



Information Insert

CELLXTRACT™ Autologous Cell and Bone Marrow Extraction

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

Indications for Use

CELLXTRACT™ Autologous Cell and Bone Marrow Extraction 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.



DO NOT
RE-USE



STERILIZED USING
ETHYLENE OXIDE

Instructions for Use

1. Inspect the package for proper integrity. If undamaged, open the package using aseptic technique.
2. Remove the needle from the packaging 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 desired 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. The needle may be retracted to expose the cannula tip to new marrow areas.
12. When aspiration is complete, remove the syringe from the needle, and then remove the needle.

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

Product is not made with natural rubber latex.

CELLXTRACT is a trademark of Bioventus LLC. Bioventus and the Bioventus logo are registered trademarks of Bioventus LLC.

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