

Clinical Process Instruction Manual

Cardiovascular Tissue Recovery Process Instruction

Policy:

Multi Tissue Recovery Coordinators (MTRC) are responsible for carrying out procedures for the recovery, packaging, labeling, and shipping of donated heart for valves, pericardium and descending aorta and for completion of all related documentation. Recovered tissue and all pertinent documentation are transported to the accepting tissue bank for processing and determination of final tissue disposition.

Process:

General

1. Compliance with the following principles shall apply to cardiovascular (CV) tissue recovery.
 - 1.1. Recovery of tissue shall be performed in an operating room (OR) or pre-approved designated site, such as the coroner's tissue recovery suite.
 - 1.2. All tissue shall be recovered under sterile conditions, employing aseptic surgical techniques.
 - 1.3. Tissue shall only be recovered from one donor at a time at a recovery site.
 - 1.4. Recovery activities shall be conducted in compliance with Health Canada's *Safety of Human Cells, Tissues, and Organs for Transplantation (CTO) Regulations* and according to current *Canadian Standards Association (CSA)* and *American Association of Tissue Banks (AATB) Current Standards for Tissue Banking*.
 - 1.5. For refrigerated donors the warm ischemic time shall not exceed 24 hours, where the warm ischemic time is defined as time of death to placement of cardiac tissue into cold transport solution at the time of recovery. For donors not refrigerated within 12 hours of death, the warm ischemic time shall not exceed 15 hours. See On-Site Medical Records Review for Multi-tissue Recovery Process Instruction, CPI-9-263.
 - 1.6. Tissue recovery procedures shall not occur after autopsy or embalming procedures have begun.
 - 1.7. All recovery staff shall follow routine practices and shall wear personal protective equipment (PPE) when in contact with the donor. See *Routine Practices and Personal Protective Equipment Process Instruction, CPI-9-1504*.

Clinical Process Instruction Manual

Cardiovascular Tissue Recovery Process Instruction

- 1.8. There shall be a minimum of one sterile recovery technician scrubbed in for each heart valve recovery procedure.

Equipment and Supplies

2. The recovery of CV tissue includes the following materials:
 - *Multi-Tissue Recovery Form* or electronic equivalent
 - heart valve recovery instrument tray
 - heart recovery pack
 - zip-lock bag containing: three syringes, five 18G needles, four alcohol swabs, four 10 cc Vacutainer® tubes (two EDTA tube and two red top tube)
 - one screw-top sterile plastic container
 - 0.9% Normal Saline
 - Steri-Drape isolation bag
 - large non-sterile plastic bag with twist ties
 - one validated Styrofoam shipping container for recovered cardiac tissue and blood samples

Cardiectomy and Pericardium Recovery

3. Cardiectomy includes recovery of the whole heart with an intact aortic arch, including the first three aortic branches (brachiocephalic, left common carotid, and left subclavian arteries), and an intact pulmonary trunk with the right and left pulmonary arteries.
4. Once the donor is prepped and draped the recovery may begin. See *Multi-Tissue Donor Prepping and Draping Process Instruction, CPI-9-550*.
 - 4.1. Avoid skin abrasions and puncture wounds while making incisions for retrieval.
5. Either a V-incision or a U-incision shall be used to open the chest cavity for adult and pediatric donors.

