Challenges of reprocessing new medical products

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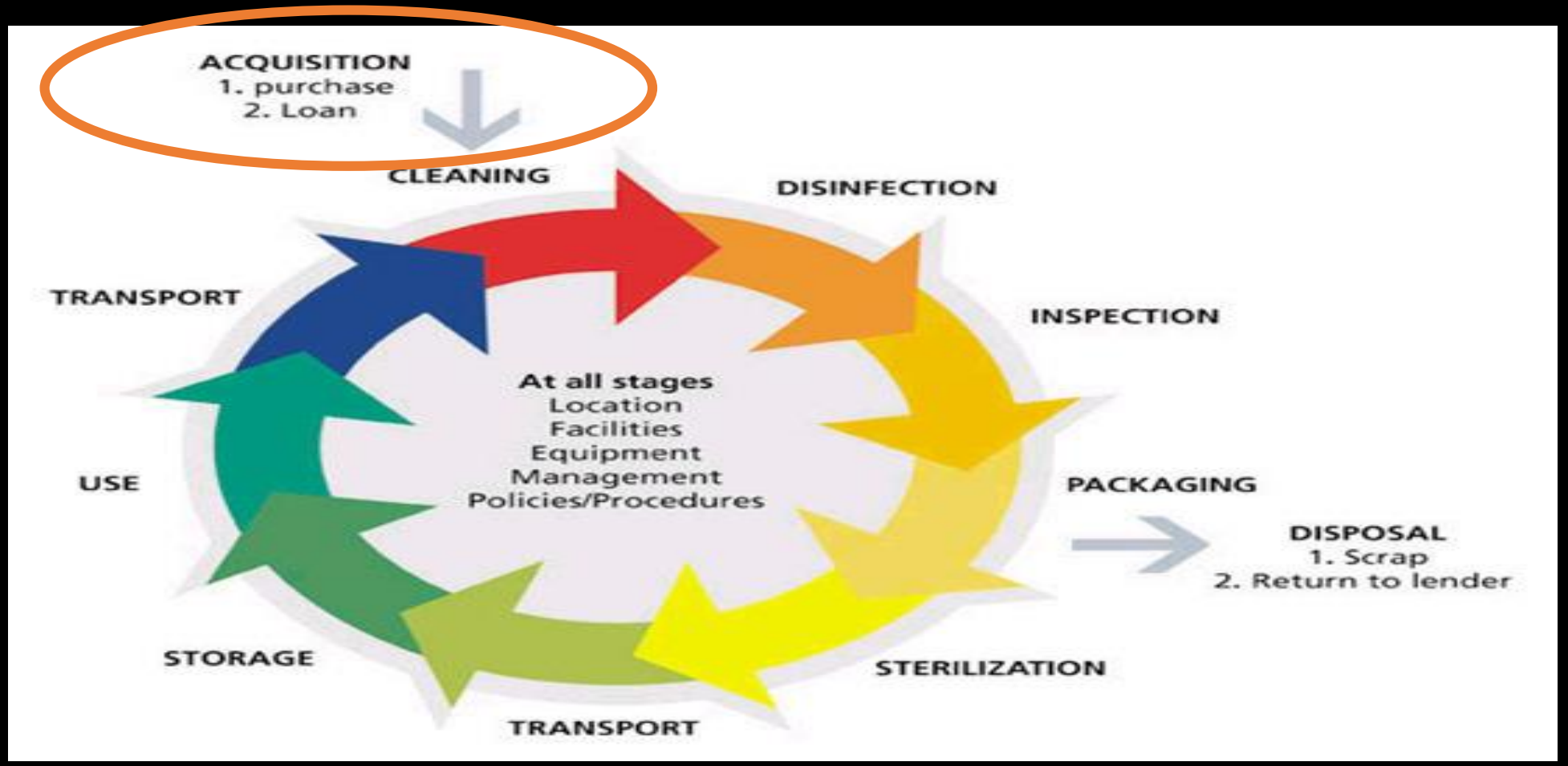
Objectives :

- To identify challenges when processing new instruments.
- Mention contributing factors .
- Provide examples for complex devices .
- Suggested solutions .

