

AMBU OBTAINS FDA CLEARANCE FOR FIRST-EVER SINGLE-USE FLEXIBLE CYSTO-NEPHROSCOPY SOLUTION

The FDA clearance for the Ambu® aScope™ 5 Cysto HD marks a historic milestone as the first ever single-use cysto-nephroscope to receive such clearance in the US. It follows the CE mark in Europe earlier this year, representing an important step forward in endoscopic technology and reinforcing Ambu's commitment to innovation and advancement in urology care.

Today, Ambu announces that the US Food and Drug Administration (FDA) has granted expanded 510(k) clearance for the Ambu® aScope™ 5 Cysto HD, authorising the endoscope's use in percutaneous nephrolithotomy (PCNL) procedures. It is a procedure performed in the operating room, with the purpose of removing large or complex kidney stones by creating a small passageway through the patient's back to the kidney.

The expanded clearance marks the first time a single-use flexible cysto-nephroscope has been cleared for this specific indication in the US. With the latest indication, Ambu now provides urologists with a complete single-use endoscopy solution for kidney stone management, covering the full pathway from diagnosis to treatment.

The US urology portfolio subsequently includes three single-use endoscopes - aScope™ 4 Cysto (cystoscope), aScope™ 5 Cysto HD (cysto-nephroscope) and aScope™ 5 Uretero (ureteroscope) - all in full integration with Ambu's aView™ 2 Advance and aBox™ 2 endoscopy systems. All endoscopes and systems leverage the same digital technology platform, offering urologists a unified, advanced and high-performance solutions portfolio that enhances procedural efficiency - in line with Ambu's strategic focus.

Ambu's cysto-nephroscope is designed to work in combination with the company's ureteroscope, both of which are compatible with the Ambu's two endoscopy systems. This integration enables simultaneous connection and dual visualization of the aScope™ 5 Uretero and the aScope™ 5 Cysto HD during combined ureteroscopy and PCNL procedures, enhancing urologists' visualization and workflow efficiency in the operating room.



The FDA clearance of our cysto-nephroscopy solution underpins our commitment to expanding our innovation and leadership in urology. With three single-use endoscopes integrated into one digital platform, we offer a leading portfolio that enables clinicians to efficiently perform a broad range of urology procedures, advancing the standard of care for 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.