Example Policy of Enhanced Visual Inspection of Medical Devices

NOTE: This document is an example of a policy that may be instituted in a healthcare facility for the Enhanced Visual Inspection of medical devices. The actual policy in a facility must be based on variables, logistics, and risk-assessments that are specific to your facility.

Subject: Enhanced Visual Inspection of medical devices

Department: Sterile Processing

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter the date when it takes effect]

Revised: May 2022

Purpose: To provide a means of inspecting the cleanliness of medical devices with enhanced visual inspection (i.e., magnification, flexible inspection scopes, cameras...) as part of a departmental quality improvement process to ensure all medical devices are clean, functional, and can proceed to their next step in their reprocessing cycle.

Policy: The Sterile Processing manager (or their designee) shall be responsible for selecting the type of medical devices and the frequency of the monitoring of those medical devices by enhanced visual inspection.

Rationale: Visual clean is and always will be the standard. Every sterile processing professional knows if a medical device is dirty, they must send the medical device back to be cleaned properly. A sterile processing professional must make sure all medical devices are clean and functional before they get sterilized or High Level Disinfected (HLD).

The process of using the unaided-eye alone or in conjunction with various aids (e.g., handheld magnifier, borescope, stain identification) is essential to providing clean and functional medical devices, and to inspect for defects in a) Functionality, b) Pitting, c) Stains, d) Imperfections during its processing cycle, and e) Rejecting the medical device according to the medical devices' IFU. Thus, the term enhanced visual inspection means using some form of magnification to enhance the visual inspection process.

Standards and Professional Society Recommendations:

"Make sure instrument surfaces are visibly clean and free from stains and tissue."[1]
"Instruments must be checked visually – tactile and be macroscopically clean (i.e., free from visible residues). This is checked by visual inspection. Critical area(s), such as handle structures, joints, or jaw serrations (particularly atraumatic toothing) require

especially careful checking. It is advisable to use working lights, such as light magnifying glasses with lenses of 3 to 6 diopters when checking filigree working ends."[2]

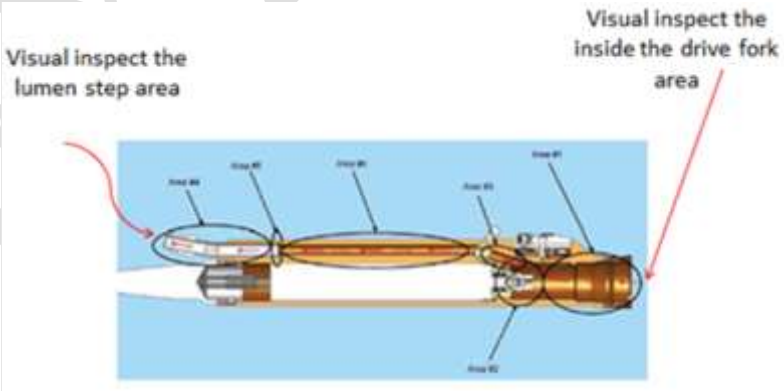
"Cleaning encompasses the removal of patient secretions and excretions and of microorganisms from the patient or from handling or water exposure during reprocessing. After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil. Inspection using magnification might identify residues more readily than the unaided eye."[3]

"The most common method is a visual inspection, sometimes involving the use of a lighted magnifying glass. 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."[4]

All medical devices should be cleaned and inspected according to recommended standards and the manufacturers published Instructions for Use (IFU)[3,4]. Visual inspection of instruments provides a means of ensuring each complex medical device can be routinely cleaned in the department. Many medical devices are difficult to inspect and are better viewed using enhanced visual inspection like a flexible inspection scope (FIS) or magnification devices. The department shall incorporate these tools to visually inspect both the external and internal surfaces, use such devices to ensure medical devices are visibly clean, and ready them for the next step in the reprocessing cycle.

The term "visual clean" will be defined by referencing the IFU of the medical devices being inspected. This could be different for each medical device that is being inspected. An example is the orthopedic shaver:

Shavers: Areas to inspect include the following:



IFU Support for using a Flexible Inspection Scope (FIS):

- Arthrex Hand Piece: The IFU states the following, "Check the device for visible soil. It is recommended that the cannulation be inspected with an illuminated, magnifying scope. Clean the device using the guidelines for manual cleaning if any soil is visible…"[5]

- STRYKER Shaver Hand Piece: The IFU states the following, "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…"[6]

In an FDA Safety Communication, "Consider inspecting the inside of the devices following cleaning to ensure that they have been cleared of any tissue or fluids. There may be multiple ways to accomplish this. As one example, the facility that brought this situation to our attention uses a three (3) mm video scope to inspect the channels of the shaver handpiece."[7]

If using magnification, it is important to document/record on the count sheet record as a task performed to ensure the device is clean and functional.

