

A microscopic view of various bacteria, including rod-shaped and spherical forms, against a blue background. The bacteria are rendered in shades of blue and white, showing detailed surface textures.

WHITEPAPER

Is contamination of duodenoscopes really a problem?

What we know...

Duodenoscope contamination is still a concern

Multiple European studies show the contamination rate of the reusable duodenoscope post-decontamination range from 11-75% (Figure 1)¹⁻⁶

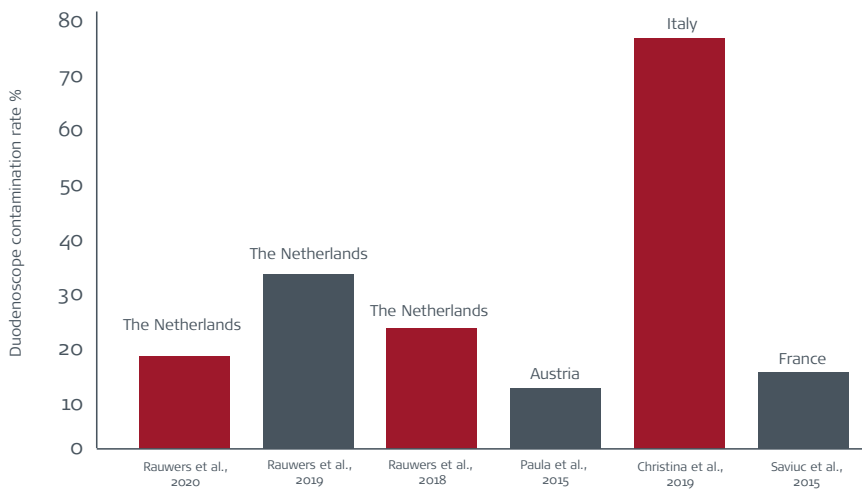


Figure 1. Duodenoscope contamination rate after scope decontamination reported in European studies

More healthcare-associated infections are related to contaminated endoscopes than to any other medical device. Despite the availability of international, national and local endoscope reprocessing guidelines, contamination and transmission of microorganisms continue to occur. Besides, the rise of multidrug-resistant organisms is linked to increasing numbers of duodenoscope-related infection outbreaks, resulting in a substantial financial burden to healthcare systems across the world.

Inadequate cleaning of flexible endoscopes is continuously listed on the Emergency Care Research Institute (ECRI) Top 10 Health Technology Hazards list

ECRI Top 10 Health Technology Hazards 2010-2020

- 2020 **5.** Device Cleaning, Disinfection and Sterilisation⁷

- 2019 **5.** Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections⁸

- 2018 **2.** Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk⁹

- 2017 **2.** Inadequate Cleaning of Complex Reusable instruments Can Lead to Infections¹⁰

- 2016 **1.** Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens¹¹

- 2015 **4.** Inadequate Reprocessing of Endoscopes and Surgical Instruments¹²

- 2014 **6.** Inadequate Reprocessing of Endoscopes and Surgical Instruments¹³

- 2013 **8.** Inadequate Reprocessing of Endoscopic Devices and Surgical Instruments¹⁴

- 2012 **4.** Cross-Contamination of Flexible Endoscopes¹⁵

- 2011 **3.** Cross-Contamination of Flexible Endoscopes¹⁶

- 2010 **1.** Cross-Contamination of Flexible Endoscopes¹⁷

The rationale behind alarmingly high contamination rates associated with duodenoscopes includes inadequate reprocessing or challenging decontamination processes.

