

# SoftBiopsy®

SFT-1000

Gynecological Biopsy Device

056-0001 rev B

**Physician and Clinician Primer  
Resource Guide  
Ver: Jan 2014**



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**Q 1: What is Kylon® and how does it work to obtain a biopsy?**

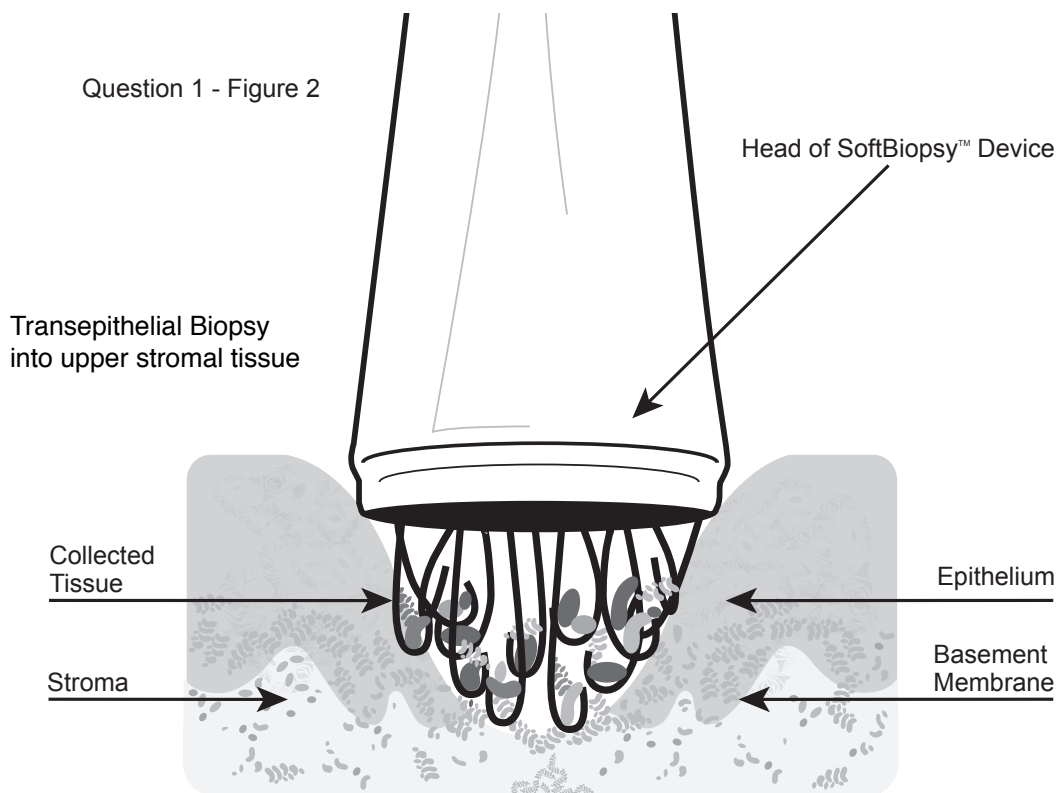
Kylon® is a hooked nylon fabric tissue collection system that can be mounted to the applicator stick, that when pressed on tissue surfaces, allows the hook tip to contact the target tissues, and with pressure and rotation, a trans-epithelial biopsy is obtained and stored for transport to the lab (Figure 1). The procedure of applying, pressing, and rotating a Kylon® covered device onto the surface of the lower genital tract or cervical tissue with moderate pressure and rotating it to obtain a biopsy specimen is called a **Soft-Biopsy®** (Figure 2).

Question 1 - Figure 1

Histologics SoftBiopsy® Gynecological Biopsy Device



Question 1 - Figure 2



**Q 2: Why were biopsy tools using this patent pending “hooked” curettage fabric called “Kylon®” developed?**

Biopsy of mucosal tissues inside a body cavity, such as the cervix or vagina can be traumatic, physically (with evidence of pain and bleeding) and psychologically (fear of cancer, fear of pain or trauma). If trauma is “perceived” by the clinician or the patient, either or both might be less inclined to perform necessary biopsies or seek care to receive them (health seeking behavior may decrease). Neither is good for the quality of the care rendered or received. A minimally invasive biopsy tool was developed with the intent to remove and retain a **high quality trans-epithelial tissue biopsy while simultaneously collecting most of the specimen inside the fabric**. The device is intended to be minimally invasive, keeping the patient care experience in mind. The goal of any diagnostic procedure is also to reduce or eliminate the sampling error associated with biopsy procedures with the dual purpose of harvesting and retaining the sample optimally. Thus, both the clinician and the patient are inclined to deliver and receive the necessary care to make the diagnosis and guide therapy.

Clinical trials have been performed, and are ongoing to demonstrate the intended goals of using the Kylon fabric to obtain a biopsy. The clinical trial showed that specimens from the exocervix and squamous lower genital tract using **SoftBiopsy®** appear as multiple trans-epithelial punch biopsy specimens, while the specimens from the endocervix using **Soft-ECC®** are curettings.

**Q 3: What is Soft-Biopsy®?**

Softbiopsy® is comprised of a trumpet shaped tip acrylic applicator with a small round platform from which a nylon hooked fabric tip extends to achieve an epithelial biopsy. It is intended to be gently placed on a lower genital target tissue such as the cervix to obtain a cervical biopsy when indicated in settings that include colposcopy. The fabric tip is pressed against the exocervical lesion with a pressure force similar to tooth brushing, and then rotated 3 complete revolutions clockwise, then 3 complete revolutions counterclockwise, and removed. The tip is then snapped apart from the handle at the fracture line, becoming the second component of the device, a non-sterile fabric basket container for specimen storage and transport, that is then placed in a pathological fixative vial. The vial with the sample tip is emptied according to standard lab operating procedure and processed at the pathology lab in similar fashion to the conventional lower genital tract biopsy specimen.



