

MEDLOCK (MM version)

- IT** - Dispositivo per biopsia/aspirazione del midollo osseo
- EN** - Bone marrow biopsy and aspiration system
- FR** - Dispositif pour biopsie/aspiration de la moelle osseuse
- DE** - Vorrichtung für Biopsien/Aspiration von Knochenmark
- ES** - Dispositivo para biopsia/aspiración de médula ósea
- PT** - Dispositivo para biopsia/sucção da medula ósea
- EL** - Συσκευή για βιοψία/αναρρόφηση του μυελού των οστών
- NL** - Hulpmiddel voor biopsie/aanzuigen van beenmerg
- FI** - Väline luuytimen biopsiaan/imunäytteen ottoon
- SV** - Benmärgsbiopsi och utsugning av benmärg
- DA** - Anordning til biopsi/aspiration af knoglemarv
- PL** - Urządzenie do biopsji/pobierania szpiku kostnego
- CS** - Zařízení pro biopsii/aspiraci kostní dřeně
- RU** - Устройство для биопсии/всасывания костного мозга

INTENDED USE

MEDLOCK biopsy system must be used for bone marrow aspiration and the posterior iliac crest biopsy.

COMPOSITION OF THE DEVICE (version with spoon)**Model with additional protection cap (Fig. 1a)**

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|-------------|--|
| A - Handle | E - Extraction cannula (spoon version) |
| B - Mandrel | F - Additional protection cap |
| C - Cannula | G - MLL cap |
| D - Stylet | H - Cover accessory: «Safety» |

Model without additional protection cap (Fig. 1b)

| | |
|-------------|--|
| A - Handle | E - Extraction cannula (spoon version) |
| B - Mandrel | G - MLL cap |
| C - Cannula | H - Cover accessory: «Safety» |
| D - Stylet | |

INSTRUCTIONS FOR USE**Preliminary activity:**

- Assist the patient to lie and keep the most suitable position.
- After locating the point of penetration, use aseptic technique for the preparation of the sterile field.
- Disinfect the area of skin and proceed with administering an adequate level of anaesthetic.
- If necessary use a scalpel to make a localized incision into the skin prior to inserting the needle.

Procedure:

1. Hold firmly with the palm of the hand the needle provided with the mandrel and insert it perpendicular to the bone surface (fig.2).
The needle must be introduced using a constant vertical pressure while rotating it approximately 45° in clockwise-counterclockwise.
2. Upon reaching the marrow cavity, stop the needle penetration (entrance into the marrow cavity is determined by a decrease of resistance to penetration) and remove the mandrel (B) from the needle handle (A) by pulling upwards (fig.3).
3. If provided, apply the additional protection cap (F) onto handle needle (A) to achieve better handling.
4. Push the needle for a further 2 or 3 cm with rotating maneuvers of approximately 45° in clockwise and counterclockwise direction.
5. Slowly insert the proper graduated stylet (D) to verify the actual size of the bioptic sample obtained. If the size of the sample obtained is deemed insufficient, remove the graduated stylet, (if provided, apply the additional protection cap onto handle needle) and push the needle further in, using the rotating movements described in point 4; if not, proceed with the below described operation to detach the sample.
6. Insert the extraction cannula (E) into the handle needle until its interlocking (fig.4).
7. Rotate the extraction cannula or the complete device (needle with extraction cannula) at least 360° (fig.5). During this phase it is essential to neither plunge nor remove the needle.

8. Remove the extraction cannula (E) from the needle and verify the adequacy of the sample collected; otherwise remove the complete device (needle with extraction cannula) by pulling upwards while rotating it of approximately 45° in clockwise and counterclockwise, up to the complete extraction from the bone and remove the extraction cannula from the needle.
9. Insert the stylet (D) into the extraction cannula (E) to retrieve the bioptic sample collected (fig.6).
10. At the end of the procedure, remove all devices and accessories with care, following all the necessary precautions for potentially contaminated materials.
11. Throw away after use and dispose together with the hospital waste following the laws in force.

Note:

- 1 - If the extraction cannula is not used for the collected bioptic sample retrieval, place the cover accessory «safety» (H) onto the distal cannula tip and insert the stylet (D) into the «safety» to remove the sample collected.
- 2 - If a marrow aspiration, explant or perfusion is to be performed before the bone marrow biopsy, connect an appropriate syringe to the luer cone and aspirate.

LIMITATIONS AND WARNINGS

- Usage allowed only to qualified physicians. MEDAX declines every responsibility for damages caused to the patient when the device is used in an improper way, with wrong maneuvers or if handled by non qualified personnel.
- The procedure described is for guidance only: the use of the device must be based on the clinical training of each physician.
- Do not move the needle sideways into the narrow without inserting the mandrel.
- To avoid the possibility of breaking the steel cannula, avoid strong and fast movements backwards and forwards, as well as traction angles that are too elevated during sampling.
- Non-pyrogenic, sterile device: do not reuse, resterilize or recondition in any way.
- Single-use / single-patient device: reuse of the device may cause cross infection to patient and/or user.
- Verify the integrity of the packaging and the validity of the product before use.
- The product must not be used if the package is unsealed, damaged or wet.
- Keep in a fresh and dry place, avoid exposure to light and high temperatures.
- Do not use in magnetic resonance (MR) environment.