

TATOpro models

| AVAILABLE GAUGE RANGE | STANDARD POWER LEVEL TO USE [W] | SUGGESTED MAXIMUM POWER NOT TO BE EXCEEDED [W] |
|-----------------------|---------------------------------|--|
| 11 Gauge | 50 W | 60 W |
| 14 Gauge | 25 W-35 W | 40 W |
| 17 Gauge | 20 W-25 W | 30 W |
| 18 Gauge | 10 W | 15 W |

14G and 17G TATOpro are available also with pierced tip and luer lock.
To be used exclusively with Biomedical's microwave thermal ablation device "TATO".



List of symbols

| | |
|--|--|
| | Do not use the device if the packaging is damaged |
| | Keep dry |
| | Keep away from any source of light |
| | Upper temperature limit |
| | Do not use multiple times <i>Nenaudoti daugiau nei 1 kartą.</i> |
| | Sterilization by ethylene oxide Sterilizuotas etileno oksidu |
| | Do not sterilize multiple times |
| | No rubber latex |
| | No phthalates |
| | Attention |
| | Consult the guidelines for use |
| | Manufacturer |
| | Catalogue number |
| | Batch code |
| | Date of manufacture |
| | Use-by date |
| | Quantity |

Intended use

The applicator for microwave thermal ablation "TATOpro" needs to be used with Biomedical's microwave thermal ablation device "TATO" for percutaneous, laparoscopic and open-surgery-performed coagulation of soft tissues (liver, lung, kidney, prostate also transectally, thyroid, pancreas and breast) and bones, including ablative procedures of non-resectable tumors. It consists of an extreme hyperthermia procedure, which is aimed at destroying even deep tumor masses through the application of electromagnetic energy, which comes from the radiation tip of TATOpro applicator. This applicator is made up of a thin and extremely small-sized needle (between 18 G and 11G), which is inserted into the patient's body, usually under ultrasound guidance, until it reaches the tumor mass.



WARNING!
The device is not supposed to be used in cardiac procedures.



WARNING!
The device must be used by doctors and medical personnel, which have been adequately trained to use this technology and the precautions relating to it.



WARNING!
To be used exclusively with devices made by Biomedical.



WARNING!
Make sure that the personnel has read and understood this manual, particularly the safety notes.



WARNING!
The operator is responsible for the compliance with the regulations applicable to the prevention of incidents and safety.



WARNING!
Do not activate the applicator before fully inserting the radiation section into the tissue that needs to be treated.



WARNING!
Only use Biomedical-approved applicators and accessories.



WARNING!
The applicator is a disposable device. Do not use it for multiple treatments.



WARNING!
The antennas for thermal ablation are provided sterile and must be disposed of after every single procedure. Do not re-sterilize.



WARNING!
Do not use the equipment if the cables or the components of the device are damaged.

Preservation

Keep TATOpro applicators away from humidity and direct heat.
 Dispose of the product if it is damaged, or if the sterile packaging is damaged or open.
 Dispose of the products that have exceeded the expiry date reported on the packaging.

Guidelines for use



ATTENTION!
Examine each applicator before use. Do not use visually damaged applicators. Lesions to the user or the patient may occur.



WARNING!
At the end of the procedure, the temperature by the radiation section of the applicator may still be high. Do not touch it and do not place it on the patient or near flammable material.

Important

For detailed instructions related to the correct configuration and use of the microwave generator, refer to the **User Manual** of TATO Microwave Generator.

1. Set the generator for microwave ablation TATO on the basis of the appropriate user guide and instructions of use.



WARNING!
Do not activate the applicator before fully inserting the radiation section into the tissue that needs to be treated.

2. Take the sterile bag with TATOpro applicator out of the packaging by using the proper aseptic techniques.
3. Take the applicator and the detachable cable, if available, out of the sterile bag.

During the ablative procedure

1. Place the applicator under ultrasound guidance or CT scan into the tissue that needs to be treated.
2. Join the connector of the detachable cable to the applicator and to the output in the power switch that needs to be activated.



WARNING!
Near big blood vessels and ductal structures, the characteristics of the ablation may experience some variations (the so called "heat sink effect"). Pay attention.



WARNING!
Do not use power levels higher than those suggested by the manufacturer.



WARNING!
Before proceeding with the treatment on a pacemaker patient, contact the cardiologist of the patient and the producer of the pacemaker in order to confirm the procedure. Request a cardiological examination after the ablative procedure in order to verify the correct functioning of the pacemaker.



WARNING!
The use of the device on pregnant patients is not recommended. The potential risks for the patient and the fetus have not been established yet.



WARNING!
Before using the device, carefully evaluate the compatibility of the microwave thermal ablation procedure with the patient's clinical history.



WARNING!
Do not use the defibrillator on the patient with the applicator inserted in their body. Fully take out the applicator before using the defibrillator.