ANVISA Registration N° 80455630052
Rev.:01

INSTRUCTIONS FOR USE

TECHNICAL NAME: Boxes, trays, bowls, etc.

TRADE NAME: TRAUMEC Family of Aluminum Boxes, Containers and Trays

MEDICAL PRODUCT
NON-STERILE PRODUCT

WARNING: Please read carefully all instructions before use. Follow all warnings and precautions mentioned in this instruction. Disregarding these points may lead to occurrence of complications.

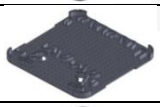
1. Product Identification

The boxes and trays are manufactured for packaging implants and / or instrumental used in orthopedic surgeries and bone correction, and for each type of surgery and for each set of products there is a specific case. The purpose of the boxes and trays is for packing and easy transport and sterilization of instruments and materials - health products - identifying them as a way to make the surgical instruments and sterilization by autoclave easier.

2. Instrument Raw Materials

The following materials are used in the manufacturing of the cases: Aluminum.

These Instructions also regard the following products:

CODE	DESCRIPTION	ILLUSTRATION
PA.02.06.0136	Tray 1/2 Superior Standard	
PA.02.06.0137	Tray 1/2 Inferior Standard	
PA.02.06.0138	Tray 1/2 Superior Reinforced	
PA.02.06.0139	Tray 1/2 Inferior Reinforced	
PA.02.06.0140	Tray 1/2 Superior Compact	

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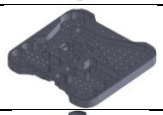
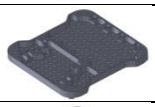
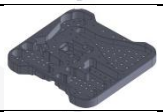
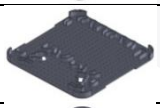
PA.02.06.0141	Tray 1/2 Inferior Compact	
PA.02.06.0142	Tray 1/2 Superior Vario Case	
PA.02.06.0143	Tray 1/2 Inferior Vario Case	
PA.02.06.0144	Tray 3/4 Superior Standard	
PA.02.06.0145	Tray 3/4 Inferior Standard	
PA.02.06.0146	Tray 3/4 Superior Reinforced	
PA.02.06.0147	Tray 3/4 Inferior Reinforced	
PA.02.06.0148	Tray 3/4 Superior Compact	
PA.02.06.0149	Tray 3/4 Inferior Compact	
PA.02.06.0150	Tray 3/4 Superior Vario Case	
PA.02.06.0151	Tray 3/4 Inferior Vario Case	
PA.02.06.0152	Tray 1/1 Superior Standard	
PA.02.06.0153	Tray 1/1 Inferior Standard	
PA.02.06.0154	Tray 1/1 Superior Reinforced	
PA.02.06.0155	Tray 1/1 Inferior Reinforced	
PA.02.06.0156	Tray 1/1 Superior Compact	
PA.02.06.0157	Tray 1/1 Inferior Compact	

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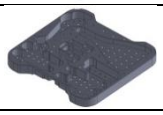
PA.02.06.0158	Tray 1/1 Superior Vario Case	
PA.02.06.0159	Tray 1/1 Inferior Vario Case	
PA.02.06.0160	Container 1/2 x 100 for Sterilization	
PA.02.06.0161	Container 1/2 x 100 for Sterilization Punched Base	
PA.02.06.0162	Container 1/2 x 135 for Sterilization	
PA.02.06.0163	Container 1/2 x 135 for Sterilization Punched Base	
PA.02.06.0164	Container 1/2 x 150 for Sterilization	
PA.02.06.0165	Container 1/2 x 150 for Sterilization Punched Base	
PA.02.06.0166	Container 1/2 x 200 for Sterilization	
PA.02.06.0167	Container 1/2 x 200 for Sterilization Punched Base	
PA.02.06.0168	Container 1/2 x 260 for Sterilization	
PA.02.06.0169	Container 1/2 x 260 for Sterilization Punched Base	
PA.02.06.0170	Container 3/4 x100 for Sterilization	
PA.02.06.0171	Container 3/4 x100 for Sterilization Punched Base	
PA.02.06.0172	Container 3/4 x135 for Sterilization	
PA.02.06.0173	Container 3/4 x135 for Sterilization Punched Base	
PA.02.06.0174	Container 3/4 x150 for Sterilization	

