

Inspection, assembly and packaging (IAP) ?Pneumatic–Powered Pneumatic (air) powered devices work the same as electrical devices but instead of being connected to an electrical outlet are connected to a compressed air line of a cylinder (tank) that uses a regulator to maintain a stable pressure Battery–Powered Devices powered by battery are the easiest to use of the three available power systems as there are no cables restricting movement in the sterile field.Electric–Powered Devices powered by electricity require a cable that attaches to the handpiece and to a power supply/control unit connected to an electrical outlet.To reduce the chance of sets being out of service due to device servicing and repairs it is critical to: Identify most frequently used surgical sets and critical items that will require servicing Plan for repairs by purchasing additional critical items to substitute for originals when they are sent for servicing Ensure all devices are inspected carefully for cracking or damage, especially around TC inserts Device Lubrication Surgical devices with moving parts must be lubricated in accordance with the manufacturer's IFU.The IAP room is usually the central point of CSSDs and where the crucial job of inspection, function testing and appropriate maintenance of cleaned reusable medical devices takes place All reusable medical devices and accessories are inspected to ensure that they are clean, intact and that there are no chips, worn spots, flaking or other damage The functionality of all RMD are tested or checked before being packaged for further processing or storage.Recap The steps completed--so far we have to:

- o Checked that the Washer–disinfector cycle has been successful and the load is released
- o Removed the tray of devices from the washer carriage
- o Placed the tray on a clean workbench surface
- o Inspected each individual device for cleanliness and functionality
- o Assembled the devices that were disassembled for washing
- o Laid the tray out in a manner that ensures good presentation of the devices and that they are protected against damage in accordance with the tray list

?Check all screws on jointed RMD for tightness as they may become loose during the cleaning process Check cutting edges (such as scissors, rongeurs, chisels, curettes) for sharpness

<https://youtu.be/lkFz34OXLfg?si=bDdpyGKtp4DnD5Nr> ?Device Identification The most effective way to identify surgical devices is to keep accurate checklists of tray contents that identify the manufacturer and model number and give an accurate description Many facilities use marking methods to speed up and simplify identification such as: Acid base etching--uses a stencil, solutions, and electricity to mark stainless steel.Electric etching (physical)--this old method of electric etching or engraving was performed as it was quick and easy to do but this method should never be used as it damages devices and makes them more difficult to use Heat–fused nylon--a color–coding process referred to as dipping, that is typically done only in a repair facility.King Abdulaziz University (KAU) The Applied Faculty Health Information Technology Department (HIT) – Sterilization Technician Program INSPECTION, ASSEMBLY AND PACKAGING (IAP) Dr. Hayfa Almutary 2023 ?To determine how well the IAP room is being cleaned and give you a good idea of contamination during traffic flows and peak periods, part of the sampling program should be carried out when the facility is unoccupied to achieve a baseline contamination level prior to sampling when occupied.Manually Cleaned Device Acceptance Quality checks must also be carried out when accepting items that were not processed in a WD. These quality checks consist of: Soil or staining--any visible soil or staining is rejected and items must be sent back for reprocessing.Excessive wetness -- excessive wetness could be caused by blocked arms, incorrect

loading or problems with the automated washer disinfectors (WD) settings so should be investigated.

**o o Inspection and Function Testing** All surgical devices must be inspected for cleanliness, stains, corrosion, cracks, breakage, and stiffness of movable parts before being placed in device sets.

**Environmental Requirements for IAP Ventilation** for the inspection, assembly and packing room meets clean room standards according to ISO 14644-1: 1999 Class 8 or other internationally accepted equivalent standard. Specialists working in the IAP wear a freshly laundered scrub suit. Scrub suits are low-linting attire that minimize bacterial shedding and provide comfort and a professional appearance. These are some standard processes that should also take place: Check that the chart record for the cycle conforms to the information established during validation and that all recorded variables are within the parameters permitted. All powered surgical devices are highly complex and fragile with hand pieces that cannot be submerged in fluids and often have lumens, channels and attachments with special cleaning requirements. The results of the analysis are then compared to baseline counts of microorganisms (accepted levels of contamination) predetermined by either the microbiologist or a contracted specialist.

Following on (Is) we are now ready to unload the washer-disinfector containing clean, disinfected surgical instruments and accessories.

**Inspection and Function Testing**

**o o o Inspection and Function Testing**

**o o o Devices** that have an outer insulation coating, for example diathermy forceps, require close inspection to ensure that the insulation remains intact. Once the barcode label is scanned by the specialist preparing the tray it automatically produces a packing list and also generates a unique barcode label which contains the serial number specific to that tray and process. Aim to leave all forceps with ratchets open but if stringers are not available close devices with ratchets on the first ratchet only, to ensure that steam can penetrate all surfaces. This method is inexpensive and very simple to install but requires excellent quality inspections to ensure it is properly replaced and won't risk patient safety.

For application, the following steps must be followed:

- Wash your hands to remove oils, grease, and any possible dirt.

