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Singapore approves AI software tool CystoSmart for bladder cancer detection

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Device is intended to be used with white light cystoscopy



Intelligent Scopes Corp (ISC), specialising in state-of-the-art image enhancement and precision AI software solutions for urology and gastroenterology, has announced that CystoSmart™ has received regulatory clearance from Health Sciences Authority (HSA), the National Regulatory Agency for medical products and devices in Singapore.

CystoSmart™, an AI software tool for bladder tumor detection in patients undergoing screening and surveillance endoscopic examination of the bladder is brand agnostic and compatible with flexible and rigid scopes, including single-use scopes. The device is intended to be used with white light cystoscopy to aid clinicians in improving detection accuracy of bladder tumors in real-time and post processing conditions.

The HSA clearance for CystoSmart™, which comes eleven months after it was approved by ANVISA, the Brazilian medical devices regulator, marks a significant milestone. Not only does it clear CystoSmart™ for use in Singapore, but, through the 'Access Consortium' collaboration, it paves the way for accelerated regulatory clearances in Australia, Canada, Switzerland and United Kingdom, countries that are part of the Access Consortium group.

Bladder cancer is the tenth most common cancer worldwide, and the sixth most common malignancy in men. With increasing incidence globally, bladder cancer has a high rate of progression and recurrence (up to 80%) requiring repeated follow up examinations. White light cystoscopy is the standard and most widely used method for bladder tumor detection and surveillance, however, as per published studies, between 10% and 20% of bladder tumors are regularly missed by standard white light cystoscopy.

As per clinical and technical evaluations conducted, CystoSmart has a sensitivity (true positive rate) of over 95% and a specificity (true negative rate) of over 98% in bladder tumor detection thereby aiding clinicians to improve accuracy.