

FIGURE 1

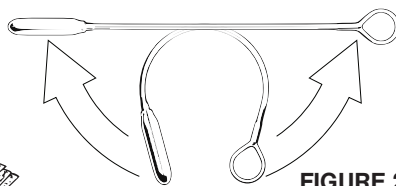
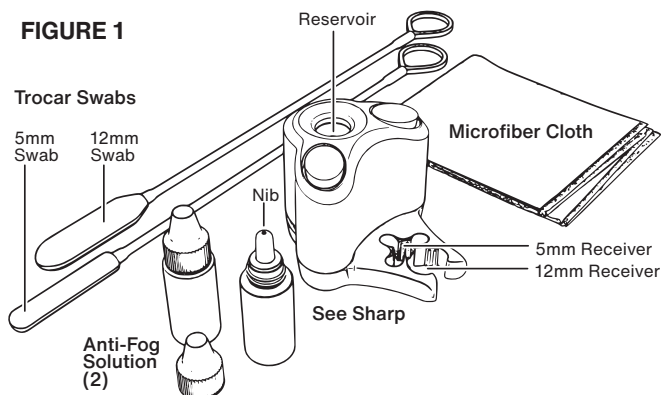


FIGURE 2

FIGURE 3

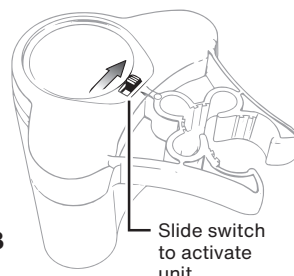
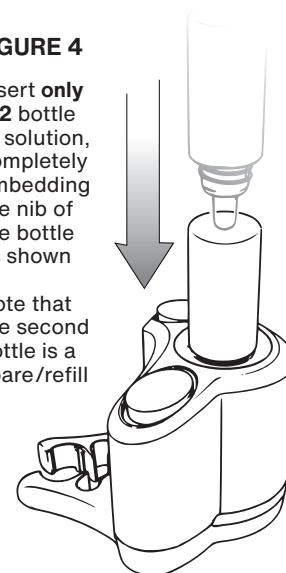


FIGURE 4

Insert **only** 1/2 bottle of solution, completely embedding the nib of the bottle as shown

Note that the second bottle is a spare/refill

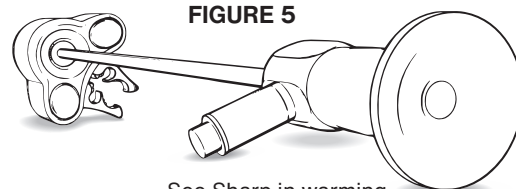


PREPARATION

1. Peel the label from the package and remove the contents (*figure 1*) which include: one (1) See Sharp™ unit, one (1) microfiber cloth, one (1) 5mm trocar swab, one (1) 12mm trocar swab, two (2) bottles of anti-fog solution.
2. Straighten Trocar swabs so that they are no longer curved. (*figure 2*)
3. Invert the See Sharp unit and activate the switch (*figure 3*) on the underside of See Sharp. The unit will emit a blue light indicating a "powered on" status which will last up to 5 hours.
4. Place the See Sharp unit on a level surface.
5. Remove the lid from one (1) of the bottles of anti-fog solution.
6. Completely insert the open nib of the anti-fog solution bottle into the reservoir opening of the See Sharp unit. (*figure 4*)
7. Squeeze the sides of the anti-fog solution bottle, emptying no more than half the bottle of solution into the reservoir and save the remaining fluid for a refill. **Note that the reservoir capacity is 1/2 of one bottle.** The second bottle is a reserve supply.
8. Allow five (5) minutes for See Sharp to reach optimal temperature.
9. Once the unit is warmed, insert the lens of the laparoscope into the opening of the See Sharp reservoir to the full depth of the reservoir to initiate scope warming. Note that the See Sharp may be placed on its side to facilitate scope warming on the back table. Allow five (5) minutes to complete initial laparoscope warming. (*figure 5*)

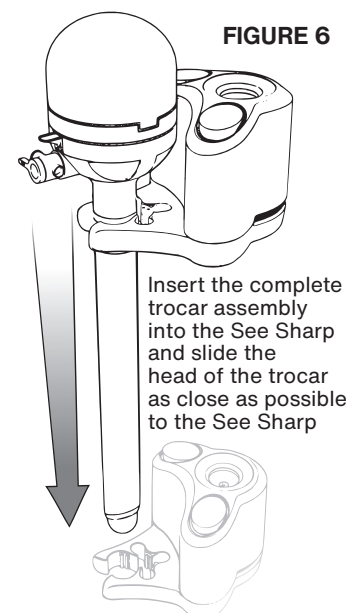
NOTE: To diminish fogging risk, limit the duration of laparoscope exposure to open OR environment.

