GOOD PRACTICES IN REPROCESSING FROM THE POINT OF USE

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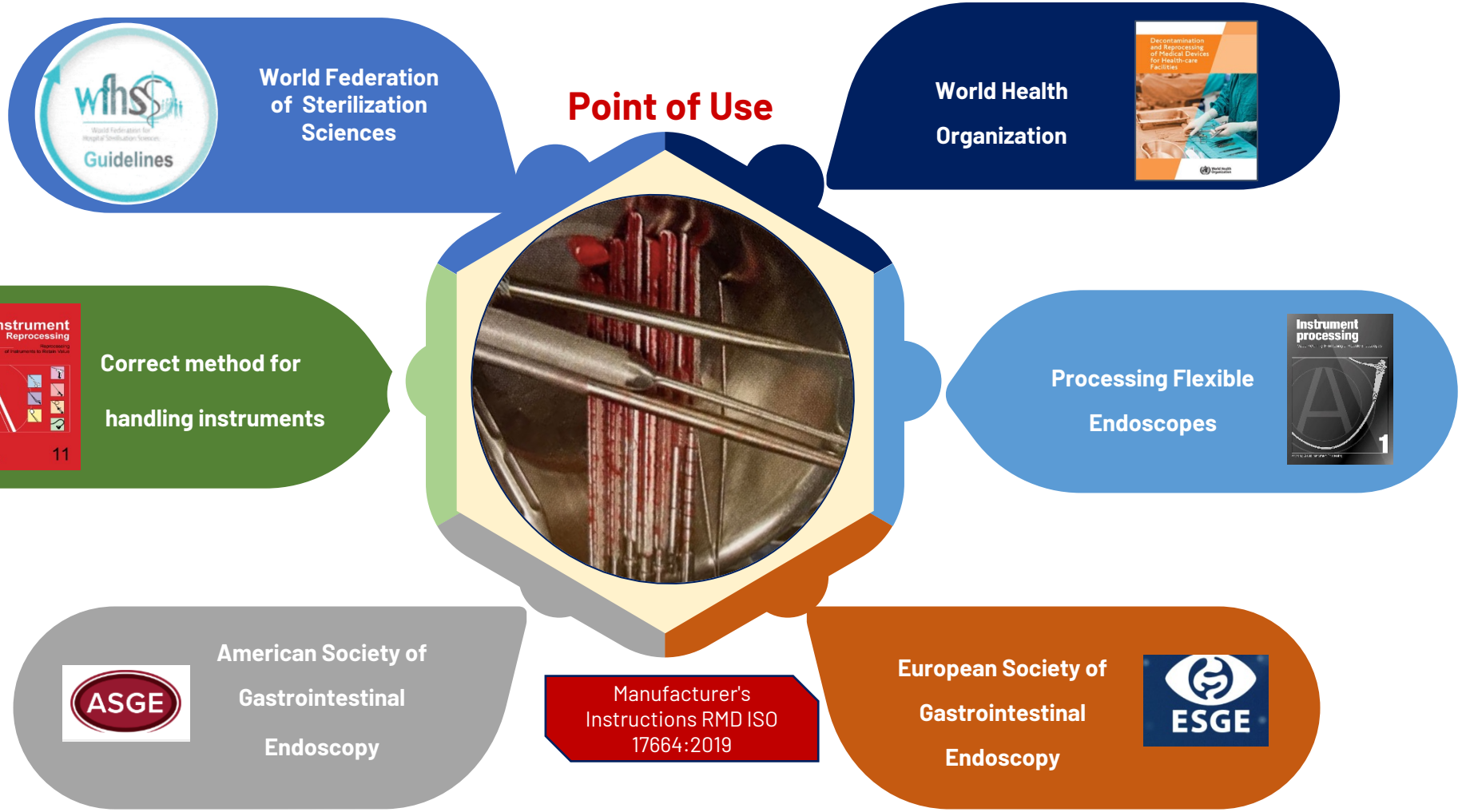
SPECH
Sociedad de Profesionales en Esterilización de Chile

Conflict of Interest Declaration

No conflict of interest

Content

1 Introduction



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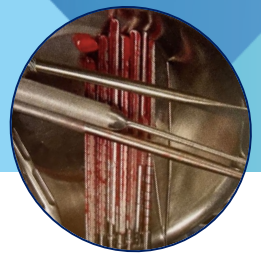
RMD REPROCESSING CIRCLE



