TOOTH
TRANSFORMER

USER MANUAL

TT Tooth Transformer S.r.l
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This publication is supplied for the purpose of use and servicing of the only device named: TT Transformer.

TT TOOTH TRANSFORMER S.R.L. is responsible for the reliability and performance of the equipment only if the following points are observed:

- all repairs and modifications are carried out by Manufacture or Authorised Personnel;
- the equipment is used in accordance with the instructions for use in the User Manual.

TT Transformer is specifically intended to grind and process an extracted tooth of patient in order to produce an autologous graft material for bone regeneration to be used in the same patient.

The responsibility of the manufacturer is limited to the appropriate use of the device for its specific purpose. The manufacturer is not responsible for consequences deriving from improper use of the instrument.

Revision of user manual Rev. 10 of 30.04.2023

The manufacturer reserves the right to update and correct this document whenever necessary to add relative information regarding the use of the device

The instructions for use (IFU) are in leaflet form, provided with the TT Transformer device in the languages accepted by the EU member states where the device is on sale.

The user can request the updated IFU leaflet of the device directly from the manufacturer or download it electronically in PDF format from the official internet site as instructed below.

MANUFACTURER

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1. INTRODUCTION

Carefully read and understand the information set out in this manual prior to installation, operation, maintenance or any handling of the device.

Always keep this manual close at hand for future reference.

IMPORTANT: Carefully read and understand all 'Safety Instructions' in this manual to avoid any potential personal injury or property damage. This manual contains two types of hazard statements according to the severity of potential damage or harm:

The information set out in this manual is intended to help the operator to familiarize with instructions for safe and proper use, installation and maintenance of the device.

DO NOT TAMPER with the device or any of its components.

Should you detect any anomaly, please contact the dealer.

Any attempt by the user or any unauthorized personnel to tamper with the device or alter it in any way will void warranty and neither the Manufacturer nor the Distributor shall be liable for any personal injury or property/product damage that may result from any such attempt.

The information and illustrations herein are current as of the date of publication as set out on the last page of this manual.

TOOTH TRANSFORMER SRL (the 'Manufacturer') upgrades its products on a regular basis, including by changing system components. In the event of any differences between the contents of this manual and your device please contact the dealer.

Use of this manual for purposes other than those for which it is intended, i.e. providing instructions for installation, operation, and maintenance of TT TRANSFORMER (the 'Device') is strictly prohibited.

Any serious incidents regarding the TT Transformer device should be reported to the manufacturer and appropriate authorities.

2. TT TRANSFORMER

TT Transformer is a medical device that allows the use of one or more extracted teeth in order to obtain, with an automatic process, autologous graft material for bone regeneration in the dental field.
Built with the most advanced technologies, the device is equipped with a display able to show signals for every single fault or anomaly.

Intended use of the TT Transformer device: automatic preparation of autologous graft material, to render it usable for bone regeneration

Therapeutic indication

The intended use of the device functions with two principal applications depending on the receiving site:
Regenerative: all the procedures of bone regeneration which need a preparatory substrate and/or scaffold on insertion of the implant;
Periodontology: periodontal regenerative therapies.

CONTRAINDICATIONS

Pathologies which exclude or advise against regenerative bone treatment with autologous material produced by the TT Transformer are the same as those which comprise total or relative contraindications for grafts.

The main contraindications are the following:

recent radiation therapy of the treated region with high x-ray doses, sepsis, periodontal pathologies in the acute phase or purulent, severe debilitation with general impaired health, systemic diseases, excessive use of tobacco, drug or alcohol abuse, recent myocardial infarction, valve prosthesis, severe kidney disorders, oxyomalacia, aggressive periodontitis, patient receiving bisphosphonates, treatment-resistant diabetes, drug-taking, diseases and tumors in the terminal phase.

Contraindications of minor entity but to be taken into consideration also in the management of the surgical intervention are:

chemotherapy, mild renal disorders, hepatic disorders, endocrine disorders, psychological disorders and psychosis, AIDS, seropositivity, prolonged use of corticosteroids, calcium phosphorus metabolism disorders, erythropoietic disorders, cardiovascular diseases, respiratory diseases.

2.1 Description of TT Transformer

Figure 1 shows TT Transformer and its components.

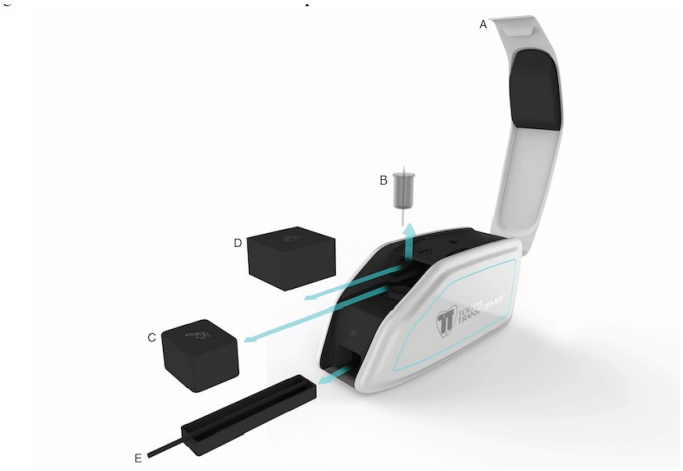


Fig.1 : TT Transformer
A: LID
B: Maker+Cylinder
C: Tank
D: Mill
E: Waste

Device is provided with the following elements:

- **DEVICE**: it's equipped with a switch, a display and an opening lid.
- **MAKER**: it’s a single use accessory put in the cylinder to collect the resulting autologous material.
- **CYLINDER**: it's a single-use tank where the liquids are collected after use.
- **LIQUIDS TANK**: it’s a single-use tank that includes liquids and dedicated reagents.
- **MILL**: this component includes blades that grind the tooth.
- **WASTE**: it collects residual of the producing and simplify the device cleaning.
- **USER MANUAL**

2.2 SAFETY INSTRUCTIONS

2.2.1 TT TRANSFORMER

TT Tooth Transformer srl shall not be liable for any and all direct or indirect loss or damage to property, death or personal injury in the event that:
• TT Transformer is used for purposes other than its intended use as set out herein.
• TT Transformer is used in a way that is not compliant with any and all instructions and requirements set out in this manual.
• The electrical system of the premises where TT Transformer is used is not compliant with applicable standards and regulations.
• Storage and preservation conditions of TT Transformer are not compliant with the specifications set out in the relevant section herein.

