



## Technical Data Sheet

### TOTIM® Patient Cushion Immobilization System in Radiotherapy

**Product Name:** TOTIM® Patient Cushion Immobilization system

#### General Description

TOTIM® is a fully sealed polyurethane foam cushion covered with microfiber polyester tissue for patient positioning and immobilization during simulation, planning and radiation treatment. The cushion shapes and molds around the patient after activation of the internal components. It maintains its formed shape during all sessions of radiotherapy treatment, enabling reproducibility of patient position. The device is molded at the back of the patient's body, parts of the body or the head in order to hinder the usual range of movement occurring with non-customizable supports.

#### Indications for use

TOTIM® Patient Cushion Immobilization System is indicated to position and/or immobilize adult and pediatric patients undergoing 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. System Intend Use: The device is part of a system intended to immobilize, position and reposition patients undergoing radiation therapy including SBRT. The device is for single patient use intended to be used multiple times until 4 months throughout setup and treatment cycle.

<b>CE Marked</b>	<b>Basic UDI-DI: 80580452T3000BY Class I</b>
<b>FDA Clearance</b>	<b>K 190894 Class II</b>
<b>Biocompatibility</b>	ISO 10993-5:2009, 10993-12: 2012, ISO 10993-10: 2010

**Manufacturer:** ESSEBI MEDICAL SRL dba TOTIM®

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**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

Cushion with external cover in microfiber comfortable and 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 modeling of the external cover in microfiber polyester tissue fully sealed. Single-patient, single-use - Radiotransparent - MR safe. The TOTIM® Patient Cushions Immobilization System device is manufactured of non-magnetic materials. The device is used in a healthcare facility/hospital. The device is intended to be used on adult and pediatric patients.

### Dosimetric Properties

Thickness	Transmission	Attenuation 6 (MeV)	Attenuation 15 (MeV)
2,47 cm	10 x 10	1,0	0,3
3,98 cm	10 x 10	1,5	0,8

\* Performance Specifications are for reference only, values may vary based on setup and equipment

### PROTON WATER EQUIVALENT THICKNESS (WET)

Machine	Make	Model	Project Code	SN	PART	LOCATION	PROTON WET R80 (mm)
CT Scanner	General Electric	2377708-555	N/A	418003CN0			
Cyclotron	IBA	Cyclone C235	PAP:12	1095526692	T 3006	Foil	2,4
					T 3006	No Foil	2,2

\*for reference only

### 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

### Product Number

ADULT			
Codes	Name	Measure cm	Quantity pcs.
T3001/L	BODY L	70 x 110	10
T3001/XL	BODY XL	90 x 100	10
T3002	JOLLY	70 x 70	10
T3003	ARM	70 x 90	10
T3004	LEG	70 x 130	10
T3006	LIMB	70 x 30	10
T3008	SKULL/SPINAL AXIS	70 x 150	10
T3008/S	SKULL/SPINAL AXIS S	70 x 90	10
T3015 T	T SHAPE	85 x 110	10
T3009	TOTAL BODY	70 x 200	5

## HEAD AND NECK

T3005/S	CERVICAL S	70 x 45	10
T3005/M	CERVICAL M	70 x 50	10
T3010/XS	NECK	20x25	20
T3010/S	NECK	25x35	20
T3010/M	NECK	30x35	20

### PEDIATRIC

T3001/P	BODY	60 x 100	10
T3002/P	JOLLY	60 x 50	10
T3006/P	LIMB	60 x 30	10
T3007/P	SKULL/SPINAL AXIS	60 x 140	10

## HEAD AND NECK

T3015/P	CERVICAL	60 x 40	10
T3010/XSP	NECK	20x25	20
T3010/MP	NECK	30x35	20

\* Pediatric codes differs in sizes, color / pattern and quantity of foam specific for the child's body weight

## PROTON TOTIM®

### ADULT

Codes	Name	Measure cm	Quantity pcs
T3008 PTN	SKULL/SPINAL AXIS PROTON	60 x 140	5
T3008/S PTN	SKULL/SPINAL AXIS S PROTON	60 x 85	10
T3020/S PTN	JOLLY S PROTON	60 x 40	10
T3005/M PTN	CERVICAL M PROTON	60 x 50	10
T3010/M PTN	NECK M PROTON	30 x 35	20

### PEDIATRIC

T3007/P PTN	SKULL/SPINAL AXIS P PROTON	50 x 140	5
T3010/MP PTN	NECK MP PROTON	30x35	20