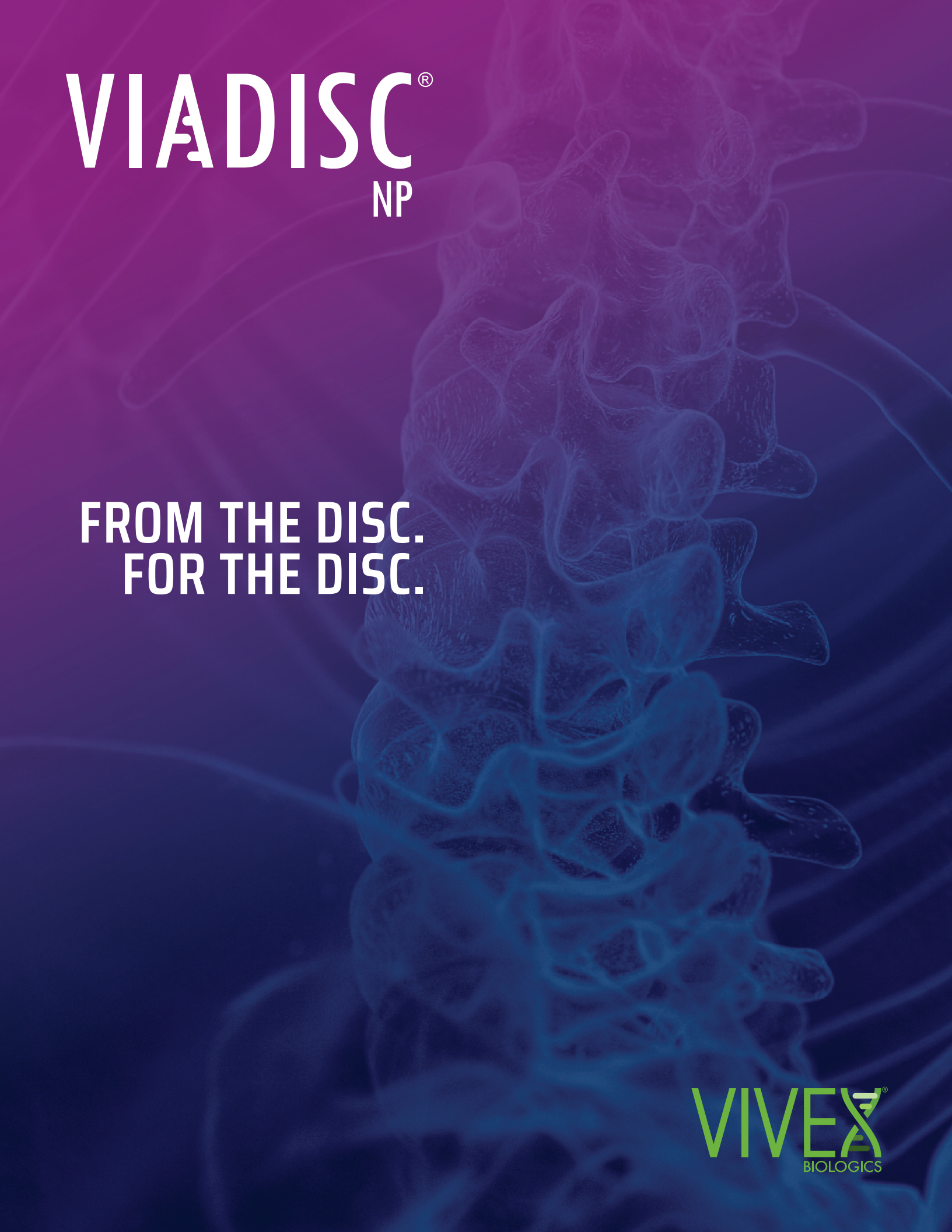
VIADISC®
NP



FROM THE DISC.
FOR THE DISC.

VIVEX® BIOLOGICS

WHAT IS VIA DISC® NP?

VIA Disc NP is the first and only nucleus pulposus (NP) allograft intended to replace a patient's tissue loss due to intervertebral disc degeneration without surgery.

