TRU-CUT ®
Soft Tissue Biopsy Needles

English

INSTRUCTIONS FOR USE

Obturator Handle

Specimen Notch

Cannula Handle
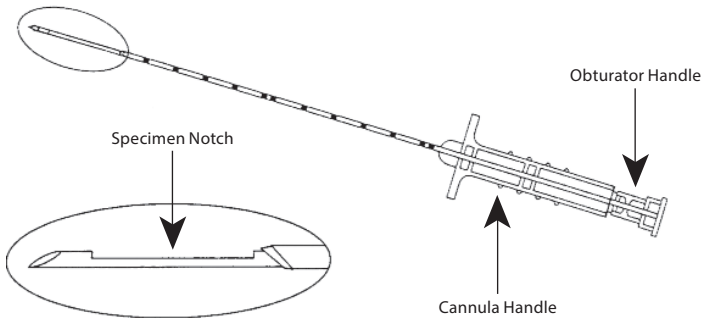
INDICATIONS FOR USE:
Tru-Cut Soft Tissue Biopsy Needle is a device that introduces a cannula into soft tissue such as breast, lungs, lymph nodes and prostate, etc. for diagnostic evaluation.

WARNING:
This needle is not designed for puncturing the skin. Excessive force or resistance when the needle is extended may result in a bent specimen notch. A bent specimen notch will interfere with needle function and possibly cause tissue tearing. Excessive lateral force applied against the obturator handle of the needle may interfere with the function of the stop mechanism and may result in deeper tissue penetration than is desired with the potential for tissue or organ damage.
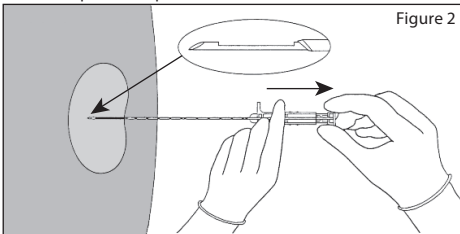
INSTRUCTIONS FOR USE:
1. Using sterile technique, prepare the biopsy site.
2. Remove packaging. Remove protective sheath.
3. Test for proper function and alignment by sliding the cannula over the obturator several times. If the parts do not move easily, the unit should be discarded.
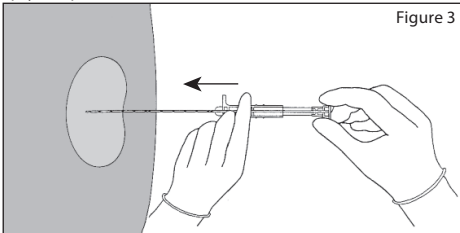
BIOPSY PROCEDURE (EXCEPT BREAST BIOPSY)
4. Retract the obturator to cover the specimen notch. Hold the cannula handle and insert the needle assembly so that the specimen notch is within the tissue to be biopsied (Figure 1).
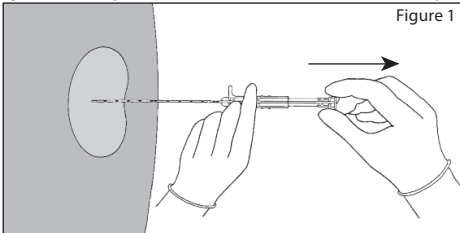
Figure 1

5. Retract the cannula to expose the specimen notch. Note: Do not move the obturator (Figure 2).
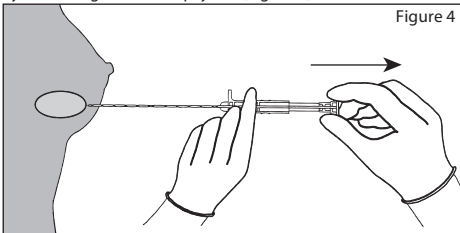

Figure 2

6. To cut the tissue, quickly advance the cannula handle (Figure 3). If another biopsy of the same tissue is required, leave the cannula positioned at the target biopsy site and follow instructions for multiple biopsy samples.

Figure 3

INSTRUCTIONS FOR THE BREAST BIOPSY
7. Retract the obturator to cover the specimen notch. Hold the cannula handle and insert the needle assembly to the edge of the biopsy site (Figure 4).

Figure 4

8. Hold cannula handle firmly. Quickly advance the obturator as far as permitted to position the specimen notch in the tissue to be biopsied (Figure 5).

Figure 5

9. To cut the tissue, quickly advance the cannula handle (Figure 6). If another biopsy of the same tissue is required, leave the cannula positioned at the target biopsy site and follow instructions for multiple biopsy samples.
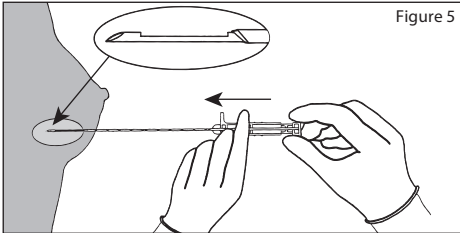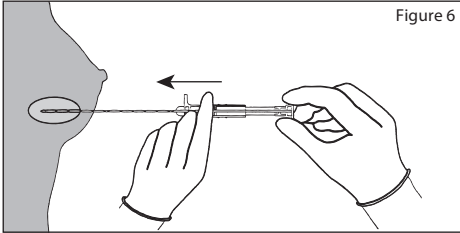

Figure 6

FOR MULTIPLE BIOPSY SAMPLES
- Hold the cannula handle in a fixed position.
- Lift the obturator shaft slightly to clear the stop mechanism.
- Pull the obturator back to remove it from the cannula.
- Remove the sample from the specimen notch.
- To reinsert the obturator into the cannula, align the obturator shaft with the open side of the cannula handle and the specimen notch facing up. Slide the obturator forward until the obturator shaft locks into the handle.
- Follow one of the sampling procedures described to take additional biopsies.

10. Hold cannula handle firmly. Quickly advance the obturator as far as permitted to position the specimen notch in the tissue to be biopsied (e).
11. To cut the tissue, quickly advance the cannula handle (f). If another biopsy of the same tissue is required, leave the cannula positioned at the target biopsy site and follow instructions for multiple biopsy samples.

WARNING:
- Not intended for use in bone.
- Do not use if package is damaged.

CAUTION: For single use only. Re-use may result in a non-functional product or contribute to cross contamination.

Only clinicians who have been properly trained in this procedure, including patient preparation, sample preservation and the use of image guidance for percutaneous biopsy, should use this device.

SYMBOL	DESIGNATION
⧖	Use By: YYYY-MM-DD
LOT	Lot Number
REF	Catalog Number
STERILE R	Sterilized using Irradiation
⊘	Do Not Use if Package is Damaged
②	Single Use
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

Medical Device.
Sterile Package.

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