

Clinical Process Instruction Manual

Skin Recovery Process Instruction

Policy:

Multi Tissue Recovery Coordinators (MTRC) are responsible for carrying out procedures for the recovery, packaging, labeling, and shipping of donated skin and all related documentation. Recovered tissue is transported to, and all pertinent documentation is shared with, the accepting tissue bank for processing and determination of final tissue disposition.

Skin grafts may be recovered from the anterior and/or posterior surfaces of the donor. These areas include the abdomen, back and both legs. A sterile amalgatome is used to recover split-thickness skin that should range between 0.012" – 0.018" in thickness. Immediately following the skin recovery, the skin and donor blood samples must be packaged in a transport container that has been validated to maintain the temperature from > 0°C – 10°C during transport. This ensures that, following recovery and during transport, the skin is maintained in the required environmental conditions. The posterior trunk and posterior leg skin and the anterior skin shall all be kept in separate, sterile containers.

Process:

General

1. Compliance with the following principals shall apply to skin tissue recovery:
 - 1.1. Recovery of tissue shall be performed in an operating room, or pre-approved designated site such as the coroner's recovery suite.
 - 1.2. All tissue shall be recovered under sterile conditions, employing aseptic surgical techniques.
 - 1.3. Access to, and movement in and out of, the recovery suite will be limited during skin recovery.
 - 1.4. Tissue recovery procedures shall not occur after autopsy or embalming procedures have begun.
 - 1.5. Tissue shall be recovered from only one donor at a time within the same recovery suite.
 - 1.6. All recovery staff shall follow routine practices and shall wear Personal Protective Equipment (PPE) in addition to surgical attire when in contact with the donor. See *Routine Practices and Personal Protective Equipment Process Instruction, CPI-9-1504*.
 - 1.7. To enable funeral homes to provide cosmetically acceptable results, no skin should be removed from the donor's arms, neck, face or upper chest.
 - 1.8. Skin prep shall commence within 24 hours of asystole, provided the body was refrigerated within 12 hours of asystole. Skin prep shall commence within 15 hours of asystole if the donor has not been refrigerated. See *On-Site Medical Records Review for Multi-tissue Recovery Process Instruction, CPI-9-263*.

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- 1.9. There shall be at least two sterile MTRCs scrubbed in for the skin recovery procedure. One scrubbed MTRC is responsible for operating the amalgatome and performing the surgical recovery of skin, while a second scrubbed MTRC assists. The circulator is responsible for set up and documentation of the procedure as assigned by the Team Lead.
- 1.10. Skin with tattoos, incisions, abrasions, or other types of trauma that has caused the skin to tear should not be recovered.
- 1.11. Skin may not be recovered from areas with open fractures, deep lacerations, avulsions, abrasions, recent operative sites, or any open skin wound contaminated with dirt or debris. Such areas require special consideration and must be isolated prior to skin preparation and recovery.

Supplies and Instruments

2. The recovery of skin tissue includes the following materials:
 - custom skin recovery pack
 - pre-packaged bag of extra supplies if anterior skin is to be recovered
 - amalgatome power pack
 - power cord
 - sterile amalgatome
 - sterile screw driver from amalgatome case
 - 1 sterile amalgatome blade; 1 extra amalgatome blade if anterior skin is to be recovered
 - 1 bottle of chlorhexidine soap or Scrub Stat-41, sterile Tis-U-Sol[®] solution, 1000 mL (double if both anterior and posterior skin are to be recovered)
 - BBL Culture Swabs (Regenmed)
 - RMAC Skin labels or equivalent
 - validated transport cooler
 - 4 sterile Ziploc bags (double if both anterior and posterior skin are to be recovered)
 - Clean yellow biohazard bags or equivalent
 - 11.5 lbs of wet ice (double if both anterior and posterior skin are to be recovered)
 - 2 security seal zip ties

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Amalgatome Preparation

3. An MTRC opens the case, removes the amalgatome, and places it on the sterile instrument table.
4. The blade should be handled with extreme caution and kept at one corner of the instrument table until needed.
5. The amalgatome electrical cord shall be held within the sterile field, and extended the minimum length of cord required to reach the power pack and clamp the cord to the amalgatome container using a dull towel clip provided in the custom skin recovery pack.
6. Only the end of the cord shall be handled to plug the cord into the power pack and turn it on.
7. A scrubbed MTRC depresses the on/off lever to ensure that power is reaching the hand piece.
8. The electrical cord that extends from the amalgatome to the edge of the operating room (OR) table is sterile. Any portion that has moved below the edge of the table is no longer sterile and if it comes into contact with the table the sterile field is breached. To prevent the cord from moving during the retrieval secure the sterile portion of the cord to the drapes above the table edge using a dull towel clip. Keep as much cord in the sterile field as possible to allow for adequate movement of the amalgatome. Take care not to perforate the drape, as this will also breach the sterile field. If the sterile field is breached, the recovery cannot proceed unless a complete new set up can be redone in an aseptic fashion.

Amalgatome Skin Recovery

9. As per the manufacturer's instructions, a single amalgatome blade is utilized for each skin recovery— changing blades during the recovery is not required. A new amalgatome blade may be used if anterior skin will be recovered.
10. The skin site about to be recovered should be pulled taut as the amalgatome is applied or by applying hand pressure at the end of the strip using a sterile laparotomy sponge to keep the skin taut. For Regenmed skin recoveries, recovery site can be extended to the axilla, buttocks etc.
11. Strips should be cut as long and as wide as possible. Preferred dimensions are 8cm wide by 30cm long. Regenmed is able to accept any dimensions of strips for evaluation by tissue bank.
12. The circulator opens 5 – 6 bottles of chlorhexidine soap, mixed 1:1 with sterile normal saline, and aseptically pours them into a sterile basin. The remaining bottles are opened as necessary during the procedure.