**Q 4: How do I use the SoftBiopsy® device to obtain an gynecological cervical biopsy?**

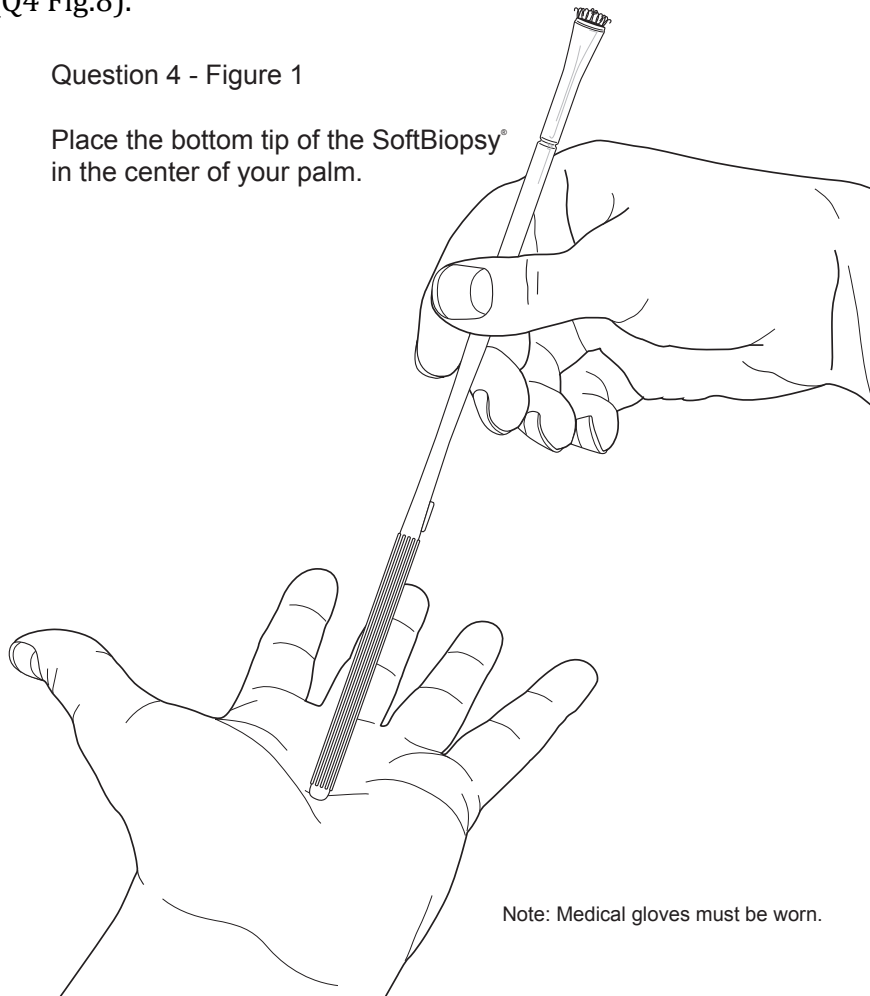
Place the handle of the device in the palm and hold the near portion of the shaft in between the thumb and first two fingers (Q4 Fig 1). This will permit a twirling motion during the rotational biopsy. (Q 4 Fig 2 and Fig 3). Gently apply the rounded tip on to the tissue surface and press with moderate firmness similar to moderate “tooth brushing”. If the tissue is excessively moist, dry the lesion or area targeted for biopsy prior to beginning the biopsy procedure to avoid skating or slippage. Twirl or rotate the device two to three complete 360 degree turns clockwise, then three complete revolutions counterclockwise. This can be done with a single hand (Q 4 Fig 3 and Fig 4) or with two hands with the second hand steadying the device on the lesion with pincher fingers in the indented waistline of the device shaft (Q 4 Fig 3.5).

Alternatively, one could press and rotationally agitate (like a washing machine effect) 5-8 times while rotating with a 180 degree twist of the wrist while pressing moderately on the surface to completely contact the lesion or target area (Q4 Fig 5).

Once an adequate tissue specimen is obtained (Q 4 Fig 6), simply snap off the device head (Q4 Fig 7) from the shaft of the device at the scored area and place the non sterile fabric container filled with tissue into the non-alcohol based fixative vial provided by the laboratory (Q4 Fig.8).

Question 4 - Figure 1

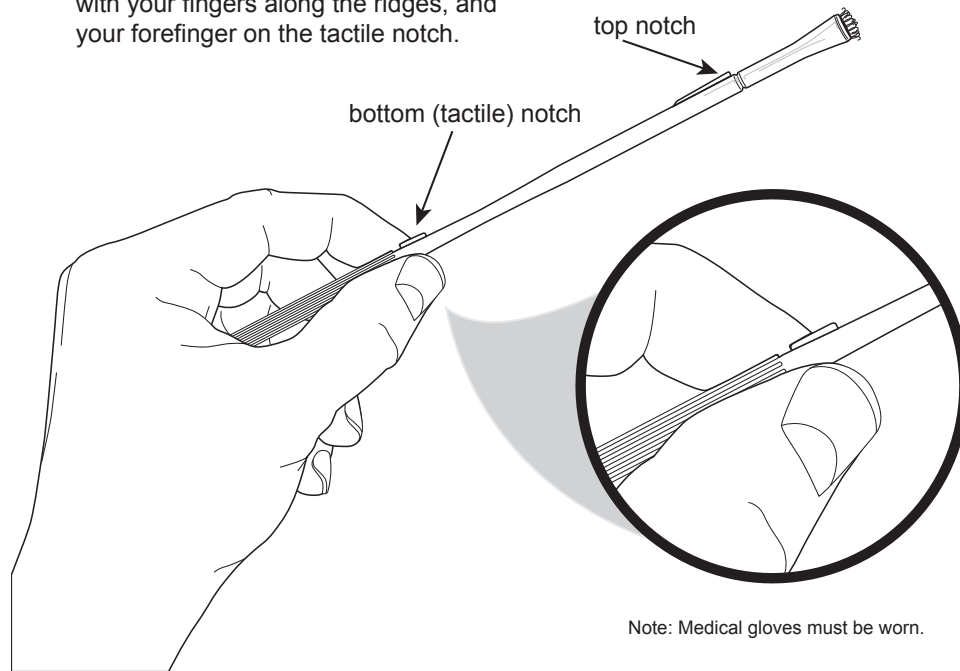
Place the bottom tip of the SoftBiopsy® in the center of your palm.



