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Brief report

Disinfection of an infrared coagulation device used to treat hemorrhoids

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Infrared coagulation devices are used to treat internal hemorrhoids, and as semicritical items should undergo high-level disinfection between patients. We developed and validated a method for disinfecting an infrared coagulation device that cannot be immersed in disinfectant solution.

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Hemorrhoids are a common disease, afflicting approximately 4%-5% of the population.[1] Treatment of internal hemorrhoids includes rubber band ligation, bipolar diathermy, laser photocoagulation, sclerotherapy, cryosurgery, and infrared coagulation (IRC).[2] Using an IRC device is a nonsurgical procedure that involves applying infrared light to compress and seal the hemorrhoid veins.

The Spaulding classification system, which subdivides medical devices into 3 categories (critical, semicritical, and noncritical), serves as a guide for disinfection and sterilization methods.[3] For safety, critical devices that enter sterile body tissues (eg, surgical instruments, implants) must be sterile. Semicritical devices that come into contact with nonintact skin or mucous membranes also should undergo high-level disinfection between patients. Noncritical devices that come into contact with intact skin should undergo low-level disinfection between patients. Cleaning always must precede high-level disinfection or sterilization. The Centers for Disease Control and Prevention (CDC) 2008 guideline for disinfection and sterilization in health care facilities recommends that as a semicritical device, the IRC probe should be subjected to high-level disinfection between patients.[3] However, the manufacturer of the IRC device that we studied (IRC 2100; Redfield Corp, Rochelle Park, NJ; http://www.redfieldcorp.com/irc2100.html) does not specify a method for such high-level disinfection, but instead recommends the use of a single-use sterile probe sheath to prevent contamination of the device. Multiple studies have demonstrated that probe sheaths/covers/condoms can fail due to tears or rips, leading to contamination of the device.[3] In addition, the manufacturer states that the lightguide will be damaged by immersion in a disinfectant (because the lightguide is not sealed at the end, and the disinfectant gets between the quartz glass and the covering), so using an immersion procedure that achieves high-level disinfection is not an option. For this reason, we investigated an alternative method of achieving high-level disinfection.

Contamination of a semicritical device that comes into contact with the rectum could potentially transmit such pathogens as hepatitis A, norovirus, cytomegalovirus, human papilloma virus, *Pseudomonas aeruginosa*, *Salmonella* spp, and vancomycin-sensitive *Enterococcus faecalis*. In addition, if rectal bleeding were present, the device could transmit hepatitis B, hepatitis C, and human immunodeficiency virus. Because the IRC device is a semicritical device, we developed and validated a method for disinfection, as follows.

Before each run, the IRC device was sterilized using ethylene oxide. The device was then inoculated with 10 μL of a culture of microorganisms containing $>10^6$ organisms and subjected to the disinfection procedure. Test organisms included *E faecalis* (American Type Culture Collection [ATCC] 29212), *P aeruginosa* (ATCC 27853), and *Mycobacterium terrae* (ATCC 15755). Five replicates per organism were performed. After inoculation, the probes were allowed to air-dry in a biological safety cabinet for 30 minutes before disinfection. Disinfection was achieved by wiping the shaft of the probe for 2 minutes with a sterile laparotomy sponge that had been soaked in a freshly prepared hypochlorite solution (ie, 1:10 dilution of 6.00% sodium hypochlorite, 6,000 ppm). After 2 minutes of drying time, the probe was wiped for 1 minute using a sterile laparotomy sponge that had been wetted in sterile water. The probe was air-dried for 2 minutes and then placed in a 10-mL tube of either trypticase soy broth (for *P aeruginosa* and *E faecalis*) or 7H9 broth (for mycobacteria). The tube was then sonicated (Health Sonics, Pleasanton, CA) for 30 minutes and gently vortexed (Vortex Genie 2; Fisher Scientific, Lenexa, KS) for 1 minute

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Table 1
Efficacy of hypochlorite disinfection of contaminated IRC device*

Test organism	Average $\log_{10}$ reduction†	Total positive plates
M terrae	6.89*	1/5‡
P aeruginosa	7.47*	0/5
E faecalis	7.29*	0/5

*Five replicates per test organism.
†Average $\log_{10}$ inoculum was identical to the log reduction.
‡1 CFU was recovered on the filter of 7H11 plate.

(setting 5), after which the broth was filtered and plated to either sheep's blood agar or 7H11 agar (Remel, Lenexa, KS). The plates were incubated at 37°C for 48 hours (for bacteria) or 14 days (for mycobacteria), and colonies were counted. Log_{10} reduction was calculated by comparing the colony counts before and after disinfection. The efficacy of cleaning was assessed by handling an inoculated probe in exactly the same manner, but using only sterile water for wiping.

We found a >6 $\log_{10}$ reduction in all test microorganisms on the probe after applying our disinfection method (Table 1). In only a single run using *M terrae* did an inoculated probe demonstrate any growth (1 CFU recovered on a filter). Cleaning the probe with sterile water alone resulted in a >3 $\log_{10}$ reduction in microorganisms. The numbers of organisms remaining after cleaning alone was as follows: *M terrae*, 6.42×10^3 CFU; *P aeruginosa*, 6.06×10^2 CFU; *E faecalis*, 2.63×10^2 CFU.

Contaminated devices that are inadequately cleaned/disinfected can transmit infections among patients. The use of probe sheaths has been demonstrated to be an inadequate method for preventing contamination of devices. For this reason, the CDC guideline recommends that semicritical devices undergo high-level disinfection between patients even when a probe sheath is used. Our data demonstrate that cleaning alone was insufficient to eliminate the test organisms inoculated on an IRC probe. We found that the IRC probe can be successfully disinfected by a 2-minute wipe with a 1:10 dilution of 6.00% sodium hypochlorite (6,000 ppm hypochlorite), a 2-minute air-dry, and finally a 1-minute rinse with sterile water. This method, which removed or inactivated ≥ 6 $\log_{10}$ of *E faecalis*, *P aeruginosa*, and *M. terrae*, should be sufficient to eliminate all potential contaminating pathogens. We recommend the following procedure, which is consistent with current CDC guidelines for high-level disinfection of this IRC probe, a semicritical device:

- Unplug the IRC unit from the power source before cleaning.
- Discard the sheath covering the IRC probe.
- If the probe is visibly contaminated, wipe the probe with a clean, wetted cloth to remove any debris.
- Wipe IRC handle with 1:10 diluted bleach.
- Wipe IRC lightguide/lightsource for 2 minutes with 1:10 diluted bleach ($\sim$5,250-6,000 ppm) using a cotton washcloth, lightly dampened, not dripping wet.
- Allow the lightguide to air-dry for 2 minutes.
- Wipe the lightguide for at least 1 minute with sterile water.
- Cover the probe when dry with a clean towel and store it in a clean, dry location.

This wiping procedure is consistent with the manufacturer's instructions and should prevent transmission of pathogens between patients.

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