In the past most of these required manual cleaning and disinfection and could not be processed in automated washer disinfectors, and so presented a higher risk to CSSD specialists. The area where inspection takes place is designated and controlled to optimize the effect of the sterilization process and minimize the risk of contamination of the RMD sets. All rooms in the department are ventilated and controlled to provide a comfortable working environment of 18–25 C and a relative humidity within the range 30–60%.

**Environmental cleaning** must follow policies and procedures that have been approved by the hospital infection control committee. Depending on your specific equipment this may be an automated process using conveyor belt-type unloading mechanisms. If not automated, the washer carriage can be manually removed from the chamber taking care to wear heat-resistant gloves if necessary—remember the temperature in the chamber can reach over 90°C.

**Soil or stain** — any soil or staining seen on visual inspection is rejected and items must be sent back for reprocessing.

**Damage due to configuration** — for example if items were impacted by spray arms or the RMD was not compatible for WD processing.

**Completed documentation** — load contents and any non-conformances and rejected loads must be documented and reported to the line manager. Check that the operating cycle selected is in accordance with the specification for the load, e.g. surgical instruments or anesthetic equipment would need different cycle types.

**Documentation completed**—manually cleaned

items and any non-conformances and rejected items must be documented and reported to the line manager. Critically inspect all areas of the devices e.g., box joints, serrations and crevices, for cleanliness. They can also be arranged by size so they don't get tangled or from Surgeon and OR Nurses preferences, but the most important aspect is to have an accurate checklist that all specialists follow to ensure consistency. Lubricants must be approved for use as a surgical device lubricant and used in the hinged areas or any working component such as a moving or sliding area o o o ? These devices are powered by electric motors, compressed air (pneumatic) or batteries and dramatically improve procedure times to the benefit of patients. Fortunately, most newer powered surgical devices are designed to allow automated processing and therefore greater safety to specialists and patients

### Powered Surgical Devices

? One method of monitoring involves placing contact or settle plates in pre-planned locations in the room and then sending them to the lab for culturing and analysis. Quality checks consist of:

- Correct cycle--for example, if a container cycle was inadvertently used for instruments then the load should be rejected and sent back for reprocessing. A more serious issue may be where the specialist notices the spray arm rotation has been hindered and therefore the whole load has been compromised and must be returned for re-processing. If staining and/or residue are present, this may be due to the configuration of the load, overloaded cart or malfunction in the washing cycle. The fabrics are of differing thickness and density and provide appropriate test consistency for different devices
- Scissors : Test: must be able to cut cleanly through to the tips of the device, two to three times. Older designs relied on batteries that were sterilized, which could Negatively impact power storage, but many newer systems allow for batteries to be loaded in the operating room to ensure a full charge.
- Spray arms not blocked -- If arms were blocked by RMD during cycle the load must be rejected as correct cleaning and disinfection may not have occurred.
- Devices correctly disassembled -- If items were not disassembled, adequate cleaning would not have occurred so the full set should be returned for reprocessing. Unless there is clear indication why a small percentage of RMD in a load were not cleaned and/or dried effectively, the entire load should be returned for re- processing.
- Excessive wetness--items that have been manually cleaned and disinfected must be dry before moving to the IAP room.
- Correctly disassembled devices--if items were not disassembled, adequate cleaning would not have occurred so the item is returned for reprocessing. o o o

### Assembly and Checking

Once the devices have been inspected and function-tested they are now ready to be assembled into their respective trays. In the IAP room the track and trace system usually consists of handheld barcode readers connected to PC's that log and store the information for each tray. Most often items are arranged from left to right in accordance to when they will be required in a procedure, for example, the scalpel handle used to make the initial incision is the first device on the left and the needle holders used to close the wound are on the far right. Tray liners (2) or silicone mats (3) may also be used to protect delicate devices but placing them in a manner that protects them, especially away from heavy devices, is also very important. 123 Any missing or extra devices found while assembling the tray should be reported to the supervisor for further action and a non-conformance documented. Heat-fused nylon leaves a thin layer of color on the device that can last years but must be fully removed and replaced when chipping occurs. The use of a neutral pH lubricant reduces friction, making it easier to use and extends the life of the device. This freedom of movement, however, comes with a price where batteries

