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# JETT PLASMA For Her II

## Instruction for Use

R<sub>X</sub> Only

CE<sub>1023</sub>

Manufactured by the company **COMPEX, spol. s r.o.** in the Czech Republic.

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## 1. General information

Prior to using the JETT PLASMA For Her II device, you must read, understand and follow all the safety and security precautions described in this Instruction for Use. Observe all safety instructions during the treatment. Be all the time advised about appropriate indications and contraindications, when using the JETT PLASMA For Her II device.

The JETT PLASMA For Her II device may be operated only by the physician provably trained by the manufacturer or the authorized distributor or by the person who may work with the medical devices in conformity with the national legislation and treat the indication shown in sec. 3.3.1, within the scope of the Instruction for Use, who has been familiarized well with the commonly known risks and with the benefits of using thermal stimulation of the treated area. This trained person may further train other physicians or medical staff within his/her workplace in accordance with the national legislation. Disinfection and sterilization of the device and its accessories may also be performed by a nurse trained by a physician. A written record must be kept about each passed training.

JETT PLASMA For Her II is a portable DC electrocautery. It is a medical device intended for gynecological indication, which operates on the physical principle of direct current, which performs membrane depolarization and reversible electroporation and thermal stimulation.

Prior to first putting the device into operation the TAPE calibration has to be performed (see sec. 5.2 – Commissioning and operation)!

JETT PLASMA For Her II may only be operated with the supplied XP Power ACM18US05 adapter.



Prior to putting the JETT PLASMA For Her II device into operation, be so kind and read these instructions carefully and thoroughly. Observe all cautions and warnings contained herein.

## 2. Pack contents

### 2.1 Standard contents

**JETT PLASMA For Her II** with holder for  
Plasma Pen III/G



**Instruction for Use**



**Plasma Pen III / G**



**Connection cable for G-Applicators**



**G-Applicator 30 mm**



<b>G-Applicator Wave</b>	
<b>2x Flat applicator 10 mm</b>	
<b>Maquette of G-Applicator 30 mm</b>	
<b>Connection cable for cylinder electrode</b>	
<b>Curly connection cable for disposable electrode</b>	
<b>Network adapter with relevant end piece</b> XP Power ACM18US05	

**Extension cable for the network adapter**



**Cylinder electrode**



**20 pcs of disposable CE electrodes**

4 pcs of electrodes in a pack

HRTR59BP

50x94 mm



**Foot switch**



**Rechargeable battery**

NR18650-30Q, napětí 3,6 V, 24 000 mAh



## 2.2 Optional accessories

**Maquette of G-Applicator 20 mm**



**G-Applicator 20 mm**



**THE DEVICE MAY BE USED WITH ORIGINAL ACCESSORIES ONLY PROVIDED BY THE MANUFACTURER!!!**

The device is intended for repeated use marketed in a non-sterile state. The accessories, ie G-Applicators and Flat Applicator, are intended for single-patient use and supplied in a sterile state.

### 3. Purpose of use

JETT PLASMA For Her II is a medical device intended to a rejuvenation of the tissue in the vulvovaginal area to mitigate, treat or prevent disease. The device based on the physical principle of direct current performs membrane depolarization, reversible electroporation and generates heat, which activates the formation of a new collagenous connective tissue that breaks down and replaces the old tissue. A stronger and more elastic fibrous structure is formed and tissue rejuvenation occurs.

#### 3.1 Treatment

For vulvovaginal laxity treatment, an intensity setting of 1 is used and then is gradually increased according to the patient's tolerance. The treatment is based on the physical principle of heat, which is generated by direct current. The maximum temperature does not exceed 45 °C, so the treated tissue is not damaged. The effect of heat on the tissue allows the tissue to be restored, firmed and improved, and it also strengthens the tissue's resistance and defenses. The cells of the mucosa contain channels that serve to pass water, anions and cations, the aging of the cells leads to the closure of these channels and insufficient exchange of sodium and potassium ions. A direct current is used to open these channels by membrane depolarization. There is also a low-threshold electrical electroporation.

The temperature of 45 °C must not be exceeded, which is achieved by a trained person by controlling the temperature by a touch thermometer.

It is recommended to undergo the treatment 3 times, with a time interval of 10-14 days between treatments. The average period of the treatment is about 15-25 minutes (15 minutes vagina treatment and 10 minutes vulva treatment standardly).

After treatment, it is recommended to avoid sexual intercourse and a sedentary bath or swimming in the pool for 5 days. After the treatment, you can use over-the-counter products that are used intravaginally (tampons and others).

#### *Example of treatment*

*In the case of the treatment vulvovaginal laxity the G-Applicator 30 mm, the G-Applicator Wave or the G-Applictor 20 mm is used. The treatment using JETT PLASMA For Her II is performed in the treated area - vaginal mucosa. We use an indifferent conductive gel that is applied to its end and surface before inserting the G-Applicator into the vagina. This achieves excellent applicators electrode contact with the wall of the vagina. After insertion into the vagina, the device is turned on and the intensity 1 is set (the intensity may be increased according to the patient's comfort) and the front and rear vagina walls are treated for 15 minutes by gradually inserting and withdrawing the G-Applicator in the vagina. After the set time has expired, the device is switched off and then the G-Applicator can be taken out of the vagina safely. The DC increases kinetic activity of ions in the cells. The increasing kinetics and oscillations of ions in the cells induce a thermal effect. This leads to rejuvenation of the treated tissue.*

### **3.2 Action on the tissue**

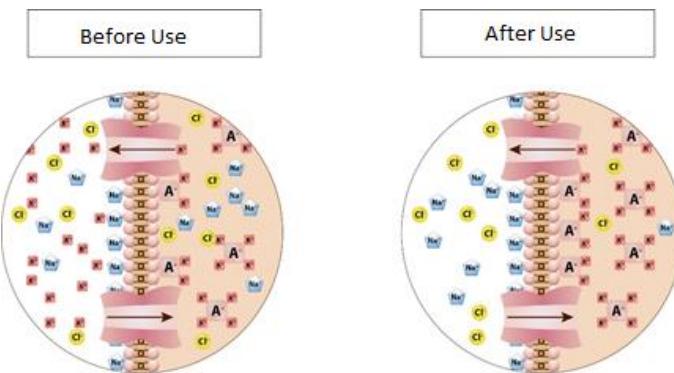
The therapeutic effects are achieved by means of direct current which performs membrane depolarization, reversible electroporation and generates heat. Direct current, like other heat sources, triggers collagen activation and strengthens the tissue structure.

Because of the passage of direct current, energy is released when it collides with mucosal cell molecules, and tissue-absorbing molecules vibrate. This results in an increase of the tissue temperature. The electric current that passes through the circuit is caused by the movement of electrical charges performing the work. Because of the interaction of electrons with the lattice, their kinetic energy is converted into heat. In this way, the mucosa and skin are heated to a maximum safe temperature of 45 ° C (higher temperatures can not be reached by this method) and thus a specific reaction mechanism is triggered.

#### **Depolarization of cell membranes**

Each cell has a membrane potential on its membrane (difference of electrical potential between two membrane sides). There is a negative charge on the inside of the cell membrane and the positive charge on the outside. Ageing of the skin results in uneven distribution of the electrical charge (potential) across the cell membrane and, thus in change of the electrical voltage of the membrane.

The membrane potential is generated and further affected by potassium and sodium cations, the sodium cations pass through the cell membrane with great problems only, while the potassium cations penetrate very easily.



The direct current, passing through the cells, leads to change in the membrane potential (membrane depolarization). Depolarization results in change of positions of individual types of ions possibly their passage through the membrane. By correctly distributing the ions on the inner and outer sides of the membrane, the membrane potential will again be stabilized. Electrical voltage of the cell membrane is increased and the membrane is stretched. If this process occurs in the majority of skin cells in a particular area, then tissue stretching can be visible by the naked eye.

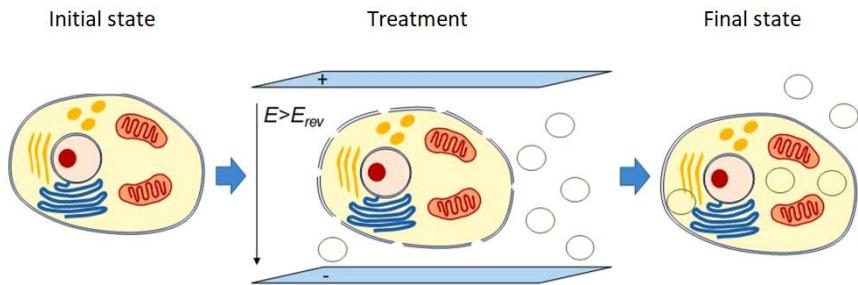
Other electrocautery devices utilizing alternating current are unable to depolarize the membrane, because effects of the alternating current on the cell are either irritating, trophic or analgesic (the effect depends on the used frequency and intensity) and not depolarizing, because the alternating current is unable to pass through the cell membranes.

