

AMBU EXPANDS CE MARK FOR EXISTING UROLOGY SOLUTION, ENABLES NEW TYPE OF PROCEDURE

With the CE mark expansion for Ambu® aScope™ 5 Cysto HD, urologists will now be able to use the medical technology as a single-use flexible cysto-nephroscopy solution, reflecting Ambu's commitment to addressing a growing range of urology needs for patients and healthcare professionals.

Today, Ambu announces expansion of the European regulatory clearance (CE mark) for its Ambu® aScope™ 5 Cysto HD solution. This additional clearance enables Ambu's existing HD technology to function as a single-use flexible cysto-nephroscopy solution, addressing a new niche procedure within urology.

In the operating room, cysto-nephroscopes are used to perform percutaneous nephrolithotomy (PCNL) procedures - a minimally invasive procedure designed to remove large and complex kidney stones. This technique involves creating a small passageway to the kidney through a small incision in the patient's back.

Globally, ~300,000 PCNL procedures are performed every year. In spite of the narrow market, the extended CE mark clearance is a reinforcement of Ambu's commitment to advancing urological care by meeting a wide range of procedural needs through an extensive and versatile urology portfolio.

Integrated with the company's digital endoscopy systems, Ambu® aView™ 2 Advance and Ambu® aBox™ 2, Ambu's cysto-nephroscope and newly launched ureteroscope are designed to complement one another. The endoscopy systems enable simultaneous connection, providing urologists with a dual view of the Ambu® aScope™ 5 Uretero and Ambu® aScope™ 5 Cysto HD during combined PCNL and ureteroscopy procedures.

Ambu will now engage in a controlled market release, kick-starting the initial evaluation phase to assess the solution's performance in PCNL procedures at key European hospitals.

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This expanded European clearance reflects our dedication to addressing a growing range of customer needs in urology. Although the market potential for procedures requiring cysto-nephroscopes is relatively modest, this expansion showcases our ongoing efforts to enhance our urology offering and provide the best possible care and solutions to urologists and their patients.

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ABOUT AMBU

Since 1937, Ambu has been rethinking solutions, together with healthcare professionals, to save lives and improve patient care. From development and manufacturing to distribution and sale, we oversee the entire product lifecycle for our healthcare solutions across the fields of single-use endoscopy, anaesthesia and patient monitoring. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our high-quality solutions.

Headquartered in Denmark, Ambu employs around 5,000 people in North America, Europe, Latin America and Asia Pacific.

For more information, please visit Ambu.com.