Laborie

FOR DIGNITY. FOR LIFE.

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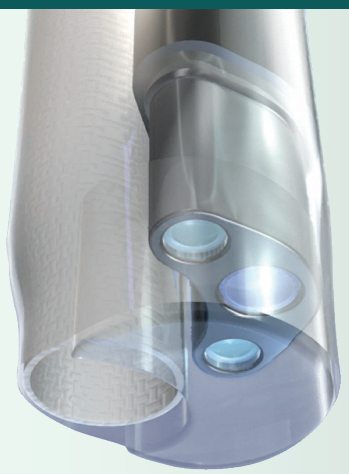
PrimeSight®

A high-performance, sterile cystoscopy system

UROLOGY & UROGYNECOLOGY

PrimeSight delivers advanced diagnostic capabilities in an economic, safe and flexible system suitable for a variety of clinical environments.



ANSI/AAMI ST91: 2021 Update

The economy of a reusable. The safety of a single-use.

EndoSheath® Protective Barrier

Always ready. Always sterile.™

Proven performance. Simplified Safety.

- Proprietary, FDA-cleared microbial barrier for flexible endoscopy, proven effective against organisms as small as 27 nanometers[1]
- Designed from a latex-free polyurethane polymer to stretch and maintain its integrity, and not to tear or break during procedures[2]
- PrimeSight with EndoSheath is FDA-cleared to undergo intermediate-level disinfection, eliminating the need for high-level disinfection (HLD) or sterilization between procedures, thereby reducing the time and complexity of reprocessing[3]
- 100% leak tested during manufacturing with a 0% acceptable failure rate, capable of detecting a 5 micron hole[4]

Recognition in National Standards and Guidelines

- ANSI/AAMI ST91:2021 National Standards for Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities
- 2023 AORN Guidelines for Perioperative Practice
- HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities
- AUA/SUNA Guidelines for Cystoscope Reprocessing

PrimeSight is included in the 2021 ANSI/AAMI ST91: National Standards for Flexible and Semi-Rigid Endoscope Processing

[1]Kimuli M, Lloyd SN. Out-patient flexible cystoscopy using a disposable slide-on endosheath system. Ann R Coll Surg Engl. 2007 May;89(4):426-30. doi: 10.1308/003588407X183346. PMID: 17535625; PMCID: PMC1963604. [2]Laborie Medical Technologies, Data on File [3]CST 5000, 5000i User's Manual: UR-MAN-999-EN 09645-EN-K User Manual CST-5000-5000i; pg. 49 and CST 4000, 4000i User's Manual: UR-MAN-999-EN LBL-00069C-User Manual CST-4000-4000i; Pg. 47 [4]Laborie Medical Technologies, Data on File

Released in Spring 2022, ANSI/AAMI ST91:2021 contains guidelines that are intended to provide comprehensive information and direction in the processing of reusable endoscopes

Key Updates:

High-Risk: Cystoscopes (and others) are now considered High Risk Scopes.[5] "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 scopes, linear ultrasound endoscopes, ureteroscopes, and others as determined by the facility."

Leak-Testing: Full leak testing recommendation changed from 30 to 60 seconds.[6]

PrimeSight® leak testing is only required if the PrimeSight endoscope will be put through high-level disinfection, sterilization or otherwise submerged in a liquid of any kind.[11]

Cleaning Verification: "High-risk endoscopes shall be monitored with cleaning verification tests after each cleaning."[7]

Sterilization: Sterilization is recommended for all reusable scopes.[8]
Manual Disinfection: Manual Disinfection is NOT recommended but if necessary due to facility or resource limitations, consult the endoscope manufacturer's written IFU.[9]
Automated Endoscope Reprocessor: May provide efficiency and cleaning/disinfecting consistency.[10]

Unlike other endoscopes, the PrimeSight system has been cleared by the FDA allowing intermediate level disinfection (ILD) when used with the EndoSheath sterile microbial barrier and where the endoscope shows no signs of sheath integrity failure after the procedure.

"High-level disinfection is a multistep process and is expected to be able to inactivate the most pathogenic bacteria, viruses, and fungi, but may not readily inactivate certain types of microorganisms including bacterial spores."[11]

Drying Time: NEW RECOMMENDATION - "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."[12]

PrimeSight does not have a working channel that requires drying. See PrimeSight User Manual for drying instructions.

Other Recommendations: The 2021 ANSI/AAMI ST91: National Standards for Flexible and Semi-Rigid Endoscope Processing also has specific recommendations related to the location allocated to performing high-level disinfection, including rinsewater testing and disposal, chemical material handling and storage, air flow, and endoscope storage.

