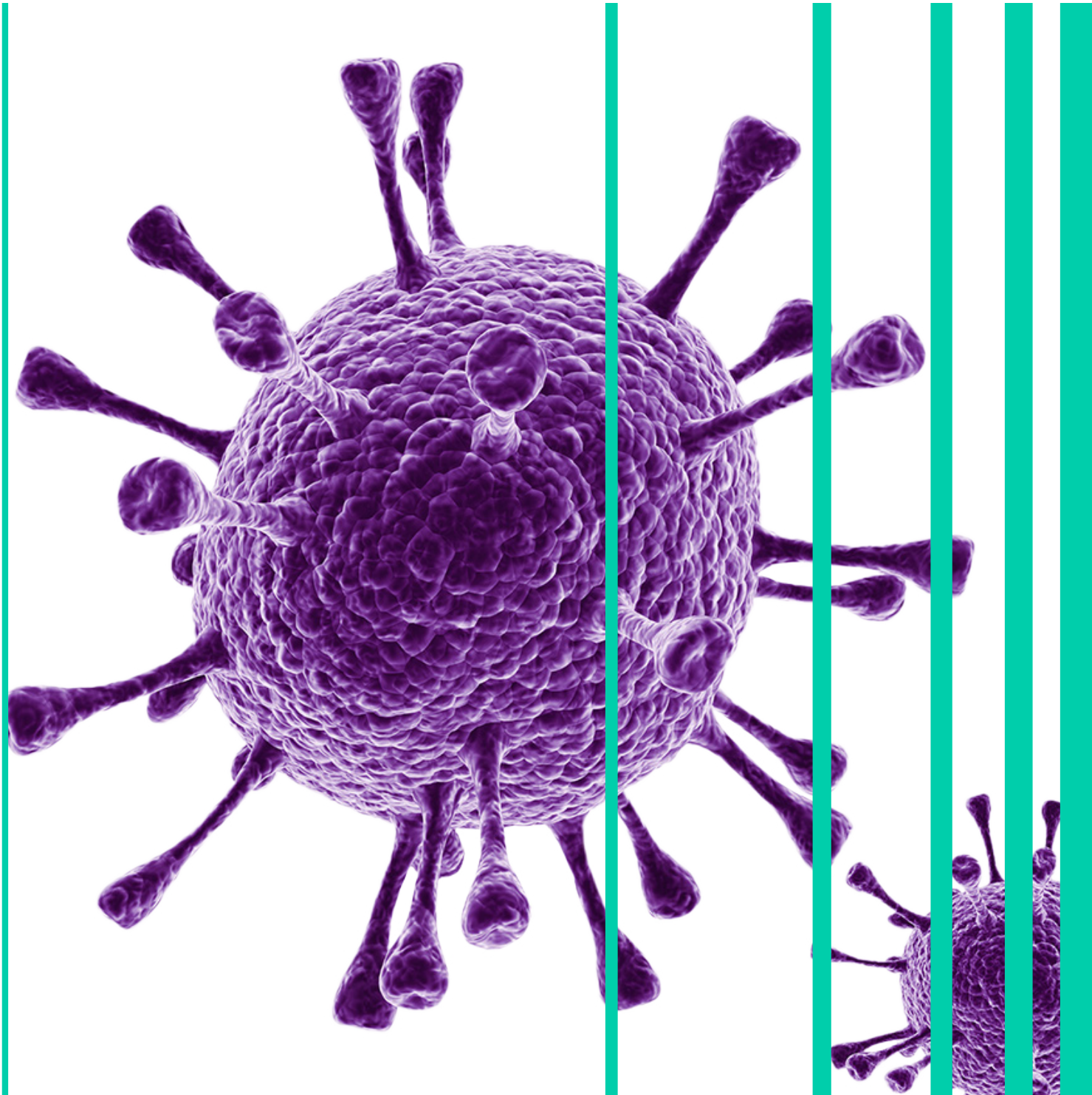
Challenges of Medical Device Reprocessing

Advanced Sterilization Products

An overview of the evidence and leading technologies to minimize the impact



Understanding the Challenges of Medical Device Reprocessing

Healthcare-Associated Infections are a Major Global Safety Concern

Healthcare-associated infections (HAIs) can occur in patients receiving medical care and are associated with significant morbidity, mortality and healthcare costs.[1] They are an alarming safety concern, representing the most frequent adverse event in healthcare delivery worldwide.[1] In Europe, the average prevalence of HAIs is 7.1%, with more than 4 million patients affected by HAIs every year.[1] However, given the acknowledged reporting gaps in existing surveillance systems, the scale of the problem is considered to be greatly underestimated.[2]

