Sterilization Procedures

Sterilization:

Gas (Ethylene Oxide):  
- The lumen should be free of any visible droplets prior to wrapping, but need not be forcibly dried.
- Coils tubing in a large loop avoiding kinks and crossover of tubing on tubing. Wrap in clean muslin or linen and tape or tie the bundle loosely.
- Follow the specific directions of the sterilization equipment manufacturer as to gas type, concentration, times, and temperatures. Maintain humidity within the prescribed limits, generally between 30 to 65%.
- In cases where aeration equipment, such as vacuum drying, is prescribed, follow the recommended times for de-gassing to insure against gas retention and reduction of residue, according to limits known to be safe.
- In cases where aeration equipment is not available or is malfunctioning, sterilized package should be stored in a sanitary area and not used for 14 days to permit thorough gas and residue release.
- It is highly recommended that sterility testing be periodically conducted to insure that all procedures regarding any aspect of sterilization are fully operative.

Steam Sterilization:  
- Coils tubing in a large loop avoiding kinks and crossover of tubing on tubing. Wrap in clean muslin or linen, or other approved barrier pack and tape or tie the bundle loosely.
- Load the autoclave, avoiding stacking of heavy objects on the packed tubing.
- Sterilize at 250°F (15 pounds steam) for a minimum of 30 minutes. After autoclave cycle, reduce steam pressure gradually to normal atmospheric pressure and evacuate. Dry heat temperature of no more than 150°F for 2 to 2-1/2 hours will complete the cycle and dry the tubing.
- Upon removal from autoclave, allow the packs to return to normal temperatures in a sanitary area, avoiding stacking or heavy objects on the pack.

Radiation Sterilization:
- If possible, fabrication or kit assembly should be done in a clean-room area.
- Cap ends, if required.
- Packaging for sterilization depends on source, gamma or electron beam cycle, and required Mrad of exposure. U.S. sterility of product tests should be performed to determine radiation dose.
- Radiation should be specified for product and GMP.

Tubing Preparation:

1. Inspect tubing for cleanliness and evidence of any particles in the lumen. Check for evidence of damage in storage, packing or shipment.
2. Cut tubing with a clean, very sharp edge scalpel or knife by slightly stretching the tubing. Avoid a sawing motion because multiple strokes create undesirable micro fibers.
3. Rinse the tubing lumen with tap water, to be followed by distilled water, Water for Injection, or saline solution. Avoid detergents if possible.
3. This tubing is not intended for implantation.

4. This tubing is made of Thermoplastic Material, and as such, the performance is affected by temperature and pressure. The user must conduct tests to determine suitability for use in the user's process or application.

5. Tubing performance, including life in a specific application, is affected by the materials that come into contact with the tubing as well as the operating environment. It is the responsibility of the user to determine suitability of tubing formulation for each application.

6. Some drugs, medications, and other fluids can be absorbed by tubing material or can extract substances from tubing material. It is the responsibility of the end user and/or medical device manufacturer or assembly designer to specify and document tubing performance and safety requirements.

7. The Lot Number of this product should be recorded and retained, as it provides manufacturing and raw material traceability as required by regulatory directives.

Cutting, piercing or other damage to lengths of tubing actually used in any medical packs, kits or other assemblies

• Tubings are not intended to be used as injection ports. Punctures with hypodermic needles will not reseal and air bubbles can be drawn into the fluid stream.

2. No tubing will last forever. This is especially true in peristaltic pumping applications where, upon extended use or improper installation, the tubing will rupture. The following factors have been found to influence tubing life in peristaltic pumps:

• Fluid being pumped or transported
• % occlusion of tubing walls
• Pump speed (i.e. roller impacts/minute) and total number of impacts
• Amount of system back pressure
• Temperature of fluid being transported as well as temperature of the operating environment
• Frictional drag due to improper maintenance or wearing of rollers and guides
• Twisting, kinking, or excess lengths of tubing installed in pump raceway
• Wall thickness and thickness variation

WARNING: This tubing is intended to be used only in applications in which limited peristaltic action is involved. DO NOT USE this tubing as a component in an ECMO (extra-corporeal membrane oxygenation) pump head or in any other application in which extended peristaltic action is involved. Improper use of this tubing in an ECMO pump head, or as a component in any other application in which extended peristaltic action is involved may lead to premature tube failure or rupture which could cause serious bodily injury or death. To avoid tubing failure and possible injury resulting therefrom, each of the foregoing variables should be carefully set up and monitored during use of the tubing in peristaltic pumps. When using tubings in peristaltic pumps involved in medical procedures ALWAYS:

• Read and heed the instruction of the manufacturer or supplier of the pump apparatus in use, regarding tubing installation, pump roller, guide rollers and raceway maintenance and calibration.
• Inspect tubing for any damage prior to installation.
• Check that proper tubing length is contained in the raceway portion of the pump and that the tubing is not twisted or kinked.
• Always select occlusion and RPM settings that achieve the desired flow rate with minimum stress to the tubing.
• Always carefully re-set occlusion whenever the tubing is either moved or changed in the pump’s raceway.
• Always constantly monitor the tubing circuit during actual procedures, and immediately after actual use, the tubing beginning to crack, leaks, or air infusion and take appropriate action when observed.

To avoid possible life threatening leaks, catastrophic disconnection, air bubbles or flow disruption during medical use:

• The expert professional end user must provide system back up and adequate procedures in case of tubing rupture.
• Always use retaining clamps or adhesive when affixing tubing to fittings and/or connectors.
• Always carefully inspect finished assembly for tubing damage prior to shipment and again prior to actual use.
• Always carefully read and follow the instructions of the manufacturer of the equipment in use, regarding tubing specifications and installation.
• When installing tubing and setting up the equipment or pump for actual use, the responsible perfusionist and/or technician must always take great care to avoid nicking,