【今回の主な変更点】

(1) セミクリティカル器材も基本的には滅菌をすべきである

(2) ハイリスク内視鏡の選定と洗浄評価を実施する

(3) 内視鏡内腔の乾燥の重要性を強調（10 分以上の乾燥時間を推奨）

(4) 保管する場合は、内腔まで十分に乾燥させてから保管する

(5) 消毒後の内視鏡は手袋を着用して取り扱う

(6) マニュアルでの高水準消毒は推奨しない

(7) 内視鏡洗浄機のすすぎ水の定期的微生物検査を行う

(8) 汚れ固着のリスクを鑑みて、アルコールフラッシュの推奨度が低下

(9) FDA が承認した洗浄機能付き AER は用手洗浄の代用となりうる

(10) 70 ページ（2015 年の旧版）から 190 ページ（2021 年版）へ拡充された

各変更点に関係する **ST91** の原文

(1) セミクリティカル器材も基本的には滅菌をすべきである

(page xiii, 15/190) Introduction, Endoscopic transmission of infection

Critical devices are devices that are introduced directly into the bloodstream, or which contact a normally sterile tissue or body space during use and for which sterilization is required. Semi-critical devices come in contact with mucous membranes or non-intact skin. These items should be thoroughly cleaned and then sterilized. If sterilization is not possible, high-level disinfection is the minimum advised processing method (FDA, 2015 [334]).

It is advised that flexible and semi-rigid endoscopes to be used in semi-critical applications be sterilized prior to use (Spaulding, 1972 [301]; FDA, 2015 [334]; AORN, 2018 [367]).

(2) ハイリスク内視鏡の選定と洗浄評価を実施する

3.31 high-risk endoscopes： endoscopes that have been associated with infectious outbreaks including those that are difficult to process and increase the risk of incomplete clearance of contaminating infectious organisms, including bronchoscopes, cystoscopes, duodenoscopes, endobronchial ultrasound endoscopes, linear ultrasound endoscopes, ureteroscopes, and others as determined by the facility

7.8.4 Cleaning verification：High-risk endoscopes (e.g., duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes, and as determined by the facility) shall be evaluated with cleaning verification tests after each use (see 13.5.3).

13.5 Verification and monitoring of the cleaning process

13.5.1 General Considerations：Cleaning verification indicators provide an independent, objective assessment of the cleaning process.

Manual cleaning of flexible endoscopes that are not determined to be high-risk should be verified

using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g., at a statistically significant frequency based on the number of procedures performed).
13.5.3 Cleaning verification tests for users：Cleaning verification tests are performed following cleaning and before disinfection or sterilization and are used to verify the effectiveness of a cleaning process to remove or reduce to an acceptable level the clinical soil that occurs during the use of an endoscope.
Methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be implemented.
Annex F (informative) User verification of cleaning processes

(3) 内視鏡内腔の乾燥の重要性を強調（10 分以上の乾燥時間を推奨）

8.2.5 Endoscope drying
8.2.5.1 General considerations：Flexible endoscopes with channels should be dried for a minimum of 10-minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air (Ofstead, 2018 [242]; Barakat, 2018 [79]; Perumpail, 2019 [254]; Alfa, 1991 [53]).
3.37 instrument air：medical gas that falls under the general requirements for medical gases as defined by NFPA 99, Health care facilities code) [216], is not respired, is compliant with ANSI/ISA S-7.0.01 (Quality standard for instrument air), and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40 °F (-40 °C)
8.2.5.2 Manual drying：The endoscope should be dried promptly after every reprocessing cycle. This means that the endoscope should be dried whether the endoscope is intended for immediate patient use or for storage (Rutala and Weber, 2016 [281]; Petersen et al., 2017 [255]), with the exception of liquid chemically sterilized endoscopes that are used immediately.
Annex K (informative) Endoscope drying

(4) 保管する場合は、内腔まで十分に乾燥させてから保管する

8.2.5 Endoscope drying
8.2.5.1 General considerations：Endoscopes should never be stored wet or before decontamination has been completed as such storage supports the growth of microorganisms and biofilms (AORN, 2019a [71]; Beilenhoff et al., 2018 [87]).
11.2.1 Storage procedures：Before storage, the channels of the high-level disinfected endoscope should be dry to help prevent bacterial growth and the formation of biofilm (see 8.2.5). If a drying cabinet is not used, dryness can be checked by using dryness indicators.
All critical devices (e.g., ureteroscopes, bronchoscopes) not used immediately should be processed again before use.