Note: Medical gloves must be worn.

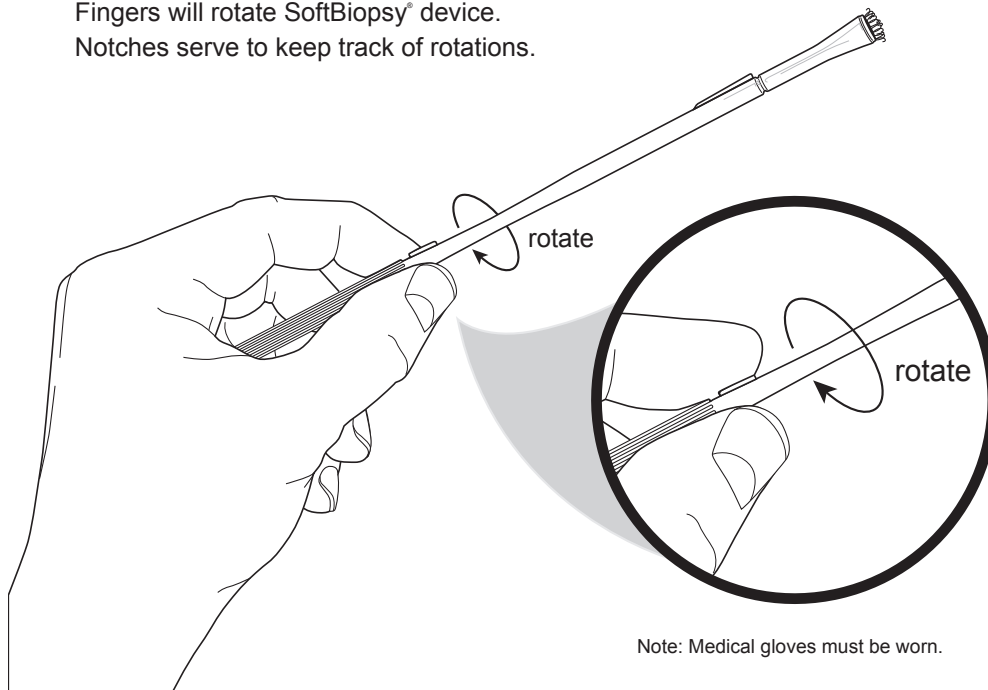
Question 4 - Figure 2

Close your hand around the SoftBiopsy<sup>®</sup>, with your fingers along the ridges, and your forefinger on the tactile notch.



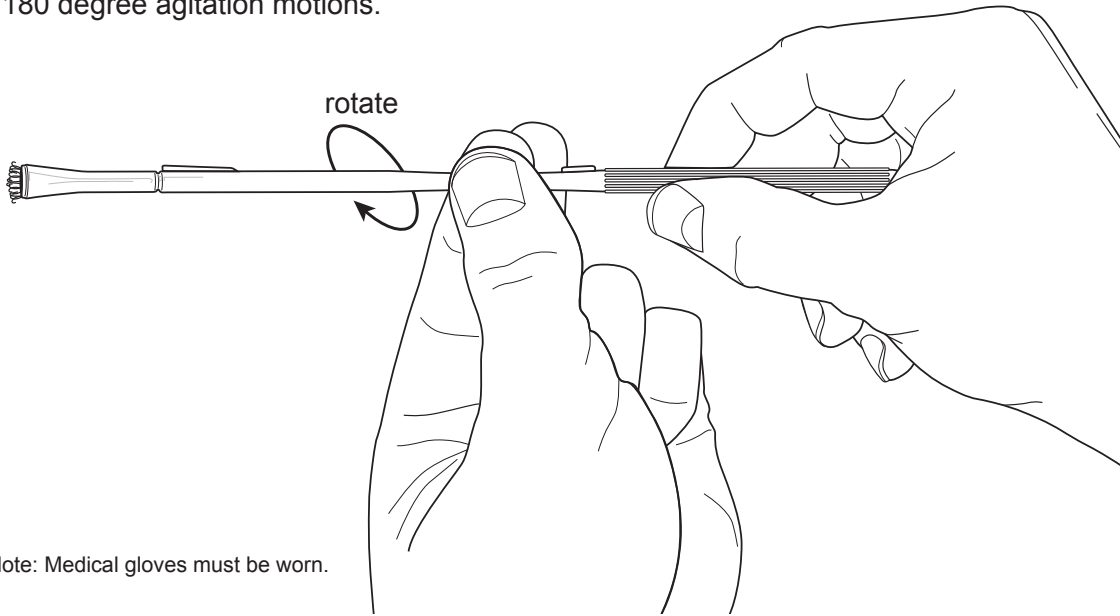
Question 4 - Figure 3  
Single Hand Rotation Technique

Fingers will rotate SoftBiopsy<sup>®</sup> device.  
Notches serve to keep track of rotations.