1. Significant increase in concentration of type I collagen.
2. Increase in extracellular  $\text{Na}^+$  concentration.
3. Increase in intracellular  $\text{K}^+$  concentration.
4. Increase in chemotaxis.
5. Increase in growth factor level and increase in NO (nitric oxide) concentration.
6. Proved increase in migration of fibroblasts and their proteosynthesis.
7. Increase in skin permeability and reduction of the skin barrier function for penetration of the positively charged ions or water-soluble compounds.

8. New orientation of the newly generated or formed collagen fibres in the direction of the DC current.

### Low threshold reversible electroporation

When the cell is exposed to an extreme electric field under a pierced channel in the gel, the cell membrane is depolarized. The ion channels open and the ions move between the both media. When a certain threshold value of the membrane voltage is exceeded, new randomly distributed additional channels are generated alongside the existing ion channels, as a result of the increased electrical intensity.



The molecules can penetrate through these channels inside and outside the cell for which the membrane is impermeable for normal state. Movement of substances through these channels is uncontrolled. Due to all these phenomena, water gets inside the cells and leads to their recovery and regeneration. Cells are conditioned for activity.

The electroporation effect associated with cell membrane depolarization is determined by a local increase in electrical intensity at the point of breakdown of the gel between the applicator and the vulvovaginal mucosa. The change that occurs in the process is characterized by values of electric intensity at the lower edge of the common values used in medicine (5 kV DC). As mentioned, this type of electroporation has a significant impact on the effective outcome of the procedure.

### 3.3 Indications and contraindications

#### 3.3.1 Indications

##### **Vulvovaginal laxity**

Vulvovaginal laxity - in the vulvovaginal area the pelvic muscles become weak, the syndrome of relaxed vaginal walls occurs. Vulvovaginal laxity is mainly due to vaginal delivery, aging or hormonal changes during or after the menopause, as well as insufficiently moistened vagina, burning and itching in the vaginal entrance, yeast infection and inflammation. Incontinence is also a consequence of changes in the

intimate parts of the woman, and, last but not least, the worsening of sexual life due to vaginal dryness and irritability, reduced tightness, elasticity and sensitivity.

### 3.3.2 Contraindications

The trained operator is obliged to make sure provably that the patient to be treated does not suffer from any of the following contraindications, which fact is subject to recording (the Informed Consent):

- pacemaker, Holter ECG monitoring system,
- another implanted electrical device,
- epilepsy,
- pregnancy,
- metal implants in the treated area (including intrauterine device)
- skin diseases or inflammations in the treatment area,
- urinary tract infection,
- collagen vascular disease,
- oncological disease in vulvovaginal region,
- menstruation,
- any untreated/badly treated disease in vulvovaginal region,
- birth defects of vagina,
- stenosis and strictures of vagina,
- synechia of vulva.
- virgin women

The treatment is not limited to a certain period of the cycle, except for menstruation, when the treatment can not be performed.

For the evaluation of contraindications, a gynecological examination not older than 1 year, including cytology, is necessary.

### 3.3.3 Profil of a patient

The JETT PLASMA For Her II is intended to be used, after excluding the above stated contraindications, for women suffering from vulvovaginal laxity, mainly women after vaginal delivery peri and post menopausal women. Treatment may be performed only after the puerperium and it is recommended to perform it one year after vaginal delivery. The treatment can be performed independently of breastfeeding and is also suitable for a woman who is planning another giving birth. The treatment is recommended for women from 18 years of age. There is no upper age limit.

### 3.3.4 Possible side effects

Like all treatments, this medical device can have side effects, but may not occur with everyone.

The following side effects may occur when using JETT PLASMA For Her II:

- temporary vaginal tingling and/or numbness, to minimize them it is necessary to use an ultrasonic gel,
- temporary painful cramps and cutaneous depressions, to minimize the risk, it is important to follow the treatment time according to the treatment protocol. In addition, do not treat patients with contraindications.
- increased urinary tract problems, to minimize the risk, it is important to follow the treatment procedures.
- pain, erythema and edema, to minimize them it is necessary to use a ultrasonic gel and keep procedural recommended treatment time.
- burn, scarring, bruising and ecchymosis, to minimize them it is necessary to use an ultrasonic gel and keep procedural recommended treatment time. Don't stay in one place for too long.
- dyspigmentation, hyperpigmentation, to minimize them it is necessary to use an ultrasonic gel and keep procedural recommended treatment time. Don't stay in one place for too long.

#### 4. Warnings and precautions

Safety instructions in this part of the Instruction for Use as well as in its other parts.

##### 4.1 Introductory precautions

Protect the device from falls and shocks to avoid damage of the device.

Do not use the accessories other than those delivered by the manufacturer.

All parts of the device must be connected in their designed precise positions.

Do not plug the device in greasy, smoky, humid or dusty environments and at the places where the device could get into the contact with water.

Follow the recommended treatment time and treatment method.

If a patient reports any unusual feelings during the treatment, interrupt the treatment immediately and contact the manufacturer!

Bend neither the supply cable nor other accessories by force and do not place any heavy or sharp things on them (danger of fire or electric shock).

Do not plug more electric devices into one power source (danger of fire).

Check the designed power source prior to plugging the device. If the power source other than recommended one is used, network adapter can be damaged or fire ignited.

Never leave the high voltage on unattended above the device applicator position, unwanted approach or touch could result in patient or operator injury, fire or explosion of flammable vapours.

Occurrence of an incident or suspicion of an adverse event shall be reported immediately to the dealer or manufacture.

#### 4.2 Warning messages on device display

**The battery is running low**

Rechargeable battery INR18650-30Q, voltage 3.6 V, 24 000 mAh is discharged, connect the device to the network for charging.

#### 4.3 Error messages on device display

**Device internal error**

The device is not possibility to use and have to be sent to the manufacturer.

**The accessory is not connected or wrong accessory is connected**

Make sure you have the accessories connected or that the accessories do not belong to the device other than JETT PLASMA For Her II. If the message still appears after connecting the correct acessories – send the device to the manufacturer.

**Change the battery**

Battery INR18650-30Q, voltage 3,6 V, 24 000 mAh is damaged or has reached the end of its service life. Order a new battery from the manufacturer (the battery is user replaceable)

**The foot switch is not connected**

The foot switch is incorrectly connected or is not working. Check the foot switch connections. If the error still appears, send the device to the manufacturer.

#### 4.4 Warnings following from use of the device

**Original accessories**

JETT PLASMA For Her II may only be used with original accessories from the manufacturer. Using other than original accessories (adapter, applicators, connecting elements) could cause injury and damage the device.

**Correct treatment**

The trained operator may treat the permitted areas only (see Indications). It is permitted to use the device only within the scope of the Instruction for Use and training. Otherwise there is the risk of tissue damage and injury.

**Replacement of the applicator tip, Plasma Pen III/G, G-Applicator**

When replacing the applicators, the JETT PLASMA For Her II device must be disconnected demonstrably. There is a risk of burns to the operator.

#### **Plasma Pen III/G**

In case of damage anywhere on the connection cable (insulation is broken), it must be sent to the manufacturer.

#### **Connection cable for G-Applicator**

In case of damage anywhere on the connection cable (insulation is broken), it can not be used and it have to be replaced.

#### **G-Applicator**

In the case of sterile packaging is damaged it is forbidden to use it without performing the higher disinfection.

#### **Flat applicator 10 mm**

In case of sterile packaging is damaged it is forbidden to use it without performing the higher disinfection.

#### **Work with network adapter**

Do not pull cable of the adapter by force and do not touch it with a wet hand. There is the risk of electric shock.

#### **General risks**

In case of a thunderstorm, lightning or earthquake, stop work with the device immediately and disconnect the network adapter (risk of fire or electric shock).

#### **Risk of explosion or fire**

Do not use the device in locations where flammable substances such as anaesthetics, flammable disinfectants, alcohol, gas or solvents can be present. We recommend using non-volatile compounds, if possible. If any volatile, flammable substance is used on the patient, then it is necessary to wait until possible flammable vapours are vented away.

Energy is so high that it can ignite even other combustibles such as paper, textiles as well as oils or flammable creams (e.g. paraffin wax), etc., both on the patient and anywhere in the neighbourhood, if safe handling is not observed.

#### **Danger of electromagnetic interference**

Do not use the device in close proximity to other electronic and electrical devices as there is the risk of mutual electromagnetic interference.

#### **Written approval, staff training**

**The device may be used only by demonstrably trained doctors or by the staff as permitted by the national legislation! The operator must not have a pacemaker, Holter ECG meter or other implanted electrical device!**

Before each treatment, the trained staff must make sure that the patient does not suffer from any contraindication, and the informed consent must be filled in by the patient. Training of the operators is provided either by the manufacturer or by the authorized distributor. The trained staff receives a certificate authorizing its holder to work with JETT PLASMA For Her II device. The trained staff must make sure that no untrained person will work with the device in the workplace. The person trained by the manufacturer or by the distributor may train other persons on the relevant workplace.

**The trained staff must permanently follow the working procedures set by the manufacturer and must avoid the following safety risks.**

#### **Special attention of the staff**

The device is able to achieve a current density of up to 4.3 mA / cm<sup>2</sup> and requires special attention of the operator.

