ASTM Workshop on Medical Device Cleanliness

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Standard Practices & Guides for Processing Reusable Medical Devices
Can we develop a standard guide or practice for cleaning and processing reusable devices for subsequent uses, particularly cannulated medical devices?

**Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera (ASTM F 1518-00)**


Can we develop a standard guide or practice for cleaning and processing reusable devices for subsequent uses, particularly cannulated medical devices?

**Standard Practice for Care and Handling of Orthopedic Implants and Instruments (ASTM F565 – 04- 2009)**

**Standard Guide for Care and Handling of Stainless Steel Surgical Instruments (ASTM F1744 – 96- 2008)**
Can we develop a standard guide or practice for cleaning and processing reusable devices for subsequent uses, particularly cannulated medical devices?

Existing Guides & Practices:

- Update & Revise
- Add Discussion or Recommendations for Verification of Cleaning (non-visual)

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Residual soil on reusable medical devices: A challenge to the standards community
Cleaning of Reusable Medical Devices

- Disease Transmission
- Occupational Exposure to Potentially Infectious Materials
- Interference with Subsequent Disinfection or Sterilization
- Device Performance

Visibly Clean & Device Design

- Serrated edges
- Hinges
- Acute angles
- Coils
- Junctions between insulating sheaths
- Long or narrow opaque lumens
Recent History

Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A guide for device manufacturers (AAMI TIR12—1994)

Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (FDA-1996)

Standard Test Methods

Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test) (ASTM E2314 – 03 - 2008)

Tests the efficacy of a cleaning process for reusable medical instruments artificially contaminated with mixtures of microorganisms and simulated soil.
Standard Test Methods

Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors (ASTM D7225 - 06)

Standard test soil correlating to coagulated blood suitable for screening tests and the evaluation of the cleaning efficiency of washer-disinfectors used for reprocessing of surgical instruments.

Cleaning Review

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices (AAMI TIR30:2003)

Compilation of available information that can be used by medical device manufacturers to validate cleaning processes for reusable medical devices.
A Cleaning Review

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices (AAMI TIR30:2003)

• Device design & materials
• Available cleaning processes
• Test soils
• Test methods, equipment, and acceptance criteria
• Regulatory considerations

Standard Test Methods

Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)

Defines general performance requirements for washer-disinfectors and that are intended to be used for cleaning and disinfection of re-usable medical devices.
Standard Test Methods

Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)

Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)


Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008)


“The current state of knowledge has not permitted development of a single internationally acceptable test method”
Standard Test Methods


– The 19 test soils and methods from national standards and published documents

  Blood                                      Wallpaper Paste
  Instant Potato Flakes                      Eggs / Egg Yolks

– Acceptance criteria are based on visual inspection (n=18) and/or a microbiological end-point (n=6).

Moving Forward


Revision of Part 5:

1. Artificial Soil (organic)
2. Quantitative Endpoint
4. [Need for relevant verification tests]