

BONE MARROW ASPIRATION NEEDLE (MALLARME)

INSTRUCTIONS FOR USE

INDICATIONS FOR USE

Disposable biopsy needle used to aspirate sternal or iliac bone marrow.

REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

STORAGE

Keep the devices in their packaging, flat in the original box. Store in a cool dry place (below 26 °C) away from humidity and direct heat. Do not use after expiry date.

PRECAUTIONS

The operator should not use the device before being trained and before reading the instructions for use. It is a disposable device. After use, each component of the device may be a potential biohazard. Handle and dispose such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

INSTRUCTIONS

- 1) Check expiration date and integrity of the packaging.
- 2) Position the patient according to the technique used (sternal aspiration or iliac aspiration technique).
- 3) Using a sterile technique, prepare the puncture site.
- 4) Infiltrate the skin, especially the periosteum, with local anesthetic.
- 5) A scalpel blade may be used to puncture the skin prior to inserting the needle.
- 6) Introduce the needle through the incision and, using firm pressure, advance the needle. Decreased resistance generally indicates entrance into the marrow cavity.
- 7) Pull the stylet out of the cannula.
- 8) Attach a syringe to the cannula hub.
- 9) Apply negative pressure by quickly drawing the syringe plunger. Disconnect the syringe and remove the aspirated specimen.

Note: It is advisable to obtain a bone marrow aspirate in conjunction with a core biopsy specimen, since aspiration alone does not always permit an adequate evaluation of the functional state of the marrow.

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|  | Single Use |  | Do not use if package is damaged |
|  | Temperature limitation |  | Do not resterilize |
|  | Caution: consult accompanying documents | | |
|  | For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service | | |
|  | Sterilized using Ethylene Oxide | | |



CE 2797
www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095
U.S.A.
1-801-253-1600
U.S.A Customer Service
1-800-356-3748



Authorized Representative:
Merit Medical Ireland Ltd,
Parkmore Business Park
West, Galway, Ireland
EC Customer Service
+31 43 3588222

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