Infuse™ Bone Graft rhBMP-2/ACS

Instructions for Preparation and Handling

Medtronic
Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

IN NON-Sterile FIELD

1. Observing proper sterile technique, open the outer Absorbable Collagen Sponge (ACS) package and place the inner package containing the one ½” × 2” collagen sponge in the sterile field. Open and place one of the two 3mL syringe/needles in the sterile field.

2. Using one needle and 3mL syringe/needle, withdraw 0.9mL of sterile water for injection.

3. Reconstitute the rhBMP-2 with 0.9mL of sterile water.

4. Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Inspect the solution. If dark particles are observed, do not use and return to sponsor.

IN Sterile FIELD

5. Open the inner ACS package leaving the collagen sponge in the plastic tray.

6. In the sterile field use the 3mL syringe/needle to withdraw 0.7mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

7. Uniformly distribute 0.7mL of reconstituted rhBMP-2 on the ½” × 2” collagen sponge. Inspect the sponge. If dark particles are observed, do not use and return to sponsor.

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.
Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

**IN NON-SterILE FIELD**

1. Observing proper sterile technique, open the outer Absorbable Collagen Sponge (ACS) package and place the inner package containing the one 1” × 2” collagen sponge in the sterile field.
2. Open and place two 3mL syringes/needles into the sterile field.
3. Using one of the two remaining 3mL syringes/needles withdraw 0.9mL of sterile water for injection.
4. Reconstitute one vial of the rhBMP-2 with 0.9mL of sterile water.
5. Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Using a second 3mL syringe/needle repeat steps 2-3 with the remaining vial of sterile water and vial of rhBMP-2. Inspect the solution in both vials. If dark particles are observed, do not use and return to sponsor.

**IN STERILE FIELD**

1. Open the inner ACS package leaving the collagen sponge in the plastic tray.
2. In the sterile field use the 3mL syringe/needle to withdraw 0.7mL of reconstituted rhBMP-2 from the first vial held by the person in the non-sterile field.
3. Uniformly distribute 0.7mL of reconstituted rhBMP-2 on half of the 1” × 2” collagen sponge.
4. In the sterile field use the second 3mL syringe/needle to withdraw 0.7mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.
5. Uniformly distribute 0.7mL of reconstituted rhBMP-2 on the other half of the 1” × 2” collagen sponge. The total amount of reconstituted rhBMP-2 delivered to the sponge is 1.4mL. Inspect the sponge. If dark particles are observed, do not use and return to sponsor.

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.
7510200 Small Kit (2.8cc)

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

IN NON-SterILE FIELD

1. ACS
2. Using the other 5mL syringe/needle, withdraw 3.2mL of sterile water for injection.
3. Reconstitute the rhBMP-2 with 3.2mL of sterile water.
4. Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

IN STERILE FIELD

5. Open the inner ACS package leaving all collagen sponges in the plastic tray.
6. In the sterile field use the 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.
7. Uniformly distribute 1.4mL of reconstituted rhBMP-2 on one of the 1” × 2” collagen sponges.
8. Using the same 5mL syringe/needle, repeat steps 6 and 7 for the remaining 1” × 2” collagen sponges.

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.
7510400 Medium Kit (5.6cc)

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

**IN NON-STERILE FIELD**

1. **ACS**
   - Observing proper sterile technique, open the outer ACS package and place the inner package containing the four 1” × 2” collagen sponges in the sterile field. Open and place two of the four 5mL syringes/needles into the sterile field.

2. **3.2mL**
   - Using one of the two remaining 5mL syringes/needles, withdraw 3.2mL of sterile water for injection.

3. **1.2mL**
   - Reconstitute one vial of the rhBMP-2 with 3.2mL of sterile water.

4. **Gently swirl (do not shake)**
   - Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Using a second 5mL syringe/needle, repeat steps 2 and 3 with the remaining vial of sterile water and vial of rhBMP-2.

**IN STERILE FIELD**

5. **Open the inner ACS package leaving all collagen sponges in the plastic tray.**

6. **In the sterile field use the 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.**

7. **Uniformly distribute 1.4mL of reconstituted rhBMP-2 on one of the 1” × 2” collagen sponges.**

8. **Using the same 5mL syringe/needle, repeat steps 6 and 7 for the second 1” × 2” collagen sponge.**

9. **In the sterile field use the second 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.**

10. **1.4mL on 3rd ACS**
    - Uniformly distribute 1.4mL of reconstituted rhBMP-2 on the third 1” × 2” collagen sponge.

11. **1.4mL on 4th ACS**
    - Using the second 5mL syringe/needle, repeat steps 9 and 10 for the fourth 1” × 2” 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.
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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.

**7510800 Large II Kit (8.0cc)**

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

### IN NON-STERILE FIELD

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.

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

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

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

### IN STERILE FIELD

5. Open the inner ACS package. Using sterile scissors, cut the 3" x 4" collagen sponge into two 1 1/2" x 4" strips. Return the cut collagen sponges to the plastic tray.

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.

7. Uniformly distribute 4.0mL of reconstituted rhBMP-2 on one of the 1 1/2" x 4" collagen sponges.

8. Using the 10mL syringe/needle, repeat steps 6 and 7 for the remaining 1 1/2" x 4" collagen sponge.
BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR:
INFUSE™ BONE GRAFT/LT-CAGE™ LUMBAR TAPERED FUSION DEVICE
INFUSE™ BONE GRAFT/INTER FIX™ THREADED FUSION DEVICE
INFUSE™ BONE GRAFT/INTER FIX™ RP THREADED FUSION DEVICE

The INFUSE™ Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1, who may also have up to Grade I spondylolisthesis or Grade 1 retrodislocation at the involved level. The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach. INFUSE™ Bone Graft with either the INTER FIX™ or INTER FIX™ RP Threaded Fusion Device is to be implanted via an anterior open approach.

The INFUSE™ Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device consists of two components containing three parts—a metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. These components must be used as a system for the prescribed indication described above. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document. The INFUSE™ Bone Graft component must not be used without the Medtronic Titanium Threaded Interbody Fusion Device component.

NOTE: The INTER FIX™ Threaded Fusion Device and the INTER FIX™ RP Threaded Fusion Device may be used together to treat a spinal level. LT-CAGE™ Lumbar Tapered Fusion Device implants are not to be used in conjunction with either the INTER FIX™ or INTER FIX™ RP implants to treat a spinal level.

The INFUSE™ Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device 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 any active malignancy or patients undergoing treatment for a malignancy; in patients who are skeletally immature; in pregnant women; or in patients with an active infection at the operative site or with an allergy to titanium or titanium alloy.

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. 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, definition of DDD, and other important medical information. The package insert also matches the sizes of those sized devices that are indicated for use with the appropriate INFUSE™ Bone Graft kit.

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