3M™ Steri-Strip™ Skin Closures

General Description

3M™ Steri-Strip™ Skin Closures are CE marked as Class I (sterile) medical devices and complies with the needs and requirements of the European Medical Device Directive 93/42/EEC.

3M™ Steri-Strip™ Skin Closures are made of porous, nonwoven material and are available in three types:

3M™ Steri-Strip™ Skin Closures, (Reinforced) are reinforced with filaments for strength and coated with a hypoallergenic adhesive.
Catalog Numbers: R1540, R1541, R1542, R1546, R1547, R1548, R159

3M™ Steri-Strip™ Blend Tone Skin Closures, are natural skin tone coloured and coated with a hypoallergenic adhesive.
Catalog Numbers: B1550, B1551, B1553, B1557, B1559

3M™ Steri-Strip™ Elastic Skin Closures, are designed to allow for tissue expansion and movement and are coated with a hypoallergenic adhesive.
Catalog Numbers: E4540, E4541, E4542, E4546, E4547, E4548, E4549

Note: This Document is valid for the European Union only. The registration status in other geographies must be confirmed

Intended Use

Steri-Strip Skin Closures are intended for use as skin closure devices in the treatment of lacerations and surgical incisions. They may be used in conjunction with skin sutures and staples or after their removal for wound support.

Contraindications, Warnings and Precautions

Contraindications

- Steri-Strip skin closures are contraindicated where adhesion cannot be obtained. Potential causes of inadequate adhesion are presence of exudate, skin oils, or hair.
- Use of Steri-Strip skin closures on infected wounds is contraindicated
- Steri-Strip skin closures are contraindicated for use with high tension wounds which cannot be easily approximated with fingers or forceps.

Warnings

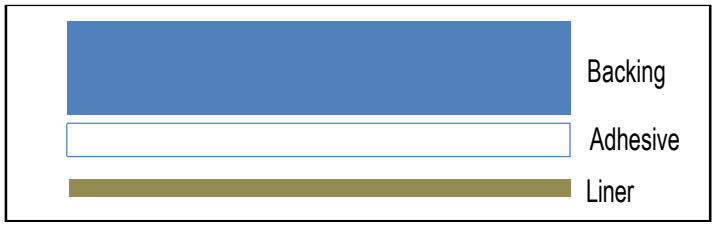
- The development of postoperative edema may cause skin shearing, skin blistering, or loss of tape adhesion to occur at either end of the strip.
- Application of any surgical tape or adhesive skin closure may result in skin stripping upon removal.
- As with all adhesive products applied to the skin, a small percentage of individuals may experience hypopigmentation or hyperpigmentation following removal.
- Occasional cases of mild acne and folliculitis have been observed in testing on healthy volunteers.

Precautions

- The skin should be clean, dry, and free of skin oils to assure good adhesion
- Do not apply skin closures under tension. Skin shearing, skin blistering, or loss of adhesion may result if excessive tension is applied.

Product Composition

3M™ Steri-Strip™ Skin Closures (Reinforced, Blend Tone, Elastic)



Materials used

Family / Reference Number	Components	Material
Steri-Strip – Reinforced	Backing	Nonwoven Polyester/Rayon Blend Polyester Filament
	Adhesive	Acrylate
	Liner	Paper Liner
	Package	Polyester Film Plastic Tray
Steri-Strip – Blend Tone	Backing	Nonwoven Rayon Fabric
	Adhesive	Acrylate
	Liner	Paper
	Package	Polyester film Plastic Tray
Steri-Strip – Elastic	Backing	Polyurethane
	Adhesive	Acrylate
	Liner	Polyester
	Package	Polyester Film Plastic Tray

Packaging Composition

Each set of closure strips is packaged into an envelope (immediate wrapper). Several envelopes are packaged into a primary plastic box (skin closures only) which then goes into a paperboard carton. Several cartons are then placed in a corrugated shipper box.

