

SURGICAL TECHNIQUE

Marrow Cellution™ Bone Marrow Aspirate (BMA) and Stem Cell Harvesting System

Stem Genix Solution is the most empowering source of biologics solutions offering an unmatched combination of therapies, services and expertise. Our CellFUSE products can be enhanced by combining cellular-rich bone marrow aspirate using the Marrow Cellution Needle Kit. Our Marrow Cellution Needle Kit provides a safe and simple technique for aspirating marrow and/or autologous blood from the iliac crest or vertebral body.



Improves stem cell and progenitor cell recovery and reduces peripheral blood infiltration.¹

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Marrow Cellution Aspiration Needle Kit

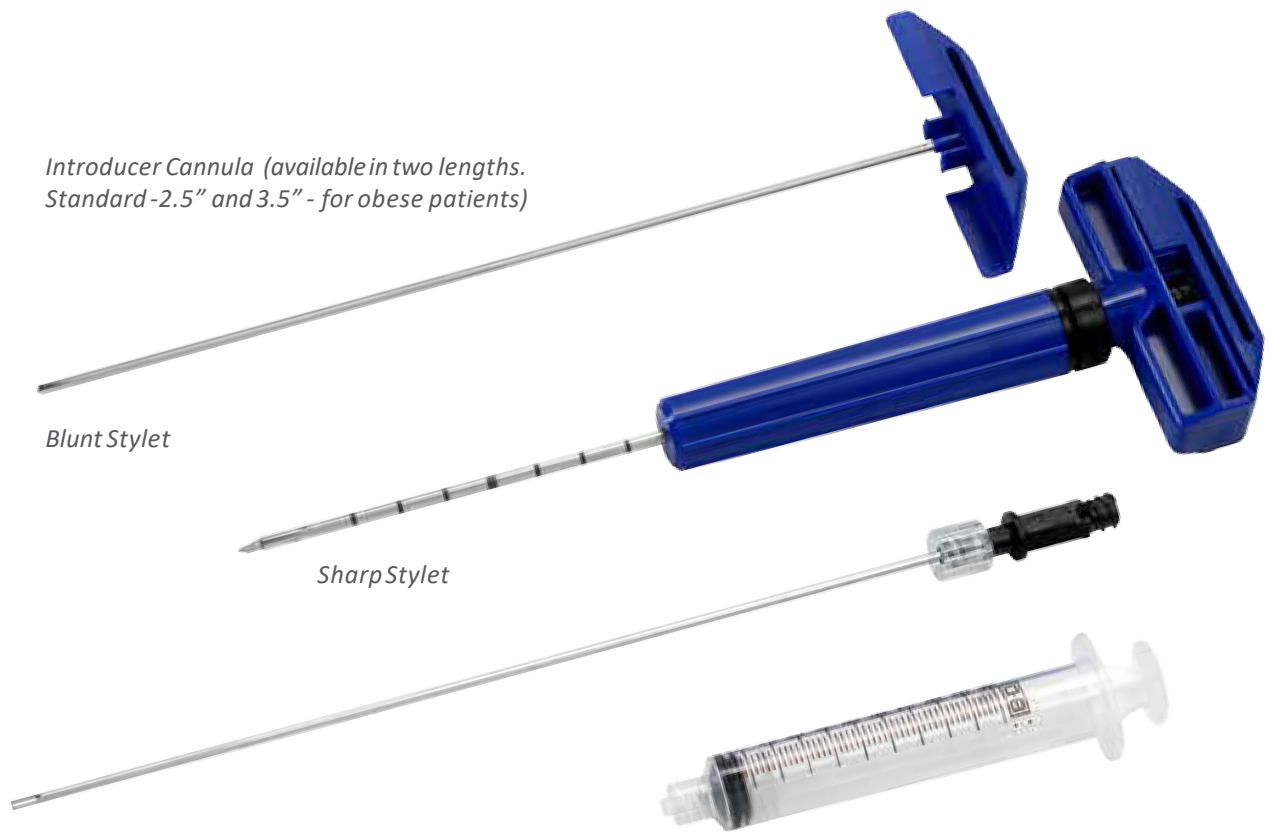
*Introducer Cannula (available in two lengths.
Standard - 2.5" and 3.5" - for obese patients)*