Procedure:

The Sterile Processing manager (or their designee) is responsible for determining the type of medical devices to be visually inspected using some type of enhanced magnification (i.e., FIS or other means) according to that specific medical device's IFU. In cases where the manufacturer's IFU state, ". . . inspection should be done under magnification,"[8,9] all such devices should be inspected in this manner every time they are reprocessed. Unclean or dirty medical devices pose a potential risk not only to patients but staff. Medical devices that are visibly dirty will be sent back to be recleaned according to the medical device manufacturers' IFU. All inspection results are recorded, and, in turn, this allows the Sterile Processing staff the ability to monitor and improve the cleaning process based on the problem analysis
In AAMI ST79 Visual inspection is described as a verification of the cleaning process. Section 7.6.4.5 states the following:

- Cleaning encompasses the removal of organic residues (e.g., blood, tissues, bone fragments, secretions, and excretions) and microorganisms from the patient, from handling, or from water exposure during reprocessing.
- Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye.
- Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues

> that are not detectable using visual inspection should be considered in facility cleaning policy and procedures (see Annex D for available methods).

The manager of the Sterile Processing Area will determine when and which type of magnification (i.e., handheld, bench magnifier, borescope, etc.) should be used to inspect medical devices within their process.

"Procedures must be developed, with support from the infection prevention and control and hazardous materials personnel, to protect personnel, patients, and the environment from contamination and to comply with OSHA regulations limiting occupational exposure to blood-borne pathogens (29 CFR Part 1910.1030)." [10] "The problem risk analysis should identify, define and quantify the risk and identify actions that can be taken to resolve or prevent the risk. The system should be monitored to ensure that the risk has been corrected or prevented."[11]

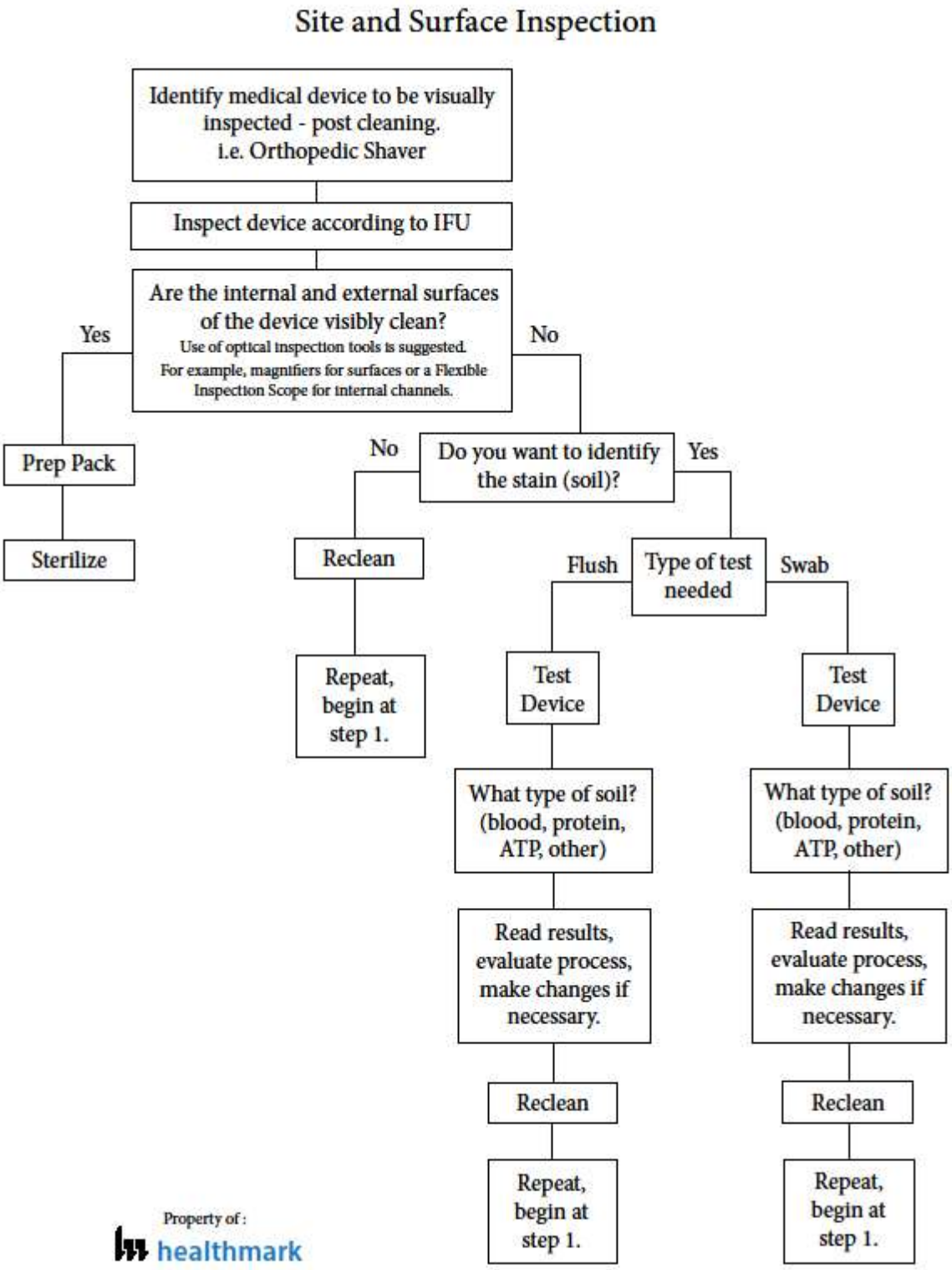
> **Documentation is important**: ". . . if a process is not documented it was not performed…Jurors view good record keeping as an indicator of good care — poor documentation can create an aura of poor care and damage the credibility of the healthcare providers."[12]