Packaging Level	Material
Envelope (Immediate Wrapper)	Polyester Printed Film
Plastic Tray	Polystyrene
Carton	Paperboard
Shipper	Corrugated board

Product Range

Name of Product / Description	Reference number	**Content** Items per envelope / envelopes per box / box per shipper
3M™ Steri-Strip™ Skin Closures (Reinforced)		
1/8 in. x 3 in. (3mm x 75mm)	R1540	5 / 50 / 4
1/4 in. x 3 in. (6mm x 75mm)	R1541	3 / 50 / 4
1/4in. x 1-1/2 in. (6mm x 38mm)	R1542	6 / 50 / 4
1/4 in. x 4 in. (6mm x 100mm)	R1546	10 / 50 / 4
1/2 in. x 4 in. (12mm x 100mm)	R1547	6 / 50 / 4
1 in. x 5 in. (25mm x 125mm)	R1548	4 / 25 / 4
1/2 in. x 2 in. (12mm x 50mm)	R1549	6 / 50 / 4
3M™Steri-Strip™Blend Tone Skin Closures		
1/8 in. x 3 in. (3mm x 75mm)	B1550	5 / 50 / 4
1/4 in. x 3 in. (6mm x 75mm)	B1551	3 / 50 / 4
1/4 in. x 4 in. (6mm x 100mm)	B1553	10 / 50 / 4
1/2 in. x 4 in. (12mm x 100mm)	B1557	6 / 50 / 4
1/2 in. x 2 in. (12mm x 50mm)	B1559	6 / 50 / 4
3M™ Steri-Strip™ Elastic Skin Closures		
1/8 in. x 3 in. (3mm x 75mm)	E4540	5 / 50 / 4
1/4 in. x 3 in. (6mm x 75mm)	E4541	3 / 50 / 4
1/4 in. x 1-1/2 in. (6mm x 38mm)	E4542	6 / 50 / 4
1/4 in. x 4 in. (6mm x 100mm)	E4546	10 / 50 / 4
1/2 in. x 4 in. (12mm x 100mm)	E4547	6 / 50 / 4
1 in. x 5 in. (25mm x 125mm)	E4548	4 / 25 / 4
1/2 in. x 2 in. (12mm x 50mm)	E4549	6 / 50 / 4

GENERAL CHARACTERISTICS

Parameter	Product Performance	Test Method	Results
3M™ Steri-Strip™ Skin Closures (Reinforced)			
Adhesion	Measures adhesion of Steri-Strip to steel	TS-208	450-1200g/25mm
Tensile Strength	Measures the force needed to break Steri-Strip	TS-771	8000g/25mm Minimum
Elongation	Measures the amount of stretch (increases in length) before breaking	TS-771	7-60%
Tensile Strength at 5% Elongation	Measures the force per width, needed to stretch Steri-Strips to 5% elongation	ISO 527-3 /1B/ 200	Typical average: 41.2 N/25.4mm
3M™Steri-Strip™Blend Tone Skin Closures			
Adhesion	Measures adhesion of Steri-Strip to steel	TS-208	4.5 oz Minimum
Tensile Strength	Measures the force needed to break Steri-Strip	TS-771	Crossweb: 2-5 lbs Downweb: 5-14 lbs
Elongation	Measures the amount of stretch (increases in length) before breaking	TS-771	Crossweb: 30-70% Downweb: 9-24%
Tensile Strength at 5% Elongation	Measures the force per width, needed to stretch Steri-Strips to 5% elongation	ISO 527-3 /1B/ 200	Typical average: 17.5 N/25.4mm
3M™ Steri-Strip™ Elastic Skin Closures			
Adhesion	Measures adhesion of Steri-Strip to steel	TS-208	4-24 oz.
Tensile Strength	Measures the force needed to break Steri-Strip	TS-722	2.5 lbs Minimum
Elongation	Measures the amount of stretch (increases in length) before breaking	TS-722	100 % Minimum
Tensile Strength at 5% Elongation	Measures the force per width, needed to stretch Steri-Strips to 5% elongation	ISO 527-3 /1B/ 200	Typical average: 2.6 N/25.4mm

Parameter	Product Performance	Test Method	Results
Sterility	Sterile	Sterilzation validation	Pass
Shelf life	Can be stored up to 5 years	Stability study	Pass
Adhesion	Adhesion to skin	In-house clinical study	**Reinforced:** Good initial adhesion to skin **Elastic and Blend Tone:** Good adhesion to skin **All:** Minimal adhesive residue
Permeability to air and moisture vapour	MVTR*	BS EN 13726-2 (3.2) upright	**Elastic:** > 380 g/m²/24h **Blend Tone:** > 1700 g/m²/24h **Reinforced:** > 1800 g/m²24h
Conformability	Conformable in use	In-house clinical study	**Elastic:** Stretch with body movement or edema, flexible, conformable
Cosmetic outcome	Support cosmetic outcome	Clinical study	Permit early staple/suture removal Help to improve cosmetic outcomes compared to sutures staples and tissue adhesives
Comfort	Patient comfort	Clinical study	Improve patient comfort compared to sutures and staples
Time	Time saving	Clinical study	Shorten postoperative care compared to suture and staples Save time compared to sutures and tissue adhesives
Cost	Cost saving	Clinical study	Save costs compared to sutures, staples and tissue adhesives
Pain	Pain decrease	Clinical study	Decrease pain or help decrease post-operative pain compared to sutures
Bacterial Growth	Reduced bacterial growth	Clinical study	May suppress bacterial growth on skin compared to sutures Help reduce the risk of infections compared to sutures and staples

*These measures are performed to confirm the breathability of Steri-Strip. Neither its design nor physical dimensions allow protection against moisture/fluids.

