

Instructions for Use

BONEAID™

Bone Marrow Biopsy Needle

Description:

Bone Marrow Biopsy Needles are supplied along in a kit with accessories such as trocars and stylets to make the procedure easier. Each needle has a stylet with trocar point and a cannula with five cutting edges. The needles have a coloured-code ergonomic handle. They are available in variety of gauges and lengths for various applications & have a Luer Lock connection for a syringe. They have a remover guide provided with indicators to facilitate the sample expulsion and to check its length during the procedure. A special cap is provided for a safe removal of the sample collected.

Indications for Use:

BONEAID™ Bone Marrow Biopsy Needles are intended for the purpose of harvesting bone marrow specimens.

Contraindications:

This device should only be used as indicated.

Warnings and Precautions:

1. Rx Only. The device must be used by trained physicians only.
2. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in severe patient injury or death.
3. Sterile by EO, Single Use: Do not reuse, reprocess or re-sterilize under any circumstance.
4. Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
5. Aseptic techniques must be used wherever possible, especially during removal from packaging.
6. Don't move the needle sideways into the marrow without the mandrel inside the cannula.
7. To avoid possible break of the steel cannula, avoid strong and fast movements backward and forward, with traction angles too elevated during sampling.

Instructions for Use:

1. Insert the needle with the stylet perpendicular to the bone surface.
2. Slowly turn and push the needle forward until the bone marrow cavity has been reached.
3. Remove the mandrel.
4. Remove the mandrel rotating the handle anticlockwise, as indicates the arrow printed on the handle, and pull it out from the cannula.
5. Push the needle for 2 or 3 cm with rotating movement.
6. Slowly insert the graduated stylet to verify the length of the bioptic sample. Remove the stylet.
7. Withdraw the needle for a few millimetres and then insert it again with a different angle: this movement allows to obtain the bone marrow sample.
8. Close the handle with the cap.
9. Withdraw the needle slowly and completely with a rotating movement.
10. Remove the bone marrow sample obtained pushing it out from the proximal end of the needle (handle side) inserting the remover guide from the distal end (tip side) with the help of safety cap.
11. At the end of procedure, remove all devices and accessories paying attention to the necessary precautions for potentially contaminated materials.
12. If marrow aspiration, or explant or perfusion is to be performed, insert an appropriate syringe into the Luer cone and aspirate.

Disposal:

13. The device can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal.













Potential Complications / Adverse Effects


Bone Marrow Biopsy Needles should not be used by physicians unfamiliar with the possible complications. Possible complication may include but not limited to Excessive bleeding or drainage from the biopsy site, Infection of the bone at the biopsy site, Tumour seeding, redness or swelling at the aspiration site, Fever.

Warranty and Limitations

Bone Marrow Biopsy Needles are sold in 'as is' condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or malfunction of any product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

Symbols Glossary

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code
	Catalogue Number
	Manufacturer
	Use-by date
	Keep dry
	Temperature Limit

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