

AMBU ANNOUNCES FDA CLEARANCE OF FIRST-GENERATION SINGLE-USE COLONOSCOPE

With the new colonoscopy solution, Ambu complements its gastroenterology offering by bringing single-use efficiency to colonoscopists and patients for interventional and diagnostic procedures.

Today, Ambu announces 510(k) regulatory clearance from the U.S. Food and Drug Administration (FDA) of its single-use colonoscopy solution, the Ambu® aScope™ Colon and the endoscopy system, the Ambu® aBox™ 2.

With a 3.7 mm working channel and just 11.5 mm outer diameter, the new colonoscopy complements Ambu's gastroenterology (GI) portfolio, consisting of the Ambu® aScope™ Gastro and the Ambu® aScope™ Gastro Large - all of which are supported by the ecosystem software platform featured in the Ambu® aBox™ 2.

The colonoscopy market is the biggest endoscopy segment, not only in GI, but across all endoscopy segments, representing approximately 40 million procedures annually. Ambu's colonoscopy solution is designed to meet the needs pertaining to 1.5 million of these procedures, and with the FDA clearance, Ambu will apply an initial market test approach in a few dedicated U.S. centers to evaluate clinical performance, in close collaboration with physicians.



The Ambu aScope Colon is a pioneer step, making the single-use concept available for colonoscopy. We are looking forward to evaluating the performance and potential patient benefits of this technology.

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REAPING THE REWARDS OF SINGLE-USE EFFICIENCY AND STERILITY

The Ambu® aScope™ Colon constitutes a new sterile tool for GI professionals during interventional and diagnostic procedures. Due to the guaranteed sterility of the single-use colonoscopy, the risk of cross-contamination is removed, and the scope can hereby serve as a unique medical device for the treatment of patients who suffer from serious infections or are immunocompromised.

Moreover, Ambu's colonoscopy presents the opportunity for colonoscopists and nursing staffs in the U.S. to reap the rewards of single-use in terms of availability, efficiency and workflow optimisation. GI professionals using single-use endoscopes are not limited by the number of available scopes at hand - nor are they subjects to the rigid reprocessing requirements that come with reusable endoscopes. Instead, they are offered the flexibility of single-use and, with that, the opportunity to improve their planning and management of schedules, in turn, potentially saving patients from the bother of cancellations and rescheduling.



In line with our strategic decision to apply a niche-based approach on our GI journey, we are dedicated to engaging with selected U.S. customers to test the performance of our new colonoscopy solution. Our entry into the gastroenterology market is one of learning and focus, and as we gradually expand our offering, we are looking forward to bringing the power of single-use efficiency and sterility to a growing number of healthcare professionals and patients.

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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 4,500 people in Europe, North America, Latin America and Asia Pacific. For more information, please visit Ambu.com.