Blunt Stylet

Sharp Stylet

Aspiration Cannula

10mL Syringe



FEATURES

- Single puncture which allows you to retrieve high quality bone marrow from numerous sites within the marrow geography.
- Designed to aspirate and recover perpendicular to and around the channel, avoiding peripheral blood infiltration.
- Improves stem and progenitor cell recovery while reducing peripheral blood infiltration¹

Marrow Cellution Aspiration Needle.



ILIAC CREST ASPIRATION TECHNIQUE

Prior to the aspiration procedure, please follow the heparin flush procedure steps (see Page 10).



STEP ONE:

Begin by determining the bone site.

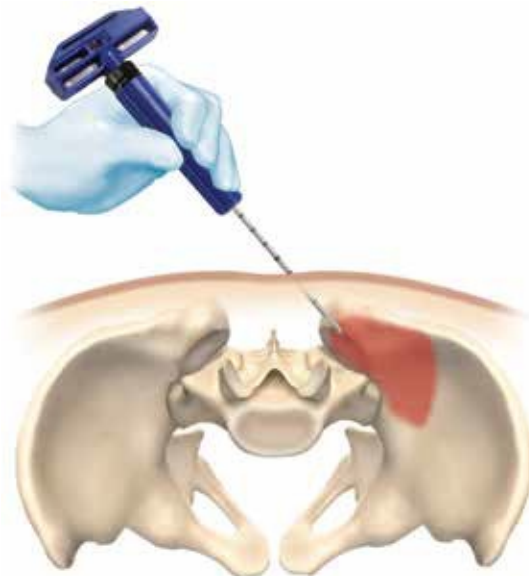
- Posterior Iliac Crest: Palpate the patient to locate the superior aspect of the posterior iliac crest.
- Anterior Iliac Crest: Palpate the patient to locate the anterior aspect of the superior iliac crest.

Using sterile technique, prepare surgical site.



STEP TWO:

Make a small stab incision to be used for the insertion of the Aspiration Needle with Sharp Stylet.

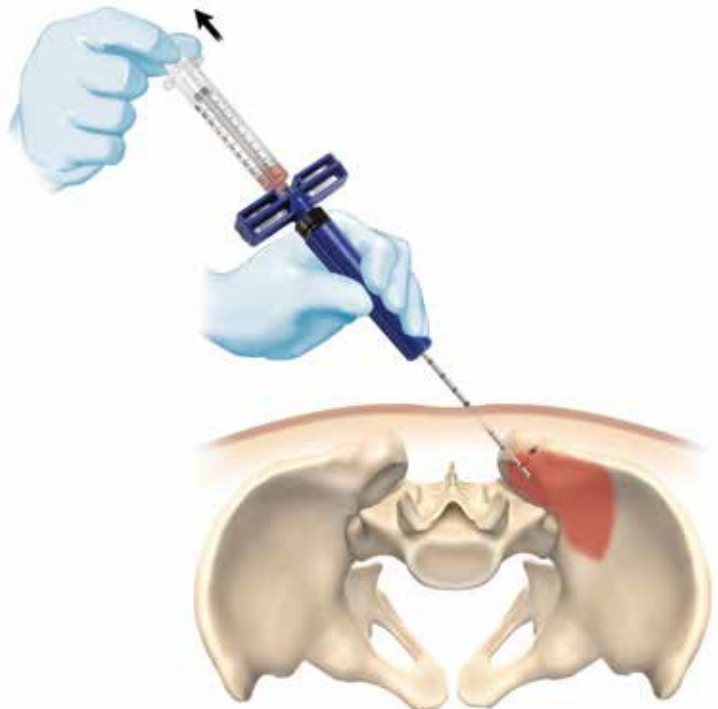
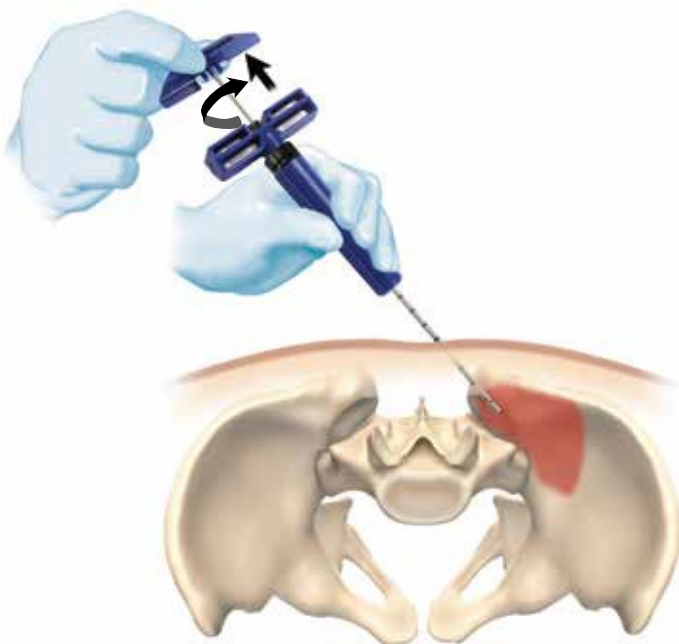


