

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

1.2.5.

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
	Sterilization by ethylene oxide
	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

1.1.2.

Intended use 1.2.1.

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 transrectally, 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.

1.2.2.



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.

- 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.

- Take the sterile bag with TATOpro applicator out of the packaging by using the proper aseptic techniques.

- Take the applicator and the detachable cable, if available, out of the sterile bag.

During the ablative procedure

- Place the applicator under ultrasound guidance or CT scan into the tissue that needs to be treated.
- 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 cardiologist 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.



WARNING!

The tip of the applicator is sharp: handle with care.

WARNING!

Do not touch the cannula of the applicator during the energy release.

WARNING!

Do not touch the mobile system and the patient at the same time during the energy release.

WARNING!

For help with the correct selection of the settings of power levels and duration of the therapy, consult the "Examples of ablation zones" section.

WARNING!

Always use the lowest settings of power and duration that allow obtaining the result.

Note

It is possible to supply the applicators with up to a total maximum of 100 W for 15 minutes of time.



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.



WARNING!

If faced with resistance while inserting the applicators into the tissue that needs to be treated, use a scalpel to make a small incision. The use of an excessive force while inserting the applicator may cause its breaking, thus provoking lesions to the patient.

WARNING!

Handle the applicator with care while inserting or taking out the antenna. The use of excessive lateral forces may cause its breaking, thus provoking lesions to the patient.

WARNING!

Do not bend the applicator.



WARNING!

Do not activate the applicator if it is in contact with metallic objects or tools.



WARNING!

The applicator's temperature becomes rather high by the radiation section. Make sure it does not get in contact with parts of the tissue that do not need to be treated.



WARNING!

The applicator's temperature becomes rather high by the radiation section. Do not touch the applicator during the therapy.



WARNING!

If faced with resistance while taking out the applicator, try to use a rotation movement before extracting it.

The applicator's tip must be considered a sharp bio-contaminated component; therefore, it must be disposed of accordingly.

3. Push the **OK** button in the screen *Confirm start of therapy*.

At the end of the procedure, when the energy stops being delivered, carefully take the applicator completely out of the tissue.

After the ablative procedure

1. Verify that the generator is switched off.
2. Dispose of the applicator in compliance with the practices of the belonging institution.



WARNING!

If a failure occurs during the treatment, turn the device off and carefully remove the applicator from the patient's body. In case of failure in the touchscreen, press and hold the power key for few seconds in order to turn the device off.

Examples of ablation zones

The below-reported ablation examples have been drawn by using Biomedical's applicators for microwave thermal ablation in an *ex-vivo* animal tissue model. The ablations have been performed on freshly slaughtered swine liver at a temperature between 30°C and 37°C. The dark-blue parts in the pictures represent the tissue coagulation zone that has been created around the radiation section of the applicator.

Ablation with one single applicator

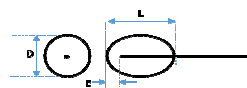


Figure 1: Ablation zone with one applicator

Chart 1

14 G	25 W			30 W			35W		
⌚ (min)	5:00	10:00	15:00	5:00	10:00	15:00	5:00	10:00	15:00
L (cm)	3,6	4,6	5,3	4,0	5,5	5,7	4,2	6,0	6,0
D (cm)	2,2	2,8	3,1	2,3	2,7	3,3	2,6	3,6	3,8
E (cm)	0,6	0,7	0,9	0,7	0,9	1,1	0,8	1,0	1,0

Chart 2

17 G	20 W			25 W			30W		
⌚ (min)	5:00	10:00	15:00	5:00	10:00	15:00	5:00	10:00	15:00
L (cm)	3,2	4,2	4,3	3,4	4,4	4,8	4,2	5,0	5,6
D (cm)	1,7	2,3	2,4	1,9	2,6	2,8	2,3	3,5	3,8
E (cm)	0,6	0,7	0,9	0,7	0,8	1,0	0,7	0,9	1,2

Chart 3

18 G	10 W			15 W		
⌚ (min)	5:00	10:00	15:00	5:00	10:00	15:00
L (cm)	2,2	2,6	3,1	2,4	2,8	3,2
D (cm)	1,2	1,7	1,6	1,4	1,9	2,1
E (cm)	0,4	0,5	0,7	0,7	0,6	0,7