VIA DISC NP KEY FEATURES

DESIGNED TO MIMIC NATIVE, HEALTHY NUCLEUS PULPOSUS

- Nucleus pulposus contains **~80% water content** by weight in its native state
- VIA Disc NP tissue maintains its **water binding** ability and can be reconstituted to its original state[1]

PROPRIETARY NP ALLOGRAFT

- **Optimized particle size:** NP tissue is lyophilized and cryomilled during processing to obtain desired particle size for percutaneous delivery after reconstitution with saline
- **High affinity to water:** Proprietary Integrity Processing™ preserves the tissue's natural ability to absorb water, an essential property for the cushioning function of the disc
- **Hydrophilic and viscous:** Allograft becomes "gel-like" in-situ, similar to native nucleus pulposus tissue, supporting the cushioning function of the disc

NON-SURGICAL, MINIMALLY INVASIVE PROCEDURE

- **Percutaneous delivery** of allograft through a 20G spinal needle
- **Outpatient procedure** with short recovery time
- **Anatomy preserving**, minimally invasive option performed with fluoroscopic guidance

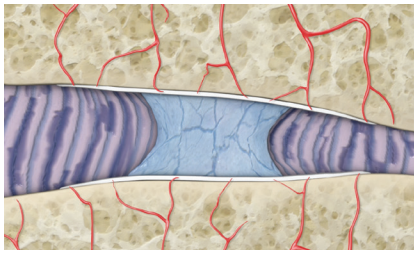
OFF-THE-SHELF

- Ready-to-use, **ambient temperature storage** (2°C to 30°C)
- **No second site harvest** required
- **E-Beam sterilized** for sterility assurance level (SAL) of 10^{-6}

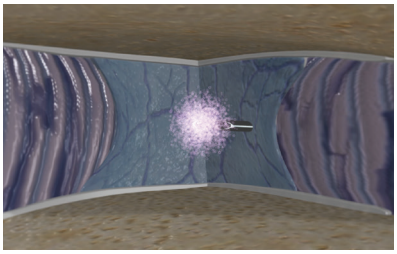
PROPRIETARY CLOSED MIXING

- **Consistent preparation** and optimal reconstitution with saline before delivery
- **Fully-closed** system to reduce contamination risk

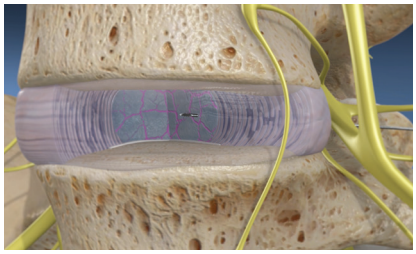
HOW DOES VIA DISC NP WORK?



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



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



After delivery, VIA Disc NP supplements the degenerated intervertebral disc.

STRUCTURE AND FUNCTION OF THE INTERVERTEBRAL DISC AND NUCLEUS PULPOSUS

THE INTERVERTEBRAL DISC STRUCTURALLY CONSISTS OF THREE REGIONS:

- **Nucleus pulposus:** Hydrophilic gelatinous core rich in proteoglycans, Type II collagen, and water[2] (Figure 1)
- **Anulus fibrosus:** Outer ring of concentric lamellae rich in Type I collagen fibers, proteoglycans, and elastin[3]
- **Cartilaginous endplate:** Permits diffusion and provides the main source of nutrition for the disc[4]

THE NATURAL FUNCTION OF THE NUCLEUS PULPOSUS IS MECHANICAL:

- High water content of nucleus pulposus allows load distribution across the spine
- Nucleus pulposus acts as an elastic shock absorber, or natural cushion, due to the water-binding and release capacity of proteoglycans[5]

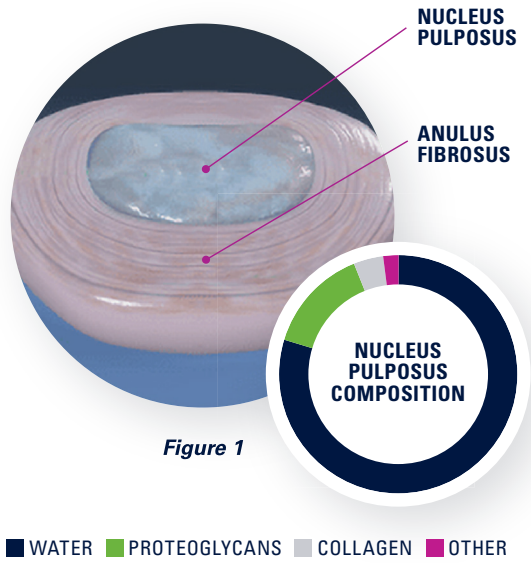


Figure 1

DISC DEGENERATION MANIFESTS IN THE NUCLEUS PULPOSUS

- Loss of proteoglycan content (Figure 2)
- Reduced hydration and water-binding capacity
- Loss of hydrostatic intradiscal pressure
- Compromised biomechanical function

One of the most common causes of chronic low back pain is degeneration of the lumbar intervertebral discs.