(5) 消毒後の内視鏡は手袋を着用して取り扱う

11.2.3 Identification of endoscopes during storage：The user should perform hand hygiene and don new, clean, non-latex gloves, according to the facility's policy, when handling processed endoscopes.

(6) マニュアルでの高水準消毒は推奨しない

8.2 High-level disinfectant systems and liquid chemical sterilant processing systems and procedures
8.2.1 General considerations：Manual high-level disinfection and liquid chemical sterilization is not recommended due to variability and inconsistency in the personnel responsible for the process (see 8.2.4).
8.2.4 Manual high-level disinfection and liquid chemical sterilization processes

8.2.4.1 Manual processing procedure：Manual processing is not recommended but if necessary due to facility or resource limitations, consult the endoscope manufacturer's written IFU to determine the compatibility of the device with the selected LCS/HLD solution (see 8.2.4).

(7) 内視鏡洗浄機のすすぎ水の定期的微生物検査を行う

4.3.11 Water quality：The health care facility should monitor and control the water supply quality to endoscope processing sinks and equipment.
8.2 High-level disinfectant systems and liquid chemical sterilant processing systems and procedures
8.2.1 General considerations：This is a particular risk when tap water is used to rinse the endoscope following the antimicrobial process. As part of the facility water management plan, periodic microbial assessment of the AER and processing equipment should be considered to identify water contaminants or contaminated equipment which may contribute to recontamination of the device after high-level disinfection (Ofstead, 2016 [247]). Periodic microbial assessment of the water used for final rinse should be considered to identify any contaminants which can contribute to recontamination of the device after high-level disinfection (Ofstead, 2018 [242]; Seidelman, 2019 [288]; Ofstead, 2016 [247]).

(8) 汚れ固着のリスクを鑑みて、アルコールフラッシュの推奨度が低下

8.2.3.2 Automated high-level disinfection/liquid chemical sterilization procedure
m) If the endoscope manufacturer requires it as part of the validated reprocessing protocol, perform a final flush of the endoscope channels with alcohol. However, if alcohol use is a concern because of its fixative properties, a multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should review the effects of alcohol on the endoscopes and establish a policy on its use (Costa et al., 2017 [125]).
8.2.5.2 Manual drying：Drying can be facilitated by use of a preliminary flush of 70 % to 90 % ethyl or isopropyl alcohol. Isopropyl alcohol is considered a fixative. If the use of alcohol is a consideration, a multidisciplinary team that includes infection preventionists, endoscopy and

perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should conduct a risk assessment to determine whether endoscope lumens should be flushed with 70 % to 90 % ethyl or isopropyl alcohol (Costa et al., 2017 [125]).

(9) FDA が承認した洗浄機能付き AER は用手洗浄の代用となりうる

7.7 Automated cleaning, rinsing, and drying

Some AERs have cleaning cycles that are validated and FDA-cleared to replace manual cleaning of some endoscopes prior to placing them into the AER. An automated cleaning cycle on an AER is not intended to replace point of use treatment, and most AER automated cleaning cycles also are not intended to replace manual cleaning of endoscopes prior to placing them into the AER. If considering replacement of manual cleaning with a validated and FDA-cleared automated cleaning cycle, facilities should convene a multi-disciplinary team to conduct a risk assessment (see 13.14.2). Consult your AER manufacturer for validated data concerning cleaning capability and allowed FDA 510(k) claims. Verify that they meet or exceed current cleaning requirements set forth by the FDA. For duodenoscopes, the FDA currently recommends that "the AER cleaning cycle only be used as a supplement to thorough manual cleaning according to the duodenoscope manufacturer's instructions" (FDA, 2018 [344]).