Question 4 - Figure 3.5  
Two Hand Rotation

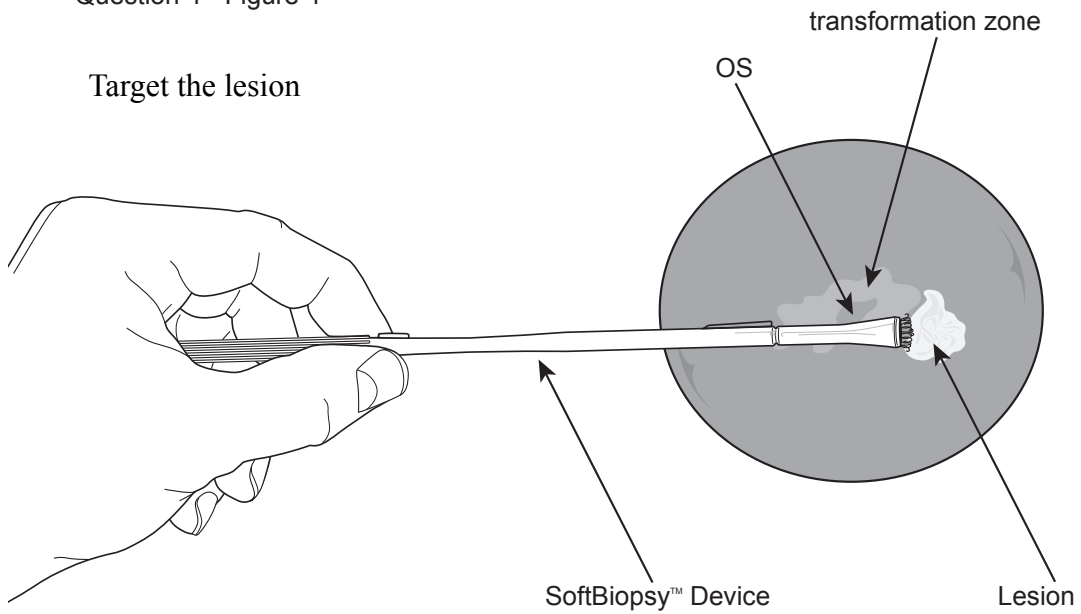
The handle is rotated with one hand while the pincher fingers are placed at the tapered waist at the mid shaft. This is smooth and permits guided rotation or 180 degree agitation motions.



Note: Medical gloves must be worn.

Question 4 - Figure 4

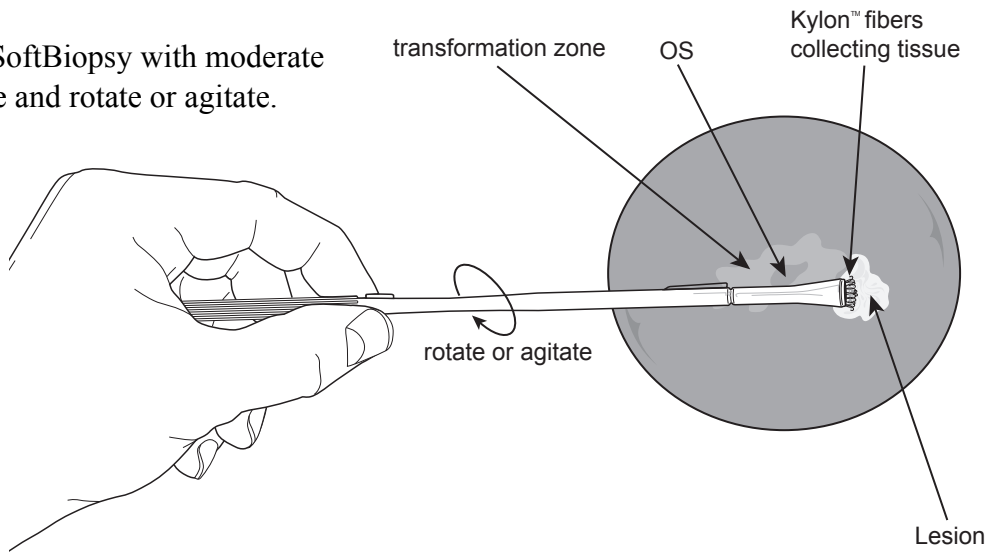
Target the lesion



Note: Medical gloves must be worn.

