PATIENT INFORMATION

SIGNIFY®

BIOACTIVE

Life moves us

Outside the US Only

GLOBUS MEDICAL

SIGNIFY®
Bioactive

Patient Information

This brochure will help you understand more about:

- **Bone Grafting and Common Applications**
- **Types of Bone Grafts**
- **SIGNIFY® Product Information**

The decision to receive medical treatment is individualized to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment, or outcome, as surgical techniques vary and complications can occur. It is important to discuss the viability of this procedure with your physician to decide whether this treatment option is right for you.

This brochure is intended to be an educational resource only and is not meant to be a warranty or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results, and other important medical information that pertains to this procedure.

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Bone Grafting

Within your bones are living cells that create and maintain structure. These cells can help repair and heal bone when necessary.

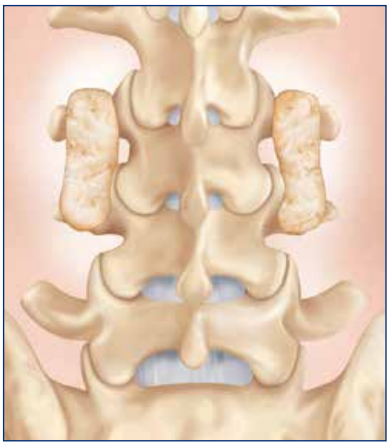
When a bone is broken, the body's natural healing process begins. As long as the break is not too large, bone cells can repair it. However, if the injury results in a large loss of bone, the bone might not fully heal without a bone graft.

Bone grafting refers to surgical methods that support new bone growth. During a bone grafting procedure, the surgeon inserts the graft where a bone needs to heal or join.

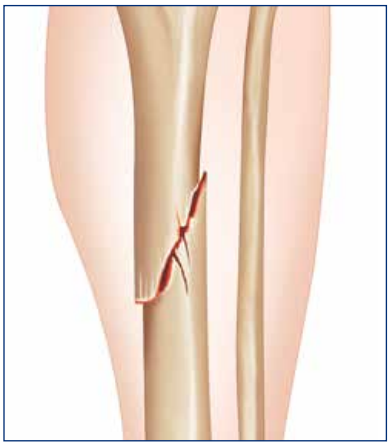
Surgeons often perform bone grafting as a part of another medical procedure. For example, if you have a fracture, the surgeon may place screws and a plate, in addition to the bone graft.

There are many clinical applications for bone grafting, including:

- Spinal fusion (joining of bones) surgery
- Helping to heal new fractures or fractures that have not healed
- Fusion between bones across an unhealthy joint
- Supporting new bone growth following trauma, infection, or disease



Spinal fusion



Fracture healing

Fusion across a diseased joint

Regeneration following trauma

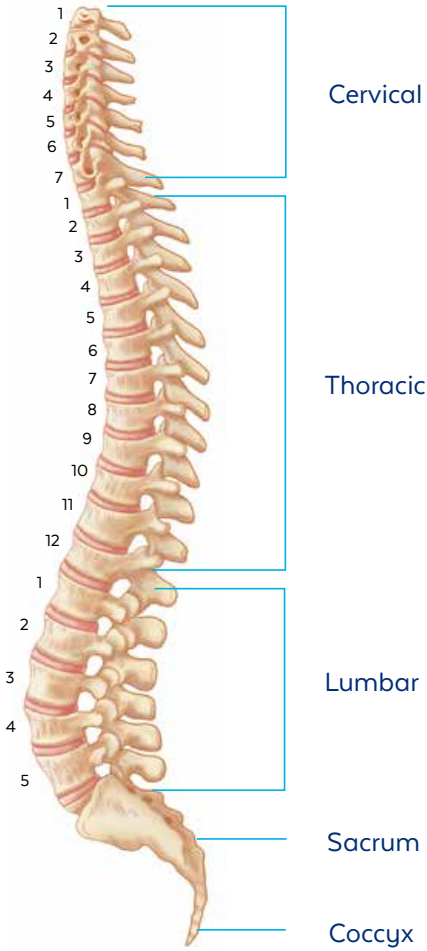
The Healthy Spine

The spine is one of the most important structures of the human body. It supports much of the body's weight and protects the spinal cord, which carries information from the brain to the rest of the body. The spine is strong but flexible, allowing for a wide range of movements.

The spine is made up of vertebrae (bones) and is divided into three main sections:

- Cervical (7 vertebrae)
- Thoracic (12 vertebrae)
- Lumbar (5 vertebrae)

The vertebrae are separated by intervertebral discs that act as cushions or shock absorbers.



