

INSTRUCTIONS FOR USE PEMCO INC. INTRACARDIAC SUCKERS

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 Intracardiac Suckers are designed to be used for suction of fluids from an incision sight. Various means of suction are available for use with the Pemco Intracardiac Suckers.

INTENDED USE

Pemco Intracardiac Suckers are a manual, hand held surgical instrument intended for use in cardiac surgery when attached to a suction device provides suction to the chest cavity. Pemco Intracardiac Suckers may also be used for other surgical procedures where suction is required.

CONTRAINDICATIONS

There are no known contraindications to Pemco Products.



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INSTRUCTIONS FOR USE

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

One end of the sucker handle is barbed for suction line and the other end is threaded either for interchangeable tips or as supplied with a non-removable tip.

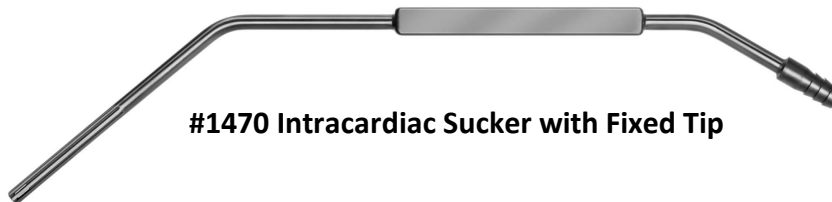
The Intracardiac Suckers are a hand held instrument. The handle is bent in such a way that they can lie across the chest cavity. When the instrument is in this position a means of attaching to the O.R. table drape must be used.

The tips of the Intracardiac Suckers, either fixed or removable, have equally divided slots at the tip end to prevent clogging and improve suction.

After probes have been sterilized, securely attach desired tip to handle if applicable. Attach tubing to barbed end of sucker handle.

Barb Sizes:

- * 1450-01 and 1450-01-90 have a barb with both 3/8" (9.5mm) and 1/2" (12.7mm) diameters (use 5/16" (7.9mm) and 7/16" (11.1mm) Inside Diameter tubing (I.D.) respectively)
- * 1460, 1470, 1470JR-01, and 1480 have a 5/16" (7.9mm) diameter barb (use 1/4" (6.3mm) I.D. tubing)
- * 1450JR-01 and 1450JR-01-90 have a 3/8" (9.5mm) diameter barb (use 5/16" (7.9mm) I.D. tubing)



WARNING:

Do not attempt to repair, alter or modify a Pemco Inc. Intracardiac Suckers 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. For Intracardiac Suckers with removable tips, the tip and handle should be separate for cleaning.
2. Remove excess soil on instrument as soon as is reasonably practical following use.
3. It is expected that commercially available products for the use of cleaning are used.
4. 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.
5. 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.
6. Instrument should be thoroughly rinsed with distilled water after cleaning to remove any residual debris or cleaning agent.
7. Dry immediately after cleaning.
8. 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.
- * Steam Gravity Autoclave: Sterilize with 1-cycle at a minimum of 132°C (270°F) for 10 minutes. Pemco has validated this sterilization method.

Pemco Intracardiac Suckers 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 Intracardiac Suckers according to the instructions provided. Failure to do so could result in cross-contamination to the patient or health care professional.

CAUTION: When Intracardiac Suckers are placed in the surgical site they should be attached to the surgical drape via the handle or attached tubing.

CAUTION: Always keep the Intracardiac Sucker in sterile field during use.

CAUTION: Disassemble Intracardiac Suckers with removable tips only prior to cleaning. Intracardiac Suckers with non-removable tips require no disassembly.

CAUTION: It is recommended to avoid excessive negative pressure (suction) or high RMPs when using this suction device when in contact with tissue (using high negative pressure can harm the patient).

SERVICING & REPLACEMENT

Pemco recommends Intracardiac Suckers 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 Intracardiac Suckers be replaced after six years when properly maintained, depending on usage.

Pemco Intracardiac Suckers 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.