



MesaLabs

INSTRUCTIONS FOR USE

ProLine Process Challenge Device Biological Indicator

ProLine is a Biological Indicator Process Challenge Device specifically designed for use in the validation or monitoring of Steam/EtO sterilization cycles of tubing ranging from 1/8" to 5/8" tubing ID. The ProLine PCD (Process Challenge Device) contains a filter paper disc impregnated with bacterial spores of *Geobacillus stearothermophilus* (steam) or *Bacillus atrophaeus* (EtO). The spore disc is packaged in a glassine envelope and is located in the center of the ProLine housing. If adequate sterilization cycle parameters are met, the spores on the spore disc will be deactivated and verify an adequate sterilization cycle.

Assembly:

For a given length of tubing being sterilized, the most difficult area of the tubing to be sterilized is the mid-point of the tubing length. This is where the ProLine device must be placed. To do this, a test piece of tubing should be cut at its mid-point. The two half lengths should now be attached to the ProLine device by slipping one end of each cut length of tubing over the tapered ends of the ProLine device. The ProLine device is now located in the center of the length of tubing, the most difficult area to sterilize.

Use and Placement:

The ProLine device with its two attached lengths of tubing should be packaged according to protocol and then placed in the sterilizer along with a normal load in which tubing would be included.

Post Sterilization Testing:

Once the sterilization cycle is completed, the ProLine and attached lengths of tubing are removed from the sterilizer and transferred to an area where an aseptic transfer of the spore disc to growth media can be performed. To do this, grasp both sides of the ProLine device and break the chamber open exposing the glassine packaged spore disc. Aseptically transfer the spore disc to a tube of sterile TSB (Tryptic Soy Broth) and incubate:

Steam: 55-60°C for 7 days for Growth/No Growth testing.

EtO: 30-35°C for 7 days for Growth/No Growth testing.

Discard the opened ProLine device halves and the rubber gasket. This device is a "single use only" product.

Interpretation of Testing Results:

Observe the growth media tube daily over the 7 day incubation period and record results. A tube remaining clear after 7 days is an indication of a successful cycle. A cycle failure is indicated by color change of pH indicator and/or turbidity in the tube of media.