Cryomed Aesthetics

LOTUS GYNOLASER

CLINICAL MANUAL

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1 Introduction

Lotus GynoLaser offers predictable, effective treatment for the symptoms of vaginal relaxation syndrome (VRS), vaginal atrophy (ageing) and stress urinary incontinence (light bladder leakage). These conditions can affect women of all ages, causing physical discomfort as well as emotional stress, and a loss of confidence, both personally and in intimage relationships.

Lotus treatment works by stimulating the body's own regenerative processes to improve blood circulation, regenerate healthier cells and create more moisture for the cells. This in turn can improve the strength and elasticity of the pelvic floor muscles, and may contribute to a tighter and better lubricated vaginal wall, and increased bladder control.

The results of Lotus GynoLaser treatment begin to be apparent at the cellular level from the first treatment. For maximum benefit, it is best to do a complete cycle of three sessions at intervals of approximately 30-60 days. The full number of sessions can be tailored to the patient's unique situation, particularly the degree of vaginal atrophy or laxity to be treated.

A thorough examiation of the patient should always preceed the development of a specific therapeutic plan. Contraindications should be observed at all times.

Once the desired level of improvement has been reached, it is advisable to perform one or two maintenance sessions approximately one year after the end of the treatment cycle.

2 Vaginal Mucosa: Histology Overview

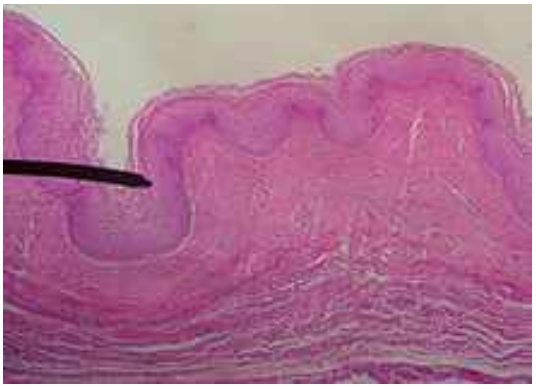
The vaginal wall consists of a mucosa of non-keratinised stratified squamous epithelium with an underlying lamina propria of connective tissue, under which is a layer of smooth muscle with bundles of circular fibres internal to longitudinal fibres, then a thin dense outer layer of connective tissue, the adventitia. The two sublayers of the mucosa, the epithelium and lamina propria, are often considered as two separate layers.

The mucosa forms folds or rugae, which are more prominent in the caudal third of the vagina. They are like transverse ridges, and they provide additional surface area for the vagina to extend and stretch.

The vaginal mucosa itself has no glands. The vaginal epithelium is responsible for the support and nutrition (trophism) of the vaginal lining. It consists mainly of macromolecues known as proteoglycans, which are attached to long chains of hyaluronic acid through special proteins, and which have the ability to retain large quantities of water. The level of hydration of the lamina propria depends on the proteoglycans, and this in turn influences the easy transport of nutrients and metabolites throughout the vaginal structures and mucosa. If the ground structure of the vagina is poor and lacking in hydration, the epithelium likewise will not receive proper nutrition and will lose hydration.

Oestrogen causes the intermediate and superficial cells to fill with glycogen. When oestrogen is lost, due to natural or induced menopause, these cells gradually lose their glycogen and the epithelium thins out.

When the vagina's connective tissue is correctly hydrated, the entire vaginal mucosa benefits. Symptoms of poorly hydrated vaginal mucosa include dryness, painful intercourse, light bleeding during sex, itching, stinging and burning sensations, and general discomfort.



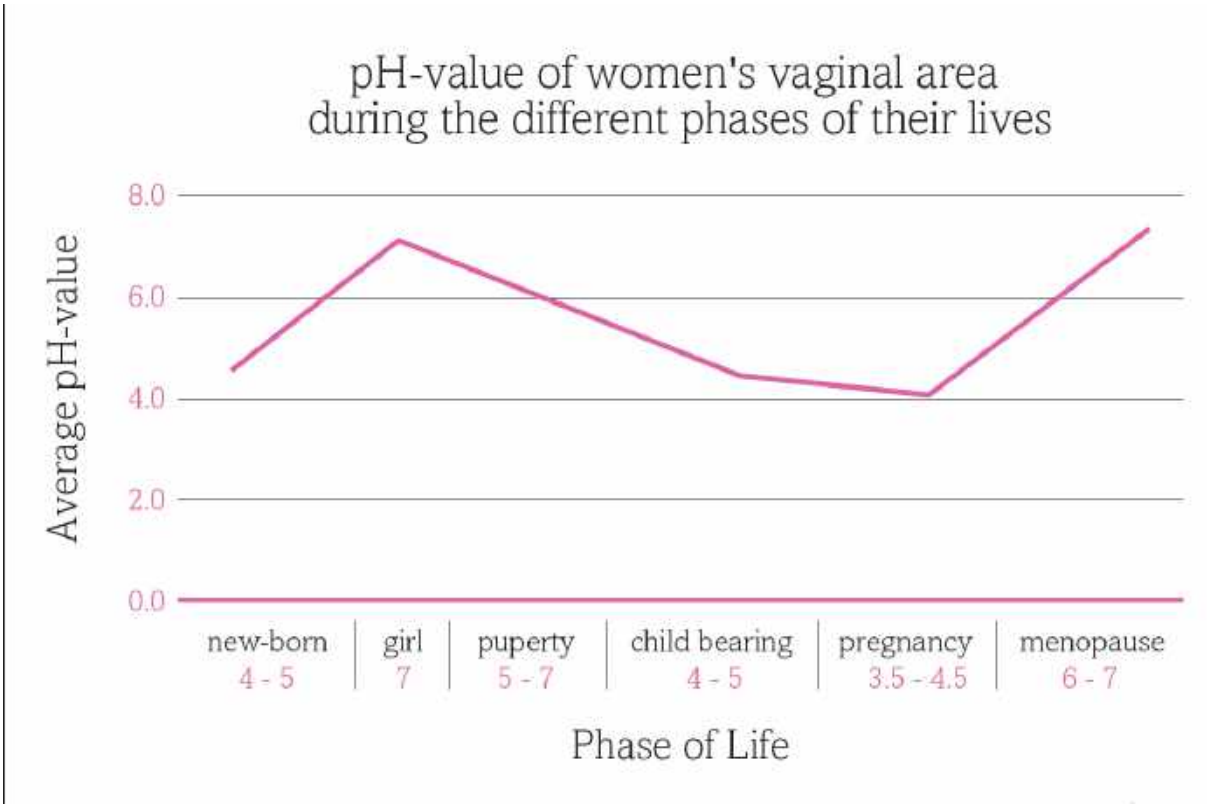
Cross-section of the vaginal wall showing the stratified squamous epithelium and underlying connective tissue. The black line points to a fold in the musosa.

