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Cleaning Instructions for Device #2

Important

For satisfactory and long lasting results, the bioptome must be cleaned **immediately** after each procedure

I. Preliminary Catheter Cleaning

1. Rinse the exterior of the instrument under running water.
 2. Seat new or inspect that the 2 white cylinder shaped seals are in place one in the handle and one in the cleaner base.
 3. Place unlocked Bioptome on the base plate of the cleaner and locate the adjustment mechanism of the Bioptome in the elongated slot.
 4. Center the junction of the Bioptome's inner wire and its housing over the hole in the cylinder shaped seal (see figure 1)
 5. Bring down the cleaner handle, making sure the Bioptome's handle dose not move from its location over the lower seal.
 6. Push down the cleaner handle with light pressure. Make sure the Bioptome's adjustment mechanism is still located in the slot in the cleaned base.
 7. Press the cleaner handle down until it touches base. Then position the metal locking bar over the handle (See figure 2)
 8. Insert a 5cc syringe into the cleaner handle. (See figure 2)
 9. Pressurize with 4cc of enzymatic cleaning solution. The liquid should eventually come out clean. If it dose not, repeat the procedure. Remove the instrument from the cleaner.
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Note:

The Enzymatic solution stays inside the catheter at this point.

II. Exterior Cleaning

1. Soak the Bioptome for 20 minutes in the enzymatic solution.
2. Place the Bioptome in the ultrasonic cleaner with enzymatic solution for 10 minutes
3. Carefully brush the cutting mechanism with a soft brush to remove all foreign materials.
4. Rinse throughly with water.

III. Final Interior (Catheter) Cleaning and Lubrication

1. Repeat steps 3, 4, 5, 6, 7 and 8 of stage 1 (Preliminary Catheter Cleaning).
 2. Pressurize with 4cc of cleaning liquid (Enzymatic cleaning solution/peroxide) until the cleaning solution appears clean at the distal end of the cathater. If it does not, repeat the procedure.
 3. Several pressurizations with air only will remove the cleaning solution.
 4. Rinse by pressurizing with 4 cc of water.
 5. Several pressurizations with air will only remove the rinsing water.
 6. Pressurize with 1 cc of steam permeable instrument lubricant until liquid comes out through the distal end of the catheter. (Cutting mechanism)
 7. Several pressurizations with air only will remove the excess lubricant (steam permeable instrument lubricant). The Bioptome may now be removed from the cleaner.
 8. Place the Bioptome on the Scholten autoclaving/storage plate and wrap for sterilization. Wash the cleaner and store in open position.
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Important:

If the bioptome does not obtain a proper biopsy, it may be reconditioned.

Reconditioning consists of catheter replacement, inspection and evaluation of each component. The bioptome is guaranteed to perform as **new**.

Sterilization of the Scholten Bioptome

Based on a study conducted by a distinguished & independent US-FDA accredited laboratory, The Scholten Bioptome can be effectively sterilized by any of the following validated standard hospital sterilization procedures:

Important:

The Scholten bioptome must be clean before it can be effectively sterilized

We suggest that the Bioptome and storage plate be wrapped in two layers of your standard wrap before sterilization.

1. Place the Bioptome on the Scholten Autoclaving/Storage Plate with the handle of the Bioptome in unlocked position, jaws open. Do not autoclave the Bioptome with the jaws in the locked, closed position.

2. Pre-vacuum Steam Sterilization Cycle at 132° C for 6 minutes.
3. Gravity Displacement Steam Sterilization Cycle at 121° C for 15 minutes.



Figure 1

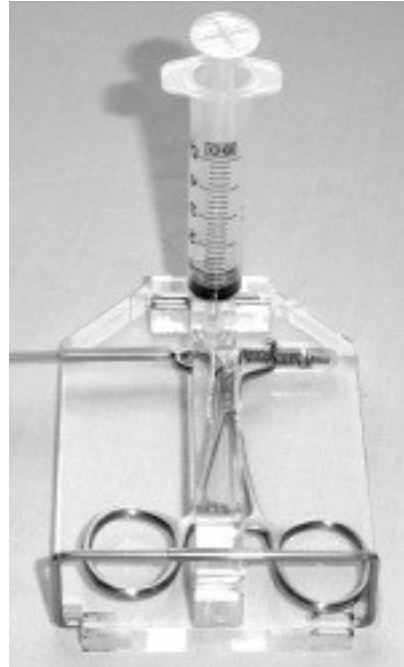


Figure 2