



Workshop on Medical Device Cleanliness: How Clean is Clean Enough?
Sponsored by ASTM Committee F04 on Medical and Surgical Materials and Devices

ASTM Workshop on Medical Device Cleanliness

Steve Goldstine Consultants
SteveGoldstine@Yahoo.com

11/16/2010

ASTM: Cleanliness of Medical Devices

ASTM Workshop on Medical Device Cleanliness

Standard Practices & Guides for Processing Reusable Medical Devices

11/16/2010

ASTM: Cleanliness of Medical Devices



Workshop on Medical Device Cleanliness: How Clean is Clean Enough?

Sponsored by ASTM Committee F04 on Medical and Surgical Materials and 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)

Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes (Reapproved 2007) (ASTM F 1992-99)

11/16/2010

ASTM: Cleanliness of Medical Devices

3

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)

11/16/2010

ASTM: Cleanliness of Medical Devices

4

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)**

11/16/2010

ASTM: Cleanliness of Medical Devices

5

ASTM Workshop on Medical Device Cleanliness

Residual soil on reusable medical devices: A challenge to the standards community

11/16/2010

ASTM: Cleanliness of Medical Devices

Cleaning of Reusable Medical Devices

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

11/16/2010

ASTM: Cleanliness of Medical Devices

7

Visibly Clean & Device Design

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

11/16/2010

ASTM: Cleanliness of Medical Devices

8

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)**

11/16/2010

ASTM: Cleanliness of Medical Devices

9

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.**

11/16/2010

ASTM: Cleanliness of Medical Devices

10

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.

11/16/2010

ASTM: Cleanliness of Medical Devices

11

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.

11/16/2010

ASTM: Cleanliness of Medical Devices

12

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**

11/16/2010

ASTM: Cleanliness of Medical Devices

13

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.

11/16/2010

ASTM: Cleanliness of Medical Devices

14

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 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)

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

Part 5: Test soils and methods for demonstrating cleaning efficacy (ISO/TS 15883-5:2005)

11/16/2010

ASTM: Cleanliness of Medical Devices

15

Standard Test Methods

Part 5: Test soils and methods for demonstrating cleaning efficacy (ISO/TS 15883-5:2005)

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

11/16/2010

ASTM: Cleanliness of Medical Devices

16

Standard Test Methods

Part 5: Test soils and methods for demonstrating cleaning efficacy (ISO/TS 15883-5:2005)

- 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).

11/16/2010

ASTM: Cleanliness of Medical Devices

17

Moving Forward

Part 5: Test soils and methods for demonstrating cleaning efficacy (ISO/TS 15883-5:2005)

Revision of Part 5:

- 1. Artificial Soil (organic)**
- 2. Quantitative Endpoint**
- 3. Standard Instrument Test Loads**
- 4. [Need for relevant verification tests]**

11/16/2010

ASTM: Cleanliness of Medical Devices

18



11/16/2010

ASTM: Cleanliness of Medical Devices

19