A disruptive innovation that will revolutionize the field of women’s health
Traditional and video colposcope
When and why to perform a colposcopy?

- To assess abnormal smear and and/or positive HPV test
- To exclude invasive cancer in a suspicious cervix
- To assess abnormal symptoms
Diagnosis of cervical pre-cancers

Image of cervical pre-cancer and cancer in different stages
Major weaknesses with today’s screening process

- Cervical cytology can fail to detect abnormal cervical lesions
- The HPV test is becoming the gold standard screening test, however many women will spontaneously heal their HPV infection
- Stationary colposcopes are expensive, heavy, cumbersome to use, stationary, and require an electrical grid
So we developed: The Gynocular
The Gynocular

- Gynocular first clinically used in 2012
- First Gynocular unit sold in October 2013 in Sweden
- FDA approved in 2014
- Number of Gynoculars in use 395, including 26 new in November
The Gynocular – Value Propositions

- **Convenience**
  - Gynocular can be shared within departments and examining rooms, making a physician’s job more convenient

- **Clinical accuracy**
  - Gynocular has a proven clinical accuracy equal to the conventional stationary colposcopes

- **Cost Value Props**
  - Gynocular is more affordable than stationary colposcopes
  - Strong reimbursement in most countries including US, can use existing CPT codes
  - Shorter examination time due to easy-to-use equipment: enables more patients per day
Designed for Today’s Physicians

- Intuitive design
- Long battery time with standard mobile battery
- Light weight
- Easy to disinfect
- Developed in close cooperation with clinicians
Gynocular - Technical features

- Color rendering: 96-100 CRI
- Effective light intensity: 95 CRI
- DOF
Technical Hardware

Hardware

► Light (CRI 95, intensity 12,000 Lux, effective 24,000)
► Programable firmware (service notification & reset, Activity log)
► Expected life 5y: Mechanics + LEDs
► Drop tests (~100cm in the new version, 60cm before)
► Nokia battery one day of examination (1080mAh, )
► Designed for Fool-proof assembly
► 2.0 generation (Optics, electronics, illumination, mechanics)
Certifications

- ISO 9001:2016 certified
- ISO 13485:2016 certified
  - Radiated RF Emissions
  - Radiated RF Immunity
  - ESD immunity (Electrostatic discharge)
- FDA approvals
  - Gynocular - class 1 medical device, as colposcope.
  - T2D Software - a Medical Device Data System (MDDS), under 21 CFR 880.6310.
- Software developer ITON/ICREA certifications
  - CCHIT (The Certification Commission for Healthcare Information Technology)
  - CMMI® Maturity Level 3 rating for the Software development (Capability Maturity Model Integration)
- Additional Approvals
  - CE Marked (EU)
  - Australia, Canada, China, India, New Zealand, Russia (pending), Thailand, various countries in Africa
Made in Sweden

- Gynius maintains a Quality Systems program and follows Medical Device Reporting regulations, the design, packaging, labeling, and manufacturing.
- Swedish quality
- The assembly, QC, and packaging are done by Gynius, in Stockholm
Securing Patient Data

- Gynocular T2D is implemented with a high security process from the registration to every transaction of API calls between the mobile application and Cloud API. This involves a two stage process:
  1. Identity Security in CLOUD API
  2. Encrypting and Decrypting Data using AES 256 bit Algorithm
- Https protocol is used for secure communication
Examiner has explained to the patient of colposcopy examination procedure and treatment cervical lesions.

2. Examiner has explained to the patient of collection of samples for laboratory or histopathology or images of examination findings for analysis and documentation.

3. I have also been informed that I can refuse the whole or part of the examination at any stage. In this event I have been informed about the possible medical/legal implications or consequences of refusal of evidence and documentation. I have further been informed that this refusal will not have any impact on the quality of treatment provided. All this has been explained to me in a manner and language that I can understand.

4. Picture(s) of marks on the body for identification.
Building a unique global database

- Built as a research database/protocol – Big data
- Already 13,300 patients entered
- HPV incidence
- HPV in vaccinated/unvaccinated populations
- Results pap smear/LBC
- Biopsy results
- Swede score to support diagnosis and choice of treatment
- Referral network
- Evaluate performance of user
- Artificial intelligence image recognition?
- Possibility to expand database-
- Barcode HPV test-scanner-test result
Log in to the web application
2015-2016: 13,300 patients entered into T2D

Logbook for colposcopists under training

Quality control /review of users/feedback to organizations

Unique GLOBAL research data base on pap smears, HPV strands in different populations....

Global network of T2D users, sharing clinical problems

Master trainers in different countries, referral doctors

E-learning of triage
Clinically validated in several studies

- The quality of the examination was equally good when performed by use of the Gynocular™ or a stationary colposcope in detecting high grade cervical lesions.
- No significant differences when a colposcopy examination is performed by a nurse trained in colposcopy trained or doctor.
- Gold-standard colposcopy can be performed under essentially any conditions.
- Cervix examinations with the Gynocular reduced overtreatment with 70%.

“Gynocular has a great promise as a triaging tool for screen positive women in determining suitability for biopsy or immediate treatment and also decide on the nature of treatment “
Ongoing research

Gynius Academic Research program

- Multiple site study Latin America and Africa
- Bern University: first PhD student
- Karolinska Institute; Health informatics masters on T2D
- EU network RESISTE application for Horizon 2020. EWS PI Swedish study arm- Cervical cancer screening in European women of low socio-economic status.
- Ghana: colposcopy training
The Complete Package

- Completes screening evaluation of positives of cervical cytology/HPV test
- Turnkey integration of hardware and software for large health groups and small clinics
- Strong reimbursement in most countries including US, can use existing CPT codes
- T2D software enables quality control and follow up of users/clinic data
- T2D enables networking and telemedicine in rural areas, saves time for the patient and the healthcare provider
eTestify

- Documentation of sexual violence through secure app and webapplication
- Store up to 40 images
- Protocol to follow as to support health workers for correct documentation
- Includes section on forensic colposcopy
- In use in the US market since 2016
In summary

- Good for patients
- Good for physicians
- Good for clinics