Technical Data Sheet

Product Name: TOTIM® Memory Foam Cushion Positioning

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:
Improve comfort during rest or sitting, adapting to the body's shape.
TOTIM memory foam cushion designed to improve comfort and ensure proper positioning of different parts of the body. Custom-made for each individual, it retains its shape to provide optimal support.
Adaptive Comfort, Personalized Support.
Engineered to enhance comfort during rest or sitting, the TOTIM memory foam cushion adapts precisely to the body's contours. Designed for optimal positioning and pressure relief, it provides stable, lasting support for various body areas. Each cushion is custom-made to meet individual needs, retaining its shape to ensure consistent comfort and effective immobilization over time.
Reduced mobility or long-term wheelchair users Post-surgical recovery or physical therapy sessions
Office workers or remote professionals with sedentary routines
Support and comfort during travel or daily commuting
Targeted relief for pressure-sensitive zones and posture correction A memory foam body cushion is designed to:

1. Improve comfort during rest or sitting, adapting to the body's shape.
2. Provide proper support to various body parts such as the back, legs, arms, and neck, reducing pressure points.
3. Promote correct postural alignment, especially beneficial during post-operative care or rehabilitation.
4. Prevent pressure sores in individuals who remain in the same position for extended periods, such as in wheelchairs or in bed.
5. Alleviate muscle and joint pain by evenly distributing body weight.

Ideal for use in wheelchairs, operating rooms, post-surgical recovery, physiotherapy and rehabilitation, cars, office

CE Marked	**MD**	**Basic UDI-DI: 80580452T3000BY Class I**
FDA Clearance		**K 190894 Class II**

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

Dispositivo Medico / Medical Device: TOTIM® Patient Cushion Positioning System
SRN (Single Registration Number): SM-MF- 000056722
Identificazione del dispositivo / Identification of the device: TOTIM® Codes T3000
Basic UDI-DI: 80580452T3000BY Medical Device Class I Not Sterile
European Authorised Representative (EO ACTOR):
ID/SRN: IT-AR-000036939
Email: quality@totim.it

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 use. TOTIM® **Memory Foam Cushion Positioning** is a medical device made of non- magnetic materials. The device is used in healthcare/hospital facilities and is intended for use on adult and pediatric patients and by persons who require a cushion that adapts to different parts of the body. Single-patient, single-use - Radiotransparent - MR safe. The TOTIM® Memory Foam device is manufactured of non-magnetic materials.
The device is intended to be used on adult and pediatric.

Product number:

Suitable for all parts of the body

T3111	**All parts of the Body or head**	**Sizes 50x40cm**	**Q.ty 50 pcs**
T3600	**Lumbar support**	**Sizes 40x20cm**	**Q.ty 50 pcs**
T3602	**All parts of the Body or head M/L**	**Sizes 50x50cm**	**Q.ty 50 pcs**
T3601	**Lumbar support**	**Sizes 40x30cm**	**Q.ty 50 pcs**
T3603	**Limb support or all parts of the body**	**Sizes 60x30cm**	**Q.ty 50 pcs**

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**

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