Out of the labyrinth together: The best way to retain instrument value

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Instrument reprocessing is an important part of infection prevention. Using standardised, validated procedures, items to be reprocessed are cleaned and disinfected so that they no longer present a risk of infection. The methods and processes used are defined according to the following parameters: temperature, time, mechanics and chemistry.

In addition to their effect on contamination and pathogens, these factors also affect the items to be reprocessed (e.g. instruments, containers) and the reprocessing equipment (e.g. cleaning and disinfecting equipment). Under extreme conditions, the physical sterilisation process is also influenced by the aforementioned factors. The Instrument Reprocessing Working Group's (Arbeitskreis Instrumentenaufbereitung, AKI) red brochure entitled Reprocessing of Instruments to Retain Value lists numerous examples on this subject, for example "Surface changes", and provides basic guidelines regarding causes and corrections.

In day-to-day practice, the reprocessing parameters should provide results that are stable and inconspicuous: clean medical devices that function well. The medical devices are visually inspected and surface changes are uncommon.

However, sudden changes do occur. Finding the cause is not always easy, since numerous influencing factors can be involved. Pinpointing these influencing factors can be labyrinthian. There are detours and dead ends and it can be difficult to see the big picture, even when one's objective is just around the corner.

Who is responsible here, the manufacturer of the chemicals or the manufacturer of the equipment? Or is it the instrument manufacturer? What information do the parties need and who coordinates communication between the companies? These are among the questions that the user needs to ask. In addition, there is no standard form with all the required information, meaning that the period of time that elapses before the cause is found can sometimes be very long due to queries still needing to be answered.

For this reason, the AKI Task Group*, under the responsibility of the AKI, developed a questionnaire for the recording of processes, for the purpose of documenting the entire process and identifying possible causes. This questionnaire serves as a map of the "labyrinth" both for you as a user and for the companies involved, letting you avoid unnecessary dead ends and keep a bird's-eye view of the objective at all times.

This survey is the first to be jointly developed by specialists from the areas of process chemistry, instruments to be processed, cleaning and disinfecting equipment manufacturing and steriliser manufacturing. This multi-disciplinary approach makes it possible to take the various areas of specialisation into account when asking specific questions and coming up with an assessment. Another goal is for the questionnaire to help the parties (equipment manufacturers, instrument manufacturers, chemical manufacturers) reflect on the processes and their communication in order to identify the causes of faults.

Here are two possible use cases.

Situation 1

Once upon a time, there was a central sterile supply department (CSSD). The space was well-lit and the air was clear and a pleasant temperature, even on the hottest summer days. The instruments were spotlessly clean and

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instrument reprocessing and surgical employees all got along well and respected one another. But one day, dark clouds gathered and the surgical staff began to complain more and more about slight blueish deposits on the instruments. Reprocessing employees also began to notice surface changes in the cleaning, disinfecting and steam sterilising room. Everyone was at a loss, and people grew increasingly disgruntled.

Trying to counter the stormy weather, they quickly downloaded the process documentation questionnaire from the AKI website (www.a-k-i.org), filled it out completely and sent it to the processing manufacturer. It was received and analysed there, but no adequate explanation for the change could be found. The processing manufacturer then contacted the manufacturers involved in the processes to discuss further steps. Together the parties decided on an on-site appointment, which was held promptly in order to discuss all possible influencing factors with the customer. It was then determined that silicic acid leakage in the ion exchanger had caused temporarily decreased water quality. The ion exchanger was regenerated and adapted to the current water consumption volume. The dark clouds dissipated along with the silicic acid.

Figure 1: Abdominal hook with silicate layer.
Figure 2: Silicate layer on cleaning and disinfecting equipment due to poor water quality.
Source: aseptica 1/2011

Situation 2

You hear a presentation at a convention about pitting corrosion, hygiene scandals and clinic closures. You intensify your own visual inspections and find isolated instances of deposits. What now? The chemical process consultant happens to be on the premises. They check the chemicals being used and their concentrations, but find nothing wrong. He gives the hint that it could be due to the water quality. The cleaning and disinfecting equipment service technician is there for routine maintenance and says the water quality is fine, but maybe the steam supply is to blame. The manufacturer has just revalidated the sterilisation process, and the technician then suspects that since the steam quality meets EN 285, perhaps the quality of the instrument materials is to blame. The instrument manufacturer is based in another country and hard to reach by phone. However, since the deposits only occur in isolated instances and on particular instruments, there doesn't seem to be a systematic error. What now?

