

INFORMATION INSERT
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

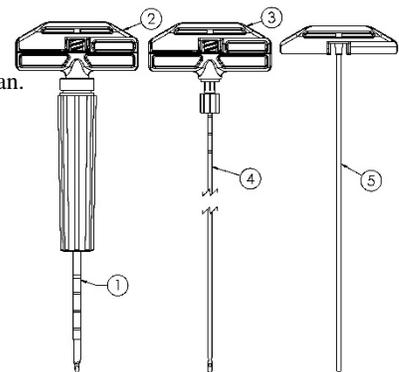
1. Inspect the package for proper integrity. If undamaged, open the package using aseptic technique.
2. Remove the components from the pouch and inspect the tip of the Needle (1), Stylets (2 & 3) and Aspiration Cannula (4) for any damage or other imperfections that would prevent the proper operation 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 (1) adjacent to the aspiration site.
4. Using gentle, but firm pressure, advance the Access Needle (1) 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 (2) and insert the Blunt Stylet (5). 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 (5) and insert the Aspiration Cannula (4). Tap the Stylet Handle (3) 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 (3) and attach a syringe to the Aspiration Cannula (4).
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 (4). If a bone/bone marrow biopsy is required, remove the Aspiration Cannula and follow the Bone Marrow Biopsy instructions on the backside of this document. If no bone marrow biopsy is required, remove the Access Needle from the patient.

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.
1-800-2RANFAC (272-6322)
(US ONLY)

29150-04M REV 1.1

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**INFORMATION INSERT
FOR BONE MARROW BIOPSY
WITH NEEDLE IN PLACE AFTER ASPIRATION**



A. INDICATIONS FOR USE

The Ranfac Bone Marrow Needle is intended for the purpose of harvesting bone marrow specimens.

B. CONTRAINDICATIONS

For use only for biopsies of bone marrow 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 biopsy. The procedure should be performed on patients that are suitable for such procedure only.

WARNING: This device must not be used for sternal procedures.

CAUTION: For single patient use only. The design of this device may not perform as intended by the manufacturer if it is reused. 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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C. INSTRUCTIONS FOR USE

1. Pull the needle (1) back with minimal pressure enough to direct its tip at a slightly different angle.

CAUTION: Applying too much pressure when redirecting the needle may bend the needle.

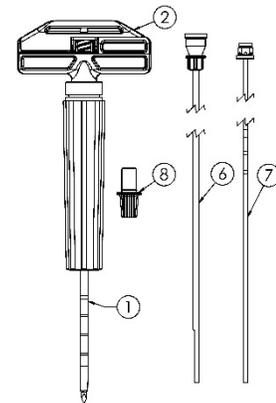
2. Very slowly and gently, advance the needle (1) using clockwise-counterclockwise motion until an adequate depth is achieved (2-3cm).
3. Insert the marked probe (7) without force to check the sample length in needle lumen. Sample length is referenced by the marks in comparison to the needle hub. Remove the probe (7).
4. Insert the Cellution cannula (6) fully into the needle cannula.
5. Slowly rotate and remove the Cellution cannula (6) and needle cannula (1) together with the same clockwise-counterclockwise motion.
6. Remove the Cellution cannula (6) from the needle cannula (1) and push the specimen out with the probe (7).
7. The probe guide (8) can be placed on the distal end of the needle (1) to clear any portion of the specimen in the needle using the probe (7).

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