Laser for genital treatment

DOSSIER
1. LASER INNOVATION FOR WOMEN’S WELLBEING AND QUALITY OF LIFE
Vaginal atrophy
(VAGINAL TIGHTENING MODE)

Vaginal atrophy is an involution of the mucosal tissue of the vulva and vagina (VVA), which is caused by the decrease in estrogen during the menopause and in some cases also occurs in younger women.

Typical changes are the progressive loss of elasticity, thinning of the vaginal walls or the appearance of petechiae, among others. The secretions from the sebaceous glands are reduced and lubrication decreases greatly or is absent.

These changes are associated with dryness, calor, burning, pain, irritation, dysuria and dyspareunia. The weakness of the tissue can lead to trauma, bleeding and infections.
There are different treatment options, which include:

- **Lubricants**, which are generally used during sexual intercourse to alleviate vaginal dryness, the use of moisturizers, estrogens, etc. among others.

- **Hormone replacement therapy (HRT) and local estrogen treatments** are most commonly used in the treatment of vulvovaginal atrophy (VVA). Local estrogen applications at low doses are a safe and effective therapy and in principle are recommended in vaginal atrophy and to alleviate its symptoms. HRT in women with breast cancer or a history thereof or estrogen-dependent problems require an individualized therapy and/or they may be a criterion for exclusion.

- **Fractional CO₂ laser** has proved effective in the induction and production of collagenic and elastic skin fibers and in tissue remodeling in different parts of the body such as the face, neck or chest without side effects. Today it is also used in the treatment of atrophic vaginitis.

### Gynelase™: How it works

The minimally invasive treatment with Gynelase™ fractional CO₂ laser achieves vaginal tissue contraction or tightening through the thermal effect of the interaction of laser light with the tissue.

Gynelase™ provides precise control of laser pulse energy into the vaginal canal thus causing tissue heating and the contraction of its collagen fibers.

This thermal effect causes the collagen fibers to be shortened and to reorganize and, therefore for the tissue to retract. Subsequently, a remodeling or the generation of new neocolagenesis collagen occurs.

In gynecologic mode the Gynelase™ fractional CO₂ laser by INTERmedic (Barcelona-Spain) emits an especially designed pulse.

- First, a pulse with a high peak power and short duration, which causes vaporization of the superficial mucosa.

- It is then followed by a pulse of significantly lower power and much longer duration for an in-depth thermal effect.

### Procedure

**Treatment for vaginal atrophy** consists in treating the length of the vaginal canal by irradiation with the laser, while during the second phase both introitus and vestibule are irradiated. For this purpose, a device designed specially for the vaginal canal is used. This speculum-like accessory, inside which the laser beam travels, facilitates the introduction of laser light into the vaginal canal.
Laser light travels through the center of the speculum and on impacting on the mirror is thrown onto the mucosa. A mechanism that allows the mirror to rotate facilitates the treatment of the entire 360° of the vagina walls.

Laser energy is finally delivered 360° onto the vagina walls and on its circumference through a quick and precise application.

The following figure shows the sole, speculum-like accessory, which is **perfectly regulated** for a precise control of the treatment. The laser passes through the inside of the device and is delivered **fractionally** onto the tissue, that is, with laser energy impacts separated by healthy tissue.

The laser energy is applied throughout the vaginal canal, in the form of patterns without overlap.

Depending on the length of the vaginal canal, the speculum shaped accessory is introduced more or less deeply, while the vagina walls continue to be irradiated in a perfectly homogeneous way at all times.
The laser energy is deposited in an orderly and completely homogeneous way. It is an automatic process, which does not depend on manual dexterity.

These laser impacts are fractional, i.e., a random dot matrix. This allows for healthy tissue between laser impacts, and thus a rapid recovery of the mucosa. As a rule, sexual intercourse can be resumed in approximately 7 days.

One advantage of Gynelase™ is that it delivers laser energy in a random sequence and with precise control of depth, percentage of treated area and density of energy delivered per point, all generated by the Gynescan™ scanner. This controlled effect on the vaginal wall causes an immediate retraction of the tissue and starts collagen remodeling and new collagen synthesis in the vaginal mucosa.

