The Fast Changing World of Reusable Device Processing

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Experience:

- M.S. and B.S. in Microbiology
- Senior Manager of Technical Consulting/Senior Scientist (NL for 17 years)
- Active committee member of many working groups with the International Organization for Standardization (ISO), Association for the Advancement of Medical Instrumentation (AAMI), and American Society of Testing and Materials (ASTM).

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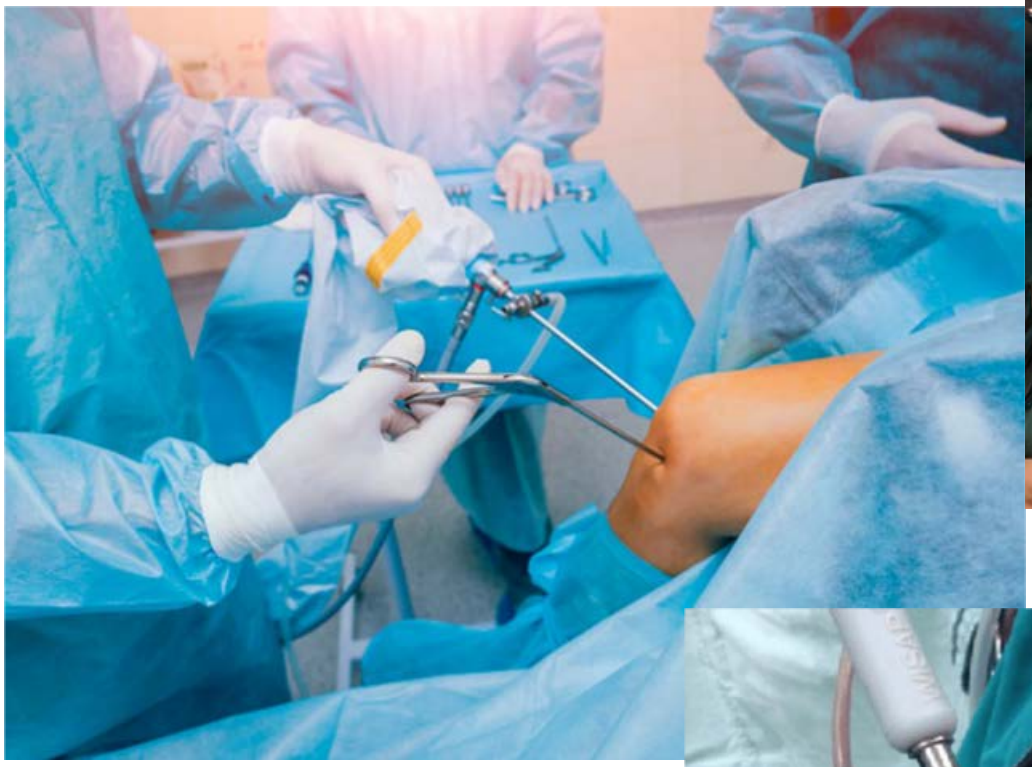