This current density corresponds to a safe current through the patient of max 2 mA. This current density, as calculated in the clinical trial, causes a maximum heating of  $\Delta T = 8,3$  °C from the standard body temperature and is therefore absolutely safe for the patient. Higher current densities cannot be achieved because they are bound to a double control in the device which does not allow patient current to exceed 3 mA.

#### **Plasma Pen III/G connector**

Never use a device with an unlocked or damaged connector. There is a risk of further damage or fire!

#### **Foot switch connector**

Never use a device with a damaged connector; there is a risk of uncontrolled starting of the high-voltage generator!

#### **Connecting of connection cable**

Always connect the patient connection cable to the device before connecting the patient or giving her cylinder electrode. On the contrary, always disconnect the patient before disconnecting the cable from the device. Otherwise, if the connection connector falls into a liquid or humid environment, the patient may be injured by electric shock!

#### **Use of a high-frequency surgical device**

Simultaneous use of a high-frequency surgical device with a JETT PLASMA For Her II device on a patient may cause burns and damage the device.

## 4.5 Precautions following from use of the device

### **Skin protection from electric discharge**

A sufficient layer of indifferent conductive gel must be applied to the application area. The application tip must be led by the trained operator in the application gel.

### **Patient-device connection**

Before starting treatment, the patient must be connected by a disposable CE electrode. This electrode is stucked by the operator as close as possible to the treatment area – it is forbidden to stick it on the back, chest, head, eyes and front of the neck or by using a cylinder electrode (if the patient's self-adhesive electrode is uncomfortable). Wrong electrode application may increase the risk of cardiac fibrillation! Alternatively using a cylinder electrode (if disposable electrode is uncomfortable to patient) which patient have to hold firmly throughout the treatment. The patient's hand is moistened with a cloth for better conductivity before inserting the cylinder electrode into the hand

### **Do not touch active area**

Neither the operator nor the patient should touch the active area during application.

### **Do not touch the patient**

The trained staff may not touch the patient conductively. If there is a need to touch the patient's skin, a non-conductive rubber glove has to be used.

**Before the first use and after each use, the device, the Plasma Pen III/G and the cylinder electrode must be cleaned and disinfected properly. Otherwise, there is a risk of infection!**

**After using the G-Applicators and the Flat Applicator, it is necessary to perform a higher disinfection. Otherwise there is a risk of infection!**

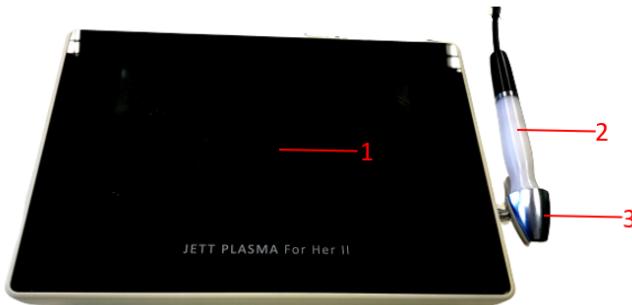
### **Cleaning the device and the Plasma Pen III/G**

Neither the device or Plasma Pen III/G is waterproof. It must not be exposed to excessive moisture or liquid flow.

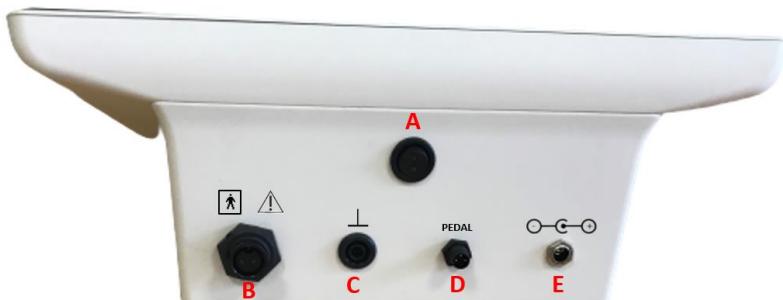
## 5. Device control

### 5.1 Device description

Before each start-up, carefully check the condition of the power adapter, the electrode with the connecting cable and the condition of the device, including the applicators. If you encounter a malfunction, do not operate the unit and contact the manufacturer.



- 1) Touch screen
- 2) Plasma Pen III/G
- 3) Plasma Pen III/G holder



- A) ON/OFF switch
- B) Socket for Plasma Pen III/G
- C) Socket for connection cable for patient device connection
- D) Socket for foot switch
- E) Socket for network adapter

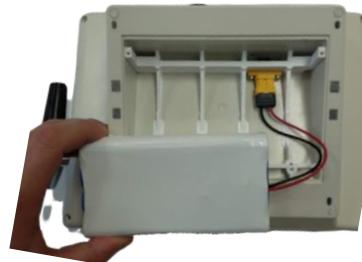
## 5.2 Commissioning and operation

JETT PLASMA For Her II is powered by a rechargeable battery or included network adapter to charge the battery. To charge the battery, plug the adapter to the network 100-240 V, 47/63 Hz and the other end into the JETT PLASMA For Her II socket.  The JETT PLASMA For Her II device can also be used while the battery is charging. Before using of device connect all accessories to each connector on the back panel of the device. The Plasma Pen III/G or G Applicator connector must be locked by turning union nut clockwise. To disconnect the Plasma Pen III/G or G-Applicator connector is necessary to disconnect the connector by turning the union nut counter-clockwise and then pull out the connector.

### a) Connection and replacement of the battery

Connect the battery before the first use of the device. Using a PH1 screwdriver, unscrew the battery cover and connect the battery using the connector. Insert the battery into the device and put back and screw the battery cover.





b) Turn on the device and setting the treatment parameters

The device is switched on using the switch on the back of the device. After switching on, touch the GYNECOLOGY symbol to access the treatment settings.

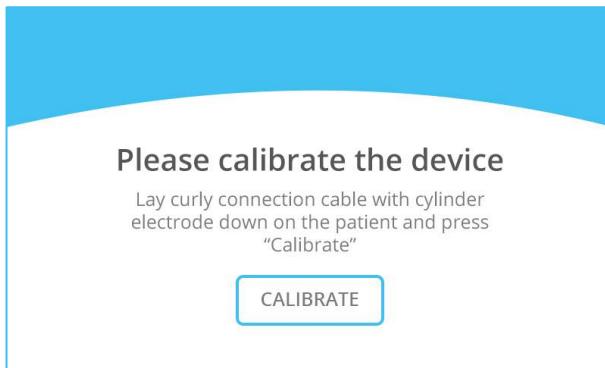


It is possible to switch to another language variant using the gear wheel.

c) TAPE CALIBRATION

TAPE calibration is required to correct patient and device connection (if the device is powered by a battery without charging, calibration should be performed before each treatment).

Connection cable lay on the patient in a way that the terminal of connection cable should not touch the patient conductively. Now calibrate the device with calibrate button.



After TAPE calibration, on the screen you will see a notification for setting of intensity and duration of treatment. If it is necessary the patient connection calibration can be repeated by clicking on the symbol 

d) Patient device connection 

Once the patient is ready for treatment, the patient must be galvanically connected to the JETT PLASMA For Her II using the connection accessories:

- **disposable electrode** - it is necessary to clean the site before application; its use is recommended for one treatment only; store the unused electrodes in the original sealed packaging. The disposable electrode must be stucked as close as possible to the area to be treated - on the thigh or abdomen, it is forbidden to stick to the back or chest.
- **cylinder electrode** – has to be held firmly in the hand. Cylinder electrode is used only in the case when the disposable electrode is unpleasant to the patient.

Plug the connection cable connector into the socket of device  and the other end to electrode. The correct patient device connection is indicated by

symbol . If the symbol flashes on , check that disposable electrode does not peel off or rest on the patient's skin. Or that the cable has not been

disconnected or the patient has not released the cylinder electrode or has dry palm.

If it is necessary the patient connection calibration can be repeated by clicking on the symbol 

e) Intensity settings

Now it is possible to set the intensity of the treatment. Intensity selection is made on the touch screen. The intensity is set using the arrows. To select an intensity is made by touch the intensity on the circle on the screen (the circle will turn blue). After setting the intensity it is no possible to change the intensity. This function can be unlocked by touch the circle again with the selected intensity. The confirmed intensity is unlocked and the treatment is stopped by interrupting the patient's conductive connection with the device.

The treatment time can be set by touching the + and - symbols on the screen. Touch these symbols will change the time by 1 minute after a while holding by 10 min. The maximum set time is 40 min. The time is counted when the high voltage generator is switched on. When the patient is receiving current a green flash appears on the screen.



f) Switching on the high voltage

If the intensity of the device is set (Plasma Pen III / G lights orange), it is possible to activate the high voltage connection to the active area of the G-Applicator or flat applicator by pressing the footswitch and start the treatment. Plasma Pen III/G or the G-Applicators glows green when the patient is already receiving current and also there is a green flash on the screen



- g) Types of applicators
  - 1) G-Applicators  
G-Applicators (G-Applicator 20 mm, G-Applicator 30 mm and G-Applicator Wave) are designed for vaginal rejuvenation.
  - 2) Plasma Pen III/G  
The Plasma Pen III/G is used with a 10 mm flat applicator and is designed to treat the vulva.
- h) Termination of the procedure  
The procedure is terminated by releasing the foot switch and deselecting the instrument intensity setting.
- i) Replacing the Plasma Pen III / G with a G-applicator  
If necessary, the Plasma Pen III / G can be replaced with a G-Applicator and vice versa. This can be done by pulling the connector out of the socket and inserting the corresponding connector.
- j) Switching off the instrument  
After completing the procedure, turn the instrument off by the ON / OFF button. You can then plug it in to charge the battery.

