Ambu Supports FDA's Recommendations on the Use of Single-use Bronchoscopes

COLUMBIA, MD – June 25, 2021 – The U.S. Food and Drug Administration has updated a safety communication on reprocessed flexible bronchoscopes. The FDA recommends that healthcare providers consider using single-use bronchoscopes where there is increased risk of spreading infection, or no support for immediate reprocessing available. Additionally, the FDA recommends healthcare facilities consider using sterilization for reprocessing instead of high-level disinfection. This latest update follows recent recommendations from the American Association for Bronchology and Interventional Pulmonology (AABIP) on treating COVID-19 patients.

The FDA communication also summarizes 867 medical device reports (MDRs) submitted to the agency from 2015-2021 related to infections or device contamination associated with reusable flexible bronchoscopes – an almost eight-fold increase from the 109 MDRs received by the FDA from 2010-2015. The FDA safety communication was first issued in 2015 and drew attention to reprocessing failures as well as continued use of devices with mechanical and maintenance issues.

The FDA and endoscope-associated infections

Reusable flexible endoscopes have been under increasing scrutiny from the FDA in recent years due to reported device-related infections – including from multidrug-resistant bacteria – and patient fatalities. In August 2019, the FDA specifically recommended duodenoscope manufacturers and healthcare facilities transition to duodenoscopes that are partially or completely single-use. These recommendations were born out of investigations into infection outbreaks traced back to contaminated duodenoscopes in 2015.

More recently, in April 2021, the FDA announced new investigations into more than 450 medical device reports describing patient infections and other possible contamination issues related to urological endoscopes and sent a letter cautioning healthcare providers of the risk of infections associated with reprocessing urological endoscopes.

Ambu supports FDA recommendation
Ambu believes the FDA recommendation will improve patient safety during bronchoscopy procedures and that single-use products can play an important role to support the new guidelines. Ambu believes that any patient that enters the OR or ICU should not be exposed to further risk of infection. The FDA recommendation for healthcare systems to move to sterilization of reusables also further increases the economic attractiveness of single-use bronchoscopy and will accelerate the transition to make single-use bronchoscopy the standard of care.

"Technologically advanced single-use endoscopy products provide healthcare systems and patients around the world with solutions that are convenient, affordable and without risk of contamination," said Juan Jose Gonzalez, CEO of Ambu A/S.

"We pioneered and are the leader in single-use bronchoscopy. We are bringing our fifth generation single-use bronchoscope to enter into the Broncho suite," said Bassel Rifai, Chief Marketing Officer of Ambu. "This is an example of our commitment to healthcare systems that would like to transition to single-use bronchoscopy."

In 2020, more than 1 million Ambu single-use endoscopes were used around the world, making Ambu the world's largest supplier of single-use endoscopes. Within bronchoscopy, 96 percent of the top 500 hospitals in the U.S. use Ambu's single-use bronchoscopes.

Contacts

U.S. media
NorthAmerica-PR@ambu.com
Ambu Inc., 6230 Old Dobbin Lane, Suite 250, Columbia, Maryland, 21045, United States, www.ambuusa.com

European and APAC media
Mikkel Trier Wagner, Director Corporate Communications, tel. +45 4191 0830, email: mtw@ambu.com
Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup, Denmark, tel. +45 7225 2000, CVR no.: 63 64 49 19, www.ambu.com

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 & diagnostics solutions. The manifestations of our efforts have ranged from early innovations like the Ambu® Bag™ resuscitator and the Ambu® BlueSensor™ electrodes to our newest landmark solutions like the Ambu® aScope™ – the world's first single-use flexible endoscope. Moreover, we continuously look to the future with a commitment to deliver innovative quality products that have a positive impact on the work of doctors, nurses and paramedics. 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.

###