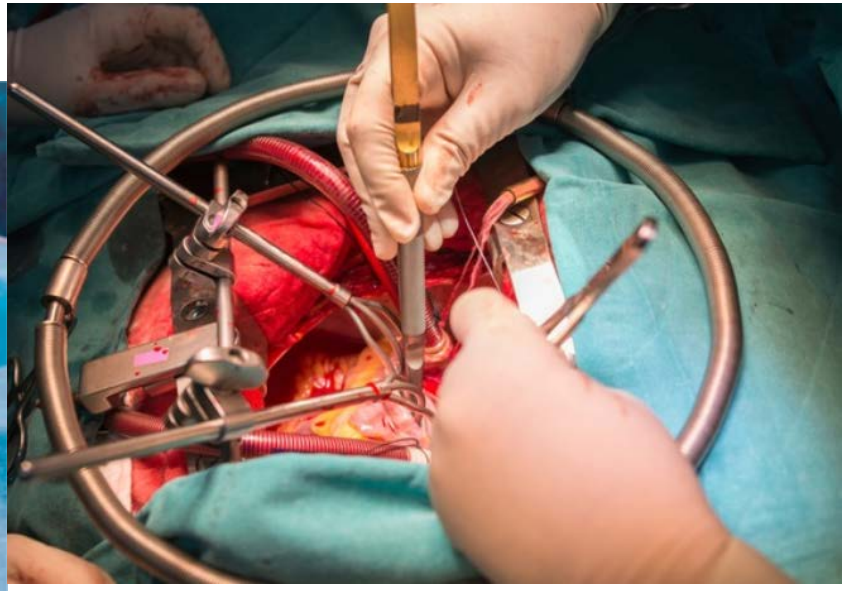

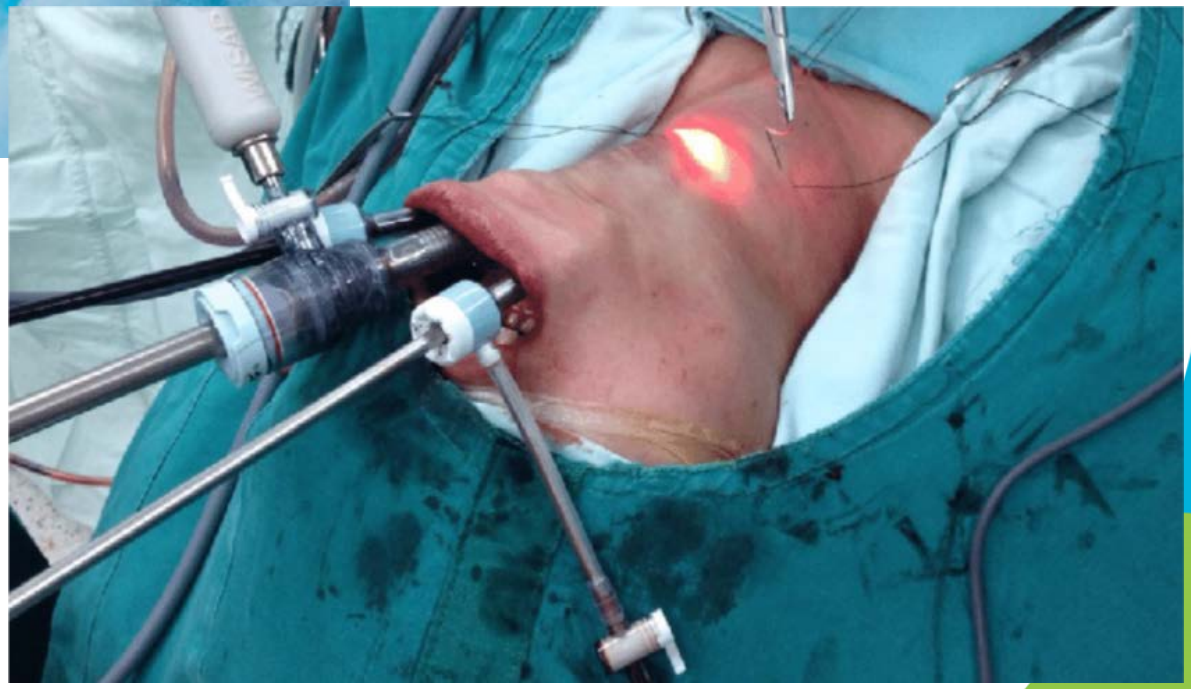

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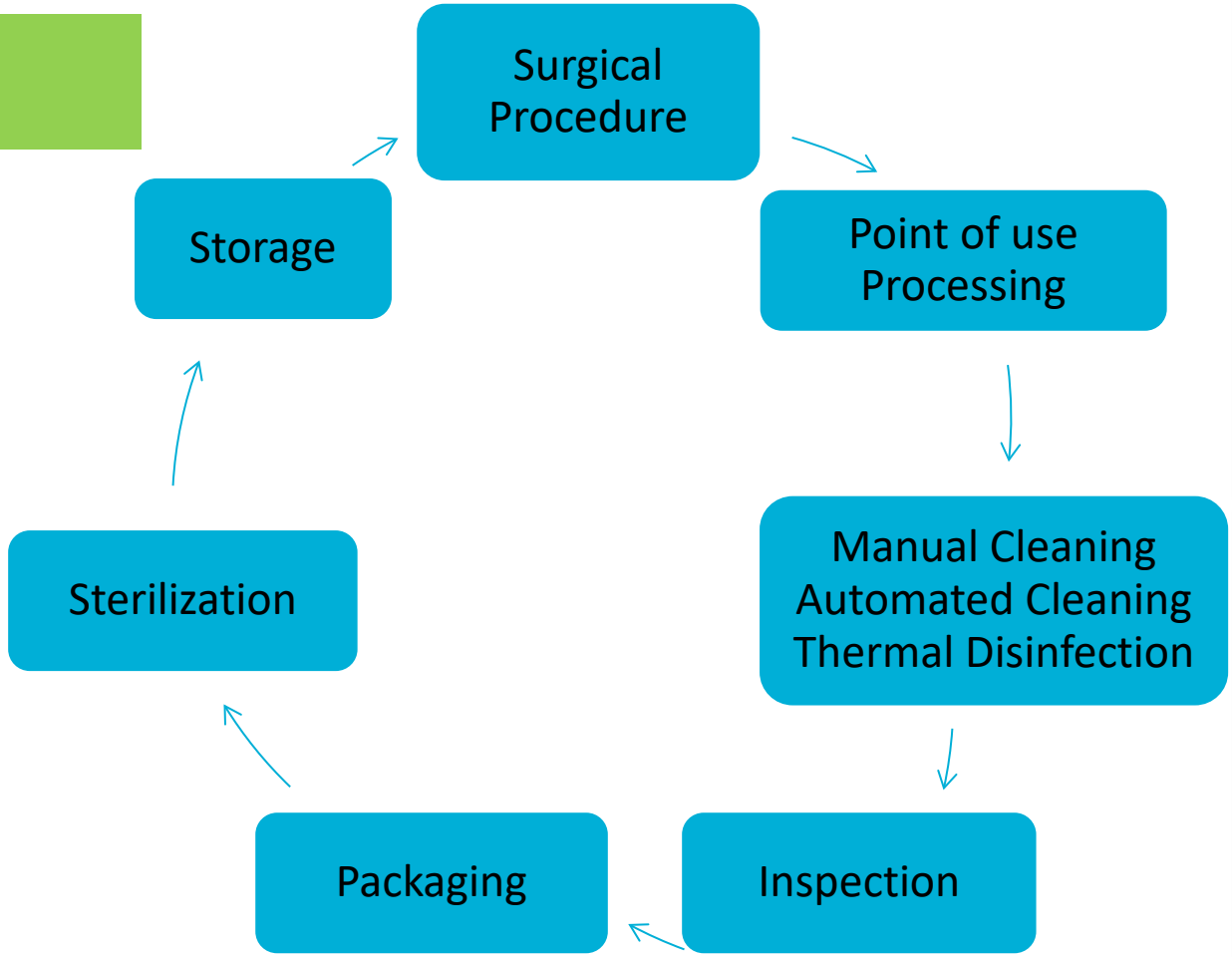
Processing Cycle (for critical devices)

What do we validate?