### 5.3 Applicators and their use

Always ensure that **the device is switched off** before disconnecting the Plasma Pen III/G or in case of change of applicator otherwise there is a risk of electric shock.

#### a) G-Applicators for treatment of vulvovaginal laxity

G-Applicators are designed to treat vulvovaginal laxity. The G-Applicator is for single-patient and one series of treatments use only! At first, a sufficient amount of an ultrasonic

indifferent conductive gel must be applied on the Applicator surface and on its end. This ensures excellent contact of the Applicator electrode with the vagina wall. When inserted into the vagina, the device switches the intensity 5 or higher. The intensity is adjusted according to the patient's heat tolerance. To achieve the maximum comfort, safety and result of treatment, the following procedure has to be observed:

1. Applying the ultrasonic indifferent gel on the Applicator.
2. Inserting the G-Applicator into the vagina.
3. Withdrawing the Applicator to the beginning of the vagina - adjustment.
4. Adjusting intensity of treatment.
5. Start the treatment with the foot switch and slowly move the application roller back and forth - rejuvenation along the entire vagina depth (treatment duration approx. 10 minutes). The diode in the G-Applicator 30 mm (G-Applicator 20 mm) lights when the patient is receiving current.
6. Deactivate the device using the foot switch.
7. Rotating the application roll by 180°.
8. Commencement of treatment with the foot switch (pedal) and slow movement of the application roll here and there - rejuvenation all the entire vagina depth (treatment time - approx. 10 minutes).
9. Deactivating the device using the Play / Pause button.
10. Pulling the G-Applicator out and completing the procedure.

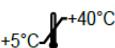
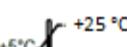
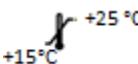
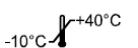
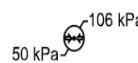
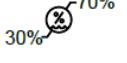
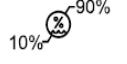
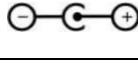
**b) Flat applicator 10 mm**

The flat applicator is intended for application on larger areas, in particular for treatment of vulvar laxity. These applicators move on the skin and mucous membrane covered with a conductive indifferent gel, and the cells are stimulated thermally by DC. The flat applicator 10 mm is intended for single-patient and one series of treatments use only. The applicator is replaced by pushing the head towards the body of the Plasma Pen III / G and withdrawing. Then simply push the new applicator into the Plasma Pen III / G head.

**c) Maquettes**

The maquettes are used by the doctors to test correct size and shape of the G-Applicator. When using the maquette, it is necessary to put a vaginal probe (or a condom) on it as a protection, which the ultrasonic gel is applied on, and then the maquette is introduced into the patient to test the size and adhesion in the patient's vagina.

## 5.4 Symbols on the cover of the device, on the device itself and on accessories

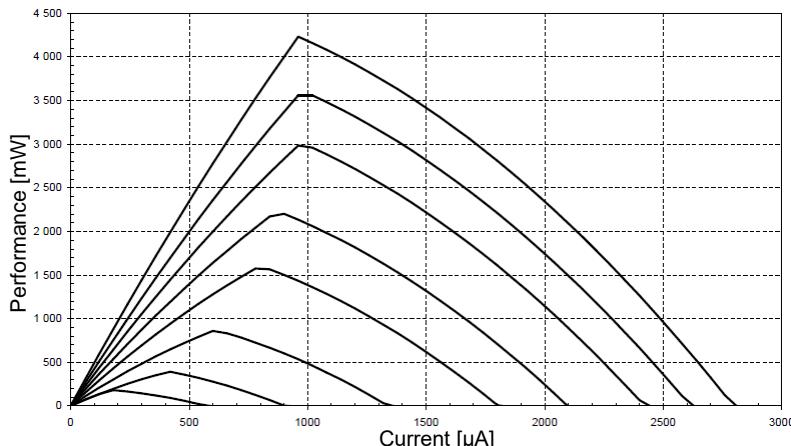
Graphic symbol	Meaning	Graphic symbol	Meaning
	Follow instructions in the Instruction for Use.		Galvanic connection with the device
	Manufacturer		Temperature range for use min. temperature +5°C, max. temperature +40°C
	Serial number		Temperature range for storage min. temperature +5°C, max. temperature +25°C
	Lot		Temperature range for storage of sterile G-Applicators and Flat applicators min. temperature +15°C, max. temperature +25°C
	Applicator of the BF type		Temperature range for transportation of the device, min. temperature -10°C, max. temperature +40°C
	Use by date		Pressure range, min. 50 kPa, max. 106 kPa
	Electric waste after expiry of the service life of the device may not be disposed of together with the municipal waste.		Restriction of humidity for use and storage of the device, min. 30 %, max. 70 %.
	Device of the class of protection II.		Restriction of humidity for transportation of the device, min. 10 %, max. 90 %, without condensation.
	Use indoors.		Protect from rain.
	Protection from a lightning.		Designation of the socket for connection of the network adapter
	Sterile		Designation of the Plasma Pen III/G or G-Applicator socket

	Designation of the galvanic connection socket		Caution (warning)
	Catalogue number		Designation of the socket for connection of foot switch
	Federal law restricts this device to sale by or on the order of a physician or of a person who may work with the MD in conformity with the national legislation.		

## 6. Basic characteristics

Class of protection against electric shock	II
Class of protection	IP20
Device type model	with the applied part of BF type
Power supply – external source (adapter) – built-in accumulator	5 V (DC), max. 2,5 A 3,6 V, 24 000 mAh (Li-Ion akumulátor)
Automatic battery charging	after connecting an external power supply
Battery charge status indication	bargraph on display
External power supply type (supplied accessories)	XP Power ACM18US05
Power supply input voltage	100-240 VAC
Power supply input frequency	47-63 Hz
Power supply input current	Max. 0,5 A
Power supply output	5 VDC, max. 2,5 A, 
No-load HV generator voltage	(1,2 – 5) kV (DC), (without detecting patient connection, the output voltage is zero – the HV generator cannot be turned on)
Output impedance of generator	600 kΩ (+5%)
Maximum power on applicator (plasma)	(0,2 – 4,2) W (impedance 4,6 MΩ)
Maximum output current (at output short circuit – applicator and indifferent electrode)	(0,6 - 2,8) mA (DC)
Time for safe tip voltage after shutdown	max. 7 s
Detection of patient connection	yes
Dimensions	275 x 100 x 183 mm
Weight	cca 1,7 kg

### Power characteristics of Plasma JETT PLASMA For Her II



## 7. Service life

Device	5 years
Network adapter	10 years
Plasma Pen III / G	2 years
Extension cable	2 years
G-Applicator 20 mm	3 higher disinfection *
G-Applicator 30 mm	3 higher disinfection *
G-Applicator Wave	3 higher disinfection *
Maquette of G-Applicator 20 mm	10 years
Maquette of G-Applicator 30 mm	10 years
Flat applicator 10 mm	3 higher disinfection *
Cylinder electrode	30 sterilization
Disposable electrode	See expiration date
Curly connection cable for disposable electrode	1 year
Connection cable for cylinder electrode	1 year
Connection cable for G-applicators	1 year
Foot switch	2 years

\* The applicators are supplied in a sterile state. The sterility of the supplied applicator is limited by the expiration date stated on the package.

The service life of the device and accessories is calculated from the beginning of their use. However, it does not apply to disposable electrodes, which have a manufacturer's lifetime.

**Any modification of the medical device JETT PLASMA For Her II is strictly forbidden!!!**

## 8. Storage, maintenance and safety technical inspections

### 8.1 Operating, storage and transport conditions

Operating conditions	the device may not be used in an environment where any combustible gases may be present, either in the primary form of gas or as fumes of flammable substances (see chapter 4.4 for further information; relative humidity 30-70 rel.%; at a temperature of 5-40 °C and atmospheric pressure of 50-106 kPa)
Storage conditions	store in the original package in well-ventilated indoor areas, outside direct light and humidity 30-70 % without condensation at +5-+25 °C, for sterile G-Applicators and Flat Applicators is the storage temperature +15-+25 °C, atmospheric pressure 70-106 kPa, the device is stored disconnected from the power supply
Transport conditions	transportation in the original package in a sheltered transportation vehicle, at the temperature of -10 °C - +40 °C and relative humidity of 10-90 %, without condensation; atmospheric pressure range 50-106 kPa

G-Applicators and the Flat Applicator are delivered in the sterile state and are labeled by the date of sterilization, date of expiry, and by the code of the person responsible for the accuracy of the data. When transporting and storing the sterilized applicators, the sterilization packaging is protected from damage by the transport packages.