Point of use preparation for cleaning

Manufacturer's Instructions RMD ISO 17664:2019

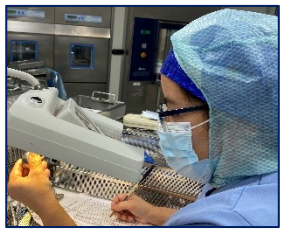
Transport of contaminated RMD

Reception

Cleaning and disinfection

ISO 15883-5:2021 Washer-disinfectors

Inspection and maintenance



Preparation and packaging

ISO 11607 Requirements for the packaging of terminally sterilized medical devices

Sterilization

ISO 17665-2024 Sterilization of Health care products

Storage

Transport of sterile RMD

QUALITY MANAGEMENT
Quality Management Systems - Requirements for regulatory purposes (ISO 13485:2016)

Risk Management applied to Medical Products ISO 14971

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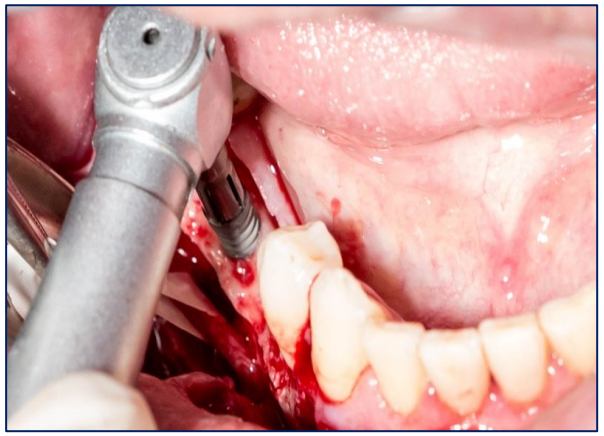
2 Point of use processing

All operations performed at the point of use before transporting a reusable medical device (RMD) to the CSSD.

Following the manufacturer's instructions for use (IFUs) for reusable medical devices.



Decontamination and reprocessing of medical devices for health-care facilities. Geneva: World Health Organization; 2016 https://apps.who.int/iris/handle/10665/250232
WFHSS Guidelines https://wfhss-guidelines.com
The Instrument Reprocessing Working Group (AKI) https://www.a-k-i.org

Objectives of Point of Use Treatment

Cleaning begins at the point of use, where the removal of key contaminants enables:

- Reduce the nutrient material that supports microbial growth.
- Prevent residue from drying on instruments.
- Reduce the number of microorganisms.
- Prevent biofilm formation that can begin within minutes of use
- Preventing rust and corrosion of RMD
- Reduce the possibility of contamination in the event of a spill
- Improving RMD care and preserving value

IMPORTANT

Point-of-use treatment only involves removing large debris and washing lumens.
Thorough cleaning should only be done in the decontamination area.

Key Operations for Point of Use Processing

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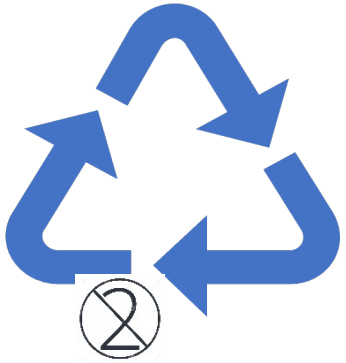
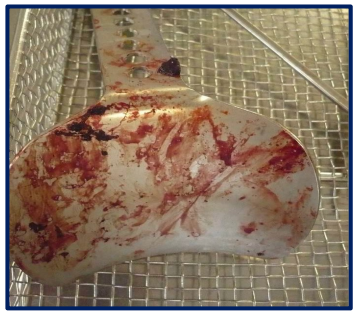
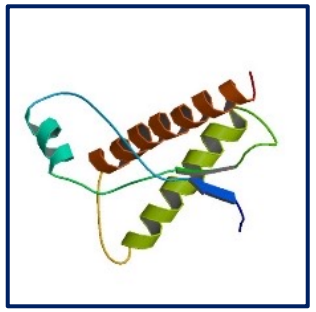
Separate RMDs from single-use devices and waste.



Single use items and waste are disposed of according to waste management regulations.



Prevent organic matter from drying on the RMD

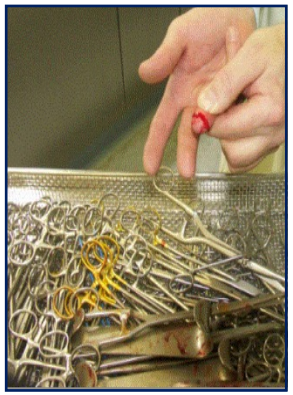


Isolate the RMD affected by specific prion risk

Prepare RMDs for transport to the CSSD

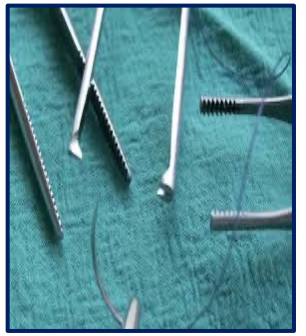
Operators at the point of use

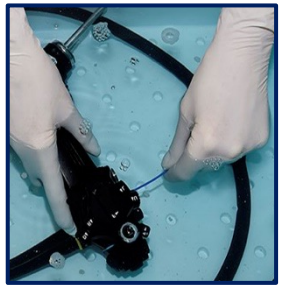
Operators at the point of use are using appropriate personal protective equipment



They are aware of the risk of injury from sharp objects and know the measures to be taken in the event of an accident.

