INSTRUCTIONS FOR USE

Product Data:

Technical Name: IMPLANTABLE DENTAL DISTRACTOR

Trade Name: TRAUMEC TRANS-PALATAL DISTRACTOR.

Models: The TRAUMEC TRANS-PALATAL DISTRACTOR family consists of the following items (table 01):

Special features: TRAUMEC TRANS-PALATAL DISTRACTORS are supplied together with the instruments required for their application.

Composition:

Table 01 – (**TRAUMEC TRANS-PALATAL DISTRACTORS**).

Item	Denomination	Composition	Quantity
1	**Pillar Plate**	Pure Titanium (ASTM F67)	2
2	**Trigger module**	Titanium alloy (Ti6Al4V – ASTM F136/NBRISO 5832-3	1
3	**Self-drilling Screw**	Titanium alloy (Ti6Al4V – ASTM F136/NBRISO 5832-3	4

(Note: the indicated quantity of items refers to a single TRAUMEC TRANS-PALATAL DISTRACTOR)

Item	Code	Description	Template	Module
1	PA.01.05.0001	TRANS-PALATAL Distractor Air-gap of 9mm		1
				

(Note: illustrative images)

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Item	Code	Description	Template	Item
2	PA.01.05.0002	TRANS-PALATAL Distractor Air-gap 15mm		2
				

(Note: illustrative images)

Item	Código	Descrição	Template	Item
3	PA.01.05.0003	TRANS-PALATAL Distractor Air-Gap 20mm		2,5
				

(Note: illustrative images)

Item	Code	Description	Template	Item
4	PA.01.05.0004	TRANS-PALATAL Distractor Air-Gap 27mm		3
				

(Note: illustrative images)

Item	Code	Description	Template	Item
5	PA.01.05.0005	TRANS-PALATAL Distractor Air-Gap 33mm		4
				

(Note: illustrative images)

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1 – Medical Product Description.

The TRAUMEC TRANS-PALATAL DISTRACTOR consists of a medical device made of titanium alloy, and pure titanium, composed of three parts, whose purpose is to expand or distract the jaw quickly and accurately, and aims to correct maxillary constrictions, (unilateral or bilateral) cross bites as well as correction of anterior crowding and buccal corridors.

Note: TRAUMEC TRANS-PALATAL DISTRACTOR is a single device, supplied assembled and sterile by gamma rays (CO 60)

2 – Composition

TRAUMEC TRANS-PALATAL DISTRACTOR is manufactured in titanium alloy and pure titanium as per specifications of ASTM F136 and ASTM F67.

The titanium alloy is known for its extreme chemical passivity, and excellent biocompatibility, in addition to possessing physical properties suitable for a good biomechanical behavior in the long term. Its low modulus of elasticity is another advantage as it minimizes backpressure, and this is transferred to the bone. This relative importance against pressure is increased as the size of the implant increases. Although no material is completely free of adverse reactions, clinical experience has shown that this material has a good biological response if used in appropriate applications.

3 – Ancillary Components

The TRAUMEC TRANS-PALATAL DISTRACTOR has no ancillary components.

4 – Instrumentals

For placement and use of the *TRAUMEC TRANS-PALATAL DISTRACTOR* it is necessary to use specific instruments (Table 2).

The *TRAUMEC TRANS-PALATAL DISTRACTOR* Placement Kit **is not part of this product and neither is of this registration process.**

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(Table 02.)

Item	Code	Description	Application
1	PA.02..11.0002	Quick coupling cable for palatal distractor	This cable is used together with the pentagonal introducer keys that can be used for placement of all Traumec trans-palatal distractors.
			

Item	Code	Description	Application
2	PA.02.11.0003	Articulated Wrench 7mm	This wrench can be used for all Trans-palatal distractors Traumec
			

Item	Code	Descrição	Application
3	PA.02.11.0004	Palatal distractor positioning clamp 7mm	This clamp can be used for all Trans-palatal distractors Traumec
			

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Item	Code	Description	Application
4	PA.02.11.0005	Fixed wrench 7mm	
			This wrench can be used for all Trans-palatal distractors Traumec

Item	Code	Description	Application
5	PA.02.11.0006	External pentagonal introductory wrench	
			This wrench (along with quick coupling cable) can be used for all Trans-palatal distractors Traumec

Item	Code	Description	Application
6	PA.02.11.0007	Internal pentagonal introductory wrench	
			This wrench (along with quick coupling cable) can be used for all Trans-palatal distractors Traumec

(Note: Illustrative Images)

5 – Use Indication.

