Simulated-Use Testing: Biopsy Forceps

Objective

To evaluate cleaning procedures for biopsy forceps with single-use biopsy forceps, which are most easily subjected to destruction testing.

Methods

Prepare biopsy forceps (SBF), intended for testing, in a class IIB biosafety cabinet wearing appropriate personal protective equipment. Soil equipment using Artificial Test Soil (ATS), which is formulated to mimic "worst-case" soiling expected in gastrointestinal endoscopy procedures, and allows for quantitative assessment of cleaning efficacy for protein, carbohydrate, hemoglobin, and endotoxin.

Bioburden

Supplement ATS with approximately 10^6 colony-forming units (cfu)/mL of *Enterococcus faecalis* (ATCC 29212) as well as approximately 10^6 cfu/mL of *Geobacillus stearothermophilus* (ATCC 12980) spores. Inoculum counts should be performed to confirm the concentration of both organisms for all experiments.

Test Devices and Inoculation Procedure

The test devices are new biopsy forceps. This type of biopsy forceps has a friction-reducing sheath (Endoglide), a working length of 240 cm, an outside jaw diameter of 3.3 mm, and is for use with a biopsy channel that has a minimum internal diameter of 3.8 mm. To inoculate the forceps with ATS, utilize a retroflush lumen adaptor from Medisafe. Force soil upwards through the retroflush lumen adaptor into the forcep until excess soil is noted exiting at the handle. Store inoculated SBFs at room temperature for 2 hours, and then clean with the method(s) being evaluated.

Test Methods

Quantitative indirect evaluation of soil parameters and count of viable organisms:

1. After cleaning single use forceps with method being evaluated, aseptically cut up into approximately 4.5-cm lengths.
2. Pool the segments from each separate forcep into a 50-mL sterile test tube. Stand each segment vertically within the test tube.
3. Once the entire length of the forcep (excluding the handle) is cut up, completely immerse in 25mL of sterile, reverse osmosis (RO) purified water to the test tube.
4. Mix the tube containing the forcep segments in a vortex mixer for 1 minute.

5. Sonicate for 4 pulses of 5 seconds each.
6. Centrifuge at 3,500 rpm for 10 minutes at 4°C (to ensure that all lumens are perfused with liquid).
7. Mix by a vortex mixer for an additional 1 minute.
8. Use the eluted sample to test for protein, carbohydrate, hemoglobin and endotoxin.
9. Count viable organisms by spreading 0.1mL of each dilution of the sample over the surface of 2 tryptic soy agar plates.
10. Incubate one set of inoculated plates at 55°C (to detect *G. stearothermophilus*); Incubate the other set at 35°C (to detect *E. faecalis*).

An example of utilizing this method for testing can be found here:
http://www.wfhss.com/html/educ/articles/educarticle_0007_en.pdf