The Evolution of cannulated instrument Cleaning

Markus Auly / Dr. Christine Denis
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Fundamentals / Key principles

- Only clean medical device can be disinfected or sterilized
- Standardized and validated cleaning processes are required for **ALL** MD
Validated cleaning process in practice?
Validated Cleaning?

Validation

documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. (from EN ISO 15883-1)

Standardization of processes

is a necessary precondition for validation of a cleaning process. How you would otherwise guarantee that the process will CONSISTENTLY yield results as specified?
Want repeatable cleaning?

Then control the four factors of Sinner…

- Temperature
- Chemical
- Time
- Mechanics
Validation of an Automated Cleaning process

Chemical constant

Time constant

Temperature constant

Mechanics constant (Pressure)

constant cleaning result
Validated WD process

contaminated

ISO 15883 compliant WD with validated cleaning cycle

Repeatably clean

HUMAN FACTOR

?
Validated WD process...

Degree of dependency on the human factor?

1) Open Instrument  2) Don’t overload tray  3) Avoid spray shadows

Feasible… but needs education & discipline…
Validated cleaning process in practice?
Validated cleaning process in practice?
Overview of the Presentation

1. Why is standardized cleaning of hollow instruments such a challenge?

2. Approaches to hollow instrument cleaning around the world

Part 1
Why is standardized cleaning of hollow instruments such a challenge?
Why such a challenge?

- Wide variety of instruments: different shapes, lengths, diameters, connections..
- Complex design
- Continuous input of new devices
Why such a challenge?

- Visual control of every instrument is impossible…
  Is it clean?

- Example of a reamer
  Video F.Cavin

- Needs the help of devices for aided visual inspection
Part 2
Approaches to hollow instrument cleaning: Observation from travels around the world
What is the right SOP for a specific instrument?

Lumen Instrument

Manual Cleaning  Ultrasonics  Instrument Rack  MIS Rack  Washer Disinfector
Current cleaning methods for hollow instruments

Manual Cleaning

Manual cleaning

Autoclave

HUMAN FACTOR
### Current cleaning methods for hollow instruments

#### Manual Cleaning

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**HUMAN FACTOR**

- Manual only
Current cleaning methods for hollow instruments

Manual Cleaning + Washer-Disinfector

Manual cleaning

Instrument Rack

Washer-Disinfector

Autoclave
Current cleaning methods for hollow instruments

Manual Cleaning + Washer-Disinfector

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HUMAN FACTOR

Manual + WD
Current cleaning methods for hollow instruments

Ultrasonics (+/- Irrigation) + Washer-Disinfector

Manual cleaning → Ultrasonics

Instrument Rack → Washer-Disinfector → Autoclave
Current cleaning methods for hollow instruments

Ultrasonics (+/- Irrigation) + Washer-Disinfector

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Irrigated US + WD
US + WD
Current cleaning methods for hollow instruments

Washer-Disinfector + MIS Rack

Only minimal precleaning

MIS Rack → Washer-Disinfector → Autoclave
Current cleaning methods for hollow instruments

Washer-Disinfector + MIS Rack

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WD with MIS Rack

HUMAN FACTOR

Belimed
Infection Control
Current cleaning methods for hollow instruments

What is the challenge of all those methods?
Is the cleaning of cannulated instruments standardized?

….it still depends too much on the individual technician!
What is the right SOP for a specific instrument?

Lumen Instrument

- Manual Cleaning
- Ultrasonics
- Instrument Rack
- MIS Rack
- Washer Disinfector
Responsibility for the choice of the applied method

Responsibility for the process result

- CSSD manager
Critical analysis of IFU

IFU do not help the standardization

Positive
- provide information (according ISO 17664)
- Assumption is that manufacturer knows his instrument best
- Indications on dismantling
- Manufacturer has to provide an adequate reprocessing method

Negative
- Main concern = keep the MD functional
- Lack of knowledge regarding the organization of a CSSD and the guidelines
- Recommend numerous ways of cleaning not compliant with the guidelines
- Manual cleaning is the most frequent recommendation
- Are they validated? According to what?
Take home message

- At the moment it is very hard to implement a cleaning process that deserves to be called «validated» for all cannulated instruments of a given CSSD
  - Lack of standardization
  - Dependency on human factor
- Too frequently relying on IFU instead of expertise
Part 3
Evolution of MIS Racks: A New Solution
How to go a step forward in the evolution?