HAIs prolong hospital stays, cause long-term disability, increase antimicrobial resistance, cause unnecessary deaths and represent a significant financial burden for health systems.[3]

Annually, across Europe, HAIs cause:

16 million extra days of hospital stay[1]

€7 billion in healthcare cost alone[2]

37,000 deaths, whilst contributing to a further **110,000** deaths[1]

In order to understand how to prevent HAIs from occurring in the first place, we need to know what causes them. The occurrence of HAIs is indeed complex; factors can be categorised into environmental, patient and healthcare-related and clearly, a multimodal approach is required to tackle them.[4]

Inadequate Medical Device Reprocessing is a Preventable Source of Healthcare-Associated Infections

Despite the existence of reprocessing guidelines and advances in device reprocessing methods, inadequate reprocessing of medical devices contributes to a significant proportion of HAIs. In fact, 22% of all surgical site infections (SSIs), one of the most common types of HAI,[5] are related to equipment reprocessing.[6-10] A significant proportion of these HAIs is considered preventable.[11]

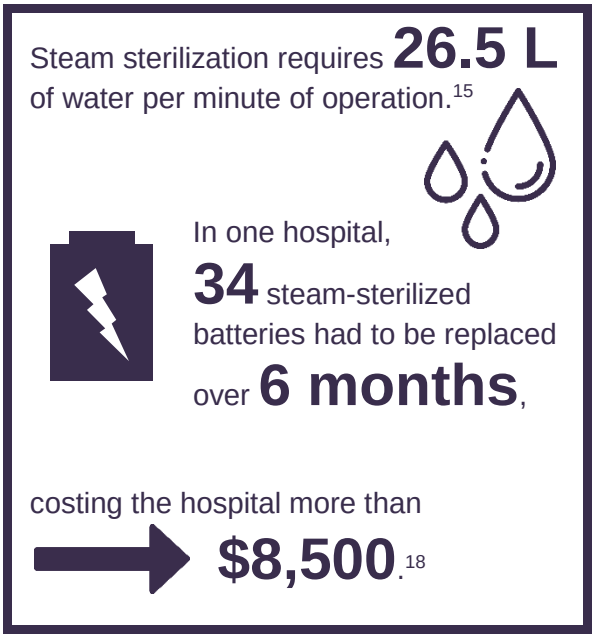
Even with clear advances in preventative procedures, HAIs arising from medical devices continue to be a problem for hospitals and health care facilities around the world. In this article, we will highlight the key challenges surrounding medical device reprocessing that lead to HAIs, describe the evidence around these challenges, and discuss how leading technologies can minimise the incidence and burden of such infections.

High-Temperature Sterilization Methods can Damage Devices Deemed Heat- or Moisture-compatible

Whilst many modern devices are deemed unsuitable for high-temperature reprocessing methods such as steam sterilization, some can be deemed compatible despite being sensitive to the harmful physical effects of temperature and humidity. There are reports of such sensitive devices becoming damaged over time,[12, 13] which not only reduces the efficacy of such devices, and therefore the likelihood of a successful procedure, but also exacerbates known risks factors for inadequate sterilization, namely the development of damaged sites that act as hot spots for biofilm formation and potential HAI outbreaks.[14]

However, the impact on patient safety is not the only important consideration. High-temperature sterilization methods such as steam is also energy- and water-intensive.[15-17]

In addition to these wasted costs and resources, the damage to devices caused by steam sterilization can lead to high costs associated with early replacement.[18] One study estimated that a single large-scale healthcare facility could look to spend more than $1 million over 10 years on repairs of heat-compatible devices that could have been avoided if using a more appropriate reprocessing method.[17]



In Avoiding High Temperatures, Some Low-Temperature Sterilization Methods use Sterilants that may Harm Users and Patients

For the many modern-day devices that cannot tolerate high temperature steam sterilizers, low-temperature sterilization (LTS) methods are available that reprocess devices without exposing them to such high temperatures and humidity, and therefore reduce the risk of device damage. Ethylene oxide (EtO) and formaldehyde gas (FO) are amongst the traditional LTS methods,[19] but present unique challenges of their own. Both use sterilant gases that are considered toxic and carcinogenic by the World Health Organization (WHO),[20, 21] thus putting patients at an avoidable risk of harm if devices are not properly aerated. For example, exposure to EtO or it's toxic by-products through contact with reprocessed medical devices has been shown to lead to serious health complications such as allergic reactions, burns[21] and health conditions such as toxic anterior segment syndrome (TASS).[22]

TASS has occurred as a result of EtO-sterilized vitrectomy packs, leading to the syndrome in 19/893 (2%) eyes studied.