[5]ANSI/AAMI ST91:2021 3.31 [6]ANSI/AAMI ST91:2021 Page 34 [7]ANSI/AAMI ST91:2021 Page 62 [8]ANSI/AAMI ST91:2021 pg xiii [9]ANSI/AAMI ST91: 2021 8.2.4.1
[10]ANSI/AAMI ST91:2021 8.2.3.1 [11]ANSI/AAMI ST91:2021 pg. xiv [12]ANSI/AAMI ST91:2021 8.2.5.1

PrimeSight® Cystoscopy: The safety of a single-use

Because of its design, PrimeSight® with EndoSheath® is described in ANSI/AAMI ST91:2021, which supports the use of Intermediate-Level Disinfection as an acceptable processing method.

According to the ANSI/AAMI ST91:2021 Chapter 9, "The IFU for some of the cleared devices recommend alternative processing instructions to conventional liquid chemical sterilization/HLD when the sheath remains intact after endoscope use. For these endoscopes and sheaths, the endoscope and sheath manufacturers' written IFU should be followed (AORN, 2018 [367])."

Reduction of Infection Risk

It is well known that the working channel is the most difficult part of an endoscope to clean. **EndoSheath eliminates this potential infection risk by housing all ports, channels and seals within the sterile sheath.** Once an exam is completed, the entire sheath is disposed, eliminating the need to clean hard-to-access parts. EndoSheath makes compliance easier for staff and the practice.

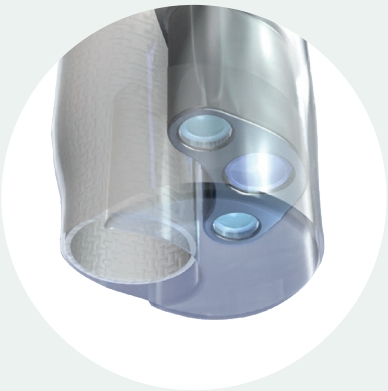
▲ The single-use EndoSheath barrier includes the channel, ports, and seals. EndoSheath is used with the D-shaped PrimeSight cystoscope.

Proven sterility

The EndoSheath microbial barrier is proven effective against organisms as small **as 27 nanometers** per FDA guidance and testing[1]

100% Leak Tested

100% of EndoSheaths are leak tested with pressurized equipment capable of detecting a 5 micron hole[4]



▲ Prior to each procedure, the PrimeSight cystoscope is inserted into the sterile EndoSheath barrier. Together they form a fully functional cystoscopy system.

PrimeSight® with EndoSheath® is Different

According to the PrimeSight® User Manual, as cleared by the FDA, "After use with an EndoSheath® Technology and proper cleaning, the endoscope should undergo intermediate-level disinfection."

Sterilization or High-level disinfection is not required, as there is no working channel. Endoscope leak testing is only required if the PrimeSight endoscope will be put through high level disinfection, sterilization or otherwise submerged in a liquid bath of any kind.[11]

Required Cleaning/Disinfection - Intermediate Level Disinfection (ILD)

Step 1

Remove endoscope from EndoSheath protective barrier. Do not handle the endoscope with contaminated gloves.

Step 2

After removing the EndoSheath protective barrier, inspect the endoscope insertion tube and distal bending section and confirm these areas are dry and undamaged.

Note: *If moisture is observed on the endoscope insertion tube, this may indicate a breach of the barrier during the procedure if the endoscope was dry when the barrier was installed. In this case the endoscope should undergo high level disinfection or sterilization. Refer to the User Manual for recommended protocols.*

Step 3

Gently wash all external surfaces of the endoscope with an appropriate instrument grade detergent or EndoWipe® enzymatic sponge.

Step 4

After washing, thoroughly rinse the outside of the endoscope. Exercise care to avoid tightly bending or kinking insertion tube.

Step 5

Wipe down the entire endoscope with an EndoWipe ethyl alcohol towelette or gauze soaked in 70% ethyl/isopropyl alcohol. Ensure full coverage of alcohol. Allow alcohol to dry completely.

Step 6

Ensure all external surfaces of the endoscope are dry prior to installing another EndoSheath protective barrier.

[11]CST 5000, 5000i User's Manual: UR-MAN-999-EN 09645-EN-K User Manual CST-5000-5000i; pg. 49 and CST 4000, 4000i User's Manual: UR-MAN-999-EN LBL-00069C-User Manual CST-4000-4000i; Pg. 47 The steps in this brochure do not replace the instructions in the User Manual. Please consult the User Manual for complete instructions.

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