Step C

PREPARING CARDIOVASCULAR TISSUE ALLOGRAFT FOR IMPLANTATION

RestoreFlow® Allografts

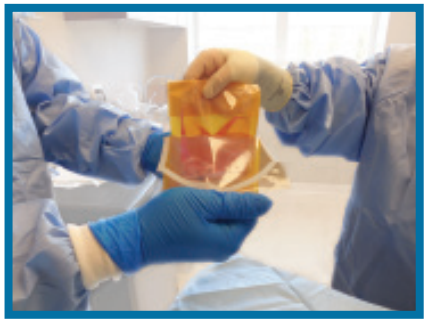
Supplies Required: **Vascular:**
1 liter sterile isotonic solution (i.e. heparinized saline or lactated ringers),
3 sterile basins, 2 luer-lock syringes and sterile scissors
Heart Valves / Patches / Aortolliac:
2 liter sterile isotonic solution (i.e. heparinized saline or lactated ringers),
3 sterile basins and sterile scissors

NON-STERILE FIELD

1). Tissue is packaged in a triple barrier system, with the outer pouch being non-sterile.

2). At the completion of STEP B, the packaging shall be wiped dry prior to opening.

3). Non-sterile Surgical Tech shall peel back outer pouch and present secondary pouch to sterile surgical tech.



STERILE FIELD

4). Surgical Tech shall then peel back secondary pouch and remove inner pouch.

5). The inner pouch is not a peel pouch and requires scissors to open. Cut at square end of inner pouch as shown.

6). Pour contents of inner pouch into a sterile basin.

7). Prepare two basins: approximately 500ml of isotonic solution for vascular allografts or approximately 1 liter of isotonic solution for cardiac allografts in each basin.

8). Remove tissue from cryopreservation solution and place into first basin containing isotonic solution.

9a). **Vascular**

- Attach luer-lock syringe to cannula on tissue and flush solution through tissue for a total of 120cc of flushing.
- Remove tissue and place into second basin containing isotonic solution and flush tissue again for another 120cc of flushing.

9b). **Heart Valves / Patches / Aortolliac**

- Allow heart valve to passively rinse for 5 minutes in basin.
- Remove tissue and place into second basin containing isotonic solution. Tissue should remain in solution until ready for use.

10). Tissue is ready for implant.

11). If tissue is delayed for implant for more than 30 minutes, tissue and basin shall be covered and placed on ice bath until ready for use.

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