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Cleaning complex surgical instruments

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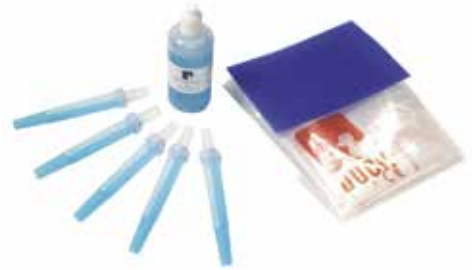
The cleaning of complex reusable surgical instruments requires different considerations and processes, compared to conventional reusable instruments. Samuel Morais BScEng (Hons), from STERIS, offers some advice on tackling some of the key challenges around decontamination of complex surgical instruments – from cleaning and transport, through to reprocessing.

Samuel Morais

With modern advancements in science and technology, we find ourselves faced with continuous challenges due to changes in the design of reusable medical devices. These challenges typically occur due to the competing requirements of making the medical device fit for its surgical purpose, versus the need for safe decontamination of the device, ready for its next use. When dealing with these decontamination requirements, the first step is to consider how these medical devices can be safely and correctly cleaned, in order that subsequent processing steps, such as sterilization, are not compromised.

Even typical solid or box joint constructions can present cleaning challenges. However, the complex designs that we find in robotic surgical instruments do present new and sometimes very unique challenges, especially due to the large array of different complex surgical instruments that are now available for use. While these complex surgical instrument advancements bring huge possibilities for innovative surgical techniques and intervention to the fields of medicine and surgery, they also bring additional challenges and complexities to the decontamination process.

With that, CSSD departments inherit the responsibility to effectively reprocess instruments of all types and complexities, within the scope of the processing instructions provided by the medical device manufacturers. These instructions may typically make use of pre-cleaning solutions that are used even before the medical device enters the central sterilization department (CSSD). CSSDs also need an effective and appropriate washer-disinfector installed to process their range of surgical instruments as part of the decontamination cycle.



The Distal Duck Kit keeps instruments moist after use and protected during transport for reprocessing

The three important factors for safe and effective cleaning, which become augmented when related to a complex reusable surgical instrument, are as follows:

- Preparation for cleaning and transportation
- Validation of automated cleaning
- The synergy of cleaning chemistries (detergents) with the washer-disinfector.

There are often a number of questions that arise from the above:

- How do we keep instruments with a complex construction not only moist but also protected during the transportation stage between the point-of-use in the operating theatres and the CSSD?
- How do we maximise the performance of a washer-disinfector without compromising productivity?
- How do we deliver a precise cleaning process in order to reduce protein residues to acceptable levels, without excessive time and utility consumption? Time has always been a scarce resource, and it is increasingly becoming a more and more valuable commodity in our day-to-day scenario. We would all benefit from having more time, and so many solutions to adequate processing are often focussed on ways to reduce time – while, at the same time, enhancing the decontamination process.

Answering these questions and ensuring successful alignment to recognised consensus guidance and standards of cleaning of complex instruments is imperative for CSSDs in hospitals, worldwide.

The important step of preparation for cleaning and transport

Preparation of complex surgical instruments immediately after use and prior to any activities in the CSSD is a process that has long been recommended by manufacturers of medical devices and the decontamination equipment used to process them, and is also one of the central tenets of the UK guidance document *Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care (Part A: Management and provision)*, that specifies:

- Ensuring maximum efficiency in protein detection and decontamination.
- Improving instrument set integrity.
- Ensuring that a separate pool of new neuroendoscopes and reusable surgical instruments is available for high risk procedures on patients born since 1 January 1997, as it is thought that people born since 1 January 1997 have had lower exposure to prions via the food chain

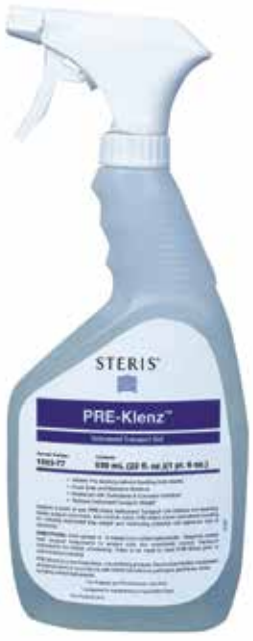
or blood transfusion.
- Ensuring contingency for dropped or unavailable instruments.
- Ensuring a continuously moist environment for instruments between use and reprocessing.
- Having a system in place for surgical instrument management and to cover the quality, condition and suitability of reusable surgical instrument.

