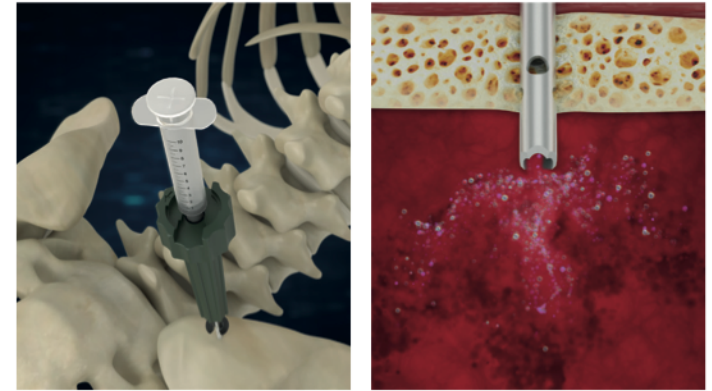


Prior to aspiration procedure, please follow heparin flush procedure steps on reverse of page.

- 1 Insert Access Needle past cortex just into medullary space. Ensure longitudinal orientation.



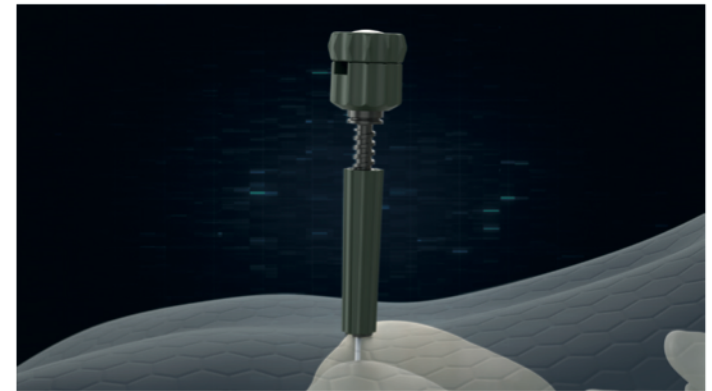
- 2 Remove Sharp Stylet, attach Syringe, draw 1mL to test proper localization of Access Needle tip.



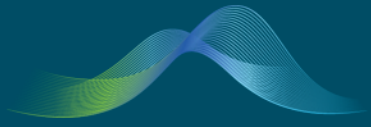
- 3 Remove Syringe, Insert Blunt Stylet, continue to advance Access Needle to desired



- 4 Rotate Outer Housing clockwise to skin level and remove Blunt Stylet.

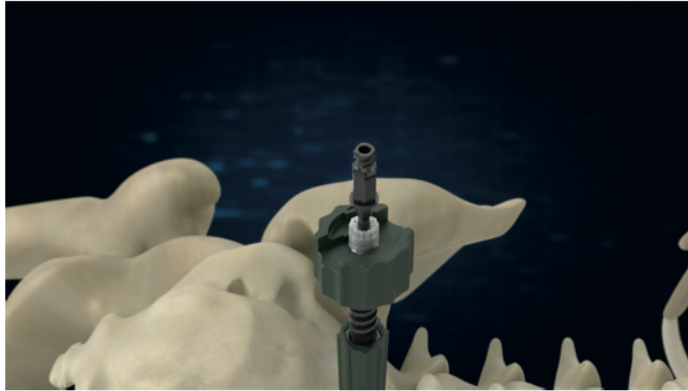


*Abbreviated Instructions. Please refer to the package insert for complete instructions for use.

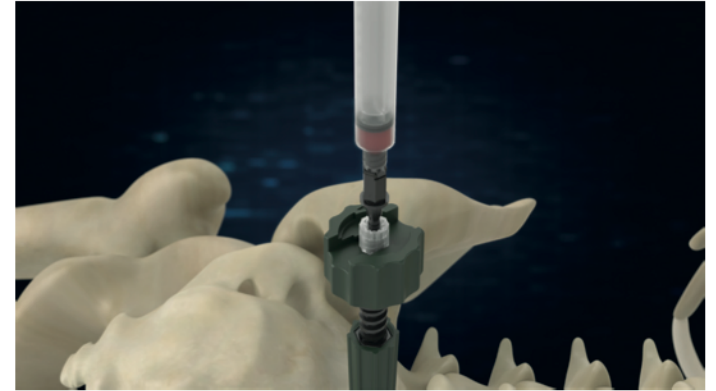


Prior to aspiration procedure, please follow heparin flush procedure steps on reverse of page.

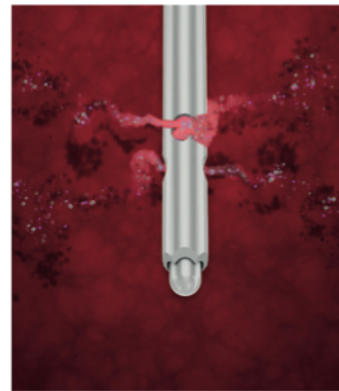
- 5 Insert Aspiration Cannula & Attach to Access Needle.



- 6 Attach syringe & draw 1mL of marrow.



- 7 While holding Outer Housing in place, rotate handle 360° underclockwise with opposite hand to raise Cannula tip into new geography.



- 8 Continue to Draw Marrow in 1cc intervals, while moving to fresh zone of cells every rotation



*Abbreviated Instructions. Please refer to the package insert for complete instructions for use.