Identify damaged RMDs and initiate the repair/maintenance or replacement process.





They handle RMDs with care and know the process to apply in case of a fall.

Manage RMDs in a way that prevents the dispersion of contaminants into the atmosphere and environmental surfaces.

Decontamination and reprocessing of medical devices for health-care facilities. Geneva: World Health Organization; 2016 https://apps.who.int/iris/handle/10665/250232
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3 During Surgery

1. Keep surgical instruments free of blood and organic matter with a sterile water moistened compress.
2. Keep instruments with lumens clear and irrigate periodically.
3. Remove remnants of medications used for hemostasis, lubricants, cauterizers, cements, acrylics, and skin asepsis.

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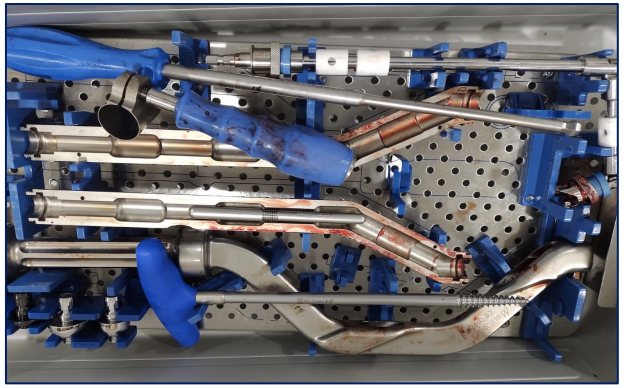
3 After Surgery

1. RMDs composed of multiple parts and surgical motors are disassembled according to the manufacturer's instructions.
2. Recommendation for soaking complex devices, with lumens or complex geometries, at the point of use.
3. Arrange RMDs neatly in transport containers.

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Collaboration between users and the CSSD

Surgical staff do not always disassemble and clean used surgical instruments

Shared responsibility between users and the CSSD due to lack of collaboration and compliance with established SOPs.

The processing time for RMDs will be longer than the standard, because the decontamination stage will be extended.

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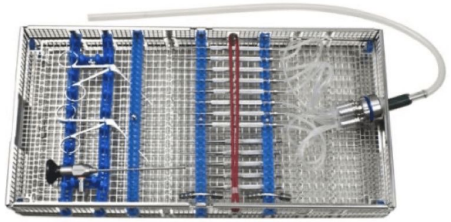
Collaboration between users and the CSSD

Prepare instruments that can be opened by placing them in the open position.

Protect delicate instruments from damage (placing heavier instruments on the bottom and lighter ones on top).

Instruments should be placed in an orderly manner.

Damaged instruments must be identified (tagged) so they can be removed.



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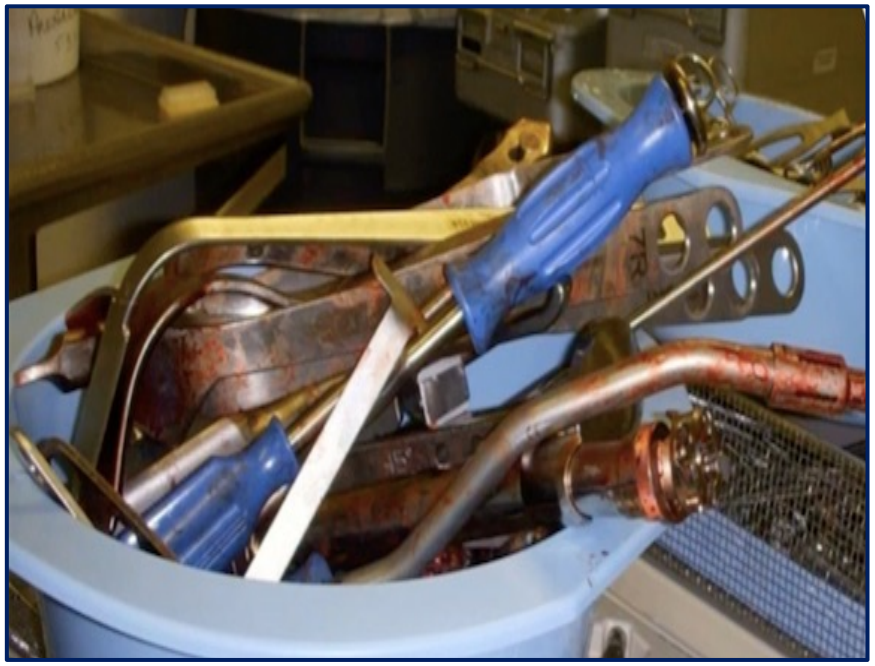
Collaboration between users and the CSSD



Ineffective point-of-use instrument care by the surgical team prevents efficient cleaning and decontamination, increases sharps hazards, and increases the likelihood of lost, incorrect, or damaged instruments.