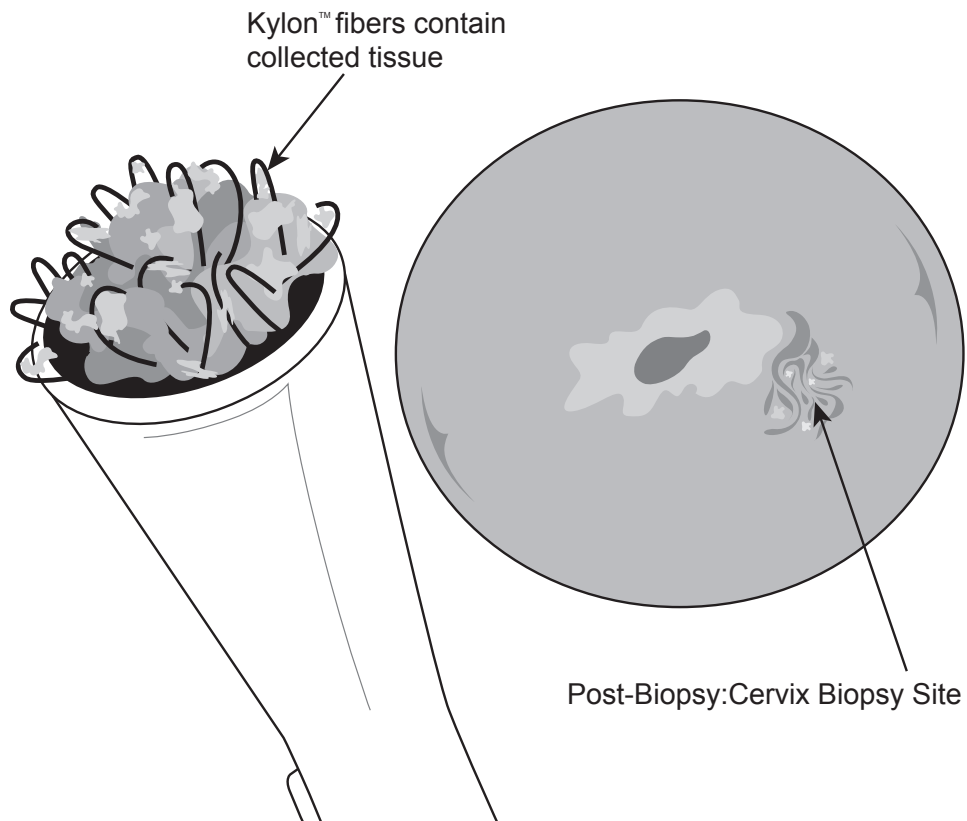
Question 4 - Fig 5

Apply SoftBiopsy with moderate pressure and rotate or agitate.



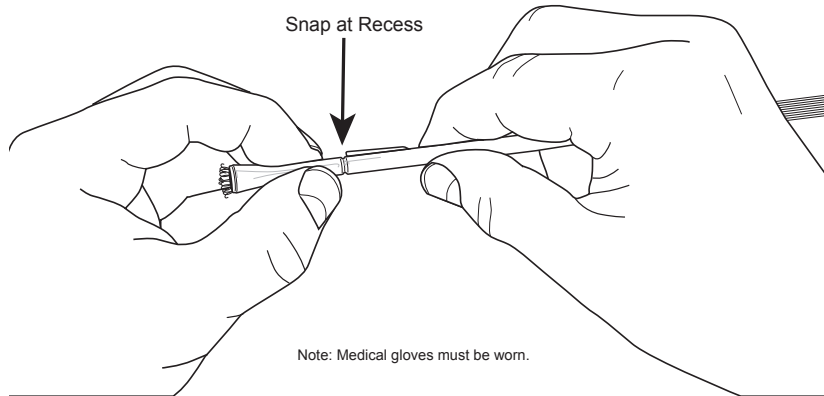
Note: Medical gloves must be worn.

Question 4 - Figure 6

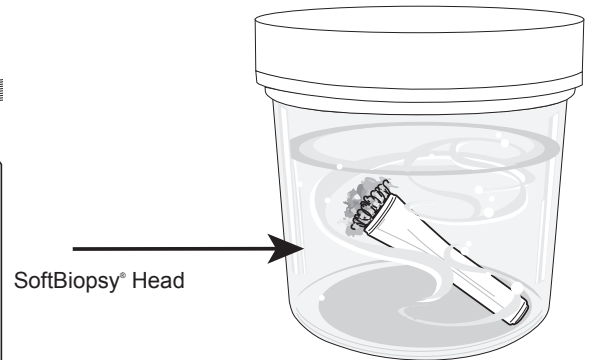


## SoftBiopsy® Tip in Vial with Tissue

Question 4 - Figure 7



Question 4 - Figure 8

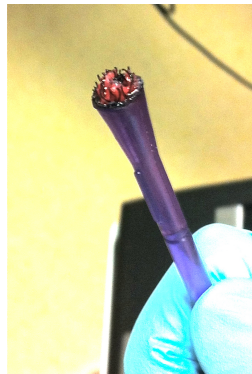


The tip was applied onto a cervical lesion and a fabric biopsy obtained.

Tissue acquisition should be confirmed visually after the biopsy obtained and the tissue can be clearly seen stored in the device head which is submerged into the liquid fixative.

The specimen was transported to the lab and combed out of the fabric onto a Telfa-pad to be prepared for processing.

**Tissue  
on  
Device**



**Tissue in  
Fabric Head  
in the vial**



### Q 5: Why is the tip of the SoftBiopsy device shaped in a more focal round design?

The device is designed to cover the average lesion in one quadrant of the cervix. It is large enough to take the equivalent of several small punch biopsy specimens, or larger strips or clumps of intact trans-epithelial specimens to the stroma. If applied with moderate pressure, a good portion of the **Kylon®** pad will excavate tissue and simultaneously capture and collect the tissue within the hooks and rows of the **Kylon®** fabric. In the majority of cases, the biopsy will result in some slight excoriation or scratching of tissue, but the fabric will fill with mucoïd material that is comprised of the epithelial biopsy.



