

Segmenting ERCP patients by infection risk allows endoscopists to make more informed decisions about the risk-benefit ratio of using single-use duodenoscope technology in the care of their patients.

With respect to patient infection and/or colonisation associated with ERCP procedures, there are two significant pathogen reservoirs, the patient and the duodenoscope.

1 Infected/colonised patients



Active or history of **multidrug resistant organism (MDRO)** infection/colonisation



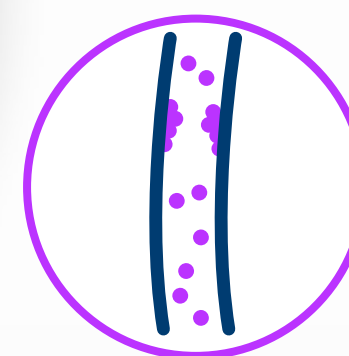
Protect your vulnerable patients by protecting your scope fleet: Use EXALT™ Model D on defined patients.

← Breaking the potential connection →

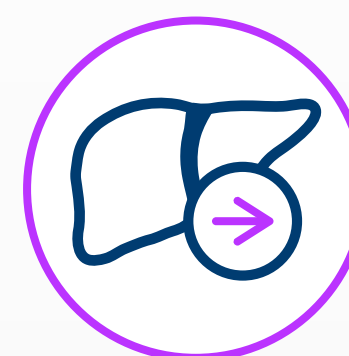
2 Patient factors: increased susceptibility to infection



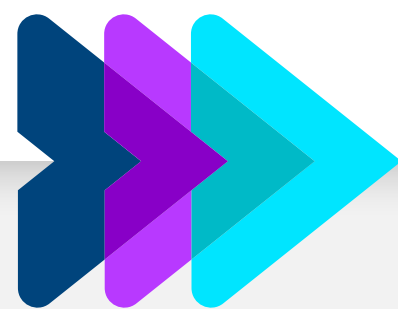
**Immune suppression** by systemic chemotherapy; special circumstances of immune suppression



**Incomplete drainage** Cholangiocarcinoma with hilar stricture, Primary Sclerosing Cholangitis (PSC)



**Liver transplant** potential, candidate or recipient

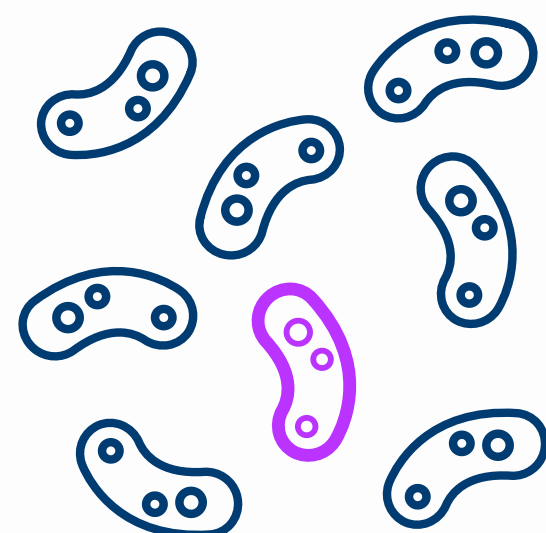


## PROTECTION OF DUODENOSCOPE INVENTORY



### Active or history of MDRO infection/colonisation

(Carbapenem-resistant *Enterobacterales*, *E. coli*, *Kl. pneumoniae*, *Pseudomonas*, *Salmonella*)