With Gynescan™ the delivery of points follows a random pattern to prevent heat accumulation in the tissue. The processor which controls the scanner allows the physician to monitor the main parameters:

- Separation between points or more precisely the percentage of treated mucosa.
- Energy density in each point (heat effect). Thus the level of retraction of the tissue caused by the laser light can be adjusted.

Prior to performing the laser treatment, vagina and vulva should be washed, disinfected and rinsed.

No special post laser treatment is required. Sexual abstinence for at least 72 hours after the application of the treatment is recommended. The completion of a treatment session requires between 10 to 20 minutes.

This is a safe, easy-to-perform and outpatient procedure. Treatment with INTERmedic’s Gynelase™ falls within the therapeutic range and strategies promoting genital and sexual health and is a therapeutic option in the treatment of vulvovaginal symptoms caused by aging and lack of estrogen.
Vaginal relaxation syndrome  
(VAGINAL TIGHTENING MODE)

Vaginal relaxation syndrome, also known as vaginal laxity, is a condition characterized by the alteration of the shape of the vagina and atrophic vaginitis.

This syndrome is associated with factors such as aging and the menopause, but may also be due to a distension of the vagina during childbirth. These changes can cause decreased sexual satisfaction due to urine leakage, thus altering the quality of life.

Laxity, loss of elasticity and loss of thickness of the vagina walls are known signs of the vaginal relaxation syndrome, where the muscles lose tone, relax, lose strength as well as their support effect and both the internal and the external diameter of the vagina increases. The walls of the vagina also thin down.
Because of less friction, this phenomenon has an important impact on sexual gratification. Also, many women experience and involuntary loss of urine, or urinary incontinence (UI) of different degrees: from a few drops caused by small efforts such as coughing, sneezing or running, to a strong, sudden urge to urinate when the bladder is full or during sex.

There are different methods of treatment for vaginal relaxation, such as the surgical tightening of the vaginal canal or laser. INTERmedic’s Gynelase™ laser causes tissue heating, thus inducing its retraction, but not removal. With precise control, laser energy pulses are directed selectively at the mucosa and submucosa.

This collagen, exposed to an appropriate temperature, leads to the contraction of its fibers and tissue. The effect is not just temporary, but long lasting in order to induce remodeling and neocollagenesis.

Procedure

Laser energy is delivered into the mucosal tissue in a rapid sequence of laser pulses with subablative fluences. When separation between pulses is greater than the thermal relaxation time (TRT) of the surface of the mucosa, the latter will have sufficient time to cool down, while the heat dissipates deep inside the tissue. This produces a controlled effect in the mucosa.
Before
(Vaginal relaxation)

The minimally invasive procedure Gynelase™ Vaginal Tightening Mode (VTM) uses the photothermal interaction between laser and tissue. The handpiece is inserted deep into the vaginal canal where laser energy pulses are delivered along the vaginal canal from the deep layers of the tissue to the superficial ones, thus causing the heating of both tissue and collagen. This results in a shortening, thickening and retraction of the collagen fibers.

After Gynelase™
(Vaginal contraction and tightening)

The treatment effect of GyneLase™ is a tissue contraction and the start of neocollagenesis.

Tissue is thicker, more elastic and vaginal laxity improves.
Urinary incontinence
(INCONTINENCE MODE)

The incorporation of the GyneLase™ laser to the battery of treatments in uro-gynecology has meant a substantial improvement in the treatment of stress incontinence.

The speculum-like device, through which passes the laser energy is introduced into the vaginal canal with an angular adapter, which is integrated into the system depositing the laser energy along the anterior vaginal wall and the endopelvic fascia. Several laser impacts are applied with the Incontinence Mode.
Vulvovaginal rejuvenation laser (VVRL)

Gynelase™ provides an effective and sensitive solution for rejuvenation and aesthetic vulvovaginal treatments.

As a minimally invasive treatment, which produces a controlled thermal effect, it is indicated for the treatment of:

- Vaginal laxity - Laser Vaginal Tightening (LVT)
- Stress incontinence (SUI)
- Vaginal Atrophy
- Female external genitalia

**Patient benefits**

A non-ablative and minimally invasive treatment, it is also safer, faster and more comfortable for the patient.

- No incisions or sutures
- Outpatient
- No downtime
- Rapid recovery

This treatment avoids the potential complications of surgical methods for vaginal tightening.