### 8.2 Maintenance and cleaning

- Maintenance - the operator is obliged to observe all provisions of the Instruction for Use. It is not permitted to interfere with the device, all maintenance operations have to be performed by the manufacturer within the scope of the annual inspections.
- The device, Plasma Pen III/G, network adapter, extension cable, foot switch and connection cables have to be disinfected before the first use and after each application, using standard disinfectants (see sec. 8.2.2)! Cylinder electrode is necessary to sterilize before the first use and after each application (see sec. 8.2.3). G-Applicators and Flat applicator 10 mm is necessary to be disinfected after each application, using higher disinfection (see sec. 8.2.4)!

Products:	JETT PLASMA For Her II
ADVICE:	<p>Reprocessing procedures have only limited implications to a cylinder electrode and applicators. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device.</p> <p>In case of damage the device should be reprocessed before sending back to the manufacturer for repair.</p>

	<p>Chlorine-containing chemicals must not be used to clean / disinfect the device.</p>
Reprocessing Instructions	
Preparation at the Point of Use:	Before first use it is necessary to do cleaning and disinfection of the device, Plasma Pen III/G and accessories – see section 8.2.2, sterilization of cylinder electrode – see section 8.2.3 a TAPE Calibration – see section 5.2
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The device must be reprocessed in a disassembled state.
Pre-Cleaning:	Removal of visible surface contaminations with Bacillol® 30 Tissues
Cleaning:	Clean and disinfect the device with all accessories using Bacillol® 30 Tissues or cleaning brushes soaked in Bacillol® AF surface.
Drying:	Drying at room temperature.
Functional Testing, Maintenance:	Visual inspection for cleanliness. If necessary, perform reprocessing process again until the device is visible clean.
Packaging:	When you don't use the device, keep the device and all accessories in the original package.
Sterilization:	<p>The cylinder electrode has to be sterilized by following procedure:</p> <ol style="list-style-type: none"> <li>A. Bomix® Plus - cleaning and disinfection - dipping the electrode in 0.5% solution for 15 minutes or 2% solution for 5 minutes. If the applicator or cylinder electrode becomes dirty, the applicator or cylinder electrode is wiped with a brush during immersion.</li> <li>B. Rinse with tap water and dry</li> <li>C. Packed in a steam sterilization wrap</li> <li>D. Steam sterilization at 134 ° C for at 3 minutes or in conformity with the national legislation.</li> <li>E. Storage for further use - bulk can be used 6 days after sterilization with intact sterile packaging.</li> </ol>

Higher disinfection:	<p>G-Applicators and flat applicator have to be disinfected by higher disinfection by following procedure.</p> <ol style="list-style-type: none"> <li>A. BODEDEX forte – cleaning (detergent), - parts of the applicators that are less accessible (eg recesses, connections, etc.) should be thoroughly cleaned with icleaning brushes soaked in detergent before cleaning. Subsequently, the applicator is dipping in a 1% solution for 10 minutes.</li> <li>B. Rinsing – ten times</li> <li>C. KORSOLEX med AF – disinfection – parts of the applicators that are less accessible (eg recesses, connections, etc.) should be thoroughly disinfected with icleaning brushes soaked in disinfection. Subsequently, the applicator is dipping in 5 % solution for 5 minutes, 1,5 % solution for 15 minutes, 0, 5% solution for 30 minutes or 0,25 % solution for 1 hour.</li> <li>D. Rinsing – ten times</li> <li>E. KORSOLEX BASIC – higher disinfection – parts of the applicators that are less accessible (eg recesses, connections, etc.) should be thoroughly disinfected with icleaning brushes soaked in disinfection. Subsequently, the applicator is dipping in 5 % solution for 15 minutes.</li> <li>F. Rinsing – ten times</li> </ol>
Storage:	<p>Store in the original package indoors, on a dry place with the temperature ranging from 5°C to 25°C and relative air humidity of 30–70 %.</p> <p>G-Applicators and Flat applicators must be stored in the original package indoors, on a dry place with the temperature ranging from 15°C to 25°C and relative air humidity of 30–70 %.</p> <p>Cylinder electrode can be used 6 days after sterilization.</p>
Manufacturer:	<p>COMPEX, spol. s r.o. Palackého třída 924/105 612 00 Brno Czech republic e-mail: <a href="mailto:info@jett.eu">info@jett.eu</a></p>

### 8.2.1 Commissioning

For the correct usage of the device you need this accessories and tools:

- Steam sterilizer and steam sterilization wraps
- Cleaning brushes – diameter 5 mm and 11-16 mm
- Bacillol® 30 Tissues
- Bacillol® AF surface disinfectant
- Bomix® Plus
- BODEDEX forte
- KORSOLEX med AF
- KORSOLEX BASIC
- Tank for immersion applicators and cylinder electrode

Before first use it is necessary to do cleaning and disinfection of the device, Plasma Pen III/G and accessories – see section 8.2.2, sterilization cylinder electrode – see section 8.2.3 a TAPE Calibration – see section 5.2.

### 8.2.2 Cleaning and disinfection

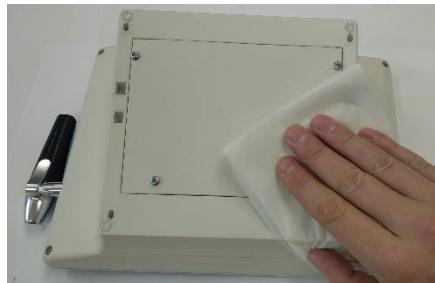
Firstly, the precleaning procedure is done. Removal of visible surface contaminations with Bacillol® 30 Tissues.

Before the first use and after each treatment, thorough disinfection of the device, Plasma Pen III/G, curly connection cable for disposable electrode, connection cable for cylinder electrode, connection cable for G-Applicators, network adapter, extension cable, foot switch and maquette must be performed, using Bacillol® 30 Tissues.

The device body and the Plasma Pen III/G, adapter, connection cables and adapter extension cable are not waterproof, just disinfect them by wiping them with wipes so that the disinfected surface is moist for at least 1 minutes or using appropriate cleaning tools (e.g. cleaning brushes diameter 5 mm and 11-16 mm) which are soaked in Bacillol® AF surface disinfectant. Parts of the medical device that could not be directly reached by Bacillol® 30 Tissues (e.g. deepening, connections, etc.) should be thoroughly cleaned and disinfected by cleaning brushes soaked in Bacillol® AF surface disinfectant.

Each component must be disinfected separately.

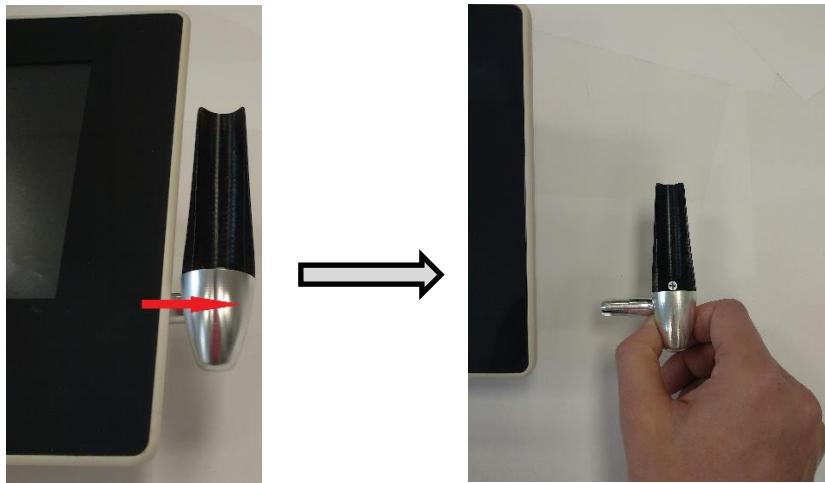
1. Thoroughly clean and disinfect the device body from the front and back by wiping with Bacillol® 30 Tissues.



Clean and disinfect the connectors with a cleaning brush and Bacillol® AF.



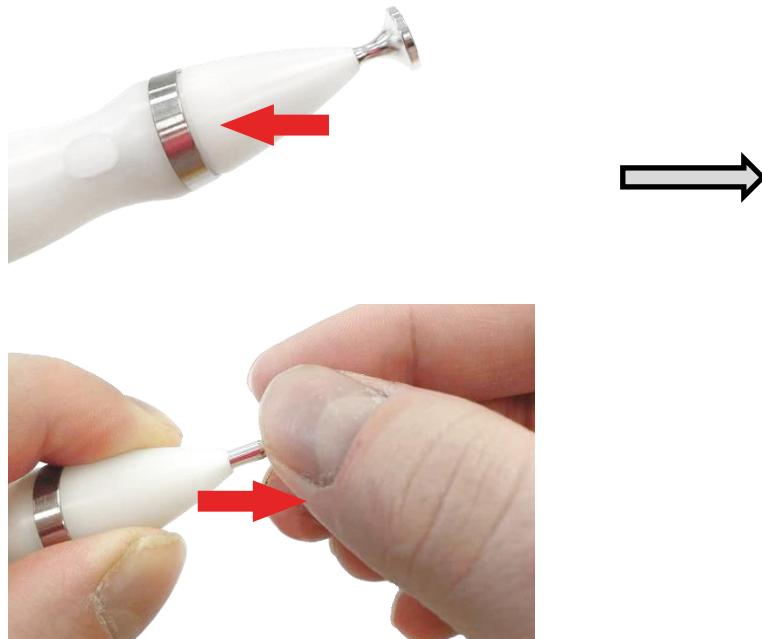
2. Remove the Plasma Pen III/G Holder by pulling



Thoroughly clean and disinfect the disassembled holder by wiping with a Bacillol® 30 Tissues, including the socket connection for holder - clean and disinfect the socket with a Bacillol® AF and the cleaning brush.