Instrument Life Cycle



What is the new Instrument for you ?

- It could be loan.
- It could be made of new material .
- Purchased instrument with Difficult design .
- Require new Reprocessing requirements.
- New staff not familiar with existing instruments.

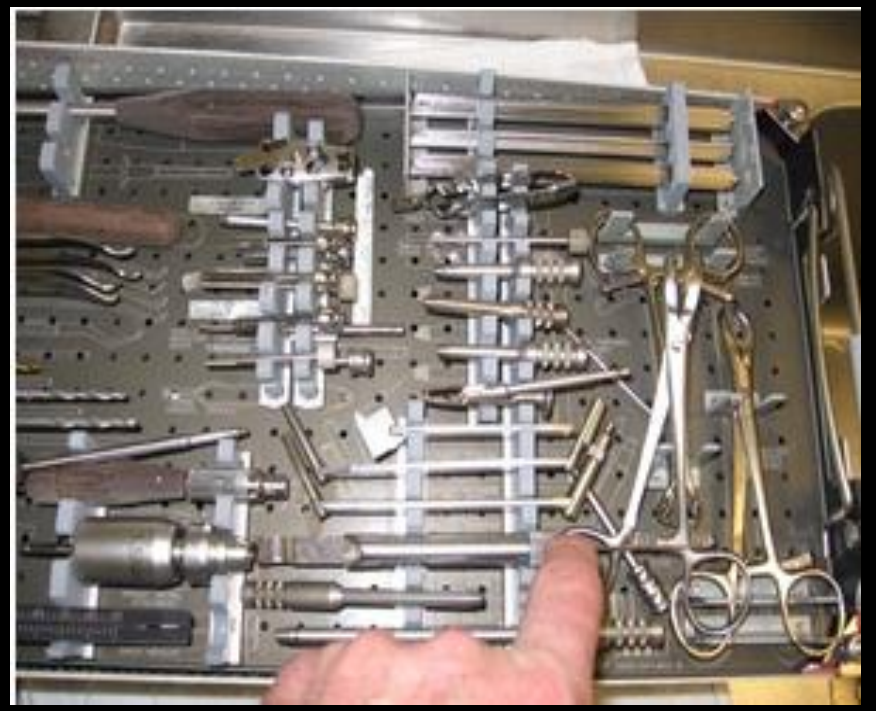
Loan Instruments

- 16% of the loaner instruments tested positive for blood.

(AORN Journal;3/2007,Volume 85,#3; page 566)

- Particles of tissue were found in cannulated instruments

(Pennsylvania Patient Safety Authority 2006;page 1)



Instrument design

- Medical devices have become more complex the issues of how to perform acceptable cleaning, disinfection and sterilization have become greater.

Stakeholders include:

There are many stakeholders involved in cleaning, disinfection and sterilization of medical devices.

- Regulatory agencies, FDA, CDC, state departments or ministry of health;
- Manufacturers of medical devices.
- Reprocessors of medical devices.
- Standards setting organizations.
- Test labs.

Problems with cleaning medical devices include:

- The IFU is difficult to understand.
- The IFU is incomplete.
- The IFU is difficult (if not impossible) to follow.
- The person performing the cleaning process was not adequately trained.
- The person performing the cleaning process did not follow the process.

Examples

- Recently in 2014 and 2015 there have been several documented cases where duodenoscopes have been implicated in causing a HAI known as carbapenem-resistant Enterobacteriaceae (CRE) (Cdc.gov, 2015)

GI Endoscopes debates : Shift from Disinfection to Sterilization

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.[1] Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.[1]

In this issue of *JAMA*, Epstein and colleagues[2] report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)–producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

Related article page 1447

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.[3,4] High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.[3] However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)–cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care–associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.[3,5] However, until now,

Rutala, Weber. JAMA 2014. 312:1405-1406; Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

Cleaning Accessories .