An example of a log sheet to record enhanced visual inspection is included with this policy. This can also be accomplished if you have a computer system, and this would be considered a task that must be checked off before going to the next task. Also, a reference flow chart on inspection is later in this sample policy.

Responsibility:

The Sterile Processing manager (or their designee) is responsible for ensuring staff training, initiation, completion, documentation, and analysis of the enhanced visual inspection policy for the department.

According to ANSI/AAMI ST79, the Sterile Processing Area is the area within a healthcare facility that processes and controls medical supplies, devices, and equipment (sterile and not sterile) for some or all patient care areas of the facility. This department is also known as the central service department, sterile processing, central processing and distribution and other names. Thus, for the purpose of this policy the Sterile Processing Area will be used to be consistent with ANSI/AAMI ST79.



Inspection Table
Results of Visual Inspection

Date of Inspection	Inspector initials	Medical device tested/ make / model / serial number	Visual Clean* Yes / No	Comment
			Visual Clean Yes / No	
			Visual Clean Yes / No	
			Visual Clean Yes / No	
			Visual Clean Yes / No	
			Visual Clean Yes / No	

**If a medical device is found to be visually dirty (unclean) by inspection according to that specific medical device IFU, it must be sent back to be re-cleaned and then re-inspected until visually clean to proceed to the next step in its reprocessing cycle.*

Sample Competency Record for the Visual Inspection of Medical Devices

Name:

Competency Statement: Complies with policy and procedure for . . . [list policy here].

Key
1 = Performs independently and consistently. Asks for assistance in new situations.
2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

Comments:

_____
_____
_____

Competency Achieved: _____ Date: _____

Evaluator: _____

Learner: _____

Since there are different methods/equipment able to be used to visually inspect medical devices this is a generic competency, and the user must select the correct inspection device for that specific medical device that will need enhanced visual inspection. It is suggested in AAMI ST79 that "Cleaning encompasses the removal of patient secretions and excretions and of microorganisms from the patient or from handling or water exposure during reprocessing. After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil. Inspection using magnification might identify residues more readily than the unaided eye."

"The most common method is a visual inspection, sometimes involving the use of a lighted magnifying glass. 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.

Critical Behaviors	1	2	3
Review Hospital Policy on visual inspecting medical devices using the enhanced visual method of inspecting.			
Describes the purpose of visually inspecting medical devices.			
Gather appropriate supplies/equipment to perform the task of visually inspecting medical devices (i.e., (FIS), magnifying glass with illumination, etc.).			
Read the specific IFU for the medical device you are going to inspect.			
First, visually inspect the medial device with your natural eyesight and light. If the device is visually dirty, reclean it according to its specific IFU.			
If the medical device's IFU states to use some enhanced form of inspection beyond the unaided-eye like a bench-style magnification product, use it to inspect the medical device. If the device is found to be clean, follow the IFU for the next step in the process. If found dirty send it back to be recleaned according to the IFU.			

If medical device is visually clean by natural eyesight and light and basic magnification, proceed to the form of enhanced visual inspection found in the IFU (e.g., orthopedic shaver suggests using some type of FIS to look inside various parts of those devices to ensure it is visibly clean).			
If upon enhanced visual inspection the device is dirty, send it back to be recleaned. If deemed clean and not visually dirty, then send the device to the next step in its process.			
Document all results of the inspection on a log sheet/record book/computer system. (NOTE: Sometimes this documentation entails recording the serial and model number of the device checked with enhanced visual inspection is recorded.)			

Follow Hospital Policy on enhanced visual inspection of medical devices.

Remember to always follow the manufacture's guidelines (IFU) on inspecting medical devices.