At the convention, you also attended a workshop about a process documentation questionnaire, so you download that questionnaire from the AKI website (www.a-k-i.org). Filling out the survey allows you to take into account all the reprocessing steps at once. You notice that the problem occurs with particular instruments from one particular department, which has a lengthy wait time from removal to reprocessing. In addition, these instruments have high levels of organic contamination after use, and this dries out due to the long standing time. You then optimise your process and use a suitable product for pre-moisturing the instruments until reprocessing starts. No deposits on the previously affected instruments have been seen since.

Conclusion

Generally, reprocessing occurs in an inconspicuous, unproblematic fashion. But, "true life is lived when tiny changes occur" (Leo Tolstoy), and tiny changes require attention and straightforward action. A tool like the newly created process documentation form (on the following pages) can help facilitate a structured inquiry. It provides a map of the labyrinth that helps all parties involved (users as well as manufacturers) identify causes and find solutions together.

Return to manufactuer in charge:

ARBEITSKREIS INSTRUMENTEN-AUFBEREITUNG

Questionnaire for your problem statement / your question

For the processing, we kindly ask you to return the completed questionnaire to the processing company. By returning the questionnaire, you confirm that the companies involved in the process (from the questionnaire) may exchange the data with each other in order to ensure the best possible solution process.

1. Contact Information			
Contact Person:	*Surname:*	*First name:*	*Date:*
	Tel No.:	*Email:*	
Address:	*Name of Institution:*	*Department:*	
	Street:	*No.:*	
	Zip Code:	*City:*	*Country:*

2. Product Information (if applicable to the return shipment)	
Product / Type:	
Article No.:	Order No.:
Age of product:	LOT/SN (if applicable):
Please describe the error image (also information about material, specific product groups, etc.) or the examination to be carried out in a few words (if possible, attach photo material of the product)	

3. Description of the situation				
Detailed description of the problem:				
Type of problem:	Residue ☐	Coloration ☐	Corrosion ☐	Cracks / Breaks ☐
Other:				
How often does the problem occur?		Once ☐		Repeated ☐
Since when did the problem occur?				
Are other products affected?		Yes ☐	No ☐	
Remarks:				

Return to manufactuer in charge:

ARBEITSKREIS INSTRUMENTEN-AUFBEREITUNG

Current changes in the reprocessing process				
Product	New	Maintenance / Service	Repair	Executing company
Instruments	☐	☐	☐	
WD	☐	☐	☐	
Water Treatment	☐	☐	☐	
Steam Generator	☐	☐	☐	
Sterilizer	☐	☐	☐	
Process change	manual to automated ☐ automated to manual ☐	☐ ☐	chemothermal → thermal ☐ thermal → chemothermal ☐	☐ ☐
Change of:	Process Chemical	Sterile packaging	Disposal	Pre-Treatment
	☐	☐	☐	☐
Others / Remarks:				

4. Information to the disposal

Pre-treatment at location of use?	Yes ☐		No ☐	
If yes, with what?				
Disposal of contaminated Instruments?	Wet ☐	Moist ☐	Dry ☐	
If wet or moist, with what?				
Average standing time before further reprocessing?				

5. Information to manual cleaning / disinfection

Manual Cleaning / Disinfection	Yes ☐	No ☐
If NO, please process with item no 6		
Specification of process chemicals	Cleaning	Disinfection
Name		
Manufacturer		
Concentration used		
Contact time in min		
Application Temperature in C°		
Water quality used		
Ultrasound used	Yes ☐ / No ☐	Time of US

6. Information to automated process						
ATTENTION: Please enclose batch report separately						
Automated Reprocessing?	Yes ☐	No ☐				
If NO, please fill in item no 5						
Specification Washer Disinfector						
Manufacturer:						
Type:						
Rack type:						
Specification Process chemicals	Name	Manufacturer	Cons. %	Contact time in min	Application Temp..	Water quality
Detergent 1 Manual Pre-Cleaning						
Detergent 2 WD						
Additive (e.g. Oxivario process) WD						
Neutralization WD						
Disinfection product WD						
Rinse Aid WD						
Other products used (e.g. Instrument milk) Manual / WD						

7. Information to the Sterilization		
ATTENTION: Please enclose batch report separately		
Sterilization carried out?	Yes ☐	No ☐
If YES, please proceed with item no 7		
Method	**YES**	**NO**
Steam sterilization	☐	☐
If yes, central steam supply existing?		
ATTENTION: Please enclose analytical results of last feed water and steam condenser probes		
Ethylene oxide (EO)	☐	☐
Formaldehyde (FORM)	☐	☐
Hydrogen Peroxide	☐	☐
Ozon	☐	☐
Other method:	☐	☐
If yes, which method:		

Specification Sterilization tool	
Manufacturer:	
Type:	
Sterilization program:	
Used sterile barrier system	

MANY THANKS FOR YOUR HELP!