PH Levels of the Vagina

Vaginal pH is a measure of the acidity of the vaginal environment. In a healthy woman of reproductive age, vaginal pH is typically 3.5 to 4.5, which is slightly acidic.

During the follicular phase of the ovarian cycle, the epithelial cells of the vagina synthesise and store glycogen as they migrate towards the surface of the vaginal wall, from where they shed as a result of exfoliation. As they exfoliate, they release the

glycogen, which is used by vaginal lactobacilli to produce lactic acid. This maintains the acidic environment of the vagina, which prevents pathogen colonisation.



With menopause and the decline of oestrogen levels, the epithelium and the underlying lamina propria begin to atrophy. Glycogen in the epithelial cells decreases, with an associated negative impact on the lactobacilli, which need the glycogen to thrive. Because the lactobacilli are responsible for the maintenance of an acidic pH environment, the vagina loses its optimal acidic pH.

Any restoration of proper nutrition and hydration to the vaginal mucosa results in an increase in glycogen levels, creating the best environment for recolonisation by lactobacilli and a return to better vaginal acidity.

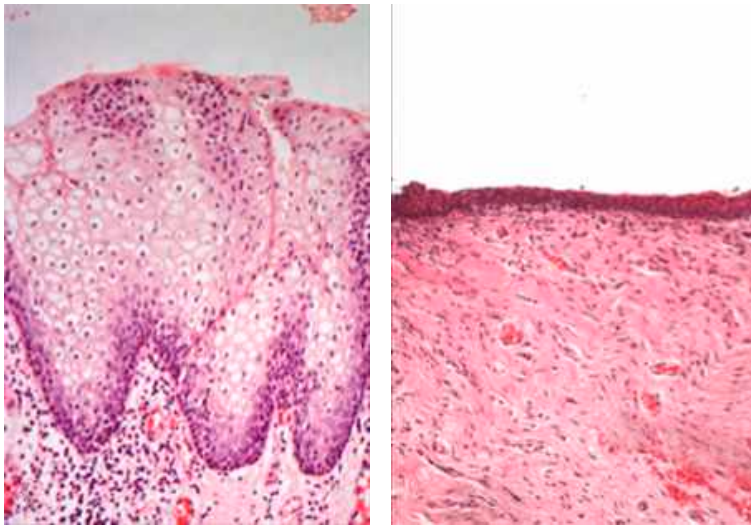
This is the purpose of Lotus GynoLaser treatment and is dealt with more fully in later sections.

3 Vaginal Health

3a Menopausal Vaginal and Urogenital Health

Urogenital complaints such as urinary incontinence, dysuria (painful urination), recurrent urinary tract infection, vaginal discomfort and dyspareunia (pain during sexual intercourse) have been reported by large numbers of menopausal and postmenopausal women. These symptoms can be distressing and are often blamed for a poorer quality of life.

Natural or induced menopause occurs when the ovaries gradually cease production of oestrogen or when oestrogen production ceases abruptly with the removal of the ovaries. The production of oestrogen can also be adversely affected by medical conditions that require treament with radiation therapy or chemotherapy. The relationship between these symptoms and a reduction in the amount of oestrogen is well documented, and urogenital complaints are a common reason for menopausal and postmenopausal women to seek medical attention.



A: Vaginal mucosa in reproductive age: the mucosa is well supplied with vessels and the epithelium consists of many more cell layers, which are rich in glycogen.

B: Post-menopausal vaginal mucosa at the same magnification. Decreased oestrogen levels and significantly fewer vessels have contributed to a thinner epithelium with lack of glycogen.

A range of symptoms are associated with the decline of oestrogen in the body. Some, such as hot flushes and night sweats, will be relatively transitory. However, the symptoms associated with vaginal and urethral atrophy can become more pronounced with time, requiring more direct intervention.

Specifically declining oestrogen levels during natural or induced menopause are associated with the following:

- Morphological alterations of the epithelium of the vaginal mucosa;
- Reduction of blood flow and of vaginal secretion (resulting in vaginal dryness); and
- Decrease of vaginal lactobacilli and increased vaginal pH levels.

Alteration of the Epithelium of the Vaginal Mucosa

The epithelium of the vaginal mucosa is important for the protection of the mucosa against mechanical friction during sexual intercourse.

As oestrogen levels begin to decline during menopause, collagen in the connective tissue of the vaginal mucosa declines, and the transitional epithelium of the trigone and the urethra becomes thinner. The volume of blood flowing through the urethral vascular plexus decreases, and with the thinning of the epithelium, the area becomes more susceptible to trauma. Collagen provides structural and functional support for the epithelium, so its reduction causes a loss of surface rugosity in the vagina.

Any reduction in those levels can cause a correspondingly drier vaginal environment. Menopausal women who are sexually active report the problem of vaginal dryness most frequently because of problems with dysareunia (painful sexual intercourse).

Reduction in Vaginal Lactobacilli and Increased Vaginal PH Level

The bacteria which colonises the vagina plays an important role in protecting the vagina from infection. Lactobacilli, for example, are important in maintaining a appropriately acidic vaginal pH produce lactic acid, thereby preventing the growth of pathogenic microorganisms. Adequate oestrogen levels help maintain vaginal pH at around 3.5–5.0, where lactobacilli provide an adequate barrier. With a natural or induced menopausal decline in oestrogen levels comes a parallel decline in vaginal lactobacilli, and a corresponding increase in the pH value (6.0–8.0). These lower acidic levels encourage the growth of pathogens, such as yeasts and bacteria. This higher pH can also be resonsible for unpleasant vaginal odour.

	Sexual maturity	Pregnancy	Post-menopause
Oestrogens	++	+++	–
Epithelium of mucosa			
Glycogen	+	++	-
pH	3.5-5	3-4.5	6-8
Population of microorganisms	lactobacilli	lactobacilli	mixed

3 b Effect of Lotus GynoLaser Treatment for Menopausal Vaginal and Urogenital Health

Once a woman has been diagnosed with vulvo-vaginal atrophy, CO_2 fractional laser treatment with Lotus has dual purposes:

- **Genital Regeneration**
  The aim of treatment is to restore the normal physiological and chemical environment, in order to address the thinning of the vaginal epithelium.

- **Symptom Relief**
  Genital rejuvenation can lead to the disappearance of many of the distressing vaginal symptoms associated with menopause, such as dryness, superficial and deep dyspareunia, vaginal bleeding, inflammation and discharge.