Damage due to improper reprocessing is not covered by the warranty.

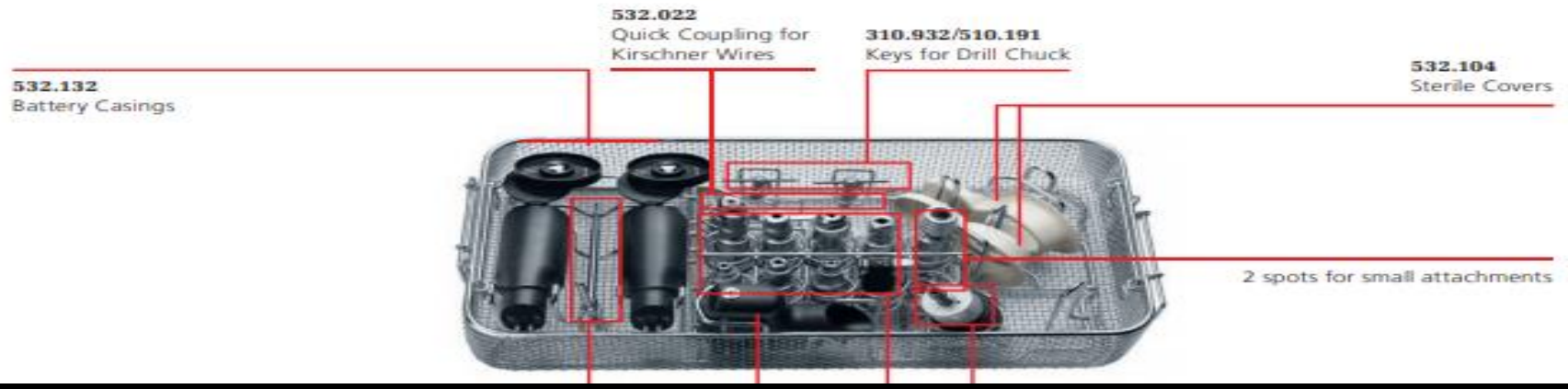
Note: A lid (68.001.602) is available for the washing basket. This can be used for sterilization, but is not required for machine washing.

Warning: Do not wash the system in the Synthes Vario Cases (68.001.255, 68.001.253).

Dimensions of the Washing Basket (Length × Width × Height):

Washing Basket without Lid:	500 × 250 × 112 mm
Washing Basket with Lid:	504 × 250 × 150 mm