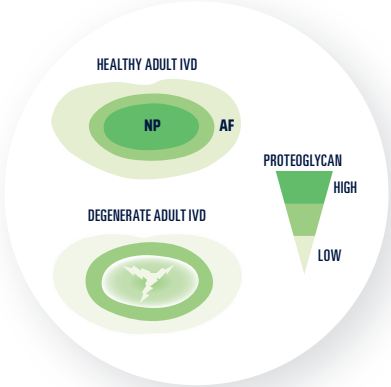


Figure 2: *Schematic representation of proteoglycan content in a healthy vs. degenerated human adult spine motion segment*[6]

WHY VIA DISC NP ALLOGRAFT?

- VIA Disc NP provides a graft for water absorption capacity through its glycosaminoglycan (GAG) content within proteoglycans.
- Mechanical cushioning, the key function of native nucleus pulposus, is supported through the unique hydrophilic properties of the allograft.

GAG CONTENT → **WATER ABSORPTION CAPACITY** → **MECHANICAL CUSHIONING**

- The GAG levels in VIA Disc NP (Figure 3) are similar to or higher than GAG levels referenced in literature in intervertebral discs with Thompson Grade 2 of degeneration (Figure 4).
- On average, VIA Disc NP has shown capacity to absorb greater than 500% of its weight in water (Figure 5).

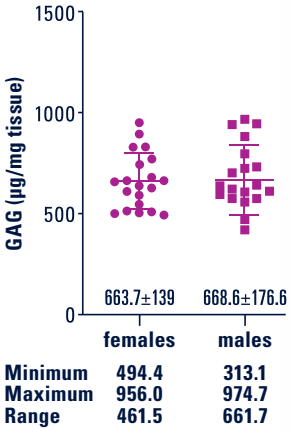


Figure 3: *GAG content in papain-digested VIA Disc NP tissue (n = 40 donors)*[1]

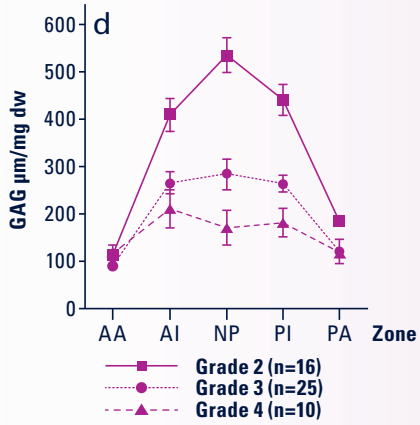


Figure 4: *Changes in GAG content by Thompson grade within disc zones*[7]

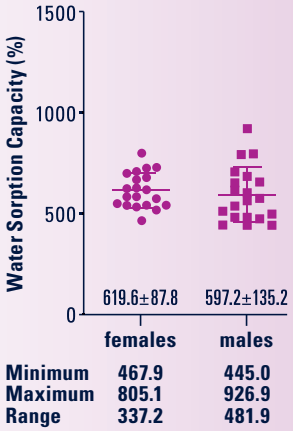


Figure 5: *Water sorption capacity (%) of VIA Disc NP (n = 40 donors)*[1]

INTEGRITY PROCESSING

The VIA Disc NP allograft is aseptically processed in current Good Tissue Practice (cGTP) conditions at VIVEX's state of the-art manufacturing facility. Processing occurs in ISO 5 clean rooms using procedures and screening criteria that meet the requirements set forth by the American Association of Tissue Banks (AATB). Microbiology testing is performed before processing to ensure safety, and the final product is packaged (Figure 6) and terminally sterilized by electron-beam radiation for a sterility assurance level (SAL) of 10^{-6}.