**Q 6: Do the hooks puncture the tissue when pressed? How does the abrasive fabric compare with other biopsy devices?**

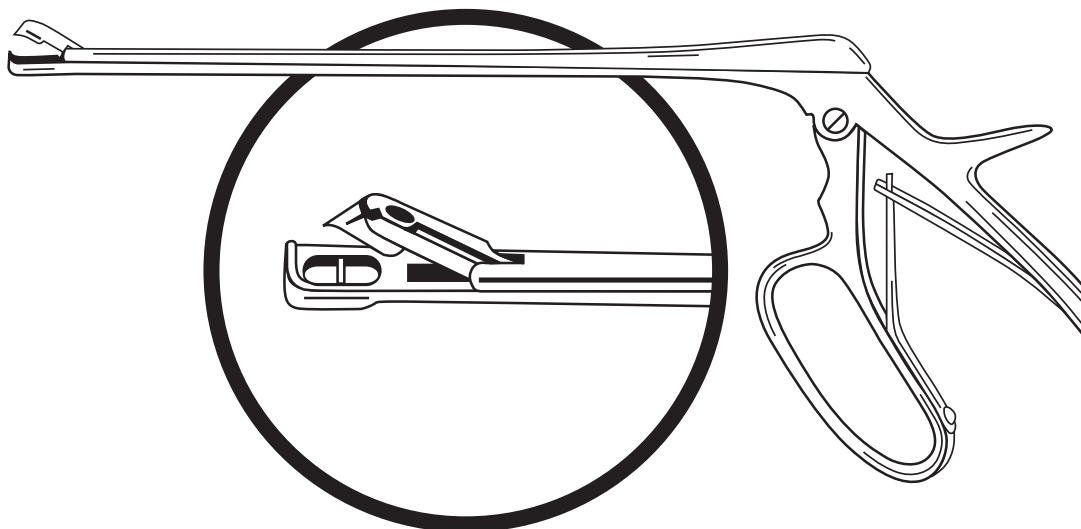
No, the tips of the hooks angle away from the tissue surface before pressure is applied. Once pressed, the hooks open to allow the nylon fibers to contact the tissue surface to perform the frictional biopsy. With agitational or rotational forces, the hook tips then frictionally abrade the tissue surface, causing it to buckle and fracture. The hooks then recess under the basement membrane lifting the pieces of trans-epithelial tissue into the fabric. The device provides pieces of tissue commensurate with what is expected when taking multiple small punch biopsy specimens. The rows hooks function to also collect the fragments, as is what is commonly seen with punch biopsy devices (tissue remains in the fabric biopsy rows of hooks).

Other biopsy tools that use a cutting surface, like a forceps, a curette, or a stiff bristle brush bristle are more rigid and are not curved, thus, with pressure, they will puncture or enter the surface with initial placement or pressure. With rotation or lateral motion, the tissue is first sheared, then torn free from the underlying stroma.

With a conventional curettage sharp or bristle brush instrument, the tissue can fall free from the tip or straight bristle, and may be incompletely collected in the specimen. If the cutting surface is sharp, the tissue will be shaved or dissected in intact fragments.

Question 6 - Figure 1

Sharp Punch Biopsy Forceps



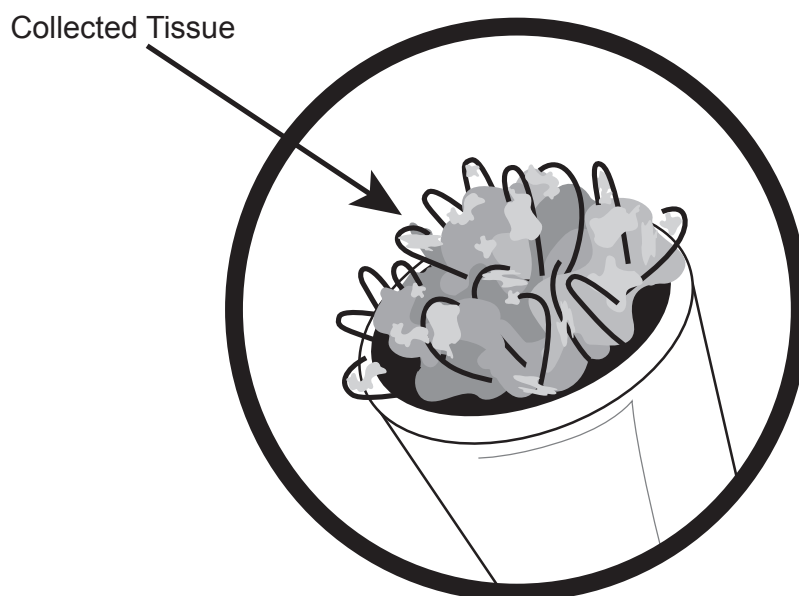
**Q 7: How do I apply the device and how much pressure do I apply when pressing the applicator stick and Kylon® pad on to the tissue surface?**

Pressure on a flat, irregular, or rounded tissue surface (like exocervix or vagina) is applied perpendicularly to the lesion or target epithelial epithelium. The amount of pressure needed to expose the hook surface to the epithelium would be equivalent of a light massage or moderate tooth brushing, depressing the device into the tissue surface so it is firmly applied, but not so hard as to depress the tissue surface more than two or three millimeters.

**Q 8: How do I know I have obtained a sufficient sample? What do I do to save the sample for analysis?**

After performing the biopsy procedure, gently lift the applicator tip away from the tissue surface. You will note the “excavated” tissue has recessed between the fiber hooks, and will be combined with some blood tinged mucous. The tip is research proven to trap and retain the excavated specimen, and is then released (snapped off) from the handle with moderate lateral traction, decoupled from the device, and dropped in a vial of fixative. If you do not see any tissue or mucoid material in the fabric, repeat the procedure.

