

AMBU OBTAINS FDA CLEARANCE FOR NEW GENERATION DUODENOSCOPY SOLUTION

To meet the unique needs of gastroenterologists performing ERCP procedures, Ambu's new generation aScope Duodeno 2 solution constitutes a step change from previous generations, driven by valuable collaboration with healthcare professionals.

Today, Ambu announces 510(k) regulatory clearance from the U.S. Food and Drug Administration (FDA) of its new generation duodenoscopy solution, Ambu® aScope™ Duodeno 2 and Ambu® aBox™ 2, for use in ERCP¹ procedures.

In the development of the new generation solution, Ambu has worked closely with a range of experienced gastroenterology professionals and ERCP specialists to rethink its duodenoscopy solution, with a clear focus on enhancing critical performance factors and enabling integration with the aBox™ 2 endoscopy system.

“ I am impressed with the improvements in the new aScope Duodeno 2, and I believe that it holds potential for ERCP in the future. Ambu has clearly taken the customer feedback into the development of this new duodenoscope. I highly valued the collaboration throughout the development phase, and I am looking forward to continuing to engage with Ambu on future innovations.

ABHITABH PATIL, M.D.²

Interventional Gastroenterology
President of Florida Gastroenterologic Society, St. Petersburg, FL

PROVIDING FLEXIBILITY AND STERILITY WITH PATIENT-READY DUODENOSCOPES

The new generation aScope™ Duodeno 2 solution is designed to meet the high-performance expectations in ERCP and furthermore relieve the burden of complex and time-consuming reprocessing conducted today. As aScope™ Duodeno 2 is 100% sterile, the solution enables physicians and hospital systems to adhere to the safety recommendations issued by the FDA³ in 2019 and 2022, urging U.S. hospitals and endoscopy facilities to transition to duodenoscopes that are partially or completely single-use.

Furthermore, given the often long and physically demanding nature of ERCP procedures, the handle of Ambu's new generation aScope Duodeno 2 solution aims to alleviate strain on endoscopists through improved ergonomics. In addition, Ambu is planning to include bioplastic materials in the handle of the new generation solution over time - materials that are derived from a mix of fossil-based and second-generation bio-based feedstock, e.g., recycled food waste, ensuring a raw material with a lower carbon footprint.

“ Our new generation duodenoscope solution is a result of a close partnership with gastroenterologists. Based on their feedback, we have developed a solution to meet the distinct procedural needs in ERCP. We are dedicated to continuing Ambu's focused journey within GI, anchored in profound customer understanding as a pivotal driver for unlocking long-term potential - for gastroenterologists, patients and Ambu.

BRITT MEELBY JENSEN

Chief Executive Officer, Ambu

Ambu will conduct an extended controlled market release with key hospitals to evaluate the clinical performance in a real-life setting. The solution will be available in the market from 2024/25, and the FDA clearance will therefore not change the financial guidance for 2023/24.

¹ ERCP stands for endoscopic retrograde cholangiopancreatography and serves both diagnostic and therapeutic purposes for various conditions affecting the bile ducts and pancreas, including gallstones, strictures and tumours.

² Dr. Patil a paid consultant of Ambu A/S. He has not been compensated for his quote in this press release.

³ [Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication | FDA.](#)



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ABOUT AMBU

Since 1937, Ambu has been rethinking solutions, together with healthcare professionals, to save lives and improve patient care. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anaesthesia and patient monitoring solutions. Headquartered near Copenhagen in Denmark, Ambu employs around 4,600 people in Europe, North America, Latin America and Asia Pacific. For more information, please visit [Ambu.com](https://www.ambu.com).