PRESS RELEASE

8 April 2024

AMBU OBTAINS FDA CLEARANCE FOR WORLD'S FIRST SINGLE-USE THERAPEUTIC GASTROSCOPE

Ambu's aScope™ Gastro Large, with its 4.2 mm working channel and endoscope handle made with bioplastics, expands the company's single-use portfolio for upper gastroenterology (GI) procedures. The expanded portfolio allows physicians to address an extended range of needs across the ICU, OR and endoscopy suite.

Today, Ambu announces 510(k) regulatory clearance from the U.S. Food and Drug Administration (FDA) of its therapeutic gastroscope solution, Ambu® aScope™ Gastro Large and Ambu® aBox™ 2.

The clearance signifies an extended solution offering for surgeons and gastroenterologists performing upper GI procedures. With the expanded endoscope portfolio – consisting of the aScope™ Gastro and the aScope™ Gastro Large – physicians are now equipped to address a wider range of needs in various hospital settings, covering the operating room (OR), the intensive care unit (ICU) and the endoscopy unit. Globally, the aScope™ Gastro Large targets 1.5 million annual procedures, while the aScope™ Gastro is expected to meet needs within a market of 2 million annual procedures.

The aScope™ Gastro Large is, with its 4.2 mm working channel and powerful suction performance, designed to addresses acute therapeutic procedures in the ICU, such as bleed management and food impaction, as well as direct endoscopic necrosectomy and stenting in the endoscopy unit. Compared to the industry-leading 3.7 mm therapeutic gastroscopes on the market, the working channel of the aScope™ Gastro Large delivers significantly higher suction performance[1], both with and without tools, thereby constituting a valuable tool for managing acute upper GI bleeding. Complimentarily, the aScope™ Gastro targets procedures outside of the endoscopy unit, such as surgical gastroscopies in the OR and bedside procedures in the ICU.

> **"I look forward to utilizing the innovative aScope Gastro Large single-use gastroscope technology for interventions that require superior suction. The gastroscope's 4.2 mm working channel will facilitate clot and blood clearance and removal of necrotic debris during direct endoscopic necrosectomy. Operationally, the immediate availability of a disposable scope to be utilized in urgent cases in various locations without the need for reprocessing will improve downstream efficiencies and minimize barriers to providing urgent endoscopic care to our patients."**
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> **MARK A. GROMSKI, MD, FASGE** [2]
> Director, Advanced Endoscopy, Indiana University School of Medicine

TWO WORLD'S FIRSTS: 4.2 MM WORKING CHANNEL AND HANDLE MADE WITH BIOPLASTICS

The aScope™ Gastro Large represents two world firsts within the endoscopy market. Not only is it the first single-use therapeutic gastroscope with a 4.2 mm working channel; it is also the world's first endoscope made with bioplastics.

The bioplastic materials in the gastroscope handle are derived from a mix of fossil-based and second-generation feedstock, e.g., recycled food waste, ensuring that it has a lower carbon footprint. The large gastroscope is the first of Ambu's fleet of endoscopes to be manufactured with bioplastics and thus represents an important step forward in the company's commitment to integrating bioplastics in all future endoscope handles by the end of 2024.

Ambu announced European regulatory clearance (CE mark) of the aScope™ Gastro Large in September 2023 and now

[1] Suction data based on bench top test with 10 Fr bipolar probe.
[2] Dr. Gromski is a paid consultant of Ambu A/S. He has not been compensated for his quote in this press release.

extends its commercialisation to North America. CEO Britt Meelby Jensen is excited about the FDA clearance and to bringing an expanded and advanced gastroscopy portfolio to customers in Ambu's biggest market:

> **Our therapeutic gastroscope solution is a vital step forward in our gastroenterology journey. Not only does it expand and strengthen our gastroscope portfolio, empowering U.S. physicians with two complimentary high-performance solutions for upper GI procedures targeting diverse clinical needs; it also marks an important way forward for hospitals and GI professionals wishing to alleviate the strain of reprocessing, optimise workflow and bring faster care to patients.**
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> **BRITT MEELBY JENSEN**
> Chief Executive Officer, Ambu

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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.