The main challenges associated with gastrointestinal (GI) endoscope reprocessing

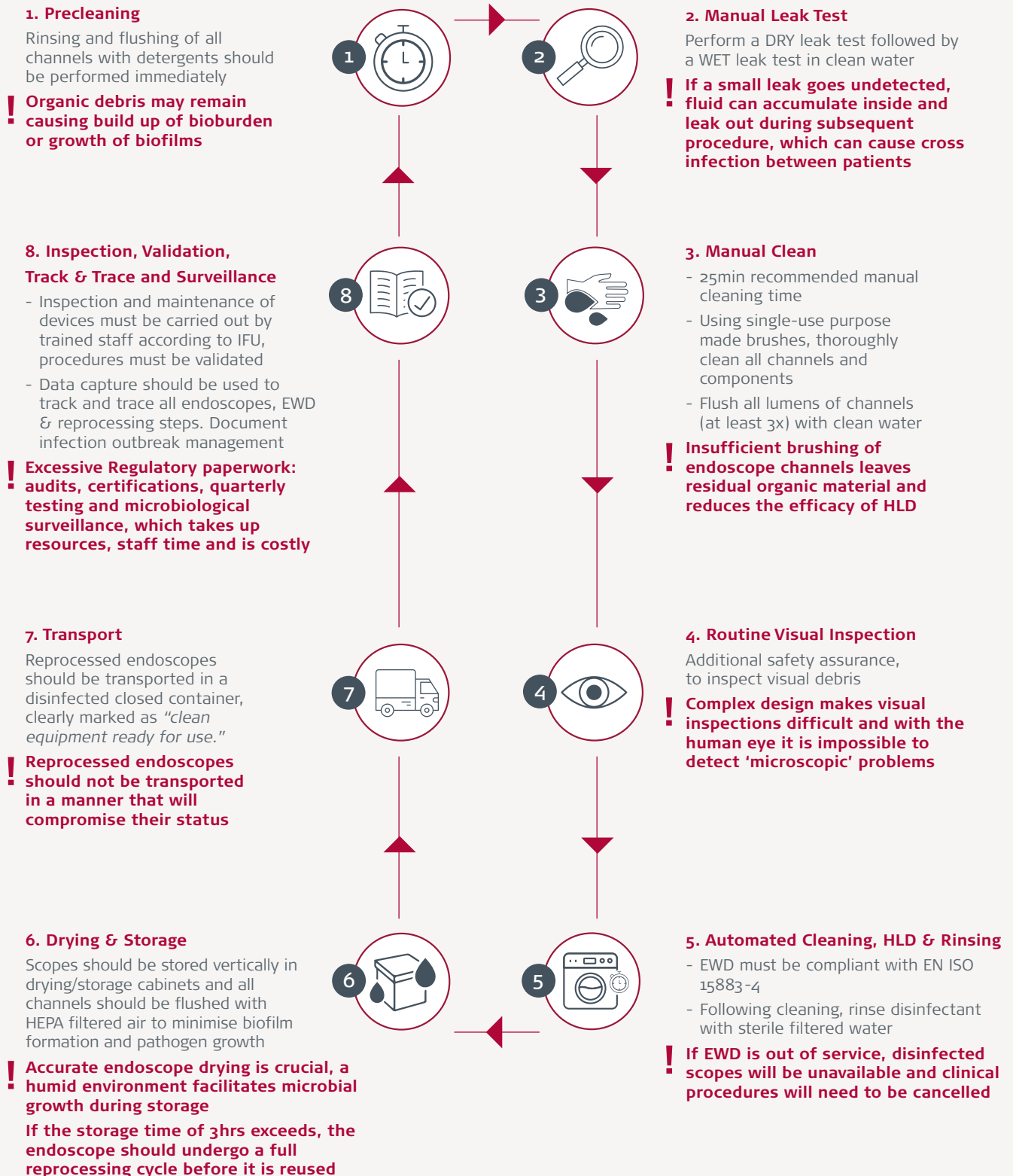


Challenge 1

Complex, hazardous, and ineffective cleaning processes

Reprocessing one endoscope is **highly complex**; one cycle involves 130 steps, different scopes have different reprocessing manuals, and each reprocessing cycle is repeated per patient procedure.

In addition, reprocessing is **resource-demanding**; dedicated reprocessing area, specialised equipment and personnel are required, and strict standards & guidelines need to be adhered.



During reprocessing, the health and safety of both patients & reprocessing personnel are at risk.

Reprocessing steps such as high-level disinfection pose an occupational hazard to reprocessing staff due to the use of highly volatile chemicals, if not performed correctly.

Toxic chemicals used during high-level disinfection require various lengths of device contact time to be effective, which prolongs the exposure time of the reprocessing staff, hence increasing the health hazard.

In addition, residual high-level disinfectants due to insufficient rinsing of reusable endoscopes may cause adverse events in patients, potentially prolonging hospital stay (Table 1).



