

INSTRUCTIONS FOR USE



INFORMATION INSERT

MARROW CELLUTION BONE MARROW ASPIRATION NEEDLE

Sterile: Contents sterile unless package is opened, damaged or expired. Do Not Re-sterilize

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.

Note: *These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.*

INSTRUCTIONS FOR USE

1. Inspect the package for proper integrity. If undamaged, open the package using aseptic technique.
2. Remove the needle from the tray and inspect the tip of cannula and stylet for any damage or other imperfections that would prevent the proper operation of the needle.
3. Following proper placing technique, locate the needle adjacent to the aspiration site.
4. Determine the desired depth of insertion and set the Adjustable Guide to that distance.
5. Using gentle, but firm pressure, while holding the mated handles of the Aspiration Needle and stylet together, the user advances the Aspiration Needle with either a clockwise/counterclockwise twisting motion or advancement can be by use of a bone mallet.
6. Entrance into the marrow cavity is generally detected by decreased resistance.
7. Advance the Aspiration Needle into the marrow cavity until it reaches the desired depth. Advance the depth stop so that the tip is touching the patient.
8. Remove the stylet.
9. Attach a syringe to the needle using the luer lock connection.
10. Apply negative pressure by quickly withdrawing the syringe plunger. Aspiration will begin.
11. Hold the body of the Adjustable Guide and turn the Aspiration Needle handle counter-clockwise one full revolution (360°). (The Syringe will turn with the Aspiration Needle.) This will expose the Aspiration Needle tip to a different marrow area.
12. When aspiration is complete, remove the syringe from the needle, and then remove the needle.

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

Rx Only Not Made With Natural Rubber Latex.
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(US ONLY)



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