Estimates show

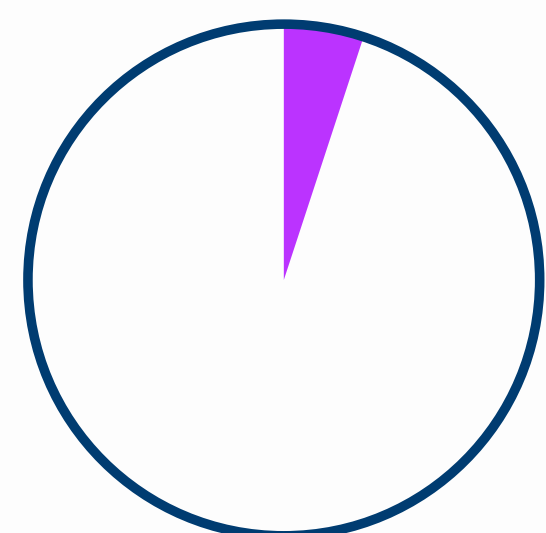
# 670 K+

infections each year, occur in the EU/EEA due to MDRO.<sup>1</sup>

Approximately

# 33 K

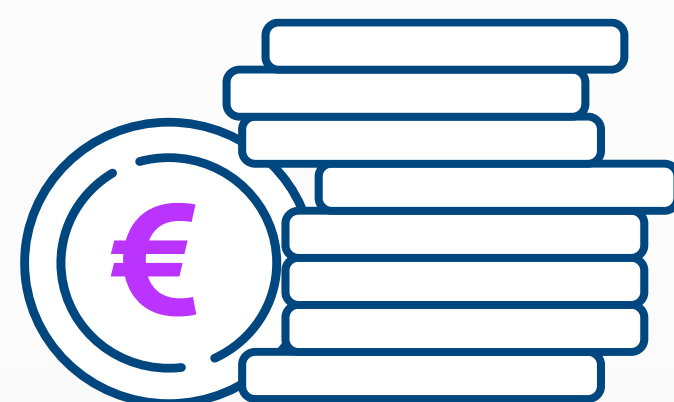
people die as a direct consequence of MDRO infections.<sup>1</sup>



Around

# €1.1 B

is the related cost to the healthcare systems of EU/EEA countries.<sup>1</sup>



### Protect your scope fleet

#### Persistent Contamination of Duodenoscopes

Persistent contamination of a duodenoscope results from the interplay of events involving exposure to infected/colonised patients, ineffective reprocessing protocols, and complex duodenoscope design.<sup>2-5</sup>

The primary factors that contribute to persistent biofilm formation and microbial contamination are mentioned below:

- **Inadequate manual cleaning impedes high-level disinfection/sterilisation.**<sup>5</sup>
- **Incomplete drying resulting in storage of wet endoscopes which promotes biofilm formation.**<sup>6,7</sup>
- **Complex endoscope design impedes proper reprocessing.**<sup>5</sup>

[Click here ▶](#)





## PATIENT FACTORS

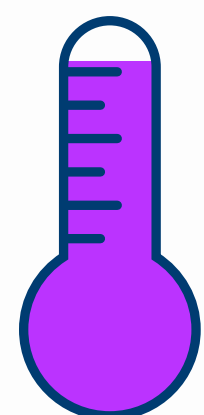


### Immunosuppressive therapy

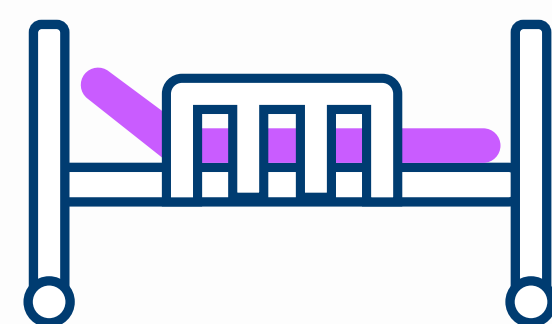
Patients taking immune-suppression medications; patients undergoing systemic chemotherapy; special circumstances of immune suppression (bone marrow transplant patient, severe neutropenia <500, etc)<sup>8</sup>

**Chemotherapy** and/or radiation patients w/low white blood cell count (WBC range <3 is considered low, healthy is 4.5 – 11)

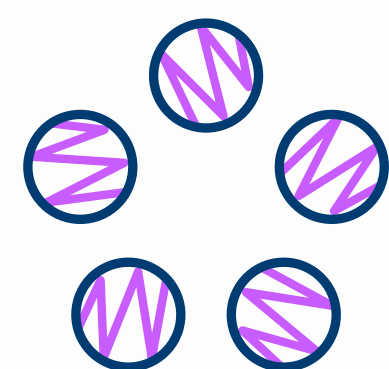
Colonised patients with acute myeloid leukemia undergoing intensive induction chemotherapy **suffered from:**



significantly **more days with fever**

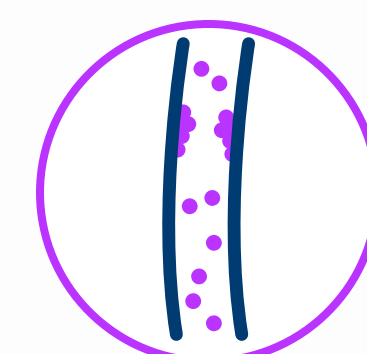
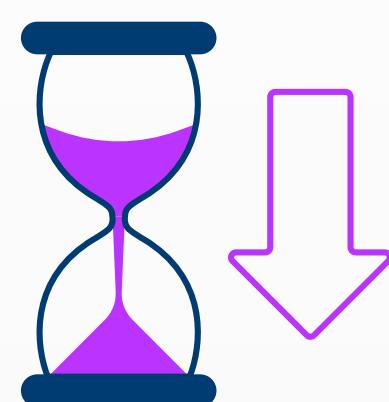


spent **more days on the intensive care unit**



and had a **higher median C-reactive protein value** during the hospital stay.