⚠ WARNING**: use of parts that are not made or authorized by TT Tooth Transformer srl ('use of non-genuine parts'),** may cause damage beyond repair to the device which as a result may no longer function as it is supposed to, and put the patient at risk.
Use of non-genuine parts will void the Manufacturer's warranty and product certification!

⚠ WARNING**: qualified and specialized personnel.**
The device must be used exclusively by qualified, adequately trained personnel.
If the device is used as instructed, no side effects will ensue.

⚠ WARNING**: intended Use**.
Use the device only for the uses for which it is intended.
Failure to do so may cause serious injury to the patient and the operator, device damage or faults.

⚠ WARNING**: cleaning, disinfection, sterilization of new or repaired products.**
Before treatment, all products - be they brand new or repaired - must be thoroughly cleaned, disinfected and/or sterilized following the instructions set out in the "Cleaning and Disinfection" section herein.

⚠ WARNING**: infection control.** For utmost patient and operator safety always use clean, disinfected and sterilized accessories.

⚠ WARNING: use only genuine TT Transformer accessories and spare parts.

⚠ WARNING**: check device conditions prior to using it to process the extracted tooth.**

Always make sure there is no water underneath/do not set on a damp surface.
Before each treatment session, always make sure the device is in perfect working order and check the efficiency of accessories. Should you detect any anomalies in functioning, do not use the device. Contact the authorized dealer if the anomalies concern the device.

⚠ WARNING**: DO NOT install in places where there is risk of explosions.**
DO NOT operate TT Transformer in the presence of flammable gases or liquids.

⚠ WARNING: a warning label is applied near the cylinder (figs.15-21, fig.29 and fig.33) which indicates that it is near an area where there is the presence of potentially corrosive reagents (cartridge and cylinder) and that the metallic surface which surrounds the cylinder can be hot.

2.2.2 SINGLE USE COMPONENTS

The only permitted use is as a replacement of TT Transformer equipment. Maker, cylinder and liquids tank are single-use components. Use only if the disposable blister is intact and DO NOT USE these components more than once. TT Transformer can only be used with components supplied by the manufacturer. Single use components must be ordered from the manufacturer. When opening the disposable blister, check the integrity of the cartridge. If the cartridge loses substances DO NOT USE, dispose it in special waste and insert a new cartridge into the device.

1. DANGER IDENTIFICATION Label elements

Labeling according to Regulation (CE) n. 1272/2008. Pictograms:

The symbol indicates the presence of a corrosive chemical product

The symbol indicates the presence of an irritant chemical product

Danger Hazard

H290 May be corrosive to metals.

H314 May cause severe skin burns and eye damage. H335 May cause respiratory irritation

Precautionary Statements P261 Avoid breathing vapors. P280 Wear protective gloves / eye protection / face protection. P305 + P351 + P338 IN CASE OF CONTACT WITH EYES: Rinse thoroughly for several minutes. Remove any contact lenses if it is easy to do. Continue to rinse. P310 Immediately call a POISON CENTER / doctor.

2. FIRST AID MEASURES

Description of first aid measures. General information: Consult a doctor. Show this safety data sheet to the attending physician. In case of skin contact: Wash with soap and plenty of water. In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a doctor. If swallowed: DO NOT induce vomiting. Rinse the mouth with water.

3. MEASURES IN CASE OF ACCIDENTAL RELEASE

Environmental precautions: Do not allow product to enter drains. For disposal, refer to the "Disposal considerations" section.

4. HANDLING AND STORAGE

Precautions for safe handling: Avoid contact with eyes and skin. Do not inhale vapors or mists. Conditions for safe storage, including any incompatibilities: store in a cool place. Keep the container tightly closed in a dry and well-ventilated place. Other types of usage: apart from the usage described, no other specific usage is contemplated.

5. EXPOSURE CONTROL / INDIVIDUAL PROTECTION

Eye / face protection: tightly fitting safety goggles. Skin protection: handle with gloves. Gloves must be checked before being used. Use a suitable technique for removing gloves (without touching the outer surface of the glove) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with current legislation and good laboratory practices. Wash and dry your hands. Physical protection: complete protective clothing. Respiratory protection: use a mask. Environmental exposure controls: do not allow product to enter drains.

6. TOXICOLOGICAL INFORMATION

Inhalation of vapors may cause: burning sensation, cough, asthma, shortness of breath, spasm, inflammation and laryngeal edema, spasm, inflammation and bronchial edema, pneumonia, pulmonary edema.

7. DISPOSAL CONSIDERATIONS

Waste treatment methods. The disposable cartridge and the disposable cylinder, containing the liquids collected after the processing cycle, must be disposed of in special waste containers.

2.3 STANDARD SYSTEM COMPONENTS

Standard set composition may vary during promotional campaigns.

Fig.2

n° 1 TT TRANSFORMER unit


Fig.3

n° 1 external power supply


Fig.4

n° 1 TT Mill

3. INSTALLATION

⚠ **WARNING**: the electrical system of the premises where TT TRANSFORMER is installed and used must meet all applicable standards and regulations for electrical safety.

⚠ **WARNING:** DO NOT install in places where there is risk of explosions. DO NOT operate TT TRANSFORMER in the presence of flammable gases or liquids (anesthetics, oxygen, etc.).

⚠ **WARNING**: install TT TRANSFORMER in an impact-proof place, which is also free from inadvertent spurts of water or other liquids.