In comparison, no TASS cases were observed with non-EtO sterilized packs.[22]

In addition to the risk these technologies put on patients, the challenges placed on protecting users and the environment and minimising resource use should also be considered.

EtO is associated with high water use, and the lengthy aeration time leads to high electricity use.[23, 24]

Extended aeration leads to very long cycle times; approximately 16 hours. This leads to a low rate of instrument turnover, increasing the demand for large and costly device inventories.

Through high resource use and emission of toxic gases, EtO poses a significant risk to the environment; the US Environmental Protection Agency released regulations in 2007 that aims to reduce air pollution for EtO sterilizers.[15]

Reprocessing Classifications may be Insufficient to Meet the Needs of Modern-Day Practice

The pragmatic approach to disinfection by Earle H Spaulding historically determines the level of reprocessing required based on the degree of risk involved in their use (Table).[25]

However, with the Spaulding Classification first proposed more than 50 years ago, and the rapid advancements in medical devices, materials science and procedures, this classification may be insufficient to meet the needs of modern-day practice.[25, 26]

> It is not uncommon for semi-critical devices to be used critically in surgical procedures; Central Sterile Services Department (CSSD) managers may not always be aware of a device's next use and whether a different reprocessing method would be required. As such these devices that require sterilization may only undergo high-level disinfection (HLD), potentially not eliminating pathogens leading to infections.[26]

> Different parts of the same device can have different reprocessing needs. A semi-critical device could also be used in conjunction with a critical device contacting sterile tissue during a procedure.[23]

> Semi-critical devices may unexpectedly encounter sterile tissue, for example if bleeding is present. These situations can lead to devices that have only been disinfected being used in a critical environment, putting patients at a preventable risk of infection.

Inadequate reprocessing of an urological endoscope was identified as the cause a multidrug-resistant NDM-1 Klebsiella outbreak in 12 patients, due to cross-contamination from the 'non-critical' camera head. Sterilization of the entire device was recommended.[27]

Accordingly, the US FDA now recommends sterilization as the appropriate reprocessing method for semi-critical devices, given it offers the highest margin of safety.[28]

Overview of Spaulding Classification

Spaulding Classification	Minimum Level of Reprocessing	Rationale	Device Example
Non-critical	Low-level Disinfection	Items only contact intact skin and are used in circumstances where there is virtually no risk of infection transmission	Blood pressure cuffs
Semi-critical	High-level Disinfection	Items contact mucous membranes or non-intact skin and should be free of microorganisms, small numbers of spores may be present	Endoscopes
Critical	Sterilization	Items enter sterile tissues or vasculature and must be free of all microrganisms, including bacterial spores	Surgical forceps

Limitations in Reprocessing Guidelines that do not Consider all Eventualities

Despite improvements in device reprocessing guidelines, HAIs continue to be a substantial concern. Various factors are not always fully considered in guidelines and impact the success of sterilization:

> The complex structures of modern devices make reprocessing more challenging and increase the risk of transmission of HAIs. The FDA have identified design features that are prone to retaining biological debris, including hinges, sleeves, blades, inserts and features that cannot be disassembled.[29]

Over an 8-month period at two US hospitals, inadequate reprocessing of duodenoscopes led to HAIs in 13 patients. These HAIs were linked back to contamination of the elevator channel. Such small, heat-labile parts are difficult to reprocess and thus contribute to a higher risk of HAIs.[30]

> Manufacturers may not consider how post-market modifications impact the reprocessing method. Poor communication between manufacturers and users when reprocessing instructions for devices are revised may lead to processes being outdated or inadequate.[29]

> Complex devices are prone to damage; damaged surfaces serve as HAI hotspots for biofilm formation.[14]

12 patients contracted *P. aeruginosa* that was traced back to a damaged bronchoscope, despite undergoing suitable HLD.[31]

