HOW TO GET TO VISUALLY CLEAN | SITE & SURFACE INSPECTION

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BACKGROUND

Visual inspection is the most often specified technique for inspecting medical devices. Standards, guidelines and articles all support the use of visual aids and tests for stain identification to ensure medical devices are clean and functional before they are high level disinfected or sterilized and then ultimately used on a patient.

"...inspection should be done just prior to sterilization. Inspect all instrument surfaces and individual parts for: Cleanliness of instruments, i.e. no debris, blood, tissue, etc. If not fully clean, repeat previous cleaning steps or properly dispose of the instruments..."[1]

"...After cleaning, visually inspect all surfaces, ratchets, box locks, holes, channels and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination..."[2]

"Visual inspection is defined as the process of using the unaided eye, alone or in conjunction with various aids, as the sensing mechanism from which judgments may be made about the condition of a unit to be inspected."[3]

"...visually inspect the hand piece, including all internal surfaces, for remaining soil. Use an endoscopic camera and endoscope if necessary to see the inner surface of the lumen. If soil remains, repeat the manual cleaning procedure, focusing on those areas..."[4]

"...If areas are difficult to inspect visually, check for blood by immersing or flushing the device in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse devices thoroughly after using hydrogen peroxide solution. If soil is still present, re-clean the device..."[5]

"...A stain is a discoloration on an instrument's surface. Rust is a red or orange coloration on the surface of surgical instruments resulting from oxidation. Note: Ensure that a "stain" observed is not dried blood... Use the eraser test to check for rust by rubbing an eraser over the stain/rust. If the spot is easily removed, it is a simple stain. If you discover pitting under the stain, it cannot be repaired..."[6]

"Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye"[7]

"...Inspection using magnification and additional illumination might identify residues more readily than the unaided eye... tools such as video borescopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices..."[8]

"...protein is a marker commonly used to evaluate cleaning efficacy... health care personnel inspect every device for visible organic soil and contamination in a simple functionality check, usually as part of the inspection, preparation, and packaging procedure..."[9]

So, what is visually clean and what are the steps a medical device reprocessing professional should take to ensure a medical device is visually clean? It is a simple process of site and surface inspection that must be performed each time a medical device is handled.

Visual inspection is a process of using the unaided eye, alone or in conjunction with various aids (borescope, magnifier, stain identification) to inspect medical devices for defects in functionality, pitting, stains, and imperfections during its processing cycle and rejecting the medical device according to the medical devices IFU if any imperfections are found. Stain identification is a process of using various methods to detect what the makeup of that stain is, and correct it from appearing again.

The standard, "is the medical device visually clean?" and understanding the type and source of the stain helps you reduce the chance of it reoccurring again in your process.

First, if it is visually dirty, you must re-clean it (unaided eye detection).

Second, visually inspect with the use of a magnifying glass.

Third, use enhanced visual inspection (Borescope, Flexible Inspection Scope, USB microscope), consider hard to see areas of a medical device, like a lumen.

Fourth, stain identification. You want to know what the stain is composed of (rust, organic soil, blood, protein, or another bioburden). Then, work towards resolving the issue to prevent it from appearing again.

DISCUSSION

Who is telling medical device reprocessing professionals to visually inspect instruments? The manufacturer of the instruments with their IFU (Instructions for Use) then the standards, guidelines, articles and studies, and lastly, the customer, who is the patient. They want a clean and functional medical device. The facility must decide what medical devices should be inspected, how often, and with what. Deciding how to reach "visually clean" can only be accomplished with research (risk or gap analysis) into the specific issues of that facility. Researching these solutions should be done as a team made up of medical device reprocessing professionals, risk management, infection control and other key members of the facility.

STAIN COLOR	POSSIBLE CAUSE
BROWN/ORANGE	HIGH pH OF CLEANING SOLUTION
GRAY	EXCESSIVE USE OF BLOOD MALEDICTOR
BLACK/PURPLISH	CONTACT WITH ANAEROBIA
LIGHT/DARK COLORED SPOTS	WATER DROPLETS DRYING ON THE SURFACE

STAINS OF PROTEIN ON STAINLESS STEEL

EXAMPLES OF DEBRIS FOUND IN SHAVERS AFTER CLEANING

DEBRIS FOUND IN DOPPLER PROBE TIPS USING A USB MICROSCOPE

STAINS THAT COULD BE MISTAKEN FOR HARD WATER SPOTS. TESTED POSITIVE FOR HEMOGLOBIN

SOLUTIONS

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EXAMPLES OF ENHANCED OPTICAL INSPECTION TOOLS

EXAMPLES OF SURFACE TEST METHODS

Surface hemoglobin test:
This swab method produces a colorimetric result that is easy to interpret. Sensitive down to 0.1ug hemoglobin.

Surface protein test:
This swab method produces a colorimetric result that is easy to interpret. Works for both soluble and insoluble proteins; detection limit of 1.0ug within minutes.

KEY AREAS TO EXAMINE WITH A FLEXIBLE INSPECTION SCOPE THAT THE UNAIDED EYE CANNOT SEE

A SAMPLE FLOW CHART FOR A MEDICAL DEVICE REPROCESSING DEPARTMENT