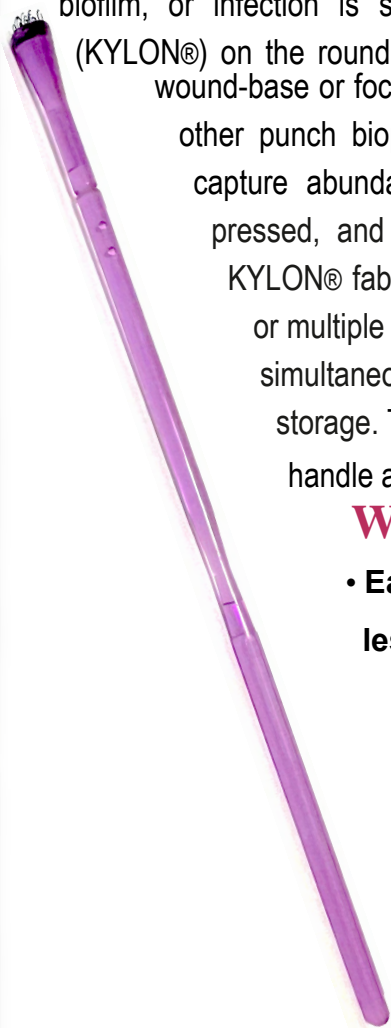


SoftBiopsy® is the new simple and gentle approach to perform a wound-base tangential brush biopsy

During clinical settings such as managing an chronic non-healing wound where neoplasia, biofilm, or infection is suspected, the SoftBiopsy® device, with a multi-patented fabric (KYLON®) on the round tip, can be used to frictionally biopsy and collect tissue from the wound-base or focal lesions areas, instead of a fluid collection swab, or as an alternative to other punch biopsy devices if tissue sampling is desired. This device is designed to capture abundant tangential biopsy samples. When carefully applied to the lesion, pressed, and rotated, the round flat platform tip (just under 1/2 inch in diameter) KYLON® fabric will excavate numerous abundant tissue pieces resembling curettings or multiple small punch biopsies. The SoftBiopsy® microscopically lifts, removes, and simultaneously collects the specimen within the basket rows of hooks and fabric for storage. The KYLON® pad and distal device head can be simply snapped from the handle and the tip placed in a vial or tube for transport to the laboratory.



WHY USE THE SoftBiopsy® DEVICE?

- **Ease of use: apply with moderate pressure to the wound base or lesion and rotate to biopsy using a gentle approach.**
- **No deep punch or cutting of tissue.**
- **Minimally invasive design.**
- **Abundant histological sample: simultaneous tissue collection and storage of the specimen for transport.**
 - **Process as is customary for biopsy sample for anatomic, culture or molecular evaluation.**

What is KYLON®?

KYLON® is a fabric with hooks that gently biopsies by compressing and frictionally lifting intact tissue fragments and simultaneously collects the specimen within the rows of hooks and fabric.



SoftBiopsy®
Model SFT-1000
manufactured by:

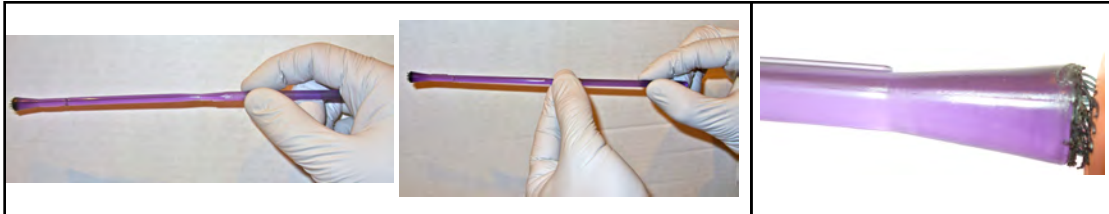
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Summary on wound biopsy using: the SoftBiopsy® Surgical Biopsy Device

Refer to Instructions for Use for SoftBiopsy®(SFT-1000) prior to clinical use.

