REPROCESSING OF **Bronchoscopes**

ASP Advanced Sterilization Products

IS IT **Time For A Change?**

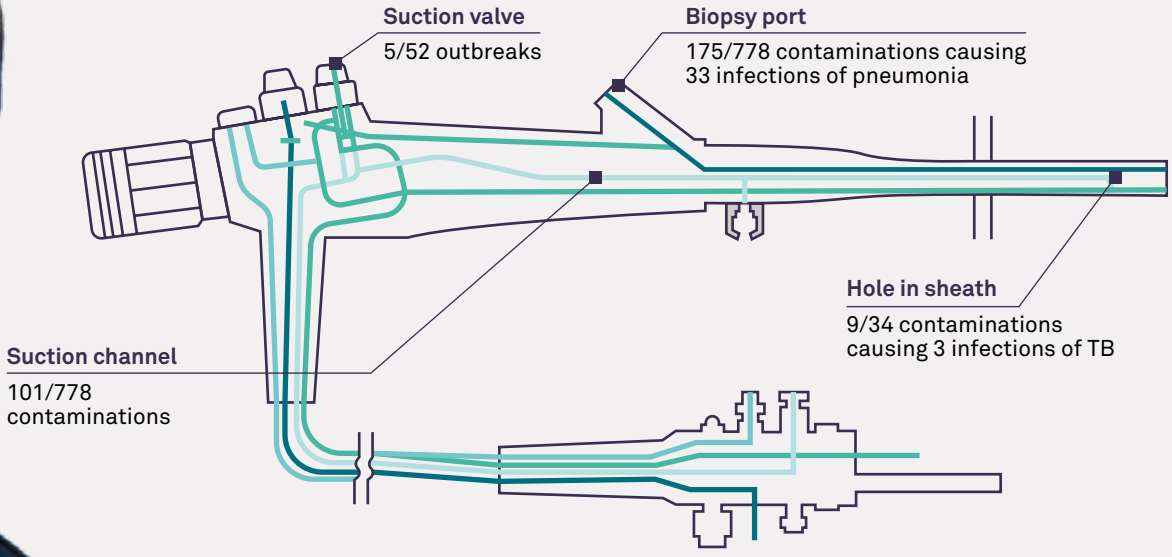
Reports of healthcare-associated infections (HAIs) associated with contaminated bronchoscopes are increasing, including outbreaks of disinfectant – and drug – resistant pathogens; the narrow margin of safety provided by high-level disinfection may lead to avoidable patient infections.

Sterilization would provide the highest standard of patient care with a substantially larger margin of safety, offer a more convenient reprocessing method, and could reduce the financial burden of HAIs.

Bronchoscopes are used in bronchoscopies, a procedure that allows a pulmonologist or thoracic surgeon to view and treat abnormalities in the lungs. They are **inserted into the nose or mouth and maneuvered into the lungs**.

These specialized endoscopes can be **flexible or rigid**, with surgeons deciding between the two depending on the exact procedure that is to be performed. **This factsheet will focus on flexible devices**. These contain heat- and moisture-sensitive components.

COMPLEX BRONCHOSCOPE DESIGN LEADS TO PATHOGEN HOTSPOTS RESPONSIBLE FOR NUMEROUS HAI OUTBREAKS[1]



Data presented as n/N, where N = total number of patients exposed to a contaminated bronchoscope, and n = number of patients where contamination was caused by the design element in grey text.

01 | DEVICE REPROCESSING

Bronchoscopes **are typically used semi-critically**, according to the Spaulding Classification, and **require a minimum of high-level disinfection** (HLD) when reprocessed.[2]

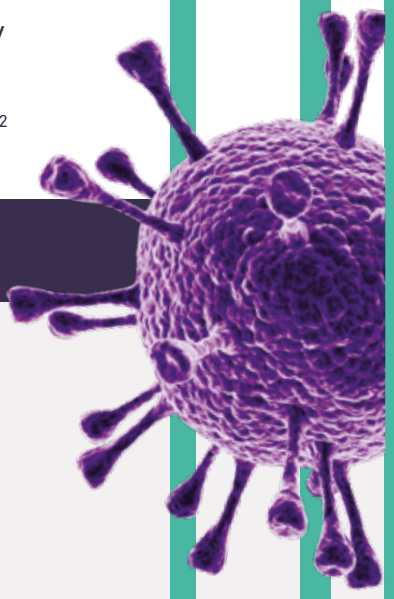
However, advances in procedures and technology mean that **bronchoscopes are now increasingly utilized** alongside equipment used critically, such as biopsy forceps or surgical scissors, which penetrate into the tissue and therefore **may become contaminated by non-sterile bronchoscopes**.

There are also situations where bronchoscopes **may come in contact with otherwise sterile tissue**, for example if bleeding is occurring in the lungs. These situations can lead to bronchoscopes that have only been reprocessed by HLD being used in a more critical environment, putting patients at a preventable risk of infection.