TRAUMEC TRANS-PALATAL DISTRACTORS are devices that aim to expand or distract the jaw quickly and accurately, and aim to correct maxillary constrictions, (unilateral or bilateral) cross bites, as well as correction of anterior crowding and buccal corridors.

The use of this device consists of a revolution in the area of palatal distraction.

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Specifically, we can mention that the use of *TRAUMEC TRANS-PALATAL DISTRACTORS*, brings numerous benefits in relation to conventional dental distraction.

Among these benefits, we can mention:

- Significant reduction of possible anchorage loss;
- Decreased skeletal recurrence during and after the expansion period. What makes a later correction unnecessary;
- Removal of the anchorage loss once the abutment plates are fixed in the palatal bone;
- No or very little skeletal recurrence can be expected, since the expansion and retention actions are immediately on the bone;
- There is no compression of the periodontal membrane, root reabsorption or cortical fenestration, as the teeth do not come in contact with the system
- There is no dental torsion.

6 – Recommendations to the Surgeon.

The placement of TRAUMEC TRANS-PALATAL DISTRACTORS must be done according to the area that has to be more expanded. If the posterior area has to be expanded more than the anterior one, the device is placed in the molar area. If the anterior area has to be expanded more than the posterior, the device should be placed in the premolar area.

Note: *If one side moves more than the opposite side during placement, stop the placement and rotate the module in the opposite direction until it is symmetrical again. This can happen when the horizontal bone cut is not made in a size sufficient to accommodate the pillar plate.*

7 – Recommendations to the Orthodontist.

Orthodontic appliances can be placed before or after the operation. In the case of the appliances to be placed before the operation, the archwire must be cut into two during the operation.

Orthodontic alignment may begin six weeks after the placement of the TRAUMEC TRANS-PALATAL DISTRACTORS.

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8 – Contraindications.

For the following situations the use of TRAUMEC TRANS-PALATAL DISTRACTORS is contraindicated:

- Suspicion of active or latent infection;
- Limitations of blood supply and/or previous infections that may slow the healing process and increase the possibility of infection;
- Any degenerative disease process that could adversely affect the placement of the medical product;
- Inadequate layer with healthy tissue;
- Procedures in which there is an environment in non-sterile conditions, that is, open cavities, such as fistulas;
- Patients with qualitative or quantitative insufficiency of healthy bone that will support the medical product;
- Impaired vasculature; Irradiated patients (> 40 Gy); Patients who smoke.

9 – Adverse effects.

Pain, discomfort and/or abnormal sensation due to the presence of the medical product; Superficial and/or deep infection;

10 – Warnings

- *TRAUMEC TRANS-PALATAL DISTRACTORS* are supplied gamma-ray sterile (CO 60);
- Proper handling of the medical product is extremely important;
- The medical product should not be reused and the explanted medical product should never be re-implanted. Small defects and internal stress patterns may be present, even if the medical product appears intact, and can cause damage to the product;
- Providing patient instructions is a key factor in determining the success of the surgical procedure. Monitoring and care in the postoperative period are very important;

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- The success of this medical product depends on the special care in handling it and good surgical technique. The surgeon should avoid scratching or cutting the surface of the medical product. The use of excessive torque for implanting the screws in the bone tissue may also cause the screws to cause fracture while using it;
- Whenener using any medical product, there is a risk of introduction of strange materials and particles, including talc used in surgical gloves, cleaning and disinfecting agents (germicides) and other surface contaminants. Every effort should be done to limit the handling of the medical product. In addition, if the medical product comes into contact with body fluid, it should not be reused because of potential transmission of pathogens from the blood which can be potentially infectious;
- Proper selection of the model and size of the medical product will increase the potential for its use success. The surgeon must thoroughly master the surgical procedure to be used with the medical product, the method of application and the instruments and accessories to be used. The patient should be aware of the risks of using the medical product, including possible adverse effects;
- Special considerations are required in the use of this medical product for pediatric patients. The use of this medical product in the pediatric population should only be performed by qualified, expert medical personnel who have received adequate and highly specialized training;
- The instructions for use and the warnings provided by the manufacturer of the instruments and accessories must always be revised, as improper use can cause serious damage to the medical product and to the patient. Safety glasses should always be used at all times to protect the eyes;
- The surgeon in charge is responsible for completing the proper process of training, selection, and appropriate placement of the medical product.