Decontamination and reprocessing of medical devices for health-care facilities. Geneva: World Health Organization; 2016 https://apps.who.int/iris/handle/10665/250232
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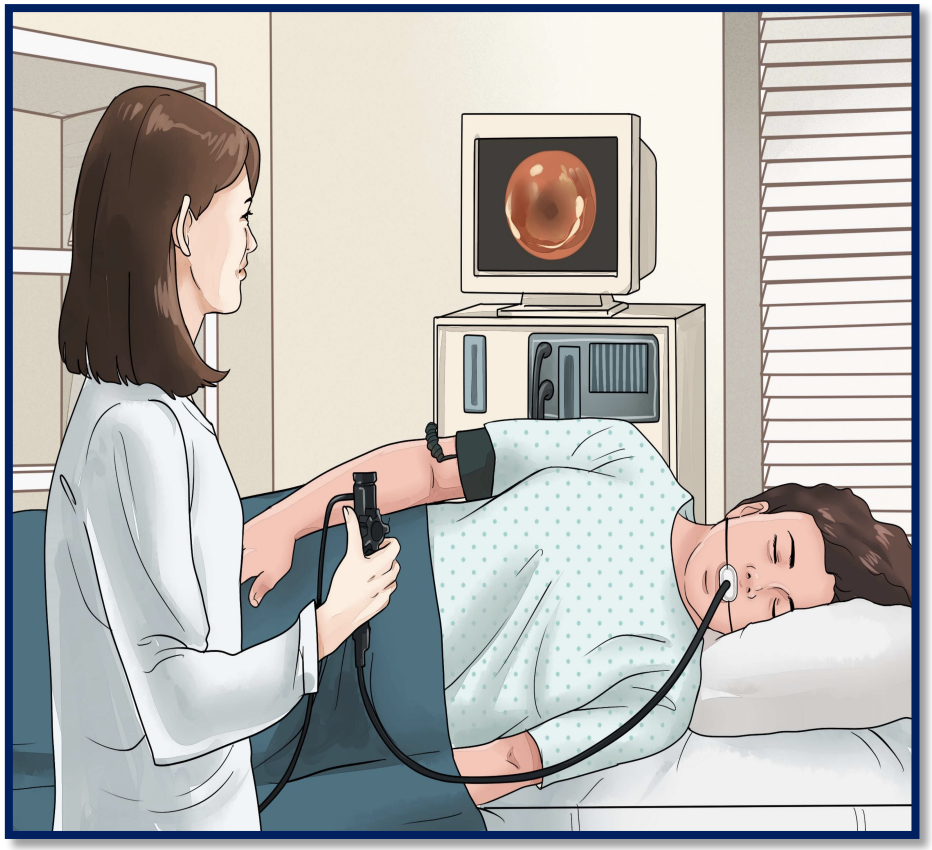
3 Endoscopy Room



1. Immediately after the procedure is completed.
2. External pre-cleaning
3. Residue removal without disconnecting the endoscope from the tower
4. Prevention of residue hardening in channels and on external surfaces

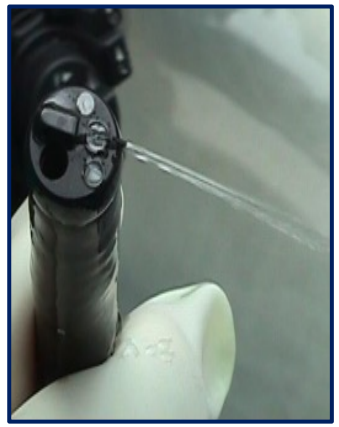
ASGE Multisociety guideline on reprocessing flexible GI endoscopes and accessories. Update November 2020.
ESGE- ASGENA Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018.