Rejuvenation

Ageing cells, along with the tissues, organs and anatomical structures which they make up, lose their optimal functionality. While this is a gradual process, and much of it results in minimal physical disruption, on occasion a person experiences more serious problems. This is particularly so with brain cells or the cells that make up a person's sight mechanism, for example. There is currently a plethora of research focusing on how cells can be manipulated to 'remain young' for longer, or even indefinately.

This concept also applies to the vaginal mucosa. Female menopause involves all of a woman's reproductive organs, including the vagina, and it generally results in some degree or other of vaginal atrophy.

Researchers have reasonably assumed that because the cells of the vaginal mucosa have such a major impact on the viability of a healthy and youthful vagina, then their rejuvenation to a pre-menopausal structure should assist in alleviating the physical changes that cause vaginal atrophy and thereby its distressing symptoms.

Lotus GynoLaser has been designed for this purpose. Histological studies of the effects of microablative fractional CO_2 laser treatment on atrophic vaginal tissue have confirmed the success of tissue remodeling of vaginal connective tissue with neoformation of collagen and elastic fibres, without causing damage to surrounding tissue[1].

Lotus GynoLaser treatment stimulates the functional activity of fibroblasts with renewed collagen synthesis. It also restores the correct composition of the extracellular matrix, so that collagen fibres inside the ground substance are adequately supplied with water content. Thus the permeability of the connective tissue is restored and various essential nutrients can be transferred from capillaries to tissues. In vaginal atrophy, this transfer process is compromised to the extent that the epithelium, which does not contain its own blood vessels, does not receive nutrients. This lack of nutrients causes it to deteriorate in quality, becoming thinner and leading to the symptoms of vaginal atrophy already described. Lotus GynoLaser treatment is able to stimulate the body to provide the necessary nutrients to the epithelium.

The reduced functionality of the fibroblasts also contributes to vaginal dryness: lower functioning fibroblasts mean a lower level of hydration, and when this is combined with a diminished blood flow, the resultant reduction in cell nourishment means a less turgid connective tissue, the ground matrix for the vagina.

1 Salvatore S, Maggiore L, Athanasiou S, Origoni M, Candiani M, Calligaro A, Zerbinati N: *Histological study on the effects of microablative fractional CO2 laser on atrophic vaginal tissue: an ex vivo study* (August 2015)

NATIONAL CERVICAL SCREENING PROGRAM AND PAP SMEARS AUSTRALIA

The Cervical Screening Test replaced the Pap test in 2017. The new cervical screening test procedure is similar to a Pap smear test. For both tests a doctor or nurse takes a sample of cells from the cervix. However, the Pap smear test used to look for abnormal cells in the cervix, while the cervical screening test looks for HPV infection. The new test for HPV can identify women who could be at risk of cervical cancer earlier than the Pap test could.

If you have previously had a Pap test, you should have your first HPV cervical screening test two years after your last Pap test. A better test means you will only need to screen every five years after your first HPV cervical screening test.

Women aged 25 to 74 years of age should have a cervical screening test two years after their last Pap test. Subsequently, you will only need to have the test every five years if your results are normal.

NCSP Clinical Guidelines – This fact sheet outlines important changes to the NCSP's clinical guidelines pathway for women at intermediate risk. These guidelines come into effect from 1 February 2021.

https://www.health.gov.au/initiatives-and-programs/national-cervical-screening-program

https://www.health.gov.au/initiatives-and-programs/national-cervical-screening-program/about-the-national-cervical-screening-program

https://www.cancer.org.au/cancer-information/causes-and-prevention/early-detection-and-screening/cervical-cancer-screening

https://www.cancer.org.au/cancer-information/causes-and-prevention/early-detection-and-screening/understanding-your-cervical-screening-test-results

NATIONAL CERVICAL SCREENING PROGRAM AND PAP SMEARS NEW ZEALAND

The National Cervical Screening Programme recommends cervical screening every 3 years. People who have previously had abnormal tests may need to have them more often – if you're unsure, ask your health provider.

https://www.timetoscreen.nz/cervical-screening/your-results/understanding-your-results/

https://www.health.govt.nz/system/files/documents/publications/cervical-screening-guidelines-aug08.pdf

https://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/cervical-cancer/cervical-screening#:~:text=The%20National%20Cervical%20Screening%20Programme,unsure%2C%20ask%20your%20health%20provider.

3c Postpartum Vaginal and Urogenital Health

Vaginal and Urogenital health after pregnancy and childbirth is an important issue, and studies have found that levels of sexual dysfunction and dissatisfaction are very high. Along with dyspareunia, vaginal laxity (looseness or relaxation) is reported as a physical and psychological problem for many women and their partners.

Dyspareunia

Dyspareunia is the term used for any pain or soreness that occurs during sexual intercourse. As seen below[1], increased problems after childbirth have been documented. Dyspareunia is said to be 'deep' or 'superficial', depending on the location of the discomfort.

Some temporary reduction in libido is acceptable after childbirth, however, this should not include dyspareunia. Pain during intercourse that is untreated can leave a woman with ongoing fear of intercourse, as well as escalating emotional and physical relationship problems.

Therefore, early intervention and sensitive treatment are critical, both in treating the immediate problem and in preventing long-term issues. Doctors should take the initiative in assessing women for postpartum vaginal and sexual health, as many women are reluctant to be proactive in reporting problems. It is also important to remember that problems can be psychological or physical, or a combination of both.

Superficial dyspareunia involves pain around the introitus, and can also involve the vulval and urethral areas. Sometimes superficial dyspareunia results from scar formation, vaginal dryness, or poor anatomical reconstruction following perineal trauma during childbirth.

- An important factor in the incidence and severity of postpartum dyspareunia is the type and degree of perineal injury sustained, which is in turn is impacted by the method of delivery. Episiotomy, instrumental delivery, and perineal tears are more likely to result in sexual pain and problems. Childbirth with an intact perineum generally offers the best outcome in terms of sexual function and avoidance of painful intercourse. A number of studies have assessed the impact of various

1 M Khajehei, M Doherty, P J Tilley, K Sauer: *Prevalence and risk factor of sexual dysfunction in postpartum Australian women* (Curtin University, Perth, WA, Australia, 2015).

Results: Almost two-thirds of women (64.3%) reported that they had experienced sexual dysfunction during the first year after childbirth, and almost three-quarters reported they experienced sexual dissatisfaction (70.5 %). The most prevalent types of sexual dysfunction reported by the affected women were sexual desire disorder (81.2%), orgasmic problems (53.5%), and sexual arousal disorder (52.3%). The following were significant risk factors for sexual dysfunction: fortnightly or less frequent sexual activity, not being the initiator of sexual activity with a partner, late resumption of postnatal sexual activity (at 9 or more weeks), the first 5 months after childbirth, primiparity, depression, and relationship dissatisfaction.

materials and methods, and have reported varying results. Scar tissue from sutures at the introitus is a quite common cause of dyspareunia. Moderate to severe pain can be experienced during penetration, and the scar can even split and bleed during intercourse.

