Single use components

Single use components lower the risk of HLD failure but do not eliminate the risk of contamination. A randomized clinical trial found reduced contamination in single use elevator cap duodenoscopes following HLD, compared with standard scope designs (3.8% single use versus 11.2% standard) without affecting technical performance and safety of endoscopic retrograde cholangiopancreatography (ERCP).[194]

Single use accessories

Facilities may choose reusable or single use endoscope accessories (eg, biopsy port caps, valves, buttons).[195,196] Some evidence has supported reduced risk of transmission with single use biopsy forceps, compared with reusable biopsy forceps[197] due to challenges in adequate cleaning reusable biopsy forceps.[198] When reusable accessories are used, reprocess them according to MIFU.

In addition to infection prevention considerations, facilities may evaluate how single use products may affect patients' access to care, institutional finances, and the environment. Access to care, financial, and environmental considerations were not included in the scope of this document, and the authors cannot recommend frameworks or models for evaluating them.

36. When available and feasible, should facilities use sterile, single use endoscopes?

Recommendation: Facilities may choose sterile, single use endoscopes to eliminate the risk of transmission of pathogens from the device to patients, especially when the available resources (physical space, expertise, training, and staffing) do not support processing.

Rationale: The intricate design and configuration of reusable flexible endoscopes or certain components of the endoscope (eg, elevator mechanism) represent significant challenges to effective cleaning and processing. Facilities may not have available resources (eg, physical space, expertise, training, staffing) to support safe processing of reusable endoscopes.

For many procedures that are performed by experienced endoscopists, evidence supports the technical performance of single use duodenoscopes versus reusable duodenoscopes.[199–201] A systematic review of 21 studies of single use flexible ureteroscopes and cystoscopes showed no difference in clinical outcomes.[202]

Investigational devices

37. How should facilities process critical or semi-critical investigational reusable medical devices?

Recommendation:

1. Only use investigational devices following:
   a. Issuance by FDA of an investigational device exemption (IDE) or approval of an investigational new drug (IND) application, *OR*
   b. Approval by the facility's Institutional Review Board (IRB) with determination that the device is "minimal risk" and with approval of cleaning and sterilization or HLD instructions by both IPC experts and the IRB.
2. When using investigational devices in accordance with the above recommendations, involve IPC in processing protocols developed for investigational reusable medical devices.

Rationale: The FDA and the facility's IRB needs to approve the use of all investigational devices that pose a "significant risk."[92] For devices that are deemed to pose a "non-significant risk" (ie, "a study device does not meet the definition of a significant risk device") the IRB may approve the study without the investigators obtaining an IDE from the FDA. For devices that pose a "non-significant risk," the IRB and IPC should ensure that methods have been established and put in place for processing any investigational reusable medical devices. It should be noted that most healthcare facilities have neither the equipment nor adequately trained HCP to conduct the necessary cleaning and sterilization or HLD validations to be able to establish safe and effective processing.

38. How should 3-dimensional-printed (ie, 3D-printed or additively manufactured) critical or semi-critical reusable medical devices be processed?

Recommendation:

1. Ensure that devices that are 3D-printed are legally marketed per FDA.
2. Follow the validated processing instructions provided in the MIFU.
3. When a 3D-printed device is considered investigational, follow the requirements for investigational devices (see *37*).

Rationale: Devices that are produced using 3D printers may also be referred to as "additively manufactured." These may include a subcategory of devices referred to as "patient-matched devices." Often, these are unique in design. FDA recommends that the manufacturers of 3D-printed devices establish a "design envelope" that effectively brackets the device's design. Once the cleaning and sterilization instructions have been validated on devices that represent the most challenging extremes, these brackets may serve as surrogates, and it can be assumed that these, as well as all intermediate, mid-sized versions of the device, have been adequately evaluated to be legally marketed per FDA.

Experimental, investigational 3D-printed devices that are manufactured onsite should not be used unless they present a "non-significant risk," and the IRB and IPC ensure that methods have been established and put in place for processing these medical devices (see *37*). 3D-printed devices that are manufactured at a healthcare facility are likely to present unique designs for which surrogates are not available as subjects for conducting cleaning and sterilization validations. For example, a study of orthopedic fracture models demonstrated that gas plasma failed to sterilize the inside of a hollow model and steam sterilization deformed the model.[203] Additionally, 3D-printed devices should be manufactured in a manner to ensure that residual manufacturing materials have been reduced to levels that are safe. Most healthcare facilities do not have the equipment and cleaning methods to sufficiently remove manufacturing materials or the adequately trained HCP to conduct cleaning and sterilization or HLD validations.

Tracking reusable medical devices

39. What is the best method for tracking reusable medical devices' preventative and interval maintenance?

Recommendation:

1. Use electronic tracking for reusable medical devices' preventative and interval maintenance by the manufacturer. If electronic tracking is not feasible, records may be kept on paper.
2. Adhere to recordkeeping practices per state and local requirements.

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