

PRODUCT INFORMATION SHEET
SILEX® SILICONE FLANGE EXTENDER
REF : TR1060

Intended use:
 Extend stoma bag flanges to improve protection from leakage

Method of administration:
 The flange extender can be used before or after your appliance has been placed on your body. Ensure that the skin is clean and dry. Remove the release liner as indicated No.1 Position where appropriate on your appliance. Remove the release liner as indicated No.2 and smooth securely in place.

Features & benefits	One piece removal	Atraumatic removal	Thin profile	Highly Flexible
	Leaves no residue	Less skin irritation	For greater comfort and flexibility	Allows for more freedom of body movement

Product form:
 A silicone flange extender packed in a clam pack of 20 pieces



Packaging information:	1 ⁰	Clear PETG Clam Pack	20 Flange extenders / pack
	2 ⁰	Corrugated outer box.	24 packs / 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. [PCL-B-028] Harlan Laboratories Study # 41401277	
	Shelf-life:	2 years. Expiry date printed on clam pack.	
	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.	
Web site information: www.TrioOstomyCare.com			

DATE OF ISSUE: January 2015

Issue: First issue

Change History

DATE	REASON
Jan 2015	First issue.