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PA.02.06.0175	Container 3/4 x150 for Sterilization Punched Base	
PA.02.06.0176	Container 1/1 x100 for Sterilization	
PA.02.06.0177	Container 1/1 x100 for Sterilization Punched Base	
PA.02.06.0178	Container 1/1 x135 for Sterilization	
PA.02.06.0179	Container 1/1 x135 for Sterilization Punched Base	
PA.02.06.0180	Container 1/1 x150 for Sterilization	
PA.02.06.0181	Container 1/1 x150 for Sterilization Punched Base	
PA.02.06.0182	Container 1/1 x200 for Sterilization	
PA.02.06.0183	Container 1/1 x200 for Sterilization Punched Base	
PA.02.06.0184	Container 1/1 x260 for Sterilization	
PA.02.06.0185	Container 1/1 x260 for Sterilization Punched Base	

Note: illustrative images

4. Operation principle

Accommodate in a systematic and organized way the implants and instruments in order to maintain the physical integrity of the instruments, facilitating handling both during surgery, as in transportation procedures, storage and sterilization.

5. Directions

Each model case for packaging surgical implants and instruments has a specific form of packaging of implants and / or instruments that are provided by the IDs of each case, facilitating the recognition of the instruments and / or implants. The kits do not come accompanied by instruments and implants for surgeries; they are purchased separately, and then put in their respective cases.

PROCEDURES IN ORDER TO USE AND REUSE THE MEDICAL PRODUCT

Directions of the product

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Case Inspection: Check through a visual inspection, if there is any physical damage to the case, such as scratches, dents, characteristics associated with conservation and its functionality. This technical inspection must be performed by a qualified professional.

If any part failed, it must be separated for a review and maintenance by the supplier or intended for disposal.

Packaging of instruments and / or implants in the case: The instruments and / or implants should be handled carefully and in small batches to avoid bumping or dropping the mounting assembly. All instruments and / or implants should be positioned according to the IDs of their respective cases.

After this assembly the case should be submitted to a technical inspection by an officer enabled.

Sterilization: The instruments are supplied fully decontaminated, clean and non-sterile; they must be sterilized before use. TRAUMEC recommends the sterilization methods described below.

The parameters suitable for (physical or chemical) sterilization processes for each equipment and volume must be analyzed and conducted by people trained and specialized in sterilization processes, ensuring the complete efficiency of this procedure.

In order to do so, the manufacturer instructions and methods in accordance with the internal guidelines of the hospital establishment must be followed.

In all cases, the sterilization process selected should, in any case, comply with the standard EN556-1, which establishes that the theoretical probability of the presence of vital microorganisms is at most 10-6 (SAL [Sterility Assurance Level] - level of sterility assurance = 10-6). It is the user's responsibility to guarantee the use of an adequate sterilization process and the sterility of all devices at any stage of the process.

It is recommended that the following physical sterilization parameters to be applied to autoclaves (saturated steam):

Cycle	Temperature	Exposure Time
Regular (pressure of 1 atm)	121°C (250°F)	30 minutes
Regular (1 atm pressure)	132°C (270°F)	15 minutes
Gravity	132°C (270°F)	45 minutes
High-Vacuum	132°C (270°F)	4 minutes

NOTE: *Only start timing when the heat from the sterilization chamber reaches the desired temperature*. The instruments must be sterilized in autoclaves before use, according to a validated method and in compliance with NBR ISO 17665 Part 1: 2010.

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Reuse of Cases: The process for re-use cases for packaging implants and surgical instruments involves at least five basic steps:

Pre-cleaning, Decontamination, Washing, Rinse and Drying:

It is recommended that every case, container and tray must be cleaned immediately after the end of the surgical procedure, thus avoiding the hardening of soils from the procedure.

All manual cleaning procedures must be carried out using appropriate personal protective equipment. In automatic equipment cleaning operations, manufacturers' instructions should be followed closely, particularly with regard to product care and the quality of the water used in the process. Cases and trays when appropriate should be introduced open or disassembled.

Water quality is a fundamental factor both for the cleaning process and for the preservation of the cases and trays, so the presence of particulates, the concentration of elements or chemical substances, and the pH imbalance can deteriorate the cases and trays during the cleaning process.

