

# Product Safety Data Sheet

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REFERENCE NO.: PSDS 105		
Compiled by:  Laboratory Technician	Approved by  QA/RA Officer	Approved by:  Technical Manager
Effective date:	Revision no.: 00	Issued by:
Supersedes: N.F.I.		Quality Assurance

<b>1.0</b>	<b>Name of the Product</b>	<b>Tensoplast ® STK</b>
<b>2.0</b>	<b>Product Description</b>	Adhesive and non-adhesive skin traction kits that is devised to provide a support system to enable suitable traction weights to be applied to a limb. The kit is available in two presentations : adhesive and non-adhesive; and in three sizes: adult ,child and Infant.
2.1	Characteristics	<p>One kit for entire traction period</p> <p>Easy to use and adaptable to any technique of limb skin traction</p> <p>Reliable and secure</p> <p>Provides good cushioning</p> <p>Excellent conformability</p>
2.2	Intended use	Devised and used to provide an efficient and reliable method of adhesive/non-adhesive skin traction, wherever it is needed in orthopedic treatment.
2.3	Instructions for use	To be used as indicated on package insert.
2.4	CE - class GMDN - code	Class 1, Rule 4, non – sterile
2.5	Composition	The kit consists of a stitch bonded fabric coated with a clear acrylic adhesive, a spreader plate, a polyester cord, soft open cell foam. A cotton/polyamide/polyurethane bandage with an aluminium clip is included in the kit.
2.6	Latex in product and packaging material	Latex present in product
2.7	Phthalate/Lanolin/Colophony in product	Phthalate/Lanolin/Colophony
2.8	Controls	<p><b>Unspread stitch-bonded non woven fabric</b> : Appearance Mass per unit area Thickness Av. Length shrinkage Av. Width shrinkage Tear across warp Tear across weft Fluorescence</p> <p><b>Spread stitch-bonded non Woven fabric</b> : Appearance Mass of adhesive Adhesion to steel Moisture vapour permeability Length Width</p> <p><b>Adhesive No.8</b> : Appearance Viscosity at 25 °C Solids content Zinc oxide content Resin content</p>

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		<b>Tensolastic Bandage</b> : Appearance Density Extensibility Regain Threads/10cm Dimension		
2.9	Product range			
	<b>Product Codes</b>	<b>Variant &amp; Size</b>	<b>No. of kits per wrap</b>	<b>No. of kits per shipper</b>
	71544-00	Adult Adhesive	1	12
	71554--00	Child Adhesive	1	12
	71555-00	Adult Non-Adhesive	1	12
	71556-00	Child Non-Adhesive	1	12
	71554-10	Infant Adhesive	1	12
	71555-10	Infant Non-Adhesive	1	12
2.10	Storage conditions	Store in a dry, well ventilated place. Keep away from direct sunlight (heat). Store below 25°C		
2.11	Shelf life/Storage time	3 years for optimum use		
<b>3.0</b>	<b>Safety Information</b>			
3.2	Physical & Chemical Properties	Combustible solid.		
3.3	Health Hazards	No health hazard is anticipated during normal handling of this product.		
3.4	Contra Indications	Not applicable.		
3.5	Fire Hazard and Emergency action	If ignited may give off toxic fumes, carbon dioxide, carbon monoxide, smoke containing particulate matter. In case of fire any standard fire extinguisher may be used. Wear self-contained breathing apparatus.		
3.6	Transport Precautions	Not applicable.		
3.7	Handling / Use / Protecting Clothing	Not applicable.		
3.8	First Aid	a) Inhalation b) Contact with skin c) Contact with eyes d) Ingestion	- - - -	Not applicable Not applicable Not applicable Not applicable
3.9	Disposal	Controlled incineration according to local environmental health guidelines.		
3.10	Additional Information	Not applicable		
<b>4.0</b>	<b>General Information</b>			
4.1	Name, address and telephone number of legal manufacturer	BSN medical (Pty) Ltd. 30 Gillitts Road Pinetown, 3610 South Africa Tel. + 27 31 7108111 Fax. + 27 31 7108108		
4.2	Name, address of EC/REP	BSN medical GmbH Quickbornstrasse 24, 20253 Hamburg, Germany		
4.3	Certificate	ISO 9001:2008 and ISO 14001: 2004 (notified body: SABSA - South African Bureau of Standards) ISO 13485: 2003 (notified body: Lloyd's LRQA)		

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MASTER DOCUMENT TO BE KEPT AT: QUALITY ASSURANCE/REGULATORY AFFAIRS  
DEPARTMENT

NATURE OF CHANGE: NONE – FIRST ISSUE.