STEP THREE:

- Percutaneously introduce the aspiration needle into the harvest site.
- Posterior Iliac Crest: angle the needle approximately 40 degrees lateral from the sagittal plane and 35 degrees to 45 degrees inferior from the transverse plane.
- Anterior Iliac Crest: angle the needle medially in line with the iliac wing as gauged by palpation.
- Vertebral Body: introduce the needle through the same trajectory that will be used for the pedicle screws.
- Insert the Access Needle past the cortex just into medullary space.

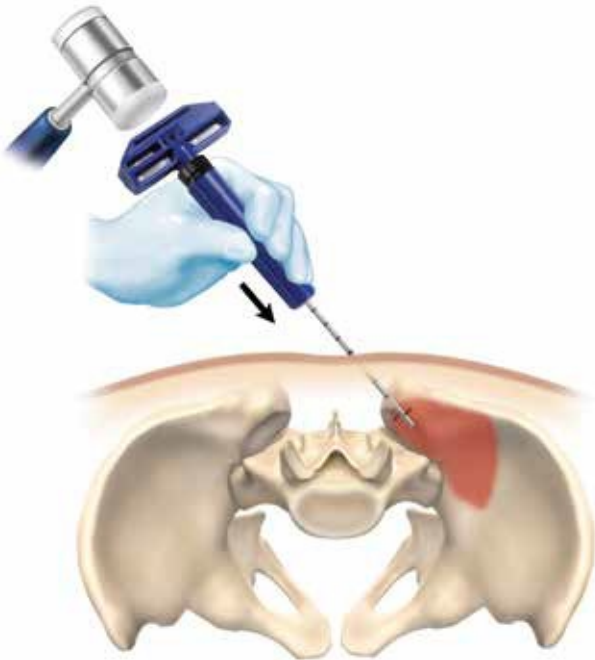
STEP FOUR:

- Ensure longitudinal orientation. Next rotate and remove the Sharp Stylet and attach the Syringe to draw 1 mL to test the proper localization of the Access Needle tip.



