



MEDONE

- IT** - Dispositivo monouso automatico per biopsia ai tessuti molli
- EN** - Soft tissue automatic disposable biopsy system
- FR** - Dispositif à usage unique automatique pour biopsie tissus mous
- DE** - Automatisches Einweg-Biopsiegerät für die Entnahme von Weichgewebeproben
- ES** - Dispositivo automático desechable para biopsias de tejidos blandos
- PT** - Dispositivo automático descartável para biopsia em tecidos moles
- EL** - Αυτόματη συσκευή βιοψίας μιας χρήσης σε μαλακούς ιστούς
- NL** - Automatisch medisch hulpmiddel voor eenmalig gebruik voor de biopsie van zachte weefsels
- FI** - Automaattinen kertakäyttöväline pehmytkudosten näytteenottoon
- SV** - Automatisk anordning för engångsbruk för biopsi av mjuka vävnader
- DA** - Automatisk anordning til engangsbrug til biopsi i blødt væv
- CS** - Automatické zařízení na biopsii měkkých tkání na jedno použití
- PL** - Automatyczne urządzenie jednorazowe do biopsji tkanek miękkich
- SK** - Jednorázový automatický nástroj na biopsiu mäkkých tkanív
- SL** - Avtomatska naprava za biopsijo mehkih tkiv za enkratno uporabo.
- HU** - Egyszer használatos automatikus lágyszövet biopsziás eszköz
- RU** - Одноразовое автоматическое устройство для биопсии мягких тканей

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INTENDED USE

MEDONE biopsy system must be used for histological biopsy of soft tissues.
It is not intended for use in bone biopsy.

INSTRUCTIONS FOR USE

Preliminary activity:

- Using appropriate aseptic technique, remove the device from its package.
- Before using inspect the device to exclude the presence of damaged tip, bent mandrel or other imperfections that would prevent proper function. If the needle components are damaged, do not use the device.
- 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 area where puncture is to take place, in order to facilitate access of the needle cannula.

Biopsy procedure:

- Load the Medone biopsy system by pulling back the loading lever located on the top of the handle:
 1. the first click indicates the loading of the cannula (pulling back the lever for withdraw the cannula and lock it on «load position»);
 2. the second click indicates the loading of the mandrel (pulling back the lever for withdraw the mandrel and lock it on «load position»).
- Now the device is ready to be used.
- Slowly insert the needle to reach the proximity of the lesion to be biopsied.
- When the needle is in the right position, maintaining unchanged the needle orientation and the device's position, press one of the two fire button located either on the side and on the back of the device.
In this way the mandrel and the cannula will advance automatically.
- Slowly draw out the needle from patient.
- To remove the specimen reload the cannula by pulling back the loading lever in order to withdraw the cannula and expose the mandrel's notch.
- Remove the specimen.
- If additional biopsies of the same organ are required reload the device by pulling back the loading lever, in order to withdraw the mandrel and repeat the above described procedure.

Warning: Before repeating the procedure make sure that the needle has not been damaged during the biopsy maneuvers (bending needle or damaged tip).
If you note the presence of damaged or imperfections of the needle do not use the device.

Biopsy procedure with coaxial introducer needle:

The coaxial introducer needle must be used when multiple biopsies of soft tissue are required.

Used with Medone biopsy needle allows multiple accesses to the biopsy site with a single puncture causing less trauma to the patient.

- Slowly insert the coaxial introducer needle into the tissue up to the biopsy area.
- Remove the stylet.

- Insert the Medone biopsy needle into the coaxial cannula and proceed with the sampling (refer to the biopsy needle instruction for use described in the previous section).
- Remove the biopsy needle and insert it again to perform multiple biopsies.
- At the end of procedure, remove all devices and accessories paying attention to the necessary precautions for potentially contaminated materials.
- Throw away after use and dispose together with hospital waste following the laws in force.

LIMITATIONS AND WARNINGS

- Usage allowed only by 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.
- Never test the device by firing into the air. Damage may occur to the needle or patient/user injury.
- Before using, inspect the needle to exclude the presence of damaged tip, bent mandrel or other imperfections that would prevent proper function.
If the needle components are damaged or bent, do not use the device.
- Unusual resistance against the mandrel during the biopsy maneuver may cause the mandrel to bend at the specimen notch.
A bent specimen notch may interfere with the needle function.
- Non-pyrogenic, sterile device: not to be reused, resterilized or reconditioned 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 temperature.
- Do not use in magnetic resonance (MR) environment.