Performed at Health Care Facilities

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Agenda

New regulatory information

Challenges to medical device manufacturers

How medical device manufacturers can save time and money and meet regulatory requirements

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New Regulatory Information

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New Regulatory Information

EU MDR

ISO 17664-1 and ISO 17664-2

ISO 15883-1 and ISO 15883-5

AAMI ST98

AAMI TIR12

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MDR Information

EU MDR (Regulation (EU) 2017/745) consolidates and replaces the MDD 93/42/EEC.

MDR is an extensive and detailed document encompassing many important rules that will be new to medical device manufacturers, specifically involving reusable devices on the market.

MDR Processing of Reusable Medical Devices – 1/2

New classification of reusable medical device - Class 1r. Annex VIII, Chapter III, 5.2 Rule 6

If the device is reusable, information on the appropriate processes for allowing reuse, including **cleaning**, **disinfection**, packaging and, where appropriate, the validated method of **sterilization** appropriate to the Member State(s) where the device is placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses. Annex I 23.4 (n)

An indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements. Annex I 23.4 (o)

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MDR Processing of Reusable Medical Devices – 2/2

Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or sterilization. Chapter II, 11.2

In the case of reusable surgical instruments, to the aspects related to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use. Article 52 7 (c)

Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilization or refurbishing between uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device. Annex VI Part C 4.10.

UDI shall bear, if applicable, restricted number of reuses. Annex VI Part B 17

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MDR: Definitions in Relation to Processing Reusable Medical Devices

Medical device – any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used… for human beings … intended for cleaning, disinfection or sterilization of devices as referred to in Article 1 (4)…

MDR Article 2 (1)

Reusable surgical instrument - … intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device …intended … to be reused after appropriate procedures such as cleaning, disinfection and sterilization ….

MDR Article 52

Accessory for a medical device – an article which… is intended by its manufacturer to be used together with one or several particular medical deices

MDR Article 2 (2), Article 4 1.

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ISO 17664-1 and ISO 17664-2

ISO 17664-2:Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices

ISO 17664-1:Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices

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ISO 15883-1 and ISO 15883-5

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

ISO 1583-5:Washer-disinfectors - Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

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AAMI ST98

AAMI ST98: Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices

- Previous AAMI TIR30
- Now is going to be a standard
- New information on sample sizes
- Will go through one more comment period

AAMI TIR12

AAMI TIR12: Designing, testing and labeling reusable medical devices for processing in health care facilities: A guide for medical device manufacturers

- Addition of examples of cleaning and categorization of devices for cleaning

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Challenges to Medical Device Manufacturers

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Challenges to the Medical Device Manufacturer

Lack of harmonization in the US vs OUS regarding the requirements of in relation to processing reusable medical devices.

MDMs are missing information on acceptance criteria for each of the steps (i.e. soiling, analyte values, log reduction and specific organism requirements for disinfection) meeting national requirements.

Acknowledged banning of specific devices as non-processable (due to wear or contact to risk tissue e.g. cutting or scraping blades, drills or components wearing off)

Missing data on shelf life testing including biocompatibility after full life cycle processing.

Biocompatibility in general of materials that may leach substances due to processing.

Challenging geometries (lumens, disassembly/reassembly)

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Challenges to the Medical Device Manufacturer

Historical lower surveillance on processing of reusable medical devices (less Notified Body involvement).

No validation of processing procedures.

Lack of technical documentation.

Missing thorough risk assessment in relation to each step of the processing steps (i.e. point of use, cleaning, disinfection, maintenance, packaging, sterilization).

Lack of consistency in the IFU and state of the art descriptions of the cleaning, disinfection, and sterilization processes.

No assurance of available equipment and cycles in health care facilities .

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Challenges to the Medical Device Manufacturer – Validations Needed

A manufacturer can only publish a process in an IFU if:

- The process was validated (no process allowed to be specified that was not validated on the device)
- Robust rational is written for product adoption

All processes and all equipment used are specified in:

- ISO 17664
- ISO 15883
- ISO 17665
- ISO 11135
- ISO 11607

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How Medical Device Manufacturers can save Time and Money and Meet Regulatory Requirements