- While vaginal atrophy is most usually associated with a loss of oestrogen during menopause, lactation also contributes to a decrease in oestrogen levels, and can result in symptoms of urogenital atrophy. This is caused by the loss of placental oestrogen after childbirth, and can be exacerbated by the high levels of prolactin associated with breastfeeding, as these have an antagonistic effect on oestrogen production. This means that oestrogen levels can be sub-optimal throughout lactation, contributing to a range of symptoms normally associated with menopause: urogenital atrophy, epithelial thinning, decreased elasticity and diminished vaginal blood flow. Typical symptoms described are vaginal dryness, itching, burning, irritation and dyspareunia. Hypoestrogenemia may also cause urinary symptoms such as dysuria, urgency and frequency.

Vaginal Laxity / Vaginal Relaxation

Vaginal delivery and pelvic organ prolapse can contribute to stretching of the vagina and introitus. Looseness or stretching has been said to contribute to diminished sexual satisfaction in some women, who may also experience some negative changes in their body image. Clinicians generally believe that this condition is under-reported, and that the majority of women 'simply live with it'. However, physicians surveyed generally believe that the condition negatively impacts a woman's well-being, and is one of the most obvious physical changes after childbirth. It has also been noted that the condition deteriorates with successive vaginal deliveries.

Postpartum Urinary Incontinence

Many pregnant women experience stress incontinence, and discover that the condition continues after childbirth. Optimal bladder function is supported by the network of nerves, ligaments and pelvic floor muscles that cooperate to support the bladder and to maintain a fully-functioning close to the urethra. Any injury or overstretching of these support areas during pregnancy or childbirth can contribute to compromised functionality.

Practice indicates that vaginal births are more likely to contribute to postpartum urinary problems than caesarean section deliveries. Assisted vaginal deliveries, particularly using forceps, appear, according to some studies, to conbribute to postpartum urinary problems. Other studies find correlations between urinary problems and a prolonged pushing stage, or even the size of the baby (i.e., the larger the baby, the greater the chance for urinary problems). The likelihood of stress incontinence increases, not only for mothers who have had multiple vaginal deliveries, but also for smokers and women who are obese.

Some women find these negative changes will resolve automatically within a few weeks, whereas others have persisting symptoms for several months or more.

3 d Effect of Lotus GynoLaser Treatment for Postpartum Vaginal and Urogenital Health

Because many of the problems faced by postpartum women are similar to those experienced during menopause (reduction in oestrogen, leading to conditions that mimic the histological characteristics contributing to vaginal dryness and atrophy), Lotus GynoLaser treatment is also useful in helping to regerate the vaginal environment and thereby reduce the severity of distressing postpartum symptoms.

Failure to address postpartum vaginal issues can lead to their becoming chronic problems.

In summary, Lotus GynoLaser can be used to address:

- Dyspareunia due to perineal trauma (episiotomy, perineal tears, instrumental delivery);
- Dyspareunia due to postpartum vaginal atrophy (lactational atrophic vaginitis due to reduced oestrogen levels); and
- Vaginal laxity or vaginal relaxation (often associated with postpartum urinary incontinence).

Dyspareunia due to perineal trauma

Patients with a perineal scar can experience intense pain, particularly near the vaginal introitus and extending back towards the rectum.

Lotus GynoLaser treatment stimulates the production of collagen on and around the scar tissue, acting to restore the correct nutritional balance of the mucosa and improving the functionality of the area.

Dyspareunia due to lactational vaginal atrophy

Postpartum atrophic vaginitis is quite similar to post-menopausal atrophic vaginitis, as both are caused by a fall in the levels of oestrogen (although the fall is more abrupt in the case of a lactating woman or a woman experiencing induced menopause).

Vaginal laxity or vaginal relaxation and postpartum urinary incontinence

We have already seen that vaginal laxity problems can occur as a result of a loss of tone of the mucosa. It should be stressed that prior to any treatment plan being designed, a thorough examination should rule out any other causes of a compromised vaginal canal, such as vaginal prolapse or other muscular problems.

By helping to restore a normal histological environment, Lotus GynoLaser can be a major contributor to alleviating the problems of postparum vaginal and urogenital health.

4 Procedures

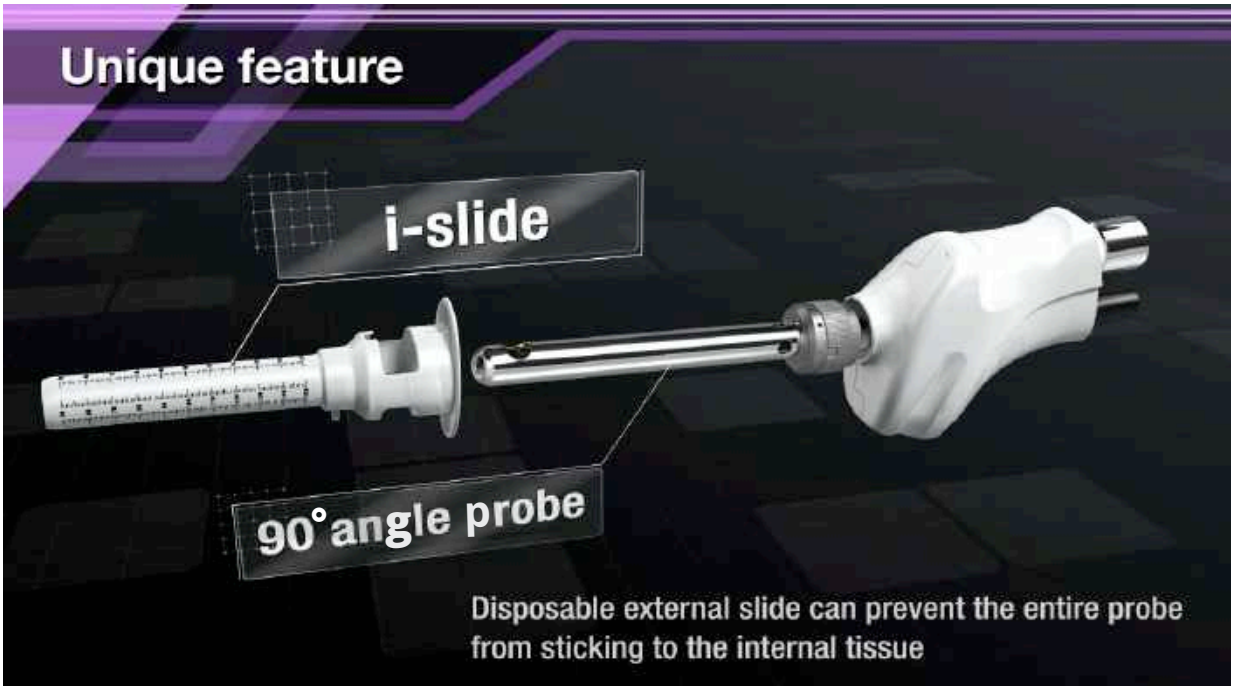
4a Intravaginal Lotus GynoLaser Treatment

Treatment with the Lotus GynoLaser CO_2 fractional laser is minimally invasive and is performed in the doctor's surgery, hospital out-patient department or a day hospital. The treatment does not require anaesthesia and no incisions or stitches are required.