Properties to improve:

- Not have to separate instrument sets
- Connect every lumen instrument
- Ensure Cleaning Efficacy (inside & outside)
- Avoid particles to get into lumens
- Facilitate standardization
Approaches for improvement…

How to improve the current systems?

- Accomodate all kind of instrument sets
- Connect every lumen instrument
- Ensure Cleaning Efficacy
- Avoid particles to get into lumens
- Facilitate standardization
Approaches for improvement…

How to improve the current systems?

- Accomodate all kind of instrument sets
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Flexibility: combine normal and cannulated instruments
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Approaches for improvement...

How to improve the current systems?

☑ Accomodate all kind of instrument sets

- Connect every lumen instrument
- Ensure Cleaning Efficacy
- Avoid particles to get into lumens
- Facilitate standardization
Different Instruments need different connectors
Green cap = multiconnector for all other connectors
Flexibility – combine normal and cannulated instruments
Fully loaded Mixed Instruments Rack
Solution for many canulated instruments per set
How to choose the right connector?
Approaches for improvement…

How to improve the current systems?

✓ Accomodate all kind of instrument sets
✓ Connect every lumen instrument

➢ Ensure Cleaning Efficacy
  ▪ Avoid particles to get into lumens
  ▪ Facilitate standardization
Validation of an Automated Cleaning process

Chemical  Time  Temperature  Mechanics (Pressure)

constant  constant  constant  constant

constant cleaning result
Validation of an Automated Cleaning process

Chemical | Time | Temperature | Mechanics (Pressure)

constant | constant | constant | constant
Inside Cleaning

The right level of pressure and flow is crucial

Maneken Pis
Approximately 0.05 bar

Washer-Disinfector

High Pressure Cleaner
Approximately 100 bar
Inside Cleaning – Save connection / Save Pressure

- Is the pressure save in your MIS Rack?

![Diagram of MIS Rack with pressure indications](image)

Remaining Pressure (%)

- $P_{\text{max}}$
- $P_{50}$
- $P_{\text{min}}$
Inside Cleaning – Save connection / Save Pressure

- Is the pressure save in your MIS Rack?
Outside Cleaning

- Same Standard as Instrument Rack
- Test according to 15883-1/2 / -5 Annex A
Outside Cleaning

- Same Standard as Instrument Rack
- Test according to 15883-1/2 / -5 Annex A

Crile Clamp (German Guideline)  
$\Rightarrow < 100 \text{ ug Protein}$

ISO TS 15883-5 Annex A  
Blood Soil 10 Clamps  
+ 10 Scissors
Outside Cleaning

Washing arms in every level - just like a normal instrument Rack.

→ Excellent outside cleaning efficacy of all Instruments
Approaches for improvement...

How to improve the current systems?

✓ Accomodate all kind of instrument sets
✓ Connect every lumen instrument
✓ Ensure Cleaning Efficacy

➢ Avoid particles to get into lumens
  ▪ Facilitate standardization
Filtered process fluids

WD process fluids are full of particles, hair etc.
Filtered process fluids

- Filter is necessary to avoid particles to get into instruments.
Filtered process fluids

- Double filter for Ophthalmic Instruments
Approaches for improvement…

How to improve the current systems?

✓ Accomodate all kind of instrument sets
✓ Connect every lumen instrument
✓ Ensure Cleaning Efficacy
✓ Avoid particles to get into lumens

➢ Facilitate standardization
Current cleaning methods for hollow instruments

Reliable loading of cannulated instruments racks?
Facilitate standardization

- Every Set gets its loading foto

- Standardized connector layout

  ➔ Standardized connection pattern per set
Facilitate standardization

- Special Preconfigured Trays - Phaco
Approaches for improvement… implemented

✓ Accomodate all kind of instrument sets
✓ Connect every lumen instrument
✓ Ensure Cleaning Efficacy
✓ Avoid particles to get into lumens
✓ Facilitate standardization
Current cleaning methods for hollow instruments

Washer-Disinfector + MIS Rack

Only minimal precleaning

Mixed Instruments Rack

Washer-Disinfector

Autoclave

[Image of hollow instruments and cleaning equipment]
### Current cleaning methods for hollow instruments

**Washer-Disinfector + Mixed Instruments Rack**

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**System attribute**

- Flexibility / instrument coverage
- Outside cleaning
- Inside cleaning
- Thermal disinfection
- Rinsing/drying
- Separation of zones
- Reproducibility
- Standardization
- Validation possible

**Mix Rack + WD**

- Green indicates positive feedback.
- Yellow indicates caution.
- Red indicates critical feedback.