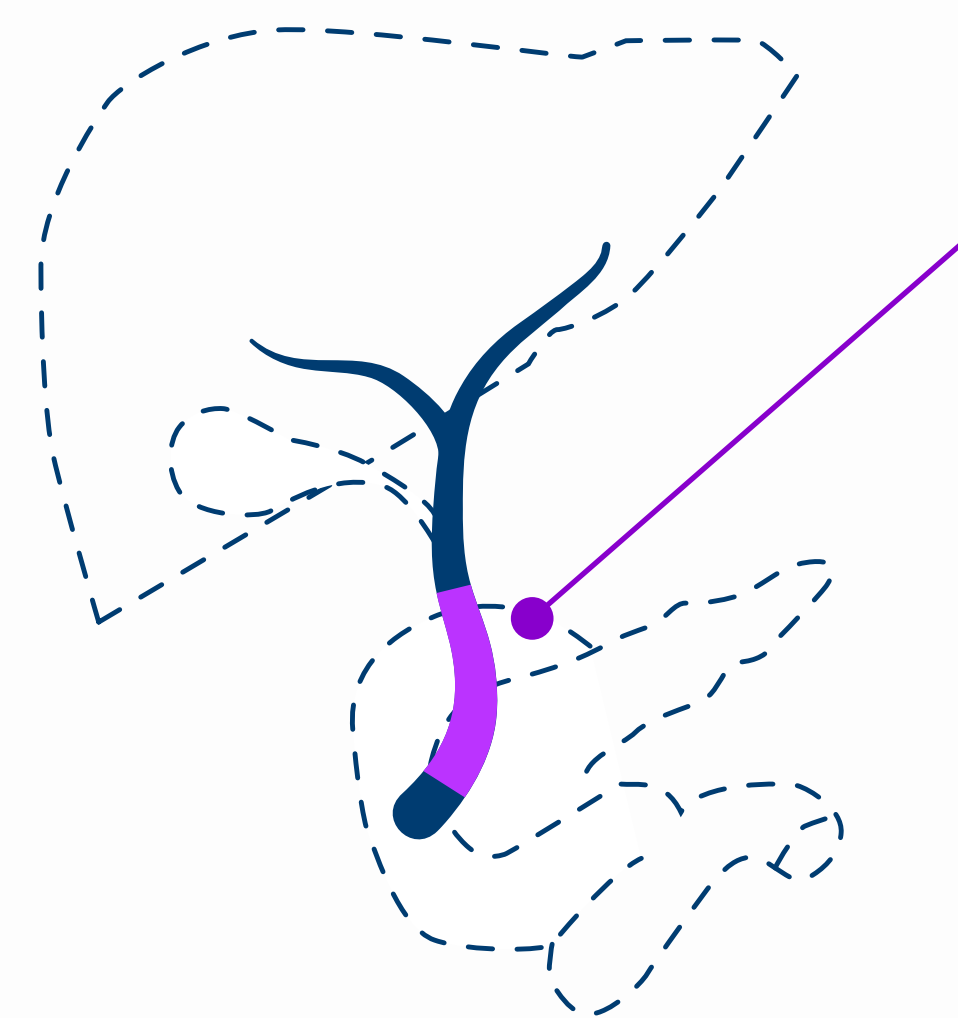
In a subgroup analysis, patients colonised with carbapenem-resistant Enterobacteriaceae (CRE) had a significantly **reduced 60- and 90-day, as well as one- and two-year survival rates** when compared to noncolonised patients.<sup>2</sup>



