



INSTRUCTIONS FOR USE PEMCO INC. PERFUSION CANNULA

Pemco Inc.

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Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Important

Pemco Products are to be used according to the instructions for use. All personnel who handle Pemco products must read these instructions prior to use of the instrument.

DEVICE DESCRIPTION

Pemco Perfusion Cannulas are designed to be used for perfusion of fluids to the heart. Various means of perfusion are available for use with the Pemco Cannulas.

INTENDED USE

Pemco Perfusion Cannulas are a manual, hand held surgical instrument intended for use in cardiac surgery when attached to perfusion device providing perfusion to the heart.

CONTRAINDICATIONS

There are no known contraindications to Pemco Products.

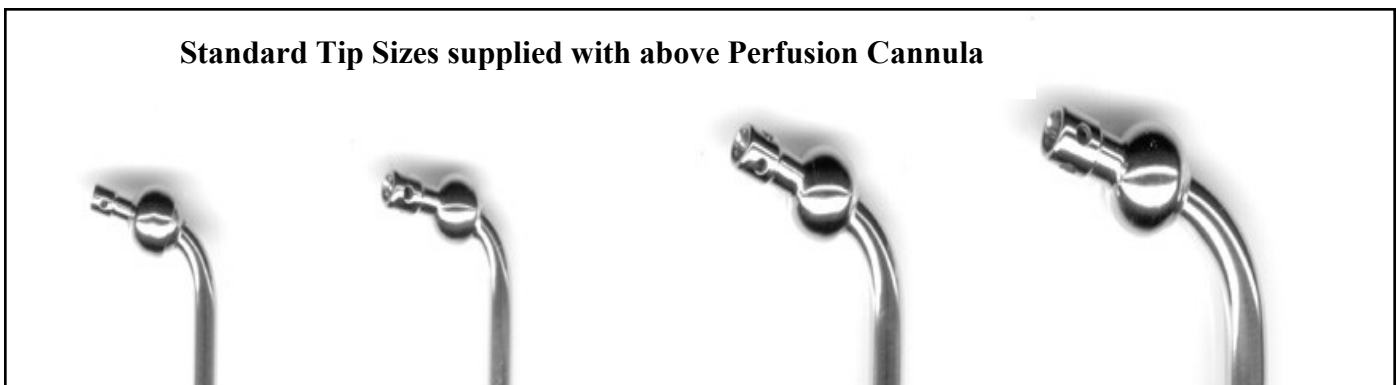
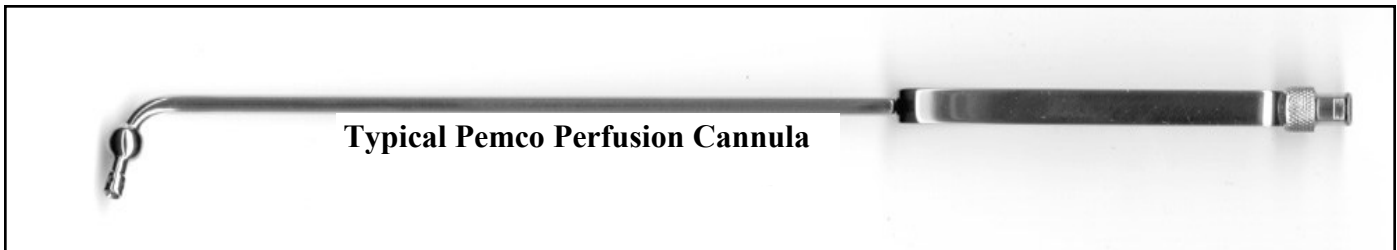
INSTRUCTIONS FOR USE

The Pemco Perfusion Cannula is a reusable hand held instrument. They are supplied non-sterile and must be cleaned and sterilized prior to initial use and all subsequent uses.

Perfusion Cannula are supplied with a female Quick-Turn Luer Lock. When ordering a 5/16" (7.9mm) barbed end may be substituted, (use 1/4" (6.3mm) inside diameter tubing). The tip is attached to the other end of the Perfusion Cannula and is not removable. The tip of the Perfusion Cannula is either attached in a fixed position on the stem or the swivel type to a ball. Tips are available in standard styles and sizes. The style and size required is determined by the user for the intended application.

After Perfusion Cannulas have been sterilized, securely attach perfusion line by luer adaptor or tubing to barbed end of perfusion cannula handle.

The Perfusion Cannulas are a hand held instrument and must be held in location during use at the desired site.