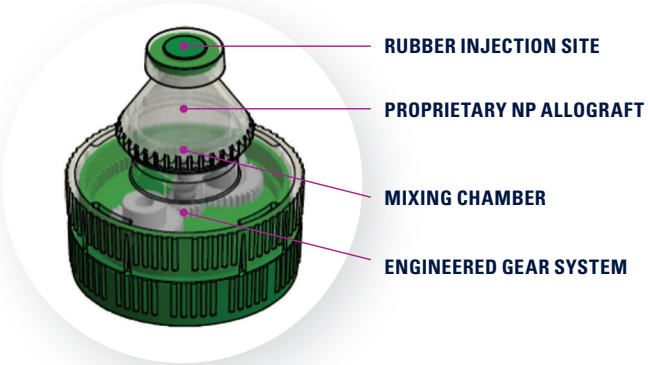
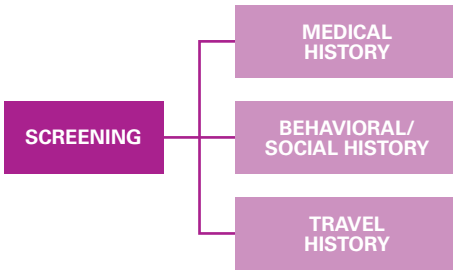


Figure 6: *Proprietary VIA Disc NP Closed Mixing System*

DONOR SCREENING AND ELIGIBILITY

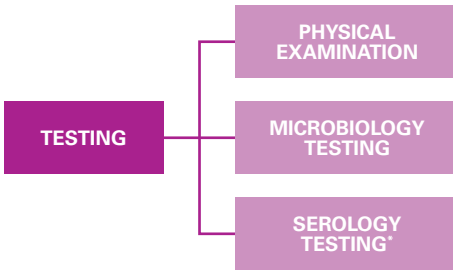
Allograft tissue is recovered from qualified donors that undergo a rigorous review process prior to being deemed suitable for transplantation. To determine donor eligibility, each donor undergoes a **Uniform Donor Risk Assessment Interview (UDRAI)** with the donor's family, next of kin, or affinity relationship.



DONOR RECOVERY AND TESTING

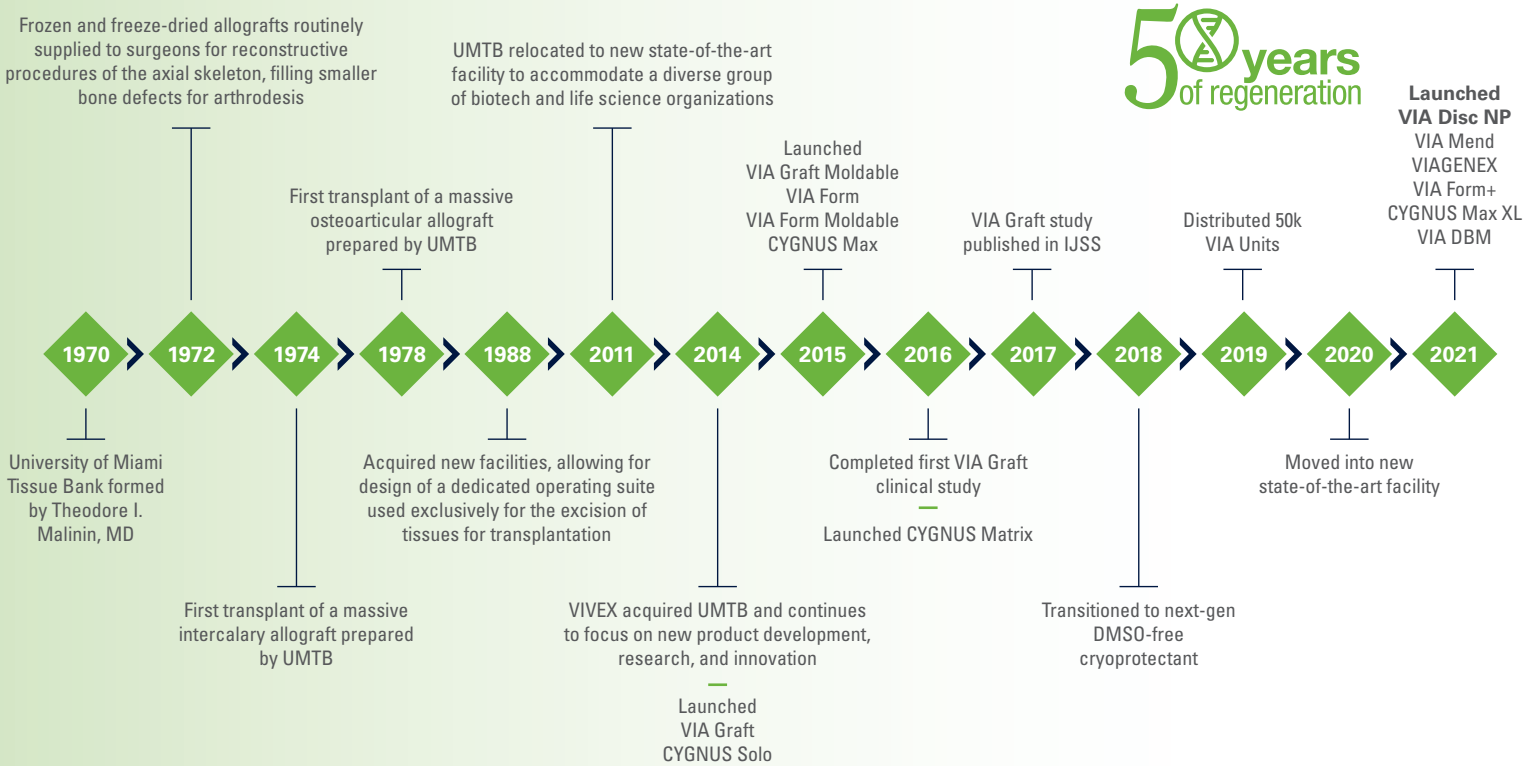
Once the donor UDRAI screening has been completed and reviewed by the Medical Director (or licensed physician designee) of VIVEX Biologics, and the donor has been deemed suitable for transplantation, recovery of the donor tissue commences. All donors must be recovered within time periods set forth by the AATB standards.

