

MEDICAL DEVICE
PATIENT LABEL

AUGMENT[®]

Bone Graft



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Medical Device Patient Label

Please read this entire document carefully. Keep this document. You may want to read it again. If you have further questions, please ask your doctor. Only your doctor can determine whether AUGMENT® Bone Graft is appropriate for you.

Glossary of Terms

Bone Graft – Bone removed from one location in a person's body and then placed in another location in the body of the same person. This bone is usually taken from the leg or hip during your surgery.

Ceramic – A nonmetallic, high strength material that is brittle

FDA – Food and Drug Administration. Part of the United States government; the FDA makes rules for companies that protect the patients who need medicine or medical implants. The FDA also helps decide when and how medical products can be used.

Sterile – Free from bacteria or other microorganisms and their spores

Metabolic – Energy consumption by the body

Endocrine – Organs that produce hormones

Physical Therapist – A person that helps you perform exercises, or forms of practice or exertion, designed to train, develop, condition, or the like

rhPDGF-BB – Recombinant Human Platelet-Derived Growth Factor-BB. Also referred to by its drug name of becaplermin, rhPDGF-BB is a man-made protein form of Platelet-Derived Growth Factor (PDGF) as described below.

Allograft – Bone from a donor

PDGF – Platelet-Derived Growth Factor. PDGF is part of blood platelets and is released from platelets at sites of injury. PDGF is also in normal bone and is released by the body when a bone breaks to help healing.

Yeast Cells – Cells produced from yeast that are used in the making of rhPDGF-BB.

Antibody – Antibodies are produced by the body's immune system when it detects something that should not be there. Antibodies are also produced when the immune system mistakenly considers healthy tissue to be foreign tissue.

Neutralizing Antibody – Antibodies that are produced by the body's immune system when it detects something that would interfere with a normal body process.

Introduction

AUGMENT® Bone Graft was shown to be at least as good as the way of collecting bone from other places in your body (bone graft) for improving your pain and movement during your daily activity after having surgery to join your bones together. Bone graft is considered as the most accepted way to heal your bones together (arthrodesis). In a clinical study, AUGMENT® Bone Graft and bone graft subjects were equally good in improving pain and movement. AUGMENT® Bone Graft subjects benefited by not having to have a second surgery to collect bone.

Purpose of the Device

AUGMENT® Bone Graft is to be used in place of bone graft (bone taken from another area in your body) in ankle and foot surgeries that would otherwise need bone graft.



Description of the Device

AUGMENT® Bone Graft is a man-made bone graft that is made up of two parts. One part is a ceramic bone-like substance called beta-Tricalcium Phosphate (β -TCP), and the other is a man-made protein called recombinant human platelet-derived growth factor (rhPDGF-BB).

The ceramic part has been used for many years to help repair bones that are located in the limbs, spine and pelvis. It works by providing a framework for bone cells to grow on. As bone grows, the ceramic part is gradually replaced by the new bone.

The second part, rhPDGF-BB, is a man-made protein (growth factor) found naturally within blood cells. When the body is injured, rhPDGF-BB (proteins) are released from the blood cells as part of the natural healing process. The rhPDGF-BB used in AUGMENT® Bone Graft works in the same way as the PDGF in the body by attracting and helping cells to repair and grow new bone.

The two parts of AUGMENT® should be mixed together in the operating room before being gently packed into a bony defect in patients who have ankle and foot surgery to relieve pain and improve movement. This product will do away with the need to have more surgery to take bone graft from some other place in the body. After AUGMENT® Bone Graft is placed in the bony defect, the bones will be held together with fixation devices (e.g. screws, pins, staples and/or wires) while it heals. AUGMENT® Bone Graft does not replace the need for fixation devices needed to hold the bones together.



Potential Benefits

- » AUGMENT® Bone Graft was shown to be at least as good as the way of collecting bone from other places in your body (bone graft) for improving your pain and movement during your daily activity after having surgery to join your bones together.
- » In addition to relieving pain and improving movement during your daily activity, there is a benefit that you will not have to have a second surgery to get small amounts of bone from other areas of your body. Without this added surgery you will not have the risk that is associated with a secondary surgery.

When the Device Should Not Be Used

AUGMENT® Bone Graft should not be used if you:

- » Have a known sensitivity to any of the parts of the product or are allergic to products that are made from yeast
- » Have cancer that is active
- » Are less than 18 years of age or if your doctor believes that you are still growing
- » Are pregnant or likely to become pregnant in the next year. The effects that rhPDGF-BB can have on an unborn child have not been studied.
- » Have an active infection of the foot or ankle where you will have surgery
- » The surgeon cannot get soft tissue to cover your wound
- » Have a metabolic disease known to damage the bones (e.g. kidney or calcium diseases), other than osteoporosis or diabetes
- » Require a structural support graft. AUGMENT® does not provide structural support to the bony defect.

Warnings

- » There is a chance that your bone will not heal in order to relieve your pain and improve your movement during daily activity.
- » If you have any allergies, especially to products that are grown from yeast, you should ask your doctor to determine if this product is right for you. It is also possible that an allergic reaction such as a rash could happen after receiving AUGMENT® Bone Graft.
- » Women trying to get pregnant should be advised that the safety of AUGMENT® Bone Graft in pregnancy, and its impact on an unborn child have not been studied.
- » The safety and effectiveness of AUGMENT® Bone Graft in nursing mothers has not been studied. It is not known if the rhPDGF-BB protein can be present in human milk. Women who want to get pregnant should be advised to not become pregnant for one year following treatment with AUGMENT® Bone Graft.
- » The safety and effectiveness of AUGMENT® Bone Graft has not been studied in other locations in your body other than the foot or ankle.
- » AUGMENT® Bone Graft must be used with bone screws, pins, staples and/or wires to fix the bones together for healing.
- » The ceramic part of the AUGMENT® Bone graft may prevent your doctor from evaluating the bones of your foot or ankle on X-rays.

