

Cryosurgery device for cervical cancer treatment and prevention

Country of origin | United States of America

Primary function | Treatment

Health problem addressed

Cervical cancer is the third most commonly diagnosed cancer in women worldwide, and yearly 90% of new cases are diagnosed in low- and middle-income countries (LMICs). This disease causes more than 250 000 deaths per year. Currently, gas-based therapy is by far the most common cryotherapy method. Many barriers exist for gas-based cryotherapy in LMICs, such as difficulty in procurement, cost, transportation, safety. This device does not use cryogenic gases, thus overcoming these obstacles.

Disease addressed

Neoplasms; diseases of the genitourinary system.

Technical descriptions

The device is designed to ablate tissue through the application of extreme cold temperature. It achieves very cold temperatures by the use of compression cooling technology, eliminating the need for gas. Medical personnel remove a cryogenic hand-piece from the system, attach a re-usable aluminum tip and perform the procedure. The system can be run on standard grid electricity or batteries.

Developer's claims of products benefits

Loop electrosurgical excision procedure (LEEP) is a popular technique for cervical cancer ablation in developed countries, but it is complex, very invasive, has many side effects and requires highly skilled personnel. Gas-based cryotherapy is another technique commonly used, but it is not designed for portability (due to weight and size), challenging to procure, costly and sometimes unreliable. The present cryogenic device requires no gas, is portable, rugged, reliable, affordable and consistently effective. It can also be operated on battery power.

Operating steps

Test the readiness of the unit with the temperature indicator. Place the aluminum tip on the tip holder. Insert the tip holder assembly into the vagina, placing the tip on the cervix. Remove the cold core handle from the unit. Fully insert the cold core handle into the tip holder assembly already in place on the cervix. The procedure lasts for 3-5 minutes (operators protocol preference). Remove the cold core handle, wait for the tip to thaw, then remove the tip holder assembly.

Regulatory status and standards compliance

United States of America (FDA).

Use and maintenance

User: Midwife, technician, nurse, general physician, specialised physician.

Training: A short in-service training is required, either by video conference or face-to-face, for approximately 30 minutes.

Maintenance/Calibration required: Yes

Environment of use

Setting: Rural settings, urban settings, indoors, primary level (health post, health centre), secondary level (general hospital), tertiary level (specialists hospital), Tertiary level (Specialists hospital).

Facility requirements: Sterilization.

Energy requirements: Replaceable batteries, continuous power supply.

Product specifications

Weight (kg): 13

Dimensions: 27mm x 25mm x 67mm

Accessories: Optional battery power convertor

Consumables: An ethanol-based solution, less than one liter per year

General product: Timer

Lifetime: 2-5 years

In UN catalog: No

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Commercial information

Reference price (USD): \$4'250.00

Year of commercialization: 2016

Number of units distributed: 0-100

Other features: Portable, reusable (assuming appropriate decontamination and/or other reprocessing between uses)