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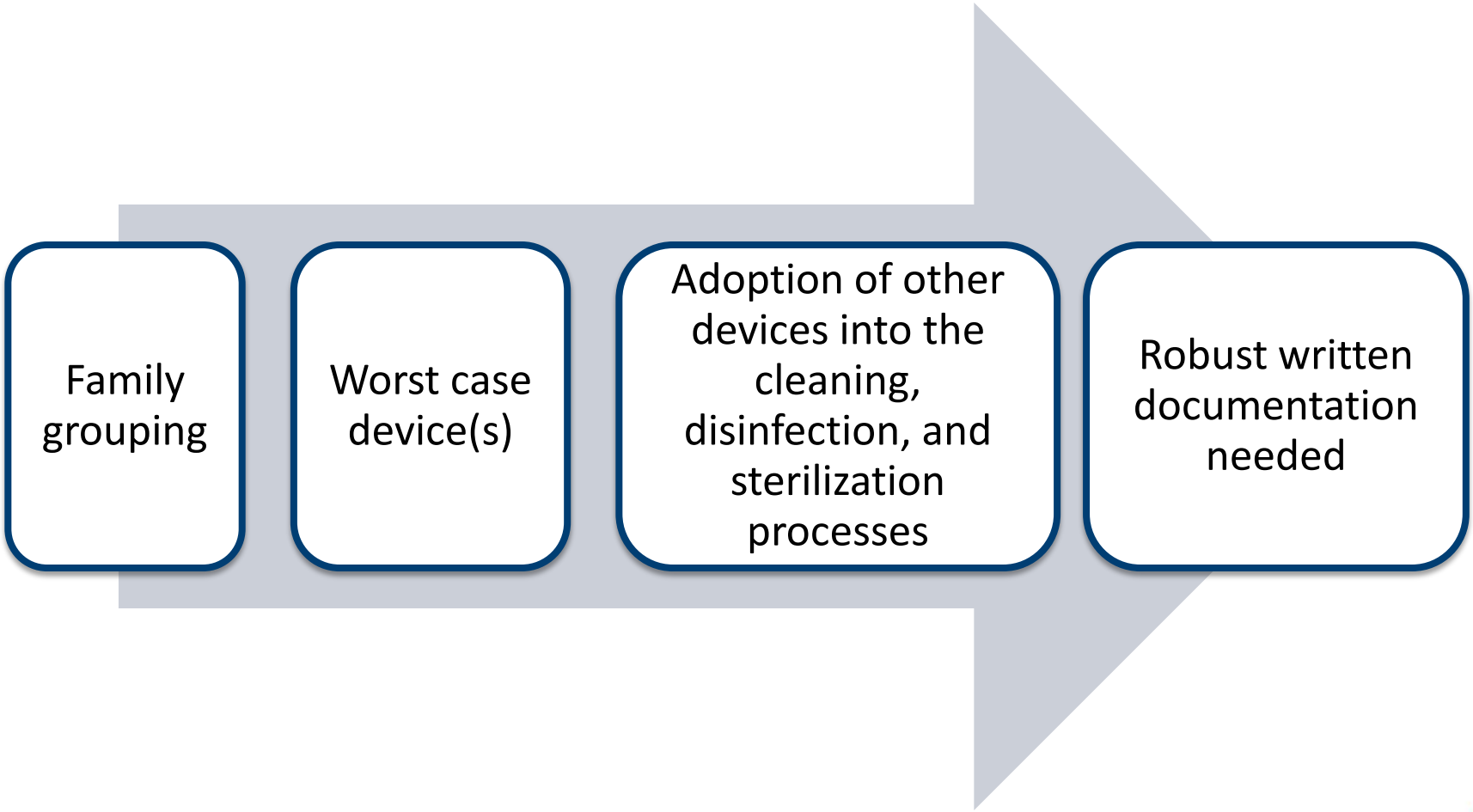
How to Save Costs and Time and Meet Regulatory Requirements



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Family Grouping and Worst Case Device Standard Information

"If a manufacturer supplies a number of different medical devices that share common attributes, then validation studies may be performed as a product family. If this approach is taken, the medical device manufacturer shall demonstrate commonality between the different medical devices and the validation studies shall address the worst case attribute(s) of the product family."

- ISO 17664: 2017, 4.3

Determining Master Products - Address the worst-case features, or attributes, of the products in the family. Select a "master product" that constitutes a worst-case challenge and will represent the product family.

- AAMI TIR12:2010

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Family Grouping and Worst Case Device Standard Information

Detailed attributes to determine family grouping and worst case device(s):

- Design
- Material
- Weight

- ISO 17665-3:2014/(R)2016

"A product family is a collection of products determined to be similar or equivalent for validation purposes…The review for product equivalence can be conducted within each product family or processing category. Alternatively, a worst-case product or representative member can be selected for the qualification study."

- ISO 11135:2014

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Family Grouping and Worst Case Device Plan

All devices, which includes accessories, need to be grouped into family and worst case devices (or trays of devices).

Validate worst case device(s)

All devices deemed less challenging to clean, disinfect, or sterilize can be adopted under those validated parameters.

MDR Chapter 1, Article 1, 1.

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Family Grouping: Cleaning Validation

Device Use: Group families by similar use during the surgical procedures

Size and Challenge Features: Group families of similar size and challenge features

Material Type: Materials hold onto residue differently and, therefore, should be grouped accordingly

Devices courtesy of Arthrex, Inc.

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Difficult Design Features for Cleaning

May harbor unwanted organisms and/or organic material

- Braided cables
- Aluminum based metals
- Pliable materials such as:
  - Silicone
  - Rubber
  - O-rings
- Textured surfaces
- Hinges
- Springs
- Lumens
- Channels
- Inaccessible cracks and crevices

Devices courtesy of Arthrex, Inc.

