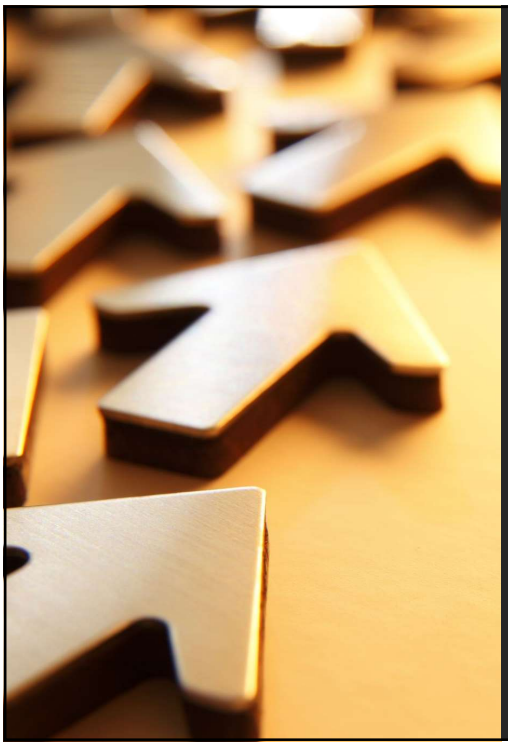

Everything Has an IFU – How do we follow it?

Mary Ann Drosnock, MS, CIC, CFER, RM (NRCM), FAPIC
Director of Clinical Education
Healthmark Industries &
Co-chair of AAMI ST91

1

Disclosure

- I am an employee of Healthmark Industries Fraser, Michigan USA
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- No compensation has been received for this presentation or for travel to and from the seminar
- All opinions are those of the presenter
- This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

2

Healthmark Policy & Philosophy

Healthmark's Policy

Is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost-effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.

Healthmark's Philosophy

It is more than just buying a product or running a test.

It is about having clinically relevant, evidence-based, products. Along with support for Healthmark products both clinically and educationally with the understanding that an educated customer is the *Patients Best Customer.*

3

Objectives

1

HOT TOPICS

Understand the legal issues when an IFU is not followed

- Do no harm

2

Review all relevant standards and guidelines that pertain to Instructions for Use for medical device used in a medical device reprocessing department

3

Introduce a template for the IFU that aligns with ISO 17664

4

Overview of Program

- Instructions For Use - known as the IFU or MIFU
- This document gives the sterile processing professional the information needed to clean, assemble and terminally process the medical device in compliance with the validated measures prescribed by the device manufacturer
- If the IFU is not properly followed, the device likely will not be safe for use on the next patient
- IFU = validated set of instructions that are submitted to the FDA for clearance
  - How do changes affect that?

5

Objective # 1- Understand the legal issues when an IFU is not followed

- Define what IFU means
- Do no Harm
- Look at the good, the bad and The ugly of not following the IFU
- Legal
- Provide the best outcome
- Doing the process the right way every time

- Auditors are asking you, are you following the IFU?
  - Where is it kept?
  - Electronic or printed?
  - Most up to date?
  - How to deal with changes?
  - Are IFUs readily accessible?

6

What is an IFU?

Is a D.F.U and M.I.F.U. the same as an I.F.U.?

- **I**nstructions **f**or **U**se (IFU)
- **D**irections **f**or **U**se (DFU)
- **M**anufactures **I**nstruction **f**or **U**se (MIFU-Canada)
  - Yes, they are the same

ANSI /AAMI ST 79

- **2.55 instructions for use (IFU): Written** recommendations provided by the manufacturer that provide instructions for operation and safe and effective use of its device.

7

FDA Guidance to Manufactures as of 3/17/2015

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf) issued April 1996.

The draft of this document was issued on May 2, 2011.

For questions regarding devices regulated by the Center for Devices and Radiological Health, contact the Infection Control Devices Branch (DICB) at (301) 796-5580. For questions regarding devices regulated by the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Office of Device Evaluation
Center for Biologics Evaluation and Research

8

Following the IFU

- A validation of the cleaning and sterilization procedure by the manufacturer
- For cleaning: it is a procedure to remove residual patient soil and must be completed by the device manufacture
- This validation should be part of the submission package and will be examined by the U.S. Food and Drug Administration (FAD) during its review
- The goal of cleaning validation is to prove that when the instructions in the IFU are followed, the residual soil levels on the device will have been reduced to acceptable levels
- It is important to note that completion of a successful cleaning validation alone does not ensure that devices reprocessed by the end user are clean
- The end user's ability to perform the cleaning by understanding and following all steps in the IFU is vital

9

Reprocessing of Medical Devices : Who is responsible for What ??

