

ASSEMBLY AND OPERATIONAL INSTRUCTIONS

The remote swabbing and microbiological sampling tool and the Teflon template tool are shipped partially assembled. Complete assembly instructions are provided below:



1. Start with the 1-1/8" diameter tube with the threaded end at the top and the end with the expansion line at the bottom.
2. Insert the 1" diameter tube into the tube in Step 1 with the threaded end first, then the 7/8" diameter tube, then the 3/4" diameter tube and finally the 5/8" diameter tube, and place this assembly flat on a table.



3. Pull each of the 1", 7/8", 3/4" and 5/8" tubes out about an inch so that the Nylon clutch rings and the aluminum clutches can be mounted.



Instruction Manual

Remote Swabbing and Microbiological Sampling and Teflon template tools

Version 052313, Rev.0

4. Mount the largest clutch ring on 1" tube, next larger one on 7/8" tube, next larger one on 3/4" tube and the smallest one on 5/8" tube as shown in the pictures below.



5. Mount the largest diameter clutch from the top of the tube assembly (i.e., over the top end of smallest diameter tube), with the threaded end of going first, on to the largest diameter tube and tighten the clutch clockwise. Then mount the other clutches on the other tubes as shown in the pictures below and tighten the clutches clockwise.





6. Loosen the smallest clutch by turning anti-clockwise and extend the smallest diameter tube about 8 inches and tighten back the clutch.
7. Insert the no-pinhole end of the mirror holder tube (about 8" long) into the lower hole of one of the two black Delrin (plastic) adapters, tighten the lower screw on the Delrin adapter, mount this assembly on to the extended end of the smallest tube, through the top hole of the Delrin adapte, and tighten the upper screw on the Delrin adapter.



8. Mount the second Delrin adapter, through the lower hole, on the extended end of the smallest tube and tighten the lower screw on this Delrin adapter.



9. Remove the end cap of the flash light, insert the rear end of the flash light through the upper hole of the second Delrin adapter, replace the end cap and tighten the upper screw of the Delrin adapter. The flash light may be turned on or off by tightening or loosening the end cap.



10. Insert the lower end of the adjustable angle adapter into the top end of smallest tube, align the pin holes on the tube and the lower end of the adjustable angle adapter, and lock the assembly by inserting the ball spring pin into the aligned holes.



11. Mount any one of the clips on the top end of the adjustable angle adapter by pressing the clip in and turning it to lock in place in the slot on the top end of the adjustable angle adapter.



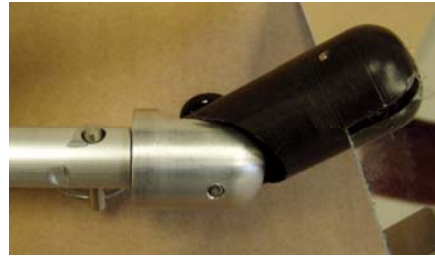
12. Adjust the angle of the adjustable angle adapter by loosening the thumb screw tilting the top part of the adjustable angle adapter to the desired angle and locking it in place by tightening back the thumb screw.



13. Any of the five clips may be attached now for microbiological or swab sampling as described further below.



14. Mount the mirror assembly by inserting the pin-hole end of the mirror adapter into the pin-hole end of the mirror holding tube, aligning the pin holes on the mirror adapter and the mirror holding tube and locking it in place by inserting the ball spring pin.



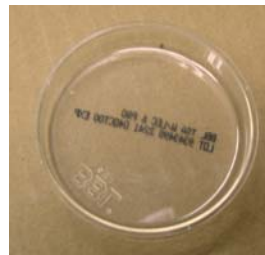
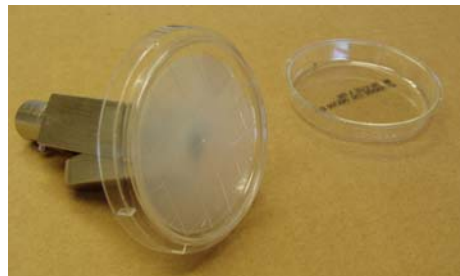
15. Adjust the angle of the mirror assembly by loosening the thumb screw on the mirror adapter, moving the mirror to the desired angle and tightening back the thumb screw. Mirror attachment helps to look underneath surfaces while swabbing.
16. Press the swabbing tool end cap on the bottom end of the largest diameter tube. Note: This end cap may be removed if it is feared that it may fall into the equipment.



Now the tool is ready for operation.

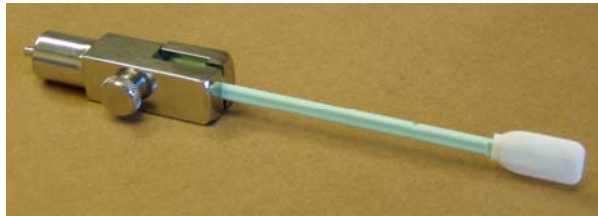
17. Extend the tool to the desired length by loosening the clutches, pulling the tube out and tightening the clutch back. Clockwise turning of the clutch loosens it and anti-clockwise turning tightens it.