A treatment session normally takes 15-20 minutes and the patient can return to her normal daily tasks afterwards. The procedure is performed while the patient is lying on the gynaecological bed.

The 90° Vaginal Tip

The slide shape of the tip has 45° reflecting mirrors, which provide vertical delivery of the CO2 laser beam onto the wall of the vagina.



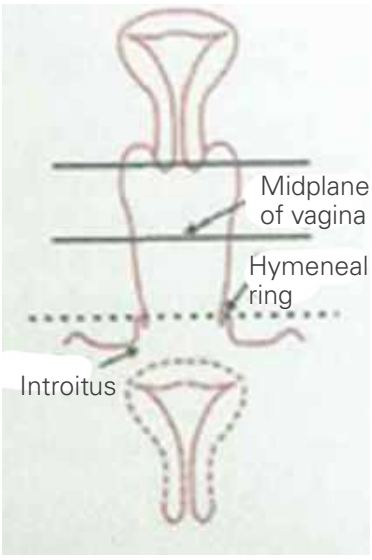
Preliminary Consultation and Diagnosis

It is critical to take a full patient history and to correctly diagnose the patient's condition before proceding to treatment. It is also important to understand the patient's expectations of treatment, and to explain how the treatment works and the outcome

the patient can expect. The patient should sign the informed consent form (Appendix 1) after the consultation and reading the patient information sheet.

Contraindications for Treatment

- Any local or systemic disease, *in situ* infectious and/or inflammatory process (urogenital tract) in acute or recurrent stage, such as candidiasis, chlamydia, genital herpes, gonorrhoea or any condition diagnosed as vaginitis. Any active disease needs to be successfully treated with an appropriate therapy according the specific diagnosis.
- Vulvar dermatosis in active stage (psoriasis, seborrheic dermatisis, lichen planus). This also needs to be successfully treated with the appropriate therapy before proceeding with treatment.
- In situ lesions with potential neoplastic and neoplasia evolution (vulvovaginal area and neck of the uterus), such as lichen sclerosus, squamous cell hyperplasia, HPV lesions, fibromi, VIN, CIN, etc. Any such conditions must be successfully treated before proceeding with Lotus treatment.
- Any erosion adverse effect post-TVM (trans-vaginal mesh) surgery.
- Abnormalities / cell changes noted in last PAP smear or Cervical Screening Test.
- Any degree of pelvic organ prolapse ≥ II (ICS POP-Q staging system).
- Mensus (wait 1 week after end of menstrual period), pregnancy, 3 months post-pregnancy or breast-feeding.



Pelvic Organ Prolapse Quantification staging system (POP-Q)

Stage 0: No prolapse

Stage 1: Most distal point > 1cm above the level of the hymen

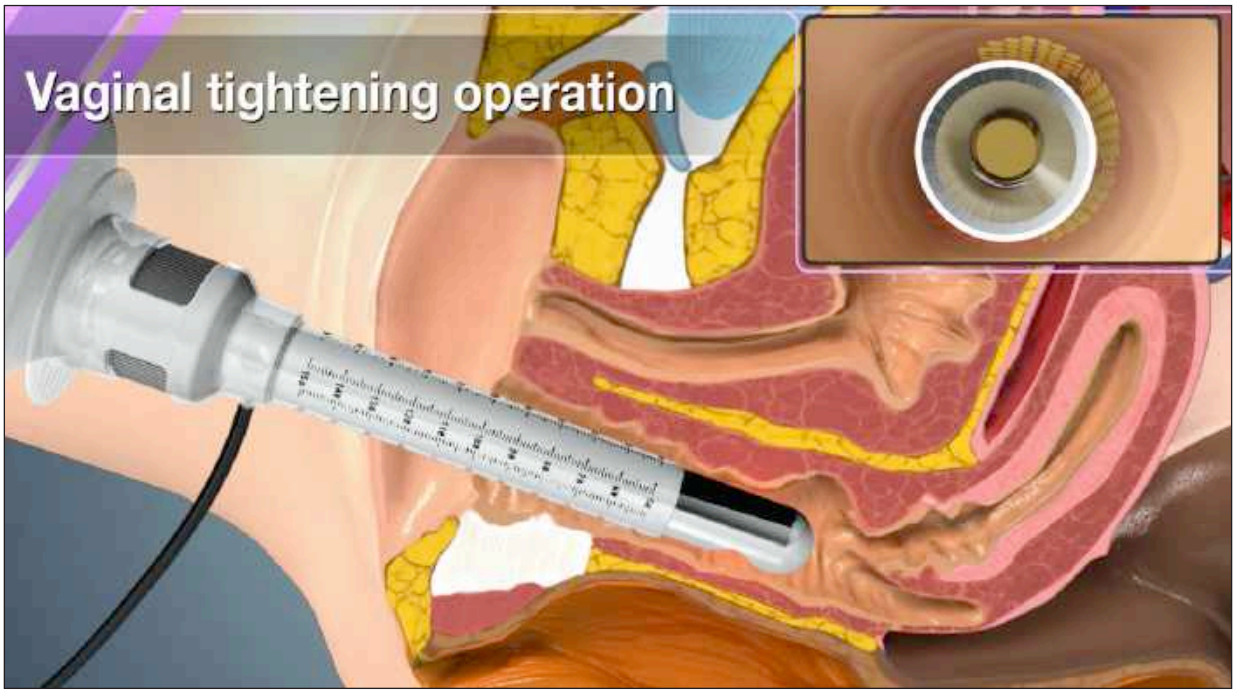
Stage II: < 1cm proximal to or distal to the plane of the hymen