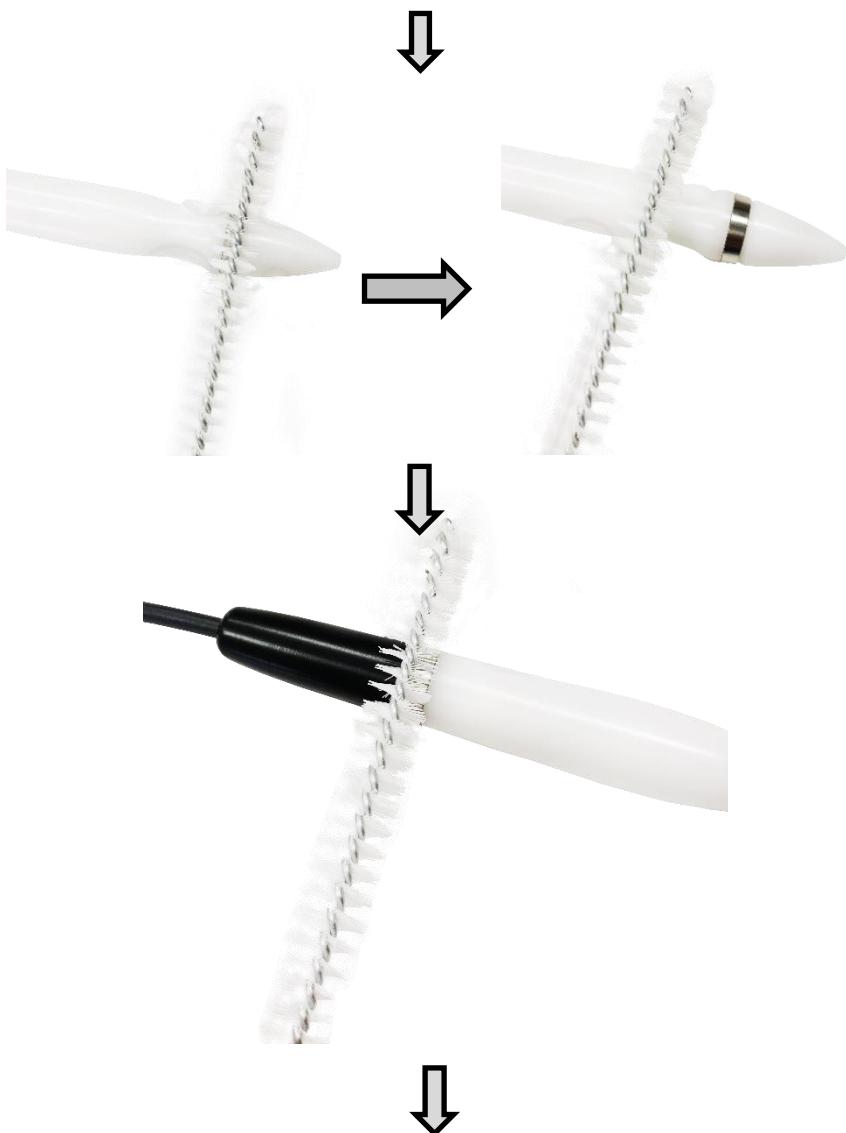


3. Disconnect the Flat Applicator 10 mm by squeezing the Plasma Pen III / G head and then pulling it out.



Clean and disinfect the Plasma Pen III/G along its perimeter, including the cable and applicator connection head.







4. Disconnect the adapter and adapter extension cables from the device and disconnect the relevant adapter end piece. Disconnect the end piece by pressing the push button and then pulling on the end piece.





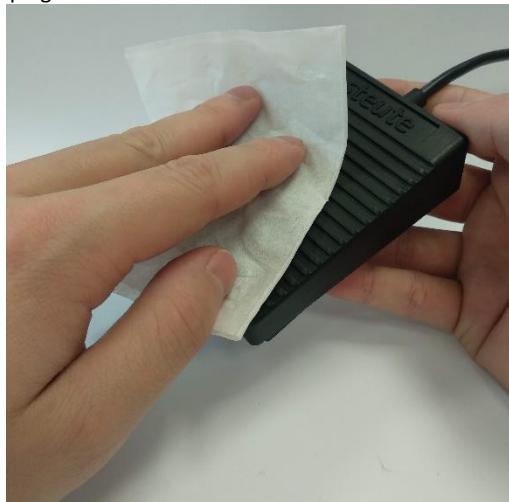
Clean and disinfect the disassembled adapter and adapter extension cable by wiping with Bacillol® 30 Tissues.

5. Disconnect the connection cable from the device for the cylinder / disposable electrode or the G-Applicator and thoroughly clean and disinfect the cable by wiping with a Bacillol® 30 Tissues.





6. Disconnect the foot switch from the device and clean thoroughly, including the cable, and disinfect by wiping with Bacillol® 30 Tissues.



7. Thoroughly clean and disinfect the maquettes by wiping with Bacillol® 30 Tissues.



### 8.2.3 Sterilization

The cylinder electrode is intended for body surface treatment and have to be sterilized by following procedure:

- A. Bomix® Plus - cleaning and disinfection - dipping the electrode in 0.5% solution for 15 minutes or 2% solution for 5 minutes. If the cylinder electrode is dirty, the electrode is wiped with a brush during immersion. Before immersion, the cylinder electrode is disconnected from the connection cable.



- B. Rinse with distilled water and dry
- C. Packed in a steam sterilization bag
- D. Steam sterilization at 134 ° C for at 3 minutes or in conformity with the national legislation.

E. Storage for further use - bulk can be used 6 days after sterilization with intact sterile packaging.

After use, the used cylinder electrode is placed in a closable container where they are stored until the end of the working day, when cleaning and disinfection and subsequent sterilization are performed.

**Sterilization is carried out before the first use and after each use.** The healthcare facility must keep information about the sterilization and the number of cycles – the accessory cylinder electrode is intended for 30 sterilization cycles. In annex 3 of this Instruction for Use is sterilization card of cylinder electrode where the worker who made sterilization can write information about the sterilization and also, he/she will see how many sterilization cycles were made.

**The healthcare facility must validate the sterilization method.**

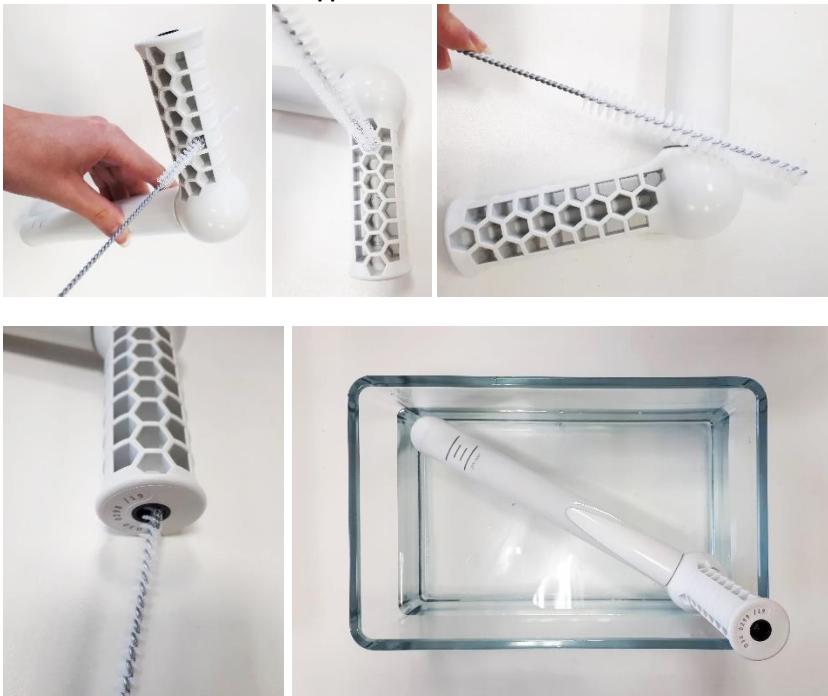
#### **8.2.4 Higher disinfection**

G-Applicators and flat applicator are intended for body surface and mucosa treatment and have to be disinfected by higher disinfection by following procedure.

