Hydraulic Dilation System

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OVERVIEW

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Cervical canal dilation - problem and its traditional solution

The classical and most widely used procedure of cervical canal dilation is mechanical dilation using the metal dilators by Hegar, shaped to fit the anatomy of the cervical canal. They have a tapered and slightly bent tip. They are inserted into the canal and taken out one by one, successively, the next dilator having a larger diameter than the previous one thus widening the cervical canal gradually. The other much rarely used method is using laminaria sticks.

- Each dilation performed in such a way, and particularly careless and abrupt one, causes damage to the muscular and collagenous fibers of the cervix, which often precedes its functional incompetence, the most often complication of this intervention later. The direct complication of the procedure (laceration of the cervix complicated by lesion of descendent branch of uterine artery; perforation of uterus) can be life-threatening for patient.

- The risk associated with this, most widely used procedure in gynecology (over 200 000 000 dilations are performed annually worldwide) made us to try to offer a different solution. As a result of ten-years work we successfully developed a different dilation concept, tested also in the clinical practice.
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Since 1789, till today, the most common method for cervical canal dilation is by using metal dilators. This method can cause multiply problems. Frontal resistance and friction during intervention cause tissue damage, and can lead to tissue laceration or uterus perforation.

This is why a great number of gynecologist avoid, or is reluctant to perform this intervention.
Gynedil® - new solution for dilation

Gynedil® is a hand-operated, pistol shaped pump, made entirely of medical plastic, filled with distilled water, already sterilized, and intended to be used under the same conditions valid for surgical instruments.

Gynedil® is disposable (single-use) product.

- This pump easily achieves the pressure needed for widening of a balloon, which is the most important element of this system. The pump injects pressurized fluid into the balloon, which causes widening of the elastic membrane of the balloon dilator to the size allowed by the fabric thus widening the cervical canal to the required radius.

- The final dimension of dilation is defined by the geometry of the high resistance polyethylene fabric, 7 times stronger than steel fabric of the same thickness.
Gynedil® – design of the instrument
Gynedil operating mode

A flexible dilation tip is inserted into the cervical canal following the cervix anatomy (curve)

By pressing the trigger dilation balloon inflates laterally without friction, causing no damage or bleeding

After 20 seconds, dilation is complete. By pressing the upper button on the handle the liquid returns to the handle.

Removing dilation tip from cervical canal. Instrument can be reused once again on the same patient, if needed.
Advantages of the new method

1. Advantages for gynecologists

2. Advantages for patients

3. Advantages for funds and hospital
Advantages of the new method

1. Advantages for gynecologists

Doctor can control the speed and rhythm of dilation until achieving a final diameter. There are two types of Gynedil: for dilation till 8 and till 10.5 mm.

There is no risk of direct complications, damage or perforation of cervical canal or uterus is excluded.

- Gynedil® is intended for single use, so the there is no risk of intrauterine infection.
- Provides total comfort to the doctor, for there is no risk of injury, and shortens the time needed for dilation.
- Gives the opportunity for all gynecologists to perform dilation without risk, even gynecologists with no previous experience.
- Dilation using mechanical dilators takes approximately 5 minutes. Dilation by Gynedil® takes between 20 - 30 seconds, without requiring that a gynecologist has previous experience.
Advantages of the new method

2. Advantages for patients
   Usage of Gynedil® excludes the possibility of serious injury. After the intervention patient has no pain, no bleeding, or tissue damage of cervix caused by dilation. No consequences for future pregnancies.
   95% of women want to be informed of all risks of a medical procedure; 69% want to be informed of all alternatives (data for EU and USA patients, Journal of Medical Ethics, July 2006).

3. Advantages for funds and medical institutions
   • Reduces possible insurance costs, as the risk of injury (laceration, perforation) is eliminated.
   • Reduces the total duration of the intervention, and thus shortens the time of occupation of surgery room (approx. for 1/4), providing approximately one more intervention in an hour.
   • For gynecological practice, this means multiplied income because it is possible to do more interventions in shorter period of time.
   • For dilation alone anesthesia is no longer required, so it reduces the cost of anesthesiologist, and costs of patient stay in the hospital.
CLINICAL TRIAL at the Clinical Hospital Center of Podgorica, Montenegro, 2009

Gynedil® was tested at the Clinical Hospital Center of Podgorica from September 2009 to January 2010.

Complete clinical trial report you can download from:


Next two pages show the microscopic findings.

More information on clinical works you can find at:

http://www.hh.um.es/Forthcoming_original_articles.htm

Additionall information on Gynedil you can find at:

http://www.gynedil.com
Histological finding of cervix after dilation by Gynedil®:

Covering and glandular epithelium is preserved
Basal membrane is continuous
There is no bleeding in the sample
Histological finding of cervix after dilation by Hegar:
Covering and glandular epithelium is damaged
Basal membrane is disrupted
Intraepithelial and stromal bleeding occurs
Thank you for your time