

PRODUCT INFORMATION SHEET

SILTAC® - SILICONE OSTOMY SEAL

REF : TR1020, 1028, 1035

Intended use:

Application to peristomal skin to provide a seal between the stoma and ostomy pouching system.

Method of administration:

Ensure that the skin is clean and dry. Gently peel the seal out of the blister pack. Stretch the seal around the Stoma. Apply to the skin and shape to fit, creating a good seal around the stoma.

Features & benefits	One piece removal	Atraumatic removal	Reduced risk of leakage.	Non-absorbent to faeces and urine
	Leaves no residue	Less skin irritation	Protects the skin and can extend the wear time of an appliance	More hygienic than hydrocolloid products, promotes healthier skin.

Product form:

A soft silicone ostomy seal housed in an individual blister pack. Available in three sizes:-

TR1020 20-28mm
 TR1028 28-35mm
 TR1035 35-44mm

Pictures:



Packaging information:	1 ^o	Clear PC blister with PP lid.	1/ Ostomy seal
	2 ^o	Inner Carton	30 Ostomy seals / carton
	3 ^o	Corrugated outer box.	24 Inner cartons / box

Instructions for use:
 Instructions for use supplied in each carton. Multilingual presentation (13 Languages).

Regulatory information:	Legal manufacturer:	Trio Healthcare Ltd Skipton, United Kingdom. Telephone: +44 (0) 1756 700599 Quality Management System Registration ISO13485:2003 – Certificate No.: MD526018 British Standards Institution.
	Classification:	Class I non-sterile medical device. MDD93/42/EEC Annex IX - Rule 1.
	Biological safety evaluation:	The product meets the requirements for biological safety in accordance with international standard EN ISO 10993. Independent biological safety evaluations and testing having been undertaken. <u>References:</u> Expert evaluation on the biological safety of Trio Healthcare Ltd silicone stoma care products – Medwise International Ltd. [PCL-B-028] Harlan Laboratories Study # 41403903
	Shelf-life:	2 years. Expiry date printed on base of inner carton.

DATE OF ISSUE: January 2015

Issue: First issue

	Special storage conditions:	This product should not be stored above 50 ⁰ C. See accompanying instruction for use.
	First placed on market:	July 2014
Environmental information:	Special precautions for disposal after use	None. Suitable for hospital / household waste streams
<p>Web site information: www.TrioOstomyCare.com</p>		

Change History

DATE	REASON
Jan 2015	First issue.