



HEALOS® Fx
Injectable Bone Graft Replacement

Surgical Technique Guide

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HEALOS Fx SYSTEM COMPONENTS

5CC GRAFT



HEALOS Fx Injectable Bone Graft Replacement components are listed below.

HEALOS Fx CONFIGURATIONS

- HEALOS Fx, 5cc (500mg of fibrous material)

OR

- HEALOS Fx, 10cc (1000mg of fibrous material)

WITH

- HEALOS Fx Graft Mixing and Delivery System

BONE MARROW ASPIRATION NEEDLES FOR THE ILIAC CREST

- 3-Hole, 4" Aspiration Needle (with 2-10cc syringes)
- 3-Hole, 6" Aspiration Needle (with 2-10cc syringes)

10CC GRAFT



HEALOS Fx BONE MARROW ASPIRATION VOLUMES

RECOMMENDED BONE MARROW VOLUMES FOR USE WITH HEALOS Fx

When aspirating bone marrow for use with HEALOS Fx, a 1:1 volume ratio of bone marrow aspirate (BMA) to graft material is recommended (Table 1).

TABLE 1

Final Graft Volume	Volume of HEALOS Fx Material Required	Volume of BMA Required
5cc	1 - 5cc (500mg) pouch	5cc
10cc	1 - 10cc (1000mg) pouch, or 2 - 5cc (500mg) pouches	10cc

HEPARIN USE* (FOR CANNULA EXTRUSION)

If delivering the final graft via cannula, the use of heparin is required when aspirating BMA to prevent the BMA from clotting (20 units heparin/1cc BMA). Heparin is not required if extruding a bone graft log from the Delivery Chamber.

Prepare the recommended diluted heparin mixture using the protocol detailed below:

- 1) Begin with heparin at an initial concentration of 1,000 units/cc.
- 2) Transfer 2.5cc of heparin into a specimen cup (concentration: 1,000 units/cc).
- 3) Add 10cc of 0.9% sodium chloride (for injection) to the specimen cup.
- 4) Draw 0.5cc of this solution into a syringe for every 5cc of HEALOS Fx material.

Aspirate bone marrow into the heparin syringe following the volume guidelines below and aspiration technique on the next page.

TABLE 2

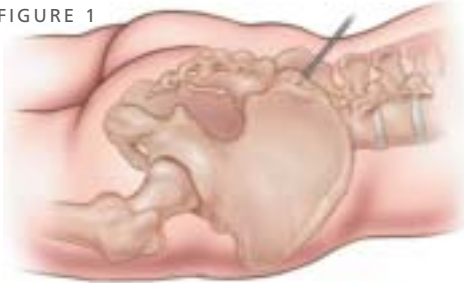
Final Graft Volume	Volume of HEALOS Fx Material Required	Volume of Diluted Heparin Mixture Required	Volume of BMA Required
5cc	1 - 5cc (500mg) pouch	0.5cc	4.5cc
10cc	1 - 10cc (1000mg) pouch, or 2 - 5cc (500mg) pouches	1.0cc	9.0cc

By using the above protocol, the total heparin dose administered is 100 units for a 5cc graft and 200 units for a 10cc graft.

** NOTE: This product may be used in conjunction with heparin. The use of heparin may be associated with bleeding or thrombocytopenia. When using heparin, follow the dosing recommendations as outlined above. This product should not be used in patients with a known hypersensitivity to heparin.*

BONE MARROW ASPIRATION FROM THE ILIAC CREST – POSTERIOR APPROACH

FIGURE 1



To use the posterior approach, manually palpate the patient to locate the superior aspect of the posterior superior iliac spine. Make a 2mm incision using a #11 blade or use the bone marrow aspiration needle percutaneously. The initial trajectory of the needle is roughly 40 degrees lateral from the para-sagittal plane and 35-40 degrees inferior from the transverse plane (aiming roughly at the tip of the greater trochanter) as shown (Figure 1).

FIGURE 2



Set the 3-hole BMA needle tip into the bone by applying firm forward pressure on the needle handle. To advance the needle tip through the cortex, continue to apply firm forward pressure or gently tap the needle handle with a mallet.

