# D.16 PRE-TREATMENT AND TRANSPORTATION OF SOILED CRITICAL AND SEMI-CRITICAL REUSEABLE MEDICAL EQUIPMENT - UPDATED

**Department of**

**Veterans Affairs**

# Memorandum

Date: JUN 0 1 2016

From: Assistant Deputy Under Secretary for Health Operations and Management (10N)

Subj: Updated Pre-treatment and Transportation of Soiled Critical and Semi-Critical Reusable Medical Equipment (RME)

To: VISN Directors, VISN CMOs, VISN QMOs, VISN Nurse Executives, VISN Sterile Processing Boards

Thru: Assistant Deputy Under Secretary for Health for Clinical Operations (10NC)

1. This memorandum is to improve current processes for pre-treatment and transportation of soiled RME from the point of use to a decontamination area in accordance with professional practice standards.

2. Pre-Treatment:
    a. Responsibility of end user
    b. Manufacturer's Instructions for Use (IFUs) must be followed
    c. Removal of all gross debris must occur prior to application of ProEZ enzymatic 12-hour precleaning spray (please see attached ProEZ validation studies). At this time, ProEZ is the only vendor validated 12-hour enzymatic.
    d. Thoroughly spray ProEZ enzymatic solution directly onto instruments to be cleaned allowing for each instrument to remain covered to dissolve bioburden.
    e. Application of ProEZ enzymatic solution is to be done immediately following RME use. This can occur at point of care or within soiled utility room.

3. Transport of RME from point of care to soiled utility/appropriate holding area:
    a. Properly labeled medical grade puncture resistant biohazard rigid container or an enclosed cart is to be used to transport all RME
    b. Two methods:

        i. Exchange transport container - the container with the soiled RME is placed in the utility room and a clean container (which has been intermediate level disinfected between uses) acquired from clean storage is taken back to the point of use.
        ii. Point of use transport container – the container with soiled RME at point of care is transported to soiled utility room

where end user will don appropriate PPE to transfer soiled RME to designated collection container that is a properly labeled medical grade puncture resistant biohazard rigid container. The point of care transport container must be intermediate level disinfected before returning to patient care area for subsequent use.

4. Transport of RME from soiled utility room/appropriate holding area, at facility and offsite locations, to decontamination area:
    a. A process for regular scheduled pick-up times and deliveries **must be established** to facilitate prompt removal of soiled RME from soiled utility rooms/appropriate holding areas. This will require multiple pick-ups from the using service and deliveries to decontamination areas for reprocessing.
    b. RME treated with ProEZ enzymatic solution **MUST NOT** be left in a soiled utility room/appropriate holding area beyond 12 hours. Note: This does not apply to flexible lumen endoscopes due to need for reprocessing within 1 hour or an extended soak must occur. The SPS chief must ensure periodic routine auditing of pre-treatment processes to verify:
        i. Gross debris has been removed at the point of use.
        ii. Instruments remain moist until delivery to SPS for reprocessing.
    c. ProEZ enzymatic product must not be reapplied as a means to keep items moist until delivery to SPS.
    d. Soiled RME sprayed with ProEZ **includes the 12-hour time limit for transportation to the main facility and must not be left overnight or over weekends/holidays**.
    e. To ensure employee safety, the exterior surfaces of transport containers must be low level disinfected so PPE is not needed for transport.
    f. For offsite locations, there are two methods of transportation, both of which must comply with the ProEZ 12-hour time limit and with applicable Department of Transportation (DOT) and state regulations:
        i. Separate vehicles for soiled and clean - Soiled RME will be placed in a properly labeled medical grade puncture resistant biohazard rigid container.
        ii. One vehicle for soiled and clean - Clean and soiled RME must be segregated and soiled RME will be placed in a properly labeled medical grade puncture resistant

biohazard rigid container placed inside a second rigid transport container with an external lock.

g. Facilities must create a transport schedule meeting workload requirements, allowing timely Veteran clinical access to care; while maintaining Veteran safety. Close of Business pick up planning should be accomplished to allow timely transport. This must include off hours or tours if present.

5. This memorandum remains in effect until further notice of additional updates and/or replacement thereof.

6. For questions regarding this memorandum, please contact Teresa Wells, Director National Program Office for Sterile Processing at Teresa.Wells3@va.gov or Seaton West, Deputy Director National Program Office for Sterile Processing at Seaton.West@va.gov.

Janet P. Murphy, MBA

Attachment

ProEZ foam
sustained holding tes

**The Dilemma of Prolonged Holding and Transport of Contaminated Medical Instrumentation: A test process to validate effective action of ProEZ foam™ enzymatic pre-cleaning spray**

Certol International, LLC

April, 2016

Introduction: What is the purpose of pre-cleaning at point of use and why should we have any concern about dried blood and other soils on medical instrumentation prior to full cleaning and sterilization?

It is well documented that when soils are allowed to dry on instrumentation, the dried soils are likely to result in biofilm development, corrosion and difficulty in soil removal due to protein denaturation and fibrin retention. Dried soils in cannulas and lumens are holding zones for transfer of infectious organisms and endotoxin. Therefore, the primary purpose for prompt removal of soils during procedures or application of pre-cleaning sprays is to ensure conditions for complete soil removal with the least damage to instrumentation.

What is the appropriate process to validate the efficacy of a product for overnight or prolonged holding of contaminated instrumentation?

There are no ISO or AAMI standards, guidelines or test procedures for spray pre-cleaners. The FDA 510 K pre-market clearance process is directed toward devices and high level disinfectants (gluteraldehyde, etc.). There are no current FDA standards for clearance of products specifically labeled as detergent cleaners. Because pre-cleaning is not intended to produce complete soil removal, the use of ATP or other tests would not be an appropriate end measure for pre-cleaning products.

