TOTIM™
TOTALLY - IMMOBILE
immobilization system in radiotherapy

CE Direttiva CEE 93/42 Dispositivo Medico
Directive EEC 93/42 Medical Device
Dispositivo Medico di Classe I
Medical Device Class I

TOTIM™
DATA SHEET
IMMOBILIZATION CUSHIONS FOR RADIOTHERAPY

DESCRIPTION OF PRODUCT

TOTIM™ is a radiotransparent medical device used to immobilize patients in Radiotherapy.

Instructions for use

The device is composed of a hermetically sealed cushion containing a bag filled with two separate reagents (polyurethane foam) that are to be mixed during usage. While reacting the reagents produce polyurethane foam, which expanding will adapt to the body of the patient wrapping it. The foam will solidify in about 5 minutes, leaving a solid shape.
The device can be provided in different forms and dimensions and can be customized according to the needs. It is radiotransparent.

CONSTRUCTION FEATURES

Double layer cover sheet: NON-WOVEN/PE (Polyethylene) film
humidity-resistant bag, containing two reagents ready to be mixed (further details are provided in the Safety Data Sheet).

TECHNICAL CHARACTERISTICS

- Cushion with external cover in absorbent water-repellent non-woven material, washable/easily sanitized
- Temperature controlled exothermic reaction
- The short window of time required for solidification allows for the correct modelling of the Device
- Comfortable external cover in non-woven material
- Hermetically sealed bag using a professional sealing procedure
- Device produced with raw material Made in Italy
- Single-patient/single-use device

ESSEBI MEDICAL Srl
Via Ranco 13/c 47899 Serravalle RSM C.O.E. SM26889 Tel. +378 0549 900360 www.totim.it
info@totim.it - totim@pec.totim.it – Business register n. 7577

TOTIM™
TOTALLY - IMMOBILE
immobilization system in radiotherapy

CE Direttiva CEE 93/42 Dispositivo Medico
Directive EEC 93/42 Medical Device
Dispositivo Medico di Classe I
Medical Device Class I

PRODUCT CODES

CODE	NAME	MEASURE in cm
Cod. T3001/L	BODY	70x110
Cod. T3002	JOLLY	70x70
Cod. T3003	ARM	70x90
Cod. T3004	LEG	70x130
Cod. T3005	CERVICAL	70x350
Cod. T3006	LIMB	70x30
Cod. T3001/XL	BODY	90x100
Cod. T3007	SKULL/SPINAL AXIS - CHILD	70x156
Cod. T3008	SKULL/SPINAL AXIS - ADULT	70x196
Cod. T3009	TOTAL BODY	70x200
Cod. T3010	NECK	20x25

GENERAL CHARACTERISTICS

Validity period
The device has a validity period of 1 year from the date of production (see the label). Do not use if the package is open or damaged. Single-patient/single-use.

Single package
Storage Conditions
Use the boxes provided to store the product. Fragile content, handle with care. Do not pile up more than 5 boxes at once. Keep the product in a fresh and dry place, do not expose it to heat sources and UVA radiations with a temperature between 17° and 25°.

Cleaning Conditions
Clean the device using soft cloth and neutral detergents. Rinse under running water. Do not immerse. Do not wash using a washing machine. Dry in the open air.

Warranty Terms
Full Risk Warranty: the Device is under warranty for 12 months from the delivery date. The warranty does also include flaws, defects in fabrication and in raw materials employed. Deterioration of any component due to negligence, improper use or failure to observe the technical data described in the technical specifications of use is excluded from the warranty.

ESSEBI MEDICAL Srl
Via Ranco 13/c 47899 Serravalle RSM C.O.E. SM26889 Tel. +378 0549 900360 www.totim.it
info@totim.it - totim@pec.totim.it – Business register n. 7577

Disposal indications:
Follow the instructions to evaluate deterioration on the device. In case of any sign of deterioration or damage, immediately proceed with the following indications:
- If the two chemical components are still separated (no reaction between the two has happened), strictly follow the current regulations concerning the disposal of special waste.
- If the TOTIM™ device has already been activated and used (hard shape already produced), proceed according to the applicable regulations in your country.
Its coding in the EWC (European Waste Catalogue) is always relative to two categories according to every Hospital's regulation.

1: Disposal of EWC code of category 180000 - WASTE FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH
EWC 180104 waste whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)

2: Disposal of EWC code of category 070000 - WASTE FROM ORGANIC CHEMICAL PROCESS

EWC 070213 waste plastic

The EWC code of reference for the disposal of the TOTIM device is based on each Hospital's regulation.

Contraindication and warnings
No contraindication have been detected except for situations of high sensitivity to the component materials. Before use, make sure there are no specific allergies to the outer materials of the device. Up to now no allergy has been observed. The product is designed exclusively for the use specified above, which is temporary immobilization of body parts. No other use is allowed. It is necessary to follow the instruction manual provided with every device for a safe and correct usage. The device can be operated only by qualified staff in radiotherapy. Avoid usage by children or people with limited understanding of possible dangers. Keep away from sharp mechanical parts or objects that could possibly damage its surface.

MANUFACTURED by: ESSEBI MEDICAL SRL - Serravalle – RSM

Directive 93/42/EEC Class I non-sterile Medical Device
TOTIM Model
CND Classification M030504 - Code T3000 – System progressive 1462725 - Non-sterile single patient use product
First year of distribution: 2016

ESSEBI MEDICAL Srl
Via Ranco 13/c 47899 Serravalle RSM C.O.E. SM26889 Tel. +378 0549 900360 www.totim.it
info@totim.it - totim@pec.totim.it – Business register n. 7577