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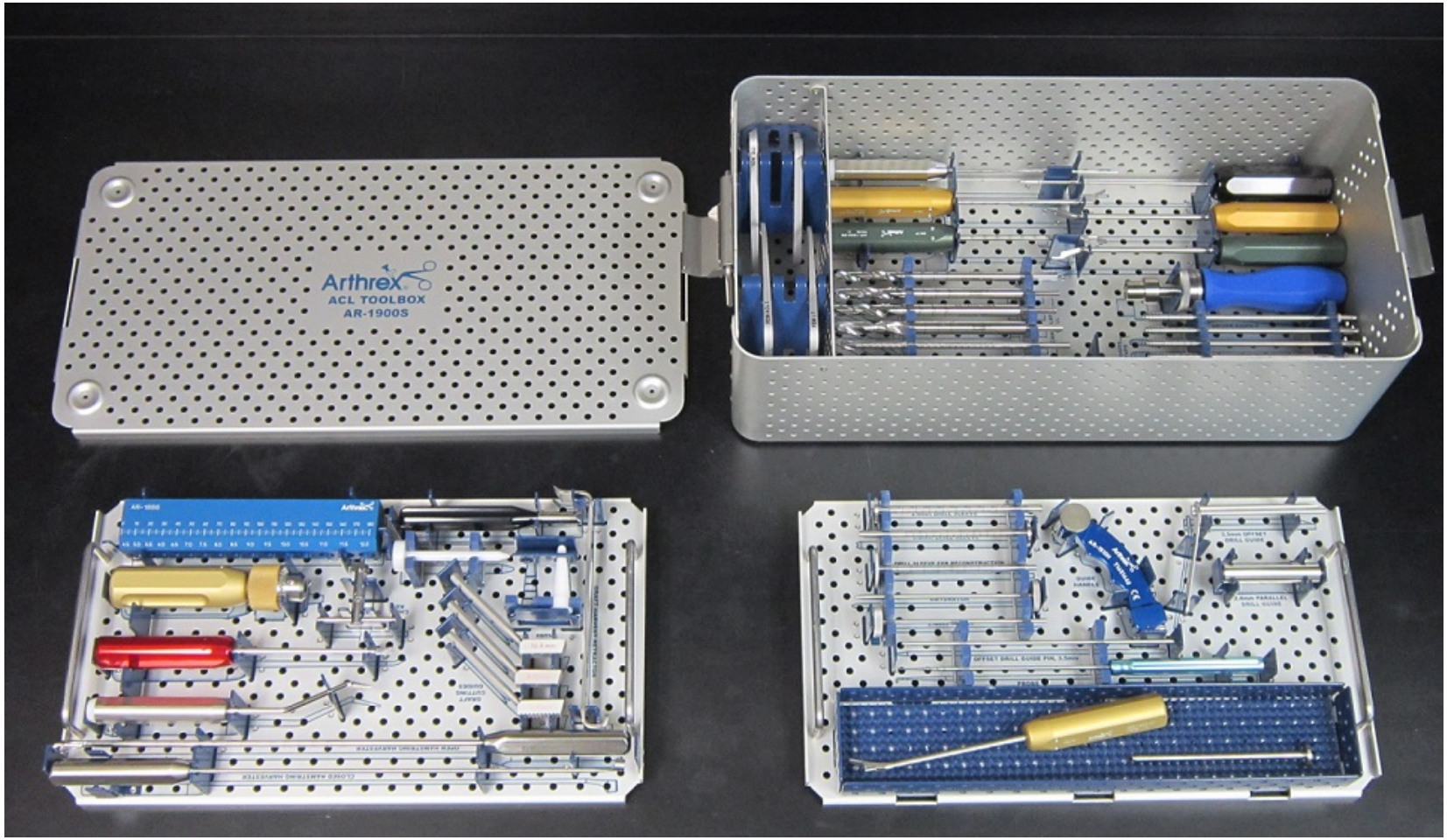
Cleaning Validation: Select Worst-case Device(s)



Devices courtesy of Arthrex, Inc.

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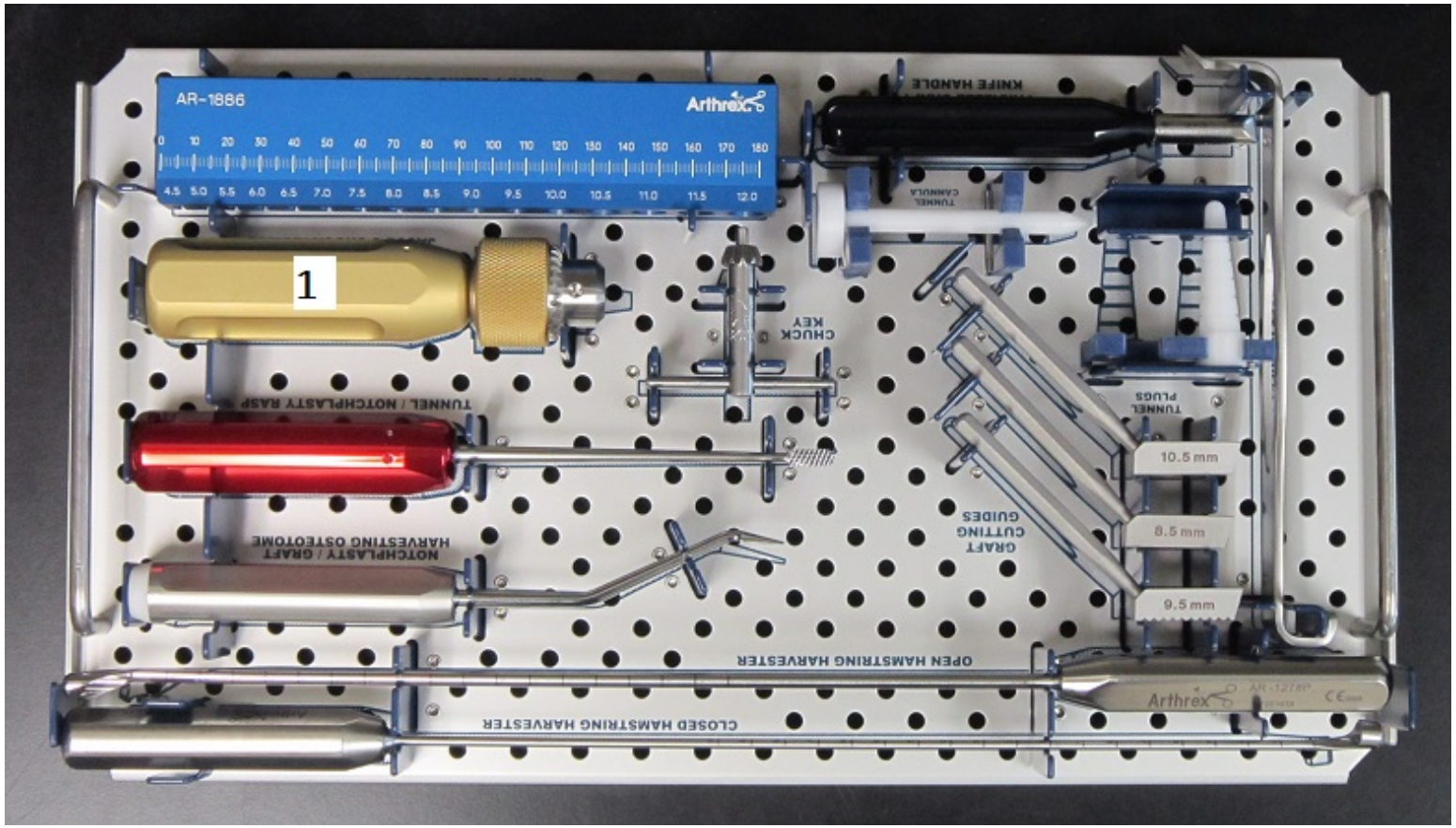
Cleaning Validation Example: Worst Case Device