- **Manufactures** validate that an instrument can be reliably cleaned and sterilized / disinfected and is therefore reusable.
- **Users** verify that cleaning / sterilization equipment is working, and that in-hospital cleaning / sterilization methods are consistently performed

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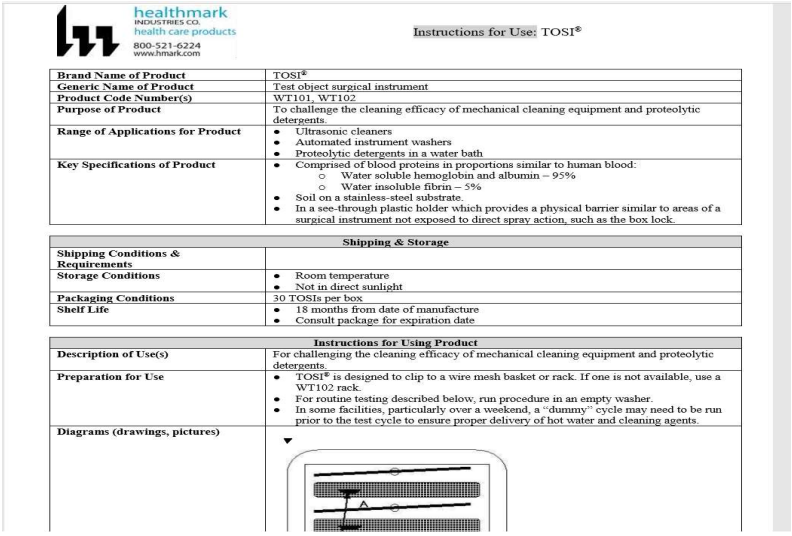
Example of an IFU



healthmark INDUSTRIES CO. health care products
800-521-6224
www.hmark.com

Instructions for Use: TOSI®

Brand Name of Product	TOSI®
Generic Name of Product	Test object surgical instrument
Product Code Number(s)	WT101, WT102
Purpose of Product	To challenge the cleaning efficacy of mechanical cleaning equipment and proteolytic detergents.
Range of Applications for Product	• Ultrasonic cleaners • Automated instrument washers • Proteolytic detergents in a water bath
Key Specifications of Product	• Comprised of blood proteins in proportions similar to human blood: ○ Water soluble hemoglobin and albumin – 95% ○ Water insoluble fibrin – 5% • Soil on a stainless-steel substrate. • In a see-through plastic holder which provides a physical barrier similar to areas of a surgical instrument not exposed to direct spray action, such as the box lock.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	• Room temperature • Not in direct sunlight
Packaging Conditions	30 TOSIs per box
Shelf Life	• 18 months from date of manufacture • Consult package for expiration date

Instructions for Using Product	
Description of Use(s)	For challenging the cleaning efficacy of mechanical cleaning equipment and proteolytic detergents.
Preparation for Use	• TOSI® is designed to clip to a wire mesh basket or rack. If one is not available, use a WT102 rack. • For routine testing described below, run procedure in an empty washer. • In some facilities, particularly over a weekend, a "dummy" cycle may need to be run prior to the test cycle to ensure proper delivery of hot water and cleaning agents.
Diagrams (drawings, pictures)	

- An **IFU** is a document outlining how the product is used
  - It is provided by the manufacturer and gives directions which must be followed
  - Step-By-Step
  - Can be used as a blueprint to help form a competency where you work

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Why must I follow the IFU?