18. Clip 4A is for microbiological sampling using an agar plate, such as a Rodak® plate. Press the suction cup on the agar plate, open the clip 4A, grab the head of the suction cup with the clip and mount the clip on the adjustable angle adapter as described in Step 11. After taking the microbiological sample by touching the surface to be tested with the agar medium side of the agar plate, place the clip, along with the suction cup and the agar plate, on the agar plate empty dish, release the suction cup, along with the agar plate, from the clip and remove the suction cup by pulling the suction cup tab. The microbiological sample is ready to go to the lab.

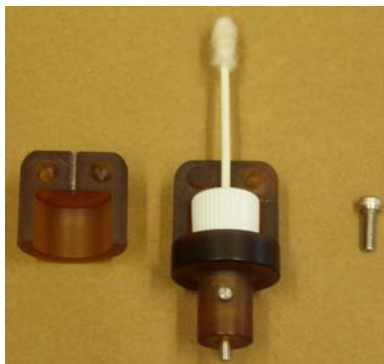


19. Clips 4B and 4C are for swab sampling. The swab may be dipped in an appropriate solvent as prescribed in your cleaning validation procedure. Mount the swab by opening the jaw of the clip by loosening the thumb screw, inserting the handle of the swab between the jaws and tightening the thumb screw back. Note: The swab handle may be shortened by cutting it off, if necessary. After swabbing is completed, release the swab and transfer to a vial. The swab sample is ready to go to the lab.





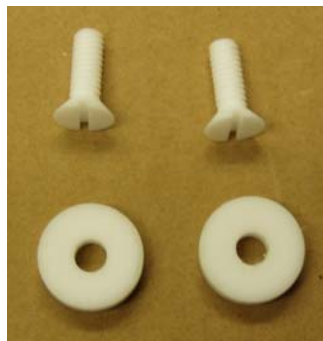
20. Clip 4D is for microbiological sampling when using the agar medium in a tube with a swab attached to the cap of that tube. In this case, separate the two parts of the clip by removing the screw, place the cap of the tube inside the clip, close the two parts of the clip and tighten the screw. The swab will be exposed while the cap remains inside the clip. After swabbing is completed, release the swab with the cap from the clip, place in its tube and send to the lab.



21. Clip 4E is also for microbiological sampling when using the agar medium in a tube with a swab attached to the cap of the tube. With this clip, open the jaw of the clip by loosening the thumb screw, insert the cap end of the swab into the opening of the clip and tighten the thumb screw. After sampling is completed, release the cap with the swab, replace it in the tube and send it to the lab.



22. The Teflon template tool is also assembled the same way as the swabbing tool. The only difference is that a Teflon template holder is mounted on the adjustable angle adapter instead of a clip. Mount the Teflon template, with an opening of a specified area, on the Teflon template holder by using Teflon washers on the inside and Teflon screws on the outside. When using the Teflon template tool in conjunction with the swabbing tool, it will be necessary for one person to hold the Teflon template tool and another person to do the swabbing with the swabbing tool.



23. When additional tube extensions are added to the swabbing tool or the Teflon template tool, same procedure described above may be followed.
24. A wrist band may be added to the bottom end of the largest diameter tube of the swabbing tool or the Teflon template tool so that the tool may be secured to the wrist to prevent it from falling into the equipment while using.
 - (a) Open the aluminum ring by pressing on the latch and insert the open end of the ring through the hole on the bottom end of the largest diameter tube and let the latch loose.
 - (b) Fasten the hook of the wrist band to the aluminum ring.
 - (c) Snap close the wrist band.
 - (d) Insert you hand through the wrist band and hold the swabbing tool or the Teflon template tool while operating.



MATERIALS OF CONSTRUCTION

The swabbing and microbiological sampling tool and the Teflon template tube, the clutches and the adjustable angle adapter are made of clear anodized aluminum.

The clutch rings are made of Nylon.

Clip 4A, 4B and 4E are made of 316 stainless steel.

Clip 4C is made of FDA approved white acetal (Delrin®)

Clip 4D is made of FDA approved plastic, polyetherimide, Ultem®

Teflon template holder is made of 316 stainless steel

Teflon templates, screws and washers are made of FDA approved virgin Teflon®

Suction cups are made of silicone or PVC.

Tool end cap is made of black PVC.

The wrist band is made of Nylon and the wrist band ring is made of aluminum.

Mirror is made of acrylic.

The locking pin is made of 304 stainless steel.

CLEANING PROCEDURE

All parts can be washed with soap and water. It is recommended that you use your own in-house cleaning method. The tools should be disassembled before cleaning. The clips should be cleaned in an ultrasonic cleaner. Dry the parts before re-assembling the tools.

The PVC storage tube should also be cleaned thoroughly with soap and water and dried.

STERILIZATION PROCEDURE

All the metal parts, the Clip 4B and Teflon templates, Teflon screws and Teflon washers can be steam or gamma ray sterilized.

The Clip 4D, the Nylon clutch rings and the tool end cap (PVC) may be sanitized in ethyl alcohol.

STORAGE

Store the washed and dried tools in the washed and dried PVC storage tube with both end caps in place on the storage tube.