SoftBiopsy® – Instructions for Use

SoftBiopsy® - Gynecological Device:
SoftBiopsy® is not designed or intended to perform an endocervical biopsy. If endocervical curettage is needed for complete diagnostic work-up, use a suitable instrument such as the Soft-ECC® (Endocervical Curette).

These are biopsy quality samples (not cytology). Tissue samples obtained with the SoftBiopsy® device may be interpreted using accepted biopsy classification systems such as the World Health Organization Classification of cervical disease including the CIN (cervical intraepithelial neoplasia) classification. Because the tissue obtained may include both intact epithelium and separated cellular pieces or elements, the tissue sample should not be used alone to establish invasive or microinvasive epithelial disease. If colposcopic or visual evidence for invasive carcinoma is suspected, an excisional procedure may be advisable (cone biopsy, LEEP, LLETZ) under the guidance of a physician or clinician with expertise.

The use of SoftBiopsy® in pregnant patients has not been studied. The benefits of using SoftBiopsy® in patients who are pregnant must be weighed against any possible risks.

SoftBiopsy® - Microscopic Interpretation:
The World Health Organization Classification System for tissue and the CIN I, II, III system should be used in interpreting and reporting analysis of tissue specimens obtained using SoftBiopsy®.

Adverse Events: None known

Clinical Evidence:


3. Published Abstract(s), ASCCP Biennial Meeting, April 2014, Scottsdale, AZ
   Diedrich JD1, Bentz J1, Rathore S2, Improvement in Endocervical Yield with Fabric Curettage
   Clark B1, Enhanced Colposcopic Accuracy for High Grade CIN
   Clark B2, Siteman A1, Enhanced Inflammatory Reaction after Fabric Biopsy

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SoftBiopsy® - 050-0011 Rev. C
**Step 2 - Transfer of the Sample to the Preservative Vial**

1. The tissue accumulated has been raked into and collected between the rows of hooks which serve as a basket for transport. Inspect the black fabric pad before placing in the vial to be sure the “fabric pad” is filled with an adequate sample of tissue.

2. Place your index and thumb on the handle/shaft of the device with the scored mark between the fingers of the right and left hand.

3. The SoftBiopsy® head will separate from the handle by bending firmly at the scored line. The handle of the device may be discarded.

4. Place the head of the SoftBiopsy® device into the formalin preservative solution in a secure manner. **Do not use alcohol preservative** which can adversely affect the fabric pad adhesive.

**SoftBiopsy® - Description:**
The SoftBiopsy® device is intended to be used once to obtain an exocervical trans-epithelial tissue specimen. The uniform disc shaped fabric covered head is designed to remove part or all of the squamous epithelial layer of the cervix. Kylon® is a specialized fabric with individually arranged hooks that gently, frictionally abrade and collect the specimen within the rows of hooks and fabric that serve as a basket receptacle. The head of the SoftBiopsy® is uniform and of optimal size for the average exocervical “quadrant”, allowing for the circular “face” of the SoftBiopsy® to be applied directly to an abnormality that is seen on the exocervix. The biopsy sample will contain multiple trans-epithelial fragments like that seen with multiple small punch biopsy specimens. The SoftBiopsy® head is a complete slightly convex cervical disc that is easily directed to the surface contour and maintained on the lesion because of a unique shape.

**SoftBiopsy® - Indications for Use:**
**Bedside:** SoftBiopsy® is intended to be used in the same clinical scenarios as the gynecological punch biopsy forceps. This includes, but is not limited to sampling lesions of the cervix that are suspected of being neoplastic, during a colposcopic examination.

**Laboratory:** Samples of tissue should be carefully removed completely from the KYLON® fabric in the laboratory and may be processed and evaluated using a standard histologic technique. The specimen resembles a collection of multiple punch biopsy specimens, but should be evaluated by a pathologist familiar with evaluation of SoftBiopsy® exocervical samples.

**Contraindications:**
SoftBiopsy is contraindicated for use in the following patients:
1. Patients with known bleeding disorders or those on anticoagulant therapy.
2. Patients with a suspected active cervicitis.
3. Patients with a known allergy to nylon or acrylic plastic.
4. Pregnancy or suspected pregnancy, when a cervical biopsy would not be indicated.

**Warnings / Precautions:**
During any biopsy procedure, including SoftBiopsy®, bleeding may occur. Silver nitrate or Monsel’s Solution may be applied to the bleeding site if necessary.

It is unlikely that the head of the SoftBiopsy® device will separate from the handle while in the vagina during the procedure. Use a clamp or ring forceps to retrieve it. If the procedure was completed prior to fracture and there is sufficient tissue on the device, place the device head into the specimen vial and discard the handle. If the specimen is insufficient, repeat the sampling procedure with a new device. If an intrauterine device (IUD) is present, take care to avoid tangling the string within the fabric hooks to avoid an inadvertent displacement of the IUD.