

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Achieve Programmable Automatic Biopsy System is a spring loaded, core needle biopsy system with delay or automatic firing options. The automatic firing mode releases the cannula and stylet in rapid sequence and captures a tissue sample with the push of a button. The delay firing method is used to verify the position of the sample notch in the target area prior to depressing the A button, which activates the cutting cannula, capturing the tissue sample.

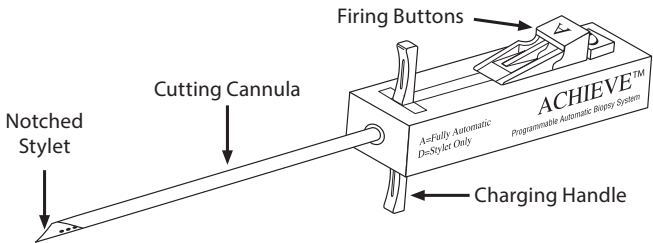


Figure 1: Achieve Programmable Automatic Biopsy System

INTENDED USE

Intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone.

The Achieve Programmable Automatic Biopsy System is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

WARNING: Test firing the needle may damage the cutting cannula and/or stylet tip and is not recommended. If test firing is performed, the cutting cannula may be protected by holding the cannula near the clear taper with moderate pressure between the thumb and fingers during firing. Keep fingers or other objects from in front of the needle as it will advance 2.5 cm very rapidly when activated. Never test fire the instrument in an unsafe direction.

In the automatic mode, the Achieve automatic biopsy device is designed to fire the cannula and stylet in rapid succession. Please exercise caution before proceeding as the device will advance 2.5 cm when activated.

Ensure the device is fully discharged before disposing of the device.

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.

Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have bleeding disorders.

Post-biopsy care may vary with the biopsy technique utilized and the individual patient's physiological condition. Observation of vital signs and other precautions should be taken to avoid and/or treat potential complications that may be associated with biopsy procedures.

CAUTION

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

Do not use if package is damaged.

Do not resterilize. After resterilization, the sterility of the device is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to the potential adverse effects on components that are influenced by thermal and/or mechanical changes.

NOTE: If collecting multiple samples, inspect the needle for a damaged point, bent shaft or other imperfections after each sample is taken.

NOTE: After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state, and federal laws and regulations.

If biasing the device prior to obtaining a sample, take care to avoid bending the stylet notch.

STEP 1: COAXIAL INTRODUCER PLACEMENT

During the pre-procedure set up, insert the biopsy device through the coaxial introducer needle to verify compatibility.

Adjust the sliding skin stop on the coaxial introducer needle to the desired location and lock in place. Insert the coaxial introducer needle until the sliding skin stop rests on the skin surface. Use imaging, if desired, to verify the tip is at or near the edge of the region to be sampled. Remove the inner stylet.

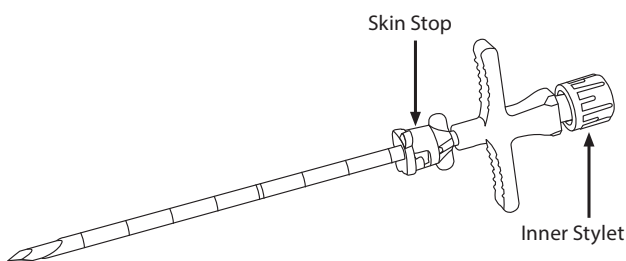


Figure 2: Coaxial Introducer Needle

AUTOMATIC & DELAY MODE

STEP 2: PREPARATION OF ACHIEVE FOR USE

To charge the Achieve biopsy device, simply pull back on the charging handle and release twice, first to charge the cutting cannula, second to charge the inner stylet. **See Figures 3 through 5.**

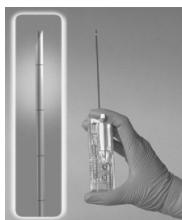


FIGURE 3:
Non-charged and after firing.

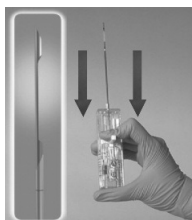


FIGURE 4:
Pull back the charging handle once to retract the cannula which exposes the notched stylet.

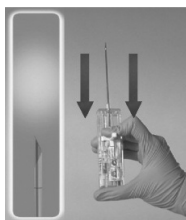


FIGURE 5:
Pull back the charging handle a second time to retract the notched stylet.

STEP 3: POSITION THE NEEDLE

Position the needle at or near the edge of the region to be sampled.

STEP 4: FIRE THE INSTRUMENT

Two firing sequence methods are available once the Achieve biopsy device is charged.

A = Automatic mode

D = Delay mode (Stylet Only)

1. Delay Mode – Depression of the **D** button releases the inner stylet into the sample area. The operator uses this delay firing method to verify the position of the sample notch in the target area prior to depressing the **A** button, which activates the cutting cannula, capturing the tissue sample.

NOTE: If desired, a slight bias may be imparted to the stylet prior to firing by forcing the stylet notch against the lesion. Take care to avoid bending the stylet notch.

2. Automatic Mode – TThe operator can choose the fully sequential mode, omitting the delay feature, simply by depressing the **A** button first. This releases the stylet and cutting cannula in sequence, capturing the tissue sample.

STEP 5: BIOPSY SPECIMEN

To retrieve the tissue sample, remove the device from the patient, hold it with the **A** and **D** buttons facing up, and pull back and release the charging handle once. This action will retract the outer cutting cannula, exposing the stylet notch with the tissue sample. **See Figure 4.**

STEP 6: OBTAINING MULTIPLE SAMPLES

After the tissue sample is removed, additional samples from the same patient may be obtained. To obtain additional samples, pull the charging handle a second time, which will retract the stylet within the cutting cannula, placing the Achieve device in a fully charged position. **See Figure 5.**

MANUAL STYLET INSERTION MODE

Reasons for performing a biopsy in this manner include: a desire to push through a dense lesion slowly with the combined strength of the stylet and cannula, and a desire to visualize the placement of the needle within the lesion prior to firing.

STEP 1: POSITION THE NEEDLE

Position the needle such that the tip of the needle extends through the target area.

STEP 2: REVEAL THE STYLET NOTCH

While holding the handle steady, pull back on the charging handle one time to charge the cannula and reveal the stylet notch. Take care to maintain the position of the stylet tip while charging the cannula.

STEP 3: FIRE CANNULA










NOTE: If desired, a slight bias may be imparted to the stylet prior to firing by forcing the stylet notch against the lesion. Take care to avoid bending the stylet notch. Press the A button to fire the cannula through the target site.

STEP 4: BIOPSY SPECIMEN

To retrieve the tissue sample, remove the device from the patient, hold it with the **A** and **D** buttons facing up, and pull back and release the charging handle once. This action will retract the outer cutting cannula, exposing the stylet notch with the tissue sample.

STEP 5: OBTAINING MULTIPLE SAMPLES

After the tissue sample is removed, additional samples from the same patient may be obtained. To obtain additional samples, press the **A** button while holding the outer cutting cannula adjacent to the handle. This action will place the Achieve device in the uncharged position, and prevent damage to the stylet or cannula tips.

SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
	Lot Number
	Catalog Number
	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged
	Single Use
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	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.
	Medical Device
Sterile Package	Sterile Package



CE₂₇₉₇

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