68.001.610
Washing Basket, size 1/1, for Colibri (II) and Small Battery Drive (II)

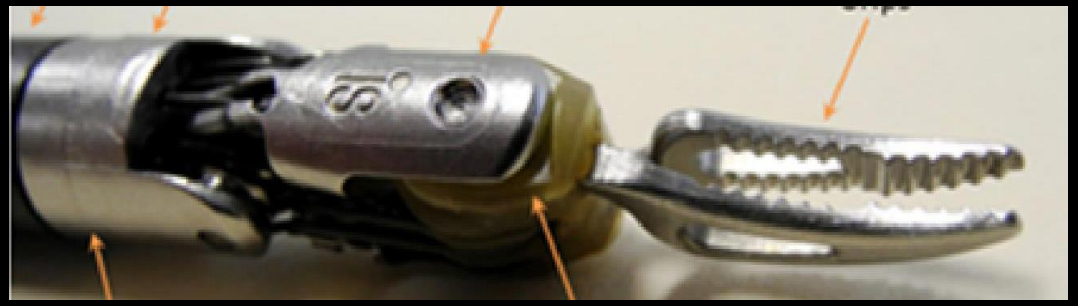


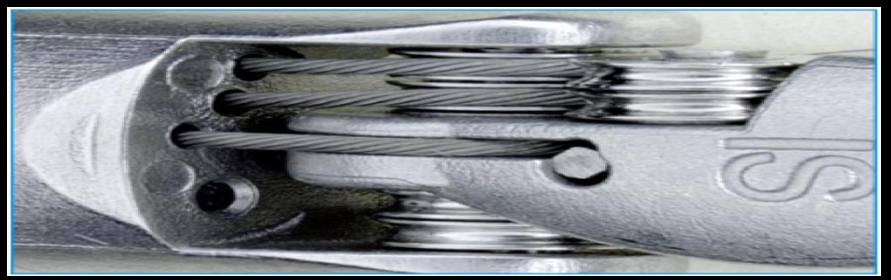
(Synthes.vo.llnwd.net, 2018.)

Robotic instruments

- Robotic instruments, with their complex structures, have a greater protein residue and lower cleaning efficacy as compared to conventional tools,
- the study found. The cleanings were 97.6 percent effective for robotic instruments and 99.1 percent effective for ordinary instruments.

(Beckershospitalreview.com, 2016)





Da Vinci washer basket

- Washer-Disinfectors:
- Type Testing according to ISO 15883-1
- Belimed WD 290
- Getinge T88
- Medisafe SI PCF
- Medisafe SI PCF Niagara
- Miele 8528
- Steelco DS1000
- Steelco DS610
- Specialized load carriers and cycles
- Refer to Appendices of user manuals

Solutions

- Professional organizations are working to develop standards that all stakeholders follow.

Solutions

- Manufacturers now look at cleaning, disinfection and sterilization as part of device design.
- Organizations like (FDA) is looking more closely at reprocessing issues when approving reusable medical devices.

Solutions

- There is still the problem of devices that already exist and that continue to be sold.

For Reprocessing of those Instruments :

- ensuring that manufacturer’s IFU’s are scrupulously followed.
- employees perform return demonstrations to show that they understand how to perform a particular cleaning procedure.
- Quality assurance and close inspections must be done.
- The reprocessing process should be subjected to verifications.

Solutions

- Finally more needs to be done to provide quality education, training and certification for the people who are expected to reprocess medical devices.

Take Home Message

- Patient and Staff Safety comes First .
- Be involved in the Purchasing process ,as part of the Product evaluation Committee .
- Follow manufacture instructions.
- Continuous Staff training and close monitoring.
- Involve the stakeholders in decision making .
- Verification process for the new products .

Reference

1. AORN Journal;3/2007,Volume 85,#3; page 566
2. Beckershospitalreview.com. (2016). *Robotic instruments are nearly impossible to clean completely, study shows: Removing all contamination from robotic surgical instruments, even after cleaning multiple times, is close to impossible, according to a study in Infection Control & Hospital Epidemiology, the journal of the Society for Healthcare Epidemiology of America.*. [online] Available at: https://www.beckershospitalreview.com/quality/robotic-instruments-are-nearly-impossible-to-clean-completely-study-shows.html [Accessed 13 Jul. 2019].
3. Cdc.gov. (2015). *CDC - Division of Healthcare Quality Promotion (DHQP)*. [online] Available at: https://www.cdc.gov/ncezid/dhqp/index.html [Accessed 13 Jul. 2019].
4. Pennsylvania Patient Safety Authority 2006;page 1
5. Rutala, Weber. JAMA 2014. 312:1405-1406; Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.
6. Swenson, D. (2015). *Challenges to Reprocessing Medical Devices | Tuttnauer*. [online] Tuttnauer.com. Available at: https://tuttnauer.com/blog/challenges-to-reprocessing-medical-devices [Accessed 10 Jul. 2019].
7. Synthes.vo.llnwd.net. (2018). [online] Available at: http://synthes.vo.llnwd.net/o16/LLNWMB8/INT%20Mobile/Synthes%20International/Product%20Support%20Material/legacy_Synthes_PDF/DSEM-PWT-0914-0026-4_LR.pdf [Accessed 13 Jul. 2019].