

Heart Valve Cryopreserved Aortic

Blood Vessel - Product code T0122



Benefits/advantages

- Supplied by Tissue Services, a specialist function of NHS Blood and Transplant (NHSBT) undertaking all aspects of tissue donor evaluation, medical screening, consent, testing, storage, cleanroom processing, quality assurance and supply
- Uniform product with minimal variation.

Product description

An aortic heart valve from a deceased donor. Processed in cleanrooms to dissect away surplus tissue, decontaminated with antibiotics and measured/sized with sterile instruments. Packaged in sterile pouches and cryopreserved. Supplied as an individual unit of a specified size.

Clinical applications

For use in cardiovascular surgery, primarily aortic valve replacement.

Processing

This product is collected aseptically by highly trained Tissue Services staff stored below -135°C at the tissue bank until donor release. It is processed in pharmaceutical grade

cleanrooms to remove excess muscle, fat and connective tissue, leaving a cleaned aortic valve graft.

Storage requirements

This graft needs to be stored frozen at -80°C . The maximum shelf life is 6 months from the date of despatch or until the expiry date on the product label if this is earlier. The expiry date on the label will be corrected for your storage requirement before dispatch. It should not be returned to storage at -135°C . Freezers need to be designated for clinical use with 24/7 alarms and monitoring. Your blood bank may be able to store this tissue in these conditions. Once thawed, using the protocol in the user information, the graft must be stored at 4°C and used within 1 hour.

Product sheet

For further information or to place an order, please contact your nearest tissue bank via the national order line

Tel 0845 607 6820 Fax 0845 607 6819

Regulatory requirements

This product contains living cells and therefore requires a storage licence if stored for longer than 48 hours. Some stages of the quality system defined by law (EU Tissue and Cells Directive) relating to storage, tracking and adverse event or reaction reporting can be managed only by the hospital. Because of this a signed current service level agreement defining responsibilities must be in place prior to the supply of tissue. Tissue Services will send this agreement directly to the hospital, usually via the CEO for signature. Details can be supplied on request.

Delivery

This product is packaged in a sterile nylon pouch inside a sterile foil pouch and transported in a heatsealed plastic bag. Delivery is in a disposable transport box containing dry ice (solid carbon dioxide - see below) validated to keep the graft frozen until the date and time provided on the box. It is delivered by either NBS Transport or via a courier, usually direct to the point of use e.g. theatre. Next working day delivery is included in the product price. More urgent delivery e.g. same day or by a specified time can be arranged at additional cost.

CAUTION - dry ice can cause burns. The product must be unpacked by a person wearing safety gloves designed to protect from the cold (-80°C). In addition, high levels of carbon dioxide can asphyxiate, so care should be taken to open and store the package in a room with adequate ventilation. The remaining dry ice should be left to evaporate in a ventilated area before discard.