Once the cortex has been penetrated, continue to advance the needle until all aspiration holes are engaged in bone. Thread the syringe onto the top of the BMA needle. Keeping in mind the total amount of BMA needed for the graft size of choice, pull back the plunger of the syringe to draw in no more than 6cc of marrow per site - the equivalent of approximately 2cc per site when using the 3-hole needle (Figure 2).

FIGURE 3



To change sites, advance the 3-hole needle 3cm parallel to the line of the crest to enter a different cubic centimeter area (Figure 3). Pull back the plunger of the syringe, to draw approximately 6cc more of marrow.

Remove the full syringe and replace with a fresh one if needed.

Continue aspirating marrow until you have sufficient volume.

See table on Page 2 for recommendations.

NOTE: Muschler, et. al. reported that drawing 2-4cc of marrow per site is important to reduce the dilution of marrow with peripheral blood.¹

Proceed to HEALOS Fx Mixing & Extrusion Technique, page 5.

¹ Muschler GF, Boehm C, Easley K. Aspiration to Obtain Osteoblast Progenitor Cells from Human Bone Marrow: The Influence of Aspiration Volume. *Journal of Bone & Joint Surgery*. November 1997;79-A;11:1699-1709.



BONE MARROW ASPIRATION FROM THE ILIAC CREST – ANTERIOR APPROACH

FIGURE 4



To use the anterior approach, manually palpate the patient to locate the anterior superior iliac spine. Make a 2mm incision using a #11 blade or use the bone marrow aspiration needle percutaneously. The initial trajectory of the needle should be medially in line with the pelvic wing as gauged by palpation of the inner and outer tables. The trajectory should be aimed slightly posteriorly at the iliac tubercle to enter the medullary canal just beneath it (Figure 4).

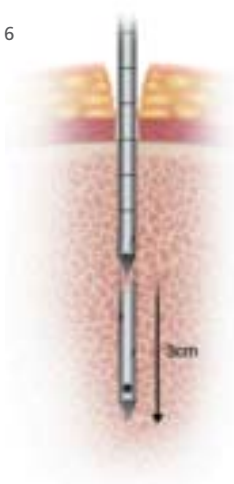
FIGURE 5



Set the 3-hole BMA needle tip into the bone by applying firm forward pressure on the needle handle. To advance the needle tip through the cortex, continue to apply firm forward pressure or gently tap the needle handle with a mallet.

Once the cortex has been penetrated, continue to advance the needle until all aspiration holes are engaged in bone. Thread the syringe onto the top of the BMA needle. Keeping in mind the total amount of BMA needed for the graft size of choice, pull back the plunger of the syringe to draw in no more than 6cc of marrow - the equivalent of approximately 2cc per site when using the 3-hole needle (Figure 5).

FIGURE 6



To change sites, advance the 3-hole needle 3cm parallel to the line of the crest to enter a different cubic centimeter area (Figure 6). Pull back the plunger of the syringe, to draw approximately 6cc more of marrow.

Remove the full syringe and replace with a fresh one if needed.

Continue aspirating marrow until you have sufficient volume.

See table on Page 2 for recommendations.

NOTE: Muschler, et. al. reported that drawing 2-4cc of marrow per site is important to reduce the dilution of marrow with peripheral blood.¹

Proceed to HEALOS Fx Mixing & Extrusion Technique, page 5.

HEALOS Fx MIXING & EXTRUSION TECHNIQUE

FIGURE 1



FIGURE 2



FIGURE 3



FIGURE 4



STEP 1: SET-UP

Remove the Loading and Delivery Chambers from the HEALOS Fx Graft Mixing and Delivery Device tray and connect them together tightly (Figures 1-3).

Open the pouch containing the HEALOS Fx material.

NOTE: While preparing the other components of the device, be sure to keep the cap on the white mixing plunger until immediately before use to prevent the filter from getting wet. A wet filter will not allow air in the chambers to clear properly and will disrupt the mixing process.

STEP 2: ADD BONE MARROW ASPIRATE

Use the tables on page 2 to determine how much BMA and optional heparin are needed to create the final graft volume. Holding the device upright, add the BMA to the Loading Chamber as shown in Figure 4.

NOTE: If you are not using heparin to anti-coagulate the BMA, be sure to proceed through Steps 3-5 immediately after the BMA is drawn from the patient to prevent the BMA from clogging the device.