Clinical Process Instruction Manual

Cardiovascular Tissue Recovery Process Instruction

6. For V-incision/U-incision:
 - 6.1. A scalpel shall be used to make a skin incision from the outer edge of both clavicles to the xiphoid process. **Discard the skin scalpel blade.** Use a new scalpel blade for muscle incisions. The skin and some of the pectoralis major muscle and breast tissue are then reflected back to expose the breastplate. The tissue should be reflected using a scalpel and tissue forceps. Use caution to avoid puncturing the skin, as this will make reconstruction difficult.
 - 6.2. Once the overlying skin and tissue has been reflected, use a scalpel or rib cutter or a pair of heavy-duty scissors to cut the costal cartilage at the costochondral junction from the first rib to the costal margin. The first rib is located behind the clavicle and can be difficult to access. Cutting through the cartilage of the sternoclavicular joint with a scalpel and reflecting the clavicle upwards can facilitate exposure of the first rib.
 - 6.3. After the cartilage is cut, remove the breastplate to expose the pericardium. The breast plate will be placed back during the body reconstruction.
7. The pericardial sac, the lining of the chest cavities, and the cavities themselves shall be observed for blood, other fluid, trauma, or tumors. The presence of tumor will probably necessitate discontinuation of the tissue recovery, however the tissue management team should be consulted prior to making this decision. This may require consultation with the Medical Director.
8. Using a pair of tissue forceps and scissors, a slightly off midline vertical incision is placed on the pericardium down to the diaphragm and up to the jugular notch. This will allow for the larger side of the pericardium to be recovered later. This is followed by a superior and inferior transverse pericardial incision. Pin the pericardium up on both sides with a pair of clamps to expose the heart. Do not to nick or cut the heart or the diaphragm.

At completion of heart recovery (and descending thoracic aorta if recovered), the pericardium shall be excised as a square sheet along the right and left borders of the pericardial sac down to the diaphragm and up to the jugular notch.

The external condition of the heart shall be observed and any unusual anatomy, positioning, or trauma, together with the presence of any fluid or fibrous adhesions in the pericardial sac itself shall be documented.

9. Avoid entering or exposing the lungs or pleural space. Isolate the lungs with a sterile towel arrangement or tack the pericardium to the skin.

Clinical Process Instruction Manual

Cardiovascular Tissue Recovery Process Instruction

10. The cardiectomy shall be continued by lifting the heart up to expose the inferior vena cava. Bluntly isolate the inferior vena cava and clamp it with two pairs of hemostats or sterile umbilical tape spaced approximately 1 cm apart. Transect the vessel between the two hemostats or umbilical ties. Clamping the vessel or ligating with sterile string before transection prevents blood from pooling in the pericardial sac and allows for better exposure during further vascular dissection. This is especially helpful for cases performed where suction is not used. This clamping and transection procedure should be used for all other vessels referred to below.
11. Blunt dissection shall be used to isolate the right and left pulmonary veins (two on each side) and then transect them as close to the lungs as possible. Take care not to cut the pulmonary arteries, as they are located in close proximity to the veins.
12. Blunt dissection shall be used to expose the right and left pulmonary arteries, beyond their bifurcations if possible, and transect them as close to the lungs as possible. Take care not to cut into or include any nearby bronchial structures in order to avoid contamination from the respiratory tract.
13. The superior vena cava shall be isolated and exposed up to the level of the innominate artery and then transect the superior vena cava.
14. Blunt dissection of the aortic arch shall continue to isolate the brachiocephalic, left common carotid and left subclavian arteries. Transect the aorta a minimum of two centimeters distal to the origin of the left subclavian artery.
15. A blood sample shall be collected from the pericardial sac, if required for transmissible disease testing.
16. Suction or laparotomy sponges, shall be used as needed to clear the pericardial sac of blood and create a clear field of vision for further dissection.
17. The heart shall be dissected free from any surrounding connective tissue. Remove the heart from the pericardial sac, proceed to rinse.
 - 17.1. The vessel clamps in the heart instrument tray are useful - take advantage of them. Try to transect each vessel completely as failure to do so will mean you have to come back to cut

Clinical Process Instruction Manual

Cardiovascular Tissue Recovery Process Instruction

them again when removing the heart, which increases the chances of accidentally cutting the vessel too short or damaging it.