⚠ **WARNING**: DO NOT install on/above/near sources of heat. Install TT TRANSFORMER in a place where there is adequate ventilation.

⚠ **WARNING**: though portable, TT TRANSFORMER must be handled with care when moved from one place to another.

⚠ **WARNING**: do not expose to direct sunlight or UV light.

⚠ **WARNING**: plug the power cord into the inlet at the back of the device. Plug the opposite end into a wall power outlet (fig.5).

⚠ **WARNING**: make sure the voltage and the frequency of the electricity supply match the power rating indicated on the external power supply.

Switching on

1. Press the on/off button at the back, switching it to ON (fig.6).
2. TT TRANSFORMER will turn on.

Switching off

1. Press the on/off button at the back switching it to OFF (fig.6).
2. TT TRANSFORMER will turn off.

Fig.5

Fig.6

3.1 FRONT ACCESS OPENING


Fig.7


Fig.8


Fig.9

Use the handle at the front (fig.8) to open the access door and lift it (fig.9) until it remains in open position.

3.2 MILL INSTALLATION

⚠ **WARNING**: verify that the Mill is clean, dry, sterilized, in its package and obstruction-free.

⚠ **WARNING:** verify that the slide is clean.

⚠ **WARNING**: verify that the Mill is not damaged.


Fig.10

Way of insertion.


Fig.11

Holding the Mill, insert it into the runners with the flap turned to the outside - as shown in figs.10-11.


Fig.12

Then gently push it until it reaches the end of the slide and gets locked into position (fig.12).

3.3 TANK, MAKER AND CYLINDER INSTALLATION

Fig.13

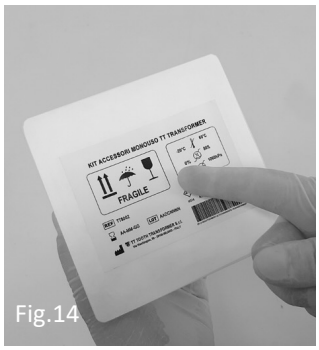


Fig.14

Fig.15

⚠ **WARNING**: verify that the sterile blister pack with single-use components is intact (figs.13-14). In case of damage do not use and dispose in special waste.

⚠ **WARNING**: Verify that the slide is clean (fig.15).

⚠ **CAUTION**: after opening the single-use blister pack, verify that the single-use components are not damaged and are not leaking. Specifically check for cracks or breaks in the MAKER, CYLINDER and that the TANK does not reveal liquid leakages.
In case of damage do not use and dispose in special waste.

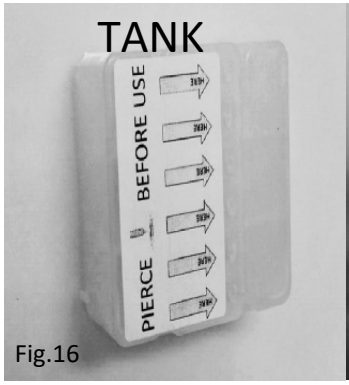


Fig.16

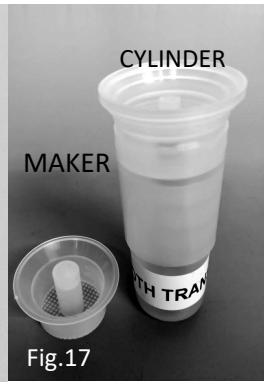


Fig.17

Fig.18

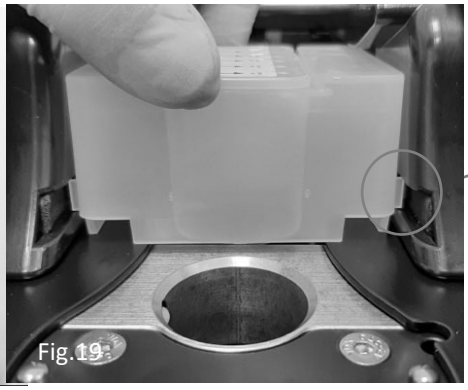


Fig.19

Insert the CARTRIDGE with the adhesive facing upwards (fig. 18) and the flaps facing forward (fig. 19).
Insert the CARTRIDGE flaps into the prepared grooves of the TT Transformer slide. Slide the CARTRIDGE into the slide.

Fig.20

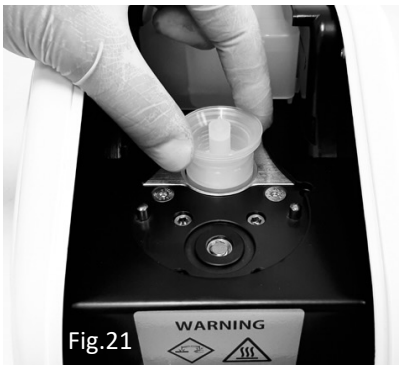


Fig.21

Follow the pre-holes and pierce with a sterilized instrument (fig.20).
Insert the CYLINDER with the maker into the slot with the pointed part facing upward (fig.21).

3.4 CONTROLS

To easily locate the controls on TT TRANSFORMER see the graphical illustration of the front panel on the right-hand side.

Description of controls
Press the central button to start processing (fig.22).

Display description and functions
The display visualizes current settings.

Fig.22

3.5 WARNING MESSAGES

TT TRANSFORMER incorporates a diagnostic system featuring audible and visual messages, with visualization on the display.

