Ambu receives FDA clearance for disposable colonoscope in the US

With this milestone Ambu is cleared to address the +15 million annual procedure market for colonoscopy in the US.

Ambu already operates in the field of single-use endoscopy for pulmonary (visualisation of the airways) with aScope, a ~5m annual procedure market, and has sold more than 700,000 aScopes since the launch in 2013.

"We are very pleased with the approval by the FDA, which we see as a clear signal that there is a need for mitigating the risks of cross contamination within endoscopy, a risk that was recently ranked as the 2nd most critical health hazard in ECRI’s report for 2018. The FDA approval marks a positive upgrade of our business potential," says Lars Marcher, CEO of Ambu.

Following the acquisition of Invendo's Gastrointestinal platform (including the colonoscope) in October 2017, Ambu is now in the process of establishing a scalable production and supply chain to be able to meet the demand. Pre-market activities are planned to be initiated with selected hospitals in the US during H2 this financial year.

As a consequence of the FDA clearance, Ambu will as planned make a milestone payment of 10 million Euro in Q2 2017/18. The FDA clearance will not impact our financial guidance for the fiscal year 2017/18, and the guidance provided in connection with closing of the Invendo transaction in October 2017 remains unchanged.

Single-use for patient safety and healthcare economy

Advanced reusable medical devices – like endoscopes – pose a contamination risk to patients as the devices are difficult to reprocess between uses. Single-use scopes, on the other hand, are sterile straight from the pack to the patient. This means that single-use scopes eliminate the risk of device-related infections and – because they do not require cleaning or repair – also improve hospital workflows.

Since 2015, US authorities have increased their focus on endoscope cross-contamination considerably. And especially reusable endoscopes for gastrointestinal use have been tied to this.

Contact and further information

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About Ambu
Since 1937, breakthrough ideas have driven our work to bring efficient healthcare solutions to life within our fields of excellence: Anaesthesia, Patient Monitoring & Diagnostics and Emergency Care. Millions of patients and healthcare professionals worldwide depend and rely on the functionality and performance of our products. We are dedicated to improving patient safety and advancing single-use devices. The manifestations of our efforts range from early inventions like the Ambu Bag™ and the legendary Blue Sensor™ electrodes to our latest landmark solutions such as the aScope™ – the world’s first flexible single-use videoscope. Our commitment to bringing new ideas and superior service to our customers has made Ambu one of the most recognised medtech companies in the world. Our head office is situated in Ballerup near Copenhagen. Ambu employs approximately 2,500 people in Europe, North America, Asia and the Pacific region. You can find more information about Ambu at www.ambu.com