



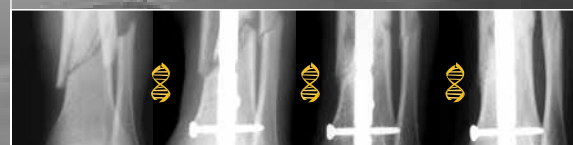
Medtronic
SOFAMOR DANEK

INFUSE[®]
BONE
GRAFT



rhBMP2

Instructions for Preparation and Surgical Application for Open Tibial Fracture



TRAUMA APPLICATION

INFUSE® BONE GRAFT FOR OPEN TIBIAL FRACTURES

INSTRUCTIONS FOR PREP

The Instructions for Preparation must be followed and the rhBMP-2 must be reconstituted to a solution concentration of 1.5mg/mL and then distributed uniformly across the entire ACS.

7510800 LARGE II KIT

IN NON-STERILE FIELD

STEP 1



Observing proper sterile technique, open the outer ACS package and place the inner package containing the 3" x 4" collagen sponge in the sterile field. Open and place one of the two 10mL syringes/needles into the sterile field.

STEP 2



Using the other 10mL syringe/needle, withdraw **8.4mL** of sterile water for injection.

STEP 3



Reconstitute the rhBMP-2 with **8.4mL** of sterile water.

STEP 4



Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

IN STERILE FIELD

STEP 5



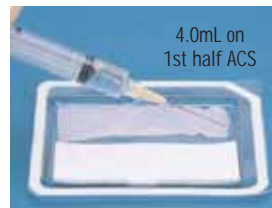
Open the inner ACS package. Using sterile scissors, cut the 3" x 4" collagen sponge into two 1½" x 4" strips. Return the cut collagen sponge to the plastic tray.

STEP 6



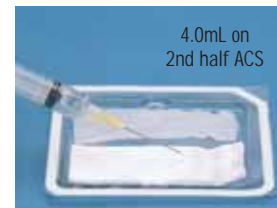
In the sterile field use the 10mL syringe/needle to withdraw **4.0mL** of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

STEP 7



Uniformly distribute **4.0mL** of reconstituted rhBMP-2 on one of the 1½" x 4" collagen sponges.

STEP 8



Using the same 10mL syringe/needle, repeat steps 6 and 7 for the remaining 1½" x 4" collagen sponge.



Allow wetted collagen sponges to stand for a minimum of 15 minutes. Use within 2 hours.



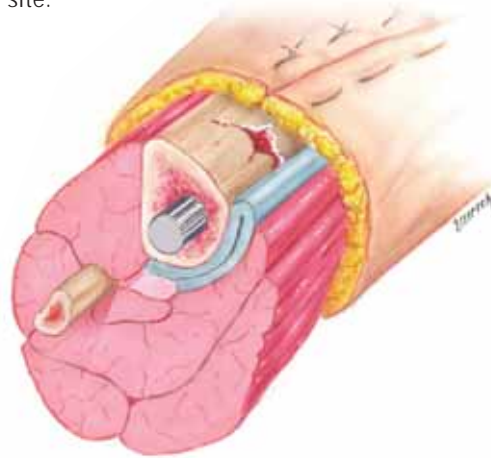
DO NOT use irrigation or suction near implanted device.

Note: During handling avoid excessive squeezing of the wetted sponge.

INSTRUCTIONS FOR SURGICAL APPLICATION

Pre-implantation

- Achieve hemostasis prior to INFUSE® Bone Graft implantation in order to provide a relatively dry implantation site.
- The volume of INFUSE® Bone Graft implanted is determined by the fracture anatomy and the ability to close the wound without overly packing or compressing the product.
- After preparing the entire ACS according to the Instructions for Preparation, fold or cut the INFUSE® Bone Graft as needed prior to implantation.



Implantation

- During implantation, use forceps to handle INFUSE® Bone Graft to avoid excessive loss of fluid.
- Place INFUSE® Bone Graft so that it bridges the region of comminution and makes good contact with the major proximal and distal fragments.
- INFUSE® Bone Graft may be placed into a void (loosely packed), folded, rolled, or wrapped, as the geometry of the fracture requires.
- INFUSE® Bone Graft should not be used to provide mechanical stability or to fill spaces in the presence of compressive forces. It should only be used after adequate fracture reduction and stabilization have been achieved.

Post-implantation

- Once INFUSE® Bone Graft is implanted, do not irrigate the wound.
 - If a surgical drain is required, place the drain remote from the implantation site or, preferably, one layer superficial to the implantation site.
 - Achieve complete soft-tissue coverage of INFUSE® Bone Graft following its implantation.
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Ordering Information 7510800 LARGE II KIT Components



INFUSE® Bone Graft Kit
Total Graft Volume 8.0mL (cc)



Sterile Water for Injection
(1) 10mL Vial



Sterile rhBMP-2
(1) 12mg Vial



Sterile Absorbable Collagen Sponge (ACS)
(1) ACS 3" x 4"

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR: INFUSE® BONE-GRAFT

The INFUSE® Bone Graft is indicated for treating acute, open tibial shaft fractures that have been stabilized with IM nail fixation after appropriate wound management. INFUSE® Bone Graft must be applied within 14 days after the initial fracture. Prospective patients should be skeletally mature.

The INFUSE® Bone Graft is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with an active malignancy or patients undergoing treatment for a malignancy. The INFUSE® Bone Graft should also not be used in patients who are skeletally immature, in patients with an inadequate neurovascular status,

in patients with compartment syndrome of the affected limb, in pregnant women, or in patients with an active infection at the operative site.

Antibody formation to rhBMP-2 or its influence on fetal development has not been assessed. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

For product availability and/or more information on any MEDTRONIC SOFAMOR DANEK USA, INC. products, contact your MEDTRONIC SOFAMOR DANEK USA, INC. Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA, INC. Customer Service toll free: 800-933-2635.



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