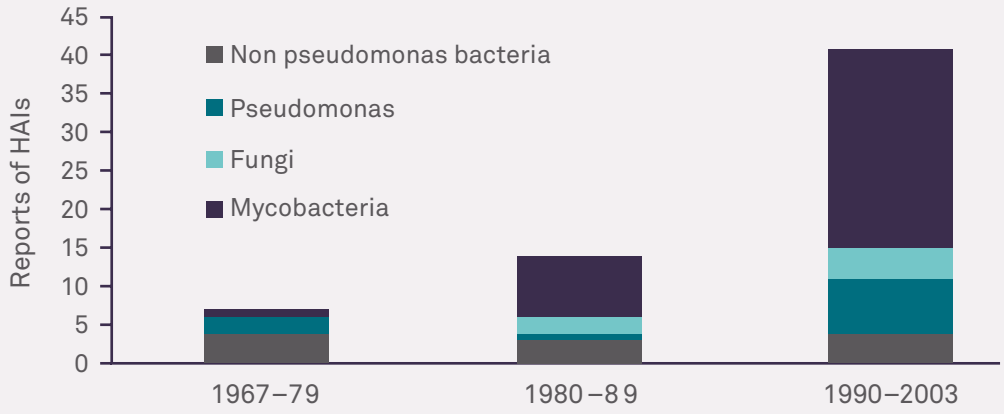
02 | OPTIMIZING PATIENT CARE

More HAIs have been linked to inadequately cleaned or disinfected endoscopes undergoing HLD, including bronchoscopes, than any other medical device.[3]

The number of HAIs related to contaminated bronchoscopes is also increasing, with some recent outbreaks caused by disinfectant-resistant pathogens.[2,4] In 2009 a significant outbreak in Brazil following surgical or bronchoscopy procedures infected over 3,000 patients with bacteria found to be highly resistant to glutaraldehyde.[2]



REPORTS OF HAIs ASSOCIATED WITH CONTAMINATED BRONCHOSCOPES[4]



03 | HLD REPROCESSING RISKS OUTBREAKS

If performed properly, HLD eliminates all micro-organisms except large numbers of bacterial spores. However, a large number of bronchoscope-related HAI outbreaks have been reported in literature across many settings[1]. There are a number of reasons why HLD can cause such outbreaks:

- HLD is labor-intensive and steps can be easily neglected.
- HLD does not provide the margin of safety required to protect patients from infection risk.
- Bronchoscopes can be used for only a few hours (based on country specific regulations) after last reprocessing by HLD, but require repeat reprocessing if stored for longer. Emergency needs may lead to the use of bronchoscopes that have not been reprocessed within this period, putting patients at risk.
- Certain bronchoscope design features are difficult to disinfect leading to potential HAI hotspots.[1]

CASE STUDY:

An outbreak of P. aeruginosa associated with contamination of a flexible bronchoscope

A teaching hospital in Georgia, USA reported 12 patients with a culture positive for Pseudomonas aeruginosa in 2007. This outbreak was traced back to a particular bronchoscope that had internal damage, making the contamination resistant to HLD reprocessing.[5]

04 | STERILIZATION

There has recently been a shift in the recommendations of many significant clinical organizations and societies towards the use of sterilization as the standard for endoscope reprocessing. In 2015, the US FDA updated their guidelines to advise that even **devices used semi-critically should be sterilized if possible**.

COUNTRY	GUIDELINE RECOMMENDATION
US (FDA)[7]	Endoscopes used in sterile body cavities, and all endoscope biopsy accessories, should be sterilized. Devices used semi-critically should also be sterilized, design permitting.
Australia[8]	Sterilization of semi-critical flexible endoscopes is preferred.
Japan[9]	Sterilization of flexible endoscopes is preferred but strictly monitored HLD is currently permitted.
Canada[10]	Sterilization of semi-critical devices is considered optimal.

Sterilization adequately reprocesses devices, providing the **largest margin of safety** whether they are used critically or semi-critically. **No repeat reprocessing is required** with sterilization since instruments are sealed which can also reduce labor requirements.

STERRAD™ offers a low-temperature sterilization method that helps protect heat- and moisture-sensitive components of endoscopes, whilst offering further benefits to patients, surgeons and sterilizer operators.

	Improve patient and staff safety	Efficiency and ease of use	Reduced financial burden
Increases the margin of safety	✓	✓	
Sterile devices are ready for use when needed		✓	
Short cycle time increases device availability without needing larger inventories			✓
Avoid pathogen recontamination (no water source or aeration needed)	✓		
Non-toxic residues	✓	✓	
Increases compliance		✓	
Reduces workload on staff		✓	✓
No need for repeat reprocessing when devices are not used	✓	✓	✓
Relieve HAI-associated costs and patient burden	✓	✓	✓

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For more information, please contact your local ASP representative or visit asp.com

AD-170025-01-CT_D-MDR