Pre-cleaning: The cases must be preferably submerged and, whenever possible, opened or disassembled in a suitable container with water and a preferably enzymatic detergent at room temperature. Afterwards, it should be dipped, opened or dismantled, when appropriate, into a suitable container with water and detergent, preferably enzymatic, at room temperature. It should then be thoroughly rinsed in running water, preferably lukewarm. This phase should always be performed with water at temperatures below 45°C, because higher temperatures cause proteins coagulation, making it difficult to remove encrustations from the instruments.

Decontamination: It is performed by immersing, whenever possible, open or disassembled cases, in a suitable container, with a solution of disinfectant in water at room temperature (chemical disinfection), or in a heated bath (thermochemical disinfection). The immersion time of the instrument depends on both the water temperature during decontamination operation, as well as the dilution and the type of disinfectant used in it.

Washing: The pieces must be thoroughly brushed, with a soft bristle brush, paying special attention to articulations, grooves and gear racks. The cases, whenever relevant, must be disassembled and each component must be washed separately. Pay special attention to areas that are difficult to reach, where organic tissue, secretions or disinfection solutions may be retained or deposited.

Rinsing: The case must be plentifully rinsed under running water; articulated instruments must be opened and closed several times during the rinsing process. It is recommended to use warm water in order to rinse the case.

Drying: You must ensure that the drying processes do not introduce humidity, particles or fluff onto the case surface. Pay special attention to articulations, grooves and gear racks. It is recommended

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that the tissue is absorbent, soft and that each part of a disassembling instrument is dried separately; and if the instrument presents cavities or slots, their inside must be completely dried.

Disposal: The disposal of disqualified parts must be performed under technical assessment and guidance. After the replacement, destroy all damaged components, preventing further improper use. When there is the need to dispose of the instrument, it must be immediately disabled, in order to prevent its inadvertent use.

The disposal of cases must comply with the standards regarding disposal of contaminant medical waste.

We recommend that the parts are sanded, bent or cut in order to be disabled. For the disposal of case, follow your local legislation in force regarding the discard of potentially contaminant products.

6. Storage conditions

The cases must be stored in a clean, dry and ventilated place, at room temperature and away from direct light. The special storage, handling and preservation conditions of the product must be observed, in order to guarantee that the components remain intact until used in the surgical procedure. Care regarding receipt, storage, transport, cleaning and batch references preservation must be adopted along the best practices of storage and distribution of medical products.

7. Handling and transportation conditions

The case must be transported and handled as to prevent any damages or alterations of their characteristics.

The case must be managed and handled carefully, in small batches, preventing bumping or dropping. Any instruments that has been dropped or handled in an unsuitable manner or even if it is suspected that it may have suffered any damages must be isolated and submitted to the responsible technician, qualified for performing the inspection, even if it has already been through this step.

Note: Any product that has been dropped or unsuitably managed, or even if it is suspected it may have been suffered any damages, must be sorted and segregated.

8. Contraindications

There are no contraindications

9. Warnings

This product can be used several times since it is not damaged by wear or shock caused by handling. Therefore, every use should be made a thorough inspection, checking all aspects of the case that

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may affect the requirements for effectiveness and safety of the product, and when detected any irregularities discard it.

Under no circumstances, we need to use steel wool or abrasives even scouring powder to remove remaining dirt from any stage of the cleaning process.

It must be assured that every case to be sterilized is effectively cleaned. The products used must be registered at ANVISA.

10. Precautions

The products must be kept in their original packages until sterilized and used. Clean it correctly after every use, in order to prevent incrustations or corrosions.

At every use, check whether the instruments have suffered any damages.

Technical name: BOXES, TRAYS, BOWLS, ETC

Trade Name: FAMILY OF BOXES, CONTAINERS AND TRAYS ALUMINUM TRAUMEC.

Business Model: TRAY 1/2 UPPER STANDARD

Code: PA.02.06.0136

Lot: XXXXXX

Quantity: 01 pc

ANVISA Registration No: 80455630052

Manufacture: XX / XX / XXXX

Validity: XX / XX / XXXX

Material: XXXXXX

Technical Director: José Luiz Caritá - CREA-SP - 0685038754

NON-STERILE PRODUCT

SPECIAL CONDITIONS OF STORAGE, CONSERVATION, HANDLING MEDICAL PRODUCT: SEE INSTRUCTIONS.

ANVISA Registration No 80455630052

Technical Director: José Luiz Caritá - CREA-SP - 0685038754

Made by: TRAUMEC TECNOLOGIA E IMPLANTES IMPORTAÇÃO E EXPORTAÇÃO LTDA

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