

MEDEASY

- IT** - Ago semiautomatico per biopsia ai tessuti molli con profondità di penetrazione regolabile
- EN** - Soft tissue semi-automatic biopsy needle with adjustable penetration depth
- FR** - Aiguille semi-automatique pour biopsie des tissus mous avec profondeur de pénétration réglable
- DE** - Halbautomatische Nadel für Biopsie für weiche Gewebe mit eindringtiefe einstellbar
- ES** - Aguja semiautomática para biopsia de tejidos blandos con profundidad de penetración ajustable
- PT** - Agulha semiautomática para biópsia do tecidos moles com profundidade de penetração ajustável
- EL** - Ημιαυτόματη βελόνα βιοψίας μαλακού ιστού με ρυθμιζόμενο βάθος διείσδυσης
- NL** - Halfautomatische biopsienaald voor zacht weefsel met afstelbare penetratiediepte
- FI** - Puoliautomaattinen biopsianeula pehmytkudokseen ja Säädettävä tunkeutumis syvyys
- SV** - Semi-automatisk biopsinål för mjuk vävnad med Justerbar stickdjup
- DA** - Halvautomatisk nål til blødvævsbiopsi med justerbar penetrationsdybde
- PL** - Półautomatyczna igła biopsyjna do tkanek miękkich z regulowaną głębokość penetracji
- CS** - Poloautomatická biopstická jehla na měkké tkáně s nastavitelná hloubka penetrace
- SK** - Poloautomatická ihla na biopsiu mäkkého tkaniva s nastaviteľná hĺbka prieniku
- SL** - Polavtomatska igla za biopsijo mehkih tkiv s nastavljiva globina penetracije
- HU** - Félautomata lágyrész biopszia tű állítható behatolási mélység
- RU** - Полуавтоматическая игла для биопсии мягких тканей с изменяемой глубиной среза

INTENDED USE

MEDEASY biopsy needle 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 biopsy needle from its package.
- 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 in order to facilitate access of the needle cannula.

Biopsy procedure:

1. Remove the protective plastic tube.
2. Cock the biopsy needle by pulling back hard on the plunger until hearing a click indicating that the needle has been cocked. It is possible to load the needle in two different positions:
The first click sets a penetration depth of 10mm;
The second click sets a penetration depth of 20mm.
3. With mandrel fully retracted (specimen notch completely covered by cannula), slowly insert needle proximal to area to be sampled. **Be careful not to press plunger until needle is inserted to desired location.**
4. Slowly move plunger with thumb to first stop to advance the mandrel and expose the specimen notch. **Be careful not to push plunger.** Move the needle back and forth a few millimeters to fill the specimen notch.
5. Press completely the plunger with thumb, automatically triggering the cannula to close, trapping a specimen in the sample notch.
6. Slowly draw needle out from the patient.
7. Pull back on plunger until second click to re-cock the spring. Push plunger to first stop exposing the specimen notch.
Be careful not to push the plunger past the stop, so as not to trigger the cannula again.
8. Remove tissue specimen from notch.

Biopsy procedure with coaxial introducer needle:

The coaxial introducer needle must be used when multiple biopsies of soft tissue are required. Used with MEDEASY biopsy needle allows multiple accesses to the biopsy site with a single puncture causing less trauma to the patient.

1. Remove the protective plastic tube of the coaxial introducer needle.
2. Slowly insert the coaxial introducer needle into the tissue up to reach the proximity of the biopsy area or the proximity of tissues at risk of injuries.
3. Remove the mandrel by turning the handle counter-clockwise.

4. NOTE: Model provided of additional blunt tip stylet

In case the zone under examination is found to be close to a critical area (arteries, veins, internal organs, etc.) it is possible to use a special atraumatic blunt tip stylet in order to reduce the risks of involuntary damaging of such areas.

- After having removed the trocar tip mandrel, insert the additional blunt tip stylet into the coaxial cannula and turn it clockwise to engage with the coaxial needle cannula hub. Proceed with the penetration to the margins of the lesion that will be submitted to biopsy evaluation.

- Remove the blunt tip stylet by turning the handle counter-clockwise.

5. Biopsy with penetration depth set to 20mm:

Insert the previously charged MEDEASY biopsy needle inside the coaxial cannula and proceed to the sample collection (refer to the biopsy needle instruction for use described in the previous section).

Biopsy with penetration depth set to 10mm:

Tighten the white-colored adapter on the Luer Lock of the coaxial needle's connector. Insert the previously charged MEDEASY biopsy needle inside the coaxial cannula and proceed to the sample collection (refer to the biopsy needle instruction for use described in the previous section).

6. Remove the biopsy needle and insert it again to perform multiple biopsies.
7. At the end of procedure, remove all devices and accessories paying attention to the necessary precautions for potentially contaminated materials.
8. Throw away after the use and discharge together with the hospital waste following, the laws in force.

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.
- Before use, make sure that the mandrel slides freely and smoothly in the cannula; forward motion must open the notch and backwards motion must cover it completely without friction. Should this not be the case, do not use the system.
- Before using, inspect the needle to exclude the presence of damaged tip, bending or other imperfections that would prevent proper function.
If the needle components are damaged or bent, do not use the device.
- Never test the device by firing into the air. Damage may occur to the needle or patient/user injury.
- 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.
- The device is sterilized by ethylene oxide and not to be resterilized or reconditioned in any way.
- Single-use/single-patient device: re-use 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 the exposure to light and high temperature.
- Do not use in magnetic resonance (MR) environment.