Should a pre-cleaning process or product kill germs?

Pre-cleaning may physically remove a high percentage of infectious organisms but disinfection is not a primary goal of pre-cleaning. ProEZ foam™ is an excellent cleaner but is not labeled or intended as a disinfectant. Products with disinfectant / bacterial kill claims (including "bacteriostatic") must submit third party tests from approved labs and go through a rigorous process for registration with the EPA. Labeling and marketing claims are strictly regulated for such products.

With the above in mind, we designed a study to simulate clinical conditions when contaminated devices and instruments must be held for prolonged periods. The test process will yield visual objective evidence to support the performance of ProEZ foam™ enzymatic spray to:

1. Reduce risk of dried soils on instrumentation when held over 12 hours after clinical procedures.
2. Start cleaning and breakdown of proteins, blood and other soils commonly found on instrumentation after clinical procedures.
3. Sustain moisture and foaming properties after application over a 12 hour period when containerized with solid lid.
4. Reduce risk of corrosion if applied on soiled instrumentation held or transported over a 12 hour period when containerized with solid lid.
5. Demonstrate easy rinsing/removal of foam and liquid after 12 hour application.

**Materials**

1. Industrial steel razor blades with carbon steel blades (Workforce brand Heavy duty utility blades .025 in., Carbon Steel blades, Home Depot.), selected as a maximum challenge for corrosion. (Carbon steel is especially prone to corrosion.)

2. Fresh non-heparinized bovine blood is used as a human blood surrogate test soil. New unused razor blades with carbon steel edges were prepared by coating with the bovine blood and allowed to dry for one hour.

3. TOSI® test coupons with fibrin infused artificial blood soil emulating dried human blood challenge are selected for the other soil challenge as a standardized objective material. TOSI® (Test Object Surgical Instrument) is a challenge device with water soluble blood proteins and insoluble fibrin, product # WT-101 (Healthmark Industries.) This test coupon is more traditionally used to test cleaning efficacy when chemistry and washer function are combined. Therefore the use of the TOSI test without water impingement provides an additional challenge.

4. Regular untreated local tap water is the control soak solution.

5. The test product is ProEZ foam ready to use enzymatic spray. This product contains anti-corrosives and four unique enzymes (protease, amylase, lipase and cellulase).

**Methods**

The test process includes the following test conditions:

(a) control pieces – razor blades not exposed to blood, water or foam;
(b) blades coated with bovine blood and allowed to dry but not exposed to water or foam;
(c) blades coated with bovine blood, allowed to dry and soaked in plain tap water or
(d) blades coated with bovine blood, allowed to dry then covered with ProEZ foam;
(e) blades with no blood covered in ProEZ foam; and
(f) Tosi test coupons with the plastic covers removed for easier viewing, then covered with ProEZ foam.

All test items are inside a clear plastic tray with solid lid. The lid is closed over all test items. Test items are exposed to the test conditions (tap water, ProEZ foam or no soak treatment) for 15 hours (4 pm to 7 am the following morning).

**Results and Discussion**

Did the test conditions simulate clinical challenges?

Yes, the test time period of 15 hours approximates conditions that frequently occur with transport of contaminated items between clinics and main processing centers, emergency rooms and labor/delivery centers.

The use of fresh animal (bovine) blood closely simulates fresh human blood. The TOSI test with the fibrin component is an effective surrogate for dried blood.

The use of carbon steel razor blades provides an additional challenge for corrosion over more durable and common stainless steel instrumentation.

The carbon steel razor blades coated with fresh blood demonstrate beginning corrosion within one hour of application.

Did the test conditions and process provide evidence of effective performance by ProEZ foam?

The blades and TOSI tests covered with ProEZ foam demonstrate minimal or no soil remaining at the end of the test. This is accomplished without added agitation or scrubbing. ProEZ foam therefore reduces risk of dried soils on instrumentation when held overnight or over 12 hours after clinical procedures.

Post test results demonstrate that ProEZ foam did break down the proteins and fibrin components of the bovine blood and the challenging TOSI simulated blood soil.

Post test observation at 15 hours demonstrates that ProEZ foam will sustain moisture and foaming properties after application overnight when containerized with solid lid.

The blades covered with blood soil demonstrate beginning corrosion within 60 minutes. After application of ProEZ foam the blades show no further corrosion even after soaking for 15 hours. When ProEZ foam was applied to carbon steel blades without blood soil, there was no corrosion after 15 hours soaking. The difference between the water soaked blades and the blades kept in ProEZ foam is dramatic.

Video footage demonstrates that ProEZ foam does not dry hard or sticky and is easily rinsed off items even after 15 hours holding time.

**Conclusion**

ProEZ foam is validated to meet the following claims:

ProEZ foam provides sustained moisture and foam coverage over 12 hours. Contaminated items should be held or transported in containers with solid lids and appropriate labeling for biohazardous material.

ProEZ foam reduces risk of dried on soils and initiates the breakdown of blood and other soils during the holding period.

ProEZ foam reduces the risk of corrosion on contaminated items over prolonged holding periods, especially if applied promptly before blood soils have the opportunity to start corrosion.

The ProEZ foam formula does not dry hard or sticky and is easily rinsed off with cold water even after prolonged holding periods when used on items that are held within containers with solid lids.

**Comments**

AAMI ST79 guidelines specifically recommend the prompt removal of soils from instrumentation and should be followed to the full extent possible in all healthcare settings.

The results obtained with the use of ProEZ foam™ enzymatic spray in this study should not be generalized to other brands of pre-cleaning sprays due to the wide variation in quality and specific chemical ingredients.

For further information please contact Certol Intl. LLC at 1.800.843.3343 x 293 or pspitzer@certol.com