3 Endoscopy Room

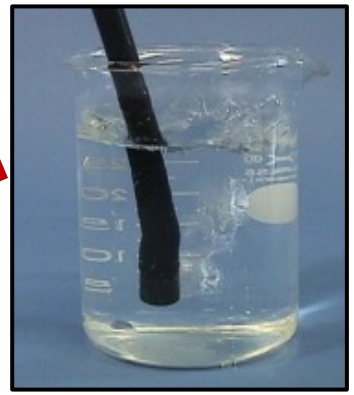
External pre-cleaning

Working channel

Water function



Air function



Transport of contaminated endoscope

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Processing and Quality at the Point of Use

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1. Establish standard operating procedures (SOPs) for point of use processing in collaboration with surgical and medical users, based on quality management principles.
2. Conduct a risk assessment for point-of-use processing.
3. Validation of the process at the point of use

   Processing controls.

   User and team training.

   Application of Waste Management Rules.

   SOPs are updated

   Traceability maintained.

Scientific evidence

1. Pre-preparation at the point of use is recognized as essential for cleaning
2. Initiating pre-cleaning after using the RMD is crucial to prevent residue from adhering to the instrument and forming biofilm.
3. How to pre-clean.
4. Biohazard during pre-cleaning.

Tschoerner M et al. Influence of drying time of removal of blood from medical devices. 2024
Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effects of drying. J Hosp Infect1991;19:89-98
Ana Clara F.V. et al .Reusable medical device. Pre-cleaning in Car units: What are the indicators to prevent Biofilm formation and Control Occupational Biological Risk?. 2024
Van der Ploeg K. et. al. Impact of duodenoscope reprocessing factors on duodenoscope contamination: A retrospective observational study. J Hosp Infect https://doi.org/10.1016/j.jhin.2024.0.018

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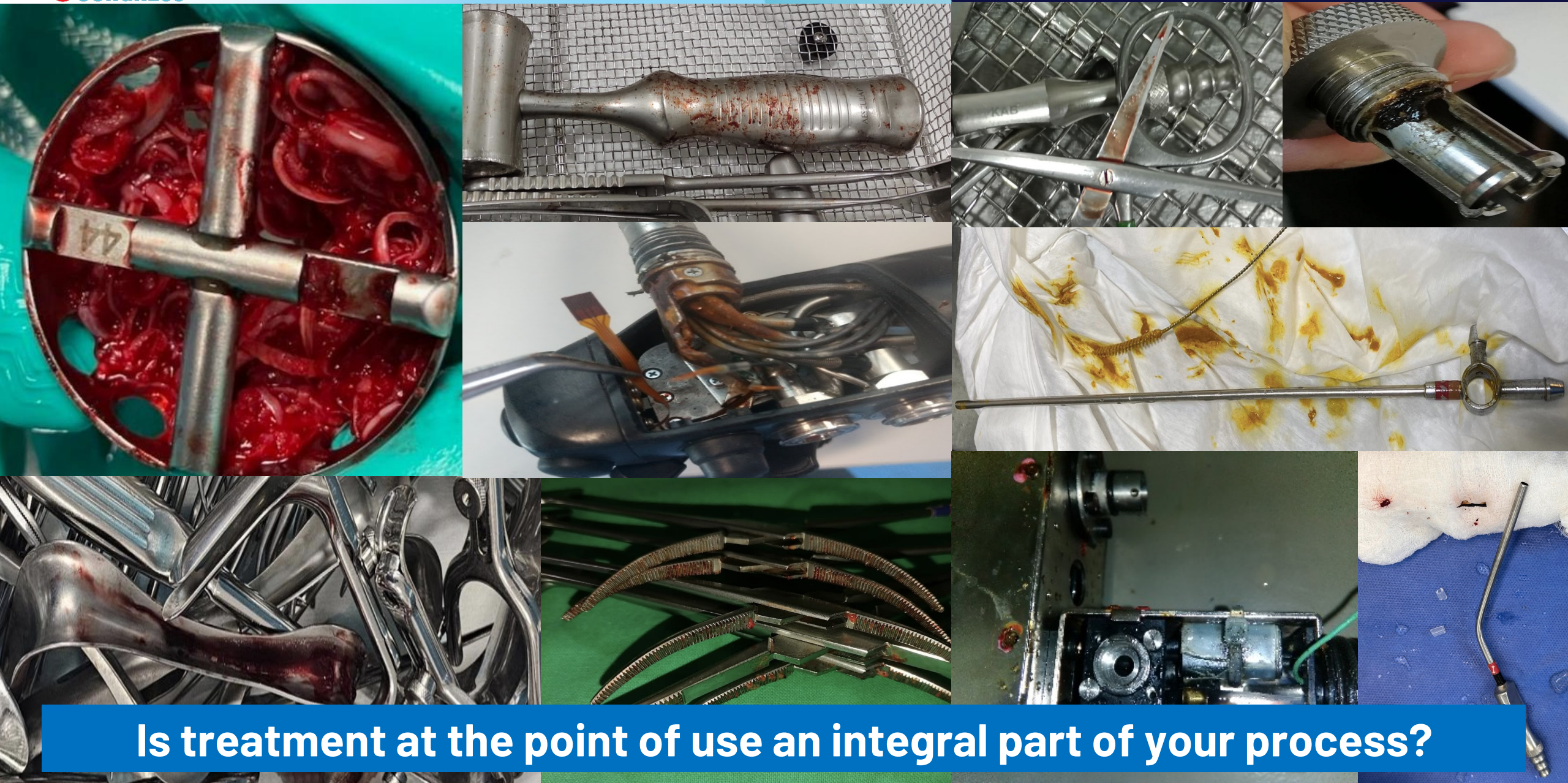