Stage III: > 1cm below the plane of the hymen

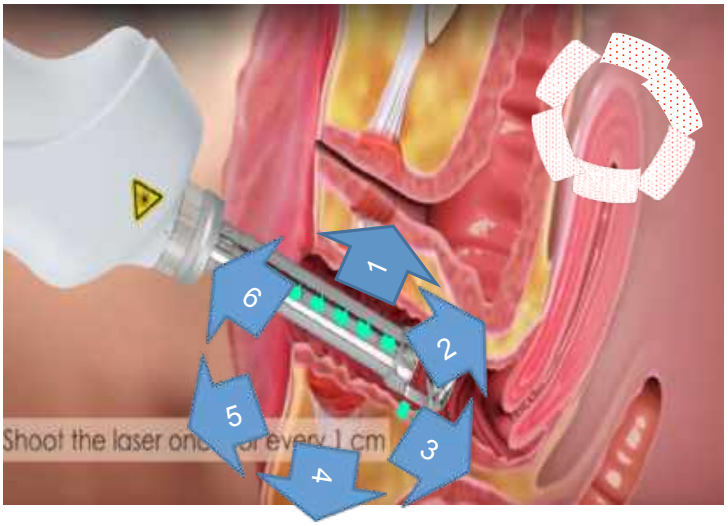
Stage IV: complete eversion of the length of the lower genital tract (tvl -2cm)

Cautions

- Treatment of oncologic patients: because of the compromised immune defences of patients who have undergone chemotherapy and/or radiotherapy, Lotus GynoLaser treatment may lead to more severe inflammatory reaction than usual. For this reason is it advisable to wait 6 months after the end of chemotherapy or



radiotherapy before treatment with Lotus GynoLaser. When treatment does proceed, the patient should be informed of the possibility of swelling of the inguinal lymph nodes, to avoid unnecessary concern if this does occur.



- Pelvic floor surgery: Depending on the severity of the prolapse being treated and the nature of the surgical treatment performed, it is advisable to wait for an extended period (approximately one year) before considering Lotus GynoLaser treatment, in order to allow the region to stabilise fully.
- **Patients with a history of genital herpes virus infection:** We recommend that a course of appropriate antiviral drugs should be commenced 6 days before Lotus GynoLaser treatment, and should continue for 5-15 days after treatment.
- **Anticoagulant medication (e.g., acetylsalicylic acid, heparin, etc.):** Treatment with Lotus GynoLaser should not commence while the patient is taking these drugs, nor until its effect has expired (the timing will depend on the specific drug).

First Treatment Session

At the beginning of the Lotus GynoLaser treatment program, it is assumed that the patient will demonstrate symptoms and characteristics of vaginal atrophy. The vaginal mucosa will be dry or dehydrated and the thickness of the epithelium will be reduced to a greater or lesser extent.

CO_2 laser treatment relies upon water content to facilitate wavelength absorption, so

the first session will focus particularly on preparing the vaginal tissue to be as receptive as possible to subsequent treatments.

The thinner the epithelium, the more delicate and susceptible to damage it is, and it is important to remember this when setting the treatment protocol. It is best to begin with a lighter treatment protocol and build gradually.

Position the patient on the gynaecological bed in the Lithotomy position, and place the metal ring at the vaginal entrance. Then insert the GynoLaser handpiece which is covered by the sterile external slide into the vagina until the tip contacts the uterine cervix. The external slide will remain fixed while the tip is rolled six time (360°) for 6 shots in the one vertical position.

After the first laser shot, turn the handpiece clockwise 60° and fire a second shot. Repeat this until six shots have been fired in the one vertical position.

Next, withdraw the handpiece 1cm towards the entrance of the vagina (away from the cervix). Exact centimetre marks are on the handpiece to ensure accuracy. Repeat the process of firing six shots in this position, rotating the handpiece 60° after each shot.

Repeat this process, withdrawing the probe in 1cm steps, until the entire length of the vagina has been treated.

Suggested Protocol for Lotus GynoLaser Treatment

Emission Mode	Power	DOT Dwell	DOT Spacing	Smart Stack	Note
DP	40	1000	1000	1	If the patient reports an unacceptable level of discomfort (most likely close to the vaginal introitus area), reduce the power to 30W and if still sensitive, reduce it to 20W.

Second and Subsequent Treatment Sessions

Studies have demonstrated that treated vaginal mucosa show signs of 'rejuvenation' within 30 to 40 days of the initial Lotus GynoLaser treatment. This is evident from improved hydration in the connective tissue (verified from biopsy material) and significant thickening of the epithelium. This indicates that the vaginal tissue is ready for more intense treatment that will provide deeper stimulation. A stronger protocol can be used for second and subsequent treatments.

Pre-Menopause Patients

There may be women who wish to undergo Lotus GynoLaser treatment as a preventative measure in order to maintain vaginal health through menopause. In this situation, based on the condition of the vaginal mucosa, a stronger protocol may be appropriate from the intial treatment.

Possible Side Effects and Post-Treatment Indications

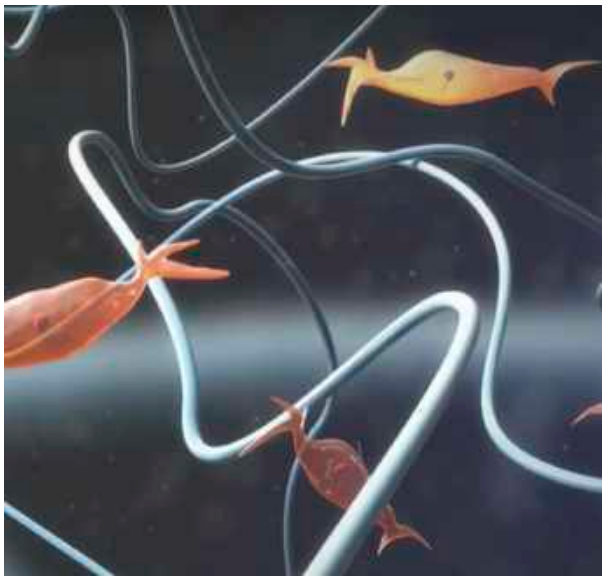
Only a small percentage of patients are docmented as having reported transitory side-effects, such as slight reddening or light swelling immediately after a treatment session. These normally resolve in a day or two of rest.

