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Triaxial Bone Marrow Aspiration Needle

ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable needle after one use by an acceptable disposal method for devices potentially contaminated with bone marrow.

DESCRIPTION

The Triaxial Bone Marrow Aspiration Needle harvests bone marrow aspirate through a double-cannulated needle by selectively opening and closing distal ports through a three-position locking mechanism.

MATERIALS

The materials used consist of medical grade polymers, elastomers, and stainless steels suitable for use in medical devices.

INDICATIONS FOR USE

The Triaxial Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow.

WARNINGS AND PRECAUTIONS

1. Single use device. Do not reuse.
2. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.
3. Do not use sterilized device if package is opened or damaged.
4. Do not use in conjunction with glass syringes. Use of glass syringes may result in an inadequate seal and could break and fragment.
5. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
6. The patient is to be made aware of the general risks associated with bone marrow aspiration. These risks include, but are not limited to hemorrhage, seroma formation, infection and/or persistent pain at the site of aspiration.

POSSIBLE ADVERSE EFFECTS

1. Damage to blood vessels, hematoma, delayed wound healing and/or infection.
2. Temporary or permanent nerve damage that may result in pain or numbness.
3. Early or late postoperative infection.
4. Pain at bone marrow harvest site.

STERILITY

The Triaxial Bone Marrow Aspiration Needle is sterilized by ethylene oxide exposure. Single use only. Do not re-sterilize. Do not use after expiration date.

INSTRUCTIONS FOR USE

NOTE: Use standard aseptic technique throughout the following procedures.

1. Remove BMA needle from its sterile package. Remove the Trocar Stylet and protective sheath from the BMA needle, and set aside.
2. Attach syringe containing anticoagulant to luer connector and thoroughly coat inside of needle lumen with anticoagulant. Next attach the syringe to the Multi-hole Stylet and coat with anticoagulant, ensuring the entire lumen is coated with anticoagulant. Coat the Trocar Stylet with the remaining anticoagulant.

3. Lock the Trocar Stylet into the BMA needle. Access the marrow cavity by rotating the BMA needle in a clockwise-counterclockwise manner until a decrease in resistance is detected.
4. Remove the Trocar Stylet and set aside. Replace with the Multi-hole Stylet by locking the stylet into the handle at 'Position 1' labeled on the stylet knob.
5. Attach a luer syringe containing the desired amount of anticoagulant to the Multi-hole Stylet hub.
6. Apply negative pressure to the syringe by pulling the syringe plunger proximally. Aspirate up to 5 ml of bone marrow. Release the syringe plunger to remove the negative pressure.
7. Disengage the Multi-hole Stylet from the BMA needle, rotate counterclockwise and reengage BMA needle at 'Position 2'.
8. Aspirate up to 5 ml at position two following the instructions of Step 6.
9. Disengage the Multi-hole Stylet from the BMA needle, rotate counterclockwise and reengage BMA needle at 'Position 3'.
10. Aspirate up to 5 ml at position three following the instructions of Step 6.
11. Reposition the BMA needle within the bone marrow cavity to gain access to virgin bone marrow.
12. Repeat Steps 4 – 11 as necessary until the desired amount of bone marrow is harvested.

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

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc. P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

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Symbol Legend



Manufacturer



Date of manufacture



Do not reuse



Caution, see instructions for use



Sterilized using ethylene oxide



Sterilized using irradiation



Sterile



Sterilized using aseptic processing techniques



Sterilized using steam or dry heat



Use by date



WEEE device



Catalogue number



Batch code



FLAMMABLE

Flammable



Authorized representative in the European Community