

**INSTRUCTIONS FOR  
CLEANING & STERILIZATION**

**Preparation**

Inspect instrument after each use for damaged, loose parts, and proper function. Remove any gross contamination. To assure cleaning of all surfaces, the clamp jaws, channel valve and the flush-port cap must be **open**.

**Pre-Rinse**

1. An initial cold water and blood/protein-dissolving enzyme solution rinse (or soak for heavy contamination) helps remove blood, tissue and debris from device lumens, joints & serrations.
2. Flush and clean interior of instrument through the Flush Port and the Catheter Channel (Fig. 1) with cold water and blood/protein-dissolving enzyme and antiseptic solution. Allow solution contact for 5 minutes.

Pre-clean clamp jaws and tips with a brush.

**Washing / Decontamination**

1. Place instrument in a separate wire basket on top shelf of the automated washer / decontaminator and allow a full cycle run.
2. Allow instrument to air dry in basket. Then remove & inspect for any residual contamination. Allow residue of rinse water to remain in instrument channels. This allows steam to form during the sterilization process. If needed, inject distilled or de-ionized water in to channels.

**Packaging**

Follow institutional Policy and Procedures. Wrap properly for steam sterilization with sterilization indicator strip in lowest and most inaccessible portion of the packaging. Use two layers of non-woven disposable sterilization wrap on outside of packaging. Seal with sterilization indicator tape. Label and initial and date.

**Sterilization**

1. Follow sterilizer manufacturer instructions for use of the steam sterilizer.
2. Recommended Minimum Exposure Times (Minutes after conditioning) for Steam Sterilization: Gravity 250 F (121c): 30 minutes. Gravity 270 -274 F (132 -134 c): 15 minutes, Pre-vac 270 -274 F (132 - 134 c): 4 minutes.
3. Remove from sterilizer and allow time to cool on sterilizer rack. Assure package integrity and store on designated shelves for sterile instruments.

Inspect instrument closely before each use for damaged, loose parts and proper function.

MANUFACTURED FOR PROGRESSIVE MEDICAL INC.  
997 HORAN DRIVE, FENTON, MO 63026  
800-969-6331

**PMI  
CHOLANGIOGRAM  
GRASPER  
IFU**



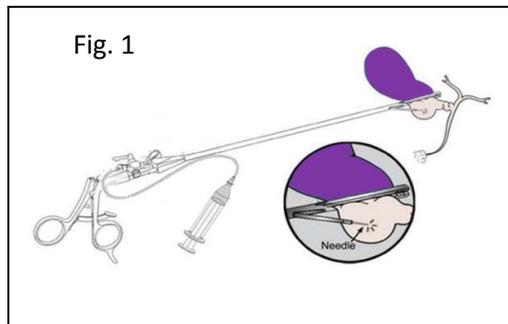
The **PMI Cholangiogram Grasper** is intended for use with the PMI Operative Cholangiogram Catheter (PMIORCA) when performing a laparoscopic cholangiography.

**DEVICE DESCRIPTION:** The PMI Cholangiogram Grasper is a reusable, stainless steel 5mm laparoscopic instrument. The device has a catheter port for the PMIORCA cholangiogram catheter and a valve for the maintenance of pneumoperitoneum, aspiration, and/or to function as a smoke vent. The grasper also has a flush port and atraumatic jaws that provide traction when dissecting the cystic duct.

#### INSTRUCTIONS FOR USE:

1. Insert the grasper through the right mid-subcostal port and apply traction at the infundibulum prior to dissecting the cystic duct. Make sure the channel valve is closed to maintain pneumoperitoneum.
2. Once the dissection is performed, the cystic duct can be milked towards the gallbladder to enhance cystic duct patency.
3. The grasper can then be reapplied across the entire lower part of the body of the gallbladder (Fig. 1), just above the Hartmann's pouch. It can be helpful to insert a grasper through the epigastric port to grasp the pouch and push it toward the clamps.
4. The compression caused by the grasper will make the Hartmann's pouch bulge and more prominent. Caution: Avoid injuring the surface of the liver when manipulating the graspers.
5. Open the channel valve and advance the PMIORCA Catheter through the catheter port.
6. Visualize the needle of the PMIORCA as it advances out through the end of the device and flush as needed.
7. Continue to advance the PMIORCA catheter as it punctures the Hartmann's pouch. You may have to manipulate the grasper by tilting or moving it.
8. To confirm proper placement, you could aspirate biliary content. You can now inject dye under fluoroscopy to perform the cholangiogram.
9. Once the cholangiogram is complete, release the grasper and aspirate via the catheter port to empty the gallbladder completely. This will facilitate an easier removal of the gallbladder from the trocar sites.

10. The catheter can be removed and the channel valve can be closed, or left open to act as a smoke vent. The grasper can be utilized to grab the gallbladder once it is detached.



#### IN THE ABSENCE OF ACUTE CHOLECYSTITIS OR HYDROPS:

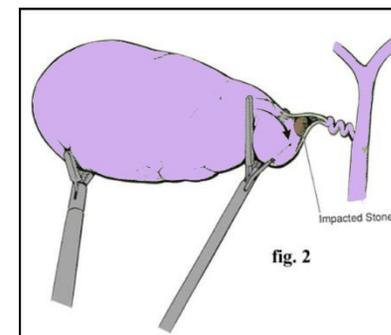
The obstruction can be eliminated by milking the cystic duct towards the gallbladder once the dissection is performed. The use of dye with the presence of very small stones is commonly performed as these usually pass without incident.

#### WITH ACUTE CHOLECYSTITIS (stones impacted at the neck of the gallbladder):

When the gallbladder is distended and cannot be grasped, insert the grasper through the right lateral port. Then, with the grasper jaws open, push the fundus of the gallbladder towards the diaphragm as much as possible (Fig. 2). Reintroduce the grasper through the mid-subcostal port and advance until the jaws are at the lowest part of the gallbladder. Ensure good visualization of the cystic duct. An additional port may be necessary to retract the viscera and improve visualization. Advance the PMIORCA Catheter through the catheter port until it reaches the lowest, dependent location of the gallbladder. Puncture and aspirate. Once the pressure is relieved from aspiration, negative pressure is created and dislodges the impacted stone.

The decompressed gallbladder can be grasped by the PMI Cholangiogram Grasper and dye can be injected as needed.

Fig. 2



#### HOW SUPPLIED

The PMI Cholangiogram Grasper is supplied non sterile. It is available in 2 sizes: PMI790-000 PMI Cholangiogram Grasper, Standard (30cm) and PMI790-001 PMI Cholangiogram Grasper, Bariatric (45cm).

#### LOOSE PARTS

Be advised of the following 4 loose parts:  
Removable tethered rubber cap over flush port  
Removable rubber cap over catheter port  
Removable channel valve assembly with a handle and screw cap

#### CLEANING AND STERILIZATION

Device must be cleaned and sterilized after each use. Clean and steam autoclave in accordance with the guidelines of the Association of Advancement of Medical Instrumentation (AAMI): Standards and Recommended Practices: Sterilization in Healthcare Facilities.

#### CONTRADICTIONS:

To avoid injury to the liver, do not use device unless able to visualize jaws at all times when manipulating.

#### CAUTION:

Federal (USA) law restricts this device to use by or on the order of a physician.

#### WARNINGS:

The device is for use by certified surgeons who have been trained in laparoscopic surgery. Operate the device using proper laparoscopic monitoring.

**Rx** only



NOT MADE WITH  
NATURAL RUBBER  
LATEX