



## **Annex 1: EXALT Model D Initial Field Safety Corrective Action (FSCA) Report Literature References**

The limitations of the PDF FSCA Report form mean that literature references cannot easily be pasted, and are therefore included below:

<sup>1</sup> Patil NS, Solanki N, Mishra PK, Sharma BC, Saluja SS. ERCP-related perforation: an analysis of operative outcomes in a large series over 12 years. *Surg Endosc.* 2020;34(1):77-87. doi:10.1007/s00464-019-06733-x

<sup>2</sup> Wu HM, Dixon E, May GR, Sutherland FR. Management of perforation after endoscopic retrograde cholangiopancreatography (ERCP): a population-based review. *HPB (Oxford).* 2006;8(5):393-399. doi:10.1080/13651820600700617

<sup>3</sup> Weiser R, Pencovich N, Mlynarsky L, et al. Management of endoscopic retrograde cholangiopancreatography-related perforations: Experience of a tertiary center. *Surgery.* 2017;161(4):920-929. doi:10.1016/j.surg.2016.10.029

<sup>4</sup> Huang J, Wen W, Tang X, Fan Z, Song H, Wang K. Cap-assisted clip closure of large esophageal perforations caused by a duodenoscope during endoscopic retrograde cholangiopancreatography (with video). *Surg Laparosc Endosc Percutan Tech.* 2014;24(3):e101-e105. doi:10.1097/SLE.0b013e318293c4b6

<sup>5</sup> Enns R, Eloubeidi MA, Mergener K, et al. ERCP-related perforations: risk factors and management. *Endoscopy.* 2002;34(4):293-298. doi:10.1055/s-2002-23650

<sup>6</sup> Kodali S, Mönkemüller K, Kim H, et al. ERCP-related perforations in the new millennium: A large tertiary referral center 10-year experience. *United European Gastroenterol J.* 2015;3(1):25-30. doi:10.1177/2050640614560784

<sup>7</sup> Dahale AS, Gupta M, Saxena P, et al. Endoscopic retrograde cholangiopancreatography-related complications - Experience from tertiary care teaching centre over half a decade [published online ahead of print, 2022 Jan 4]. *J Minim Access Surg.* 2022;10.4103/jmas.jmas\_272\_21. doi:10.4103/jmas.jmas\_272\_21

<sup>8</sup> Beilenhoff et al., Prevention of multidrug-resistant infections from contaminated duodenoscopes: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA). *Endoscopy*, 2017

<sup>9</sup> Higa, Duodenoscope-related infections: Overview and epidemiology. *Techniques in Gastrointestinal Endoscopy*, 21(4), 150623 2019

<sup>10</sup> Trindale et al., Single-use duodenoscopes and duodenoscopes with disposable end caps. ASGE Technology Committee 2021.