Devices courtesy of Arthrex, Inc.

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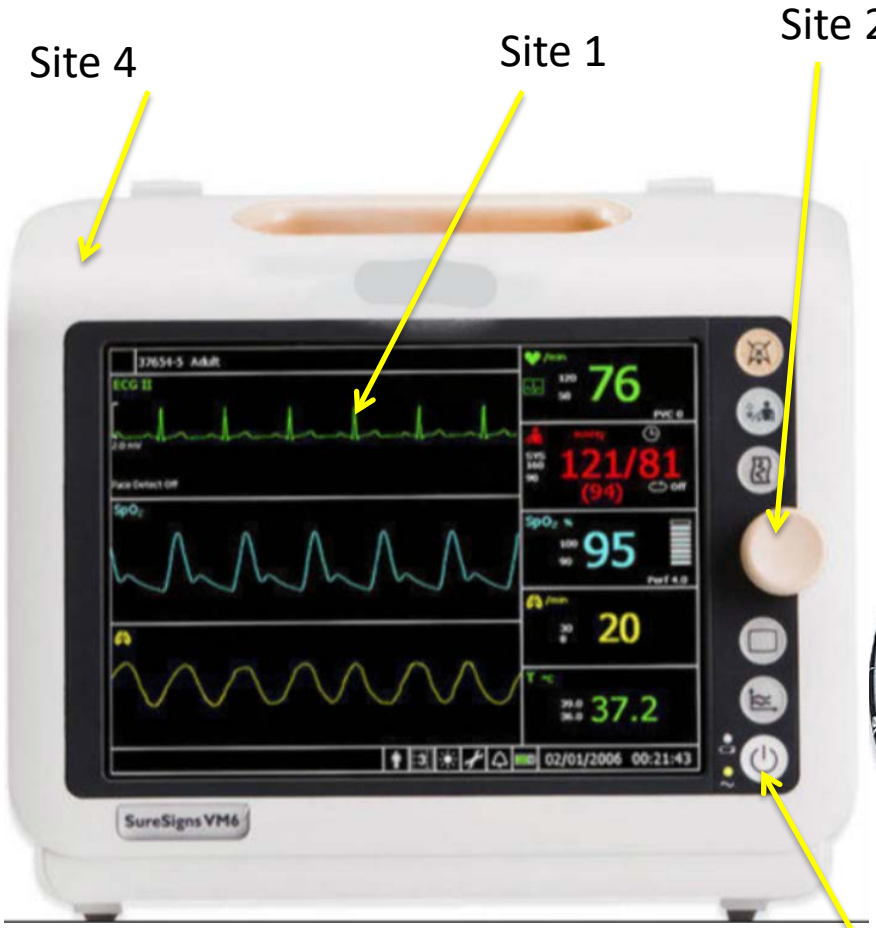
Cleaning Validation: Selecting Sites



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Family Grouping: Sterilization Validation

Determine a worst case tray by:

- Weight
- Mass
- Complexity of devices
- Volume to vent ratio
- The ability of the tray and all of the devices to allow air removal and steam penetration

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ISO 17664: 2017 Cleaning

Validated method of manual cleaning and at least one validated automated cycle using a washer-disinfector must be specified.

