REFERENCES

2. www.aatb.org/About-Us
3. The American Journal of Sports Medicine, December 2007, 35: 2148-2158. Allograft-related infection rate: 0.0004%.
5. Data on file at LifeNet Health
This booklet is designed to inform you about ViviGen cellular allograft as a bone graft substitute in your spinal fusion surgery. It is not meant to replace any personal conversations you might wish to have with your physician or any other member of your healthcare team.

This information is intended to answer some of your questions and help you ask informed questions about the procedure. Not all the information here will apply to your individual treatment or its outcome.

Your Surgeon Has Recommended ViviGen

In preparation for your upcoming procedure, your surgeon is planning for your individual case. Surgical treatment of spine and orthopedic conditions often requires a bone graft, which is used to replace missing bone and promote new bone growth.

For many years, use of a patient’s own bone (autograft) has been considered the “gold standard” for bone grafting. Using an autograft requires that a piece of bone be taken from somewhere else in the patient’s own body. ViviGen is intended to mimic the same properties of an autograft without the effects and limitations that can be associated with using your own bone. Because of the unique properties of ViviGen, your surgeon has identified this material as the best option for you.

What is Spinal Fusion?

Fusion is a surgical technique in which one or more of the vertebrae of the spine are joined together (“fused”) so that motion no longer occurs between them. Bone grafts are placed in various locations during surgery. The body then heals the grafts over time and joins the vertebrae together.

When is fusion recommended?

There are many potential reasons for a surgeon to consider fusing the vertebrae. Primarily, it is done to eliminate pain caused by abnormal motion of the vertebrae. It is also used for treatment of fractured vertebrae, deformity (spinal curves or slippages), instability, and some disc herniations.

DISADVANTAGES OF TRADITIONAL BONE GRAFTING

Autograft is the standard against which all bone grafts are measured because it contains all of the components necessary for natural bone healing, including living cells, natural signals to direct bone formation, and structural support. However, to recover enough bone for a fusion procedure, a second incision is necessary, which can lead to:

- Longer surgical procedure
- Second-site infection
- Prolonged recovery time
- Long-term pain and other side effects

Additionally, not all patients are good candidates for an autograft due to inadequate bone quantity and/or quality.

For these reasons, a number of autograft alternatives are often used. One common option is allograft, which is donated human bone from a tissue donor. However, traditional allograft materials lack living cells and thus do not contain all of the components necessary to encourage new bone growth.
How ViviGen Works

ViviGen is a comprehensive bone graft developed to mimic your own bone. ViviGen provides the following bone-forming components:

**Scaffold** – ViviGen retains the natural scaffold, or support structure, for new bone to grown on and through.

**Signals** – For bone formation to occur, specific signals are necessary to direct the process. These signals act on the cells within ViviGen, and help direct your body’s own cells to stimulate bone formation.

**Cells** – ViviGen contains viable bone-forming cells. These cells are naturally present in our bodies and are essential for bone formation and healing. They are the same as the cells building bone in your own body.

ViviGen technology preserves the live bone-forming cells in donor tissue. These cells are not manipulated or artificially added to the product, and each batch is specifically tested to contain viable cells before being approved for use in a patient.

ViviGen provides a complete bone graft because it contains all the necessary components for bone growth: the cells, the signals and the scaffold. The benefit for you, as a patient, is that you can undergo spinal fusion while avoiding the limitations of traditional bone grafts.

Is ViviGen Safe?

Yes, ViviGen is a safe bone-grafting solution. ViviGen is processed by LifeNet Health, one of the world’s most trusted providers of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies. Since 1982, LifeNet Health has helped to save lives, restore health, and give hope to thousands of patients each year, while always honoring the donors and healthcare professionals that enable the healing process. They hold the longest continuous accreditation from the American Association of Tissue Banks (AATB), and have a comprehensive range of measures in place to ensure the safety of their allograft bio-implants.

Clinical safety is another important consideration as you and your physician consider bone-grafting options.

Tissue banks distribute in excess of 2 million allografts for more than one million tissue transplants performed annually in the United States. Due to stringent standards required by the U.S. Food and Drug Administration (FDA) and American Association of Tissue Banks (AATB), the rate of infection related to those allografts is much lower than the rate associated with surgical procedures themselves. That means that using an allograft does not increase your chance of getting an infection after the surgery. To ensure the safety of ViviGen grafts, specific processing guidelines are strictly enforced:

- Tissue donors are thoroughly screened and tested to meet or exceed stringent safety requirements mandated by the U.S. Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB).
- Tissue is cleaned and specifically processed to keep only the elements to support bone growth.
- Each and every lot of ViviGen is tested to confirm that it is safe for patients.
- LifeNet Health’s recovery techniques and donor screening process help to assure that only safe and effective tissue is released for transplantation.
Frequently Asked Questions

How long will it take for bone to form with ViviGen?

The length of time it takes to grow bone and achieve fusion is a complicated process that depends on multiple factors. It can take up to a year or longer. You should talk with your physician to get proper guidance specific to your procedure.

Where is ViviGen processed?

ViviGen is processed by LifeNet Health, a non-profit tissue bank. LifeNet Health is proud of the safety record it has built over the last 30+ years. It holds the longest continuous accreditation from the AATB and has a comprehensive range of measures in place to ensure the safety of its allograft bio-implants. LifeNet Health maintains strict quality standards at all steps, including stringent donor screening methods, recovery, processing, storage, and release criteria. To obtain suitable donors, LifeNet Health maintains an extensive network of recovery partners. Additionally, LifeNet Health is a leading, federally designated Organ Procurement Organization (OPO) that coordinates recovery and transplant of organs in Virginia and parts of West Virginia. LifeNet Health only accepts donors from federally designated Organ Procurement Organizations and qualified tissue-recovery partners. These partners are regularly audited to guarantee that their recovery process meets LifeNet Health’s stringent guidelines as well as current FDA regulations and AATB standards.

TERMS TO KNOW

- **Allograft** – Tissue recovered from one individual (the donor) and implanted in another individual of the same species (the recipient). Allograft tissue is regulated by the FDA under allograft-specific regulations in the U.S.

- **Autograft** – A tissue graft take from the patient’s body. Examples of bone autograft in spine surgery include iliac crest and local bone from the surgical site. It may also be referred to as “autogenous” bone.

- **Immune response** – This is how your body recognizes and defends against substances that appear foreign and harmful. Laboratory tests confirm that ViviGen does not cause an immune response.⁵

- **Scaffold** – A supporting structure that reinforces new bone formation through cell and protein attachment. In ViviGen, the cortical cancellous bone matrix acts as a scaffold.⁵