COLD COAGULATOR

Device for Cervical Cancer Prevention

WiSAP®



CLINICAL BACKGROUND

In high-resource settings, we are fighting cervical cancer quite successfully. In these settings, secondary prevention with cervical cytology linked with timely treatment of pre-cancer has led to considerable declines in mortality. However, cervical cancer is still a major killer of women worldwide, with nearly 90% of new cases diagnosed in low- and middle-income countries (LMICs).

Unlike many other cancers, there are primary prevention strategies for cervical cancer that can lead to decreased incidence. Finding out that the human papillomavirus (HPV) is the cause of cervical cancer has led to revolutionary prevention strategies such as prophylactic HPV vaccination, which are effective against seven high-risk HPV types responsible for causing approximately 90% of cervical cancers worldwide. Unfortunately, prophylactic HPV vaccines do not treat pre-existing HPV infections and related conditions.

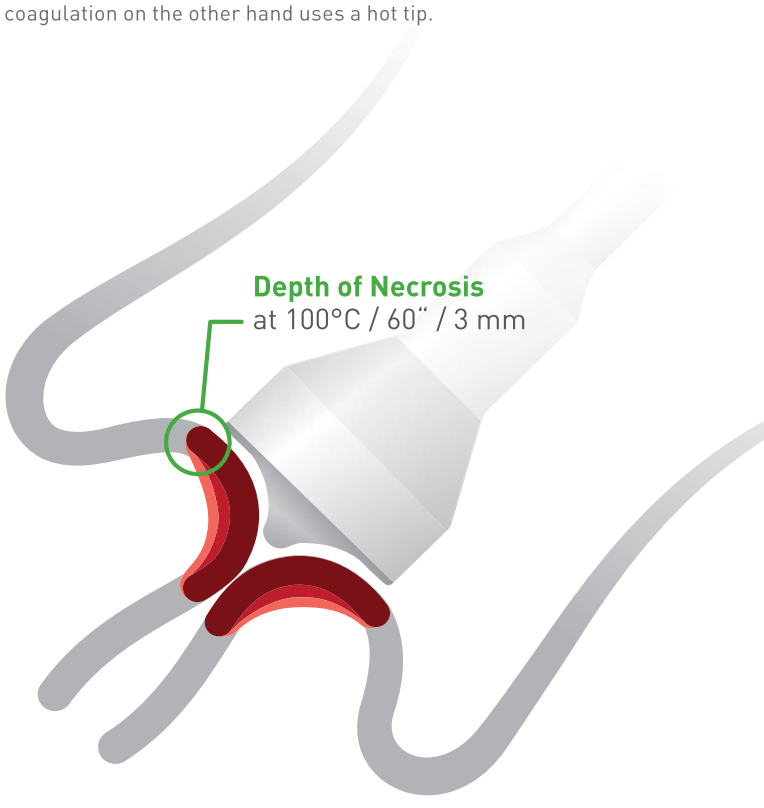
Thus, even if HPV vaccines were immediately distributed worldwide, two to three generations of currently HPV-positive women would not benefit from them. Furthermore, since only a small percentage of women are presently vaccinated, mortality will hardly decrease in the next couple of years. Secondary prevention strategies for the detection and treatment of pre-cancerous lesions are needed for the foreseeable future.

Pre-cancer is defined as cervical intraepithelial neoplasia grade 2 [CIN2], grade 3 [CIN3] and adenocarcinoma in situ [AIS], together "CIN2+". Regardless of screening strategy, access to effective treatment for women with cervical pre-cancer is crucial. In some countries, up to 80% of women diagnosed with cervical pre-cancer do not receive the recommended treatment.

Therefore it is crucial to implement a clinically tested and highly efficacious treatment method, which is easy to handle and cheap to run.

WHAT IS THE DIFFERENCE BETWEEN COLD COAGULATION AND CRYOTHERAPY?

Both systems use temperature to destroy tissue and so both are considered to be ablative treatment methods. Cryotherapy uses a cool tip (below -50 °C) to destroy abnormal tissue. Cold coagulation on the other hand uses a hot tip.











CERVICAL CANCER PREVENTION

in low- and middle-income countries

WiSAP®

HOW DOES COLD COAGULATION WORK?

The treatment method of a thermo tip can be compared to the properties of a pan, used for cooking. The thermo tip is electrically heated to up to 100 °C. The tissued is destroyed by heat. The device controls the temperature to remain at the pre-set temperature for the duration of the treatment.

The probe has an anti-stick surface to make sure that no tissue will be stuck when retracting the probe from the cervix at the end of the treatment.

Cold coagulation cannot be compared to HF coagulation though. HF coagulation uses temperatures of up to 320°C. It is run by electricity and the current flows through the tissue. The superficial epithelium blisters off after treatment, and the underlying stroma and glandular crypts are destroyed by desiccation.

WHICH ADVANTAGES DOES COLD COAGULATION HAVE OVER CRYOTHERAPY?