require charging, increased handling and space to accommodate the chargers and have a risk of not being charged enough to last a procedure. Protective clothing is worn by personnel entering the IAP room to reduce the risk of possible contamination of the clean reusable medical devices and the environment. Freshly laundered attire is changed daily or whenever it becomes visibly soiled or wet. The hat or hood must be designed so that microbial dispersal is minimized with all head and facial hair confined as well as covered. After use, headgear and beard masks should be discarded in the appropriate waste stream. Make a visual inspection of the load to ensure that there is no obvious damage, staining or residue. Check hinges (such as artery forceps and clamps) for ease of movement. Check jaws and teeth (such as found on Kocker Mosquito forceps, (Figure ) for alignment. Check that the edges of clamping RMD meet with no overlap and that teeth mesh together properly. Sharpness testing packs are available for different types of bladed surgical instruments. The system allows for the accurate tracking of the devices and device trays through the whole decontamination process. This usually consists of a pre-printed tray checklist and a manual label gun ? Follow the manufacturer's IFU for devices that should be sterilized in a particular way or disassembled. Evenly place plastic items in the tray; avoid collecting them in one area as this may also lead to moisture collection post- sterilization. Laser etching--is permanent and costlier due to setup charges so is often outsourced rather than done internally. Complex surgical procedures require specialized tools for drilling and sawing that require strong forces that standard hand tools can't provide. For all powered surgical devices, it is critical to follow exactly the specific manufacturer's IFU. Arthroscopic shavers are an example of frequently used electric-powered devices. A dedicated cleaning room is located within the IAP room to clean this area-- no outside areas should be cleaned from this location. Head/Hair Cover A clean, single-use, low lint surgical hat or hood that confines all hair is always worn in IAP. Washer-Disinfector (WD) to Sterilizer ? Be careful with utensils like gallipots or kidney dishes that may have turned upside down during the washing process and contain hot water. For example, you may notice a device that was not properly disassembled in the wash area, so the entire tray must be considered contaminated and sent back to the wash area via the transfer hatch or chamber. o o o o o Local Policy Checks After Unloading What happens to the load next depends entirely on local policies, procedures and guidelines. Damage--if the item was handled incorrectly or immersed in fluid when it should not have been it must be reported immediately to the line manager. Report any damaged, incomplete or malfunctioning devices immediately to the supervisor. Check cannulated devices to ensure channel is patent (clear). devices should be checked under magnification because small pieces of bioburden or debris can otherwise be difficult to see. Check insulated devices using a diathermy pin point tester. Device Sharpness Testing and Identification Device Sharpness Testing It is essential to monitor the sharpness of devices. Forceps should be placed on instrument pins to hold them together and reduce tangling. This ensures that all surfaces are presented to the sterilants. Spread devices evenly by weight over the tray surface to help prevent condensate flowing together. Device tape the most common and popular method for device identification is the use of colored tape that can be affixed to the device. This room must be maintained under positive pressure to ensure no contaminants can enter. Microbiological monitoring is carried out in this room according to

hospital infection control policies. This monitoring is used as an early warning system to alert staff when environmental quality is drifting out of control.

**Dress Code Requirement**

Staff movement, between dirty and clean areas is not possible without passing through a clothing change and hand-wash area. Managers ensure that protective clothing is available and all personnel are responsible for correct use and disposal. Stud earrings may be worn as long as they are totally confined within the head cover. These non-conformances must be documented and reported to the line manager immediately.

**Make a visual inspection of the load for dryness.**

**Function check telescopes and light cables** as per the manufacturer's instructions. Inspect each RMD from a set separately. Damaged surfaces allow dirt and bacteria to collect, and can also lead to a potential burn risk for the patient and/or the user.

**Inspection and Function Testing**

Check each device for free movement of all parts and non-sticking joints. A water-based lubricant may be used if required (read IFU for dilutions and application). These tests consist of color-coded test fabric and instructions for testing. The distal tips of scissors are the most crucial portion because this is the most used area and where they first become dull. Many CSSDs today are switching to one of the many types of computerized track and trace systems on the market. These systems are now accepted as one of the most essential requirements in the modern CSSD. Once a new processing cycle begins, a new unique unit number is produced each and every time. For those CSSDs that do not have such a computerized system in place, a manual system may be used. This can also be done using a forceps but isn't recommended. There are some general rules when it comes to assembling devices into trays. Validated tip protectors (1) should be placed on delicate or sharp items. This process can be done by an outside company but requires minimal tools so can also be completed in-house.

**Device Identification**

Vendor Repairs ? Another consideration is the regular maintenance required to ensure safe and effective use. Similar devices may require very different processing procedures. Most manufacturers recommend leaving the cable attached to the hand piece during cleaning to reduce the chance of fluid entering the device. Appropriate clothing is used by anyone entering this area, including staff involved in the maintenance of reprocessing equipment, and visitors. When unloading, quality checks are carried out before any further processing ? Check ratchets for easy closure and firm hold. This is an extremely important matter as an incorrect count may lead to long delays in the OR if an item is found to be missing before or after the case. It is semi-permanent, and can be buffed off.

**Care of Surgical Instruments**

? Wipe alcohol on the site of the device where the tape will be placed to remove any lubricant or moisture that might be on the device. After the tape is applied, autoclave the device to allow the heat to help bond the tape to the device. Testing results should be the same or better than this baseline. Make-up and jewelry, apart from a wedding band, are not worn in the IAP. Check each device set for completeness. Choose a location on the shaft or stem of the device. Never put tape on the distal tip that will be used on the patient as a piece could fall in the patient.

??1.2.3.4.5. Never put tape on the rings as it could interfere with action and increase the risk of the tape coming loose. ????????????