(55)

Table 1. High-level disinfectant commonly used for endoscopic reprocessing

Chemical	Recommended surface contact time and temperature for reprocessing	Irritant to eyes and mucus membranes including respiratory tract?	Potential adverse effects for patients after insufficient rinsing?
Glutaraldehyde	Minimum of 45 minutes at 25°C	✓	✓
Orthophthalaldehyde	Minimum of 10 minutes at 20°C; Minimum of 5 minutes at 25°C (when used with an AER)	✓	✓
Peracetic acid	5 minutes at 30°C or 12minutes at 50°C*	✓	✓
Chlorine Dioxide	10 minutes at 20°C	✓	✓

*Depending on formulation. Sources^{20-22, 29, 30}

“All staff involved in endoscopy and in endoscope decontamination should wear appropriate personal protective equipment (PPE) in line with local policy..

Health surveillance for staff exposed to disinfectants should be considered, in consultation with occupational health departments”²⁶

Reprocessing is not 100% effective

Multiple studies have shown that no cleaning process effectively removes bacteria.^{2, 3, 18, 31}

Human factors play a critical role in compliance with reprocessing of GI endoscopes. Challenges around reprocessing include the pressure for rapid endoscope turnaround, lack of staff knowledge on endoscopes/access to current manufacturing IFU, underestimation of contamination risk and a lack of universal training and certification.¹⁸ Due to such

challenges, there is a high-risk of human error during endoscope reprocessing.

Despite strict National and European guidelines, microbiological surveillance study findings revealed many breaches in reprocessing procedures which caused duodenoscope contamination.^{2, 5, 32-36}



EU microbiological surveillance studies findings show breaches during critical reprocessing procedures



The Netherlands

"miscommunication about reprocessing... reprocessing with small margins of safety while human errors are to be expected"²



Italy

"equipment, such as endoscope washers and device storage lockers, needed to be replaced...the manual washing area needed to be restructured"⁵



United Kingdom

The cause of the outbreak was attributed to **"inadequate decontamination of an on-loan endoscope used over a weekend"**³²



France

"pre-wash of the endoscope may have been delayed 24h... after the peracetic wash, the drying procedure was not long enough for the novel automated washer"³³



Italy

This study showed intermixing between endogenous bacteria from inpatients and exogenous bacteria on duodenoscopes...

"The surveillance allowed evidencing potential failure of reprocessing procedure"³⁴



United Kingdom

Breaches revealed **"considerable variation in how often final water filters were changed... routinely water samples were not sent for the detection of bacterial endotoxins"**³⁶



United Kingdom

"The outbreak was related to inadequate disinfection of the air and water channel of the endoscope"³⁵

Key issues highlighted in the literature included:

Inadequate performance of routine leak testing²

Inadequate reprocessing area configuration (layout of 'clean' & 'dirty' rooms combined)⁵

Delay in reprocessing after procedure²²

The endoscope and all channels not fully dried adequately before storage²³

Inadequate cleaning of the endoscope and channels before disinfection²⁴

Incorrect disinfectant selection²⁵

Unrecognised problems with water supply²⁶

"Incidents involving improperly reprocessed instruments can potentially result in devastating effects on patients, damage to organizational and provider reputations, citations and fines from regulatory bodies, prompt review by accrediting agencies, and lawsuits"¹⁸



Challenge 2

Intricate scope design makes cleaning notoriously difficult

Surfaces

- 22.2% of surface samples harboured microbes including:
 - 1 surface with >100 CFU/10 cm² aerobic spore-forming bacilli⁴

Distal tip

- 56 distal end protective caps were sampled:
 - 11% had microbial growth >20 CFU
 - 5% harbored GI/oral microbes (including high-concern organisms)³

Elevator

- 5% of elevators harboured GI/oral microbes (including high-concern organisms)³
- 25% of elevator channels harboured *Klebsiella pneumoniae* (including MDR strains)³⁴
- Elevators harboured:
 - *Pseudomonas aeruginosa* (2500 CFU/scope); including 60% MDR
 - *Klebsiella pneumoniae* including 40% ESBL+
 - *Acinetobacter baumannii* (2600 CFU/scope)⁵

