

# **INFORMED CONSENT**

## **of a client with the treatment with the device**

### **JETT PLASMA LIFT MEDICAL**

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Name and surname of client: \_\_\_\_\_

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

Scheduled treatment: Body and face treatment with JETT PLASMA LIFT MEDICAL

#### **Information about the treatment**

JETT PLASMA LIFT MEDICAL uses a plasma technology. It generates its flow and it triggers a specific mechanisms in biological tissues. This effect of plasma enables to provide a very effective peeling, tissues regeneration, their strengthening and improvement of their flexibility and immunity. The plasma discharge deliberately destroys the skin cells by using higher energies.

The device can be used only by a medical doctor and can be used for treatment of following indications:

- angioma senilis
- verrucae seborrhoicae
- verrucae plane
- angiokeratoma
- teleangiectasie
- lentigo – except lentigo maligna!
- fibroma molle
- keratoacanthoma
- conydolamata accuminatum
- moluscum contagiosum
- verrucae vulgaris
- verrucae filiformes
- naevus capillaris
- naevus araneus
- basalioma superficiale
- lymphangioma
- keratosis actinica
- keratosis senilis
- keratosis seborrhoica

Since the procedure can be painful, the doctor has to inject the anesthetic into the treated area. By the treatment are deliberately being destroyed the diseased cells, the doctor is obliged to inform the client about aftercare treatment of the treated area and familiarize the client with the healing process. The doctor is obliged to cooperate with dermatologist, who as the only one can authorize the removal of potentially dangerous malignant formations.

Warning – removal of birthmarks the doctor has to always consult with dermatologist, the examination with dermatoscope is required!

Applicators must be disinfected after each application with common disinfectants (see below). It is sufficient to disinfect the body of the device with a damp cloth.

**Disinfection:**

After each application has the device be disinfected by one of the common disinfectants:

CUTASEPT F

SEKUSEPT EXTRA N

SEKUSEPT PLUS

Application in the regime of disinfection /application tip is touching the skin/ - application tip is coming into contact with sterile environment.

To keep the device JETT PLASMA LIFT MEDICAL in operational readiness and for the need of its sterilization and disinfection is necessary to divide the device into two parts:

- a) Own device without the applicator (main body)
- b) Applicator

Sterilization and disinfection of application tip, which is coming into the contact with patient is influenced by following (below mentioned) factors, which are needed to be taken into consideration when deciding about the sterilization method or disinfection by the concrete treatment – operational intervention.

Applicators could be sterilized in autoclave at the recommended temperatures from 125°C - 145°C. Validated sterilization process has to be used according to EN 285.

The body of the device cannot be sterilized in autoclave due to high sterilization temperatures.

The body of the device can be sterilized by ETOXEN, here are low sterilization temperatures. The microbicidal gas ethylenoxid is working with low temperatures, but this process is very time demanding – sterilization lasts 48 hours.

The body of the device cannot be sterilized with formaldehyde, there is a danger that the sterilizing substance may drip inside the device.

Since the sterilization methods have the above mentioned limitations, it is possible to use modern disinfection methods for the body of the device and for the application tips /see chapter 5.A./. The time exposure here is short and high bacteriostatic efficiency is achieved. **However, it should be noted that even the best disinfection cannot completely replace the sterilization and wherever the nature of the surgery requires a high sterility is necessary to use any of those defined and validated sterilization processes.**

The applicator and the body of the device has to be before the disinfection thoroughly washed – see standard EN 15883.

For washing is necessary to use any of the detergents, e.g. JAR.

It is possible to disinfect with a mixture of detergents and disinfectants in a well-defined ratio.

There is no limit for washing the applicators. The body of the device can be washed with a damp cloth, **there is a risk that the detergent may drip inside the device!**

The client by that confirms, that he/she does not suffer from any of the following contraindications:

- Pacemaker, Holter monitor of ECG, Holter monitor of blood pressure or other implanted electrical devices
- Epilepsy
- Pregnancy
- Presence of metal objects at the treatment site
- Cutaneous diseases, skin inflammation (erysipelas)
- Any uncontrolled or poorly controlled disease
- Oncological diseases
- Allergy to anesthetics

**WARNING : the treated person is not allowed to wear any metal objects (e.g. watches, bracelets,...).**

**Client's additional questions and answers:**

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**Client's statement:**

I, signed below, state and confirm with my signature, that at the consultation taking place on ....., I was fully informed about the treatment with JETT PLASMA LIFT MEDICAL.

I understand the given information about the aforementioned treatment. I further confirm with my signature, that **I have none of the aforementioned contraindications and I am aware that by giving an information that is not true I expose myself to a possibility of health problems.**

Based on the given information that I consider full and sufficient for my decision and after a careful consideration fully and with no reservations, I give my consent with the application of the treatment.

In....., date: .....

.....  
*signature of client*

Signature of the person providing the information: .....