

## ENFD Procedure Overview

- 1. Kits will be delivered by Sales Representative or shipped directly to the provider from NovaDX**
  - a. Upon receipt of kits place freezer gel packs in freezer in preparation for shipping on biopsy day.
  - b. Materials supplied by NovaDX include:
    - i. 3mm punch biopsy kit, freezer gel pack, insulated sleeve, FedEx Clinical Pak mailer, and pre-printed FedEx return label
  - c. Forms included in ENFD kit:
    - i. **Requisition Form** (return in transport kit, along with patient's demographic sheet and copy of insurance information to NovaDX)
    - ii. **Procedure Note** (for your office, do not return)
    - iii. **Patient Consent** (for your office, do not return)
    - iv. **Patient Letter** (for patient, do not return)
    - v. **Patient Post-Procedure Instructions** (for patient, do not return)
  - d. Materials supplied by your office include:
    - i. Gloves
    - ii. Syringes and needles
    - iii. Lidocaine with Epinephrine
- 2. Procedure Preparation**
  - a. Open the biopsy kit in a sterile manner.
  - b. Complete the labels for each biopsy site and secure to Zamboni tubes prior to procedure.
  - c. Draw up lidocaine with epinephrine in syringe. Each site will require 1-2 cc for anesthetization.
- 3. Patient Positioning**
  - a. Position patient according to sites for biopsy.
  - b. For lower extremity punches, the patient should be given an exam gown or appropriate draping. Patient is placed in lateral decubitus position with pillow under head.
- 4. Mark Biopsy Sites**
  - a. For upper extremity, 2 biopsy sites are standard:
    - i. Lateral surface midway between shoulder (acromion) and elbow – lateral, proximal arm midway on bicep (Proximal Arm = PA)
    - ii. Upper (hairy or dorsal) surface of the forearm 5 cm above the wrist (Distal Arm = DA)
  - b. For lower extremity, 3 biopsy sites are standard:
    - i. 10 cm below greater trochanter (hip joint) – lateral, proximal thigh (Proximal Thigh = PT)
    - ii. 10 cm above the lateral joint line of the knee – lateral, distal thigh (Distal Thigh = DT)
    - iii. 10 cm below the lateral joint line of the knee (Calf = CA)
  - c. Podiatrists use different biopsy locations that usually include 2 biopsy sites
    - i. 10 cm above the lateral malleolus (ankle) (Ankle = A)
    - ii. Dorsum of foot in the extensor digitorum brevis muscle belly – superficial fibular nerve distribution (Foot = F)
  - d. Mark the biopsy sites with a circle the size of a dime.
  - e. Avoid scar tissue, moles, or any areas with rashes/injury, etc.
- 5. Prepare and Anesthetize the Biopsy Sites**
  - a. Wear gloves.
  - b. Cleanse biopsy sites with betadine-iodine swab followed by alcohol swab.
    - i. Application of topical anesthetic can be used prior to injection of Lidocaine with Epinephrine at the discretion of the physician.
  - c. Inject biopsy sites with Lidocaine with Epinephrine
    - i. Be sure to inject slowly.
    - ii. 1-2 cc per site is recommended.

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- iii. Infiltrate the biopsy site through the edge of the selected site at a 45-degree angle, inject a small amount of anesthetic with just the tip of the needle to create a “wheel”.
    - a. A “wheel” is a raised bleb of skin that has been saturated with anesthetic resulting in a pale, swollen appearance (similar to a bee sting).
  - iv. Inject the remaining anesthetic deeper covering the circle marked for the biopsy site.
    1. Do not inject directly over the biopsy site.
      - a. Anesthesia administered within the biopsy site may negatively affect the test quality.
    - d. Once the patient’s sites have been fully anesthetized, proceed with the biopsy.
- 6. Punch Biopsy Specimen Collection**
- a. Wear gloves.
  - b. Place thumb and index finger on outside of biopsy site and spread tissue to provide some tension with non-dominant hand.
  - c. Insert the 3mm punch tool onto the biopsy site perpendicular to the surface of the skin using the dominant hand.
  - d. The 3mm punch is advanced with gentle downward pressure and a rotating movement using the thumb and index finger.
  - e. Insert the depth of the punch instrument to  $\frac{3}{4}$  of the way down the metal cutting portion:
    - i. Allow the blade to do the work.
    - ii. The punch should enter the skin to the level of the subcutis, at least 3mm.
  - f. Remove the punch instrument and lift out perpendicular to the skin; check the punch instrument and biopsy site to see if tissue has been removed.
    - i. If tissue is found within the punch instrument, use the plunger to eject the tissue into the appropriately labeled Zamboni tube.
    - ii. If no tissue is found in the punch tool and remains within the patient’s biopsy site, carefully remove biopsy tissue with forceps, using caution to avoid crushing the surface epithelium.
    - iii. Once the biopsy tissue has been lifted out, if necessary, cut the sample loose at the base through the fatty tissue with the provided scissors.
  - g. Ensure the biopsy is placed in the correct tube that has been labeled for each location of the biopsy sites.
- 7. Clean and Cover Biopsy Site**
- a. Use gauze to apply pressure following punch biopsy until bleeding stops.
  - b. Clean biopsy sites and apply band aid.
- 8. Patient Discharge**
- a. Provide the patient the with the *Patient Post-procedure Instructions and Patient Letter*.
- 9. Packaging of samples**
- a. The biohazard bag should contain the following:
    - i. Biopsy specimens in labeled Zamboni tubes.
    - ii. Completed **Requisition Form** with patient demographic sheet and insurance information should be placed in outside pocket of biohazard bag.
  - b. Place the frozen gel pack into insulated sleeve.
  - c. Place the biohazard bag into the insulated sleeve on top of the frozen gel pack.
  - d. Place insulated sleeve into the ENFD kit box.
  - e. Place box into FedEx Clinical Pak mailer affixed with the pre-printed FedEx return label.
  - f. Call FedEx at 1-800-463-3339 to schedule pickup – biopsy should be shipped the same day the biopsy is performed.