Regional differences may require the inclusion of both manual as well as automated process instructions; for example, the US processes many more medical devices by manual means than in Europe.

As specified in the reprocessing instructions for use (IFU) supplied by the reusable medical device manufacturer, the user should observe the time limit between the point of use and the decontamination process carried out in the CSSD. In some cases, the device manufacturer advises for this time to be as short as 30 minutes due to the risk of the soil drying on the external or internal surface of the instrument, which, in the case that the instructions are not followed, will considerably increase the cleaning challenges to have the instrument adequately decontaminated.

Additionally, there are some concerns in respect of the transportation of complex surgical instruments to the CSSD. While there is always a risk of damage taking place during the decontamination process, it is much more likely to occur at the transportation stage. This transportation may be only between a CSSD and theatres within the same building or may be to and from an offsite reprocessing facility. Taking this into consideration and understanding the construction of a complex surgical instrument, we can say that the distal end of an instrument is usually, quite obviously, the most sensitive part to transit damage.

As well as being susceptible to damage, complex surgical instruments may not be packaged appropriately for transit – much sterile device packaging is designed for presentation to the sterilization process and to function as a sterile barrier, rather than for mechanical transit protection within the tray or basket. This is a challenge that has been experienced globally over the years and as such, solutions have been developed in the format of conditioning bags, sprays and other means to keep the instrument moist and also, importantly, to protect the sensitive areas of such instruments.



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Automated cleaning of complex instruments

EN ISO 17664:2017, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices, gives reusable medical device manufacturers a format and detail to provide in the IFUs with their devices; specifically, this prompts medical device manufacturers to detail the validated methods of cleaning medical devices that will preferably reference at least one automated process. The purpose of this is to reduce, if possible, the generally accepted understanding of the added risk of process failure that a manual process and the human factor brings during the cleaning stage. When reprocessing complex surgical instruments, this risk can become amplified, as, due to their intricate design, it is often not possible to verify, with the human eye, if the instrument is, in fact, clean. Washer-disinfectors and ultrasonic cleaners are used as part of a validated automated process that is detailed in the IFU of most (if not all) complex surgical instruments.

Depending on the performance of the decontamination equipment, these automated processes also can have drawbacks; historically, in order to have the most expedient and robust automated cleaning process, it has become the norm to use higher concentrations of cleaning chemistries (detergents), or to adopt high-alkaline chemistries. Indeed, in some geographical areas, exclusive use of alkaline cleaning chemistries is the norm. As a consequence of this, instrument damage may occur due to the use of these high-alkaline cleaning chemistries.

This approach can be mitigated by delivering an enhanced mechanical cleaning element of a washer-disinfector or ultrasonic cleaner, but this requires evolution in the form of development and validation of decontamination equipment and their processes from the decontamination equipment manufacturers. As well as material compatibility of the reusable medical devices, the materials of construction of the decontamination equipment must also be compatible with the process chemicals – the cleaning chemistries (detergents) and disinfectants; this highlights the importance of ensuring correct validation and type-testing of these process chemicals as an intrinsic part of the equipment and process validation.

Manual process vs automated process

This is a frequently asked question within the medical device industry for the effective cleaning of complex reusable surgical instruments. European laws – the Medical Device Directive, as well as its successor, the Medical Device Regulation, require the manufacturer of reusable medical devices to provide reprocessing instructions. This information is provided in the IFU, and, as mentioned above, is always the point of reference for the medical device user. The nature and the type of cleaning process will be completely dependent upon the reusable medical device's specific design, materials and tolerances.