SIMBOL	SIMBOL MEANING	SIMBOL	SIMBOL MEANING
CE 1936	CE mark with indication of the notified body	CE	CE Mark
REF	Catalogue reference		Fragile
SN	Serial Number		Direct corrent
	See instruction for use		Warning
	WEEE – Waste electrical and electronic equipement		Corrosive
	Humidity range for storage		Hot surface
	Pression limit for storage		Do not expose to water and Humidity
CP	Product code	MD	Medical Device
	Manufacturer		Expiration date
	Date of production	LOT	Lot
	high		Do not reuse

3.6 WARNING AND CONTRAINDICATION

⚠ **WARNING: always wear GLOVES and HALF-MASK during the managing of the tooth to reduce biological hazard.**

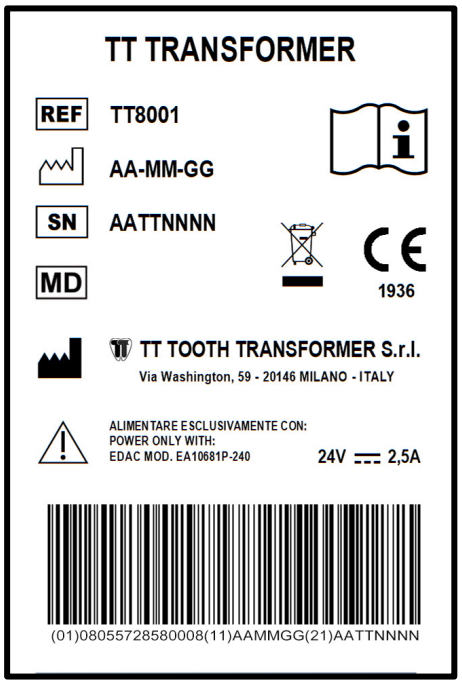
⚠ **WARNING: do not place the machine over another electronic device in order to avoid electromagnetic interference.**

⚠ **WARNING: TT transformer must always keep in the middle of a stable table in order to avoid accidental falls.**

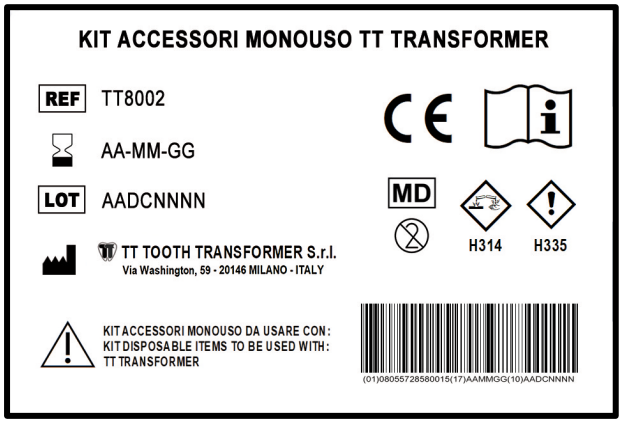
⚠ **WARNING: unauthorized personnel should not use the device or materials**

3.7 LABELS

3.7.1 TT TRANSFORMER LABEL



3.7.2 KIT DISPOSABLE ITEMS LABEL



ALARMS AND TROUBLESHOOTING

If functioning is faulty, then read the instructions again and refer to the troubleshooting guidance below.
Messages appearing on the display:

Maker is missing	Check that the maker is inserted and inserted correctly
Mill is missing	Check that mill/tank are inserted and inserted correctly
Basin is missing	Check that the lower basin is inserted and inserted correctly
Close the lid	Check the correct closing of the door
Motor error	Signals an error in the motors – stop the procedure!
Temp. error	Signals malfunctioning of the temperature probes – stop the procedure!
Mill error	Signals an error in grinding. Open the door and remove the Maker, the Tank and the Mill. Check and reposition the dental pieces inside. Insert mill, tank and maker once again

⚠ **WARNING**: creator and liquids tank are single-use component. Use only if their single use blister is intact and DO NOT use again these components.

⚠ **WARNING**: TT Transformer can be used ONLY WITH the components provided by the Manufacturer. Single use components must be ordered to the manufacturer.

⚠ **WARNING**: TT Transformer can be used ONLY WITH the power transformer provided Within the packaging. DO NOT use power transformer or replace its cord.

⚠ **WARNING**: if the use of TT Transformer does not comply with the user manual and manufacturer's instruction, the protection against hazards can be compromised.

⚠ **WARNING**: when you open the single use blister, please verify the integrity of the liquids tank. If the tank loses substances DO NOT use it and insert into the machine a new tank.

⚠ **WARNING**: if at the end of the process inside the maker you find only the minced tooth, please extract the liquids tank and verify the number of punched holes under the tank. If there are NOT punched holes, insert a new liquids tank and restart the process.

⚠ **WARNING**: at the end of the process always check that the cartridge is completely empty. In case one or more tanks are full, insert a new cartridge and restart the process.

⚠ **WARNING**: DO NOT remove the Waste when the machine is turned ON.

⚠ **WARNING**: DO NOT open the machine during the process.

⚠ **WARNING**: before opening the device you must TURN OFF and DISCONNECT the power supply from the main.

⚠ **WARNING**: DO NOT reuse the single use components (maker, cylinder and liquids tank).

⚠ **WARNING**: DO NOT open the machine if it is switched ON and connected to the main.

⚠ **WARNING**: keep it away from corrosive substances, explosive substances, high/low temperature and moisture.

⚠ **WARNING**: when it is taken from cold environment to warm and humid environment, please DO NOT use it immediately.

4. USE OF TT TRANSFORMER

⚠ **WARNING**: verify that all components are clean before using the device.

⚠ **WARNING**: use transparent disposable tape (10,2 cm x 15,2 cm) on the device in order to protect surfaces, commands and handle.

4.1 TOOTH PREPARATION

After the extraction, and before using the device, the tooth of the patient must:

1. be cleaned from residual tartar using piezoelectric instrument;
2. have radicular surface cleaned using a diamond cutter;
3. if needed, be cleaned from tooth's enamel using a cutter;
4. if possible, be broken in small parts to facilitate the work of the mill.

4.2 TOOTH INSERTION

The tooth of the patient must be put inside the mill.
So it is necessary to:

1. open the Mill component and put inside the tooth;
2. close the Mill component.

4.3 START OF THE PROCESS

Connect the power supply to the main and turn ON the device using the general switch situated on the back of the equipment.
When the word "WAIT" disappears on the display, open the lid and insert all components inside the device according to the order described in the previous paragraph.
When all components are inserted and the door of the device is closed, after the display shows the word "READY" it will be possible to press the "START" button to initiate the process.

