



Tissue Sample Kit Instructions for Medical Personnel

Prerequisites for Biopsy Procedure:

In accordance with StemCure Policy, 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:

1. Antibodies to human immunodeficiency virus type 1 (HIV-1)
2. Antibodies to human immunodeficiency virus type 2 (HIV-2)
3. Antibodies to hepatitis C virus (HCV)
4. Antibodies to hepatitis B surface antigen (HBsAg)
5. Antibodies to Syphilis

A copy of this test result must be attached to the tissue samples when the specimens will be shipped to StemCure. If one of the diseases will be detected, you should contact StemCure for further instructions.

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 safe and efficient. We have also provided you with the necessary packaging for you to properly transport the harvested skin samples at a cool temperature between +5 to +12 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 Bic Original Shaver
- 4 Alcohol Prep Pads
- 1 Syringe with Injection Needle
- 1 Ampule 2mL Lidocaine 1%
- Disposable 5mm Biopsy Punch
- 1 Suture Nyln 4-0 Look
- Bandages, and/or Steri-Strip
- 2 Pairs of Sterile Gloves

b. Incision/Drainage Pack

The Incision/Drainage Pack contains the support components for biopsy procedure and the essential components to simplify suturing. It is equipped with sealed and sterilized implements that contain:

- 4 Gauze 4 x 4 8-ply
- 1 5 1/2" Straight Kelly Hemostat
- 1 4 3/4" Adson Thumb Forceps
- 1 Alcohol Prep Pad
- 1 Poly Bag with Twist Tie
- 1 Fenestrated Drape
- 1 #11 Scalpel Blade
- 1 Towel
- 1 Pack of PVP Swabsticks (3/pk)
- All packed in a sterile tray

c. Cooler Shipping Kit

The Cooler Shipping Kit contains:

- Two 8oz Ice Bricks
- Styrofoam Refrigeration Container (small) with 2 Sterile Pre-labeled Vials with shipping medium.

IMPORTANT: Make sure that the first and last names of the patient are the same as in the Vial.

Note: Ice Bricks must be maintained in a freezer until time of use. These are called "pre-cooled" Ice Bricks. During the biopsy procedure, always keep the pre-cooled Ice Bricks in the Cooler Shipping Kit to maintain their cold temperature.

Directions for Skin Biopsy Procedure

IMPORTANT: To meet the needs of StemCure Tissue Banking Program we need to obtain one pieces of 5 mm skin biopsy from the upper armpit area.

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.

Note:

It will be easier if the doctor performs the biopsy procedure with an assistant. A piece of skin extracted from the body is sticky. In order to transfer it from the tweezers to the vial, you should do so with the help of a scalpel or scissors. In this case, the assistant will help the doctor open the lid of the vial.

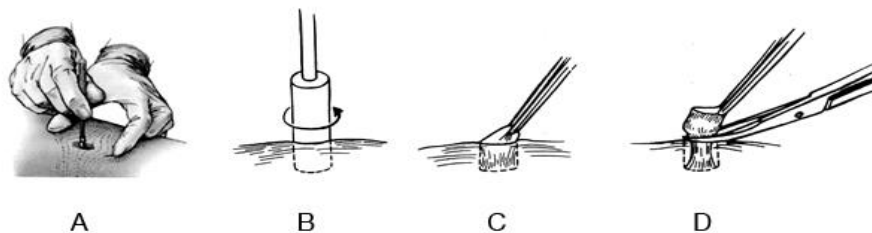
IMPORTANT: Carefully read the instructions before you begin the biopsy procedure.

During the Biopsy:

1. Material for biopsy should be collected using the sterile instruments we provide. The procedure should be performed under aseptic conditions. To reduce the risk of contamination of extract tissue, try to avoid any air flow in the room during biopsy procedure.
2. The upper armpit area, from where the sample will be taken, must first be washed with water, shaved, and then cleaned with Alcohol Prep Pad. A 1% or 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. But the anesthetic should be injected adjacent to the biopsy site rather than directly into it.
3. Before the start of the biopsy procedure, site must be cleaned with Povidon-Iodine swabsticks and swabbed with Alcohol Prep Pad. Alcohol should be allowed to completely air-dry before the biopsy is taken.

Note: If the doctor performs a biopsy procedure without an assistant, the vial cover should be loosened before procedure begins.

While stretching the skin tautly, rotate the punch in a single direction through the skin to the subcutaneous tissue. Stabilize the skin with the thumb and forefinger, stretching it slightly perpendicular to the normal skin tension lines. Place the punch instrument perpendicular to the skin and apply firm and constant downward pressure with a circular motion, avoiding back-and-forth twisting motions (figs. A-B). A slight decrease in resistance will be appreciated; when you have passed the dermis into the fat (subcutis) layer. Repeat this step for the next piece of the biopsy. Lift the skin with forceps or a skin hook and remove it by cutting the subcutaneous base with a sharp tissue scissors. Remove the punch instrument and apply downward pressure at the sides of the wound. Gently elevate the core, using aseptic forceps, and excise it at its base using small scissors or scalpel (figs. C-D). The collected skin biopsy should be immediately transferred to the provided sterile vial containing the shipping medium.



4. Apply pressure for hemostasis. 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. But under the doctor's discretion, a single suture or more will be used for closure. After you tighten the wound, overlay the top with a bandage. This will help avoid blood stained clothes if the wound will bleed. Wound management is similar to that of any other suture lacerations.
5. Once you put the skin tissues in the vial, be sure to twist the lid properly without tilting it. Once you have sealed the lid, turn it upside down and make sure that the medium does not come out. However, should a vial become damaged, the reserve vial should be used. The physician should seal the vial and pack it in the Cooler Shipping Kit with the Ice Bricks.

IMPORTANT: After the skin sample biopsy: 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 bandage until 24 hours after surgery.
- After 24 hours, remove the bandage 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 or Triple Antibiotic Ointment)
 - c. You can shower regularly.
- If you're prone to excessive bleeding or experiencing signs of pain, contact an emergency room.
- 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.