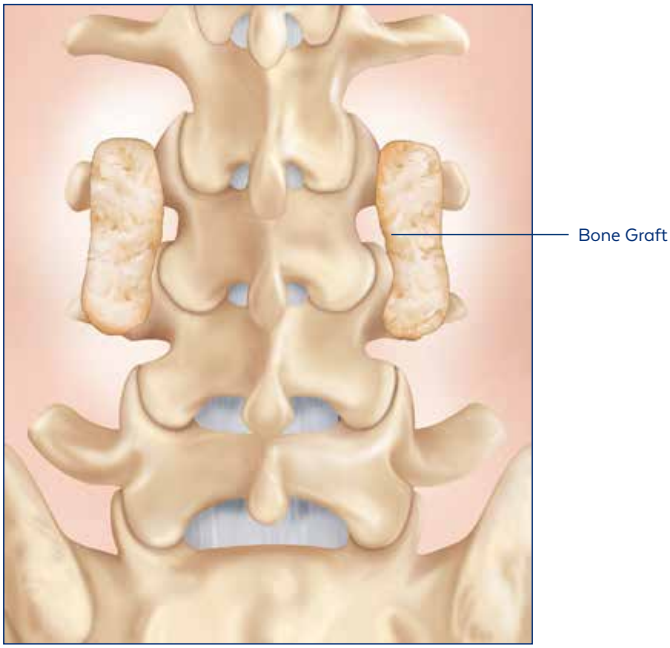
Spinal Fusion

Spinal fusion surgery is one of the most common procedures in which bone grafting is used. The surgery may be performed to stabilize a portion of the spine.

Posterolateral Fusion

Spinal fusion is a surgical procedure used to help reduce painful motion between two vertebrae. Your surgeon places graft material along the sides of the vertebrae to encourage bone growth, or fusion, in this region. This is called posterolateral fusion.

Typically, spinal devices are implanted for stability while fusion occurs. The graft material is used to encourage fusion and complement these spinal devices.



Types of Bone Graft Materials

There are three types of bone graft materials that are most commonly used in surgery. For more information, please refer to page 4 of this brochure or contact your physician.

Autograft

Autograft bone is obtained from one region of the patient's own body and then placed in another region to fill a void or to help join or fuse bones together.

Allograft

An allograft is a bone graft that is donated from a deceased human donor, thoroughly tested for safety, and then implanted in a patient.

Synthetic Bone Graft

A synthetic bone graft is designed to act like human bone but does not contain any human bone. Synthetic products are often composed of similar materials, such as minerals, to those found in human bone.

SIGNIFY® Overview

What Is SIGNIFY®?

SIGNIFY® Bioactive is a resorbable bone graft used to help repair bone holes or gaps, or to form bone along the spine. Its components help to form bone when placed in direct contact with the bone to be healed. Over time, the bone graft is resorbed by the body and fully replaced with bone.

SIGNIFY® is a synthetic (man-made) bone graft containing bioactive glass, which is made from minerals that are naturally found in bone.

SIGNIFY® contains bioactive glass, polyethylene glycol, and glycerol. Bioactive glass is composed of minerals that are naturally found in bone, and has been used for bone grafting for many years. Polyethylene glycol is an inactive substance that acts as a carrier for the bioactive glass. Glycerol a naturally occurring substance that helps hold the graft together.

SIGNIFY® has the added benefit of being more readily available in large amounts than autograft and allograft bone, which have limited supply. SIGNIFY® may be used together with autograft bone if needed, to help bone grow.

SIGNIFY® does not contain any human or animal tissue, which eliminates any risks associated with allografts.

Frequently Asked Questions

What should I expect from surgery?

Treatment with spinal implants and SIGNIFY® Bioactive may help you return to normal activities. Patients may notice improvement of some or all symptoms, and pain from surgery may diminish 2 to 4 weeks after surgery. However, recovery time varies among patients.

It is the surgeon's goal for the patient to eventually return to their preoperative activities. A positive attitude, reasonable expectations, and compliance with your doctor's post-surgical instructions may all contribute to a satisfactory outcome.

When will I be able to return to work?

The amount of recovery time needed prior to returning to work will vary depending on the surgery, your job, and you as an individual. Please consult your surgeon for an individual recommendation.

How long will I have restricted activities?

As with any surgery, the duration of time between procedure and return to normal activities is different for every patient. Your surgeon may provide a list of activities you should avoid during the first 6 weeks after surgery.

How long will my implant last?

The lifetime of SIGNIFY® Bioactive is at least one year, in which it is expected that it will achieve the intended purpose (to support fusion or bone formation) and maintain performance until it is fully resorbed and replaced by bone.

Can I have an MRI after the devices are implanted?

SIGNIFY® can be safely scanned and does not require any special conditions for an MRI. Other devices that may have been implanted along with SIGNIFY® may have specific instructions for undergoing an MRI.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for this graft material if you have an infection, a history of severe or multiple allergic reactions, severe neurological or vascular diseases, high calcium levels, a fracture that requires load support (unless rigid stabilization is obtained), systemic and/or metabolic disorders that affect bone or wound healing, renal failure, other conditions in which general bone grafting is not advisable, or are pregnant. In addition, a patient whose mental or physical impairment may interfere with their ability to follow postoperative restrictions may be at high risk during postoperative rehabilitation.

As with any surgical procedure, complications or adverse effects may occur. These can include but are not limited to deformity at the surgical site, fracture or displacement of the bone graft, wound complications, secondary surgery, incomplete bone growth, failed fusion, short-term high calcium levels, allergic reaction, loss of bone graft, and other general complications that may arise from anesthesia or surgery.

If you experience any of the above adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult your surgeon for additional information on this topic and how it applies to your particular medical condition.

If you experience a serious adverse effect with your bone graft material, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for convenience.

Region	Authority	Website
All	Globus Medical	https://www.globusmedical.com/international/about/contact/
Australia	Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	https://www.medsafe.govt.nz/
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Other	Report to your local health authority per local guidelines	

About Globus Medical: Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.

GLOBUS MEDICAL

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