



Technical Data Sheet

TOTIM® Patient Cushion Positioning System in Ophthalmology

Product Name: TOTIM® Patient Cushion Positioning system

Description:

TOTIM® is a polyurethane foam cushion for patient positioning and comfort both for the patient and the surgeon. Fully sealed, its outer material is PET microfiber.

Indications for use:

TOTIM® Patient Cushion Positioning System is used for positioning/immobilizing adult and pediatric patients undergoing eye surgery in order to ensure more comfort to the patient and the surgeon:

- ocular surface surgery
- limbal stem cells transplantation
- corneal surgery, also by Femtosecond Laser
- complex cataract surgery or in patients at risk
- glaucoma surgery
- anterior segment surgery
- posterior segment surgery
- strabismus surgery and use of Botulinum Toxin
- ophthalmology surgery in children under general anesthesia

CE Marked



Basic UDI-DI: 80580452T3000BY Class I

FDA Clearance

K 190894 Class II

Biocompatibility

ISO 10993-5:2009, 10993-12: 2012, ISO 10993-10: 2010

Manufacturer: ESSEBI MEDICAL SRL dba TOTIM®

Address: Strada Campo del Fiume 84, 47896 Faetano, Republic of San Marino - info@totim.it

European Authorised Representative (EO ACTOR): Francesco Pontara P. IVA - VAT Number: IT04503700280 - Via Monfalcone 12 - 35142 Padova - ITALY - Email: f.pontara@totim.it - DESIGNED IN ITALY – MADE IN RSM

Primary Materials: Cushion: Microfiber Polyester / PU (fully sealed) Internal Pouch fully sealed: PE/AL/PET (humidity –resistant pouch containing two reagents ready to be mixed). *(details are provided in the Safety Data Sheet)

Technical Characteristics: The microfiber cushion is comfortable and absorbent, water repellent, washable and sanitizable, it has a controlled exothermic reaction that allows the correct modeling and solidification of the completely sealed cushion. It is single patient use. TOTIM® Patient Cushion Immobilization System is a medical device made of non- magnetic materials. The device is used in health / hospital facilities and is intended for use on adult and pediatric patients.

Single-patient, single-use - Radiotransparent - MR safe. The TOTIM® Patient Cushions Immobilization System device is manufactured of non-magnetic materials.

The device is intended to be used on adult and pediatric patients.

Product number:

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Validity Period:

The device has a validity period of 24 months from the date of production (see the label). Do not use if the package is open or damaged. Single-patient/single- use.

Storage:

Point of Use Storage and Use Temperature: minimum 59°F/15° maximum 77°F/25° C.

Shipping and long term storage temperature: minimum -13°F/-25° maximum 122°F/50° C.

Disposal: waste from human or animal health care and/or related research disposal is not subject to special requirements so as to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers) - **unsorted waste – not production of energy incinerators - the box is recyclable**

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

Packaging: Unit Pack: See table **Unit / Box:** See table

Shelf Life: 24 months from the date of production (see the label)

Sterilization: Non-Sterile

Country of Production: Republic of San Marino

Technical drawing:

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