Instructions for Personal Protective Equipment and the safe chemical practices when cushions leak

WARNING: Totim cushions contain a two-part foaming agent comprised of Polyol (part A) and Isocyanate (part B) inside of a fully sealed internal pouch. In case of accidental leakage of these internal substances refer to SDS sheet for quick reference refer to the following instructions.

CLASSIFICATION

Compliant with Annex II of REACH Regulation (EU) 2020/878

Contact:

- In case of skin contact, wash with plenty of soap and water. Remove contaminated clothing and dispose.
- In case of eye contact, wash immediately with water with the eyelids open for a sufficient length of time, if irritation persists consult a doctor.
- In case of ingestion do not induce vomiting, get medical attention.

Cleaning Spill:

- Wear chemical resistant gloves, dawn smock and wear eye protection.
- Collect spills with absorbent material, such as sawdust, sand or earth. For small spills use sodium carbonate powder. Wash or wipe with plenty of water and neutral non-abrasive detergent.
- Spill of mixed or activated foam must be mechanically removed and can be disposed of with normal waste.

ESSEBI MEDICAL SRL shall not be responsible for any damage caused by either the misuse of this device or by the use outside of normal operating conditions.

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DESIGNED IN ITALY - Made in Republic of San Marino

Rev01 2025

TOTIM®
TOTALLY - IMMOBILE
immobilization system in radiotherapy

INDICATIONS FOR USE

TOTIM® Patient Cushion Immobilization System

MD

Dichiarazione di Conformità
Declaration of Conformity
MDR 2017/745

Dispositivo Medico classe I non sterile
Medical Device class I unsterile

EN

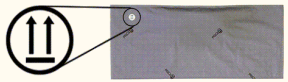
Concept "Cells Closed": *the physical reaction must not be interrupted during this phase, as the closed cells in this plastic/semi rigid phase, when touched, would be broken and would modify the homogeneity of the final mould, and consequently the shape of the rigid device.*

How to use TOTIM®

During the use and modeling of the **TOTIM** cushion it is essential to follow the recommendations in order to obtain the best final result of firmness and homogeneity in the foam.

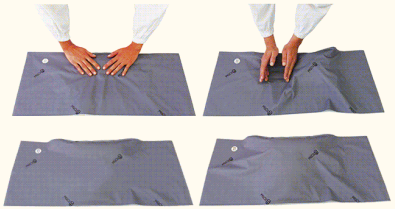
The semi-rigid polyurethane foam is composed of foam with closed cell structure that react uniformly, thus obtaining a compact and consistent mould.

1 Opening the box - place **TOTIM** on a rigid flat surface.
Identify the **"SIDE UP"** symbol on the cushion



2 Identify the internal pouch with 2 pockets - **A & B**.
Apply firm pressure with two hands on one pocket,
in the direction of the opposite pocket, so as to break
the central safety seal between them

3 Mix vigourously, 1 hand on each pocket, for about
30/35 seconds (*occasionally using a vertical hand to shift the two components from one side to the other*) until you feel warmth and observe an increase in volume
Once the inner pouch is swollen, **wait for it to 'POP' open autonomously**
COMPLETELY REMOVE THE FOAM FROM THE POCKET INSIDE THE CUSHION WITH YOUR HANDS AND CENTER THE FOAM IN THE CUSHION



4 Move the foam to the center of the cushion, then position the patient after about **50/60 seconds** taking great care to center him
The patient's body or the part of the body involved, should be carefully placed centrally, so as to displace the foam uniformly

5 Now hold pressure with your hands and/or arms, or with rigid accessories at the points of interest to create the best shape for immobilisation for the first **10/20 seconds.**
Hold this fixed position to now allow uniform expansion of the foam [see Concept "Cells Closed"] for **4/5 minutes**
WARNING: DO NOT TOUCH! DO NOT WORK THE CUSHION!
Instruct the patient not to move while the cushion is setting

6 After **4/5 minutes** the mould will be rigid enough to proceed with CT simulation. Once the CT scan is accomplished, leave the cushion on a flat surface for the final hardening

The completed TOTIM cushion will remain rigid for the entire treatment, until its disposal

Indications for use
The device is indicated to position and/or immobilize adult and pediatric patients during medical imaging or Radiation Therapy of the body, head, brain, and neck, including Stereotactic Radiosurgery (SRS), Stereotactic Radiotherapy (SRT), Surface Guided Radiation Therapy (SGRT) and electron, photon, and proton treatments. The device is also used during image acquisition, including Computed Tomography (CT), Magnetic Resonance (MR) Imaging, to support treatment planning.
The device is for single patient use intended to be used multiple times until 4 months throughout setup and treatment cycle. To ensure the device performs as designed over the life declared storing it in a dedicated areas.
Non-sterile/radiotransparent.
This Rx Only device is for use by trained medical professionals only.
Caution - Federal (United States) law restricts this device to sale by or on the order of a physician.