⚠ **WARNING**: connect the power supply cord only to main that complies with all national laws and with an adequate earth protection (max 240Vac).

⚠ **WARNING**: the device could be connected only to main with the features: 100-240Vac, 50-60Hz.

⚠ **WARNING**: equipment has to be properly positioned in order to facilitate the disconnection from the supply.

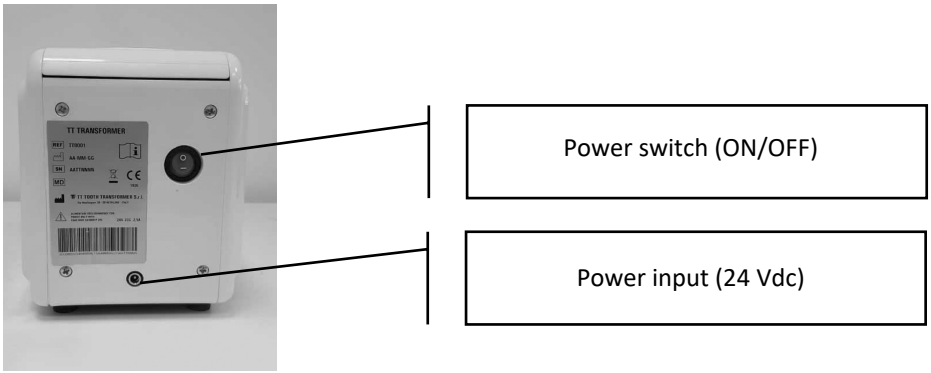


Fig.23: Power switch position

Check the absence of alert message on the display. If all check routine are ended well, the display will show "READY".
Now, the user have only to press the button "START" (fig.24) to begin the automatic process.

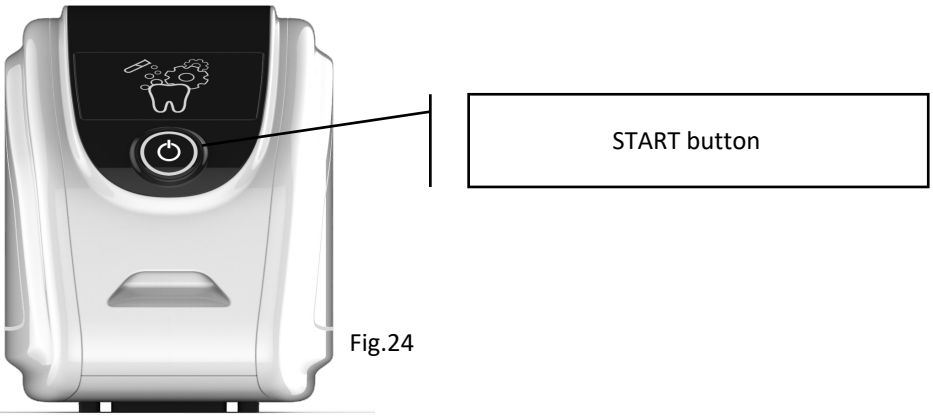


Fig.24

During the process the display will show to the user the processing's phase in which the device is.

4.4 END OF THE PROCESS

An acoustic alert advises the user that the process is finished and the display shows the message: "END TREATMENT".
Now it is possible to use the resulting autologous material (collected inside the maker) for the dedicated use.

⚠ **WARNING**: before opening the machine to keep the resulting autologous material, please TURN OFF the device using the general switch on the back of the case.

⚠ **WARNING**: user has to use GLOVES to open the device and keep the maker that collects autologous material.

5. INSTRUCTIONS FOR USE

1. Wear gloves and protective mask throughout the procedure.
2. Apply medical adhesive tape on contact points.
3. Gently remove any residue of ligaments on the root of the extracted tooth by using a diamond burr (fig. 25).
4. Remove any calculus and plaque residue from the entire tooth surface (fig.25).
5. Remove any reconstruction or foreign material using a burr (fig.25).
6. Blow air across the surface of the remaining tooth to dry it. The Tooth need to be perfectly dry.
7. Break the tooth up into little pieces.
8. Place the tooth pieces into the (perfectly dry) mill (fig. 26).
9. Turn ON TT TRANSFORMER using the switch at the back of the device (fig. 27).
10. Open the lid of TT TRANSFORMER when the word WAIT disappears on the display (fig.28).
11. Insert the MILL, TANK , MAKER and CYLINDER correctly into their respective slots (fig. 29).
12. Follow the pre-holes and pierce with an instrument (fig.20).
13. Close the lid of TT TRANSFORMER (fig. 30).
14. Press the central button to start processing when the word READY appears on the display (fig.30).


Fig.25

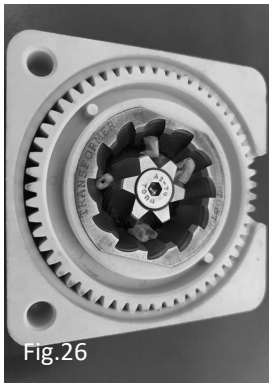


Fig.26

Fig.27


Fig.28

Fig.29

Fig.30

14. At the end of the fragmentation procedure the machine will stop to allow to control if the fragmentation has been efficient (fig. 31). Open the lid to control if the granules are present inside the maker. If all is correct close the lid and push the central button to end the procedure.
In this phase it's possible to control the mill. You can remove the tank and the mill to control inside. After this you can, following the starting procedure, close the lid and push the central button to start.
15. At the end of the procedure (about 20 min.), its completion will be marked by an audio signal and "END TREATMENT" will appear on the display.
16. Open the door and remove the MAKER drum carefully (fig. 32).
17. Place the MAKER drum where later it will be used for surgery.
18. Carefully take out the CYLINDER which by this stage will contain the liquids employed. Dispose of the CYLINDER as special waste (fig. 33).
19. Carefully remove the liquids cartridge (TANK) and dispose of it as special waste.
20. Carefully remove the MILL and treat it as any contaminated instrument following standard sterilization procedures (fig. 34).
21. Turn off TT TRANSFORMER (fig. 35) and disconnect power supply (fig. 36).
22. Clean the inside of the device using a damp cloth and a cloth to dry (fig. 37).

