

## Tissue Sample Kit Instructions for Medical Personal

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### **Prerequisites for Biopsy Procedure:**

As required by FDA regulations, all Tissue Banking samples require testing for major diseases. Prior to the performance of the Skin Biopsy Procedure your patient must have a blood test to rule out the presence of HIV and Hepatitis C. A copy of this test result must be attached to the tissue samples when they ship their specimens to StemCure.

**Important:** The Biopsy Procedure must be performed between Monday and Thursday because the tissue samples must reach our labs no later than Friday via overnight delivery.

### **About The Tissue Sample Kit:**

The StemCure Tissue Sample Kit and all its contents have been designed to make the Biopsy Procedure more safe and efficient. We have also provided you with the necessary packaging for you to properly transport the harvested skin samples at a cool 5 degrees Celsius.

Before starting the biopsy procedure, make sure the kit contains the following items.

### **a. Biopsy Set**

The Biopsy Set contains the essential components to perform the Biopsy Procedure. It is fully equipped with disposable sterile implements that contain:

- 1 Disposable 4mm Biopsy Punch
- 2 10% Povidone Iodine Swabstick
- 1 Bic Original Shaver
- 6 Steri-Strip 1/2 x 4"
- 1 Suture NylIn 5-0 Look
- 1 3ml Syringe with Injection Needle

### **b. Suturing Set**

The Suturing Set contains the essential components to simplify suturing. It is equipped with sealed and sterilized implements that contain:

- 4 1/2 floor grade straight Iris scissors (1)
- 1 x 2 floor grade Adson tissue forceps (1)
- CSR overwrap (1)
- 4" x 4" gauze sponges (8)
- 2" x 2" gauze sponges (5)
- absorbent towel (1)
- polylined fenestrated drape (1)
- 2 oz medicine cups (2)
- 5" floor grade Halsey needle holder.

### **c. Cooler Shipping Kit**

The Cooler Shipping Kit contains:

- A White Corrugated Shipping Box with a pre-paid FedEx airway bill
- Cooler Box(big)
- The Cold Gel Bag
- Styrofoam Refrigeration Container (small) with 2 Sterile Pre-labeled Vials with shipping medium

**Note.** During the biopsy procedure, always keep the Cold Gel Bag in the Cooler Box to maintain its cold temperature.

### **Directions for Skin Biopsy Procedure**

#### **Basic Preparation:**

The patient should inform their doctor of any **allergies** to any particular medication that they may have, which medications they are currently taking, and any reactions to local anesthetics such as Lidocaine, Novocain, or iodine cleaning solutions such as Betadine. The doctor should also be aware if the patient has experienced any **bleeding** problems and if they are currently **pregnant**.

#### **For Infants and Children:**

Any physical and/or psychological preparation you can provide to assist the patient's child through this quick procedure will be beneficial to preserving their age, interests, previous experiences, and levels of trust. From our experiences, children are more readily accepting of the biopsy procedure if they clearly understand the benefits of this process.

#### **Where to perform the Skin Biopsy:**

The skin biopsy procedure must be done from the underarm, right before the axillar area, making sure to avoid the brachial artery area.

#### **Risks:**

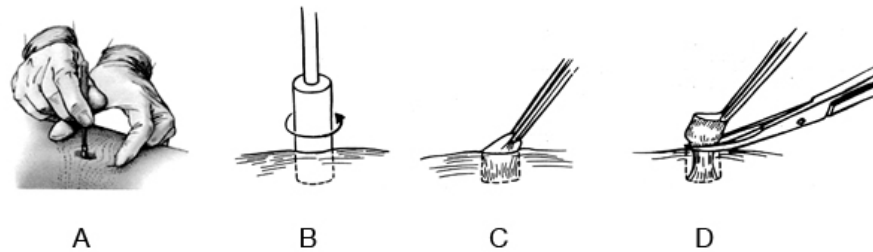
There is always a small chance of infection. If your patient tends to form scars in response to a skin injury, there is a fair chance one will form over the biopsy area.

#### **During the Biopsy:**

1. Material for biopsy should be collected using the sterile instruments we provide. The procedure should be performed under aseptic conditions. The upper armpit area, from where the sample will be taken, is first washed with water, shaved and then cleaned with 70% ethanol or a 10% Povidone Iodine Swabstick. A 2% Lidocaine injection (1 or 2 ml is sufficient) is made close to the collection site to reduce the pain sensation during the biopsy procedure.

Tumescing the injection site ( having the anesthetic injected so the skin surface becomes engorged, giving the skin an orange peel-like appearance) helps reduce the chance of injuring a blood vessel or other important anatomical structures.

2. Using the provided sterile instruments, a skin fragment (subdermally) is removed from the anesthetized area. While stretching the skin tautly, rotate the punch in a single direction through the skin to the subcutaneous tissue (Figs. A-B). A slight decrease in resistance will be appreciated; when you have passed the dermis into the fat (subcutis) layer. Lift the skin with forceps or a skin hook and remove it by cutting the subcutaneous base with a sharp tissue scissors ( figs. C-D). Apply pressure for hemostasis. As per the doctor's discretion, suturing or Steri-Strips will be used for closure. In most cases the skin edge can be approximated with a single interrupted dermal suture, although a single vertical mattress suture will provide optimum closure. Wound management is then similar to that of any other suture lacerations.



3. The collected skin biopsy should be immediately transferred to the provided sterile vial containing the specialized shipping medium. Although only one vial is needed for the patient's biopsy procedure, a second vial has been included should the first one become damaged or unusable. The physician should seal the vial and pack it in the Styrofoam Refrigeration Box with the Cold Gel Bag. Detailed instructions for packing the tissue sample is on the inside lid of the White Corrugated Shipping Box.

**IMPORTANT:** Prior to skin sample biopsy, remember the following: The patient's tissue sample will only remain viable for a short period of time. Therefore, the sample has to be shipped the same day the procedure is completed by Federal Express overnight delivery.

**After the Biopsy Procedure:**

If you have administered any stitches during the biopsy procedure, your patient may need instructions about how to keep the wound clean and dry. Please inform the client how to treat the affected area. You will probably advise them to have the stitches removed from the axilla after 10-12 days.

## **Doctor Recommended Instructions for Post-Biopsy Procedure Patients**

- Don't remove the dressing until 24 hours after surgery.
- After 24 hours, remove the dressing follow these steps to take care of the surgery area:
  - a. Mix equal parts of water and 3% Hydrogen Peroxide. Use a Q-Tip to clean the site and then dry the area and cover with a Band-Aid.
  - b. Apply a special antibacterial ointment (Bacitracin)
  - c. You can shower regularly.

Schedule your patient's next visit for suture removal.

### **Medical Provider Reimbursement:**

After receiving and crediting their processing fee, StemCure will reimburse the doctor up to \$100.00 for professional services rendered in the successful collection of the tissue sample.