- Legal
- Provides the best outcome
- Doing the process the right way each and every time
- TJC and others are asking you about the IFU
- You should have them readily accessible for staff
- The IFU is ever changing
- Gives you data and information to help purchase the correct "tools for that job"
- Be a "label reader"

12

NOT FOLLOWING THE IFU

- Healthcare professionals do not do a good job of following the **I**nstructions **F**or **U**se
- or should it be called
- Instructions Forgotten Use
- Let us look at the facts

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Survey of 334 OR Nurses

- Poster: AORN 2014 Annual Meeting, Perioperative Nurse's Knowledge of the Cleaning and Decontamination Process of Surgical instruments - Mary A Hillanbrand, DNP, RN, Major, USAF, NC, CNOR
- Some of the results:
  - 80% have a policy on Point of Use Cleaning
  - 23% maintain manufacturers IFU for use in the surgical suite
  - 59% initial orientation <1 day in decontamination area of OR
  - 64% initial orientation < 1 day in decontamination area of SPD
  - 28% **DO NOT KNOW** inadequate cleaning/sterilization of OPHTHALMIC INSTRUMENTS has been linked to most cases of TASS
  - 20% **DO NOT KNOW** instruments should be cleaned at the point of use with a soft lint-free gauze moistened with STERILE WATER
  - 28% **DO NOT KNOW** the initial cleaning of surgical instruments **BEGINS** at the point of use at the surgical field

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The Real Problems Highlighted

- June 8-9,2011 – FDA Summit on Clean
  - Report by Smith and Nephew on following concerning the shaver and following the cleaning steps in the IFU
    - 12 Facilities practices were audited
      - 78 devices (shavers) were audited (observed)
      - None of facilities complied with all cleaning instructions found in the IFU
      - 95% of devices had observations of residue on internal surfaces
      - Majority of residue in two areas (lumen step, drive fork area)
      - Hawthorne effect

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Endoscopes Poster - IAHCSMM

- Endoscope Reprocessing Adherence to Guidelines
  - 57 % did not brush all channels and components
  - 55% did not dry with force air
  - 22% leaked tested with sudsy water
  - 10% skipped final wipe down
  - 45% missed multiple steps
  - 99% missed 1 or more steps or done incorrectly
  - 1% all steps completed correctly
- Hawthorne effect

Reference: Information taken from a poster presentation at IAHCSMM Annual Conference. May 5-8,2013. Ofstead & Associates – Endoscope Reprocessing : evaluating Guideline Adherence

16

5 – Training and IFU

Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm

5

Insufficient training of clinicians on operating room (OR) technologies can result in use errors that lead to prolonged surgery, complications that require additional treatment, and even serious patient injury or death.

Errors can result if training:

- Is not provided or is insufficient or ineffective (e.g., if it does not provide an assurance of competency)
- Does not include all relevant team members, including physicians, per diem staff, and new hires, as well as regular staff
- Is not completed by all relevant team members before they use a device in clinical practice

ECRI Institute estimates that approximately 70% of accidents involving a medical device can be attributed to user error or the technique of use. Many of these incidents could have been avoided if users had a better understanding of the instructions for use and device operation.

Facilities should make training a key part of the acquisition process for new OR technologies, as well as an ongoing

17

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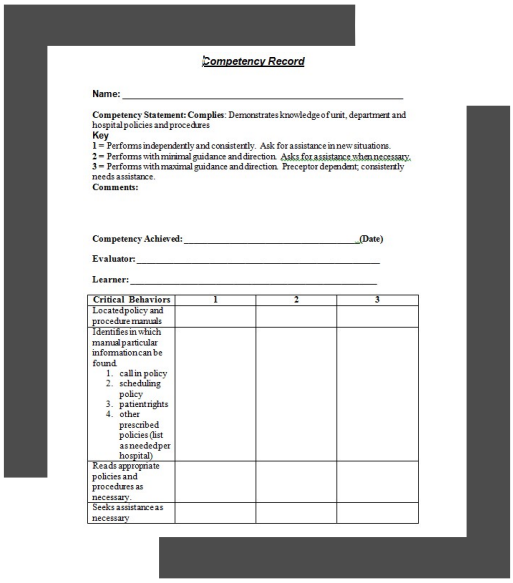
18



Competency Record

Name: _____

Competency Statement: Complies: Demonstrates knowledge of unit, department and hospital policies and procedures

Key

1 = Performs independently and consistently. Ask for assistance in new situations.

2 = Performs with minimal guidance and direction. Asks for assistance when necessary.

3 = Performs with maximal guidance and direction. Preceptor dependent; consistently needs assistance.

