

Laptop cystoscope*

Country of origin		India
Primary use		Treatment/resuscitation/palliative care/surgery
Category		Medical device (including in vitro diagnostics)

Commercial information _____

List price (USD): 1000

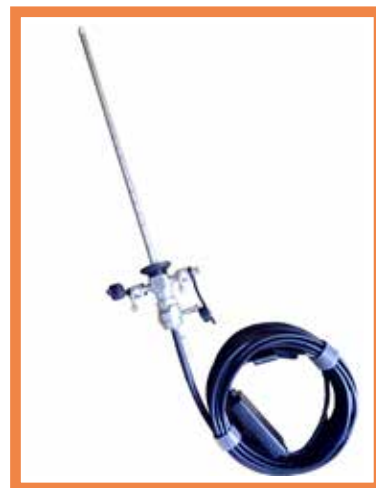
Expected year of commercialization: 2024

Number of existing prototypes in use/trials/tests: 15

Currently used in: India, Kenya, Nigeria and Uganda

Product description _____

The Laptop Cystoscope is a device that functions similarly to the conventional cystoscope used for diagnosis and minor procedures available at a small fraction of the cost of the conventional cystoscope and does not require common accessories such as a light source, camera or monitor which are required for the conventional cystoscope. It can be connected to a laptop computer or cell phone and derives power from the computer/cell phone.



Product details _____

Accessories: The complete set includes the commercially available outer sheath of the cystoscope and accessories like the graspers, bugbee electrode and the bottle for bladder wash.

Consumables: None for diagnosis. DJ stents and guide wires are needed for minor procedures like DJ stenting and bugbee electrode for vaporization of lesions

Warranty duration: One year

Lifetime: 5 to 10 years

Energy requirements: Minimal from a Laptop computer

Facility requirements: None other than privacy and for lithotomy position. Has been used for life-saving DJ stenting on both sides in remote areas with no power supply.

Contact: Gnanaraj Jesudian | **Phone:** +91 9442543377 and +91 8056310595 | **Web:** <https://bit.ly/3XPGt9Y>

* Information reported by manufacturer, October 2023

WHO assessment**

Clinical



Clinical



Recommended with caution

Lower urinary tract disorders require cystoscopy for adequate workup and management. Rigid cystoscopes allow physicians to perform biopsies, cauterize lesions, or perform ureteral stenting. Conventional rigid cystoscopes require large and sensitive equipment, making their deployment in low-resource, remote settings difficult.

This technology builds on the design of conventional cystoscopes by simplifying the device's optics and allowing connection to a laptop. The video feed can be transmitted remotely, allowing for remote training and proctoring. This can expand access to cystoscopy to patients in remote areas. However, some infrastructure is required to perform rigid cystoscopy, as it requires some degree of sedation and analgesia. Urethral damage, bladder rupture, and haemorrhage are known complications and may require surgery.









Despite extending access to this procedure, it must be performed in the correct setting.

Comparison with WHO technical specifications




















Cannot be verified.

The manufacturer provides technical information on the submission form. Additional supporting documents, such as the instruction manual, have been provided but they do not include the essential chapters, sections, and technical information that should be specified in a technical document of this nature. At the time of this report creation, WHO technical specifications were not available to compare this type of technology.

Regulatory

 Pre-market assessment	 Not available	Pre-market: This prototype product is a Class IIa medical device in the EU. The premarket documentation is not complete.
 Post-market assessment	 Not available	Post-market: The manufacturer did not submit the surveillance and vigilance documentation as well as risk management documentation (such as ISO 14971).
 Quality system assessment	 Not available	Quality management system (QMS): This manufacturing site is not certified to ISO13485:2016 quality management system. Based on the certification and standards, no documents were available to demonstrate the product is safe and effective.
 Security	 Not available	Security: The introduction of this technology leads to cybersecurity risk and no evidence of the management of this risk is provided by the manufacturer.

Health technology assessment

Indicators	Evidence assessment	Innovation	
 Medical		<p>The Laptop Cystoscope is similar or equal to a commercially available rigid or flexible laptop cystoscope. The innovativeness of this product consists of a mix of existing technologies and processes of telemedicine educative initiatives to train local non-specialist surgeons to perform urological interventions. This long-studied technology (first study published in April 2011) made it possible to respond to patients' conditions and urgent needs when the COVID-19 pandemic lockdown was imposed. Local providers to explant or implant a vesical stent which resulted in removal of more than half of the patients' urological stones. The health and social benefits are important for this prevalent condition. Surveys show that about 5% of outpatients in rural India have urological problems, and less than 2% of these patients have access to urologists. The authors claim that more than two-thirds of patients with lower urinary tract symptoms could be diagnosed and treated with just a cystoscope. These local interventions can spare waiting times patients' suffering and deterioration and prevent sequels with remote surgery supervision. This welcomed initiative can be one relevant example of improving the sustainability of the health-care system, contributing to achievement of the Sustainable Development Goals.</p>	
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Technology readiness level **6**

Technology evidence assessment **Recommend with caution**

Health technology management



 Durability	
 Ease of Use	
 Ease of maintenance	
 Environmental conditions	
 Affordability	
 Local access to technical support	
 Ease of cleaning	
 Infrastructure requirements	

Health-care delivery platform

The laptop cystoscope is a camera with an integrated light source in a cystoscope handle. It is made of surgical-grade stainless steel and is submersible, which ensures durability. The resolution is high definition. The light source is at the tip, which may pose a problem of durability, as since the tip can heat up. This may also compromise repair, as the device must be waterproof and special tools are required to repair and achieve this. It requires a user-supplied laptop, android phone, or tablet, which cannot be evaluated for durability but opens up for flexibility. The instructions for setup, cleaning, and disinfection should be more detailed. Sterilization can be done with common disinfectants such as glutaraldehyde. No preventive maintenance is required, and corrective maintenance can be performed by a trained general technician.

Intellectual property and local production

 Technology transferability	
 Open source/ access	
 Local production	

Intellectual property: The innovator claims that there are no licensing agreements related to the technology and that third-party-owned intellectual property rights are not necessary for the production and sale of the technology. However, no information is provided about the legal relation between the innovator (claimed to hold intellectual property rights for the production and sale), the inventor (claimed to own the intellectual property rights), and Karunya University (the applicant for the patent).

When the patent is granted and if not made open source, as claimed, the technology will be patent protected. To use this technology, authorization from the patent owner or the assignee will be required.

Local production: This is a potential product for local production, but first, the manufacturer must ensure that the local production plants are certified to comply with all the regulations. The low appropriateness evaluation is based on the consideration that the existing manufacturing process includes importation of the components and assembly at the manufacturing site. The documentation indicates that there are extremely specific items such as CCD cameras, LED lamps, image processing boards, stainless steel tubes for the insertion section, that are unlikely to be manufactured in LMIC. The device is used in conjunction with an outer sheath and bridge and, according to the company, those must be imported from other manufacturers. The company claims that its product is fully compatible with several brands of the above-mentioned items, without further information, thus providing flexibility for the production and use of the device, as, if some brand components become scarce, they can be substituted. This product is still in the prototype stage and should receive a few but very important updates regarding water tightness of the devices, their connectors, and cables. This should be done before the trials start; however, it should be ready soon for local production.