



PERFUSION TUBING SYSTEM INSTRUCTION FOR USE

DESCRIPTION

The Perfusion Tubing Pack is a customised pack built to user specifications. It may consist of one or all the following main components: oxygenators, craniotomy reservoirs, venous reservoirs, tubes, connectors, filters, pressure gauge protection chambers, drip chambers, clamps, stopcocks, heat exchangers, bubble traps, etc. according to requirements.

Contents of the pack is sterilized by ethylene oxide and the device is for **single-use only**. **Do not use if package is damaged.**

EXPLANATION OF THE SYMBOLS USED ON THE BOX & LABELS

For single use only
Lot number
Expiry
Sterile - Ethylene oxide sterilized
This way up
Keep in cool, dry place and away from sunlight
Fragile, handle with care

INTENDED USE

This set is intended for use in surgical procedures requiring extracorporeal support. It is not advisable to use the device for longer than 6 hours.

GENERAL SAFETY WARNINGS

- For single-use only, discard after use.
- Carefully examine the pack for leaks before and during use. Leakage may result in loss of sterility, blood loss and air embolism. If leakage is observed before and during use, replace the leaking component or re-tighten the leaking connection.
- Check all pumps and components to ensure that they are set up for proper flow direction prior to initiating bypass.
- Carefully read the instructions before using the product.
- The manufacturer is not responsible for problems arising from inexperience or improper use.
- The device is intended to be used by professionally trained personnel.
- The device is sterilized by ethylene oxide. Sterility is guaranteed only if the sterile packaging is not damaged.
- Do not re-sterilize or clean for re-use. It may cause cross-infections and alteration of the device performance.
- Do not use solvents, such as alcohol, ether, acetone, etc or halogenated liquids, as contact may cause damage to the pack.
- After use, dispose the device in accordance with the regulations in force in the country.
- Check the expiry date on the label attached and do not use the device after the date shown.
- The device must be used immediately after opening the sterile packaging.
- The device must be handled aseptically.
- Handle all the tubing carefully to prevent damage.
- Keep in a cool, dry place away from sunlight.

SET UP

When setting up the tubing system, do take care to avoid kinking, piercing the tubing and/or damage any of the component in the circuit.

CAUTION

If the set is used with a roller pump, observe the following.

- Check the tubings are not damaged before installing them in the pump. During use constantly check for any signs of wear, cracks, leaks, or air intake and take appropriate action.

- Adjust pump occlusion prior to each procedure, improper occlusion may cause deterioration of the tubing under the pump.
- Position the tubing in the peristaltic pump maintaining the natural curvature of the tubing and avoid twisting it.
- Use the right size tube clamp to prevent damage and to securely lock them.
- If the set contains a coil, do not use saline or alcohol solutions to prevent the temperature from going down to below 0°C, since this might harm the patient.
- Remove the set from the package using a sterile technique
- Connect the luer-locks without tightening them excessively but ensure that the connection is secure.
- Close the stopcocks.
- Connect the set to the oxygenator, heat exchangers, filters, and other components in accordance with the specific instructions for use.
- Secure the connections with clamps.
- Ensure that the one-way valves in the pack are in the correct position.
- Rinsing whole circuit system
- Before initiating priming procedure, the following rinsing process is high recommended.
 - Use 5% glucose solution as the pre-priming solution to wash the whole circuit system for 10 to 15min.
 - Run the solution at about 100% level of scheduled perfusion flow rate.
 - Check any leakage or damage of the whole circuit during rinsing well.
 - Then, drain out the solution completely.
 - If the pre-bypass filter is used, clamp it at this time
- Prime the circuit in accordance with the instructions for use of the circuit components.
- Ensure that there are no air bubbles in the circuit and the components.
- Ensure that there are no leaks.
- Initiate the bypass in accordance with the instructions for use of the oxygenator and following good perfusion practice.

DEVICE REPLACEMENT

A spare device must always be available during perfusion. After 6 hours of use, at the discretion of the team, the perfusionist may have to replace the device.

CAUTION

Use sterile methods during replacement of the tubings.