Comments:

Competency Achieved: _____ **(Date)**

Evaluator: _____

Learner: _____

Critical Behaviors	1	2	3
Located policy and procedure manuals			
Identifies in which manual particular information can be found. 1. call in policy 2. scheduling policy 3. patient rights 4. other prescribed policies (list as needed per hospital)			
Reads appropriate policies and procedures as necessary.			
Seeks assistance as necessary.			

Dirty Instruments

- Surgeons post dirty instruments on Facebook
  - SPD staff also
- After a two-day inspection in late August, the state Department of Licensing and Regulatory Affairs (LARA) on Thursday cited the medical facility for violating the Public Health Code by failing to ensure adequate training for sterilization workers. The state issued eight violations and gave the medical facility 60 days to fix them or face possible discipline including license suspension.*
- Issue again in fall of 2018

* Detroit News; 8/25/2016 ; DMC, managers trade blame over dirty instruments

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THE IMPORTANCE OF TRAINING

The hospital also did not ensure those employees were competent in disinfection practices, the report said. For example, the inspectors found nurses using a cleaning product without being aware that the liquid had to remain on a surface for three minutes to work.*

*http://www.latimes.com/business/la-fi-infections-ucla-cedars-hospitals-20160515-snap-story.html

For example, at hospital xxx, inspectors found that employees were not following safety standards as they packed trays of surgical instruments for sterilization in a machine. They found instruments ready to be delivered to the operating room tightly packed in a tray, with employees not opening devices like forceps and clamps at their hinges so that sterilizing fluid could get to all surfaces.*

**http://www.latimes.com/business/la-fi-infections-ucla-cedars-hospitals-20160515-snap-story.html

20

Legal - Documentation of what you do

- "In court, the medical record is the care rendered"
- "Jurors view good record keeping as an indicator of good care — poor documentation can create an aura of poor care and damage the credibility of the healthcare providers."
- ***If it wasn't documented, it wasn't done***
- Walk your talk in your Policy

- http://www.outpatientsurgery.net/surgical-facility-administration/avoid-medical-malpractice/how-to-survive-a-med-mal-suit--orx-proceedings-13?utm-source=tod&utm-medium=email&utm-campaign=tips

21

Do it right each time, sure we do

While most hospitals have policies in place to prevent health care-associated infections, clinicians often fail to follow evidence-based guidelines established to prevent these infections, according to research from Columbia University School of Nursing published in the American Journal of Infection Control.

http://www.medicalnewstoday.com/releases/272314.php

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Following the IFU is not easy

- Some feel they are not practical
- Time is a factor
- Staff do take short cuts
- Pressure to get the medical device clean, assembled, sterilized
- Medical facility takes on the legal aspect and liability when they skip steps in the process
- Need for monitoring and testing of the cleaning process

23

FDA Issues a Safety Communication on the Dangers of Monopolar Laparoscopic Surgery. Poor Insulation testing harms patients

FDA Safety

FDA Issues a Safety Communication on the Dangers of Monopolar Laparoscopic Surgery.[1]

All health care professionals involved in surgical procedures are warned:

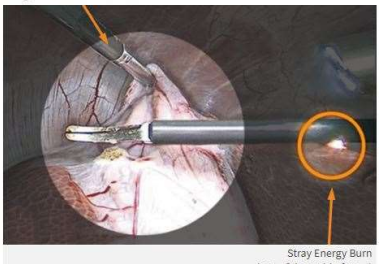
Monopolar energy use can directly result in **unintended patient burns from capacitive coupling and intra-operative insulation failure.**[1]

It's not the technique, it's the technology!

Traditional monopolar laparoscopic instruments cannot prevent stray energy from causing patient burns (due to capacitive coupling and intraoperative insulation failure).

Every 90 minutes a patient is severely burned and 1-2 people die every day from preventable stray energy burns.[2]

Surgeon's Field of View



Stray Energy Burn
(Out of the Field of View)

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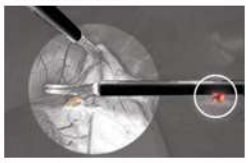
Testing Insulation

FDA Issues a Safety Communication on the Dangers of Monopolar Laparoscopic Surgery.