- Accessories
- Chemical and quantities
- Water quality
- Chemical residues
- Temperatures, concentration, and exposure times
- Techniques including rinsing

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End of Life Testing

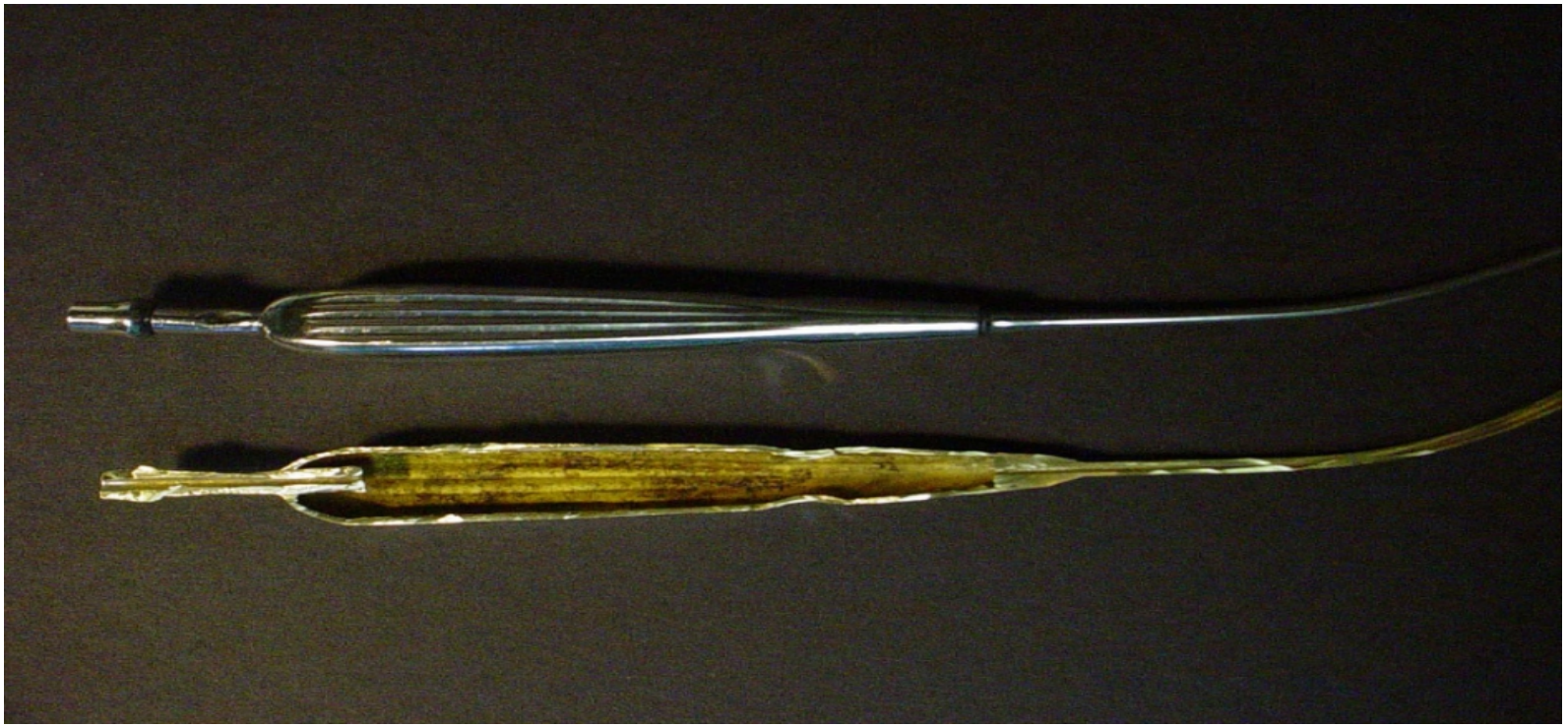

Image courtesy of University of Michigan Health System

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End of Life Testing: Standards and Guidance

MDR

- Information shall be provided to identify when the device should no longer be reused(i.e. signs of material degradation or the maximum number of allowable reuses)

ISO 17664:2017

- MDM must determine if processing leads to a degree of degradation that will limit the useful life
- MDM must determine the number of processing cycles or other indication of the end of it's life

FDA Guidance Document: 2015, (R) 2017

- Labeling should inform how many times the device can be reused based on testing
- Provide a mechanism or method to ascertain whether the device has exceeded its use life and if the device is functioning properly

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Medical Device Manufacturer's Responsibilities under MDR

Responsible for ensuring cleaning, disinfection, and sterilization instructions are appropriate and are validated

Notified Bodies review the technical files, including validations, to confirm they comply with MDR and meet the requirements specified in international standards and industry guidance.

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Gap Analysis

Medical Device Manufacturers should conduct gap analyses and perform appropriate validations.

Review all technical files for current Class 1r devices

- Identify any missing information
- Identify any testing that does not currently meet regulatory compliance
- Identify product families, worst case device(s), and adoption of all other devices

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Conclusion

Time for Class Ir devices is virtually running out:

- There is no grace period for Class Ir devices. Deadline May 2020.
- Missing processing validations are currently a bottle neck
- If current technical documentation is missing this will take time and laboratory resources