- 9 Repeat steps 7 & 8 until desired volume is attained

Suggested Heparin Flush Procedure for Bone Marrow Aspirate

1. Withdraw 2,000 units/mL* of Heparin from sterile bowl into 10mL syringe
2. Remove Stylets from Introducer Needle and Aspiration Cannula with distal end of needle inside sterile bowl
3. Connect Heparin-filled syringe to the shorter Introducer needle and inject Heparin until needle is fully rinsed (is flowing through end of needle). Aspirate Heparin back into syringe and disconnect from needle.
4. Repeat step 3 for the longer aspiration needle.
5. Rinse each stylet (3), short introducer sharp (1) and blunt (2), longer aspiration stylet (3).
6. With needle guards in place, rinse the outside of each needle by injecting Heparin into the open end of the guard.

BEGIN ASPIRATION PROCEDURE FOR IMMEDIATE USE (EX. MIXING WITH BONE GRAFT)

OR

CONTINUE FOLLOWING STEPS FOR BONE MARROW ASPIRATE INJECTION THROUGH 22 GAUGE NEEDLE

7. Rinse 22 Gauge Needle with 2,000 units of Heparin
8. Add ½ mL of Heparin into collection syringe

*It is important that the strength per mL of the Heparin rinse is at least 1,000/mL but preferably 2,000/mL and that you have adequate volume (10mL) to rinse all needles and syringes. Using a sterile bowl, add sterile Saline or PBS to dilute Heparin to 2,000 units/mL.

The tables below detail the amount of Heparin and Saline or PBS needed to dilute the Heparin to 2,000 units/mL.

Using 5,000/mL Heparin				
mL of Heparin Required	mL of Saline or PBS	Total Heparin Units	Total mL	Heparin/mL
4	6	20,000	10	2,000

Using 10,000/mL Heparin				
mL of Heparin Required	mL of Saline or PBS	Total Heparin Units	Total mL	Heparin/mL
2	8	20,000	10	2,000



Percutaneous Bone Graft Collection

Produces Autologous Cancellous Graft Material with Osteoconductive, Osteoinductive & Osteogenic Properties

Minimally Invasive Cancellous Bone Core Extraction Technique

May Be Combined with Allogeneic, Autologous or Synthetic Bone Chips Hydrated with Marrow Cellution™ Aspirate



Intact Bone Cores vs. Morselized Bone

- Harvesting intact cancellous bone cores without disrupting the highly-organized living tissue is superior to transplanting pieces of bone. Intact grafts maintain the micro-vascular network within the graft promoting bone callus formation/remodeling and do not exhibit extensive resorption.^{1,2}
- Intact bone exploits the biology of normal fracture healing rather than through slow creeping substitution associated with the slow incorporation of a non-vascularized graft.¹
- Research demonstrates the enhanced survival of a bone graft as long as its primary blood supply is preserved. A living bone graft will shorten the time for bony union because the reconstructed bone is comparable to a bone with a double fracture.^{1,2}
- Allogenic or synthetic bone chips hydrated with marrow can be packed around the living bone graft/core to accelerate anastomosis into the graft and minimize morbidity.^{1,2}

Minimally Invasive Bone Grafts

- Vascularized and cancellous autograft shows optimal skeletal incorporation but is limited by morbidity concerns.³
- Using the Marrow Cellution™ Graft Delivery Syringe and the Marrow Cellution™ Bone Core Harvest Device, the clinician can create a combination graft of a vascularized intact bone core in the center of the graft surrounded by allogeneic, autologous or synthetic bone chips hydrated with cellular marrow aspirate.
- Higher quality, less quantity, delivered appropriately minimizes host morbidity.



(1) Bleuming SA, et al. Bone morphogenetic protein signaling suppresses tumorigenesis at gastric epithelial transition zones in mice. *Cancer Res.* 2007 Sep; 1;67(17):8149-55.
(2) Ostrup LT, et al. Distant transfer of a free, living bone graft by microvascular anastomoses. An experimental study. *Plast Reconstr Surg.* 1974 Sep;54(3):274-85.
(3) Taylor GI, et al. The free vascularized bone graft. A clinical extension of microvascular techniques. *Plast Reconstr Surg.* 1975 May; 55(5):533-544.

Marrow Aspiration & Cancellous Bone Graft

The Marrow Cellution™ Bone Marrow Aspiration- & Autologous Bone Harvesting System allows physicians to combine high quality bone marrow aspirate and percutaneously harvested cancellous bone autograft.

Harvesting intact cancellous bone cores without disrupting highly vascularized and organized tissue is superior to transplanting small pieces of morselized bone.

The highly active cellular composition of Marrow Cellution™ Aspirate combined with percutaneously harvested bone core(s) deliver autograft without the associated morbidity.

- Autologous graft material with Osteoconductive, Osteoinductive and Osteogenic properties.
- Minimally invasive technique – uses an 8 Gauge Trepine Needle for bone core extraction.
- Graft material may be combined with allogenic, autologous or synthetic bone chips hydrated with highly cellularized marrow aspirate.
- Percutaneous harvesting reduces donor site morbidity associated with standard harvesting techniques.



Process Steps for Bone Collection *(Abbreviated Instructions. For Complete Instructions Please Refer To Official IFU Included In Kit)*

- Insert and advance Trephine Needle to desired depth and remove Sharp Stylet
- Insert Marked Measurement Probe to check sample length & remove Probe
- Insert Extraction Tool into the Trephine Needle cannula
- Push Extraction Tool to luer connection of the handle
- Rotate Trephine Needle and Extraction Tool together(!) to cut bone core
- Remove both tools together
- Remove Extraction Tool from Trephine Needle
- Use Measurement Probe to push out the bone core