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13. The circulator aseptically pours sterile Tis-u-Sol[®] solution into the two sterile jars.
14. The scrub MTRC shall use sterile gauze to apply chlorhexidine soap mixed 1:1 with sterile normal saline to all retrieval sites on the body.
15. The chlorhexidine soap mixed 1:1 with sterile normal saline is carefully applied to the amalgatome blade by dabbing it on with sterile gauze.
16. Using a sterile towel, stretch the skin at the superior aspect of the intended skin strip and two at the inferior aspect of the strip.
17. Using a sterile towel, stretch the skin at the inferior aspect and pull on them to keep the skin as taut as possible.
18. The amalgatome shall be held at roughly a five (5) degree angle to the skin and depress the on/off lever to start the cut. Guide the unit forward using a slight downward pressure to ensure contact with the recovery site.
19. When the amalgatome is at the midpoint of the strip, let go of the inferior edge clips/towel and pull on the superior edge clips/towel in order to keep the skin as taut as possible.
20. The amalgatome shall be lifted away from the recovery site to end the graft. If the skin remains attached cut it using sterile scissors.
21. The first piece of skin shall be assessed for quality and thickness and adjust the amalgatome setting up or down. The skin should be about the same thickness as wax paper. If it is too thick, it will readily curl at the edges. If it is too thin, it will tear easily and appear translucent.
22. If the quality of the skin remains poor (i.e., fat still visible) after making the appropriate setting adjustments, the Team Lead will decide if the skin recovery will continue.
23. If the quality of the skin is adequate, continue with the recovery following steps 16 to 28 above for each skin graft.
24. Each graft shall be placed in one of the sterile jars as it is collected. When the jar is full secure it with the lid. For RegenMed skin recoveries, each recovered skin graft should be swabbed on both sides prior to being placed into the sterile skin containers.

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25. The skin container labels shall be completed with Trillium Gift of Life Network (TGLN) number, date and time recovered, name of the skin recovery site (posterior legs, posterior trunk or anterior skin) and name of the MTRC and then attach the label to the side of the jar.
26. The second jar shall be used for the remaining grafts. Repeat steps 24 to 33.
27. When the sterile jars containing allograft skin have been properly labelled, place them in a zip-lock bag and seal the bag securely. Place each jar in a second zip-lock bag and seal securely.
28. After recovery of the posterior skin is completed, ensure the amalgatome and the sterile portion of the power cord remain sterile by placing them on one of the sterile OR tables and by securing the cord so that it does not fall below the level of the table.
29. If anterior skin is also being recovered, repeat steps 3 through 36 of this procedure once the anterior surface donor preparation has been completed.
30. There is no donor reconstruction for skin donors once recovery is complete. Thus, the recovery team may move on to the recovery of other tissues after the recovery of skin.
31. At the completion of all recovery procedures, the donor will be cleaned of all prep-solution, blood and debris that may be remaining from the skin recovery procedure. See *Multi-Tissue Post-Recovery Procedures Process Instruction, CPI-9-532*.

Packaging for Storage and Transport

32. A new yellow biohazard bag or equivalent shall be opened and placed inside the designated transport cooler. Place a layer of wet ice in the bottom of the bag.
33. The jars shall be stacked on top of the wet ice in the cooler. Fill the cooler to the top with the remaining wet ice, ensuring that the jars are covered (approximately 11.5 lbs). Tie a knot in the yellow biohazard bag or equivalent and place the Styrofoam lid securely on the cooler.
34. The donor blood samples shall be placed between the Styrofoam container and the external cooler cover to prevent damage or loss during transport. Close the external cooler cover and seal with a plastic zip-tie.
35. The cooler shall be labelled with the transport box label. Ensure that the address is visible.
36. A copy of the *Multi-Tissue Recovery Note* shall be placed in the donor's hospital medical chart or the coroner's chart. A copy shall be uploaded to the donor's iTransplant chart.

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37. Recovery documentation shall be completed, including any problems or incidents that occurred during the procedure in iTransplant or on the Tissue Recovery Form (CSF-9-146).
38. A completed and signed Recovered Skin Tissue Package Insert (CSF-9-156 Recovered Skin Tissue Package Insert - Sunnybrook or CSF-9-161 Recovered Skin Tissue Package Insert - Regenmed) and either a Recovered Skin Tissue Transplant Label–Sunnybrook (CSF-9-154) or a Recovered Skin Tissue Transplant Label – RegenMed (CSF-9-228) must accompany the tissue during transport. A copy shall be uploaded on iTransplant.

Records:

| Record Name | Form No. (if applicable) | Record Holder | Record Location | Record Retention Time (as a minimum) |
|-------------|-----------------------------|---------------|-----------------|--|
|-------------|-----------------------------|---------------|-----------------|--|

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|-------------|------|-----|-----|----------|
| Donor Chart | ---- | PRC | PRC | 16 Years |
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References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D5.300, D5.400, D5.500, D5.520, D5.530, D5.600, D5.700
- *Universal Precautions and Personal Protective Equipment Process Instruction, CPI-9-1504*
- *Multi-Tissue Post-Recovery Procedures Process Instruction, CPI-9-532*