Sample Competency Record for using the Healthmark Flexible Inspection Scope

Name:

Competency Statement: Complies with policy and procedure for . . . [list policy here].

Key
1 = Performs independently and consistently. Asks for assistance in new situations.
2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

Comments:
_____
_____
_____

Competency Achieved: _____Date**:** _____

Evaluator: _____
Learner: _____

This is a general competency that can be used for training staff on proper usage of the Healthmark Flexible Inspection Scope (FIS). This competency can be adjusted according to each facility's specific requirement.

Critical Behaviors	1	2	3
Review hospital policy on visual inspecting medical devices using the FIS.			
Describe the purpose of visually inspecting medical devices both with the unaided-eye (in natural light) and with using the FIS.			
Read/Review the specific instructions for the Healthmark FIS.			
Gather appropriate supplies/equipment to perform the task of visually inspecting medical devices with the FIS.			
Select appropriate devices for inspection with FIS. Use the FIS to make sure it passes through any instruments having cannulas or holes ≥ in mm/ diameter (according to policy)			
Visually inspect the medial device with your natural eyesight and light. If the device is visually dirty, reclean it according to its specific IFU.			
If a medical device is visually clean by natural eyesight and light, proceed to the form of enhanced visual inspection found in the IFU (e.g., the orthopedic shaver's IFU suggests using some type of flexible inspection scope to look inside its various parts to ensure it is visibly clean).			
Before using the Healthmark FIS on the medical device, ensure the scope is:			
• Plugged into a USB 2.0 port before opening software.			
• Showing the short cut icon on the computer screen.			
○ Double-click on the Healthmark software icon to run program.			
○ The program will recognize the FIS is properly connected and you can proceed.			
Demonstrates: a) Illumination feature, b) Photo capture, c) Record, and d) Review feature by clicking on software icons or scope's buttons.			

Insert scope tip into lumens or holes and show 100-degree view of lumen by maneuvering scope through lumen, avoiding any restrictive areas that may damage the scope tip.			
If upon enhanced visual inspection the device is dirty, send it back to be recleaned. If deemed clean and not visually dirty in the areas inspected send the device to the next step in its process.			
After each inspection, wipe down the FIS with alcohol, please refer to the Cleaning and Disinfecting Methods Material Compatibility Sheet for FIS Click here: Place the protective cap over the lens when not in use to protect the distal tip from damage.			
Document all results of the inspection on a log sheet/record book. Sometimes this documentation entails the serial and model number of the device checked with a FIS. Follow your facility's policy on documentation.			

References:

[1] Miltex. (2005). Miltex Surgical Instruments Catalog [found under section "Clean, Sterilization & Maintenance of Surgical instruments", n.p.]. York, PA, Miltex.

[2] AKI – Working Group Instrument Reprocessing. (2016). *Instrument Reprocessing: Reprocessing of Instruments to Retain Value* [aka "Red Book"]. (10th ed.) p. 48. https://www.mmmgroup.com/sites/default/files/brochures/instrument_reprocessing_-_publication_en_0.pdf.

[3] Stryker®. (2012). Shaver Handpieces User Guide [1000400638 R 2012/10, n.p.]. San Jose, CA, Stryker Endoscopy. www.stryker.com.

[4] Arthrex - Adapter Power System™ II (APS II); Shaver Hand pieces -DFU-0154r10; www.arthrex.com.

[5] Arthrex - Adapteur Power System™ II (APS II) Shaver Hand pieces DFU-0154r10, Inspection and Maintenance [Step 4]. www.arthrex.com.

[6] STYRKER® Shaver Hand Piece – 10000400638 R-2012/10 IFU, Inspection – EN21, [Step 9]. www.stryker.com.

[7] FDA (2015). *FDA Safety Communication: Ongoing Safety Review of Arthroscopic Shavers.* Archived content. www.fda.gov

[8] STRYKER® Shaver Hand Piece; 1000400638 R-2012/10; INSPECTION – EN 21; www.stryker.com.

[9] Arthrex - Adapter Power System™ II (APS II); Shaver Hand pieces -DFU-0154r10; www.arthrex.com.

[10] AAMI. (2017). *ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. [Section 6 Handling, collection, and transport of contaminated items, p. 33]. Association for the Advancement of Medical Instrumentation (AAMI).

[11] AAMI. (2017). *ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. [Section 14.2.1 Quality process improvement; p. 102]. Association for the Advancement of Medical Instrumentation (AAMI).

[12] O'Connor, Dan. (2013, November 25). How to Survive a Med Mal Suit: In court, the medical record is the care rendered [special edition]. *Outpatient Surgery-A division of AORN,* December – ORX Proceedings.

https://www.aorn.org/outpatient-surgery/articles/special-editions/2013/december-orx-proceedings/how-to-survive-a-med-mal-suit.