Its application results in the tightening of the vaginal canal and consequently greater sexual satisfaction and a significant improvement in women’s quality of life.

As a rule, one or two treatment sessions are recommended.
The versatility of Gynelase™ in gynecology (SURGICAL MODE)

INTERmedic’s CO₂ laser is also indicated for multiple procedures in reconstructive and cosmetic vaginal surgery, which are popular today.

- Hypertrophic clitoris labioplasty
- Reducing laser labioplasty
  This procedure shapes those labia minora, which are too large or unequal in length according to the patient. Most women do not want their labia minora to be longer than the labia majora. These techniques can also reconstruct anomalies caused by aging, childbirth or other injuries.

- Laser perineoplasty
  This treatment can rejuvenate an aged or lax perineum and also improve loose labia majora and labia minora. This procedure provides the vulva with a better and younger appearance.

- Combination of individualized laser vaginaplasty and laser vaginal rejuvenation
  These procedures can be performed together, and may also be performed in combination with other surgical procedures.

- Vulvoperineal hyperpigmentation
- Vulvoperineal condilomatosis
  - Genital warts
  - Vaginal intraepithelial neoplasia, cervical dysplasia

- Coagulation, vaporization, incision, excision of soft tissue
- Post-partum perineal scars
- Post-trauma corrections of the labia minora, vulva and hymen

### REDUCING LASER LABIOPLASTY

**BEFORE**

**AFTER**

### HIPERPIGMENTATION OF THE VULVA AND PERINEUM

**BEFORE**

**AFTER**
Other applications of INTERmedic’s CO₂ laser

CO₂ laser technology has a very long and broad history of applications in various surgical specialties.

Due to its enormous absorption by water, this energy is converted into heat and can thus produce:

- Tissue section through flash evaporation
- Coagulation simultaneous with incision
- Coagulation of bleeding vessels
- Contactless vaporization of structures

Specialties such as General Surgery, ENT, Gynecology, Neurosurgery, Dermatology, Plastic Surgery, Urology, etc. benefit from these features and advantages.

<table>
<thead>
<tr>
<th>Feature</th>
<th>CO-PRO™</th>
<th>ULTRAFINE™</th>
<th>GYNELASE™</th>
</tr>
</thead>
<tbody>
<tr>
<td>CW mode: section and coagulation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Superpulse mode: delicate vaporization</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Finepulse mode: extremely delicate vaporization</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>without carbonization (emulates Er:Yag laser)</td>
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<td></td>
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<tr>
<td>Handpiece for fine incisions, moderate hemostasis</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Handpiece for normal incisions, high hemostasis</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Fractional superficial rejuvenation</td>
<td>No</td>
<td>Yes</td>
<td>Upgrade</td>
</tr>
<tr>
<td>Fractional deep rejuvenation</td>
<td>No</td>
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<td>Upgrade</td>
</tr>
<tr>
<td>Traditional resurfacing</td>
<td>No</td>
<td>Yes</td>
<td>Upgrade</td>
</tr>
<tr>
<td>Female incontinence</td>
<td>No</td>
<td>Upgrade</td>
<td>Yes</td>
</tr>
<tr>
<td>Genital rejuvenation (atrophy, vaginal relaxation syndrome)</td>
<td>No</td>
<td>Upgrade</td>
<td>Yes</td>
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<td>Human papillomavirus (HPV)</td>
<td>No</td>
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<td>Vaginal anal bleaching</td>
<td>No</td>
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<tr>
<td>Micromanipulator for colposcope</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
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<tr>
<td>Micromanipulator for operating microscope</td>
<td>Optional</td>
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<tr>
<td>Kamani handpiece for ORL</td>
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<tr>
<td>Laparoscopy adapters</td>
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2. INNOVATIVE TECHNOLOGY FOR MINIMALLY INVASIVE GINECOLOGICAL TREATMENTS
Comprehensive treatment of the vulvovaginal zone

Gynelase™ uses multiple, minimally invasive treatment modes and specific techniques for vaginal tightening, vaginal rejuvenation and stress incontinence.

With these techniques the accuracy of the Gynepulse™ and the control of the Gynescan™ scanner allow for the selective delivery of energy into the tissue to heat the collagen. A controlled delivery of heat within the tissue is required for its homogeneous distribution in the mucosa without damaging the surface or the surrounding tissues.