**Human Factor**

**Infection Control**

**Belimed**
Real Life Test at Sterinord
Real Life Test at Sterinord
Material

Validated program
Testing conditions

- 6 weeks
- 5 experienced technicians
- Comparison with:
  - MIS RACK
  - manual cleaning or Ultrasonics + Regular rack
- 114 sets with cannulated instruments
- 66 different sets
- MIS, orthopaedics, Neuro surgery, gynecology....
Our needs and expectations:

- Flexibility

- Quick flexibility
  (Fast and easy, no tools)

- Maximum coverage to limit manual cleaning and its HF impact

- Cleaning efficacy
Flexibility

**Former basket:**
- Lay out of connectors = frozen
- CSSD technicians connect instruments according availabilities

**New basket:**
- Create your own layout easily and quickly
- Change it for each set

Universal connectors for adapters
Plug and Play

Analyze Instrument Interface

Select adapter

Connect & Plug

- Jets 8cm
- Jets 12cm
- Jets 18cm

Jet sizes:
- Ø 2mm
- Ø 3mm
- Ø 4mm
- Ø 5mm
- Ø 6mm
- Ø 7mm
- Ø 8mm
- Ø 9mm
- Ø 10mm

Max. Ø 3mm
Max. Ø 4mm
Max. Ø 5mm
Max. Ø 6mm
Max. Ø 7mm
Max. Ø 8mm
Max. Ø 9mm
Max. Ø 10mm
Some examples

OLD

NEW
Some examples:

OLD

NEW
Some examples:

OLD

NEW
Instruments coverage

- A total of 114 sets are tested / 66 different sets

**Previous Rack:**
- 60% (40) of sets are cleaned on a MIS rack
- 40% (26) are manually or US cleaned + Regular rack in WD
- Appropriate connection for 57% of the instruments

**MIX Rack:**
- 100% of the sets are cleaned on MIX rack
- Appropriate connection for 98% of the instruments
Instruments coverage
All instruments of a set in to one WD load

Keep the instrument set together on one rack

- No more losses of instruments
- Time saving
- Optimized equipment usage
Sets with only 1 or 2 hollow instruments

Manifold Concept

Flushing Manifolds
Testing of Cleaning efficacy

- With the limited tests available on site
- Visual inspection

- Soil test Browne®
- Process Challenge Devices
  - TOSI LumCheck®
  - Silicone tubes and trocars with Soil test Browne® inside
TOSI LumCheck® enhanced

Tested in all conditions:
- with all kinds of connectors
- Full load, ½ load, 1 connected device
- etc..
Results with Tosi Lumcheck enhanced

dirty indicator

clean indicator
Results

Testing of the jets
Testing of the direct connection to the rack
Only one instrument did not pass the test

- Due to the use of the wrong connector
- Conclusion: Make sure you really use the right connector for every type of instrument

The jet must be longer than the instrument

HUMAN FACTOR
To summarize the testing

- Mix Rack and connectors provide a solution for a majority of instruments
- Quick flexibility is proven
- Cleaning efficacy
- Human factor is limited by reduction of manual cleaning
- But still present:
  - Choice of the right connector
  - Different ways to lay out all the instruments of the set
- Still not 100% standardized yet…
...Further improved standardization

To achieve a goal of 100% of standardization:

A standardized loading is required

SOP with picture showing the validated lay out

- Paper form
- In the electronic Tracking System
  (scan the set and get the foto on the screen)
Standardization

Every set gets its loading foto
New Process is possible: Standardization and double check

- Clear and easily accessible loading SOP
- Double check of SOP-loading pattern on clean side
Take Home Messages

- In reality standardized cleaning of cannulated instruments is much more difficult to implement than for non-cannulated instruments

- Discussion of current cleaning strategies … and their weaknesses

- Dependency of human factor is a barrier for standardization and thus for validation
Take Home Messages

- We have designed and tested a system that improves some weaknesses of current systems

- Real live test at Sterinord Lille: 60 → 98% of all cannulated sets can be reprocessed

- Product innovation leads to a Process innovation
Innovation through close cooperation with our customers.
Any Questions?
Thank you for your Attention!

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