Fig.31


Fig.32


Fig.33


Fig.34

Fig.35

Fig.36

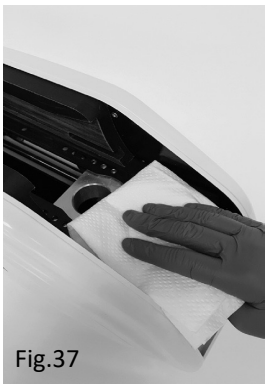


Fig.37

6. CLEANING OF THE MACHINE

Immediately after each use, TT Transformer must be cleaned.

⚠ **WARNING**: you must always wear GLOVES and HALF-MASK during the cleaning procedure.

⚠ **WARNING**: DO NOT remove the underlying drawer Waste when the machine is turned ON.

1. Turn OFF the device.
2. Extract from the machine the liquids tank and put it into its blister.
3. Extract from the machine the Cylinder and put it into its blister.

⚠ **WARNING**: manage carefully the Cylinder because now it is full of liquids.

4. Waste these components as described in paragraph “Disposal".
5. Extract the drawer named “Waste” from the machine and clean it.
6. Verify that in the Waste there is only dust.
7. Remove from the surface of the machine the transparent sticker and clean the machine with a soft gauze by saturating with a solution such as 75% isopropyl alcohol or other antiseptic solution certified as medical device.

⚠ **WARNING**: before next use, wait that surface are completely dry and there are not flammable vapour of cleaning solutions.

⚠ **WARNING**: DO NOT submerge the device into liquid and DO NOT spray any liquid on it directly.

⚠ **WARNING**: never use any sharp tool to remove dirty, since it will scratch the surface.

8. Pass firstly a clean damp cloth and then a dry one over the surface.
9. In compliance with the applicable requirements UNI EN ISO 17664-1:2021 which constitute the guidelines for determination and validation of the reconditioning process of reusable medical devices and the relative information provided by the manufacturer, the detailed instructions for the cleaning, dissection and sterilization of the grinder are provided in the following paragraph.

7. CLEANING, DISINFECTION AND STERILIZATION OF THE GRINDER

⚠ **WARNING:** the **grinder** can only be reused if it has been reconditioned under the responsibility of TT Tooth Transformer, which indicates for this purpose the cleaning, disinfection and sterilization protocol and the maximum number of possible reconditioning cycles, so that it complies with the General Safety Requirements and Performance.

⚠ **WARNING:** sterilize using only steam autoclave. **DO NOT use any other sterilization method (dry heat, irradiation, ethylene oxide, gas, low temperature plasma etc.).**

PREPARATION OF THE PART TO BE REPROCESSED
Open the grinder and divide the grinder into its three parts.

CLEANING (DECONTAMINATION AND CLEANSING)
During the decontamination it is necessary to adopt hazard control measures by using individual protection (gloves, visor, waterproof apron, mask) and applying a particularly high level of caution.

Decontamination
Emerge all the parts of the grinder in a solution containing strong ID 212 (Durr Hygiene System) at a concentration of 2% for 5 minutes.
Cleansing (manual brushing)
After extracting the parts of the grinder, clean the surfaces of each part by gently brushing using a brush with soft nylon bristles, paying particular attention to the areas of the cone cutters.

RINSING
Thoroughly rinse under running water.

ULTRASOUND DISINFECTION/CLEANSING
After manual cleansing, the parts must undergo a rigorous procedure of ultrasound disinfection/cleansing in order to remove eventual organic and inorganic residues, and consequently also any microorganisms.
After inserting the parts of the grinder in the specific perforated basket, immerse them in the tank of the ultrasound system using the following setting:
•• solution containing strong ID 212 (Durr Hygiene System) with 2% concentration;
•• water temperature 45°C;
•• ultrasound frequency of 35 Khz;
•• action time 5 minutes.

Fig.38

RINSING
Thoroughly rinse under running water.

DRYING
After rinsing, the parts must be dried accurately, preferably with compressed air as this method has proved to be more efficient compared to other procedures. Alternatively, the drying can be carried out using paper or material cloths which do not leave fibres.

CONTROL
Before packaging the parts must be carefully controlled to guarantee their working order and intactness.

PACKAGING
The packaging of the parts of the grinder is then carried out in Bags and Rolls together with polymer film (norm of reference: UNI EN ISO 11607-1 e UNI EN ISO 11607-2, UNI EN 868-3, UNI EN 868-5). The bags must be of sufficient dimensions that the materials contained therein do not take up more than ¾ of the total volume. If the bag or roll needs to be heat sealed, the heat sealing must be carried out at a temperature between l60°C and 180°C, based on the type of material.

STERILIZATION WITH STEAM AUTOCLAVE

The sterilization process by gravity displacement autoclave must be performed with one of the two standard cycles indicated below:
- 121°C for 16 MINUTES at 1atm;
- 134°C for 6 MINUTES at 2atm.

At the end of the sterilization cycle carried out, subject the shredder to drying and cooling at room temperature for 30 minutes..

All the phases of sterilization must be carried out by the operator in accordance with the norm UNI EN ISO 17665-1:2007, UNI EN ISO 556-1:2002 and ANSI/AAMI ST:46:2002.

The recommended maximum number of sterilization cycles in autoclave is 100.

8. TROUBLESHOOTING

During the normal use of the device, some malfunctions may occur. Please, follow the troubleshooting described below and if the issue persists, please contact the manufacturer.