Is treatment at the point of use an integral part of your process?

4 Knowledge level of reprocessing professionals in Latin America on point of use treatment of reusable medical devices.

Objective

To measure the level of knowledge of reprocessing professionals and the reality of the practices in health institutions in Latin America regarding point-of-use treatment of reusable medical devices, according to the guidelines of the World Health Organization (WHO) and the World Federation of Hospital Sterilization Sciences (WFHSS).

Method

An online form with questions based on WHO and WFHSS guidelines was distributed to reprocessing professionals in Latin America. 12 countries and 199 professionals participated. Additionally, an assessment of each country's regulations was conducted to determine if point-of-use treatment is defined as the starting point of reprocessing.

4 Results


Argentina


Brasil


Colombia


Chile


Ecuador


Costa Rica


México


Nicaragua

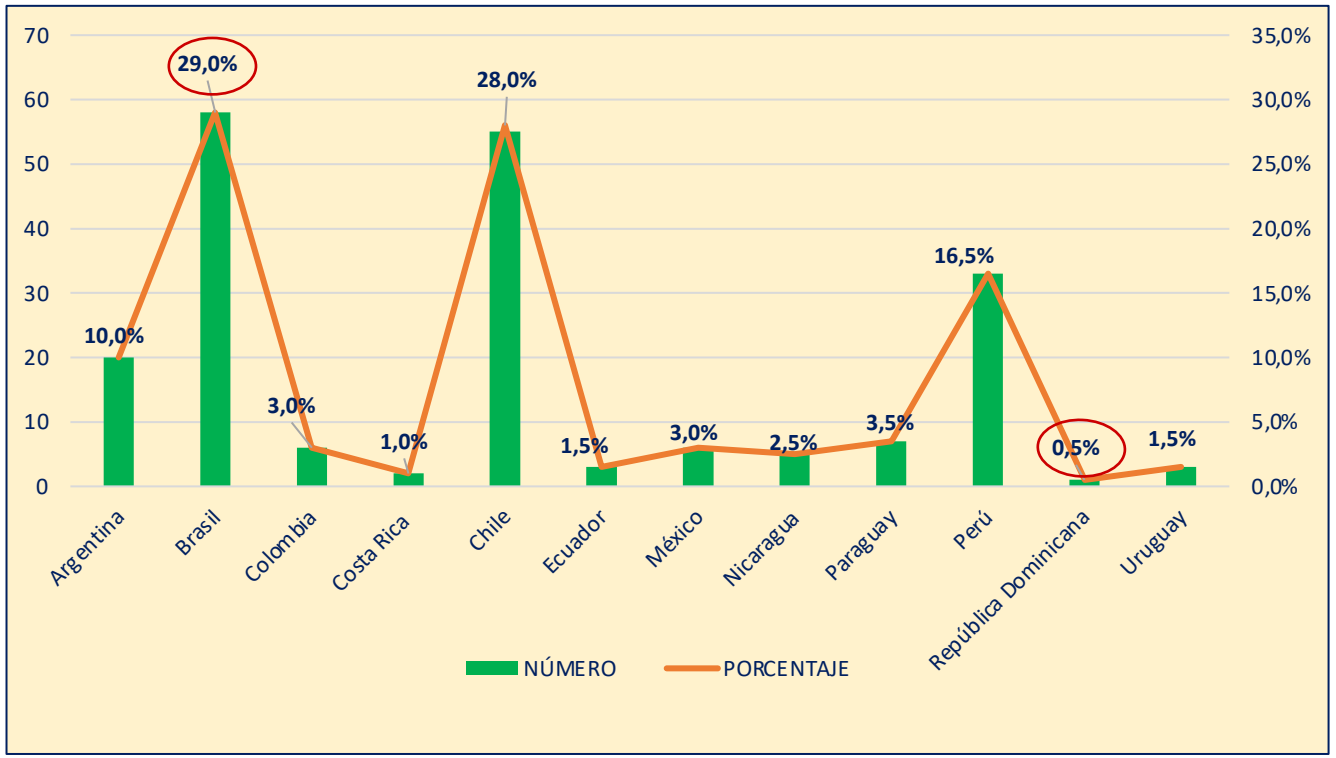

Paraguay


Perú


República Dominicana


Uruguay

Country distribution of reprocessing professionals according to online form responses



Brazil was the country with the highest percentage of reprocessing professionals who responded to the form with 29%, corresponding to 58 people.

