

INSTRUCTIONS FOR USE



INFORMATION INSERT

MC RAN BONE MARROW ASPIRATION NEEDLE

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

INDICATIONS FOR USE

The MC RAN 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.*

Contents:

- 1 Access Needle with Pointed Stylet
- 1 Blunt Stylet
- 1 Aspiration Cannula with Blunt Stylet
- 1 Luer Lock Syringe

INSTRUCTIONS FOR USE

1. Inspect the package for proper integrity. If undamaged, open the package using aseptic technique.
2. Remove the components from the pouch and inspect the tip of the Needle, Stylets and Aspiration Cannula for any damage or other imperfections that would prevent the proper operation of the device. The Adjustable Guide can be set for desired depth at this point or after insertion as explained in Step 6.
3. Following proper placing technique, locate the Access Needle adjacent to the aspiration site.
4. Using gentle, but firm pressure, advance the Access Needle with either a clockwise/counterclockwise twisting motion or advancement can be by use of a bone mallet.
5. Entrance into the marrow cavity is generally detected by decreased resistance. When this is reached, remove the Pointed Stylet and insert the Blunt Stylet. Continue to advance the Access Needle to the desired depth.
6. With the Access Needle secured in the bone, the Adjustable Guide can be advanced, if necessary, by holding the Access Needle handle stationary while turning the Adjustable Guide body clockwise so that the tip of the Adjustable Guide is touching the patient.
7. Remove the Blunt Stylet and insert the Aspiration Cannula. Tap the Stylet Handle of the Aspiration Cannula with a bone mallet until it reaches the desired depth.
8. Secure the Aspiration Cannula to the Access Needle by holding the Adjustable Guide body and turning the Access Needle handle counter-clockwise until the luer lock fittings can be connected.
9. Remove the Aspiration Stylet and attach a syringe to the Aspiration Cannula.
10. Withdraw the syringe plunger to aspirate 1ml of fluid.
11. Hold the body of the Adjustable Guide and turn the Access Needle handle counter-clockwise one full revolution (360°). (*The Aspiration Cannula handle & Syringe will turn with the Access Needle.*) This will expose the Aspiration Cannula tip to a different marrow area.
12. Withdraw the syringe plunger to aspirate another 1ml of fluid.
13. Repeat steps 11 & 12 until the desired amount of fluid is obtained.
14. Remove the syringe from the Aspiration Cannula. Remove the Access Needle from the patient.

Rx Only Not Made With Natural Rubber Latex.

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