11 – Information to be provided to the patient.

- Periodic medical follow-up is extremely important, in order to observe possible changes in the state of the implant and the adjacent bone. Only the monitoring can detect possible looseness of the components, which will impair the entire treatment cycle;

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- Once a week, TRAUMEC TRANS-PALATAL DISTRACTORS must be checked by the surgeon and / or orthodontist;
- A slight pressure might be felt at the beginning of treatment;
- If the device is loosened at any stage, the patient will have to visit the surgeon as soon as possible;
- Changes in occlusion will appear during treatment. This will be solved by aligning the teeth.

12 – Product presentation.

The product is supplied sterile by gamma rays (CO 60), packaged in blister and heat-sealed, non-toxic, which allows contact with hospital products. The blister is sealed with surgical grade paper, free of holes. The sealed blister pack is also placed in an outer carton packaging, duly labeled and identified, for further traceability.

The blister pack consists of a vacuum Forming cradle-type package.

The outer packaging is composed by TRAUMEC standard cardboard box, and has the purpose of packaging sterile products, packaged in surgical grade paper and blister, and properly labeled. The symbols used in the boxes are in accordance with standard of the NBR ISO15223: 04. The packaging used is in accordance with standard NBR 14990-1.

13– Special Conditions for the Product Storage, Conservation and / or Handling.

Date of Manufacture	DO NOT use if damaged	Expiration date
Attention, see instructions for use	Single use only. Do not reuse the product. Reprocessing Prohibited	Keep dry
Keep away from sunlight	Fragile, handle with care	

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Open the Package Aseptically.
We strongly recommend temperature of 21°C, (+/- 4° C) Ambient Humidity in a closed, ventilated place, and protected from weather.
Do not store directly on the floor (minimum height = 20cm) or in very high places, near bulbs, which could cause dryness of the packaging or damage to the label.
Do not store in locations containing contaminants such as cleaning materials, insecticides, pesticides, etc.

13– Handling and transportation of medical product

The guidelines given here must be performed after delivery of the product to the client and are intended to ensure that the implants remain free from contamination or damage prior to use. The guidelines are directed to all personnel involved in the receiving and handling of the implantable devices. It is important that all personnel are familiar with the recommended procedures in order to minimize the risk and the occurrence of damage to the device.

General guidelines for receiving: the packaging of the device must remain intact, clean and dry until the moment of use. Confirm that the product is within its expiration date. The packaging should be inspected for damage. If any damage is found, the implant should be considered non-sterile and return to the manufacturer.

Transportation: the devices must be transported in such a way as to prevent any damage or change in relation to the conditions of receipt of the implant and its packaging. No heavy or sharp objects should be placed adjacent to the product to avoid damaging the carton and prevent contamination of the implant as a result. The effects of vibration, shocks, temperature above 45°C, defective seating during handling and transport should be avoided.

Storage conditions: in all storage areas, prior to use, the implant must be stored in a manner that maintains its configuration and surface finish and does not damage its packaging. Store in metal frame or glass shelves with minimum height of the floor, not less than 20 cm, 45 cm from the ceiling and 5 cm from the background wall, thus enabling daily cleaning and hygiene. Do not store near bulbs, as the label may be erased, and the plastic of the blister can dry out, and the chemical sterilization indicator might suffer malfunction. Do not store in a place where chemicals or harmful substances are used. Ensure that the

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environment is free from particulate contamination, direct sunlight, ionizing radiation and/or subject to temperature extremes, which may affect the preservation of the stored product. The recommended maximum stack is six units.

Stock rotation: the principle "first coming in, first out" is recommended. This stock rotation practice should be adopted for all sterile and non-sterile implants in all stocking areas.

15 – Product Care or Cautions before use

Prior to the use of the product, a person, so designated by the hospital unit, must check the physical conditions of the packaging and the product. The person responsible for checking the package and product must verify that the outer packaging of cardboard is in good condition and identified with the information regarding the material on the packaging. After this verification, the designated person must open the cardboard box.