*For a full list of serology testing, please reference the VIA Disc NP Instructions for Use.



VIVEX: SAFE AND TRUSTED PARTNER

Our portfolio of allografts and other signature VIVEX solutions include viable bone matrices; demineralized bone matrices, such as cortical and cancellous bone in strips, sponges, fibers, and putties; amnion; dermis; and intervertebral disc tissue allografts. During the more than 50 years of safe and effective operations, VIVEX has delivered over 2 million allografts with no disease transmission throughout the US and eighteen countries worldwide.



VIADISC® NP

ORDERING INFORMATION

CODE	DESCRIPTION	SIZE
VCAD-00100	VIA Disc NP	100mg

TO LEARN MORE OR TO SPEAK TO A SPECIALIST, PLEASE VISIT VIADISCNP.COM

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 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. 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: 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 nflammation/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.

VIVEX Biologics has used reasonable efforts to provide accurate information herein, but this information should not be construed as providing clinical advice or as a substitute for the judgment of a health care provider.

1. *Data on file at Vivex Biologics, Inc.*
2. *Chen S, Fu P, Wu H, Pei M. Meniscus, articular cartilage and nucleus pulposus: a comparative review of cartilage-like tissues in anatomy, development and function. Cell Tissue Res. 2017;370(1):53–70.*
3. *Lundon K, Bolton K. Structure and Function of the Lumbar Intervertebral Disk in Health, Aging, and Pathologic Conditions. J Orthop Sports Phys Ther. 2001;31(6):291-306.*
4. *Adams MA, McNally DS, Dolan P. 1996. Stress' distributions inside intervertebral discs. The effects of age and degeneration. J Bone Joint Surg Br 78-B:965–972*
5. *Chan SCW, Ferguson SJ, Gantenbein-Ritter B. The effects of dynamic loading on the intervertebral disc. Eur Spine J 20: 2011: 1796-1812.*
6. *Krock E, et al: Current Stem Cell Research & Therapy, 2015, Vol. 10, No. 4*
7. *Antoniou J, Steffen T, Nelson F, et al. The human lumbar intervertebral disc: evidence for changes in the biosynthesis and denaturation of the extracellular matrix with growth, maturation, aging, and degeneration. J Clin Invest. 1996;98(4):996-1003. doi:10.1172/JCI118884*

VIVEX BIOLOGICS

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