

AMBU OBTAINS FDA CLEARANCE FOR NEW URETEROSCOPY ENDOSCOPY SOLUTION

The new clearance marks Ambu's rapidly growing presence in urology, advancing the company's urology portfolio in the U.S. market.

Today, Ambu announces 510(k) regulatory clearance from the U.S. Food & Drug Administration (FDA) for its ureteroscopy solution, consisting of the single-use ureteroscope, aScope™ 5 Uretero, and the full-HD endoscopy system, aBox™ 2.

The aScope™ 5 Uretero is designed to function as an all-purpose endoscope for urologists performing ureteroscopy procedures, both diagnostically and therapeutically. It is developed in collaboration with leading urologists for multifaceted use, versatility and reliability, requiring high-quality imaging, robustness and manoeuvrability.

From development and manufacturing to distribution and sale, Ambu oversees the entire product lifecycle for its full endoscopy portfolio. Back in November 2023, the company obtained CE mark of the new ureteroscopy solution in Europe. Following the FDA clearance, the company will proceed with a controlled market release in the U.S., where the solution will be evaluated in selected healthcare centres. Ambu expects to initiate a full-scale global launch by the end of the 2023/24 financial year.

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As an endourologist, I am excited to work with Ambu's growing single-use endoscopy portfolio. The quality and performance of Ambu's current aScope 4 Cysto has been an asset to my practice and the system I work in. I am confident that aScope 5 Uretero will provide similar value. The aScope 5 Uretero incorporates a variety of interesting features, including improved optics, small size and it being the first ureteroscope manufactured with bioplastics. I look forward to testing the clinical performance of aScope 5 Uretero in a variety of endourologic procedures.

DR. MICHAEL PALESE¹
Mount Sinai, New York, NY, USA

The ureteroscopy solution represents an advancement of Ambu's urology portfolio in the U.S. market. Building on the success of Ambu's cystoscopy solution, the aScope 4 Cysto, since 2020, the new ureteroscopy solution reflects a target market expansion of approximately 1 million annual procedures globally.

FUELLING THE TRANSITION TOWARDS SINGLE-USE

Ureteroscopy procedures primarily address kidney stones, strictures or cancer in the upper urinary tract, requiring a thin, flexible endoscope to pass through the urethra and bladder to the ureter. Single-use ureteroscopes remove the necessity for maintenance, due to breakage of the thin scope, and thereby present a strong potential for urologists and health systems to reduce downtime and enhance workflow efficiency.

Furthermore, Ambu's ureteroscope is the world's first ureteroscope made with bioplastics - materials derived from a mix of fossil-based and second-generation feedstock, e.g., recycled food waste. As previously communicated, Ambu plans to integrate bioplastics in the handles of its entire fleet of endoscopes by the end of 2024 - as the first and only endoscopic solutions provider in the world.

CEO Britt Meelby Jensen is excited about the U.S. clearance and the inherent prospects of fuelling the transition towards single-use with an expanded urology portfolio:

¹ Dr. Palese is a paid consultant of Ambu.



This clearance in the U.S. of our new ureteroscopy solution not only demonstrates a market expansion for Ambu; it is a testament to the progressive shift towards single-use solutions within the field of urology. I am confident that our continuous technology advancements will rapidly pave the way for better and more efficient patient care in the future - improving outcomes for patients, physicians and health systems alike.

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.