### Incomplete drainage

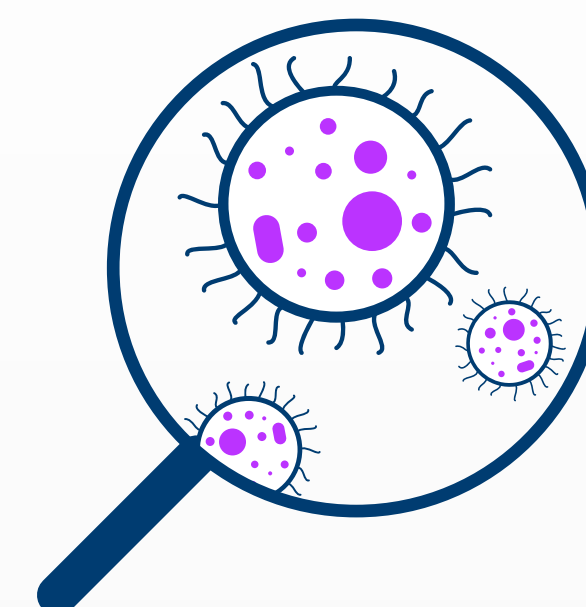
(PSC, Cholangiocarcinoma)

**Cholangiocarcinoma** history, with stent exchanges



Incomplete drainage of an obstructed biliary system is the major predictor of **post-ERCP biliary sepsis and cholangitis** occurring in up to

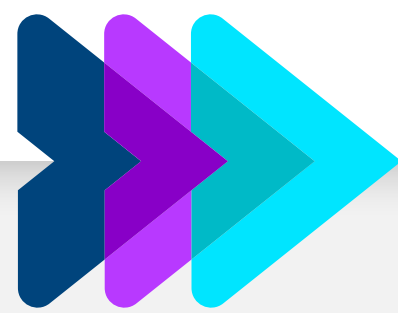
**3% of ERCP cases.**<sup>8</sup>



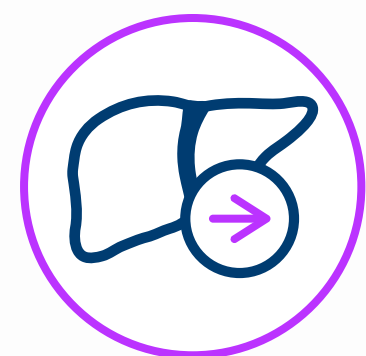
Incomplete biliary drainage was predictive of