Recovery of Descending Thoracic Aorta

18. The descending thoracic aorta shall be recovered only if requested by the tissue bank. The clamp shall be left on the aorta distal to the left subclavian artery from the cardiectomy. After removal of the heart, continue to dissect the descending thoracic aorta down to the level of the diaphragm.
19. The descending thoracic aorta runs behind the left main bronchus and close to the level of the diaphragm it is located behind the esophagus. Use caution to avoid damaging the bronchus and the esophagus during the dissection.
20. The descending thoracic aorta has many small branches along its whole length (i.e., the intercostal arteries). Make every effort to cut these branches, and the surrounding tissues, at least 0.5 – 1 cm away from the aorta during dissection in order to facilitate future tying off of these vessels during processing.
21. The descending thoracic aorta shall be transected as close to the diaphragm as possible and place it into the rinse basin.
 - 21.1. The left lung is usually exposed after heart removal. You may pull and reflect the left lung out of the left chest cavity to facilitate exposure and dissection of the descending thoracic aorta, but take care to avoid damaging the lung and thereby compromise sterility.

Rinsing and Packaging for Transportation

22. The recovered heart, pericardium, and descending aorta shall be rinsed in cold sterile isotonic solution (i.e., isotonic sterile saline).
 - 22.1. Upon arrival at the recovery site, the sterile isotonic solution shall be refrigerated or put on ice.
 - 22.2. All cardiac tissue shall be rinsed a minimum of five (5) times. If the rinsing solution is not clear after the five rinses, proceed with additional rinses until the rinsing solution remains clear.

Clinical Process Instruction Manual

Cardiovascular Tissue Recovery Process Instruction

23. Rinse the heart using either method:
- 23.1. Incise the apex of the heart with a “x” or “t” incision to facilitate the flushing of the chambers of the heart. The incision should start midway between the apex and the aortic root and extend deep into the tissue to provide opening of the ventricles for an adequate rinse. Using a basin or sterile plastic bag, pour the sterile isotonic solution over the heart to flush the chambers until the solution runs clear.
 - 23.2. An alternative method to rinse the heart, place the heart into the basin or bag containing sterile isotonic solution. Gently massage the heart rinsing the blood from the chambers. Gently massage the heart to introduce the liquid into the chambers of the heart and to flush as much blood out as possible. Using a towel clamp or similar instrument, remove the heart from the sterile basin or plastic bag and place in another basin/bag repeating the previous procedure. The heart shall be gently inverted to drain off the fluid and place the tissues in the 1 L screw-top sterile plastic container provided.
24. Do not place the heart back into the basin or bag after rinsing.
25. The container shall be filled with enough sterile isotonic solution to cover the entire tissue (minimum of 500 mL). Tighten the screw-top lid securely to prevent leakage and contamination.
- 25.1. The following tissue transport solution information must be recorded in the donor record:
- manufacturer,
 - lot number,
 - expiry date of the tissue transport solution, and
 - date and time the heart was placed in cold sterile isotonic solution.
26. The container shall be placed in the Steri-Drape isolation bag and close the bag by pulling the string. Wind the strings around the top of the bag and tie to prevent leakage and contamination and then hand off the bag to the circulator.
27. The sterile container must be labelled with the Trillium Gift of Life Network (TGLN) number and the type of tissue enclosed.
28. The tissue is placed in another non-sterile bag filled with ice. Tubes of labeled donor blood are also placed in the bag and tied securely.

Clinical Process Instruction Manual

Cardiovascular Tissue Recovery Process Instruction

29. The bag shall be placed in the styrofoam shipping container. Place any paper documentation, such as the consent and donor information form, in the plastic envelope; place the plastic envelope in the box; and then close the box.
30. The styrofoam shipping container is labelled with the TGLN number, the date and time of collection and the CV tissue type(s) identification.
31. Timely drop off of the recovered CV tissues is required as disinfection and processing must be completed within 24 hours after the time of placement into cold transport solution. Drop the tissue off at the Hospital for Sick Kids Blood Transfusion Laboratory immediately after the recovery.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Chart	----	PRC	PRC	16 Years

References:

- *Universal Precautions and Personal Protective Equipment Process Instruction, CPI-9-1504*
- *Multi-Tissue Donor Prepping and Draping Process Instruction, CPI-9-550*
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D5.300, D5.400, D5.500, D5.520, D5.700