The following may rarely occur:

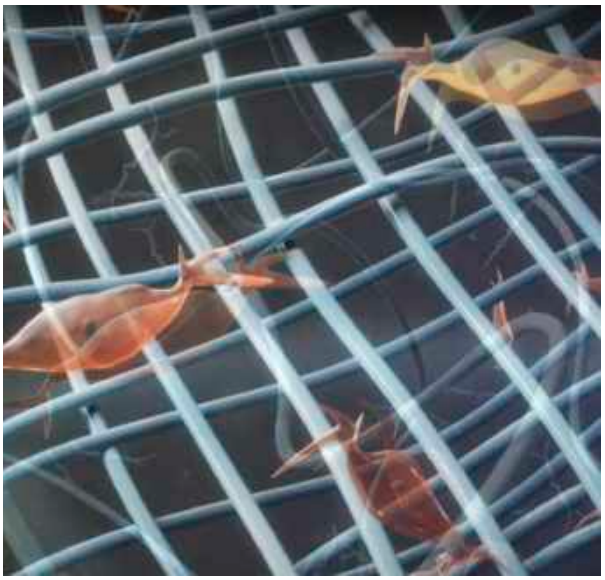
- Increased vaginal secretions during the first 2-3 days after treatment.
- Slight blood leakage: this normally resolves within 24 hours after treatment, and does not require any additional form of intervention.
- Some patients may have lower immune defences than normal, for a variety of reasons. In such cases, an immune response to the inflammation induced by the treatment may be more evident than normal, and may lead to some swelling of the inguinal lymph nodes. The patient should be made aware of this possibility as part of pre-treatment briefing.

Post-Treatment Care

- No topical post-care is required for vaginal treatment.
- The patient should be instructed that any pain, heat or swelling in the treatment area, fever or general malaise, should be reported immediately to the clinic.
- After treatment, patients should wear loose underwear made of natural fibres. Tights and tight-fitting trousers whould be avoided to allow the treated area to breathe as much as possible.
- Patients should also avoid hot baths, lifting heavy weights and strenuous exercise for a week after treatment.
- It is best to avoid sexual intercourse for a week after treatment.



Pre-treatment Fibroblast structure



Post-treatment Fibroblast structure

4b Urinary Incontinence Lotus GynoLaser Treatment

Preliminary Consultation and Diagnosis

It is critical to take a full patient history and to correctly diagnose the patient's condition before proceding to treatment. It is also important to understand the patient's expectations of treatment, and to explain how the treatment works and the outcome the patient can expect. The patient should sign the informed consent form (Appendix 1) after the consultation and reading the patient information sheet.

Contraindications for Treatment

- Any local or systemic disease, in situ infectious and/or inflammatory process (urogenital tract) in acute of recurrent stage, such as candidiasis, chlamydia, genital herpes, gonorrhoea or any condition diagnosed as vaginitis. Any active disease needs to be successfully treated with an appropriate therapy according the specific diagnosis.
- Vulvar dermatosis in active stage (psoriasis, seborrheic dermatisis, lichen planus). This also needs to be successfullt treated with the appropriate therapy before proceeding with treatment.
- In situ lesions with potential neoplastic and neoplasia evolution (vulvovaginal area and neck of the uterus), such as lichen sclerosus, squamous cell hyperplasia, HPV lesions, fibromi, VIN, CIN, etc. Any such conditions must be successfully treated before proceeding with Lotus treatment.
- Any erosion adverse effect post-TVM (trans-vaginal mesh) surgery.
- Abnormalities / cell changes noted in last PAP smear or Cervical Screening Test
- Any degree of pelvic organ prolapse ≥ II (ICS POP-Q staging system).
- Mensus (wait 1 week after end of menstrual period), pregnancy, 3 months post-pregnancy or breast-feeding.

Cautions

- Treatment of oncologic patients: because of the compromised immune defences of patients who have undergone chemotherapy and/or radiotherapy, Lotus GynoLaser treatment may lead to more severe inflammatory reaction than usual. For this reason

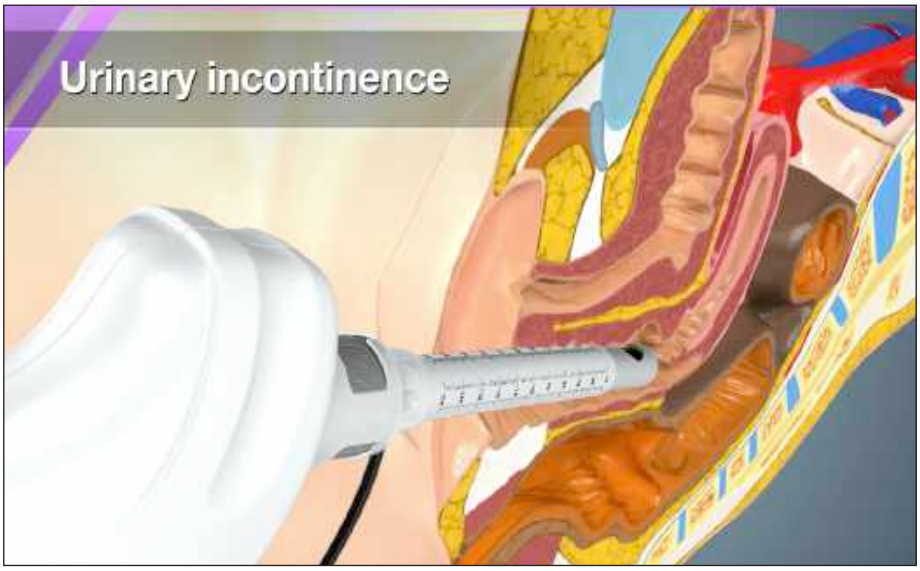
is it advisable to wait 6 months after the end of chemotherapy or radiotherapy before treatment with Lotus GynoLaser. When treatment does proceed, the patient should be informed of the possibility of swelling of the inguinal lymph nodes, to avoid unnecessary concern if this does occur.

- Pelvic floor surgery: Depending on the severity of the prolapse being treated and the nature of the surgical treatment performed, it is advisable to wait for an extended period (approximately one year) before considering Lotus GynoLaser treatment, in order to allow the region to stabilise fully.
- Patients with a history of genital herpes virus infection: We recommend that a course of appropriate antiviral drugs should be commenced 6 days before Lotus GynoLaser treatment, and should continue for 5-15 days after treatment.
- Anticoagulant medication (e.g., acetylsalicylic acid, heparin, etc.): Treatment with Lotus GynoLaser should not commence while the patient is taking these drugs, nor until its effect has expired (the timing will depend on the specific drug).

Treatment

Urge urinary incontinence is caused by an uncrollable detrusor. In order to stimulate the detrusor, the urinary incontinence tip is used. A 45° flat mirror delivers the laser. It is designed to strengthen the upper part of the vaginal muscle by stimulating the vaginal mucosa in that area.

Position the ring at the entrance to the vagina as per the intravaginal treatment instructions. Insert the urinary incontinency GynoLaser handpiece with the external slide as deeply as possible. One shot only is radiated at each position, towards the top of the vagina. Once the shot has been fired, retract the probe by 1cm and repeat until the full length of the vagina has been treated.



Second and Subsequent Treatment Sessions

Studies have demonstrated that treated vaginal mucosa show signs of ‘rejuvenation’ within 30 to 40 days of the initial Lotus GynoLaser treatment. This is evident from improved hydration in the connective tissue (verified from biopsy material) and significant

thickening of the epithelium. This indicates that the vaginal tissue is ready for more intense treatment that will provide deeper stimulation. A stronger protocol can be used for second and subsequent treatments. The same procedure should be followed as for the first session.