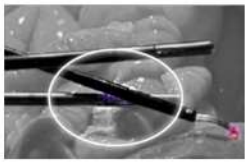
- The FDA recently issued a Safety Communication regarding capacitive coupling and intraoperative insulation failure and their risk of patient injury.
- Intraoperative stray energy burns are a more prevalent issue than many healthcare

INSULATION FAILURE*



- Evidence shows that a patient is injured by capacitive coupling or intraoperative insulation failure every 90 minutes in the USA.
- *Read the full FDA Press Release here.*

CAPACITIVE COUPLING*



Stray energy burns are completely preventable through the use of appropriate technology.

References

- Recommendations to Reduce Surgical Fires and Related Patient Injury: FDA Safety Communication
- https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm608637.htm
- Frequency and Severity of Stray Energy Burns
- https://www.encision.com/wp-content/uploads/2018/04/Frequency_and_Severity_of_Stray_Energy_Burns_MAR00032.pdf
- Martin, Moore, Tucker, Fuchshuber, Robinson., Quantifying Inadvertent Thermal Bowel Injury from the Monopolar Instrument. The Journal of Surgical Endoscopy. November 2016, Volume 30, Issue 11, pp 4776–4784.
- Nduka CC, Super PA, Monson JR, Darzi AW., Cause and prevention of electrosurgical injuries in laparoscopy. J Am Coll Surg. 1994;179(2):161-170.

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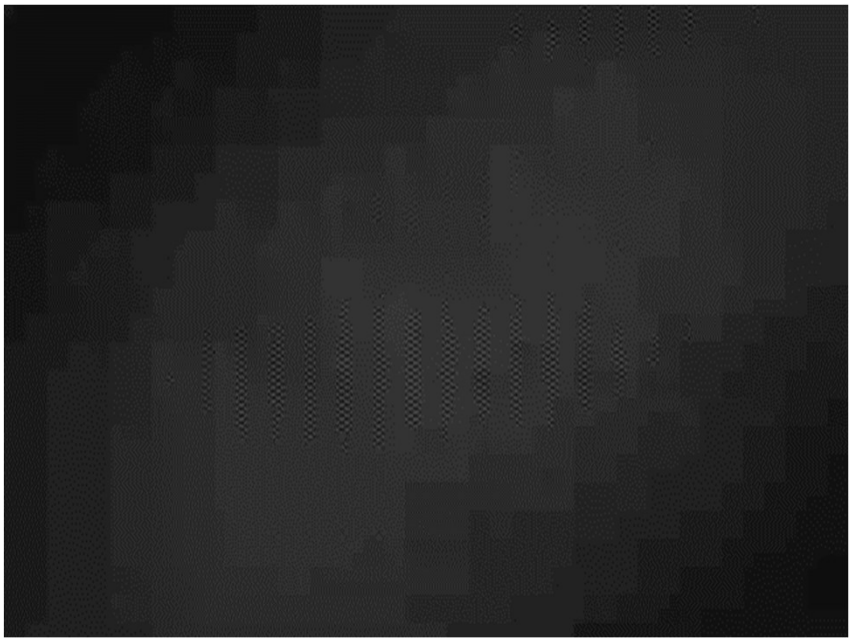
This can be prevented



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Preventing Surgical Burns

Find a solution - A product that solves the issue

- Some type of leak tester
- Read the IFU - MIS instruments
- Find clinically relevant & evidence-based products
  - Peer reviewed literature and non peer reviewed
  - Manufacture's research and guidance
  - Seek out all information
- Write a SOP
  - Make this a PQ function
  - Audit and record your work
- Team approach to the solution
  - Every person who touches this medical device has to be part of the solution
  - Physicians, surgical technicians, nurses, reprocessing staff, others