> The FDA found that many manufacturers designed inadequate test conditions to validate their reprocessing systems. Cleaning of internal components was not always considered as part of design validation.[29]

> Some semi-critical devices are simply exposed to such high levels of contamination that HLD is not always capable of effectively reducing the bioburden to safe levels.[32]

Despite normal HLD, positive bacterial cultures were obtained from biopsy channels of 10.7% (32/300) of gastroscopes and 20.8% (25/120) colonoscopes.[32]

A Solution that Addresses the Unmet Needs of Medical Device Reprocessing

Given the challenges described above, there is a clear need for a sterilization process that can help avoid harmful and costly HAIs, protect patients and users, and improve compliance.

Advanced Sterilization Products® offers a unique ecosystem of innovative technologies that address the burden of compliance, efficiency and safety for instrument reprocessing teams, and above all, contributes to a process that aims for the complete prevention of HAIs.

> STERRAD® 100NX®/NX® with ALLClear Technology™ is a sterilization platform that provides integrated quality control features to ensure sterility whilst minimising workflow disruptions.

> STERRAD® VELOCITY™ is a fully integrated biological indicator that provides sterility assurance within 30 minutes.

> ASP ACCESS™ is smart information-sharing technology that provides unique insight by allowing users to access sterilization information in real time.

Key benefits of the Ecosystem in helping to prevent HAIs include:

- STERRAD® Sterilization Systems involve the combined use of hydrogen peroxide and low-temperature gas plasma to rapidly and safely sterilize medical devices and materials without leaving toxic residues.
- The gentler action of STERRAD® Systems means it is more appropriate for devices that are heat-sensitive, helping to reduce repair costs and prevent device damage hot-spots from forming and potentially harming patients.

A side-by-side comparison of delicate microsurgical scissors sterilized by steam and STERRAD® showed that, after 30 reprocessing cycles, the autoclaved scissors demonstrated a noticeable drag in cutting whereas there was no loss of functionality caused by STERRAD® reprocessing.[12]

When considering purchase price, utilities, maintenance contracts and instrument repairs, sterilizing heat-compatible devices with STERRAD® Systems instead of steam is estimated to save a hospital $738,833 over 10 years, driven primarily from reductions in device repair.[17]

- Sterilization with STERRAD® Systems offers a higher margin of safety compared to non-sterile processes like HLD, which is especially important for devices with mixed uses or those that are highly contaminated.
- The fast read-out of STERRAD® VELOCITY™ allows a biological indicator to be processed with every load, providing the confidence that HAI risk is minimised. Automated record keeping allows CSSDs to demonstrate sterility and reduce the risk of liability.
- On-screen step-by-step instructions help to reduce the incidence of user error and optimise patient safety.
- The STERRAD® Sterility Guide is a global, online database of devices that meet STERRAD® System claims, and includes over 23,000 listings of validated devices from over 100 different medical device manufacturers. Users can be assured that compatibility is guaranteed for each specific device and thus, regardless of complexity or post-market modifications, the risk of patient harm is minimised.

To learn more about the ASP Ecosystem and how it can prevent HAIs, please contact your local ASP sales representative.

References

1. WHO. Report on the Burden of Endemic Health Care-Associated Infection Worldwide. [Accessed online at https://apps.who.int/iris/bitstream/handle/10665/80135/9789241501507_eng.pdf;jsessionid=86B33E75BBE594E6C2CBD998F1C88CA5?sequence=1 on 14.03.2019].

2. WHO. Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level. [Accessed online at https://www.ncbi.nlm.nih.gov/books/NBK401773/pdf/Bookshelf_NBK401773.pdf on 14.03.2019].

3. WHO. Health Care-associated Infections: Fact Sheet. [Accessed online at https://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf on 14.03.2019].

4. Al-Tawfiq JA and Tambyah PA. Healthcare associated infections (HAI) perspectives. J Infect Public Health. 2014;7(4):339-44.

5. Haque M, Sartelli M, McKimm J and Abu Bakar M. Health care-associated infections - an overview. Infect Drug Resist. 2018;11:2321-2333.

6. Agency for Healthcare Research and Quality. 2013 Annual Hospital-Acquired Condition Rate and Estimates of Cost Savings and Deaths Averted From 2010 to 2013. [Accessed online at https://www.ahrq.gov/sites/default/files/publications/files/hacrate2013_0.pdf on 14.03.2019].

