

MEDICAL PRODUCT
PATIENT LABEL

AUGMENT[®]
Injectable



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This brochure is designed to help you make an informed decision about your surgery. Please read this entire document carefully. Keep this document because you may want to read it again. If you have additional questions, talk to your doctor. Only your doctor can determine the types of treatment that may be appropriate for you. Please speak to your doctor about using this product, and about individualized recommendations for you. Only your doctor can determine whether AUGMENT® Injectable is appropriate for you.

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Glossary of Terms

Allograft bone – Bone from a deceased person (also called “banked” bone).

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

Avascular necrosis – Death of bone tissue due to interruption of the blood supply

Beta-Tricalcium Phosphate (β-TCP) – Synthetic bone-like substance

Bone graft (autograft) – 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.

Bovine collagen – A type of tissue taken from a cow

Ceramic – A nonmetallic, rigid material

Endocrine – Organs that produce hormones, a substance which helps regulate and control your body systems and organs

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.

Fusion – When two (or more) bones grow together to prevent movement.

Metabolic – Energy consumption by the body

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

Physical therapist – A person that helps you perform exercises to help you regain movement and strength

Platelet-Derived Growth Factor – PDGF is a protein contained in 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. It is one of the substances the body uses to help heal bones.

Recombinant human platelet-derived growth factor (rhPDGF– BB) – Also referred to by its drug name of becaplermin, rhPDGF-BB is a man-made protein form of Platelet-Derived Growth Factor (PDGF).

Sterile – Free from bacteria or other microorganisms and their spores that could cause an infection.

Yeast cells – Cells produced from yeast that are used to make rhPDGF-BB.

Introduction

You have been given this brochure because you have been diagnosed with arthritis, avascular necrosis, joint instability or deformity or another joint problem in your foot and/or ankle that causes pain and limits your activities. Your doctor has determined that you should have the diseased bones of your foot and/or ankle fused. Your doctor has also determined that bone graft will be needed to help fuse the bones in your foot and/or ankle. Your doctor believes that you may benefit from the use of AUGMENT® Injectable. AUGMENT® Injectable is an alternative to bone taken from another area in your body (autograft) or bone from a deceased person (allograft or “banked” bone).

Description of AUGMENT® Injectable

AUGMENT® Injectable is an alternative to bone graft and is made up of three parts. The first part consists of granules of a ceramic bone-like substance called beta-Tricalcium Phosphate (β -TCP). The second part is made from tissue from cow hides (bovine collagen). The third part is a man-made (genetically-engineered) protein called recombinant human platelet-derived growth factor (rhPDGF-BB).

The ceramic part has been used for many years to help repair bones. It works by providing a scaffold for bone cells to grow on. As bone grows, the ceramic part is gradually replaced by the new bone.

The bovine collagen part dissolves in the body and is used to help deliver the β -TCP and the rhPDGF-BB to the surgery site. When the collagen component is mixed with the β -TCP and the rhPDGF-BB components, the combination has a toothpaste-like consistency. This allows your doctor to apply the AUGMENT® Injectable directly to the surgery site using a syringe.

The third part, rhPDGF-BB, is a man-made (genetically-engineered) protein (growth factor) found naturally within blood cells (platelets). When the body is injured, PDGF-BB is released from the platelets as part of the natural healing process. The rhPDGF-BB used in AUGMENT® Injectable works in a similar way as the PDGF in the body by attracting cells and helping them to repair and grow new bone.



When AUGMENT® Injectable Should Not Be Used

AUGMENT® Injectable 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, bovine collagen and/or any bovine-sourced medication, supplements or products
- » 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 are likely to become pregnant in the next year. The effects that rhPDGF-BB can have on the unborn child have not been studied.
- » Have an active infection of the foot or ankle where you will have surgery
- » Do not have sufficient soft tissue to cover your wound, as determined by your surgeon
- » Have a metabolic disease known to damage the bones (e.g. kidney or calcium diseases), other than osteoporosis or diabetes
- » Require a substitute for structural support, or hardware. AUGMENT® Injectable does not provide structural support to the bony defect.

Some Warnings for the Use of AUGMENT® Injectable

- » There is a chance that your bone will not heal, and you may not obtain pain relief or improvement in your function during daily activity.
- » If you have any allergies, especially to products that are made from yeast, bovine collagen and/or any bovine-sourced medication, then 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® Injectable.
- » Women trying to get pregnant should be advised that the safety of AUGMENT® Injectable and its impact on an unborn child has not been studied.
- » The safety and effectiveness of AUGMENT® Injectable 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® Injectable.
- » The safety and effectiveness of AUGMENT® Injectable has not been studied in other locations in your body other than the foot or ankle.
- » AUGMENT® Injectable must be used with fixation devices (e.g., screws, staples or pins) to hold the bones together for healing.
- » The ceramic part of the AUGMENT® Injectable may make it difficult for your doctor to evaluate the bones of the foot or ankle on x-rays.