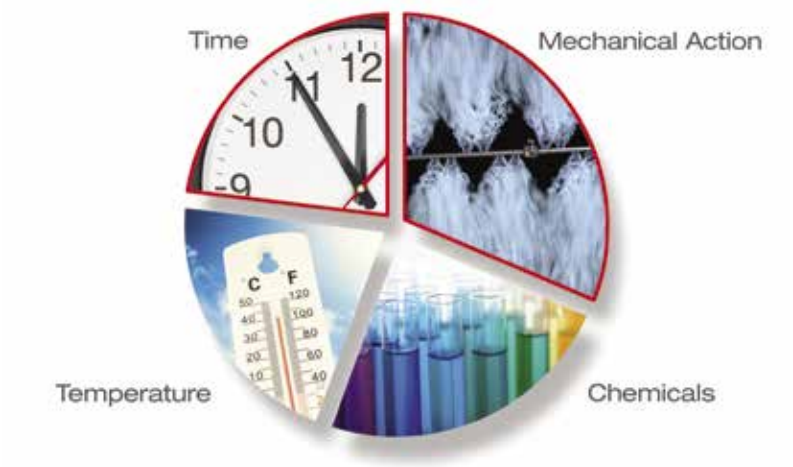
Regional differences may require the inclusion of both manual as well as automated process instructions; for example, the US processes many more medical devices by manual means than in Europe. However, when relating to the cleaning of complex reusable surgical instruments specifically, an automated process is always the preferred approach recommended by the reusable medical device manufacturer.

While mechanical action is typically delivered by brushes for a manual process, this mechanical action is delivered either by mechanical impingement in a washer-disinfector, or by cavitation in an ultrasonic cleaner. What sets complex reusable surgical instruments apart from more simple medical devices is that, in many cases, the use of ultrasonic cleaning is specified as a mandatory step by the device manufacturer, regardless of whether the medical device will subsequently be going through a washer-disinfector, prior to moving into the inspection stage in the clean area of the CSSD. This is particularly the case in many types of orthopaedic and trauma instruments.

Ultrasonic cleaning

As highlighted above, ultrasonic cleaning has become an essential part of the automated ▶

cleaning process for many complex reusable surgical instruments. It delivers mechanical action through the cavitation effect, which is the vibration of the molecules of water of the solution that the instrument is immersed in. These high frequency 'micro-implosions', when in contact with the surface of the medical device, assist with the removal of soiling from the external areas of the medical device that are submerged in the cleaning solution that receives the ultrasonic activity. The ultrasonic cleaning can also act on the internal areas of hollow, lumened or cannulated medical devices, but only if there is also an irrigation function working in tandem with the ultrasonic cavitation within the cleaning solution; this process is commonly called 'sonic irrigation'.



The automated cleaning process can be practically enhanced by using two elements of Sinner's circle; time and mechanical action, that can be used to reduce process time

High impingement washer-disinfectors

The other method of provision of mechanical action utilised in the automated cleaning process is mechanical impingement delivered by washer-disinfectors. Impingement is the mechanical action of pressurised water forced through spray jets that subsequently remove soiling from the surface of the medical devices. All washer-disinfectors utilise impingement. However, not all impingement is created equally. The water pressure is critical for the efficacy of the mechanical cleaning, but it is not sufficient to solely focus on pressure alone.

The water connection of the washer-disinfector rack to the chamber and the design of the washer-disinfector spray arms are also critical to the delivered performance. The level of impingement will be a function of the above factors, as well as the cleaning chemistries used; washer-disinfectors and processes that are validated for complex surgical instruments typically use high impingement, that, by its very nature, can cause a lot of foaming within the process.

This foaming can be caused by the formulation of the cleaning chemistries, and also by the presence of protein from the medical device soiling. Cleaning chemistries that are formulated specifically for high impingement washer-disinfectors will be inherently low foaming and will also be able to reduce foaming from the presence of protein – both of which are exacerbated by the use of high impingement technologies.

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Sinner's Circle and TACT

Herbert Sinner first described the inter-relationship of the variables necessary for cleaning; these variables are time, mechanical action, chemistry (detergent) and temperature, and can be described by the mnemonic 'TACT', for time, mechanical action, chemistry and temperature. Sinner's Circle is useful as it helps to explain the inter-relation between each of the for variables, and that a lowering of one variable can be resolved by an increase in another variable. The automated cleaning process can be practically enhanced by using two elements of Sinner's Circle; time and mechanical action, that can be used to reduce process time. An automated process uses increased mechanical action when compared to a manual process, which in turn saves time; reducing process time in a busy CSSD department means more productivity.