MRI Safety Information:

MR
MR Safe

- Device is MR safe

PROTON WATER EQUIVALENT THIKNESS (WET)
"for reference only"

DATA FOR PROCEDURE	PART	LOCATION	PROTON WET R80 (mm)	PROTON WET CT (mm)
01/03/19	TTM3006	Foil	2.4	N/A
01/03/19	TTM3006	No Foil	2.3	N/A

PRECAUTIONS FOR USE
Activate within 24 months of the manufacturing date. After activation (mixing, expansion, cooling), the cushion is firm and usable for 4 months. Discard after this period.
- Setup: Correct activation, mixing, and placement are essential for optimal results.
- Storage: Store in original packaging, away from sharp or heavy objects. Do not stack more than 5 boxes high.
- Inspection: Check for deterioration before use. If found, dispose of immediately in a lined bin.

STORAGE AND USE TEMPERATURE
Store and use between 15°C (59° F) and 25°C (77° F). Keep away from heat or cooling sources.

CLEANING INSTRUCTIONS
Important: This device is intended for single-patient use only. Follow these instructions to ensure safe and effective use.
1. **Routine Cleaning (Between Uses)**
Preparation: Wash hands and wear appropriate personal protective equipment (PPE) before cleaning.
Surface Wipe: Wipe the device surface with a soft cloth dampened with a mild detergent solution, such as Dawn® Dish Soap diluted with water (1:10 ratio). Use minimal liquid and avoid soaking the device.
Disinfection: After surface wipe cleaning, apply an intermediate level disinfectant cleaner. Approved agents are Low alcohol disinfectant towelettes, cleaning solutions such as CaviCide® Wipes or similar, or Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes or similar suitable for non-critical medical devices. Allow the disinfectant to air-dry completely or follow the manufacturer's specified contact time before use.
Inspection: Inspect the device to ensure it is clean and dry before the next use.
2. **Cleaning After Exposure to Blood, Urine, or Feces**
Preparation: Wear gloves, eye protection, and any necessary PPE to protect against biohazard exposure. Dispose of any contaminated materials (e.g., gauze) according to biohazard waste guidelines.
Pre-Cleaning: Gently remove any visible contamination with disposable paper towels or wipes. Discard used wipes in a designated biohazard container.
Deep Cleaning: Clean the device thoroughly using a disinfectant cleaner. Approved agents are Low alcohol disinfectant towelettes, cleaning solutions such as CaviCide® Wipes or similar, or Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes or similar suitable for non-critical medical devices. Apply the disinfectant cleaner per the manufacturer's instructions, ensuring full coverage of the contaminated area.
Disinfection: Follow up with a secondary application of a hospital-grade disinfectant, such as CaviCide® or Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes or similar.
Allow the disinfectant to remain on the surface for the required contact time to ensure efficacy.
Final Inspection: After disinfection, visually inspect the device to confirm it is free from visible contaminants.
Dry and store the device as directed.
Tip: It is recommended to use a clean sheet between the device and patient as a precaution to minimize cleaning requirements.

WARNING
- Never use a Totim cushion that has any sign of cut, tear or puncture.
- Leakage of the content may cause damage to objects, injury to patient or user.

Disposal
Scenario A: Totim cushion has been activated - Dispose of with normal unsorted waste – DO NOT burn or incinerate.
Scenario B: Totim cushion is not activated (liquid state) – dispose of in a lined bin as special waste follow your local municipal, state / provincial and or federal guidelines, refer to Safety Data Sheet for more information.
All packaging is recyclable
Tip: If no sign of deterioration is found and disposal is required, activate and mix the Totim cushion contents before disposing. An activated Totim cushion can be disposed of as normal waste, with no need for specialized disposal methods. *For additional disposal and safety information refer to the Safety Data Sheet (SDS).*

ESSEBI MEDICAL SRL disclaims all responsibility for damage dealt to people, animals, objects or environment caused by use of the product not in compliance with the instructions, use and maintenance found in the Indications For Use (and in its Warning section) provided with the product.