7. Dancer SJ, Stewart M, Coulombe C, et al. Surgical site infections linked to contaminated surgical instruments. J Hosp Infect. 2012;81(4):231-8.

8. Kirkland KB, Briggs JP, Trivette SL, et al. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. Infect Control Hosp Epidemiol. 1999;20(11):725-30.

9. Teillant A, Gandra S, Barter D, et al. Potential burden of antibiotic resistance on surgery and cancer chemotherapy antibiotic prophylaxis in the USA: a literature review and modelling study. Lancet Infect Dis. 2015;15(12):1429-37.

10. Tosh PK, Disbot M, Duffy JM, et al. Outbreak of Pseudomonas aeruginosa surgical site infections after arthroscopic procedures: Texas, 2009. Infect Control Hosp Epidemiol. 2011;32(12):1179-86.

11. ECDC. Healthcare-associated Infections Acquired in Intensive Care Units. [Accessed online at https://ecdc.europa.eu/sites/portal/files/documents/AER-HCAI_ICU_3_0.pdf on 14.03.2019].

12. Timm D and Gonzales D. Effect of Sterilization on Microstructure and Function of Microsurgical Scissors. Surgical Services Management. 1997;3:47-49.

13. Rogers WJ. Steam and dry heat sterilization of biomaterials and medical devices. 2012:20-55.

14. Kovaleva J, Peters FT, van der Mei HC and Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev. 2013;26(2):231-54.

15. ASP Data on File. Why Go Green Now? The Benefits of Going EtO Free.

16. McGain F, Moore G and Black J. Steam sterilisation's energy and water footprint. Aust Health Rev. 2017;41(1):26-32.

17. McCreanor V and Graves N. An economic analysis of the benefits of sterilizing medical instruments in low-temperature systems instead of steam. Am J Infect Control. 2017;45(7):756-760.

18. ASP Data on File (2005). Methodist Hospital.

19. Shah SB and Bhargava AK. Recent advances in low temperature sterilization - Moving ahead from Cidex/ETO to OPA/Ozone: An update. Indian J Anaesth. 2017;61(10):855-857.

20. WHO. Concise International Chemical Assessment Document 54: ETHYLENE OXIDE. [Accessed online at https://www.who.int/ipcs/publications/cicad/en/cicad54.pdf on 18.03.2019].

21. WHO. Concise International Chemical Assessment Document 54: ETHYLENE OXIDE. [Accessed online at http://www.inchem.org/documents/cicads/cicads/cicad54.htm on 18.03.2019].

22. Ari Ş, Caca İ, Sahin A and Cingü AK. Toxic anterior segment syndrome subsequent to pediatric cataract surgery. Cutan Ocul Toxicol. 2012;31(1):53-57.

23. CDC. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. [Accessed online at https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf on 05.04.2019].

24. U.S. Department of Energy FEMP. Water Efficiency Case Study - Veteran Affairs Hospital. 2007.

25. Rutala WA and Weber DJ. Disinfection and sterilization: An overview. Am J Infect Control. 2013;41(5):S2-S5.

26. McDonnell G and Burke P. Disinfection: is it time to reconsider Spaulding? J Hosp Infect. 2011;78(3):163-170.

27. Koo VS, O'Neill P and Elves A. Multidrug-resistant NDM-1 Klebsiella outbreak and infection control in endoscopic urology. BJU Int. 2012;110(11 Pt C):E922-6.

28. FDA. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. [Accessed online at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf on 18.03.2019].

29. FDA. Factors Affecting Quality of Reprocessing. [Accessed online at https://www.fda.gov/medicaldevices/productsandmedicalprocedures/reprocessingofreusablemedicaldevices/ucm454622.htm on 18.03.2019].

30. Dirlam Langlay AM, Ofstead CL, Mueller NJ, et al. Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg. Am J Infect Control. 2013;41(12):1188-1194.

31. DiazGranados CA, Jones MY, Kongphet-Tran T, et al. Outbreak of Pseudomonas aeruginosa infection associated with contamination of a flexible bronchoscope. Infect Control Hosp Epidemiol. 2015;30(6):550-555.

32. Chiu K-W, Tsai M-C, Wu K-L, et al. Surveillance cultures of samples obtained from biopsy channels and automated endoscope reprocessors after high-level disinfection of gastrointestinal endoscopes. BMC Gastroenterology. 2012;12(1):120.