**91% of all cases of sepsis**

associated with ERCP with the risk of post-ERCP cholangitis.<sup>8</sup>



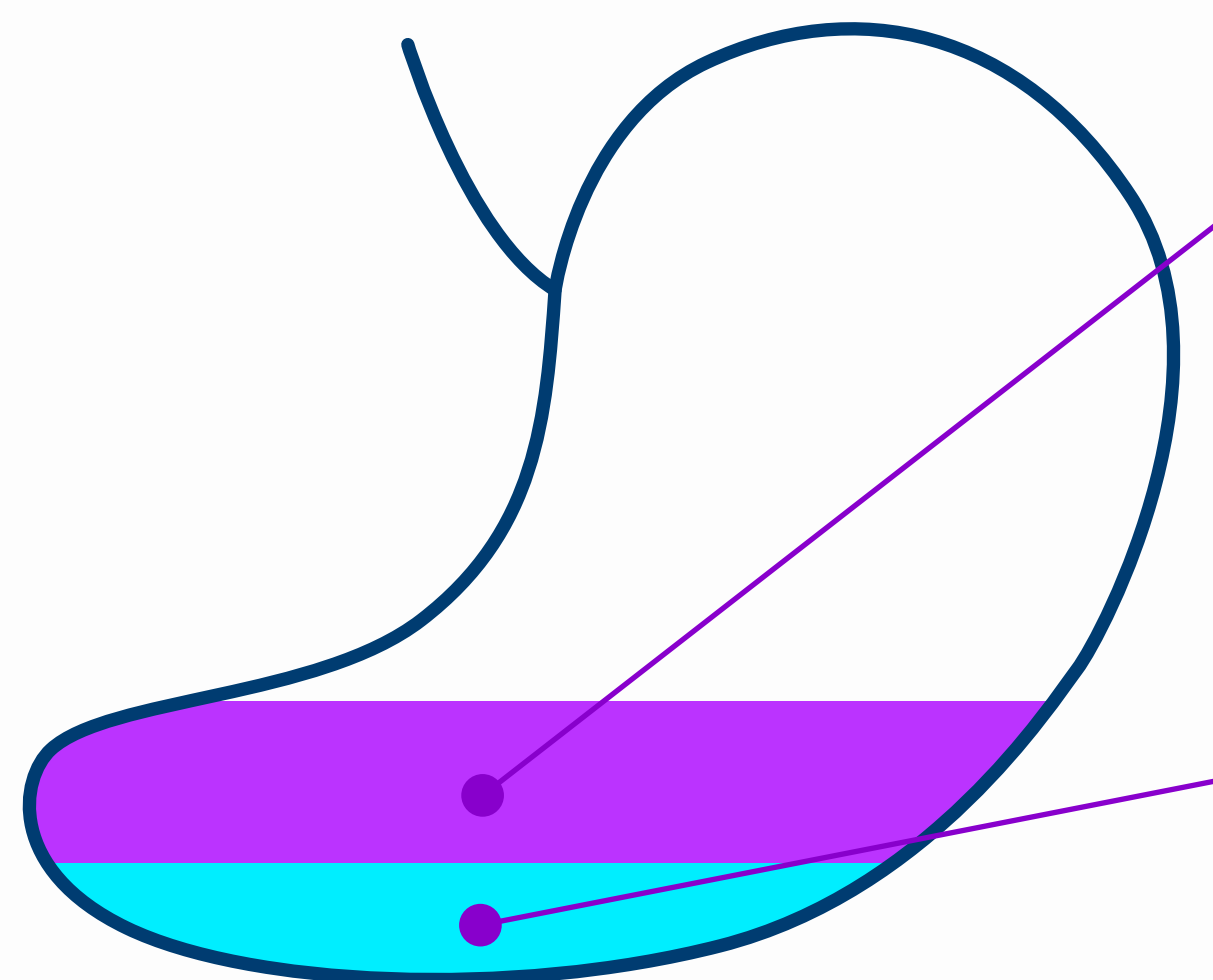
## PATIENT FACTORS



### Liver transplant potential, candidate or recipient

The risk of infection in the transplant patient is dependent on the interplay between exposure to infectious agents and their level of immunosuppression.

#### Increased risk of biliary complications



**28-32%**

of patients after liver transplantation from a **living donor**.

**5-15%**

of patients after liver transplantation from a **deceased donor**.<sup>9</sup>



**Post-LT biliary strictures occur mostly within one year**, but may also occur later and are associated with increased morbidity, mortality and reduced graft survival in LT recipients.<sup>6</sup>

For patients on a transplant waiting list, development of an infection may rapidly change their suitability for a transplant.<sup>8</sup>

1. ECDC surveillance report. Antimicrobial resistance in the EU/EEA (EARS-Net). AER 2019. 2. Ofstead CL, Buro BL, Hopkins KM, Eiland JE, Wetzler HP, Lichtenstein DR. Duodenoscope-associated infection prevention: a call for evidence-based decision making. *Endosc Int Open* 2020; 8 (12) E1769-E1781. 3. Kim S, Russell D, Mohamadnejad M. et al Risk factors associated with the transmission of carbapenem-resistant enterobacteriaceae via contaminated duodenoscopes. *Gastrointest Endosc* 2016; 83 (06) 1121-1129. 4. Wendorf KA, Kay M, Baliga C. et al Endoscopic retrograde cholangiopancreatography-associated AmpC Escherichia coli outbreak. *Infect Control Hosp Epidemiol* 2015; 36 (06) 634-642. 5. US FDA. Design of endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes may impede effective cleaning: FDA safety communication 2015 Available at: <http://wayback.archive-it.org/7993/20170722213105/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm>. Accessed June 24, 2021. 6. Alfa MJ, Singh H. Impact of wet storage and other factors on biofilm formation and contamination of patient-ready endoscopes: a narrative review. *Gastrointest Endosc* 2020; 91 (02) 236-247. 7. Ofstead CL, Heymann OL, Quick MR, Eiland JE, Wetzler HP. Residual moisture and waterborne pathogens inside flexible endoscopes: evidence from a multisite study of endoscope drying effectiveness. *Am J Infect Control* 2018; 46 (06) 689-696. 8. Thornhill, G., & Dunkin, B. (2021). Duodenoscope-Acquired Infections: Risk Factors to Consider. *Journal of Digestive Endoscopy*, 12(03), 151-159. <https://doi.org/10.1055/s-0041-1739562>. 9. Sharma et al\_2008\_Biliary Strictures following liver transplantations.

All trademarks are the property of their respective owners. All photographs taken by Boston Scientific.

**Caution:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device or at [www.IFU-BSCI.com](http://www.IFU-BSCI.com). Products shown for **INFORMATION** purposes only and may not be approved or for sale in certain countries. This material not intended for use in France. RX Only. The contents of these articles/publications are under the sole responsibility of their authors/publishers and do not represent the opinions of BSC.

**Boston  
Scientific**  
Advancing science for life™

[www.bostonscientific.eu](http://www.bostonscientific.eu)

2022 Copyright © Boston Scientific Corporation or its affiliates. All rights reserved.

ENDO-1358001-AA