- G. BODEDEX forte – cleaning (detergent), - parts of the applicators that are less accessible (eg recesses, connections, etc.) should be thoroughly cleaned with cleaning brushes soaked in detergent before cleaning. Subsequently, the applicator is dipping in a 1% solution for 10 minutes.
- H. Rinsing – ten times
- I. KORSOLEX med AF – disinfection – parts of the applicators that are less accessible (eg recesses, connections, etc.) should be thoroughly disinfected with cleaning brushes soaked in disinfection. Subsequently, the applicator is dipping in 5 % solution for 5 minutes, 1,5 % solution for 15 minutes, 0, 5% solution for 30 minutes or 0,25 % solution for 1 hour.
- J. Rinsing – ten times
- K. KORSOLEX BASIC – higher disinfection – parts of the applicators that are less accessible (eg recesses, connections, etc.) should be thoroughly disinfected with cleaning brushes soaked in disinfection. Subsequently, the applicator is dipping in in 5 % solution for 15 minutes.
- L. Rinsing – ten times

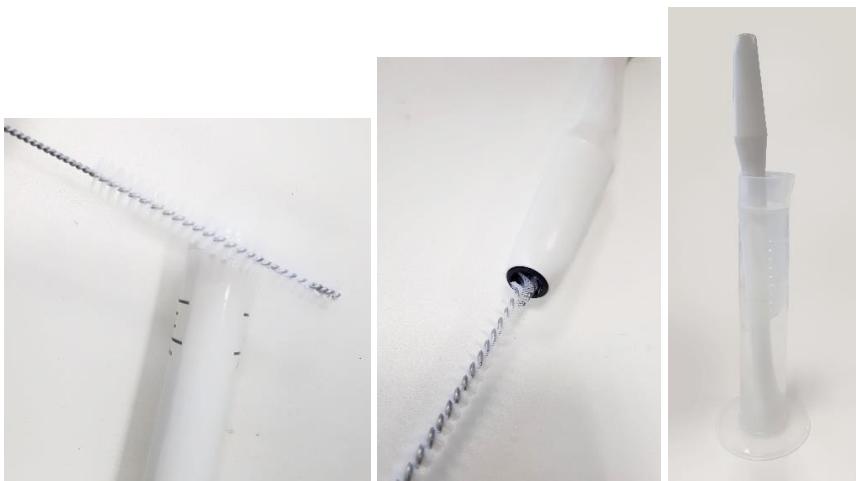
After use, the used applicators are placed in a closable container where they are stored until the end of the working day, when cleaning and higher disinfection are performed.

**G-Applicator 20 and 30 mm**



**G-applicator Wave**





**Higher disinfection is carried out after each use.** The healthcare facility must keep information about the cleaning/disinfection and the number of cycles – the accessory G-Applicators and Flat applicators are intended for 3 cleaning/disinfection cycles. In annex 4 of this Instruction for Use is Cleaning and disinfection card od applicator where the worker who made sterilization can write information about the sterilization and also, he/she will see how many sterilization cycles were made.

**The healthcare facility must validate the method.**

### 8.3 Safety technical inspections

If safety technical inspections (STI) are requested by national regulations, they should be performed once a year. STI must be performed only by the service staff of the manufacturer or by an authorized service centre. If the safety inspection was not performed within the preset term by the manufacturer or an authorized service organization, the device may not be used until the STI is done.

Service, maintenance or the preset STI of the device may not be used during treatment of a patient.

### 8.4 Product retirement and disposal



The waste consisting of electrical or electronic devices can contain dangerous substances that may be harmful for the environment or human health. The JETT PLASMA For Her II device, Plasma Pen III/G, connection cables, extension cable and adapter are included in the group

of electric waste and after expiry of its service life, it may not be disposed of with the municipal waste.

Applicators must be disposed of as infectious waste after use.

## 9. Service

Warranty and after-warranty servicing is performed by the manufacturer:

COMPEX, spol. s r.o.  
Palackého třída 924/105  
612 00 Brno  
the Czech Republic  
e-mail: [info@jett.eu](mailto:info@jett.eu)

In case of a fault or malfunction, send the device in the original box with Plasma Pen III/G to the manufacturer with the duly filled-in Complaint Protocol, being the integral part of this Instruction for Use, and with the adapter, extension cable for the adapter and with the curly connection cables and cylinder electrode to the above address. If the accessories as above are not delivered, the used accessories will be charged to you.

As soon as the complaint is settled, the manufacturer's statement will be mailed to you electronically, and the repaired device will be delivered to your billing address or to your delivery address.

## 10. Warranty

This product is covered by the warranty encompassing material imperfections and production faults for the time period of one year after delivery of the device and/or for further 12 months, if the STI has been performed by the manufacturer or the authorized service centre after the first year of use. The product has been sealed and the warranty ceases to exist if the seal/protection is damaged.

The manufacturer undertakes, depending on his possibilities, to repair the device or to replace its damaged parts for the whole term of the warranty, provided that these repairs or replacements are performed directly by the manufacturer or by his authorized representatives.

The manufacturer takes responsibility for safety, reliability and performance /effectiveness of the device only if all repairs, replacements or alterations of the product are performed by the authorized staff, if the device was used in accordance with this Instruction for Use, if the parameters of electric network (in the room where the device is plugged) satisfy all the requirements set by law.

If the product is sent back to the manufacturer, the user shall pay the transportation costs.

## 11. EMC

### 11.1 Electromagnetic interference

The JETT PLASMA For Her II device is intended for use in professional medical facilities and is classified as Class A according to CSN EN 55011 ed. 4:2017+A1:2017. It may not be used in the vicinity of active HF equipment and in the RF shielded room with the medical systems for magnetic resonance imaging, where intensity of EM disturbances is high.

Any loss or deterioration of the JETT PLASMA For Her II device function due to electromagnetic interference is not understood unacceptable risk to the patient or the operator. There is no need to adopt any measures or actions to avoid adverse events for the patient or for the operator due to electromagnetic interference.

**WARNING:** Use of the JETT PLASMA For Her II device in the vicinity of or linked with other devices can result in incorrect operation. If such use is necessary, this device and other devices must be monitored to verify normal correct function.

**WARNING:** The JETT PLASMA For Her II device may be used with the delivered connection cables only. Use of the connection cables other than the delivered ones may result in non-fulfilment of the requirements for radiation or resistance of the device.

**WARNING:** Only the delivered network adapter source ACM18US05, manufactured by XP Power, may be used for charging the JETT PLASMA For Her II device.

**WARNING:** Do not use a portable radio-communication device (incl. the end devices such as antenna cables and external antennas) at the distance closer than 30 cm (12 inches) from any part of the JETT PLASMA For Her II device, incl. the connection cables. Otherwise, its functionality may be deteriorated.

### 11.2 Electromagnetic emissions

The JETT PLASMA For Her II device meets requirements of CSN EN 55011 ed. 4:2017+A1:2017 for the lead-through emission limits, emitted for the Group 1, Class A.

Frequency band of 0.15–0.50 MHz:

- The quasi-peak value does not exceed 79 dB ( $\mu$ V) falls linearly with the frequency logarithm to 66 dB ( $\mu$ V)
- The mean value does not exceed 66 dB ( $\mu$ V) falls linearly with the frequency logarithm to 46 dB ( $\mu$ V)

Frequency band of 0,50–5 MHz:

- The quasi-peak value does not exceed 73 dB ( $\mu$ V),
- The mean value does not exceed 60 dB ( $\mu$ V)

Frequency band of 5–30 MHz:

- The quasi-peak value does not exceed 60 dB ( $\mu$ V),
- The mean value does not exceed 50 dB ( $\mu$ V)

The JETT PLASMA For Her II device meets the requirements of CSN EN 61000-3-2 ed. 4:2015 to limit harmonic currents injected into the public grid for Class A.

JETT PLASMA For Her II device meets the requirements of CSN EN 61000-3-3 ed.3:2014 to limit voltage changes, voltage fluctuations and flicker in the low-voltage distribution networks for the devices with a rated phase current  $\leq 16$  A not subject to conditional connection.

### 11.3 Electromagnetic immunity

The JETT PLASMA For Her II device meets the requirements for electromagnetic immunity in conformity with the standards shown below:

CSN EN 61000-4-2 ed. 2:2009, test immunity level, electrostatic discharge (ESD):

- $\pm 8$ kV for contact discharge;
- $\pm 2, \pm 4, \pm 8$ kV,  $\pm 15$ kV for air discharge.

CSN EN 61000-4-3 ed. 3:2006+A1:2008+Z1:2010+A2:2011, test immunity level, irradiated high frequency:

- 10 V/m, 80 MHz up to 2.7 GHz;
- 80 % AM at 1 kHz.

CSN EN 61000-4-4 ed. 3:2013, test immunity level, quick electrical transient phenomenon / pulse groups:

- $\pm 2$ kV, repetition frequency of 100 kHz.

CSN EN 61000-4-5 ed. 3:2015, test immunity level, shock coupled pulse:

- $\pm 1$ kV between the lines;
- $\pm 2$ kV between the line(s) and the ground.

CSN EN 61000-4-6 ed. 4:2014, test immunity level, irradiated high frequency:

- 3 V, 150 kHz up to 80 MHz;
- 6 V, 150 kHz up to 80 MHz, 80 %AM at 1 kHz.

high-frequency line:

- 3 V/m 80 MHz up to 2.5 GHz.

CSN EN 61000-4-8 ed. 2:2010, test level, network frequency magnetic field (50/60 Hz):

- 30 A/m 50 or 60 Hz.

