COMPEX, spol. s r. o.
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Training protocol

Device	JETT PLASMA For Her II	
Serial Number		
Manufacturer	COMPEX, spol. s r.o. Palackeho trida 924/105 612 00 Brno Czech Republic	
Lector Readable name, surname, signature		
Date of training		
Place of training		
Trained person	☐	End-customer
	☐	Distributor
	Doctor	☐ Yes ☐ No
Company		
Key doctor's name in case of „No " Readable name and surname, phone, e-mail, signature		

The lecturer's declaration

I …….. hereby certify that the above-named person was trained in all points of the training content. He / she understood everything and all additional questions were adequately answered and discussed.

In …… date ……..

.....
Signature

Training Content

A. Familiarization with the general functions and 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.

All medical procedures may be performed only by the physicians or by the person who may work with the medical devices in conformity with the national legislation and treat the indication shown above (end-user of device) after thorough medical training. This medical training is provided by the distributor or the manufacturer of the device. The training protocol is drawn up about this training. There must be given an accurate personal data of end-user – trained physicians, including the phone and e-mail, followed by the serial number of the device and the date and place of the training. At the same time, the physician who has conducted a training must be included in the protocol. This protocol is made in three versions. The first is left to the trained physician, the second is given to the distributor and the third is the distributor required to return to the manufacturer who establishes it in the framework of the certified quality management system. The distributor was familiarized with an operation of the device and the set of indications which end user can perform with this unit. The exception is a device owned by the distributor which is only for the presentation purposes.

B. Familiarization with security risk – contraindications and possible side effect

All contraindications have been discussed in detail, and the trained staff has been alerted to the fact that before the application, the final user – the physician must be able to demonstrate to his/her clients, that the conditions of contraindications are fully met, preferably in conjunction with the client's GP. This must be done with a client´s signature (informed consent).

Contraindications:

- pacemaker, Holter ECG monitoring system,
- another implanted electrical device,
- epilepsy,
- pregnancy,
- metal implants in the treated area,
- skin diseases, event. inflammations in the treatment area,
- urinary tract infection,
- collagen vascular disease,
- oncological disease in vulvovaginal region,
- allergy to disinfectants,
- menstruation,
- any untreated/badly treated disease.

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

C. Familiarization with security risk – using of device

We use an indifferent conductive gel that is applied to its end and surface before inserting the applicator. This achieves excellent contact with the wall of the vagina, without a conductive gel, the treatment would not be pleasant to the patient and the expected results would not be achieved.

D. Familiarization with security risk – transferring bacterial infection

Regular maintenance and cleaning

The device, Plasma Pen III/G, network adapter, extension cable, foot swicht and connection cabels have to be disinfected before the first use and after each treatment, using standard disinfectants. G-Applicators and flat applicator is necessary to disinfected after each treatment with higher disinfection. Cylinder electrode is necessary to sterilize before the first use and after each treatment

Applicators are supplied in a sterile condition.

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 minute 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.

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.

A. BODEDEX forte – cleaning (detergent), - parts of the applicators that are less accessible (e.g. 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.

B. Rinsing – ten times

C. KORSOLEX med AF – disinfection – parts of the applicators that are less accessible (e.g. 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.

D. Rinsing – ten times

E. KORSOLEX BASIC – higher disinfection – parts of the applicators that are less accessible (e.g. 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.

F. Rinsing – ten times

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 of 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.

Sterilisation

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 cylindrical electrode is disconnected from the interface 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.

The healthcare facility must validate the sterilization method.

A. Implementation of intervention and post-treatment therapy

For treatment vulvovaginal laxity intensities 4-8 are used and the intensity depends on the patient's tolerance. The treatment is based on physical principle of heat generated by the direct current. The maximum temperature does not exceed 45 °C, there is no damage to the treated tissue at this temperature.

Example of treatment
In the case of the treatment vulvovaginal laxity the G-Applicator 30 mm or the G-Applicator Wave are used. At the treatment we affect by device JETT PLASMA For Her II with vaginal head the treated area - vaginal mucosa. We use an indifferent conductive gel that is applied to its end and surface before inserting the head. This achieves excellent applicators electrode contact with the wall of the vagina. After insertion into the vagina, the device turns on with intensity 1 (the intensity may be increased according to the patient's comfort) and the front and rear vagina walls are applied 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 at first and then it can be taken out of the vagina safely. Action of DC current 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.

There is always a need for a patient to be trained for post-treatment therapy, information is part of informed consent.

B. Transmission of information – the experiences with the first device on the market

The distributor is required to provide the manufacturer with comprehensive information from their customers – physicians who have experience with the device every six months, e.g. whether it can be used for all the indications mentioned in the manual and whether is device safe. The manufacturer is required to obtain this information – it must be regularly implemented in the certified quality management system.

C. Adverse events

The distributor is obliged to report them immediately to the manufacturer and the local supervising authorities.

D. Performing Safety technical inspections (STI)

The deadline for implementation STI is set at once per year. STI can only be performed by manufacturer's service personnel or authorized service centre. If there has not been done an inspection within the period prescribed by the manufacturer or authorized service centre, the device may not be used until completion of STI.
The service, maintenance or prescribed STI should not take place at a time, when it is used in the patient. The distributor in cooperation with the manufacturer ensures the implementation of periodic safety checks. As part of these checks is the end-user informed in writing form that the device meets all the requirements, such as when it was launched (declaration of conformity).

Honourable statement of the trained

I, ..., confirm that I have understood everything and the additional questions have been adequately answered and discussed.

In ..... on .....

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Signature