Performance, productivity and optimisation

It is clear that the constantly evolving developments in complex surgical instrument design means that we are all continually striving to ensure adequate medical device decontamination to consensus standards and manufacturers' IFUs. These validated reprocessing IFUs can present new challenges to the end user, but these challenges can be addressed with ready-made automated decontamination solutions for the CSSD department. This holistic approach to automated reprocessing gives a lean value proposition that address three factors for the automated cleaning of complex medical devices – performance, productivity and optimisation – that are safe and effective, efficient and sustainable.

Performance

The performance of a washer-disinfector is a consequence of a number of factors; as discussed above, the mechanical action, delivered by high impingement, is one of the key focus areas of differentiation between conventional *versus* complex surgical instruments. An important consideration for washer-disinfectors is that they should also be capable of options to meet a range of IFUs, including cycle parameters to address delicate surgical instruments (e.g., ophthalmic instruments, etc) that should be cleaned with low impingement mechanical action.

Chemistry, as one of the four factors of Sinner's Circle, has a pivotal role within the washer-disinfector cleaning performance. As well as cleaning performance, medical device compatibility is also critical, hence the chemistry must be compatible with the medical device, and also of course with the washer-disinfector. The formulation of these chemistries goes hand-in-hand with the type-testing and validation of the washer-disinfectors that they are used within.

Independent monitoring of the performance of washer-disinfectors is highly desired, giving them the ability to detect anomalous or out of specification parameters. For example, factors such as foaming within the washer-disinfector can

significantly impact the delivery of high impingement performance by causing a drop of pump pressure.

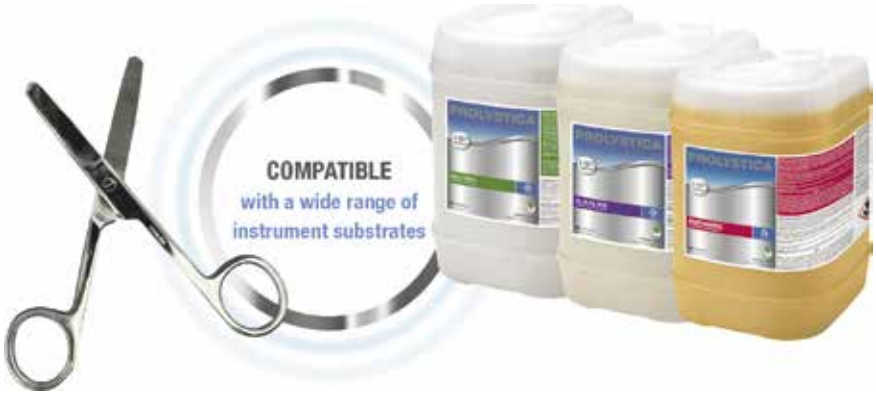
Productivity

By optimising the entire cleaning performance, in accordance with the Sinner Circle, it is possible to reduce the time variable, resulting in shorter cycle times, without affecting the overall performance of the washer-disinfector. This will allow the washer-disinfector output to increase, therefore contributing to the working day department productivity.

In order to process specific robotic instruments, dedicated accessories, such as washer-disinfector racks may be required. These solutions should be designed to offer simplicity of use, whilst being in compliance with the medical device manufacturer's IFU – meaning that use of such accessories have been validated by the device manufacturer.

Optimisation

For good reason, we are all concerned about the environmental impact of everything we do. Utility conservation is one area that we can make a big impact, and electricity and water usage should be minimised wherever possible. Areas where realistic improvements can be made is in minimising the use of power and water whenever possible, and the reuse of this heated water where practicable.



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This can be achieved by ensuring that the correct amount of water is utilised relative to the size of the rack used within the washer-disinfector, and minimising the time required to dry a smaller load in comparison to a large fully loaded rack; additionally, the water from the specific stages of the process can be stored and used for the next cycle. Cycle time and water can also be reduced by pre-heating water external to the chamber and delivering this when required into the washer-disinfector.

Conclusion

The cleaning of complex reusable surgical instruments requires different considerations and processes when compared to conventional reusable surgical instruments. These considerations typically require automated processes rather than manual processes.