Ablation with two applicators

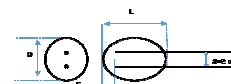


Figure 2: Ablation zone with two applicators

Chart 4

14 G	50 W TOTAL (25W Each Antenna)			60 W TOTAL (30W Each Antenna)			70 W TOTAL (35W Each Antenna)		
⌚ (min)	5:00	10:00	15:00	5:00	10:00	15:00	5:00	10:00	15:00
L (cm)	3,6	4,9	5,4	4,0	5,5	6,1	4,2	6,3	6,5
D (cm)	3,5	4,1	4,9	3,8	4,2	4,6	4,2	5,9	6,0
E (cm)	0,6	0,7	1,4	0,9	1,0	1,5	1,2	1,0	1,6

Chart 5

17 G	40 W TOTAL (20W Each Antenna)			50 W TOTAL (25W Each Antenna)			60 W TOTAL (30W Each Antenna)		
⌚ (min)	5:00	10:00	15:00	5:00	10:00	15:00	5:00	10:00	15:00
L (cm)	3,5	4,6	4,8	4,0	4,7	5,1	4,3	5,2	6,3
D (cm)	2,8	3,6	4,1	2,9	3,9	4,4	3,7	4,3	4,5
E (cm)	0,7	0,9	1,2	0,8	1	1,3	0,6	1,0	1,1

Ablation with three applicators

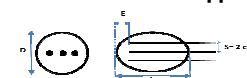


Figure 3: Ablation zone with three applicators

Chart 6

14 G	90 W TOTAL (30 W each Antenna)	
⌚ (min)	10:00	15:00
L (cm)	6,0	6,0
D (cm)	4,7	5,5
E (cm)	1,1	1,3

Chart 7

17 G	75 W TOTAL (25 W each Antenna)	
⌚ (min)	10:00	15:00
L (cm)	5,8	6,0
D (cm)	4,6	5,1
E (cm)	1,0	1,2

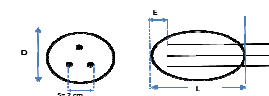


Figure 2 – Ablation zone with three applicator.

Chart 8

14 G	90 W TOTAL (30 W each Antenna)	
⌚ (min)	10:00	15:00
L (cm)	5,5	5,6
D (cm)	5,0	5,4
E (cm)	1,3	1,5

Chart 9

17 G	75 W TOTAL (25 W each Antenna)	
⌚ (min)	10:00	15:00
L (cm)	5,3	5,5
D (cm)	4,7	5,0
E (cm)	1,0	1,3

Ablation with four applicators

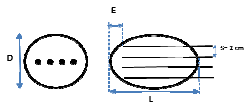


Figure 5 – Ablation zone with four applicator

Chart 10

14 G	100 W TOTAL(25 W each Antenna)	
⌚ (min)	10:00	15:00
L (cm)	6,4	6,3
D (cm)	4,8	5,1
E (cm)	1,1	1,2

Chart 11

17 G	100 W TOTAL(25 W each Antenna)	
⌚ (min)	10:00	15:00
L (cm)	6,3	6,3
D (cm)	4,7	5,2
E (cm)	1,0	1,1

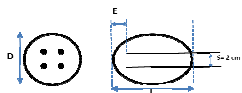


Figure 6 – Ablation zone with four applicator.

Chart 12

1.1.9

14 G	100 W TOTAL(25 W each Antenna)	
⌚ (min)	10:00	15:00
L (cm)	6,0	7,0
D (cm)	5,0	6,0
E (cm)	1,5	1,8



Chart 13

17 G	100 W TOTAL(25 W each Antenna)	
⌚ (min)	10:00	15:00
L (cm)	6,0	7,0
D (cm)	4,5	6,0
E (cm)	1,1	1,3



Note

In case of multiapplicator procedures, the recommended distance between the antennas consists of 2 cm. Shorter distances may be less effective, while longer ones may cause indentation phenomena, which lead to non-contiguous and less spherical ablations.

Use imaging support (CT scan or ultrasound scanning) to monitor the distance between the radiation section and the applicators.

1.2.

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Biomedical s.r.l.
Via G.B. Lulli, 43 50144 Firenze Italy
Tel +39 055 352678 / +39 055 332822
Internet: <http://www.biomedical-srl.com>
Email: info@biomedical-bio.net