The techniques are based on the Incontinence mode and the Vaginal Tightening mode from INTERmedic’s Gynelase™.

There are several ways to deliver the energy into the tissue:

Conventional pattern
The entire surface area receives laser treatment.

Fractional pattern
Energy impacts separated by healthy tissue.

Exclusive fractional pattern by Gynelase™
Energy impacts are separated by healthy tissue and the impact algorithm is calculated in order to maximize the separation between consecutive pulses. This seeks to achieve the unique effect of an impact without a thermal pollution or the previous impact for maximum treatment safety and effectiveness.
1. CONVENTIONAL PATTERN

Laser energy covers the entire surface of the spot. This method produces a greater retraction due to its ample thermal effect, but it produces greater side effects. Although the energy on the entire surface of the impact area (spot) is uniform, heat is concentrated in the center due to the cumulative effect.

2. FRACTIONAL PATTERN

The fractional process consists in energy being delivered in tiny spots which generate heat columns. Between these spots untreated healthy tissue remains to allow for a much faster recovery.
There are several methods to perform the fractional pattern:

2.1 Perforated template

A small perforated metal plate is placed in the laser beam. At the exit of the perforated plate multiple beams appear which are then focused onto the tissue through a lens. One disadvantage of this system is that the low energy harnessed by the main beam is divided by the number of points of the fractional matrix, thus each spot having a very low capacity. Furthermore, due to the caloric summation effect of the adjacent points, spot distribution follows a Gaussian law and is more intense in the center.

2.2. Microlens array

This is a lens matrix capable of transforming the cylindrical geometry of the laser beam into multiple beams of smaller diameters. This system has the disadvantage that there is no possibility to adjust the percentage of treated surface and the problem of a Gaussian distribution of heat in the tissue persists, that is, more heat in the center.

2.3. Gynescan™ scanner

Gynescan™ is an exclusive and sophisticated mirror system controlled by a microprocessor, which generates a figure or fractional pattern in less than 1 second.
**INTERmedic’s technology applied to Gynelase™**

This CO₂ laser system is the result of INTERmedic’s focus on research and development of technological solutions for indications in a variety of medical fields.

**Gynescan™ scanner**

With this sophisticated and more expensive system, the energy from the laser is reflected in the tissue by way of two motorized mirrors. Thanks to the computerized motion of the mirrors, the laser beam moves over the tissue while fractionally redrawing the figure onto the tissue (laser energy impacts separated by healthy tissue). This process is so fast that it takes less than one second. The laser energy impacts remain fractionally in the tissue completely uniformly and homogeneously.

This system has great advantages, since 100% of the energy contained in the laser beam is applied onto the tissue with each impact (spot). This results in a greater clinical efficacy.

The administration of points is performed randomly: before generating the figure, the software calculates the route and sequence of impacts in order to ensure the maximum possible separation between them. Thus it avoids the heat accumulation effect, which is characteristic of other systems.
Gynescan™

Gynescan™ is an exclusive and sophisticated microprocessor-controlled mirror system, which generates a figure or fractional pattern in less than 1 second.

This means maximum benefit for the tissue, because 100% of the beam energy is applied fractionally in one spot. Points are randomly applied: this achieves a uniform heat distribution in the mucosa.

All clinically important parameters can be adjusted:

- Peak power (ablation depth)
- Pulse length (caloric effect)
- Separation between points (percentage of treated mucosa)
- Stacking (overlap)

During treatment, the surface within the spot is treated with the laser beam, leaving the surrounding tissue intact, thus inducing a better immune response and better recovery of the tissue.
Gynescan™ maintains the fluence of the individual beam unaltered and it remains exactly like the original laser beam, yet with the added advantage that this laser beam moves randomly and thus provides maximum safety during treatment.

The laser energy beams are perfectly homogeneous. The distance to the tissue and the separations between points are always distributed evenly.

Given that tissue is not flat but irregular, this feature of the Gynelase™ laser allows for a homogeneous treatment of the entire vagina surface.

In Figure 1 the handpiece and its effect depend on the distance between the handpiece and the tissue.

In Figure 2 the INTERmedic handpiece delivers the laser beam in a completely homogeneous way onto the surface without the beam being affected by the irregularities of the tissue.

