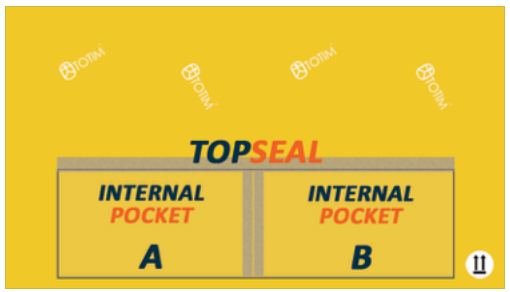


1

PLACE TOTIM ON A RIGID FLAT SURFACE.
IDENTIFY THE "SIDE UP" SYMBOL

2

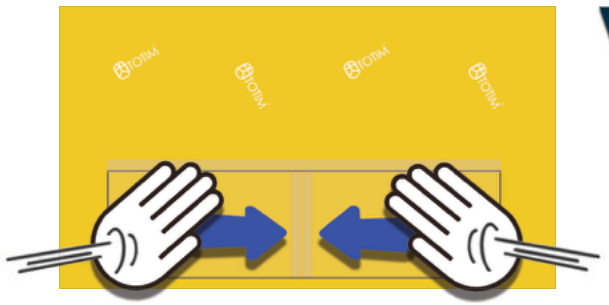
PLACE YOUR **HAND IN A DIAGONAL POSITION** AT AN ANGLE TO POP THE MIDDLE SEAL WHILE AVOIDING ACCIDENTAL POPPING OF THE TOP SEAL

3

APPLY FIRM PRESSURE DOWN WITH THE OTHER HAND IN THE DIRECTION OF THE RED ARROW, GRADUALLY **INCREASING PRESSURE IN THE DIRECTION OF THE GREEN ARROW,** AS SHOWN IN THE IMAGE

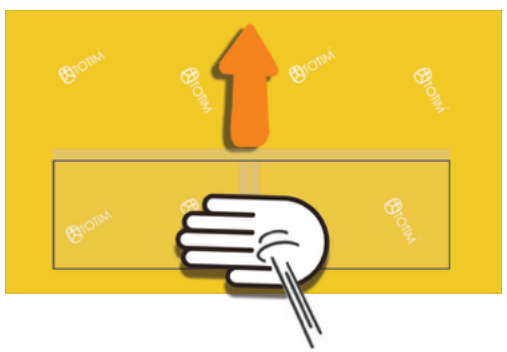
TOTIM
TOTALLY - IMMOBILE
positioning system

SHAPEDFORYOU



4

ONCE BOTH POCKETS ARE POPPED, START MIXING THE TWO LIQUIDS (FOAM) AS QUICKLY AS POSSIBLE. THE POUCH WILL START TO EXPAND UNTIL IT POPS THE TOP SEAL ON ITS OWN



5

AFTER THE "POP" **REMOVE COMPLETELY THE FOAM FROM THE INSIDE POUCH** AND SPREAD IT EVENLY OVER THE FULL SURFACE. PUSH A SMALL AMOUNT OF FOAM OVER THE INSIDE POUCH SO IT IS NOT FELT AFTER CURING

AFTER 20-30 SECONDS FROM THE TOP SEAL POP AND SPREADING THE FOAM, THE CUSHION IS READY FOR USE.
THE TIME REQUIRED FOR THE MOLDED CUSHION TO SET AND BE READY FOR USE IS APPROXIMATELY 2-3 MINUTES.

DURING THE CURING PROCESS DO NOT TOUCH THE CUSCHION AND REMAIN STILL

- **MIXING TIME: APPROXIMATELY 30 SECONDS**
- **SPREADING AND WAITING TIME: APPROXIMATELY 20-30 SECONDS**
- **MOLDING AND READY TIME: 2-3 MINUTES**

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GENERAL WARNING IFU:
Contraindications: The product does not have any know particular contraindication
*It is necessary to follow the how to use provided with every Foam cushion for a safe and correct usage
* Prohibited 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 *Any leakage of the content can cause damage to people and objects *Any Foam Cushion with superficial damage cannot be used. In case of accidental leakage of these internal substances it is necessary to follow these instructions.

If the cushion is used in direct contact with the skin, check that the skin is free from irritation, wounds, burns or any other condition that could compromise the person's health. In such situations, it must not be used directly on the skin.

How to choose size M or L based on body weight:
For size M, your body weight must not exceed 100 kg. For size L, your body weight must not exceed 70 kg. Essebi Medical is not Responsable for the incorrect use of the product.

Indications for use: The device is indicated for positioning adult and pediatric patients. Non-sterile/radiotransparent. **MRI Safety Information:** Device is MR safe **PRECAUTIONS FOR USE:** Activate within 24 months of the manufacturing date. After activation (mixing, expansion, cooling), the cushion is usable. Setup: Correct activation, mixing, and placement (How to use) are essential for optimal results. Storage: Store in original packaging. 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: 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. Disinfection: After surface wipe cleaning, apply an intermediate level disinfectant cleaner. 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. **Final Inspection:** After disinfection, visually inspect the device to confirm it is free from visible contaminants. Dry and store the device as directed. **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 waste: 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). **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.
Description of measures in case of accident leakage: Use the chemical resistant gloves. In case of skin contact, wash with plenty of soap and water. Remove contaminated clothing and dispose off safely. Areas of the body that have, or are suspected of having come into contact with the internal substances must be rinsed thoroughly with running water. In case of ingestion, do not induce vomiting and get medical attention. Methods for cleaning up in case of spills: Collect spill with an absorbent material, such as sawdust, sand or earth. For small spills use sodium carbonate powder. Wash with plenty of water and neutral non-abrasive detergent. **CLASSIFICATION:** Compliant with Annex II of REACH Regulation (EU) 2020/878
ESSEBI MEDICAL SRL disclaims all responsibility for any 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. ESSEBI MEDICAL SRL TOTIM shall not be responsible for any damage caused by either the misuse of the product or by its use outside of normal operating conditions indicated.

Manufacturer: ESSEBI MEDICAL SRL dba TOTIM®
Strada Campo del Fiume 84, 47896 Faetano - RSM
Email: info@totim.it PEC: totim@pec.totim.it- www.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

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