

AMBU OBTAINS CE MARK FOR NEW GENERATION DUODENOSCOPY SOLUTION

Having obtained both CE mark and FDA clearance, Ambu continues its controlled market release phase, focused on evaluation in key hospitals in the USA and Europe.

Today, Ambu announces European regulatory clearance (CE mark) for the new generation duodenoscopy solution, Ambu® aScope™ Duodeno 2 and Ambu® aBox™ 2, for use in ERCP¹ procedures.

Ambu obtained FDA clearance for the new generation duodenoscope solution in April 2024. With both CE mark and FDA clearance secured, Ambu continues its controlled market release phase, aimed at evaluating the performance in a clinical setting in collaboration with key hospitals in the USA and Europe.

In the development of the new generation solution, Ambu has partnered with experienced gastroenterology professionals to deliver a solution that meets the distinct high-performance needs for ERCP procedures. The new generation solution thus represents an improvement from previous generations, with enhanced functionalities and a seamless integration with Ambu's aBox™ 2 endoscopy system.

“ I am looking forward to testing the new aScope Duodeno 2 soon in various ERCP cases of different complexities to see how Ambu has translated the feedback of customers and experts into the new design with improved functionality of this next generation single-use duodenoscope.

PROF. DR. MED. HELMUT MESSMANN²

Director of the Department of Internal Medicine at University Hospital of Augsburg, Germany

ENHANCING WORKFLOW WITH SINGLE-USE DUODENOSCOPES

In addition to meeting the distinct needs of ERCP procedures, the new generation aScope™ Duodeno 2 solution offers gastroenterologists and their staff the opportunity to optimise workflow efficiency. Single-use duodenoscopes remove the burden of complex and time-consuming post-procedure reprocessing, while simultaneously representing a 100% sterile tool for physicians and hospital systems to enhance infection control, which is especially valuable for immunocompromised patients.

Furthermore, the handle of Ambu's new generation aScope™ Duodeno 2 solution has been designed with improved ergonomics in mind to relieve strain on endoscopists during the often long and physically demanding ERCP procedures.

In line with Ambu's ambition to include bioplastic material in the handles of all its single-use endoscope offering, Ambu also plans to incorporate bioplastic materials - materials derived from a mix of fossil-based and second-generation feedstock, e.g., recycled food waste - into the handle of the new generation duodenoscopy solution, over time.

“ Having both European regulatory clearance and FDA clearance for the U.S. market is another important step forward in our long-term gastroenterology journey. It is a testament to our dedication towards continuing our focused strategy within gastroenterology, through strong collaboration with leading healthcare professionals to deliver value in their patient treatment, which will unlock a long-term potential for advancement and growth.

BRITT MEELBY JENSEN

Chief Executive Officer, Ambu

The new generation duodenoscopy solution will be available in the market from 2024/25, and the European regulatory clearance (CE mark) 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 Prof. Dr. med. Helmut Messmann has not been compensated for his quote in this press release.



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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).