INTERmedic’s Gynescan™ is very important for the treatment of curved cavities such as the vagina and the pelvic floor, since it delivers a controlled and homogeneous beam onto the entire tissue surface.
**Gynepulse™**

The outermost layer of skin, the stratum corneum, constantly undergoes mechanical stresses, and thus is protected by keratin-rich cells with low water content. The vaginal mucosa and the epithelium are not keratinized and have a very high water content.

These differences have important clinical implications, given the CO₂ laser’s affinity with water, which is its chromophore. Therefore a different way to deliver laser energy into the tissue has been found, which is more suited than radiation emission to the particular characteristics of the mucosa with its different morphology.

The Gynepulse™ pulse consists of 2 distinct and consecutive parts. The first has a very high potency and very short duration and the second, a longer duration than the first, but much less power. All this is carried out in a very short time, in milliseconds.

Given its high potency characteristics, the first part of the pulse produces a superficial action in the mucosa in a short time and the second one produces a non-ablative heating effect, in order to cause a thermal injury that will then trigger a neocollagenesis reaction.

Arguably, the effect of the first segment of the pulse paves the way for the thermal effect by the second part thereof.

- Short, high-potency pulses. Superficial action on the epithelial surface of atrophic mucosa with low water content.
- Long, low-potency pulses, which are applied during the second phase of treatment. In-depth contraction action and stimulation of new collagen.

Different equipment modes and other scanner variables for different applications are also available (optional) in dermatology, general surgery, urology, ENT, etc.

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**Other pulse emission modes for multiple applications**

![Graphs showing different pulse emission modes](image)
Innovative, minimally invasive technology for gynecological treatments
INTERmedic technology applied to Gynelase™

Other modes of emission

LASER EMISSION MODES

- **C.W.**
  - POWER (W)
  - T

- **FINEPULSE™**
  - POWER (W)
  - T
  - Inferior duration compared to the epidermic TRT.
  - Very high peak power.

- **SUPERPULSE**
  - POWER (W)
  - T
  - Slightly longer duration than the epidermic TRT.
  - High peak power.

LASER EXPOSURE MODES

- **CONTINUOUS**
  - POWER (W)
  - T

- **SINGLE PULSE**
  - POWER (W)
  - T

- **REPEATED PULSE**
  - POWER (W)
  - T
  - ON TIME
  - OFF TIME

Touchscreen and software with different modes of treatment

- VAGINAL TIGHTENING MODE
- INCONTINENCE MODE
- SURGICAL MODE
- GYNE VPH MODE
- DERMATOLOGICAL MODE (Optional)
TECHNICAL FEATURES

• Laser type: CO₂
• Wavelength: 10.600 nm
• CW tube power: 50W (limited 30W)
• Peak power: >200W
• Beam structure: TEM00
• Beam guide: 635nm, 1mW, adjustable from 0 to 100%
• Beam delivery: Articulated arm with 7 elbows
• Dimensions: 114x45x30mm (Height x Width x Depth)
• Control panel: Color touchscreen LCD 8.5”

INCONTINENCE AND REJUVENATION MODES

• Emission mode: FinePulse (>100W peak) with a pulse width inferior to the TRT of the mucosa (share free)
• Spot: 800µm
• Selection of the treated zone: 20% to 90%
• Figure: 10mm hexagon
• Non hand-dependant treatment (patent pending)
• Longitudinally (every 10mm) marked speculum (size of the figure). Perfectly defined rotation clicks
• Absolute control of all parameters: peak power, % of treated area, pulse width, energy density per point, staking
• Random algorithm: to prevent heat accumulation

VPH MODE

• Spot: 400µm
• Figure: Hexagon adjustable from 5 to 15 mm
• Treated area: 100% (ablative mode)

SURGICAL MODE AND VAPORIZATION

• Modes: CW, SuperPulse, FinePulse
• Handpiece f50 (fine incision with moderate hemostasis); f100 (normal incision with high hemostasis)

DERMATOLOGICAL MODE (stretch marks, wrinkles, etc.)

• Mode: CW, pulsed, SuperPulse, FinePulse
• Spots: 500µm (superficial tightening); 190µm (very deep wrinkles)
• Figures: Square, rectangle, triangle, hexagon, circle, donut. 5x5 to 20 x 20mm (500µm spot); 2,5x2,5 to 12x12mm (190µm spot)