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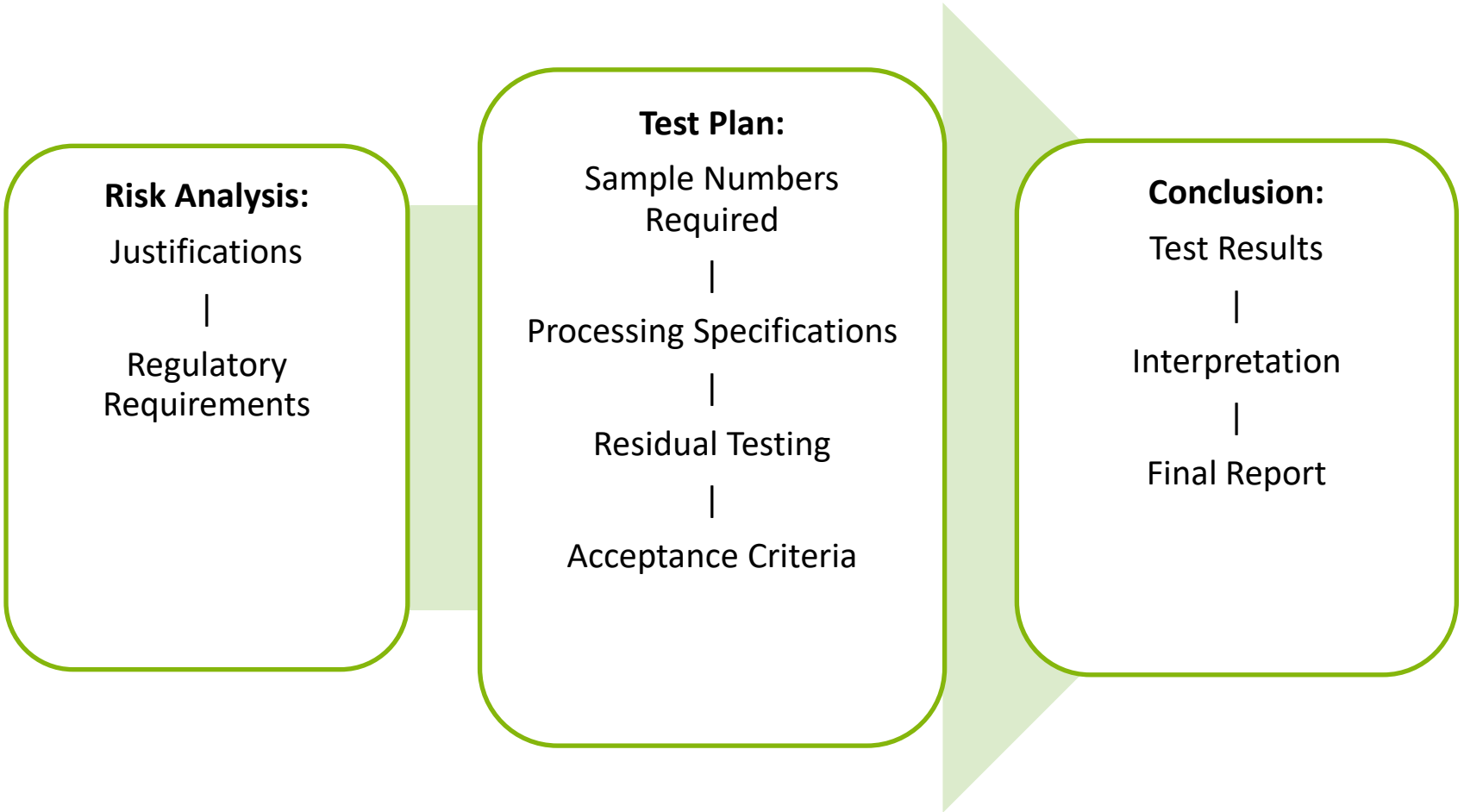
Summary of Processing Validations for Reusable Medical Devices



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References on Nelson Laboratories Website

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- Disinfection Validation- High, Intermediate & Low Level: https://www.nelsonlabs.com/Test/Disinfection-Validation-High-Intermediate-and-Low-Level
- Sterilization validations of reusable medical devices: https://www.nelsonlabs.com/Test/Sterilization-Validations-Device-or-Trays
- Device Life-Cycle Testing: https://www.nelsonlabs.com/Test/Device-Life-Cycle-Testing

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Reference Standards

Guidance for Industry and FDA Staff – Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – March 17, 2015

AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

AAMI TIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

ANSI/AAMI TIR55: 2014 (WG85) – Human Factors Engineering for processing medical devices

AAMI TIR34: 2014 (WG 95) – Water for Reprocessing of Medical Devices

AMSI/AAMI ST81: 2004 (WG12) – Sterilization of Medical Devices, Information to be provided by the manufacturer for the processing of resterilizable medical devices.

ANSI/AAMI ST79:2017 (WG 40) – Comprehensive guide to Steam Sterilization and sterility assurance in health care facilities

AAMI ST90: not published (WG86) – Processing of health care products - Quality management systems for processing

ANSI/AAMI ST58: 2013 (WG61) – Chemical Sterilization and high level disinfection in health care facilities

ANSI/AAMI ST91: 2015 (WG84) – Comprehensive guide to flexible and semi-rigid Endoscope Reprocessing in health care facilities

Reference Standards

ANSI/AAMI ST41:2008 Ethylene oxide sterilization in health care facilities: Safety and effectiveness

ANSI/AAMI ST77:2013 Containment devices for reusable medical device sterilization

ANSI/AAMI ST67:2011 Sterilization of health care products – Requirements for products labeled “STERILE”

ASTM WK31799 – Designing Medical Devices for Cleanability

ASTM WK33439 – Standard test soils for validation of cleaning methods for reusable medical devices

ISO 17664:2004 Sterilization of medical devices – information to be provided by the manufacturer for the processing of resterilizable medical devices

ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 17665-2:2009 Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1

ISO 17665-2:2013 Sterilization of health care products -- Moist heat -- Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization

ISO 15883: series (WG13) – Washer-disinfectors

Reference Standards

ANSI/AAMI/ISO 14160:2011 (WG10) – Sterilization of health care products - Liquid Chemical Sterilizing agents

ISO 14937: Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices

ISO 11135: Sterilization of health care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices

ISO 10993-7: Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residues

EN 285: Sterilization - Steam sterilizers - Large sterilizers

EN 556-2: Sterilization or medical devices – Requirements for medical devices to be designated “STERILE” – Requirements for aseptically processed medical devices

PDA Technical Report No. 1: Validation of moist heat sterilization processes: Cycle design, development, qualification, and ongoing control

Thank You!

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