What is Grafton Used For
Grafton™ Demineralized Bone Matrix is used to fill bony voids or gaps in the skeletal system that may be surgically created or as a result of traumatic injury to the bone. The graft is absorbed and replaced by your own bone during the healing process.

Product Description
Grafton™ and Grafton Plus™ Demineralized Bone Matrix (DBM) is formulated from human bone taken from deceased donors. Medtronic utilizes strict donor screening procedures to avoid the collection and use of tissue from donors who may carry infectious diseases.

Active Ingredient
• Demineralized human bone tissue

Other ingredients (based on formulation)
• USP anhydrous glycerol or
• A starch carrier

Caution
Grafton products may contain small amounts of antibiotics and other processing solutions. Caution should be exercised if the patient is allergic to these antibiotics or chemicals.

Grafton Plus™ DBM Paste contains starch. Therefore, caution should be exercised in using Grafton Plus™ DBM Paste in a patient with a starch allergy and/or amylase deficiency.

When Grafton Should Not Be Used
The following are contraindications for Grafton™ DBM and Grafton Plus™ DBM:
• The presence of infection at the transplantation site.
• Treatment of spinal insufficiency fractures (a type of stress fracture).

Precaution
Despite the extensive testing of donor tissue, transmission of an infectious disease through the use of this tissue graft is still possible. Bacterial infection at the graft site may also occur. Any adverse outcomes potentially attributable to Grafton™ DBM or Grafton Plus™ DBM must be reported promptly to your doctor. You may also report it to Medtronic at 1800 668 670 or directly to the Therapeutic Goods Administration at this link:

Adverse Effects
Implanting Grafton carries the same risks associated with any surgery:
• Infection
• Pain at the surgery site
• Bruising or swelling at the surgery site
• Bleeding at the surgery site

Seek medical advice if you experience any of these symptoms.

MRI Information
Grafton™ DBM and Grafton Plus™ DBM are non-conducting and non-magnetic and pose no risk in the Magnetic Resonance Imaging (MRI) environment.

Dosage
The contents of an individual Grafton™ DBM or Grafton Plus™ DBM container are intended for single patient use only. The volume of graft material used in each procedure is determined by the judgment of the clinician.

Record Keeping
It is important that you keep a record of your human tissue implant. You will be sent a small card similar to a credit card that you can keep in your wallet which will have the details of your implant printed on it.

Manufacturer
Legal Manufacturer
Medtronic Sofamor Danek USA, Inc.
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Memphis, TN 38132, USA

Manufacturing Facility
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This information sheet is available for download at:
http://manuals.medtronic.com/manuals/main/region
http://www.medtronic.com.au

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