

Lutech Digital Colposcopy

May 2024

Device Overview

Optical colposcopes consist of an illuminated binocular style microscope, used to magnify and examine the cervix and other parts of the lower genital tract. With technological advances digital colposcopes have entered the market. Lutech LT-300 SD and LT-300 HD are digital video colposcope systems. These systems are less invasive for the patient and examiner, more portable than traditional colposcopes, and are a hands free (foot pedal) capable device. They may be used in a variety of settings including hospitals, out-patient clinics, and physician offices. [1] Digital colposcopes process images which allows for contrast enhancement of features, including white epithelium and abnormal vasculature.[2] Lutech’s digital colposcope features a progressive green filter that enhances visualization of blood vessels, along with an auto and manual focusing ability to achieve a magnified view of the vagina, cervix, and external genitalia. This aids in selection of biopsy sites and diagnosing abnormalities. [3]

Actions for Consideration



PARTNER

ENGAGE SUBJECT MATTER EXPERTS

Assess plans for device use including: gynecologists and emergency room physicians, nurses, value analysis leaders

CONSIDER GUIDELINES FOR USE

Develop ‘criteria for use’ guidelines for digital colposcope use in specific areas

UNDERSTAND CONCERNS

Discuss and address any issues with key departments: emergency department, gynecology



CONNECT

SEEK CLINICAL IMPACT

Identify opportunities through product use to support improved quality of care, evaluate patient outcomes

CONDUCT ANALYSIS

Compare cost and capabilities of devices to understand potential savings and patient satisfaction

DETERMINE POPULATION

Work with key stakeholders to determine appropriate patient population



COMMUNICATE

EDUCATE AND TRAIN

Provide information on available training & encourage hands on demonstrations to gain familiarity with the product

PLAN AHEAD

Create and share plan to continue ongoing education about product, use, & outcomes

FOLLOW-UP FOR FEEDBACK

Create on-going feedback loop for challenges, ideas, recognition of wins, & further opportunities for success

Professional Society Statements & Clinical Practice Guidelines



The American Society for Colposcopy and Cervical Pathology Colposcopy Standards

Recommendation: “Colposcopy practice may be modified based on the risk level.

Recommendation: Multiple biopsies targeting all areas with acetowhitening, metaplasia, or higher abnormalities are recommended.

Recommendation: In nonpregnant women 25 years and older with very high risk of precancer (at least 2 of the following: high-grade squamous intraepithelial lesion cytology, HPV16 and/or HPV 18 positive, high-grade colposcopy impression) either immediate excisional treatment without biopsy confirmation, or colposcopy with multiple targeted biopsies is acceptable.” [4]



Physician Insights: HealthTrust Physicians Advisor Network

Members of the HealthTrust Physician Advisor Network in the specialty of Gynecology provided insights & experiences using these products. [5]

Physician Insights



Advantages:

- Ease of use, hands free capability
- Ease of downloading images, archivable images
- Great teaching tool for trainees
- Allows for better integration with EMR software and data sharing
- Document pelvic exams for the purposes of sexual assault cases

Disadvantages:

- Cost
- Quality of images (depending on version used)
- Camera durability concern
- Concerns regarding mounting system potential to loosen up
- Learning curve from current practices

Clinical Insights: HealthTrust Huddle Feedback

Members of the HealthTrust Huddle network provided insights & experiences using these products. [6]

HealthTrust Huddle Insights



Advantages:

- Ability to hands free image capture
- Less invasive
- Clear, precise digital photos
- Potential for exam time reduction
- Ease of use, ergonomic
- Potential for accuracy in diagnosis and treatment
- Interfaces with electronic medical records

Disadvantages:

- Cost

Locations for use:

- Hospital /Out-patient clinic / Physician offices

FDA Approval

The Lutech Digital Colposcopy carries an FDA indication to be utilized for the “magnified viewing of the vagina, cervix, and external genitalia in order to aid in diagnosing abnormalities and select areas for biopsy. The image can be viewed on a color screen or computer monitor and printed on a color printer. The device is intended to be used in hospitals and clinics.” (FDA Database Listing; [FDA 510\(k\) No. K170446](#)). [7]

Summary



HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis and product trials. [8,9]

ASK A QUESTION

PROVIDE YOUR FEEDBACK

SHARE YOUR VOICE

NETWORK WITH PEERS



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