GYNEDIL
Hydraulic Dilation System

INOVE doo, 11A, Miljakovacke staze street, Belgrade, Republic of Serbia
Tel/fax: + 381 11 7589 387
E-mail: office@inove.rs
Website: www.gynedil.com
OVERVIEW

- About us – Audiotel / Inove
- Cervical canal dilation - problem and its traditional solution
- Gynedil - new solution for dilation
  - about product
  - advantages of the new method
  - clinical trial
  - about patent and TM protection
- Estimated market potential
- Production
About us – Audiotel / Inove

1999.
- The first prototype of the device was the result of joint efforts of experts from the Faculty of Medicine and Faculty of Engineering in Kragujevac, Serbia.

- The inventors signed the License contract with the company Audiotel, Belgrade.

2002-2006.
- Audiotel develops device made of steel with changeable dilation tip. Presents the device in the form of prototype at various international congresses and fairs to the well-known manufacturers and distributors of medical equipment.

- Audiotel initiates the development of a new device, made entirely of plastic and intended for single use. The device is patent protected worldwide.

2011.
- Audiotel transfers IP rights to Inove. Start of industrial production in 2012.
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, of which over 1 000 000 patients die annually due to aftermaths of dilation) 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.
Set of Hegar dilators
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 radius of 12 mm.

- The final dimension of dilation is defined by the geometry of the high resistance polyethylene fabric, otherwise used for production of bulletproof jackets, and is 7 times stronger than steel fabric of the same thickness.
Gynedil® – design of the instrument
Advantages of the new method

1. Advantages for gynecologists
2. Advantages for patients
3. Advantages for distributors
4. Advantages for funds and hospitals
Advantages of the new method

I. Advantages for gynecologists

- Doctor can control the speed and rhythm of dilation and adjust them according to the resistance given by the cervical canal, and also adjust the diameter of cervix opening (from 3.5 to 7-8 or 12 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 there is no risk of intrauterine infection.
- The instrument is small-sized, light, mobile, easy to handle, ergonomic and already sterilized.
- 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 Hegar dilators takes from 5 to 10 minutes, depending on the experience of gynecologists. Dilation by Gynedil® takes maximally 20 seconds, without requiring that a gynecologist has previous experience.
- Reduces the total duration of the intervention, and thus shortens the time of occupation of surgery room.
- 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 intervention.
Advantages of the new method

2. Advantages for patients
   - Usage of Gynedil® excludes the possibility of serious injury or death.
   - After the intervention patient has no pain, no bleeding, or tissue damage of cervix.
   - These interventions avoid any damage to the uterus.
   - 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 distributors
   - Distributors will have a privileged status for they will sell the device that has no competition on the market, which practically gives them a chance to built a supremacy on the market. This device has no modern alternative and this helps distributors in many ways. This allows distributors to form a margin without affecting the competition.
   - Promotion of this device is focused on a very narrow circle of professionals.
   - The device is pre-sterilized, disposable, and there are no service or maintenance costs or procedures.
   - Priority right to buy the next-generation of dilators - currently under development and will soon be on the market; specific types of dilators for continuous dilatation for the esophagus, trachea, anus, etc.
Advantages of the new method

4. Advantages for funds and medical institutions

- 1% of the interventions carried out by the old method (Hegar) ends with the perforation of the uterus or severe damaging of cervical canal, which leads to additional surgery, the patient's prolonged stay in hospital, and often leads to death, all of which increase costs and responsibility.

- Damage of the cervical canal during the dilation leads to complications in the late months of pregnancy (after 6 months). Weakened and damaged cervical canal leads to premature opening of the cervix under the weight of the fetus, forcing pregnant women to spend the last 3 months of pregnancy in bed, which basically means three months of sick leave at the expense of the health fund.
Clinical trial

- **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.
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
Patent and trademark protection

- Pending patent applications
  
  **National:** RS20080130 (filing date 31.03.2008.)
  
  **PCT:** WO2009RS00013 20090331
  
  (priority number RSP20080130 20080331)
  
  Publication no. WO 2009123490
  
  **European:** EP 2 282 665
  
  **Eurasian:** EA201001584
  
  **China:** CN102083355
  
  **USA:** US2011106130
  
  **India:** 3704/KOLNP/2010
  
- **Gynedil®** is nationally registered TM from 2006.
Estimated market potential

- We have started with the only reliable data we could find, abortion statistics taken from [http://www.johnstonsarchive.net/policy/abortion/index.html](http://www.johnstonsarchive.net/policy/abortion/index.html). Of course, we are dealing with number of registered abortions only, while in many countries great number of interventions are not registered.

- From consultations with doctors and medical professionals we came to the conclusion that apart abortions there is almost the same number of other interventions on uterus, requiring cervical canal dilation, so we came to the following formula:

- **Average number of interventions for certain market, per year, is number of abortions x2.**

- Number of registered abortions in several counties:
  - China 7.000.000
  - Russia 1.600.000
  - France 230.000
  - Germany 120.000

- Taking in account great number of unregistered procedures worldwide, we came to the conclusion that shown in % on total population, the number of interventions could go from 0,5%-1% of total population for developed countries, and 2% and more for emerging markets and undeveloped countries.

- This brings us to the number of more than 200.000.000 of interventions pre year, worldwide.

- Of course, many more factors have influence on number of interventions: cultural and educational level of population, customs, life standard.
Production

- Spektar d.o.o. Serbia, Čačak, 144 Dragiše Mišovića street, is the biggest regional company specialized for production of medical plastic devices and equipment, with 20 years of experience in this field of production.

- Spektar d.o.o. produces Gynedil®, under licence agreement, *exclusively for Inove*.

- Producer has the following quality standards:
  - ISO 9001
  - ISO 13485
  - CE mark for GYNEDIL

- More about Spektar you can find on [http://www.spektardoo.co.rs](http://www.spektardoo.co.rs)
**Additional materials**

As an element of this presentation there is also:

- an animated presentation of Gynedil® showing dilation of cervical canal by old and new method.
- short movie showing dilation in operation room, performed by Dr Arsenijevic, with x-ray footage of dilation.
- You can find these items on our website: gynedil.com
THANK YOU FOR YOUR ATTENTION