Precautions

- » The need for very small amounts of bone graft should be left to the judgment of the doctor.
- » The safety and effectiveness of repeatedly using AUGMENT® Bone Graft has not been studied.
- » Other options should be discussed with your doctor before having a surgery requiring bone graft.
- » If you have severe endocrine-induced bone diseases; or are receiving therapy that suppresses your immune system; or have a known condition that may lead to problems with bleeding, you should discuss these conditions with your surgeon.
- » The safety and effectiveness of AUGMENT® Bone Graft in patients below the age of 18 years has not been studied.
- » One of the parts of AUGMENT® Bone Graft is the active part in another product. This other product is used to treat diabetic ulcers. At a higher dose, and with repeated use of this product, there were a larger number of deaths for patient who had pre-existing cancers. However, for the clinical study of AUGMENT® Bone Graft, there was no difference in the number of deaths from cancer as compared to bone graft.

Risks

Risks associated with any surgery include:

- » Problems with skin wound healing, including pain
- » Infection
- » Problems with the heart or blood movement (circulation). This could include: loss of blood, a reaction to a blood transfusion, or problems with blood forming into clumps (clotting)
- » A reaction to the drugs used to put you to sleep during surgery (anesthesia)
- » Problems with the stomach and intestines (gastrointestinal)
- » Problems with the urinary or genital systems (urogenital)
- » Problems breathing (respiratory). Respiratory problems could include: lung infection (pneumonia), lung collapsing (atelectasis), or swelling in the neck (edema).
- » In rare situations, heart attack, stroke, or death

Risks associated with foot and ankle arthrodesis include:

- » Incomplete or lack of bone healing, leading to failure of the surgery
- » Pain following the surgery
- » Surgery may not reduce your pain
- » Pain and discomfort associated with the materials used in the surgery
- » Allergic reaction to the metal in the bone screws, pins, staples, or wires
- » Healing time after surgery that is longer than after other treatment methods
- » Your foot and/or ankle symptoms may change or get worse, and you may need another surgery

Clinical Information

In a clinical study, 434 subjects were enrolled and a total of 414 subjects had surgery. Of these, 397 were treated per study requirements. The control group for the clinical study was treated with traditional bone graft. Analysis of patient information showed no differences between the study and control group. Because the radiographic review was inconclusive, effectiveness of AUGMENT® Bone Graft was evaluated using clinical and functional outcome measures as an assessment of individual subject success. The clinical trial data indicate that at 24 and 52 weeks after surgery, AUGMENT® Bone Graft is at least as effective as the bone graft control treatment, for the patient population and indications studied in terms of the individual patient success for clinical and functional outcomes, without the pain and morbidity resulting from harvesting bone graft.

Description of Adverse Events

In the clinical study for this product, patients reported problems to their doctors. Most of these problems were temporary. Common problems were reported for both groups. These events included back pain, blistered skin, decreased feeling, allergic reaction, not being able to sleep, itchy skin, pain in the foot or ankle, and rash.

Please ask your doctor for any risks related to your planned surgery.

Expectations of the Device and the Procedure Associated with the Device

Your doctor will decide if problems that you are having with your ankle and foot would benefit from a bone graft. If so, a surgery will be scheduled. Before surgery, a local or general anesthetic will be given. During surgery, the bone(s) in the foot will be prepared to receive bone graft by removing small pieces of bone, cartilage, and/or smoothing the bone surface. Once the bone has been prepared, the fixation devices (screws, pins, staples and/or wires) will be used to stabilize the bones. AUGMENT® Bone Graft will be used in place of your own bone to fill in the remaining small holes or spaces between your bones. The wound from surgery will be closed with sutures or staples. The only difference between this and the surgery with bone graft is the replacement of AUGMENT® Bone Graft for your own bone.

After Surgery

Ask your doctor about your specific plans that will help you recover from surgery. It is important to follow your doctor's instructions carefully. In general, a short leg cast or boot may be placed on the foot that has undergone the surgery. The amount of weight placed on the treated foot will be limited and may require the use of crutches and walkers. Physical therapy may also be required. Increased weight-bearing may be allowed after six weeks or when allowed by your doctor. You may need the help of a physical therapist to help you walk smoothly and without limping during your recovery. It is important to follow all instructions after surgery in order to decrease the chance that a complication may occur. Your doctor will schedule visits to check on your progress. It is common following surgery like this to have pain, swelling, redness, tenderness, and difficulty walking or other activities that require weight to be placed on the treated foot/ankle. However, you should contact your doctor immediately if you have too much pain, are sick to your stomach and vomit, or have a fever, redness or rash, itching tenderness or swelling of the foot.

Alternative Procedures

Other treatment options may include:

- » Bone graft materials that do not involve another surgery. Examples of these are other man-made products, bone from a deceased person (allograft), blood or bone marrow
- » Use of metal screws, plates, staples, or wires in your foot/ankle without bone graft
- » Using another device called a total ankle replacement (for some ankle fusion candidates)

Your doctor will have more information on each of these options and other possible treatments, as well as the benefits and risks for each of the treatment options.

When to Call the Doctor

IMMEDIATELY contact your doctor if you:

- » Have too much pain
- » Are sick to your stomach or vomiting
- » Have a fever
- » Have redness or a rash
- » Have itching, tenderness or swelling of your foot

Manufacturer Contact Information

AUGMENT® Bone Graft is manufactured by:

Biomimetic Therapeutics, LLC.
389 Nichol Mill Lane
Franklin, TN 37067
USA

Additional information on this product can be found on the website at wright.com, or in a discussion with your doctor.



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LBS104-00
August 2015