NP WORK?

1. 

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

2. 

   VIA Disc NP is delivered into the degenerated intervertebral disc through a 20G spine needle.

3. 

   After delivery, VIA Disc NP replaces tissue loss in the degenerated intervertebral disc.

WHAT TO EXPECT WITH VIA DISC NP?

PRE-PROCEDURE

Your physician may ask you to discontinue any blood-thinning medications, oral antibiotics, or other medications several days prior to the procedure.

Intravenous (IV) antibiotics will be given before the VIA Disc NP procedure to reduce risk of infection.

PROCEDURE

The VIA Disc NP procedure will be performed under strict **sterile** conditions.

The VIA Disc NP procedure may be performed under local anesthesia or monitored **conscious sedation**. Your physician will determine which method is most appropriate for you.

During the procedure, your physician will use **fluoroscopy**, a type of imaging scan that allows your physician to guide a spinal needle into your intervertebral disc.

Your physician will insert the spinal needle through the skin and muscle into the center of the intervertebral disc. The VIA Disc NP allograft will be mixed together with saline and slowly delivered into the center of your intervertebral disc.

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 return to your normal daily routine and limit physical or strenuous activity for 72 hours post-procedure.

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

A follow-up appointment may be scheduled two to four weeks post-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 NP product or the associated procedure.