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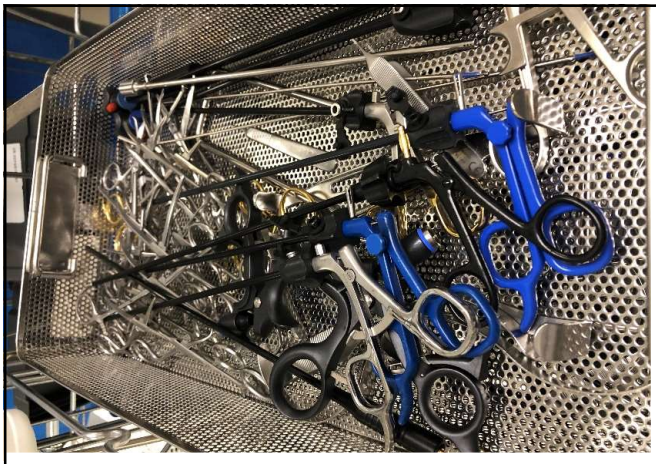
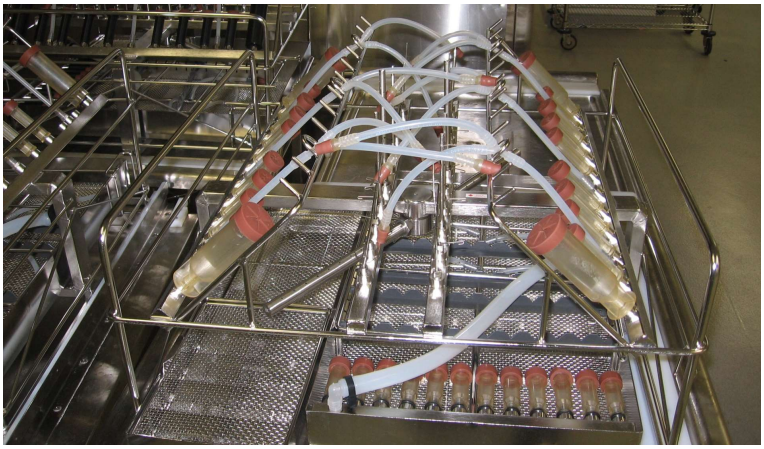


What is wrong with this picture?
Improper cleaning of these medical devices.

28



Olympus IFU *

- Automatic cleaning/disinfection procedure

Make sure that all instruments have been securely fixed to the unit's trays or baskets. Make sure that the instruments do not touch each other.

- For telescopes, use adequate instrument trays to fix the telescope.
- Instruments with lumens **must** be attached to special trays with irrigation devices or directly to the Luer-lock connectors of the machine.
- **Make sure that all lumens are sufficiently irrigated.** Check lumens for free passage before starting the procedure.
- Open all stopcocks.
- Open the jaws of hand instruments.
- Do not **overload** the washer/disinfector.
- To prevent corrosion, remove the instruments from the washer/ disinfector immediately after the automatic procedure has stopped.

*** Olympus: Instructions HiQ+; Intelligent Line Hand Instruments; W7052801_15 2018-02-27 en(US) ; © Copyright 2018 Olympus Winter & Ibe GmbH**

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Solution

- Read the IFU
- Pick the correct equipment
- Ensure that the equipment is working
- Train staff
- Document your work

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A Horror Story
We are told to follow the IFU

- **Would you go to the dollar store to buy your cleaning brushes for any medical device?**
- **Remember Bugs and Bad practice do not have any boundaries.**
- **Ask yourself this?**
- **Was harm done?**

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ANSI/AAMI ST 79 – Section 7.5.3.2

Is this type of brush in the IFU?
A dollar store Brush ?

Hospital's $1 solution to clean $30,000 superbug scope 02:18

http://www.cnn.com/2015/03/04/us/superbug-endoscope-no-permission/

https://www.cnn.com/videos/health/2015/02/21/sgmd-gupta-superbug-scope.cnn

REMEMBER!

Brushes and other cleaning implements
intended for use on medical devices should be used

DO NOT Just Go to The Dollar Store

Healthmark © 2019

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Was a $1 toothbrush in the IFU ?

- NO
- TV news is not always the best source
- CDC report on Epi-Aid Trip Report: Cluster of plasmid-mediated AmpC-producing carbapenem-resistant Enterobacteriaceae (CRE) — Washington, 2014 (Epi-2014-043)*
- A patient died
  - Manual cleaning items used at facility that deviated from the manufactures IFU
    - Use of a toothpick
    - Use of stiff bristle brush
    - Water pick
- The jury returned a verdict in the court case told the hospital they had to pay the family $750,000 because they were negligent