Complex surgical instrument manufacturers' IFUs and consensus standards help to ensure that these complex surgical instruments are adequately decontaminated. Innovations in washer-disinfectors and ultrasonic cleaners allow complex surgical instruments to be adequately processed in cycles with maximised performance that optimise productivity and environmental impact, while ensuring maximum safety of the patient. CSJ

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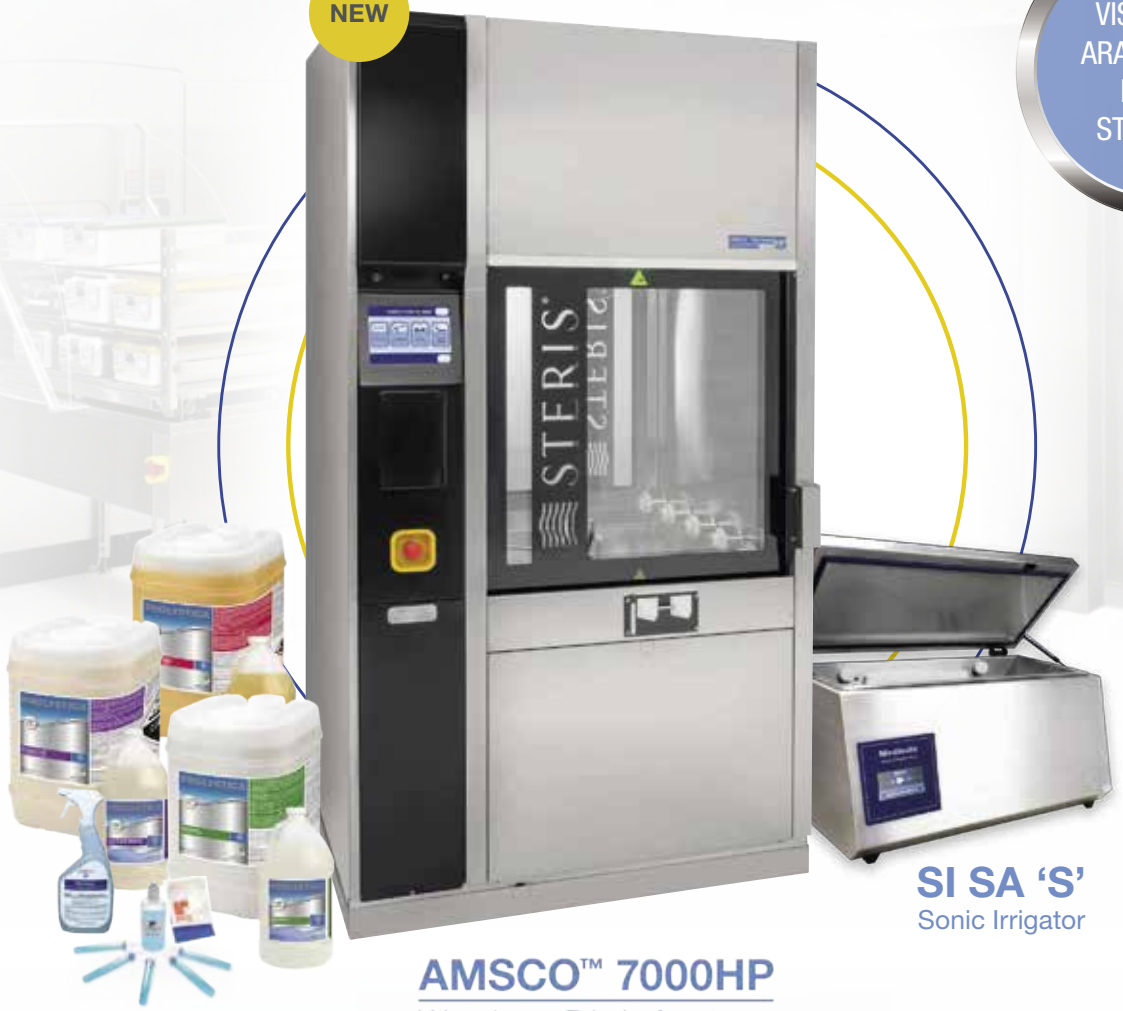

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