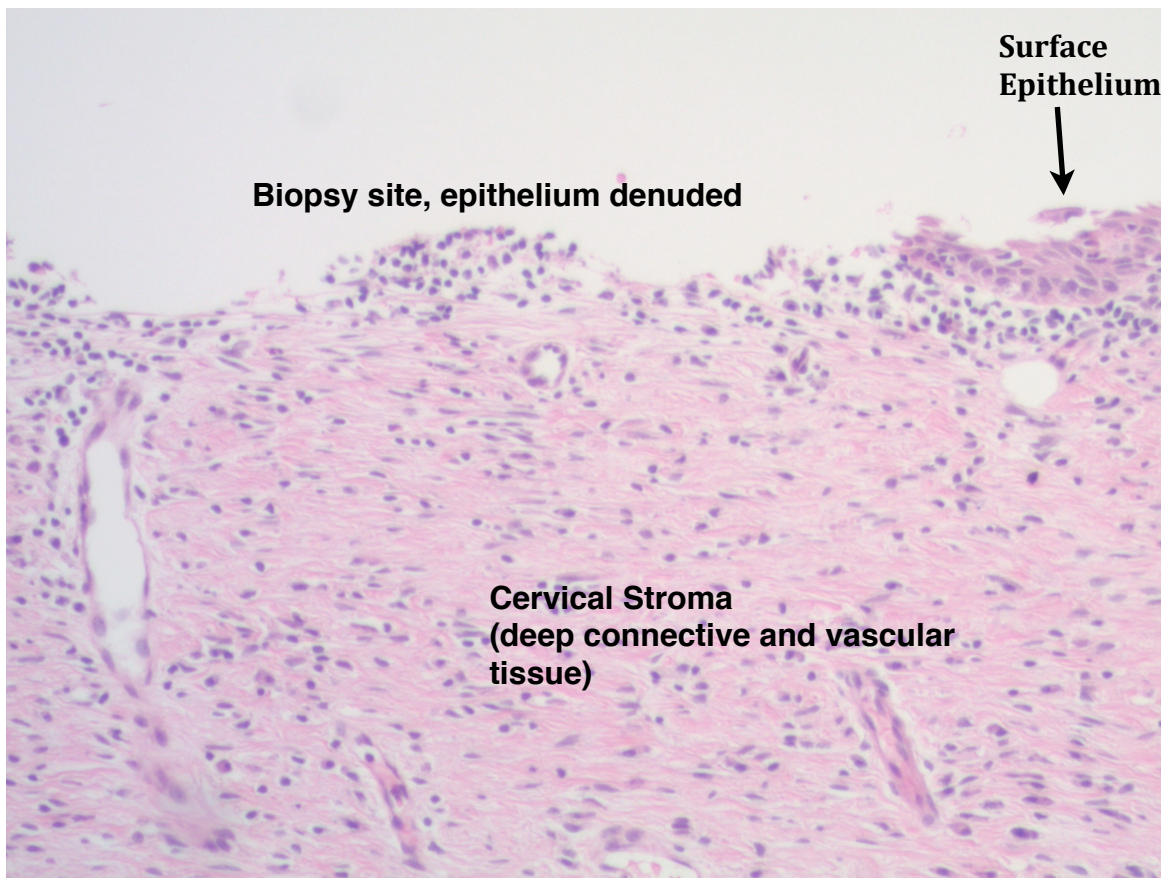
Question 8 - Figure 1



**Q-9: Is there Evidence that the biopsy taken with Soft-ECC® or SoftBiopsy® is trans-epithelial (full thickness)?****Kylon Based Trans-epithelial Biopsy Sample**

Research has shown that the biopsy sample removed with frictional abrasion using the KYLON® hooked fabric is deep enough to remove the full thickness of the epithelium of the cervix. The abundance and correlation to reference cervical LEEP specimens has been ascribed to the tissue trap containment of the entire excavated specimen. The tissue obtained includes **both** the glandular endocervical and squamous exocervical tissue. Both columnar/glandular and squamous epithelium exist together, often

## Exocervical



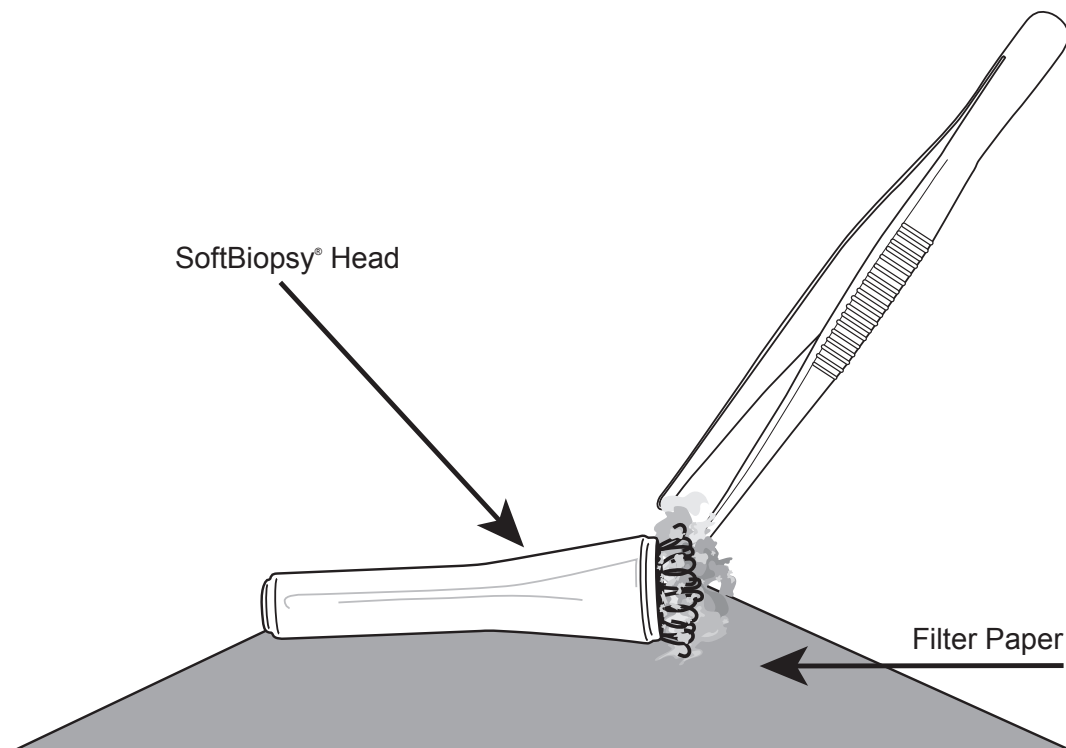
Burg et al. AAGL Meeting, 2010.