NO GAS REQUIRED
Depending on local prices for CO2 or N20 gas, the saving in running costs using a cold coagulator versus a cryo-therapy device can be between 50% to 90%

FAST PROCEDURE

VERY LOW RUNNING COSTS

EASY TO USE

ANTI-STICK-SURFACE
No adhering tissue

HOW EFFICACIOUS IS COLD COAGULATION?

In a study, 1,628 women with CIN 3 were treated by the cold coagulator. The tip was heated up to 100°C and applicated for 20 s. The cure rate was 95%. In the same study, 97% of 485 women with CIN 1 and 96.5% of 680 women with CIN 2 were treated successfully. In a different study, 725 women with CIN 1, 2 or 3 were treated. The probe was heated up to 120°C and applicated for 30-40 s. After the treatment, 87.2 % of those women had a normal cystology and a long-term negative follow-up.

HOW EASY IS IT TO TREAT COLD COAGULATION-ELIGIBLE LESIONS?

Published data shows that cold coagulation treats cervical lesions as well or better than cryotherapy. No local anaesthesia is required, the system is easy to use and so treatment can be performed by a wide range of healthcare providers. Women can be treated right after a VIA, so only one visit is necessary ("see and treat").

1 Check criteria

Make sure that the lesion is eligible for cold coagulation.

2 Prepare for procedure

Turn on the device. Set temperature to 100°C. Make sure to use sterile equipment. Wait for about 45 s until the probe has reached the set temperature.

3 Treat the cervical lesion

Apply the probe to the lesion with minimal pressure and remain in that position for 60 s. If the probe cannot cover the entire lesion, apply the probe to the remaining aceto-white areas for additional 60 s, while making sure both applications overlap each other (over 90% of cervical lesions require only one or two applications).

4 Finish the exam

Remove the hot probe and finish the exam. Hand the client a sanitary pad or cotton wool to handle possible discharge and thank the client.









COLD COAGULATOR

Device for Cervical Cancer Prevention

WiSAP®

Customer Feedback

Dr. Miriam Cremer MD/MPH,
PRESIDENT & FOUNDER OF BHI

"I believe that because of the devices simplicity the Cold Coagulator has the potential to be a global game-changer in the field of cervical cancer prevention." www.basichealth.org

Dr. Sue Makin,
DAEYANG LUKE HOSPITAL
LILONGWE, MALAWI

"At our mission hospital we have been using the WISAP cold coagulator for about a year and a half. We are very pleased with the performance, reliability and ease of use of this instrument. I can easily carry it with me to other hospitals where I offer gynecologic consultations. This wonderful instrument has revolutionized and revitalized our fight against cancer of the cervix in Malawi."

Dr. Quek Swee Chong,
GLENEAGLES HOSPITAL,
SINGAPORE

"I performed treatment in the Himalayas using a combination of LEEP and thermal coagulation, using the WISAP Cervix Coagulator. The coagulator worked perfectly and was used extensively over five days with over ten procedures performed per day."

Beatrice Kabota,
NKHOMA HOSPITAL
LILONGWE, MALAWI

"We have used the WISAP thermal coagulator for nearly three years, both at the hospital and in rural health centres. Our providers have found it to be user friendly, reliable, quick and versatile in the treatment of early cervical lesions. Overall our experience has been excellent. We don't use any anesthesia in all our patients. For the past six months, 22% of those who got treated reported no pain during cold coagulation, while 75.6% reported slight pain and 2.4% of feeling hot during procedure and none reported for severe pain."



TECHNICAL DATA

Mains connection:	Standard: 230V - 50 /60 Hz. Please indicate other requested voltages when ordering.
Power input:	66 VA
Range of temperature:	60-120°C
Regulation of temperature:	stepless
Dimensions:	w x h x d = 270 x 120 x 190 mm
Casing:	Stainless steel, aluminium / white coated
Weight:	3,6 kg

ORDER DATA CERVIX COAGULATOR

6001	Cervix Coagulator incl. country-specific power cord. Please specify voltage when ordering.

ORDER DATA INSTRUMENT CABLE

6020	Instrument cable, orange, with two coupling plugs, silicone, L = 1,5 m









COLD COAGULATOR

Device for Cervical Cancer Prevention

WiSAP®

Therapy Probes



CIN 1-3 treatment, 100°C / 45-60 s, overlapping burn



CIN 1-3 treatment, 100°C / 45-60 s, overlapping burn



Haemostasis after LEEP / LLETZ, 120 °C / 30 s



CIN 1-3 treatment, 100°C / 45-60 s, overlapping burn

AUTOCLAVE
3 bar / 134° / 5min

Cold Coagulation

Ablation of cervical lesions by „boiling“ of tissue

- Fast Procedure (20 – 60 seconds)
- Low temperature treatment (60-120°C)
- No local anesthesia required
- No tissue scarring
- Low pain scores
- Low bleeding events
- Low watery discharge

Contact and order

If you need any additional information, we are happy to help you. Please get in touch with our customer service:

Phone: 0049 8104 89 08 0
Fax: 0049 8104 89 08 90
eMail: info@wisap.com
Web: www.wisap.com



