

# SURGICAL KIT

## INSTRUCTIONS FOR USE



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### Warnings

- The device is intended for the use of medical and paramedical personnel who are aware of the sterilization processes in autoclave.
- The device is not sterile. Use only after a sterilization cycle.
- At the end of its life cycle, the device must be disposed of in compliance with the laws in force in the country of use.

#### 1. Description

The autoclavable containers are conceived and designed to contain and support surgical tools in the correct position, during transport and during sterilization in the autoclave. The sterilization cycles for which the autoclavable containers have been designed are those envisaged for steam sterilizers used for medical purposes or for materials that may come into contact with blood or physiological liquids.

Autoclavable containers:

- **keep tools in the correct position** during transport and storage and during and after the autoclave sterilization cycle: the tools are supported by the shank or handle, with the opposite edge facing upwards;
- **do not obstruct the proper performance of the sterilization process**, letting the steam pass inside the container;
- **do not contaminate the tools during or after the autoclave sterilization process**: they are sterilized by the very same sterilization cycle as the tools.

The sterilization cycles are defined by the manufacturer of the tools and surgical instruments and / or by the manufacturer of the sterilization autoclave.

The characteristics of the sterilization cycle, taken as a reference by the manufacturer for the tests on autoclavable containers, are the following:

- temperature 132°C ±3°C;
- duration of the cycle 3 min;
- pressure 2 bar.

#### 2. Precautions

Inappropriate use, breakage of the container, deterioration of the material can compromise the resistance to sterilization or the sterilization of the container; in case of damage to any component, re-use is not recommended. Exposure to sunlight induces variations in the color of the box and tray but does not compromise the characteristics of resistance to sterilization and the sterilization of the material. New autoclavable containers, complete with silicone supports, must be washed before first use. Use the tray equipped with silicone supports to support the tools, during sterilization processes. Autoclavable containers are unable to maintain sterility. For this reason it is necessary to use the specific bags inside which the autoclavable containers, containing the tools to be sterilized, will be placed.

#### 3. Indications for the use

Before each use it is advisable to wash the autoclavable containers with water and detergent with the aim of keeping the bacterial content low. In the event of suspected contamination of the autoclavable container with biological material or prolonged inactivity, it is advisable to proceed with thorough cleaning which includes the disassembly of the silicone supports and the application of disinfection procedures typical of the preparation of surgical instruments for steam sterilization. Dry the container and replace the silicone supports on the tray, if it has been necessary to disassemble them. A visual check is advisable, to verify the integrity of the box. Arrange the tools prepared for sterilization in the specific supports, which are adequate to hold the tool during handling and the sterilization cycle. The tool will be positioned with the effective part upwards and inserted on the silicone support for the stem, so as to leave the surface to be sterilized uncovered. The surgical instruments will be supported on the handle and never on the effective part. The tray with utensils will be placed in the box and the box closed. Autoclavable containers are not able to preserve sterilization, to obtain this result it will be necessary to insert the autoclavable containers with their contents in bags capable of preserving sterilization. After using the tools, the autoclavable container should be stored in a protected place in order to avoid unnecessary contamination until the next re-use.

#### 4. Sterilization parameters

CYCLE	TEMPERATURE (C°)	TIME (MIN.)	PRESSURE (BAR)
CYCLE 1	132 ±3°C	3	2
CYCLE 2	135 ±3°C	3	2

#### 5. Sterilization process

The product has been designed and built exclusively for the foreseen conditions, any other use is to be considered improper and dangerous. Being the tools reusable we recommend as follows:

- do not use abrasive agents for cleaning and washing before sterilization;
- perform sterilization as indicated below:

##### **steam:**

seal the kit (with instruments inside) in a sheet of filter paper suitable for steam sterilization and steam sterilize at 132°C - 135°C (237.6°F-243°F) for 3 minutes; respect the drying times of the devices.

Alternative for UK: seal the kit in a sheet of filter paper suitable for steam sterilization and steam sterilize at 134 ° -135 ° C (241,2°F-243°F) for 3 minutes; respect the drying times of the devices.

Where the requirements for steam sterilization are stricter than those indicated above, comply with the requirements dictated by local or national regulations on the matter.

The dentist is responsible for verifying / checking his own sterilization system.

For a good functionality, the accessories must be used exclusively for the preparation of the implant site of GIESSE dental implants. The use of non-sterile devices can lead to infections.

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### 6. Maintenance

New autoclavable containers must be washed before first use. A cleaning with water and detergent is also advisable depending on the use made of the autoclavable container before each subsequent use. It is advisable to use non-abrasive and non-aggressive products, while washing the box. No other maintenance is planned.

### 7. Instructions for disposal

For the disposal of the product, the supplier provides for incineration in a suitable incineration plant authorized by the competent authorities. It can be landfilled when local legislation allows.

### 8. Garanzie e limitazioni

GIESSE TECHNOLOGY Srl warrants to the first purchaser of this surgical set that the latter has been produced, packaged and tested with reasonable care and that it is free from defects in workmanship and materials used for a period of two years from the date of first purchase. This warranty is not valid in case of alteration or modification of the product or in case of improper storage, use or maintenance of the same. Defects resulting from the misuse of this product are not covered by this warranty. Furthermore, the warranty does not apply in case of improper use and in any case not in compliance with the provisions contained in the instructions for use, shocks, falls, conditions including environmental conditions or unsuitable agents, or in any case in which the defect of the product is caused by fact or act that is not attributable, directly or indirectly, to the fault of GIESSE TECHNOLOGY Srl. Under no circumstances will GIESSE TECHNOLOGY Srl be held liable towards the purchaser for any direct or indirect damage resulting from the manipulation or use of the product. Liability under this warranty will be limited to the replacement of the defective product or, at the sole discretion of GIESSE TECHNOLOGY Srl, to the refund of the net price paid.

 LOT	CODICE DEL LOTTO	 REF	NUMERO DI CATALOGO (CODICE PRODOTTO)
	FABBRICANTE		ATTENZIONE, CONSULTARE LE ISTRUZIONI PER L'USO
	NON UTILIZZARE SE LA CONFEZIONE NON È INTEGRA		