MALFUNCTION	POSSIBLE CAUSE	POSSIBLE SOLUTION
The process does not start.	Components are not inserted in the machine according the correct order.	Before to restart the process please turn off the machine and insert components according to User Manual.
Process failure: inside the MAKER there is only the minced tooth and not the desired processed material.	The tank for liquids and reagents is not new and is empty. The tank has not been pierced.	Please turn off the machine, insert a new liquids tank and restart the process.
The display does not show anything.	The device is not connected to the main The device is switched off.	Verify the connection of the power supply in the main. Verify the main switch of the device.
Incomplete procedure: one or more tank's tank are still full.	The tank was not completely pierced.	Switch off the device, insert a new single cartridge and restart the procedure.

9. TECHNICAL ASSISTANCE

In case of malfunction do not use the machine and immediately request support to the manufacturer at the following contact:

TT Tooth Transformer S.r.l
Via Washington 59 – 20146 Milano (MI) – Italy
VAT 09487660962 /tel. +39 02-4695435
www.toothtransformer.com / info@toothtransformer.com

Maintenance
In order to ensure its long service life, please pay attention to the instructions for use and maintenance

CONTROL/PROCEDURE	FREQUENCY	RESPONSABILITY
Integrity of power supply cord	After every use	User
Integrity of AC Adapter	After every use	User
Integrity of TT Transformer	After every use	User
Integrity of TT Transformer's components	After every use	User
Functionality of the display	After every use	User
Cleaning	After every use	User

A correct maintenance's plan and a use according to this User Manual grants the correct functionality of the device during its expected life.

10. TRANSPORT AND STORAGE

TT Transformer must be stored without the liquids tank inside the device in order to avoid loss of liquids and reagents inside the machine. The unit must be kept in its hard cover box, in an environment free of dust, at a temperature between -20 °C and +60 °C and at a relative humidity less than 80%.

⚠ **WARNING**: DO NOT move the machine in case of presence of waste in the underlying drawer.

11. WASTE DISPOSAL

According to the directive 2012/19/EU (RAEE)

TT Transformer contains inside electrical and electronic components, it is mandatory to proceed to its disposal separately from household waste as required by the Directive 2012/19/EU (RAEE). Disposal can take place only at authorized treatment centers for electrical and electronic equipment on national territory. It is therefore invited to identify, prior to disposal, the nearest authorized center.
Alternatively, the device can be returned to the manufacturer who will proceed to its recovery and recycling. Not properly manage this waste, risks to generate a consequent increase in pollution of the soil, air and water with implications for human health.
The Device must be treated and disposed of as electric and electronic waste. Failure to do so will result in penalties as per Directive 2012/19/EU (RAEE).

⚠ **WARNING: hospital waste**.
The following components must be treated and disposed of as hospital waste:

- MAKER
- CYLINDER
- TANK

12. DISPOSAL OF MAKER, CYLINDER AND LIQUID TANK

Organic waste collected in the drawer of the device, maker, cylinder and liquid tank must be managed according to the waste procedure of the dentistry's office as special waste with biological hazard.

⚠ **WARNING:** used components must be kept away from new components and immediately put with waste after use.

13. TECHNICAL SPECIFICATIONS

TT TRANSFORMER is compliant with COMPLIANT WITH THE EUROPEAN REGULATION (UE) 2017/745 ON MEDICAL DEVICE (MDR)

CE 1936

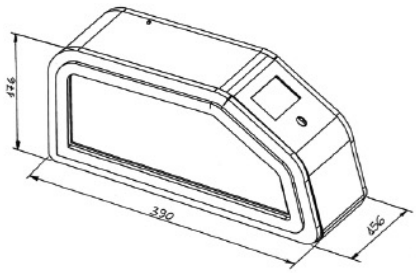
- External power supply voltage and frequency: 100-240 Vac, 50-60 Hz.
- Device power supply voltage max. absorbed power: 24 Vdc.
- Power: maximum absorbed power of 50 Watt.
- Processing cycle and warning messages.

Operating Conditions

- Operating temperature: 5°C to 45°C (41° to 99° F).
- Storage temperature: –20°C to 60°C (–4°F to 120°F).
- Operating humidity: max 80% up to 31°C (87°F), linear decrease 40°C (104°F).
- Storage humidity: <80%.
- Operating altitude: 4000 meters (13,000 feet) maximum.

Weight and Dimensions

- Weight: 6,1 kg.
- Dimensions: 390mmx176mmx156 mm.



14. ELECTROMAGNETIC COMPATIBILITY

Compliance with the requirements of the state-of-the-art standards on electromagnetic compatibility guarantee that the device can operate in professional environments suitable for the exercise of the profession of dental surgeon in compliance with safety and performance aspects.

Manufacturer's declaration and guidelines - electromagnetic emissions		
The TT Transformer medical device is intended for use in the electromagnetic environment specified below. The user must ensure that the device is used in such an environment.		
Emission test	Conformiy	Electromagnetic environment - guidance
RF emissions EN 61000-6-3 (30MHz-1GHz)	Compliant	The TT Transformer medical device uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Emission of mains terminal disturbance voltage (continuous disturbance) EN 61000-6-3 (0,15-30MHz)	Compliant	
Emission RF	Class A	The TT Transformer medical device can be connected directly to a low voltage mains power supply in rooms used for professional use in accordance with the intended use of the device.
Emission of harmonic currentsEN 61000-3-2	Class A Compliant	
Emissions of voltage fluctuations and flicker- EN 61000-3-3	Compliant	

Manufacturer's declaration and guidelines - electromagnetic immunity

The TT Transformer medical device is intended for use in the electromagnetic environment specified below. The user must ensure that the device is used in such an environment.