Some Precautions for the Use of AUGMENT® Injectable

- » The safety and effectiveness of repeatedly using AUGMENT® Injectable 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 rhPDGF-BB component of AUGMENT® Injectable is the active part in another product (REGRANEX®). 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 patients who had pre-existing cancers. However, for the clinical studies used to approve AUGMENT® Injectable, there was no difference in the number of deaths from cancer as compared to bone graft.

Possible Risks Associated with AUGMENT® Injectable

As with any surgery, there are risks associated with fusion surgery of the foot and ankle. Some complications may be severe, affecting the overall outcome of the surgery. It is possible that the surgery may not be as effective in relieving your symptoms or may cause worsening of your symptoms. Sometimes you may need additional surgery to correct complications or in order to help you feel better.

Risks associated with any surgery include:

- » Bleeding, which may require a blood transfusion
- » Damage to tissues or nerves near the surgical site
- » Healing time after surgery is longer than that after other treatment methods
- » In rare situations, heart attack, stroke, or death
- » Incomplete or lack of bone healing leading to failure of the surgery
- » Infection
- » Kidney (renal) problems
- » Mild to severe swelling
- » Nervous system problems
- » Pain and discomfort associated with the materials used in the surgery
- » Pain following the surgery
- » Problems breathing (respiratory). Respiratory problems could include: lung infection (pneumonia), lung collapsing (atelectasis), or swelling in the neck (edema)
- » 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)

- » Problems with the stomach and intestines (gastrointestinal)
- » Problems with the urinary or genital systems (urogenital)
- » Reaction to the drugs used to put you asleep during surgery (anesthesia)
- » Scar formation or other problems with the surgical incision
- » Surgery may not reduce your pain
- » Wound healing complications, including infection, drainage, collection of blood at the surgical site, pain

Risks associated with foot and ankle fusion with or without the use of AUGMENT® Injectable include:

- » Your foot and/or ankle symptoms may change or get worse, and you may need another surgery
- » Allergic reaction to the metal in the bone fixation hardware
- » Allergic reactions to the ingredients of AUGMENT® Injectable
- » Movement of the AUGMENT® Injectable from where it is placed, as is possible with any bone graft, which may result in pain, decrease or loss in physical functioning, and may require additional surgery
- » Failure of the bones of the foot and ankle to fuse
- » Temporary increase in calcium levels which may cause muscle weakness
- » Pain or discomfort in the foot and/or ankle
- » Abnormal bone formation in an unintended location
- » Excessive or incomplete bone formation
- » Arthritis or other disorders in bone formation

Please ask your doctor about any other risks related to your planned surgery.

The Surgery Associated with AUGMENT® Injectable

Before surgery, you will be given a local or general anesthetic. 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, bone fixation hardware will be used to stabilize the bones. AUGMENT® Injectable does not replace the need for fixation devices needed to hold the bones together. AUGMENT® Injectable will be placed to fill in the holes or spaces between your bones. The wound from surgery will be closed with sutures or staples. The only difference between surgery using AUGMENT® Injectable, and surgery using your own bone for bone graft, is that a second surgical procedure to collect bone from another part of your body is not required.

After Surgery with AUGMENT® Injectable

Your doctor will tell you about 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 permitted 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.

Clinical Information

The safety and effectiveness of AUGMENT® Injectable has been tested in a total of 299 patients undergoing foot and/or ankle fusion in a number of hospitals in the US and Canada. Patients were divided into two groups – the experimental group received AUGMENT® Injectable (132 patients) and the control group received their own bone (167 patients). Subjects were randomly treated with either AUGMENT® Injectable or their own bone. The study included evaluations of pain and function at multiple timepoints. X-rays of the treated bones were also taken at multiple timepoints after the fusion surgery to see if the bones had fused. Because AUGMENT® Injectable looks similar to bone on x-rays, it was difficult to determine if the treated bones actually fused. The key study results were assessed at 52 weeks after surgery. These results showed that AUGMENT® Injectable was at least as effective as autograft for treating the patient's pain and improving the patient's function.

Patients were asked to report any complications to their doctors. Most of these complications were temporary. Common complications were reported for both groups, such as back pain, blistered skin, decreased feeling, allergic reaction, not being able to sleep, itchy skin, pain in foot or ankle,

rash, and infections. The study also looked to see if a second surgery was needed to fix a problem from the first surgery. The number and types of complications appeared to be similar for the AUGMENT® Injectable and “own bone” groups.

Although the number and types of complications that were reported appeared to be similar, there were some differences with the way that complications were evaluated. This might have resulted in differences regarding the type and severity of complications being reported.

Because using AUGMENT® Injectable does not require taking bone from another part of your body, it did not have the risks associated with this extra surgical procedure.

You should ask your doctor about the potential complications associated with your individual procedure.

Alternative Treatments to the Use of AUGMENT® Injectable

Other treatment options may include:

- » Use of bone graft materials that do not require an additional surgical procedure. Examples of these are man-made products (bone void fillers) or bone from a deceased person (allograft)
- » Use of metal screws, plates, staples, or wires in your foot/ankle without any bone graft material
- » 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

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