

PRESS
RELEASE

Ambu announces FDA clearance of single-use gastroscope and next-generation display unit

Ambu enters a market of 20 million annual procedures, expanding presence in GI.

Today, Ambu announces the 510(k) regulatory clearance of the Ambu® aScope™ Gastro and Ambu® aBox™ 2 in the United States. aScope Gastro is Ambu's first sterile single-use gastroscope and includes new advanced imaging and design features in a combined solution with next-generation display and processor technology. With HD capabilities, the aBox 2 will set a new benchmark in terms of image quality and will be at the centre of Ambu's endoscopy ecosystem.

Advanced technology to support doctors, health systems, and patients

With the launch of aScope Gastro, Ambu enters the gastroscopy segment, where 20 million procedures take place annually with reusable endoscope systems.

The advanced technology, portability, and cost-effectiveness of Ambu's solution address the current limitations of reusable endoscopes, and it will be an attractive choice for customers looking to perform gastroscopies across a wide range of care settings (including endoscopy unit, OR, ICU, ER, ASC). Furthermore, the aScope Gastro will support healthcare systems in their efforts to reduce waiting lists and overcome staff shortages, which have been accentuated since the start of the COVID-19 pandemic. Finally, the sterile offering provides a solution to the growing cross-contamination risks, especially for vulnerable patients.

"The Ambu system comes at a time where we're dealing with waiting lists and staff shortages, and where the ease of setup and elimination of reprocessing, are major advantages. Also, the combination of a sterile single-use gastroscope and a compact display unit opens up the opportunity to expand endoscopy to alternative settings, such as Intensive Care Units," says Prof. Pradeep Bhandari¹, Queen Alexandra Hospital, Portsmouth, UK.

"In the OR setting, having a single-use scope that is immediately available with a small footprint, which requires much less up-front capital outlay than a reusable setup, will be valuable to many hospitals across the country," says Reginald Bell¹, M.D., F.A.C.S, Institute of Esophageal and Reflux Surgery, Lone Tree, Colorado, USA.

With this FDA clearance, Ambu will proceed with commercialisation of the aScope Gastro and aBox 2 in the United States.

Expanding Ambu's presence in GI

Together with the launch of the aScope™ Duodeno 1.5, the aScope Gastro represents the next step in Ambu's expansion into the GI segment. They will be followed by the next generation single-use duodenoscope (aScope Duodeno 2.0), a colonoscope and a cholangioscope, giving Ambu the most comprehensive single-use portfolio in GI.

"Gastroscopy is not only one of the largest segments in endoscopy, but also has all the conditions to benefit from single-use endoscopy. There is a clear need for more convenience, flexibility, and infection control, which are all addressed with the introduction of our aScope Gastro," says Juan Jose Gonzalez, CEO of Ambu. *"The technology in our aScope Gastro and aBox 2 will set a new benchmark in terms of image quality and functionality and will power all of our next-generation launches. Our expansion within GI will extend Ambu's position as the world's most innovative single-use endoscopy player."*

¹ Prof. Bhandari and Dr. Bell are paid consultants of Ambu A/S. They have not been compensated for their quotes within this press release.



Ambu® aScope™ Gastro and Ambu® aBox™ 2 form a combined solution of a single-use gastroscope with a reusable display and processor unit.



A gastroscope allows a doctor to examine the esophagus, stomach and duodenum of the patient. A procedure takes from 10 minutes to more than an hour depending on the complexity of the case.

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About Ambu

Ambu has been bringing the solutions of the future to life since 1937. 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. We continuously look to the future with a commitment to deliver innovative quality products that have a positive impact on patient care and the work of healthcare professionals. Headquartered near Copenhagen in Denmark, Ambu employs approximately 4,500 people in Europe, North America and the Asia Pacific. For more information, please visit ambu.com or ambuUSA.com or follow us on our [corporate LinkedIn](#) and [USA LinkedIn](#) pages.