WARNING:

Do not attempt to repair, alter or modify a Pemco Inc. Cannula devices in any way. Repairs, alterations or modifications may have unintended consequences. Pemco Inc. is not responsible for any device that is repaired, altered or modified in any way by the user. Any unauthorized modification will void all warranties and release Pemco Inc. from any liability. If your Pemco device is damaged, return it to Pemco Inc at the address given or an authorized distributor.

CARE AND MAINTENANCE

Repeated processing has minimal effect on this instrument. End of life is normally determined by wear and damage due to use.

Cleaning

1. Remove excess soil on instrument as soon as is reasonably practical following use.
2. It is expected that commercially available products for the use of cleaning are used.
3. If using an automated cleaning system (such as a sonicator) use a commercially available detergent approved for automatic use that is ph-neutral or alkaline. Set appropriate wash and rinse cycles according to the manufacturer of the automatic cleaning system's instructions.
4. If cleaning manually, thoroughly clean surface contamination, clean lumen with cannula brush, pipe cleaner, or wire. Soak in a neutral or alkaline pH disinfecting solution or enzymatic cleaner. Do not soak for longer than what is recommended by solution manufacturer.
5. Instrument should be thoroughly rinsed with distilled water after cleaning to remove any residual debris or cleaning agent.
6. Dry immediately after cleaning.
7. Visually inspect for any physical damage prior to use.

STERILIZATION

The following are GUIDELINES for product sterilization.

Guidelines for Sterilization :

- * Pre-Vacuum Autoclave: Sterilize with 1-cycle at a minimum of 132°C (270°F) for 4 minutes. (Pemco has validated this sterilization method). Drying time 30 minutes.
- * Steam Gravity Autoclave: Sterilize with 1-cycle at a minimum of 132°C (270°F) for 10 minutes. (Pemco has validated this sterilization method). Drying time 30 minutes.

Perfusion Cannulas are reusable instruments. They are supplied non-sterile and must be cleaned and sterilized prior to initial use and all subsequent use.

Time, temperature and other conditions required for sterilization may vary according to type of sterilizer, cycle design, wrapping material, and/or other hospital practices.

Sterilization containers: must be validated by their manufacturer for use in sterilization process. Validated cycles should be indicated in the containers Instructions for Use.

You must validate your own sterilization practice when they differ from the Instructions for Use provided by container or sterilizer manufacturer.

Recommendations for sterilization may be obtained from, AAMI (Association for Advancement of Medical Instrumentation) at <http://www.aami.org/>

PRECAUTIONS

CAUTION: Clean and sterilize the Perfusion Cannulas according to the instructions provided. Failure to do so could result in cross-contamination to the patient or health care professional.

CAUTION: Pemco Perfusion Cannulas are one piece assemblies. This includes Perfusion Cannulas with swivel tips. Do not attempt to remove swivel tips for cleaning or any other purpose. Attempting repair, alterations or modifications may have unintended consequences.

CAUTION: Always keep the Perfusion Cannula in sterile field during use.

CAUTION: Pemco Perfusion Cannulas are one piece assemblies. Do not attempt to disassemble.

CAUTION: Maximum recommended line pressure should not exceed 250 mm Hg. (Exceeding this pressure can harm the patient)

CAUTION: Use the depth marks to position the cannula in the desired location within the aorta. Placement of the cannula too distally in the central aorta can lead to cerebral hypoperfusion, severe ischemic injury, and/or death.

SERVICING & REPLACEMENT

Pemco recommends Perfusion Cannulas be refurbished every two years. A six month limited warranty on workmanship is placed on all refurbished instruments. All instruments must be decontaminated before being returned for service. Repair charges will apply to instruments repaired outside the guarantee.

Pemco recommends Perfusion Cannulas be replaced after six years when properly maintained, depending on usage.

Pemco Perfusion Cannulas are made of stainless steel and are recyclable, but must be properly cleaned prior to disposal.

GUARANTEE

When used as directed, all Pemco instruments are guaranteed to be free of defects in material and workmanship. Any product that proves to be defective in material or workmanship will be repaired or replaced at our discretion. Parts covered by this guarantee will be replaced without charge. This guarantee specifically does not cover damage to the instrument by overstress, chemicals (including those used for cleaning and sterilization), mechanical shock or improper use.

Repair, alteration or modification of any product by persons other than Pemco or products subjected to misuse or abuse, will result in immediate loss of guarantee. A repair charge will apply when Pemco instruments are damaged by accident. This guarantee will be void if Pemco instruments are used for a purpose other than originally intended.