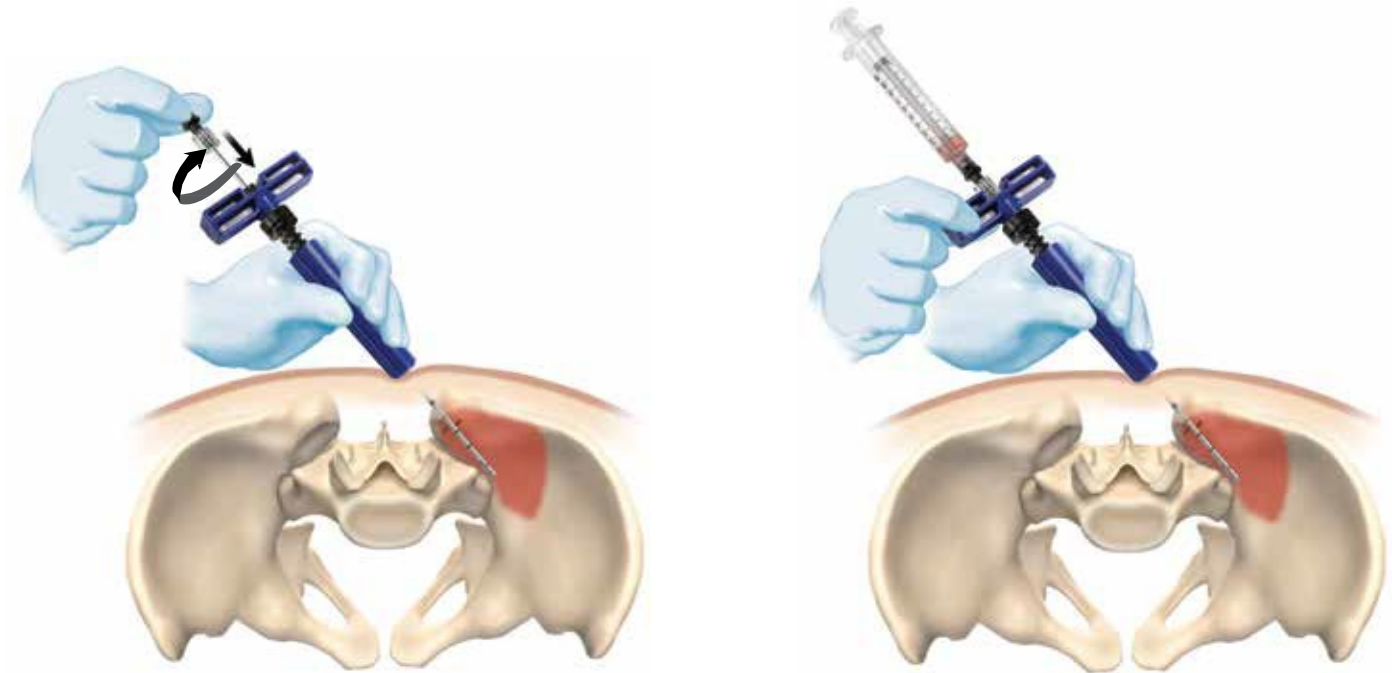
STEP FOUR (CONTINUED):

- Then remove the Syringe and thread to insert the Blunt Stylet, rotating the Blunt Stylet to lock in place.
- Continue to advance the Access Needle to the desired depth.
- Rotate the Outer Housing clockwise to the skin level, then rotate the Blunt Stylet to unlock and remove.



STEP FIVE:

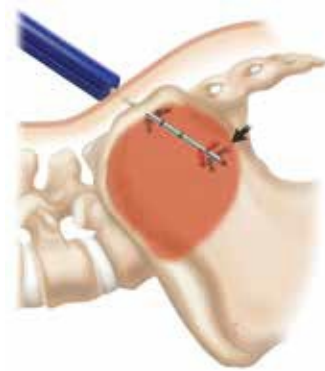
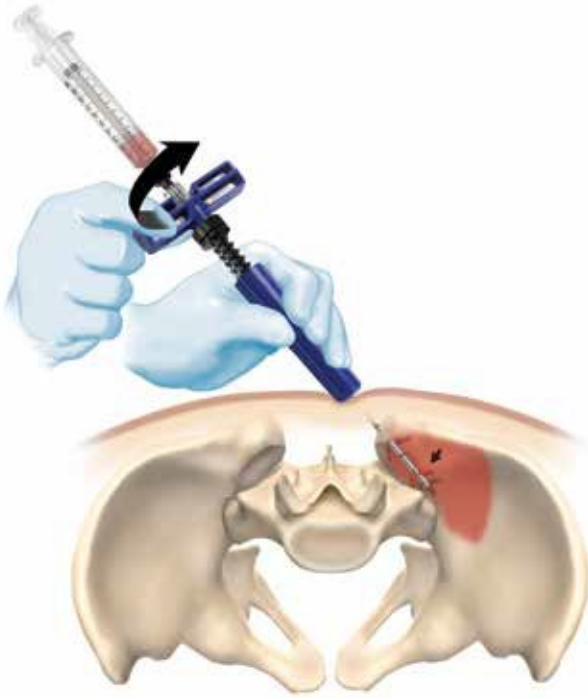
Then insert the Aspiration Cannula and thread to attach the cannula to the Access Needle. Attach the Syringe and draw 1mL of marrow.

