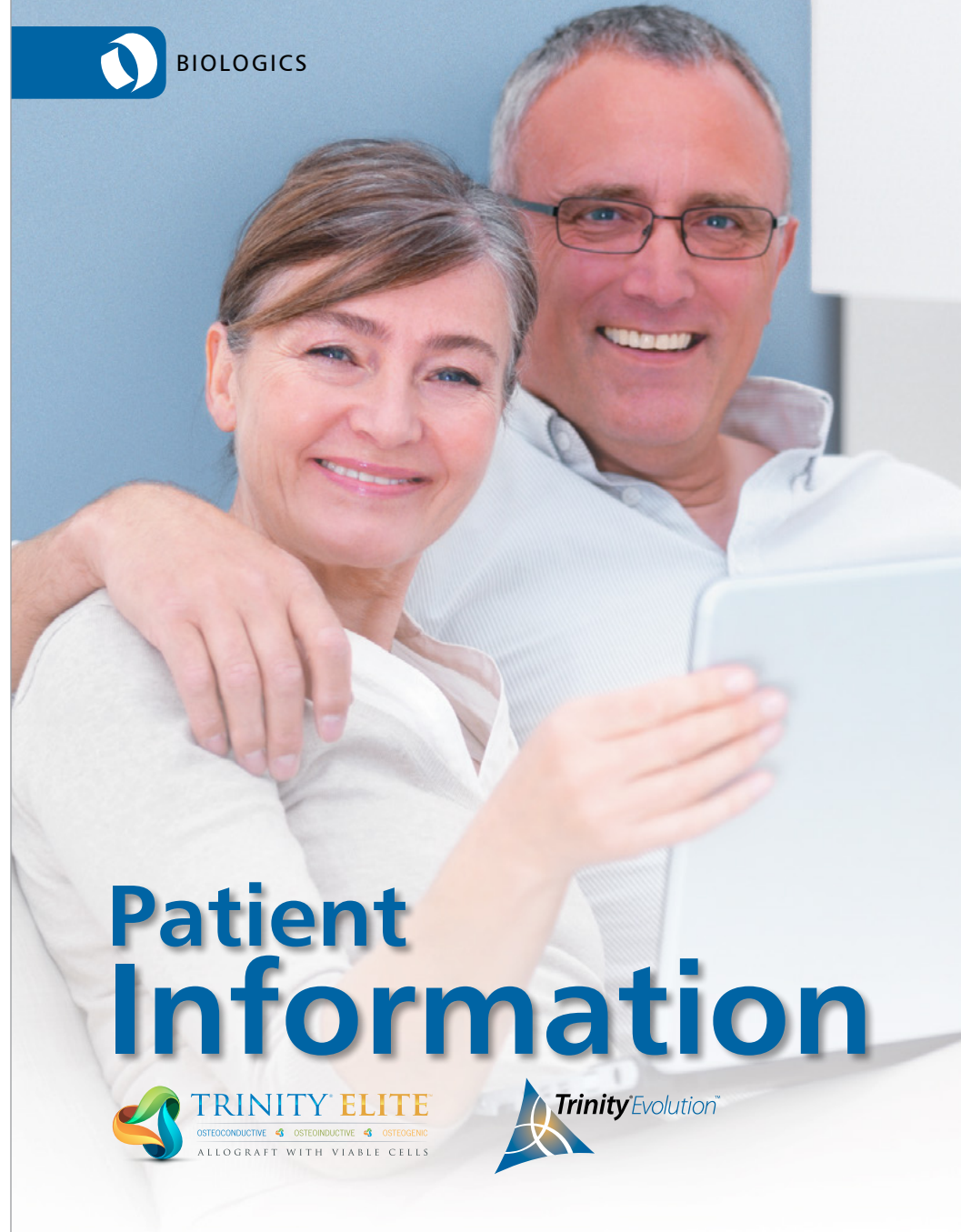




BIOLOGICS



Patient Information



This brochure is for the purpose of information only, and should not be considered a substitute for the care of a healthcare provider.

www.orthofix.com
www.mtf.org

MTF Musculoskeletal
Transplant
Foundation

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ORTHOFIX®



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Introduction

Surgical treatment for spine and orthopedic conditions often require the use of bone grafts. Your surgeon has recommended one of the Trinity® tissue forms due to their unique properties. Trinity tissue forms are donated bone grafts (or bone allografts) processed to maintain active (viable) adult stem cells. The following information will provide you with an understanding of how an allograft with viable cells works, how it is safe, and how it is a commonly used option for your surgery.

