

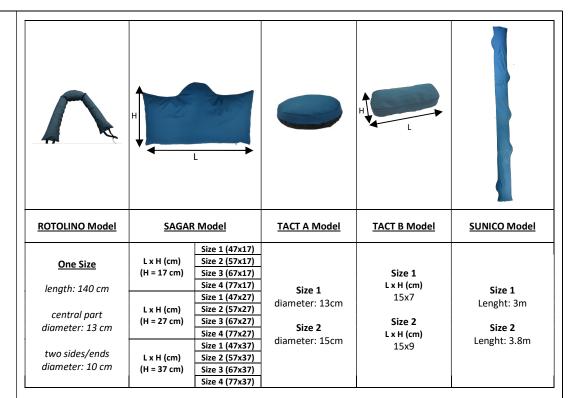


- TECHNICAL SHEET -

"MULTISOFT" Positioning Devices

Manufacturer identification	Pro Medicare s.r.l. Via Montagna Z.l. Lotto 41 72023 Mesagne (Br) VAT Number 01803920741 tel. 00 39 0831 777840 fax 00 39 0831 730739 website: www.promedicare.eu e-mail: info@promedicare.it
Device Commercial Name	MULTISOFT Range – ROTOLINO/SAGAR/TACT/SUNICO Models
UDI-DI BASIC	805571347SOLLIEVO8
<u>Device Code</u>	ROTOLINO: D09-001-1 SAGAR height 17: D00-022-1/2/3/4 SAGAR height 27: D00-023-1/2/3/4 SAGAR height 37: D00-024-1/2/3/4 TACT A: D00-025-X TACT B: D00-026-X SUNICO: D00-038-X
Code of Classification (CND)	V080302
Medical Device Class	These Devices are CE marked according to EU Regulation 2017/745 and they are classified as non sterile Class I Medical Devices without measuring function.
Intended use	SAGAR/ROTOLINO/SUNICO are devices for positioning and/or containment of the posture of a body segment or of the whole body following a temporary or permanent pathological condition and/or during clinical/surgical treatment. TACT is the device for positioning and/or containment of the posture of the hand following a temporary or permanent pathological condition and/or during clinical/surgical treatment. Their intended use is to: - treat postural disorders; - provide a suitable and fully comfortable positioning of the user or one of his/her body segments; - ensure the containment of a user's body; - support during Pressure Ulcers Treatment; - facilitate the distribution of body pressures. Positioning devices are for paediatric and adult users and are intended for professional and also for non-professional use in order to relieve and/or prevent clinical pathological conditions related to posture or post-traumatic, surgical and post-surgical conditions as well as for rehabilitation; such devices must be used in internal spaces. Multisoft devices do not have load-bearing structural features, so they do not replace the user's support (bed/mattress)
<u>Technical</u> <u>features</u>	STANDARD CONFIGURATION: Each model and size chosen include the padded and covered element, the removable cover is with anti-slip bottom surface (SUNICO is not available with anti-slip bottom surface). DIMENSIONS: Different for each model as shown by tables below WEIGHT: Multisoft ROTOLINO < 500 gr Multisoft SAGAR < 1.2 kg Multisoft TACT A/B < 100 gr SUNICO < 6 kg

Sch.Tec.Dis.Pos.Mul. EN Rev.2 12/2023 Page 1/3



PERFORMANCE AND DURABILITY: The realistic life span of these devices is 2 years (padding) valid under normal conditions of use and proper maintenance in accordance with the specifications of the instruction manual.

MATERIALS: The padded elements are made of high performance materials used in the medical sector:

- 1. Padded elements are made of polymer foams filling cuttings;
- 2. The interior and removable covers are made of PU/PES combined materials with the following characteristics:
 - antibacterial according to the standard ISO 20743-2 (Staphylococcus aureus, Methicilin Resistan Staphylococus Aureus MRSA)
 - non cytotoxic according to the standard ISO 10993-5 and ISO 10993-12
 - non irritating according to the standard ISO 10993-10 and ISO 10993-1
 - resistant to virus penetration according to the standard ISO 16604
 - antifungal according to ASTM G 21-96
 - fireproof according to the standard BS 7175; crib 5
 - biocompatible according to the standard ISO 10993
 - OEKO-TEX®
 - Latex free
 - breathable according to the standard ISO 15496
 - waterproof according to the standard EN 20811

MANTEINANCE AND CLEANING: The internal and the removable covers can be superficially sanitized with the following detergents/disinfectants:

- PERSIL EXPERT coldzyme/HENKEL
- 70% etanol
- PERFORM/Schuelke
- TPH PROTECT/Schuelke
- MIKROZID AF liquid/Oktal pharma
- DESCOGEN liquid/Antiseptica
- MANORAPID/Antiseptica
- PLIVASEPT/Pliva
- INCIDIN PLUS/Ecolab

The removable cover can be washed at high temperatures (95° max 10 washings or dry), can be sterilized at $134^{\circ}/5$ min (10 times maximum).

Do not use cleaners based on natrium hipo-chlorite for both cover.

PACKAGING: It is supplied in a plastic bag

Technical features

Technical

features

Page 2/3

Spare Parts	Additional Covers
Additional Elements	 Mobile station with complete element kit and additional covers (to be configured according to needs) Bag for a set of elements (to be configured according to needs)
Product image (images are purely illustrative)	ROTOLINO Model
	SAGAR Model
	TACT A Model
	TACT D Model
	TACT B Model
	SUNICO Model

Sch.Tec.Dis.Pos.Mul. EN Rev.2 12/2023 Page 3/3