*Trip Report, Epi-2014-043 –CDC

Thank you Ofstead group for this information

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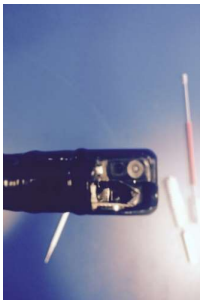
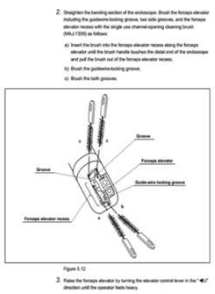
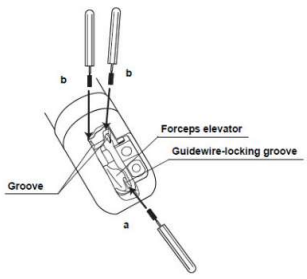
Why not a toothbrush?

- Not in the IFU
- Scratch the optic, costly repair
- The bristles are not made to brush medical devices
- Can not get into the right places
- Olympus has updated IFU on the correct type of brush you should use recently







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WE JUST SAW SLIDES WHERE HARM WAS DONE

Do No Harm is easy to say, but hard to practice…

Do it right each and every time -

That is hard to do.

Obstacles to not following the IFU:

- Not having the correct tools (products)
- Training – competent staff
- Education
- The surgeon wants it NOW!
- We only have one
- Management decisions
  - Turn it around now
  - Staffing issues
  - Boarding cases
- Competent management
- Critical thinking skills
- Standards
- Buying cheap solutions
  - No real data supporting their claims

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Objective 3

Review all relevant standards and guidelines that pertain to Instructions for Use for medical device used in a medical device reprocessing department

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New Standards and Standards Development

In recent years, new standards have been published that heavily influence how Reprocessing IFUs are created, authored and validated.

Additional related standards are currently undergoing development and are soon to be published.

These standards will further strengthen the requirements on MDMs for reprocessing IFUs.

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Regulations/Standards/Guidelines

- Regulations
  - A rule or directive made and maintained by an authority
  - Mandatory
- Standards
  - Requirements and specifications to ensure consistency and fit for purpose
  - Voluntary, but can become mandatory
- Guidelines, Recommended Practices, Technical Information reports
  - Technical guidance, information or preferred procedures regarding a given topic
  - Voluntary but with interpretation

OSHA Occupational Safety and Health Administration www.osha.gov

CDC SAFER • HEALTHIER • PEOPLE™

AAMI Advancing Safety in Medical Technology

ANSI

AORN

SGNA

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What are these based on

- All the major groups support in principal
  - Quality improvement
  - Quality assurance
  - Monitoring of your process
- Clinically relevant & evidence based practices
- Peer reviewed literature
- Other articles
- Manufacturers research and guidance
- Research and science
- Unfortunately, some practices do not have the evidence to support the practice
- Dynamic process

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What do the words mean within an AAMI Document?

MUST: used only to describe "unavoidable" situations, including those mandated by government regulation.

Shall: indicates requirements strictly to be followed to conform to the recommended practice.

Should: indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

May: used to indicate that a course of action is permissible within the limits of the recommended practice.

Can: used as a statement of possibility and capability.

These terms and their meaning are universally used in standards and guidance document writing. This is important when you read and interpret other standards or any guidance document.

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Recently Published Standards

- FDA Reprocessing Guidance
  - (2015, updated again in 2017)
- ANSI/AAMI/ISO 17664
  - **2.12 verification**
    - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled
- ASTM
  - F3208 & F3293
- Indirectly
  - ANSI/AAMI ST79
  - ANSI/AAMI ST91
  - ANSI/AAMI ST 90
    - IQ,OQ, and PQ
    - Why PQ
      - As users we confirm our process

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Standards in Development

- AAMI TIR 12 - 2010
  - Standard cleaning protocols
- AAMI ST98
  - Converting AAMI TIR30 into a Cleaning Validation standard
- ISO 15883-5
  - Converting from a TS to a standard
- AAMI TIR34 - 2017
  - Converting the water quality document into a national standard
- ISO 17664 part 2 – Non-critical devices
- ASTM D8179-18 – first standard for detergents
- We all need to be involved and active to bring about a positive change in these documents

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The process is a combination of many factors