Immunity test	Livello di prova	Livello di conformità	Ambiente elettromagnetico – guida
Electrostatic discharge (ESD) IEC 61000-4-2	± 4 kV in direct contact ± 8 kV on air ±4kV (indirect)	± 4 kV in direct contact ± 8 kV on air ±4kV (indirect)	Floors should be wood, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Transitori elettrici veloci /bursts IEC 61000-4-4	± 1 kV per le linee di alimentazione ± 0,5 kV per le linee di input/output	± 1 kV per le linee di alimentazione ± 0,5 kV per le linee di input/output	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power input lines IEC 61000-4-11	Voltage Dips: 0% residual voltage 0,5 cycle; 40% residual voltage 1 cycle; 70% residual voltage 25/30 at 50/60 Hz cycle. Voltage interruptions: 0% residual voltage 250/300 at 50/60 Hz cycle	Voltage Dips: 0% residual voltage 0,5 cycle; 40% residual voltage 1 cycle; 70% residual voltage 25/30 at 50/60 Hz cycle. Voltage interruptions: 0% residual voltage 250/300 at 50/60 Hz cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TT Transformer medical device requires continued operation even during a possible mains power failure, it is recommended to power the device from an uninterruptible power supply
Surge IEC 61000-4-3	±2,0kV (common mode) ±1,0kV (differential mode) ±0,5kV (signal)	±2,0kV (common mode) ±1,0kV (differential mode) ±0,5kV (signal)	Mains power quality should be that of a typical commercial or hospital environment
Conducted RF IEC 61000-4-6	150 kHz - 80 MHz 3V (rms unmodulated), 80% AM, 1 kHz	150 kHz - 80 MHz 3V (rms unmodulated), 80% AM, 1 kHz	**Portable and mobile RF communications equipment should not be used near any part of the device, including cables, except when they observe the recommended separation distances calculated from the following equation applicable to the frequency of the transmitter.** **Recommended separation distances:** $d = 1{,}2\sqrt{P}$ *from* **150kHz to 800MHz** $d = 2{,}3\sqrt{P}$ *from* **800MHz to 2.5GHz** **where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).** **Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.** **Interference may occur in the vicinity of equipment marked with the following symbol:** 
Radiated RF IEC 61000-4-3	80 MHz – 1000MHz / 3 V/m RMS 1400 MHz – 2000 MHz / 3 V/m RMS 2000 MHz – 2700 MHz / 1 V/m RMS 1 / 3 V/m, 80% AM (1kHz)	80 MHz – 1000MHz / 3 V/m RMS 1400 MHz – 2000 MHz / 3 V/m RMS 2000 MHz – 2700 MHz / 1 V/m RMS 1 / 3 V/m, 80% AM (1kHz)	

Notes:

(1) At 800 MHz, the equation for the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(3) Field strengths from fixed transmitters, such as base stations for radio (cellular and cordless) telephones and land mobile radios, amateur radio, AM and FM radio and TV transmitters cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TT Transformer device is used exceeds the applicable RF compliance level above, the device should be monitored to verify normal operation. If abnormal performance is observed, additional measures such as reorienting or positioning the device may be necessary.

(4) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between radiocommunication equipment portable and mobile and the TT Transformer medical device

The TT Transformer medical device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radiocommunication devices (transmitters) and the TT Transformer medical device, as indicated below, according to the maximum output power of the radiocommunication devices .

Rated output power maximum of the transmitter W	Separation distance depending on the frequency of the transmitter (m)		
	From 150 kHz to 80V MHz d=1,2 √P	From 80 MHz to 800 MHz d=1,2 √P	From 800 MHz to 2,5 GHz d=2,3 √p
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter at Watts (W) according to the transmitter manufacturer.

Notes:

(1) At 800 MHz, the equation for the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15. WARRANTY

Prior to marketing, all TT Transformer devices undergo thorough final testing to ensure their full functionality and correct operation.

TT Tooth Transformer S.r.l. warrants all purchases of its products from a TT Tooth Transformer S.r.l. dealer or importer are free from defects in materials and workmanship for a period of:
- 2 (two) years from the date of purchase unless stated otherwise, for the device.

For the warranty period TT Tooth Transformer S.r.l. will repair (or replace, at its discretion) any parts that TT Tooth Transformer S.r.l. will confirm to be defective based on its own judgment.
TT Tooth Transformer S.r.l. shall not be liable for any and all direct or indirect loss or damage to property, death or personal injury in the event that:
- The device is used for purposes other than its intended use.
- The device is used in a way that is not compliant with any and all instructions and requirements set out in this manual.
- The electrical system of the premises where the device is used is not compliant with applicable standards and regulations.
- Assembling, extensions, adjustments, modifications and/or repairs are not carried out by TT Tooth Transformer S.r.l. authorized personnel.
- Storage and preservation conditions of the device are not compliant with the specifications set out in the *Technical Specifications* section.
- Parts and accessories not made or authorized by TT Tooth Transformer S.r.l. are used. This may lead to damage to the device and injury to the patient. Using non-genuine parts or accessories will void the Manufacturer's warranty and product certification!

This warranty does not cover accidental damage to the product that results from transport/repositioning, misuse, lack of care or connection to incorrect power.
Tampering with the device or having it repaired by unauthorized personnel will void this warranty.

⚠ **IMPORTANT!**

The warranty shall be valid only if the warranty card supplied with the product has been filled out in all its parts and sent to our Company address, or, if it be the case, to the relevant TT Tooth Transformer S.r.l. dealer or importer, within 20 (TWENTY) days from the purchase date as shown on the invoice/bill of shipment issued by the dealer or importer.
In order to avail of the warranty the Customer should return, at his own expense, the product to be repaired to the TT Tooth Transformer S.r.l. dealer/importer from whom the product was purchased.
The device must be returned suitably packed (in the original packing case), along with all the accessories and an information sheet comprising:

a) owner details including telephone number;
b) dealer/importer details;
c) photocopy of Owner's purchase invoice/bill of shipment containing information about the date of purchase, the product name and serial number;
d) a brief description explaining the nature of the problem.

Transport and damage caused during transport are not covered by the warranty.
Should damage result from accident or improper use or should the warranty have already expired, TT Tooth Transformer S.r.l. will charge the cost of repair (materials and labor).

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