FIGURE 5



See Sharp in warming configuration on back table

FIGURE 6



Insert the complete trocar assembly into the See Sharp and slide the head of the trocar as close as possible to the See Sharp

Then insert into the patient

TROCAR ATTACHMENT - METHOD 1

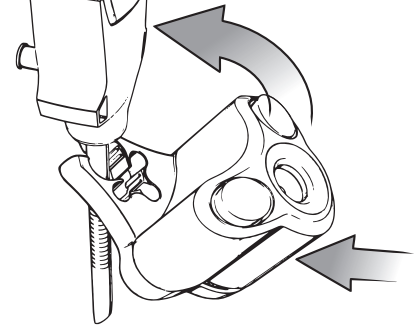
While the See Sharp may be used on the back table, it was designed to attach to a trocar — either the camera's trocar or another within the sterile field as per operator preference. Follow these steps to attach the See Sharp to a trocar:

1. Upon completing the warming phase, remove laparoscope from the See Sharp and wipe away any residual cleaning/defogging solution with the included microfiber cloth.
2. Identify the connection diameter on the See Sharp attachment clip appropriate for your trocar — the outer opening is for 12mm trocars, the inner opening is for 5mm trocars.
3. Slide the complete trocar (cannula with obturator) into the appropriate receiver (5mm or 12mm) of the See Sharp clip, drawing the see sharp close to the head of the trocar as possible. (*figure 6*)
4. Insert the **combined trocar-See Sharp** into the patient.

TROCAR ATTACHMENT - METHOD 2

1. Upon completing the warming phase, remove laparoscope from the See Sharp and wipe away any residual cleaning/defogging solution with the included microfiber cloth.
2. Identify the connection diameter on the See Sharp attachment clip appropriate for your trocar — the outer opening is for 12mm trocars, the inner opening is for 5mm trocars.
3. Align the See Sharp to the trocar as pictured (*figure 7*) so that the shaft of the trocar is centered and in contact with the tangs of the See Sharp's attachment clip and the See Sharp is angled at approximately 45° as shown.
4. Gently apply inward pressure while rocking the unit upward onto the trocar.
5. The See Sharp will snap into place on the shaft of the trocar. You may adjust the vertical position of the See Sharp on the trocar as needed. Assume that the See Sharp is as close as possible to the top of the trocar. You are now ready to use the See Sharp.

FIGURE 7 Approach trocar with See Sharp rotated to approximately 45° while applying inward pressure



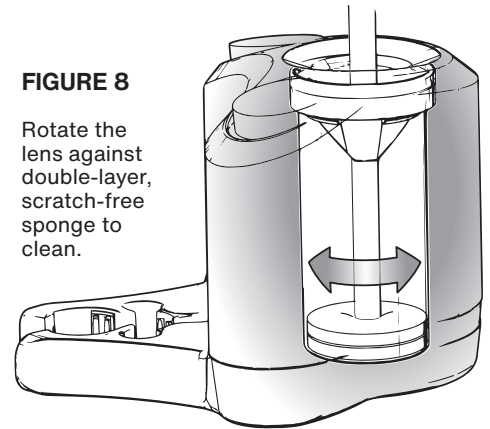
LAPAROSCOPE CLEANING & DEFOGGING

Follow these steps to restore optimal visibility to a fogged or soiled laparoscope.

1. Remove the laparoscope from the trocar and wipe away any heavy surgical debris with the included microfiber cloth.
2. Gently insert the tip of the laparoscope into the See Sharp to the full depth of the reservoir. The bottom of the reservoir is lined with a scratch-free double layer of sponge to cushion and protect the lens of the laparoscope.
3. Agitate the laparoscope with a rotary motion within the reservoir of the See Sharp. (*figure 8*)
4. Remove the laparoscope and tap the tip lightly on one of the sponges located atop the See Sharp to dissipate any excess cleaning solution.
5. Use the appropriately-sized (5 or 12 mm) trocar swab to remove any debris from within the shaft of the trocar by inserting the sponge into the trocar and swabbing in and out to ensure clean laparoscope reintroduction.

FIGURE 8

Rotate the lens against double-layer, scratch-free sponge to clean.



DISPOSAL

The See Sharp may be discarded with the single use trocar. On reusable devices, simply slide See Sharp off the end of the trocar.

WARNINGS

- This device was designed, test and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure or subsequent injury
- Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection
- Do not reuse, reprocess or resterilization this device
- After use, the See Sharp should be disposed of in accordance with local guidelines for medical waste that includes batteries
- Product complies to IEC 60601-1-2 Electromagnetic Disturbances - Device has not been evaluated against other equipment used in surgical setting
- The See Sharp should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures
- Please visually inspect for breaches of packaging integrity prior to use



702 Prominence Drive
Pittsburgh, PA 15068 U.S.A.

Tel: 724.337.5500
Fax: 724.337.0555

xodusmedical.com | info@xodusmedical.com

US Patent: 10,080,488; 10,575,722
Additional patents pending



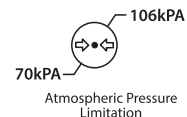
FDA REGISTERED
ISO 13485 CERTIFIED



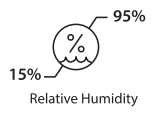
Single Use



Expiration Date



70kPA—106kPA
Atmospheric Pressure
Limitation



15%—95%
Relative Humidity



Do Not Use if Package
Damaged or Opened



Proper Disposal
Required



Consult Instructions
for Use



Caution, Consult,
Accompanying Documents



Prescription Use Only



Sterilized by Gamma
Radiation



MIN 5°C 41°F
MAX 40°C 104°F
Operating Temperature



Not Made with
Natural Rubber Latex

LITIFUSA001 R15 8/11/2020