1. Inspect the wound-base following debridement for areas suspicious for chronic infection or biofilm. Identify lesions or other areas for biopsy. Lightly brush (stroking) the entire wound base prior to selecting areas for deeper sampling with SoftBiopsy®.
2. Gently press the round tip on to the center of the target sampling areas involved. Use pressure similar to tooth brushing. You may use a one handed or two handed technique to maintain the tip of the device on the biopsy target.



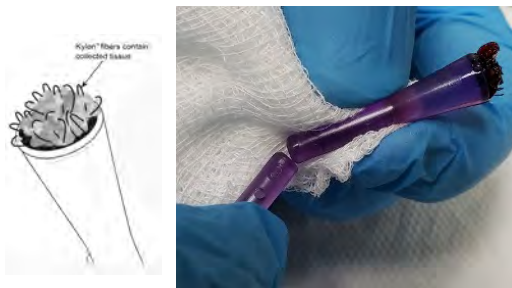
One and two handed technique on applying the device and guiding the biopsy procedure.

Softbiopsy® being applied, pressed and rotated gently.

3. Once the fabric pad is pressed firmly against the target area, rotate the device 360° clockwise for three to five rotations, then 360° counter clockwise for three to five rotations. Alternatively use wrist-twisting 6-10 half-rotations.

Remove and inspect the KYLON® fabric pad. It should be filled with tissue. Snap the tip of the SoftBiopsy® device wrapped in sterile gauze and place tip in the tube or vial of fixative. Discard or recycle the acrylic plastic handle.

4. Once the fabric pad is pressed firmly against the target area, rotate the device 360° clockwise for three to five rotations, then 360° counter clockwise for three to five rotations. Alternatively use wrist-twisting 6-10 half-rotations.



Separating head of SoftBiopsy® device

SoftBiopsy® Device SFT-1000

Clinical Considerations:
Refer to Instructions for Use for SoftBiopsy® prior to clinical use.

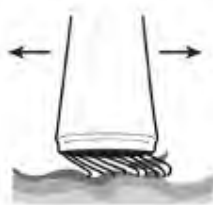
Bedside:

SoftBiopsy® can be used in clinical scenarios where a sampling of the wound base is indicated. This includes, but is not limited to sampling non-healing areas of the wound that are suspected of being neoplastic or harboring organisms after the debridement procedure.

SoftBiopsy® is contraindicated for use in clinical scenarios where wound biopsy is contraindicated such as bleeding disorders or other conditions.

Laboratory:

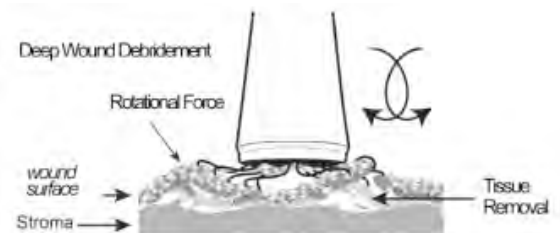
Samples of tissue should be carefully and completely removed from the KYLON® fabric in the laboratory and may be processed and evaluated using a standard histologic , culture, or molecular biopsy analysis. The specimen contains abundant multiple histology samples and may be removed by simply scraping fragments off KYLON® pad with a small fine comb, dull back of the knife blade, or tweezers (see SOP).



Optional: Light Paint Brush Motion Wound Base Biopsy



Moderate Pressure Application and Rotation for Biopsy



SoftBiopsy® frictional specimen removal, storage and transport device system: SoftBiopsy® employs a Kylon® fabric that has a dual function: when pressed and rotated on the target tissue it frictionally de-bonds the affected tissue while imparting a micro-punctate bleeding effect on the (optimally) pre-debrided wound base. It also sweeps and retains the tissue inside the fabric hooks and holds (contains) the specimen, so when send as a dry specimen, or placed in preservative, the entire specimen is transported back to the lab. This dual tissue removal and storage system is registered with the Food and Drug Administration.