Key Terms:

Bone Allograft - bone that is transplanted from a donor

Bone Autograft - bone that is transplanted from one part of your body to another

Adult Stem Cells - cells within the body that work to build, maintain, and repair the body

Mesenchymal Stem Cells (MSCs) - a type of adult stem cell typically found in bone marrow that assist in building and repairing bone or soft tissue

Viable Cells - live, active cells that are capable of performing their determined functions

Trinity Evolution® & Trinity® ELITE™- allografts with viable adult stem cells that help jumpstart and maintain bone growth and repair

Viable Cells - live, active cells



What Is Bone Allograft?

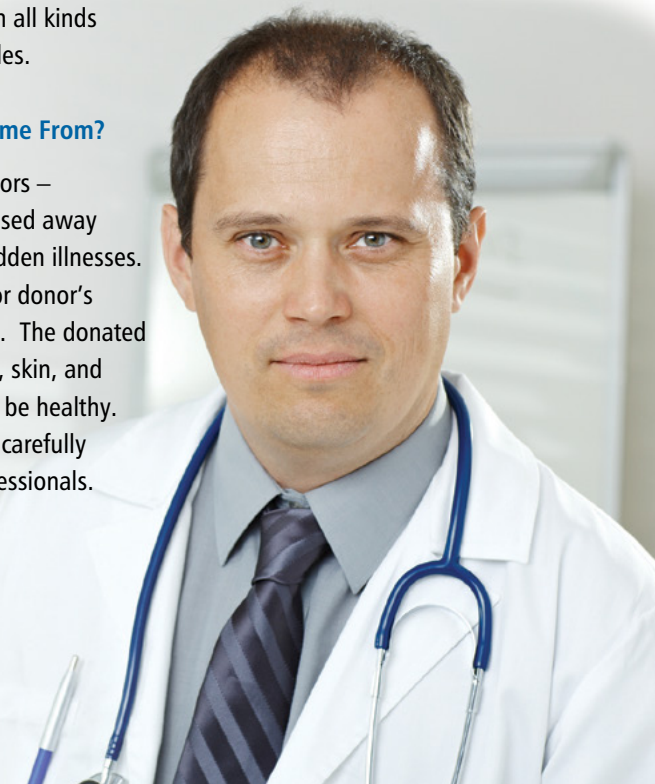
In orthopedic surgery, an allograft is bone or soft tissue that is transplanted from one person to another. There are various surgical procedures where bone, tendons, ligaments, and other tissues are used. In fact, in the U.S. an estimated one million allografts are transplanted each year. The following examples are cases where allografts are commonly used:

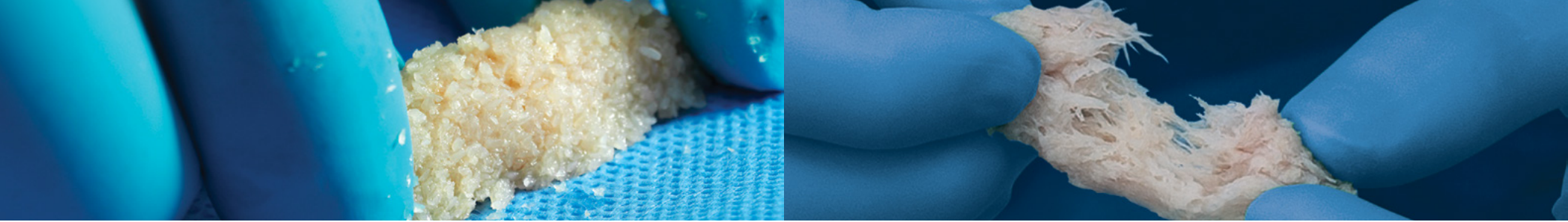
- Patients undergoing orthopedic reconstruction.
- Patients having spinal surgical procedures.
- Cancer patients receiving allografts to fill bone voids following tumor surgery.