The Dominican Republic was the country with the lowest percentage of professionals who responded to the form, with 0.5%, which corresponds to one person.

73% of the health institutions in the countries participating in the study belonged to the public system.

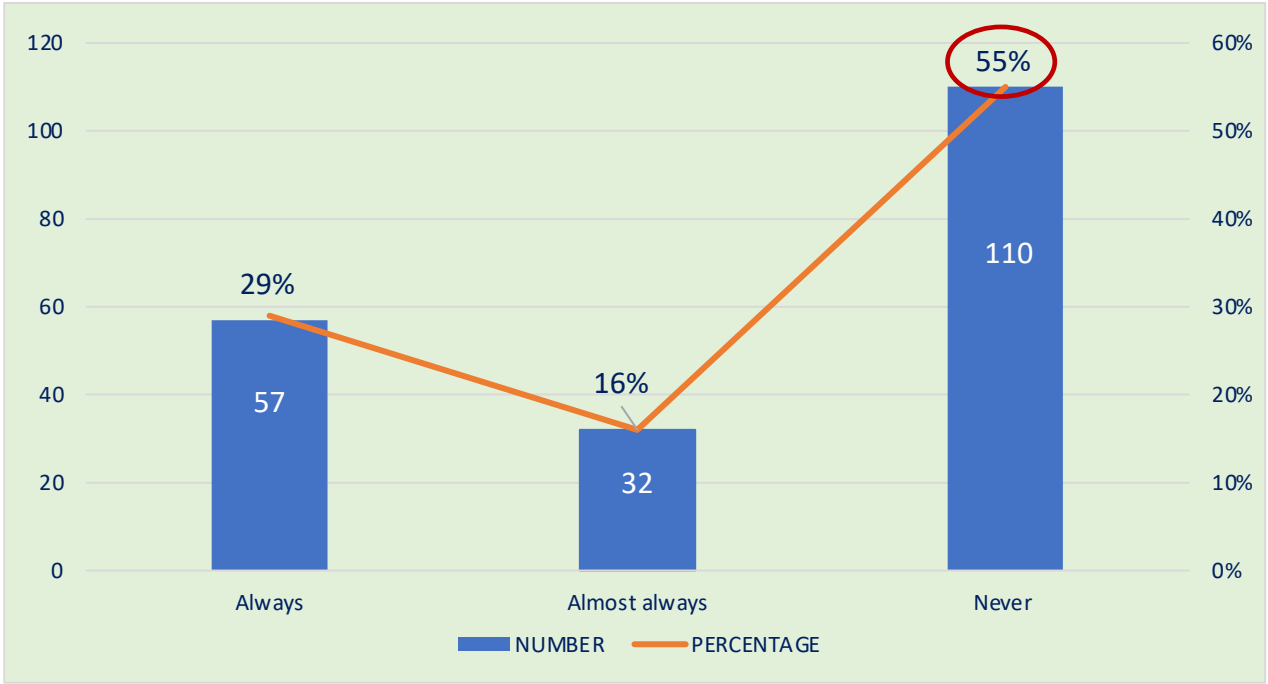
Main results related to the knowledge of professionals and government regulations

55,7 % of professionals know and identify the points of use of sterile medical devices.

34% of professionals know and identify the procedures carried out for the preparation of cleaning at the point of use