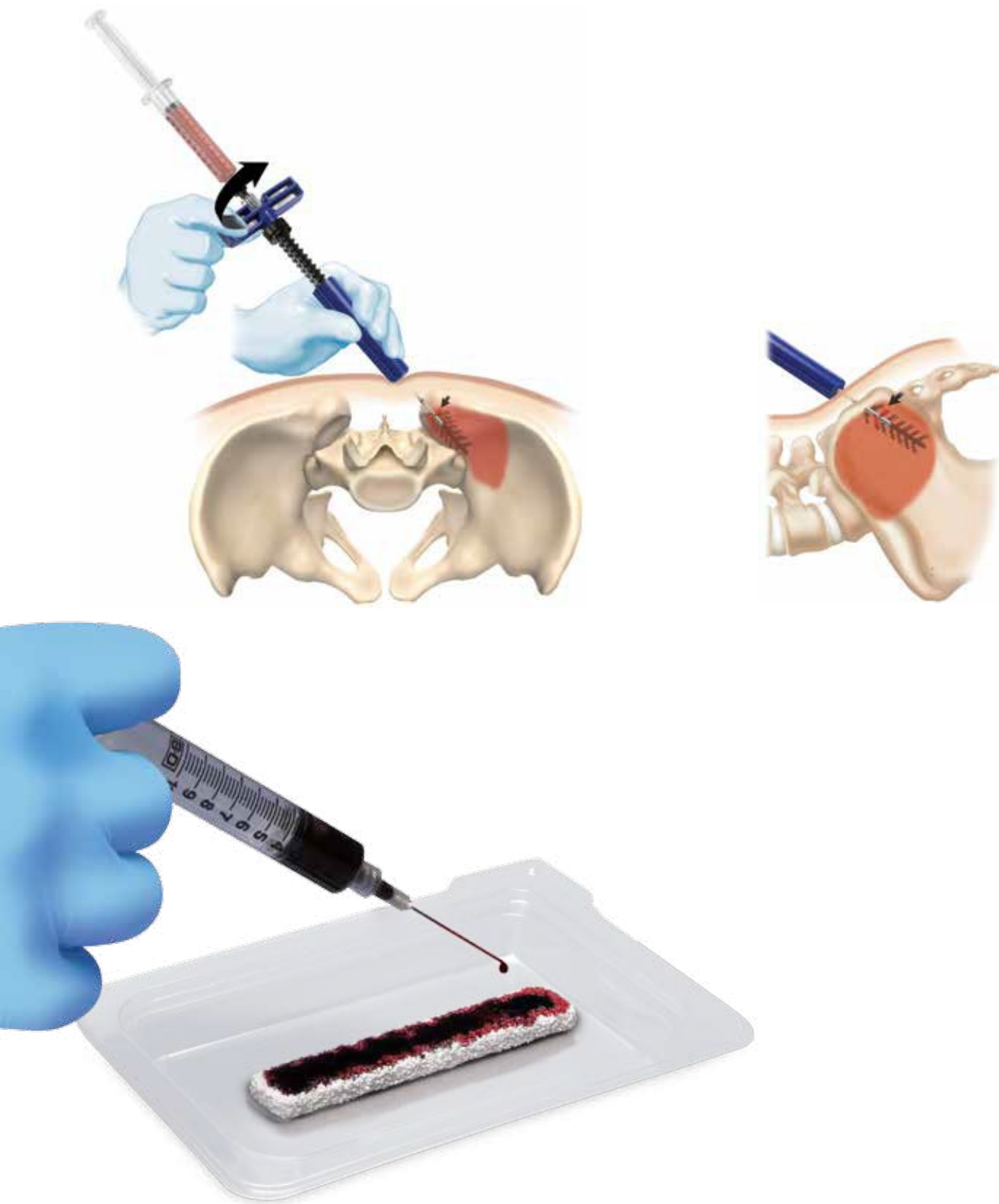


STEP FIVE (CONTINUED):

While holding the outer housing in place, rotate the handle 360 degrees counterclockwise with the opposite hand to raise the cannula tip into the new geography. Draw 1ml of marrow into the Syringe. Repeat the step of raising the cannula and drawing 1 mL of marrow until the desire volume is achieved.

Once the desired volume of marrow has been collected in the Syringe, remove the Syringe from the cannula. Then remove the cannula from the wound and close using standard surgical technique.





Shown hydrating a CellFUSE Synthetic product.

This BMA aspiration technique can be used to hydrate other products.

SUGGESTED HEPARIN FLUSH PROCEDURE FOR BONE MARROW ASPIRATE

1. Withdraw 2,000 units/mL* of Heparin from the sterile bowl into 10mL Syringe.
2. Remove the Stylets from Introducer Needle and Aspiration Cannula with distal end of needle inside sterile bowl.
3. Connect the Heparin-filled syringe to the shorter Introducer needle and inject the Heparin until the needle is fully rinsed (is flowing through end of needle). Aspirate Heparin back into the Syringe and disconnect it 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 the 22 Gauge Needle with 2,000 units of Heparin.
8. Add 1/2 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

PRODUCT ORDERING INFORMATION

Product Details			
Product Number	Description	Introducer	Components
74279-01M	MC-RAN-11C: MarrowCellution Bone Marrow Aspiration System	11 Gauge, effective length: 3.5"	11 Gauge Introducer Cannula & Sharp Stylet 11 Gauge Introducer Blunt Stylet 14 Gauge Aspiration Cannula & Blunt Stylet 10 mL Syringe
