

INSTRUCTIONS FOR USE



DO NOT
RE-USE

STERILE EO

STERILIZED USING
ETHYLENE OXIDE

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 stylets 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 Access Needle and pointed stylet together, the user advances the Access 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. Once the Access Needle is secure in the bone, remove the pointed stylet and replace it with the blunt stylet.
8. Advance the Access Needle into the marrow cavity until it reaches the desire depth. Advance the depth stop so that the tip is touching the patient.
9. Remove the blunt stylet and insert the Aspirator Cannula.
10. Attach a syringe to the needle using the luer lock connection.
11. Apply negative pressure by quickly withdrawing the syringe plunger. Aspiration will begin.
12. Hold the body of the Adjustable Guide and turn the Access Needle handle counter-clockwise one full revolution (360°). (The Aspiration Cannula & Syringe will turn with the Access Needle.) This will expose the Aspiration Cannula tip to a different marrow area.
13. 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.

Not Made With Natural Rubber Latex.

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(US ONLY)

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29150-04M REV 2.1



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INFORMATION INSERT
Bone Marrow Biopsy Needle



INDICATIONS FOR USE

The RJN Needle is intended for the purpose of harvesting bone and/or bone marrow specimens.

CONTRAINDICATIONS

For use only for biopsies of bone/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 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.

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 guard and inspect the cutting edge of both 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 (1, 2) adjacent to the biopsy site.
4. Using gentle, but firm, pressure advance the needle (1, 2) by rotating it in an alternating clockwise - counterclockwise motion. Entrance into the marrow cavity is generally detected by decreased resistance.
5. Remove the stylet cap (2) by rotating it counterclockwise, and remove the stylet (2) from the cannula (1).
6. Very slowly and gently, advance the needle (1) using clockwise - counterclockwise motion until an adequate depth is achieved (2-3cm).
7. Insert the marked probe (4) without force to check sample length in needle lumen. Sample length is referenced by the marks in comparison to the needle hub. Remove the probe (4).

To harvest the specimen mechanically with the use of the T-cannula, skip directly to step 12.

8. With a rapid motion completely rotate the needle (1) ten times to the right and ten times to the left while applying light downward pressure to allow the tapered tip to help sever the biopsy specimen.
9. Pull the needle (1) back two or three millimeters and with minimal pressure, direct its tip at a slightly different angle. Advance the needle (1) two or three millimeters further, and completely rotate to the right two more times. This technique further assists to sever the specimen before withdrawing the needle (1).

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

10. Slowly remove the needle (1) with the same clockwise-counterclockwise motion.
11. Place the probe guide (5) onto the distal tip of the cannula (1). Insert the probe (4) into the distal end of the probe guide (5). Advance the probe (4) into the needle and collect the biopsy specimen as it emerges from the opening in the handle.

The following steps are required only when completing the procedure with the use of the T-cannula:

12. Insert the T-cannula (3) fully into the needle cannula.
13. Slowly rotate and remove the T-cannula (3) and needle cannula (1) together with the same clockwise-counterclockwise motion.
14. Remove the T-cannula (3) from the needle cannula (1) and push the specimen out with the probe (4).

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