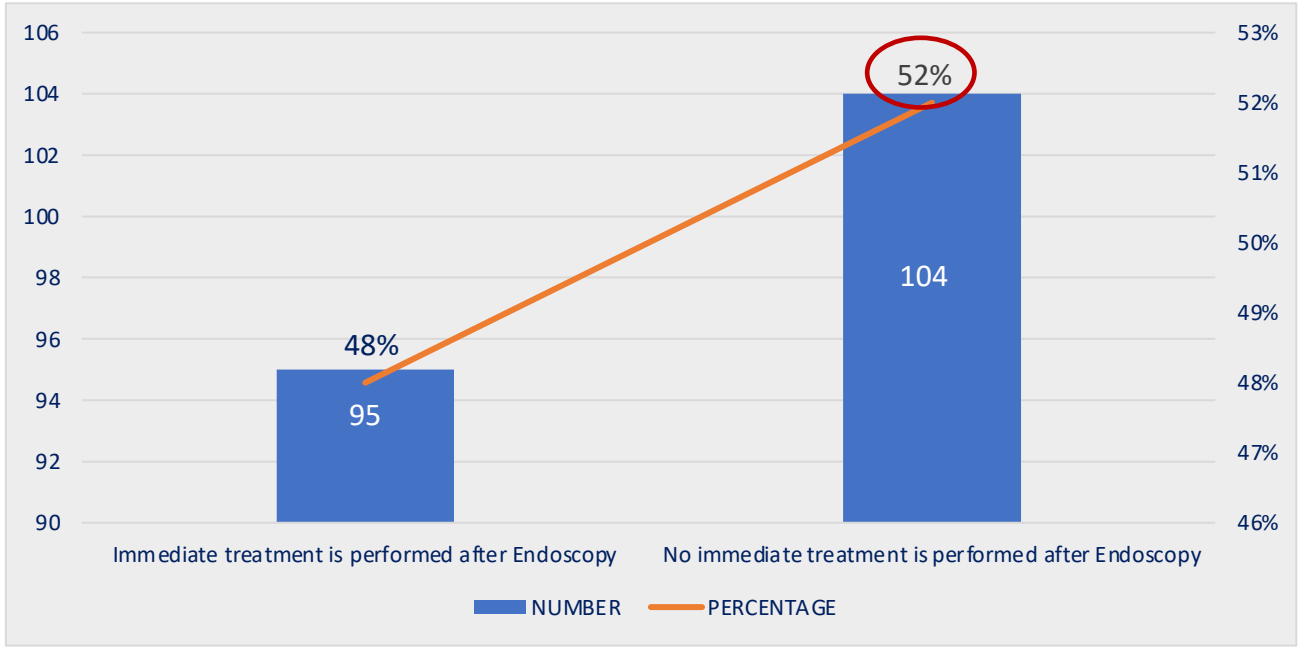
100% of government regulations in the 12 countries in the study do not consider point-of-use cleaning preparation as a key step for decontamination and disposal of reusable medical devices

Distribution of health care institutions according to practices for preparing for cleaning during and after surgery



In 55% of health institutions in Latin America, preparation is NOT carried out during and after surgeries, which corresponds to 110 hospitals

Distribution of health institutions according to practices for preparing for cleaning in the endoscopy room



In 52% of all health institutions in Latin America, flexible endoscope preparation is NOT performed after the endoscopic procedure.

Limitations

- The form was applied only to reprocessing professionals but could be expanded to include users of sterile medical devices, such as surgical, medical, and clinical service professionals. This would provide a broader view of the knowledge on the subject and help identify gaps to implement improvements in practices.
- The form only evaluated the point of use in the surgical rooms, but could include the point of use in clinical services.
- The study was conducted in only 12 countries out of a total of 33 in Latin America.
- The total number of hospitals per country was not considered.

Who is responsible for treatment at the point of use?

There is confusion regarding treatment at the point of use, when standard operating procedures have not been defined and agreed upon between users of the RMD and the CSSD.

- There is no time.
- It's not my job.
- It doesn't belong to me.

Patient safety belongs to the entire work team.

5 Conclusions

1. **While it is true that there is a basic understanding** among reprocessing professionals in Latin America regarding the procedures to be followed for **cleaning at the point of use**, **practices need to be improved** and brought to an operational level, as they are not incorporated into health institutions.

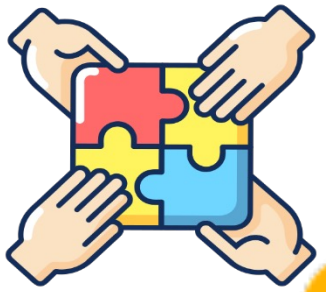
2. **55% of the health institutions** in the study **do NOT perform preparation at the point of use during and after surgery**, **and 52% do NOT prepare the flexible endoscope** after the endoscopic procedure. In light of the available scientific evidence, this leads to biofilm formation, deterioration of instruments, delays in processing, as well as the **risk of adverse events** that jeopardize patient safety.

3. **Clear government regulations** based on **WHO and WFHSS guidelines** are required to provide a **regulatory framework based on quality management and process validation** to adopt and implement good practices at the point of use and in the RMD reprocessing cycle.

Finals words

By understanding and following recommended guidelines for preparing contaminated DM you are helping to protect quality of care and patient safety.

COLLABORATIO N between the CSSD and the users of the instruments.



COMMUNICATION AND TRAINING

It will help the people of the CP and the user services to protect and improve the care of the instruments to have fluid work and reduce risks

6 References

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10. ISO 17664 2021 Processing of health care products nformation to be provided by the medical device manufacturer for the processing of medical devices
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