The product packaged in a double blister must be carefully removed from the outer carton in a surgical environment. The first blister should be opened by pulling the tab of the surgical paper, at the edge of the blister. The second blister should also be opened the same way. Remembering from that moment on, the product that is sterile must also be handled under sterile conditions. With the product in hand, it should be checked if it does not have notches, scratches or blemishes.

In the event of any adverse consequence affecting user safety, such as a non-functioning product, damage to the implantable components, the surgeon in charge must report this adverse event to the competent health agency and TRAUMEC - Tecnologia e Implantes Ortopédicos Importação e Exportação Ltda: *emailing to sac@traumec.com.br* - Telephone/Fax: +55 (19) 3524-7498

In cases of doubt, the surgeon in charge or the health professional can communicate the adverse event through the Health Surveillance Notification System at the website of ANVISA: *http://www.anvisa.gov.br/hotsite/notivisa/index.htm*

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16 – Product disuse and disposal.

All explanted implants should **never** be implanted again. Stress might lead to the development of microscopic imperfections and, even if the implant appears intact, it may lead to its failure. We recommend the parts to be trimmed, warped or cut for disablement.

Explanted devices are considered **hospital waste (potentially contaminating product)** and should be treated as such, according to local health authority regulations. According to Resolution RE No. 2605 of 08/11/06, implantable devices of any nature classified as single use are prohibited from being reprocessed.

The information highlighted below must be taken into account when discarding and disposing the product.

WARNING
SINGLE USE PRODUCT. DESTROY AFTER EXPLANTED. DO NOT REUSE THE PRODUCT. REPROCESSING PROHIBITED.

17 - Traceability

To ensure traceability of the product, it is recommended that the surgeon in charge ot the implant notifies the distributor the following data regarding the implanted product:

- Name of the Hospital Unit;
- Name of the Surgeon;
- Surgery date;
- Name of the patient who received the implant;
- Product code;
- Product batch number;
- ANVISA Product Registration Number.

In each package, in addition to the usual label (Image 06), two additional labels, one to be affixed to the patient's chart, for internal control of the hospital, and one to be delivered to the patient.

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- For information to be passed on to the patient, see the topic "Information to be provided to the patient".

Image 06.

TRAUMEC TRANS-PALATAL DISTRACTORS *receive laser marking: Containing company logo, and manufacturing lot number. If removal of the patient's implant is necessary, all of this information will remain in the product. The marking of the components of the* TRAUMEC TRANS-PALATAL DISTRACTORS *is described in the technical drawings of the products*.

The surgeon in charge should be knowledgeable about the procedures for reporting adverse events and shifting the quality of health products so that they can pass this information on to the patient. The notification of adverse events and / or technical complaints associated with the device used should be made through the competent sanitary body. For information to be passed on to the patient, see the topic "Information to be provided to the patient".

The surgeon in charge may also use the National System of Notifications for Sanitary Surveillance – NOTIVISA, on the web platform www.anvisa.gov.br, to report adverse events and technical complaints related to products under sanitary surveillance.

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18 – Complaints and Customer Service.

Any customer or user of this medical device, who has questions, or would like further clarification about the services and / or products offered, may contact TRAUMEC TECNOLOGIA E IMPLANTES ORTOPÉDICOS IMPORTAÇÃO E EXPORTAÇÃO LTDA, through the contact data contained in user instructions, available on the website and product packaging labels.

In the event of any problems that make the medical device unfit for use, the customer will send the product back to the manufacturer in a packaging that maintains the physical integrity of the medical product. The packaging should, therefore, contain all the information necessary for the identification of the medical product: the handling conditions, the cleaning and disinfection methods used, the description and batch number.

ANVISA Registration nº 80455630043

Technician Responsible: José Luiz Caritá – CREA-SP 0685038754

STERILE PRODUCT - SINGLE USE PRODUCT - REPROCESSING PROHIBITED WARNINGS / PRECAUTIONS / SPECIAL PRECAUTIONS: INSTRUCTIONS FOR USE.

Manufacturer Information:

Manufacturer:

Traumec - Tecnologia e Implantes Ortopédicos Importação e Exportação Ltda.

Address:

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