Although changes in the vaginal epithelium will occur from the first treatment, an optimal outcome will be achieve by performing a complete cycle of at least three sessions at intervals of 30-60 days. The number of sessions will depend on the degree of vaginal laxity or atrophy being treated. One or two sessions about a year after the end of the treatment cycle will assist in maintaining the results achieved.

Pre-Menopause Patients

There may be women who wish to undergo Lotus GynoLaser treatment as a preventative measure in order to maintain good urinary continence throughout menopause and beyond. In this situation, based on the condition of the vaginal mucosa, a stronger protocol may be appropriate from the intial treatment.

Possible Side Effects and Post-Treatment Indications

Only a small percentage of patients are docmented as having reported transitory side-effects, such as slight reddening or light swelling immediately after a treatment session. These normally resolve in a day or two of rest.

The following may rarely occur:

- Increased vaginal secretions during the first 2-3 days after treatment.
- Slight blood leakage: this normally resolves within 24 hours after treatment, and does not require any additional form of intervention.
- Some patients may have lower immune defences than normal, for a variety of reasons. In such cases, an immune response to the inflammation induced by the treatment may be more evident than normal, and may lead to some swelling of the inguinal lymph nodes. The patient should be made aware of this possibility as part of pre-treatment briefing.

Post-Treatment Care

- No topical post-care is required for vaginal treatment.
- The patient should be instructed that any pain, heat or swelling in the treatment area, fever or general malaise, should be reported immediately to the clinic.
- After treatment, patients should wear loose underwear made of natural fibres. Tights and tight-fitting trousers whould be avoided to allow the treated area to breathe as much as possible.
- Patients should also avoid hot baths, lifting heavy weights and strenuous exercise for a week after treatment. It is best to avoid sexual intercourse for a week after treatment.

4c Vulvar Lotus GynoLaser Treatment

Vulvar treatment with Lotus GynoLaser has two main indications:

- Vulvar atrophy
- Vulvar whitening

For both of these indications, use the vulva tip, which delivers the laser shot directly to the vulva.

Preliminary Consultation and Diagnosis

It is critical to take a full patient history and to correctly diagnose the patient's condition before proceding to treatment. It is also important to understand the patient's expectations of treatment, and to explain how the treatment works and the outcome the patient can expect. The patient should sign the informed consent form (Appendix 1) after the consultation and reading the patient information sheet.

Contraindications for Treatment

- Any local or systemic disease
- Any active infection (candidiasis, Herpes Genitalis, etc.)
- Mensus (wait for one week after completion of menstrual period), pregnancy, the three months following pregnancy or breastfeeding
- A history of radiation to the vaginal or colo-rectal tissue

Cautions

- **Treatment of oncologic patients:** because of the compromised immune defences of patients who have

undergone chemotherapy and/or radiotherapy, Lotus GynoLaser treatment may lead to a more severe inflammatory reaction than usual. For this reason is it advisable to wait 6 months after the end of chemotherapy or radiotherapy before treatment with Lotus GynoLaser. When treatment does proceed, the patient should be informed of the possibility of swelling of the inguinal lymph nodes, to avoid unnecessary concern if this does occur.

- **Pelvic floor surgery:** Depending on the severity of the prolapse being treated and the nature of the surgical treatment performed, it is advisable to wait for an extended period (approximately one year) before considering Lotus GynoLaser treatment, in order to allow the region to stabilise fully.
- **Patients with a history of genital herpes virus infection:** We recommend that a course of appropriate antiviral drugs should be commenced 6 days before Lotus GynoLaser treatment, and should continue for 5-15 days after treatment.
- **Anticoagulant medication** (e.g., acetylsalicylic acid, heparin, etc.): Treatment with Lotus GynoLaser should not commence while the patient is taking these drugs, nor until their effect has expired (the timing will depend on the specific drug).

Preparation

This procedure is minimally invasive, and does not require any sedative anaesthetic. No incisions or stitches are required and a session normally takes 10-15 minutes. The patient should ensure the area is shaved or waxed prior to presenting for treatment.

Prepare the patient by applying a topical anaesthetic to the area and allow the required incubation period. After the required incubation period, remove the topical anaesthetic and thoroughly clean the area. Using a few large cotton (mouth) swabs, clean and dry the vulval area and the vagina to removel all secretions and moisture.

Treatment

Position the patient on the gynaecological bed. Select the correct protocol for the Lotus GynoLaser vulval treatment. Suggested protocols are as follows:

Treatment	Emission Mode	Power	DOT Dwell	DOT Spacing	Smart Stack
Vulvar Rejuvenation	DP	24	400	1000	1
Vulvar Whitening	DP	10	200	200*	1

*Larger DOT spacing should be used for darkest phototypes.

Perform the treatment on the entire vulvar area delimited by the mons pubis above and the perineum below as shown in the image on the right. This includes the labia majora and labia minora. Move over the labia from top down and from left to right wihtout missing any points, but ensuring you avoid the urethra.

Possible Side Effects and Post-Treatment Indications

Most patients report only transitory side effects, such as slight reddening or light swelling immediately after a treatment session. These normally resolve within a few days.

Post Treatment Care

Daily care of the treated area is essential to ensure optimal results and proper healing, to prevent the formation of scabs and to guarantee appropriate skin cleanliness, thereby minimising any risk of infection.

- Post-treatment cleanliness: The area should be cleaned 2-3 times per day (including after showering) as follows: gently and thoroughly cleanse the skin with sterile gauze and saline solution, then apply emollient and/or antibiotic ointment. This regime should continue until clinical healing is observed (approximately 4-7 days). Following this, an appropriate moisturise can be used.

- Bathing: The patient should wait one day before showering or having a bath, and hot water should be avoided until the healing process is complete.

- Physical activity: The patient should avoid lifting heavy weights or doing intense physical exercise for 3-4 days following the treatment.

- Sexual intercourse: This should be avoided for a week after treatment.

- Clothing: Patients should wear loose-fitting underwear made of natural fibres. Tights and tight-fitting trousers should be avoided in order to allow the treated area to breathe as much as possible. This facilitates healing.

Treatment Regime

Visible results should be seen after the first session, but for optimal results, patients should be advised to undergo a full cycle of 4-5 sessions for vulvar rejuvenation, or 2-3 sessions for vulvar whitening. The sessions should be spaced at 30 to 60 days, but this is flexible, depending on the patient's circumstances.

One to two maintenance sessions a year after the end of the treatment cycle will help to maintain the results.