FIGURE 5



STEP 3: ADD HEALOS Fx MATERIAL

Using the table on page 2, add the appropriate amount of HEALOS Fx material to the Loading Chamber based on the volume of BMA added in Step 2 (Figure 5).

FIGURE 6



Once the material has been placed in the Loading Chamber, use forceps or one of the two stylettes in the kit to completely saturate the material with the bone marrow (Figure 6).

FIGURE 7



STEP 4: INSERT THE WHITE MIXING PLUNGER

Remove the cap from the end of one of the two white plungers included in the HEALOS Fx Graft Mixing and Delivery Device tray (Figure 7). Keep the filter on the end of the white plunger dry until use. Take care with wet gloves.

NOTE: If the filter on the white plunger should become wet prior to use, please discard and use the second white plunger provided in the kit.

FIGURE 8



Continue holding the device upright while maintaining downward force on the assembly to prevent movement of the blue plunger in the Delivery Chamber. Insert the white plunger into the Loading Chamber until it comes in contact with the surface of the bone marrow (Figure 8).

FIGURE 9



STEP 5: MIX HEALOS Fx WITH BONE MARROW ASPIRATE

Begin mixing the BMA and HEALOS Fx material by releasing pressure on the blue plunger and pushing on the white plunger, passing all contents into the Delivery Chamber (Figure 9).

Continue to mix the material back and forth by quickly pushing one plunger at a time until the consistency of the material is even - approximately 7 single transfers from one chamber to another (Figure 10). Do not push both plungers at once.

FIGURE 10



After mixing, push all of the material into the Delivery Chamber (Figure 11).

FIGURE 11



FIGURE 12



STEP 6: REMOVE THE LOADING CHAMBER

Holding the device upright, detach the Loading Chamber by unscrewing it from the Delivery Chamber (Figure 12).

FIGURE 13



FIGURE 14



FIGURE 15



STEP 7: OPTIONS FOR BONE GRAFT EXTRUSION

NOTE: Any irrigation of the implantation site should be done before the graft is placed or injected.

Step 7a: Moldable Graft - Extrude the Bone Graft as a Log

To extrude a bone graft log, push down on the blue plunger until the material exits the Delivery Chamber (Figure 13). The moldable material is now ready to be placed in the implant site.

OR

Step 7b: Injectable Graft - Extrude the Bone Graft via a 3" or 8" Cannula (8G)

Remove the stylet from the cannula in the tray and attach the appropriate length cannula to the end of the Delivery Chamber. Push down on the blue plunger to inject the material from the cannula into the implantation site. (Figure 14).

Disconnect the cannula from the Delivery Chamber and insert the appropriate length stylet into the cannula. Push out the remaining bone graft material into the implantation site (Figure 15).

NOTE: The 3" stylet must be used only with the 3" cannula and the 8" stylet must be used only with the 8" cannula.

A blue syringe with a silver needle, containing a dark red liquid, is shown against a white background. The syringe is angled diagonally from the top left towards the center.

HEALOS[®] Fx

Injectable Bone Graft Replacement

INDICATIONS

HEALOS[®] Fx Injectable Bone Graft Replacement combined with autogenous bone marrow is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. HEALOS Fx is a bone graft substitute that is resorbed and remodeled into new bone as part of the natural healing process.

The HEALOS Fx Graft Mixing and Delivery System is indicated for the mixing of HEALOS Fx Injectable Bone Graft Replacement with bone marrow aspirate, and delivery of this mixture to a surgical site.

CONTRAINDICATIONS

HEALOS Fx must not be used in patients with osteomyelitis at the operative site.

HEALOS Fx must not be used in patients with a history of anaphylaxis, history of multiple allergies, known allergies to bovine collagen, or who are being treated for desensitization to meat products because this product contains bovine collagen.

HEALOS Fx must not be used where the surgical site may be subjected to excessive impact or stresses beyond the load strength of the fixation hardware.

Limited Warranty and Disclaimer: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

This product may be used in conjunction with heparin. The use of heparin may be associated with bleeding or thrombocytopenia. This product should not be used in patients with a known hypersensitivity to heparin.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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