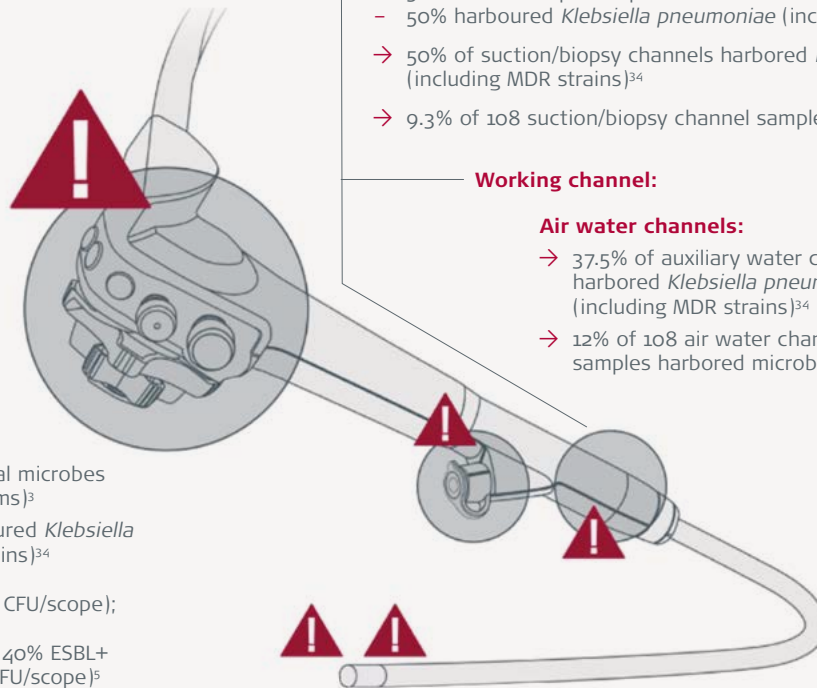
Suction/biopsy channels

- 139 duodenoscope suction/biopsy channels were sampled:
 - 12% had microbial growth ≥ 20 CFU
 - 10% harbored GI/oral microbes³
- 5% duodenoscope sampled:
 - 50% harboured *Klebsiella pneumoniae* (including MDR strains)³⁴
- 50% of suction/biopsy channels harbored *Klebsiella pneumoniae* (including MDR strains)³⁴
- 9.3% of 108 suction/biopsy channel samples harbored microbes⁴

Working channel:

Air water channels:

- 37.5% of auxiliary water channels harbored *Klebsiella pneumoniae* (including MDR strains)³⁴
- 12% of 108 air water channel samples harbored microbes⁴



European microbiological surveillance studies showing microbiological growth at the various parts of reusable duodenoscope after reprocessing.

CFU: colony-forming unit; MDR: multi-drug resistant; ESBL: extended spectrum beta-lactamase

Most GI professionals are aware that the long, narrow internal channels and bends along with the complex design of the elevator and intricate parts of the distal tip makes the reprocessing of duodenoscopes difficult.

Despite no lapses in reprocessing procedures, there is always a risk, however small, of cross-contamination of microorganisms.³⁷

The existence of biofilm is a concern, particularly for high-risk patients

For high-risk patients (e.g. immunocompromised, prior infection, ERCP for post-liver transplant anastomotic stricture, primary sclerosing cholangitis), there is a higher risk of microorganism transmission with a small window of opportunity to prevent infection associated with reusable scopes.²⁰

“Once biofilm begins to grow, it can be difficult or impossible to remove”³⁸

Multiple endoscope defects in the design such as the fixed distal cap, sealed elevator wire channel port and endoscope damage due to wear and tear (scratches/cracks in O-Ring/frayed fibres) can sequester microorganisms and promotes mature biofilm formation.^{39,40}





Challenge 3

The rise of superbugs and risk of infection associated with duodenoscopes

Pathological prions, including Creutzfeldt-Jakob disease (CJD) and variant CJD, are extremely resistant to standard decontamination, increasing the risk of transmission through endoscopes.²¹

In addition, multidrug-resistant microorganisms are the contributing factor to endoscopy related infections.²⁶

Between 2015-2020, 121 patients have been infected with a multidrug-resistant pathogen in European Hospitals (Table 2).

The number of infected patients is likely to be highly underestimated since only reported outbreaks are captured. This reported incidence is only the tip of the iceberg.

Table 2. European studies with reported patient infection from contaminated duodenoscope