- Clinically relevant & evidence-based practices
- Testing Labs
- Peer reviewed literature
- Other articles
- Manufactures research and guidance
- Research and science
  - Unfortunately, some practices do not have the evidence to support the practice
- Dynamic process
  - Consensus of voters
- Having some type of quality process within these documents when possible
  - Monitoring
  - Testing
  - Verifying (QMS)
- Then we get audited on the standards, guidelines, and our practices
  - For Better Patient Care
  - Best Outcomes
  - Best Practices
  - Based on the IFU

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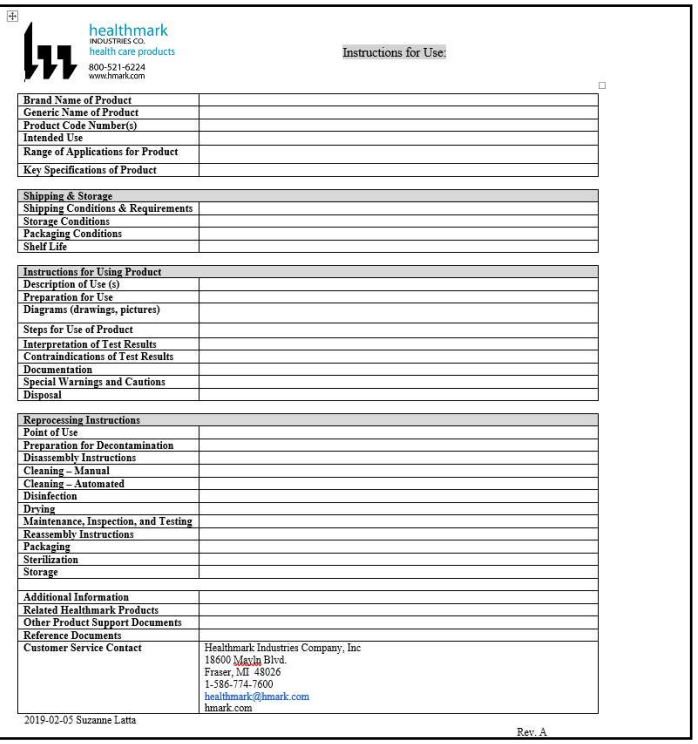
Objective 3

Introduce a template for the IFU that aligns with ISO 17664



healthmark INDUSTRIES CO. health care products
800-521-6224
www.hmark.com

Instructions for Use:

Brand Name of Product	
Generic Name of Product	
Product Code Number(s)	
Intended Use	
Range of Applications for Product	
Key Specifications of Product	

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	
Packaging Conditions	
Shelf Life	

Instructions for Using Product	
Description of Use (s)	
Preparation for Use	
Diagrams (drawings, pictures)	
Steps for Use of Product	
Interpretation of Test Results	
Contraindications of Test Results	
Documentation	
Special Warnings and Cautions	
Disposal	

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	
Disassembly Instructions	
Cleaning – Manual	
Cleaning – Automated	
Disinfection	
Drying	
Maintenance, Inspection, and Testing	
Reassembly Instructions	
Packaging	
Sterilization	
Storage	
Additional Information	
Related Healthmark Products	
Other Product Support Documents	
Reference Documents	
Customer Service Contact	Healthmark Industries Company, Inc 18600 Mavln Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

2019-02-05 Suzanne Latta

Rev. A

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Where is all this activities taking us to?

- More thorough, better defined requirements for validating cleaning/reprocessing instructions
- Instructions that are more clinically-relevant, scientifically based and more easily and successfully performed by healthcare facilities.
- As part of that, reducing the complexity of device and the challenge of effectively reprocessing devices of wide variety of designs and construction.

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What to do from here?

- Follow the IFU
- Supplement with AAMI Standards and other professional society guidelines that take it to the next level.
  - These change more frequently than the IFU
  - And are evidence-based
- Follow the peer-reviewed literature to see what we didn't know before and implement changes
  - Examples – insulation testing and leak test tester
  - Have a champion who "KNOWS" the IFU's
- Keep IFU's up to date and accessible
- Ask questions, empower staff
- Continue to learn and education
- Keep up with training and competency
- Certification

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CMS Penalizes 24 Michigan Hospitals

58 percent of penalized hospitals located in Southeastern Michigan

The cost of not following the IFU

- Poor training
- Not understanding how to use a product
- Can have these types of outcomes
- Outbreaks
- Poor patient outcomes

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Thank you so much!

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