These are just a few examples. Surgeons have used allografts successfully – in all kinds of procedures – for decades.

Where Do Allografts Come From?

Allografts come from donors – individuals who have passed away in an accident or from sudden illnesses. Consent from the donor or donor's family is always obtained. The donated bones, cartilage, tendons, skin, and ligaments are required to be healthy. Therefore, every donor is carefully screened by medical professionals.





Why Do I Need An Allograft?

Your surgeon could use bone taken from another part of your body. This is called an autograft. Autograft contains all of the necessary components for bone healing, including living cells. However, a second surgical site is typically necessary and there are some potential drawbacks associated with autografts such as:

- Longer surgical time
- Infection at the second surgical site
- Longer recovery time and potential long term pain at that site

Your surgeon may have other reasons for recommending something other than autograft for you. Your bone quality and quantity (supply) are potential limitations as well as those listed above.

What is an Allograft with Viable Cells?

An allograft with viable cells is one that contains active live cells - specifically stem cells, which may enhance the patient's bone healing. Trinity is an example of an allograft with viable cells.

Why Are Adult Stem Cells Important?

Adult stem cells are present in our organs, bones, and soft tissues. Normal wear or injury to the body will signal these cells to begin repair or rejuvenation. A Mesenchymal Stem Cell (MSC) is a type of adult stem cell which is found in the bone marrow of all individuals. MSCs are called into action when they are needed to repair bony voids within the body. Trinity contains adult mesenchymal stem cells and is applied into the surgical site to help regenerate healthy bone.

Your surgeon has chosen Trinity because it contains all three of the necessary components for bone growth:

Bony Foundation

Bone needs a platform or scaffold on which to grow. The bone chips in Trinity provide that scaffold.

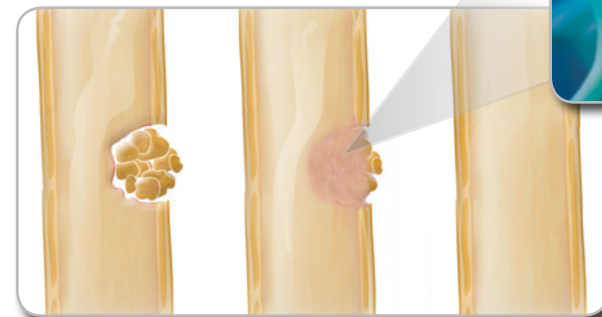
Living Cells

Trinity contains adult mesenchymal stem cells. These cells naturally reside in the bone scaffold. They are capable of helping to form bone and can jumpstart the healing process.

Growth Factors

Trinity has natural occurring growth factors which provide the signal for the cells to start the bone forming process.

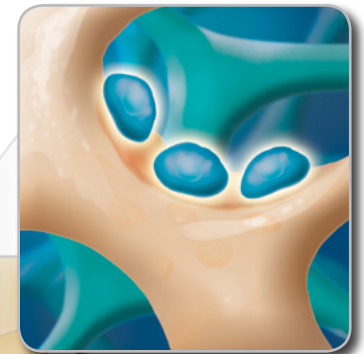
How Trinity Works



Trinity implanted into the bone void.

Trinity works with your body's own cells to build bone.

Bone is successfully healed.



Live adult stem cells signal your body's own cells to gather and grow bone at the operative site.



Where Does Trinity Come From?

Trinity is processed at The Musculoskeletal Transplant Foundation (MTF), which is the largest tissue bank in the United States. Founded by surgeons, MTF is a national non-profit organization dedicated to supporting the needs of surgeons and patients by providing allografts that meet the highest standards of quality and safety. Since 1987, MTF has provided almost 5 million allografts from nearly 100,000 donors.

Is Trinity Safe?

Yes. MTF has an exceptional safety record and every donor is screened extensively before donation. Potential donors with history of any condition that could affect the quality and long-term performance of the bone tissue are excluded. After recovery, the tissue is aseptically cleaned and then tested for sterility before it can be released to hospitals. All MTF-supplied tissue is recovered in sterile environments by specially trained technicians. MTF uses state-of-the-art recovery and processing techniques to maintain the safety and sterility of the tissue.

For questions regarding your surgery or additional information regarding Trinity tissue forms please consult your physician.