**Q 10: How is the specimen taken off the fabric so it can be processed in the Pathology Lab?**

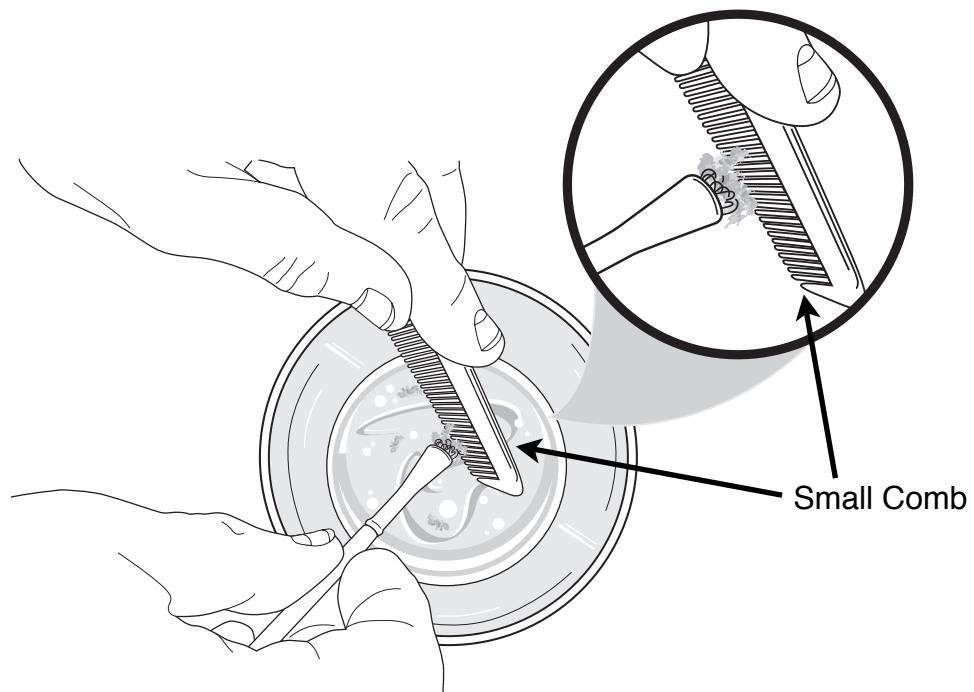
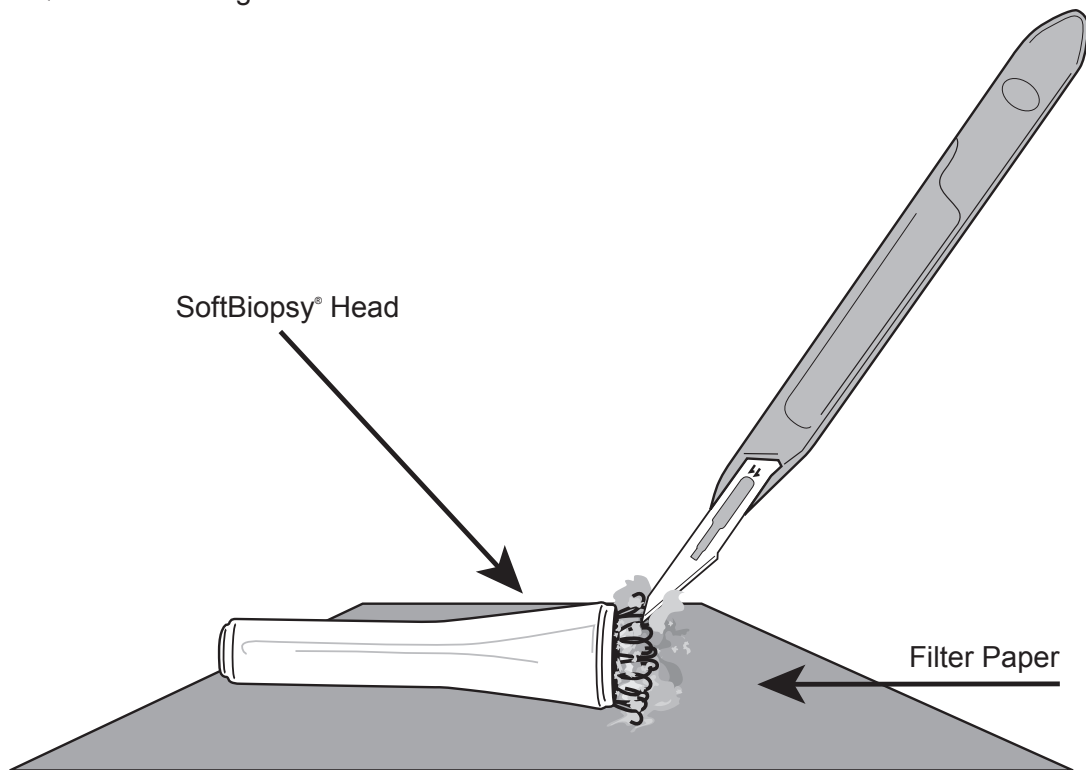
A: The pathologist has several methods available to remove the tissue from the fabric container. Tweezers or a scalpel blade can be used to gently scrape off the tissue from the hooks and fabric.

The specimen can be collected onto filter paper or telfa. Alternatively, a small comb has been developed that can be raked across the hooks repeatedly under the surface of the fixative while still in the vial, thus “combing” the tissue from the fabric into the vial. The liquid medium facilitates the release of the tissue into the vial. Once the tissue is released, it resembles multiple small punch biopsies or conventional curettings of the transformation zone where there is also squamous epithelium. The specimen can then be processed by the lab in an identical manner that is customary for the lab (tea bag or directly into cassette), including cell block if desired.

Question 10 - Figure 1



Question 10 - Figure 2



This can also be done outside the vial onto a Telfa Pad.