Study	Location	Multi-drug resistant pathogen(s)	Patients Infected	Infection rate
Fernandez-Cuenca et al., 2020	Spain	AK. <i>P. aeruginosa</i>	15	Unknown
Fugazza et al., 2020	Italy*	CR <i>Klebsiella pneumoniae</i> ESBL <i>E. coli</i>	6 1	33.3% 12.5%
Rauwers et al., 2019	The Netherlands	CR. <i>K. pneumoniae</i>	27	32.5%
Bourigault et al., 2018	France	CR. <i>K. pneumoniae</i>	5	8.2%
Robertson et al., 2017	United Kingdom	<i>Salmonella enteritidis</i>	4	Unknown
Kola et al., 2015	Germany	CR. <i>K. pneumoniae</i>	12	Unknown
Verfaillie et al., 2015	The Netherlands	VIM-2-positive <i>P. aeruginosa</i>	22	73.3%
Aumeran et al., 2010	France	ESBL. <i>K. pneumoniae</i>	16	Unknown
Carbonne et al., 2010	France	KPC-2 <i>K. pneumoniae</i>	7	41%
Kovaleva et al., 2009	The Netherlands	<i>Pseudomonas aeruginosa</i>	3	Unknown
Cryan et al., 1984	Ireland	<i>P. Aeruginosa</i>	3	6%

*Multicentre study

AK *P. aeruginosa*: Amikacin-resistant *Pseudomonas aeruginosa*

CR. *K. pneumoniae*: Carbapenem-resistant *Klebsiella pneumoniae*

ESBL *E. coli*: extended spectrum beta-lactamase *Escherichia coli*

KPC-2 K: *Klebsiella pneumoniae carbapenemase* (KPC)-producing *Klebsiella pneumoniae* type 2

Sources ^{2, 32, 35, 37, 39-45}



The financial burden to healthcare systems induced by gastrointestinal endoscopy related hospital-acquired superbug infections is significant

Infections due to multidrug-resistant organisms have increasingly become a concern in health care, due to the limited antibiotic therapeutic options, which may result in poor clinical outcomes.

ERCP-related infections often include isolated multidrug-resistant pathogens such as *Salmonella enteritidis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa* and *Escherichia coli*.^{32, 45-48}

In 2015, there were 52,971 reported cases of infections with antibiotic-resistant bacteria and 2172 deaths as a result of this.⁴⁹ In addition, antibiotic-resistance infections are rising year by year, with an estimated **65,162 infections in the UK in 2019**.⁵⁰

Locally in the UK, the cases of contamination and infections related to GI endoscopy have been under-reported, which is reflected in the high medical negligence claims filed between 2010-2015 (Figure 2).⁵¹

Claims relating to **infection control and hospital hygiene** topped the list

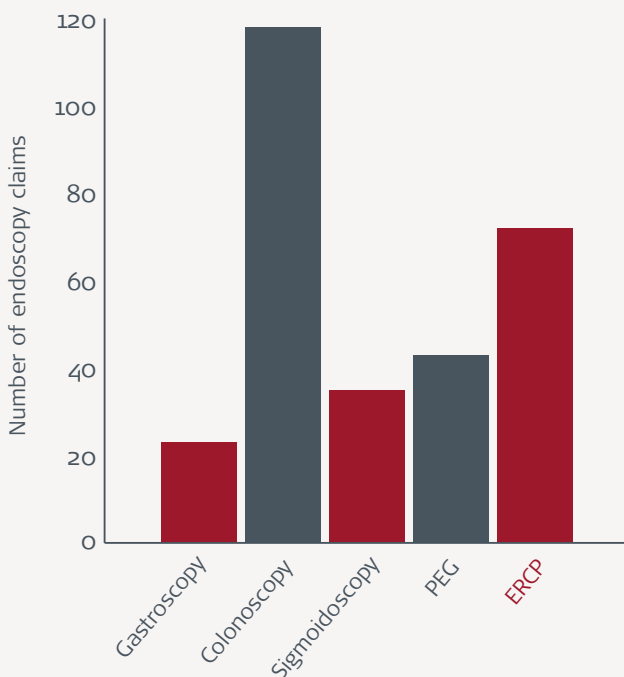


Figure 2. Endoscopy Claims By Procedure Reported Between 2010-2015 in the UK

Provide the best care possible

“Patients have a right to be investigated and treated in a safe and clean environment with consistent standards every time care is given. It is essential that the risk of person-to-person transmission of infections be minimised as far as reasonably possible”⁷

“Antimicrobial resistance is an increasingly serious threat to global public health that requires action across all government sectors and society”⁵²

“The UK’s five-year national action plan target is to reduce the incidence of a specified set of drug-resistant infections in Humans in the UK by 10% by 2025”⁵³

The cost of a carbapenemase-producing *Klebsiella pneumoniae* outbreak during a ten-month duration within 5 **West London** hospitals was **£982,262, which equates to £24,557 per patient**. Reduced capacity to perform elective surgical procedures related to bed closures (**£7791 per patient**) represented the greatest cost burden.⁵⁴

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