74279-02M	MC-RAN-11CSTS: MarrowCellution Bone Marrow Aspiration System – Same as MC-RAN-11C but with longer introducer for obese patients	11 Gauge, effective length: 4.5"	11 Gauge Introducer Cannula & Sharp Stylet 11 Gauge Introducer Blunt Stylet 14 Gauge Aspiration Cannula & Blunt Stylet 10 mL Syringe
BGS-G10	CellFuse Synthetic Bone Graft Granules		10cc Granules
BGS-G20			20cc Granules
BGS-G30			30cc Granules
	CellIFUSE Synthetic Bone Graft Strips		
BGS-s25x25x3	25 x 25 x 3 Strips		25 x 25 x 3 Strips
BGS-s25x50x3	50 x 25 x 3 Strips		50 x 25 x 3 Strips
BGS-s25x75x3	75 x 25 x 3 Strips		75 x 25 x 3 Strips

INDICATIONS FOR USE

The Marrow Cellution Bone Marrow Aspiration Needle is intended for use for aspiration of bone marrow or autologous blood using a standard piston Syringe.

CONTRAINDICATIONS

Use only for bone marrow or autologous blood aspiration as determined by a licensed physician. The device is intended to be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of bone marrow aspiration. The procedure should be performed on patients that are suitable for such procedure only.

Caution

For single patient use only. The design of this device may not perform as intended by the manufacturer if it is re-used. The manufacturer cannot guarantee the performance, safety and reliability of a reprocessed device.

After use, this product may be a potential biohazard. Handle in a manner, which will prevent accidental puncture. Dispose of in accordance with applicable laws and regulations. Carefully place the used needle in a sharps biohazard container after the procedure is completed.



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1.508.588.4400

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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

USA & Foreign Patent(s) Pending

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