CSN EN 61000-4-11 ed. 2:2005, test level, short-term voltage drops,

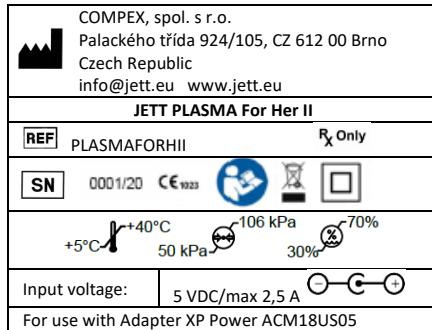
- 0 %  $U_T$  in 0.5 cycle at  $0^\circ, 45^\circ, 90^\circ, 135^\circ, 180^\circ, 225^\circ, 270^\circ, 315^\circ$ ;
- 0 %  $U_T$ , 1 cycle;
- 70 %  $U_T$ , 25/30 cycles;
- Single phase: at  $0^\circ$ .

test level – Voltage breaking:

- 0 %  $U_T$ , 250/300 cycles.

The standards have been used without any deviations.

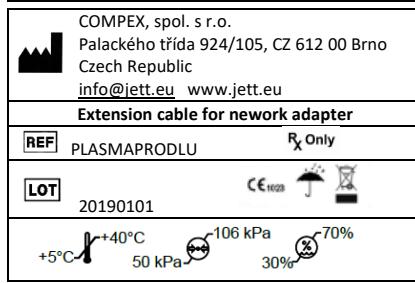
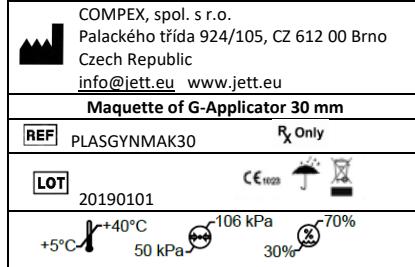
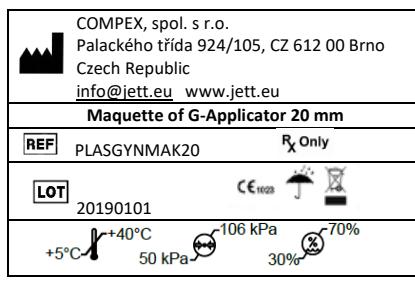
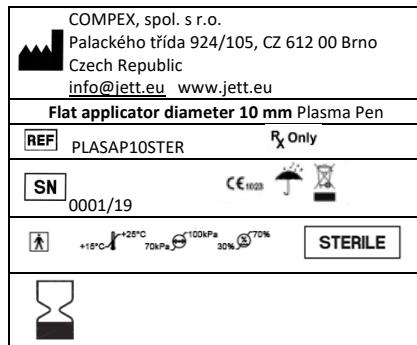
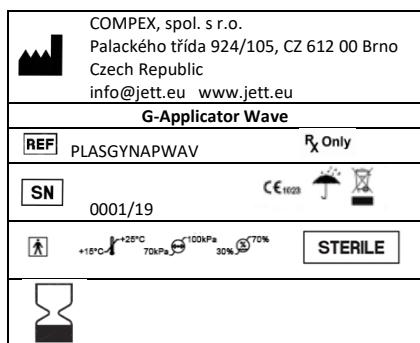
## 12. Rating plate of the device



### 13. Rating plate of accessories

 <b>COMPEX, spol. s r.o.</b> Palackého třída 924/105, CZ 612 00 Brno Czech Republic info@jett.eu www.jett.eu	
<b>Cylinder electrode</b>	
<b>REF</b>	PLASMAELKA22 
<b>LOT</b>	CE  20190101  
	+5°C  +40°C  70kPa  106 kPa  70% 
<b>Connection cable for G-Applicators</b>	
<b>REF</b>	PLASFHIICCAB 
<b>LOT</b>	CE  20190101  
	+5°C  +40°C  70kPa  106 kPa  70% 
<b>Connection cable for cylinder electrode</b>	
<b>REF</b>	PLASFHIICABL 
<b>LOT</b>	CE  20190101  
	+5°C  +40°C  70kPa  106 kPa  70% 
<b>Curly connection cable for disposable electrode</b>	
<b>REF</b>	PLASMANKABLI 
<b>LOT</b>	CE  20190101  
	+5°C  +40°C  70kPa  106 kPa  70% 

 <b>COMPEX, spol. s r.o.</b> Palackého třída 924/105, CZ 612 00 Brno Czech Republic info@jett.eu www.jett.eu	
<b>Plasma Pen III/G</b>	
<b>REF</b>	PLASMA PENG 
<b>SN</b>	0001/20 CE   
	+5°C  +40°C  70kPa  106 kPa  70% 
<b>G-Applicator 20 mm</b>	
<b>REF</b>	PLASGYNAPL20 
<b>SN</b>	0001/19   
	+5°C  +40°C  70kPa  100 kPa  30%  
	
<b>G-Applicator 30 mm</b>	
<b>REF</b>	PLASGYNAPL30 
<b>SN</b>	0001/19   
	+5°C  +40°C  70kPa  100 kPa  30%  
	



#### **14. List of Annexes**

Complaint Protocol

Informed consent

Sterilization card of cylinder electrode

Cleaning and disinfection card of applicator

# Complaint protocol JETT PLASMA For Her II

Filled in by the claimant

Manufacturer	COMPEX, spol. s r.o.	
	Address	Palackeho trida 924/105, 612 00 Brno the Czech Republic
	E-mail:	info@jett.eu
<b>**Claimant (company, contact person, phone, e-mail)</b>		
	<b>**Invoice address</b>	
	<b>**Delivery address, if it is different than invoice address</b>	
<b>**No. and date of invoice issuance</b>		
<b>**Date of detection</b>		
<b>**Serial number</b>		
<b>**Detailed description of the defect</b>		
<b>**Package contents upon delivery*</b>		
<b>**Date of the claim</b>		

## Complaint protocol JETT PLASMA For Her II

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**\*\*Claimant's  
signature and stamp**

\* Always hand over the device to the complaint in the original box with an adapter with extension cable, connecting cables, foot switch and cylinder electrode to avoid prolonged complaint and increase costs.

**\*\*Obligatory field**

# Informed Consent of the Patient with Treatment using JETT PLASMA For Her II

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Name and surname: \_\_\_\_\_

Address: \_\_\_\_\_

Planned treatment: \_\_\_\_\_

## Information about treatment

JETT PLASMA For Her II is a medical device designed to treat vulvovaginal laxity. Based on the physical principle of DC, it generates heat that has a positive effect on the trophic of the tissues, it strengthens and improves flexibility.

The device may be used by a physician only, to treat the following diseases:

- Vulvovaginal laxity

The doctor is obliged to inform the patient about the postoperative treatment and familiarize the patient with the process of healing.

The Client hereby confirms that does not suffer from any of the following contraindications:

- pacemaker, Holter ECG monitoring system,
- another implanted electrical device,
- epilepsy,
- pregnancy,
- metal implants in the treated area (including intrauterine device)
- skin diseases or inflammations in the treatment area,
- urinary tract infection,
- collagen vascular disease,
- oncological disease in vulvovaginal region,
- menstruation,
- any untreated/badly treated disease in vulvovaginal region,
- birth defects of vagina,
- stenosis and strictures of vagina,
- synechia of vulva,
- virgin women

The treatment is not limited to a certain period of the cycle, except for menstruation, when the treatment can not be performed.

For the evaluation of contraindications, a gynecological examination not older than 1 year, including cytology, is necessary.

## **Informed Consent of the Patient with Treatment using JETT PLASMA For Her II**

**WARNING: The person to be treated may not wear any metal things (watches, bracelets, ...)!**

Like all treatments, this medical device can have side effects, but may not occur with everyone.

The following side effects may occur when using medical device JETT PLASMA For Her II:

- temporary vaginal tingling and/or numbness,
- temporary painful cramps and cutaneous depressions,
- increased urinary tract problems,
- pain, erythema and edema,
- itching in the treatment area,
- burn, scarring, bruising and ecchymosis,
- dyspigmentation, hyperpigmentation,

### **Additional client's questions and answers:**

### **Client Declaration:**

I, the undersigned, hereby certify by my signature that I have been informed thoroughly about treatment with the JETT PLASMA For Her II device during the consultation which took place in/on .....

I understand the information concerning the treatment. I also confirm by my signature that I do not have any of the contraindications as above, and I am aware fully that release of false information may result in the risk of my possible health problems.

On the basis of the submitted information, considered complete and sufficient for my decision and upon a thorough and careful consideration, I agree fully and unreservedly with realization of the treatment.

In ..... , on .....

# **Informed Consent of the Patient with Treatment using JETT PLASMA For Her II**

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.....  
*Signature of the client*

.....  
*Signature of the informing person*

## Sterilization card of cylinder electrode

Accessory name:	Cylinder electrode		
LOT:			
<b>Information about sterilization:</b>			
Sterilization cycle:	Date:	Name:	Signature:
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
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30			

## Cleaning and disinfection card of applicator

Type of applicator:			
Serial number:			
<b>Information about cleaning and disinfection</b>			
Cycle of cleaning/disinfection:	Date:	Name:	Signature:
1. cleaning			
1. disinfection			
2. cleaning			
2. disinfection			
3. cleaning			
3. disinfection			