EASE OF USE

Parameter	Product Performance	Test Method	Results
3M™ Steri-Strip™ Skin Closures			
Ease of removal	Easily removed from liner	Laboratory Test	Confirmed
Ease of use	Easier to use compared to tissue adhesives	Clinical study	Confirmed

SAFETY AND SKIN TOLERABILITY (1)

Parameter	Product Performance	Test Method	Results
Basic safety	Safe for intended use 3M™ Steri-Strip™ Skin Closures are categorized as a surface device having prolonged (> 24 hours to 30 days) contact of breached or compromised skin.	ISO 10993-Part 1 (biological evaluation of medical devices- evaluation and testing)	In compliance
		ISO 14971 (application of risk management to medical devices	In compliance
Basic safety/Skin irritation	Gentle to skin/Minimal irritation	ISO 10993-10:2010	In compliance
Skin tolerability	Weak sensitizing potential	ISO 10993-10:2010	In compliance
Cytotoxicity potential	No evidence of causing cell lysis or toxicity	ISO 10993-5:2009	In compliance
Allergenic potential	Hypoallergenic	Human Repeat Insult Patch Test	Pass

The biological evaluation of this product was conducted in accordance with the following guidance:

Guidance	Edition	Title
US FDA Docket Number FDA-2013-D-0350. CDRH Document Number 1811	June 16, 2016	Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Guidance for Industry and Food and Drug Administration Staff
EU Medical Device Regulation	5 April 2017	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
ISO 10993-1	2018	Evaluation and testing within a risk management process
ISO 10993-5	2009	Tests for *in vitro* cytotoxicity
ISO 10993-6	2016	Tests for local effects after implantation
ISO 10993-10	2010	Tests for irritation and skin sensitization
ISO 10993-11	2017	Tests for systemic toxicity

ISO 10993-12	2012	Sample preparation and reference materials

SAFETY AND SKIN TOLERABILITY (2)

Parameter	Product Performance	Test Method	Results
Basic safety/ absence of toxic compounds	Not made with: - PVC - Natural rubber latex - Colophony	Raw Material Information, Formulation, Composition, LCM	Confirmed
	No antimicrobial compounds intentionally added.	Raw Material Information, Formulation, Composition, LCM	Confirmed
Basic safety/ absence of Substances of Very High Concern	The substances of the REACH SVHC candidate list as of 15th January 2019 are not present at or above 0,1% in the products or their sub-components.	Raw Material Information, Formulation, Composition	Confirmed

WOUND HEALING SUPPORT

Parameter	Product Performance	Test Method	Results
Wound closure	Wound support	Clinical study	Provide wound support and increase the tensile strength of the wound compared to sutures

PACKAGING RELATED INFORMATION

Packaging standards

Parameter	Product Performance	Norm	Status
Labeling information supplied by manufacturer	Legally correct labeling	EN 1041	In compliance
Symbols used for labeling of medical devices	Legally correct symbols used	ISO 15233	In compliance
Sterile Barrier System (SBS)	Sterile unless package is damaged or opened	EN ISO 11607- Part 1&2	In compliance
Undesirable components of packaging	Free of substances of very high concern (SVHCs) in >0,1% in weight concentration	EC Regulation 1907/2006 (REACH) for any packaging article as described in directive 94/62/EC from the EU	Stated in supplier contracts
Undesirable components of packaging	Free of PVC (polyvinylchloride) Free of silica gel Totally Chlorine Free bleaching	3M internal standards	Stated in supplier contracts
Undesirable components of packaging	Sum concentration level of Lead, Cadmium, Mercury and Hexavalent Chromium not to exceed 100ppm (by weight)	Article 9 of EC directive 94/62/EC	Stated in supplier contracts

CERTIFICATIONS

Type of Certification	3M Company Certifications	Certifying Body	Certificate Number
Manufacturing, Quality Management System Certification ISO 13485:2016	3M Company, 3M Health Care 2510 Conway Ave, Bldg. 275-5W-06 Saint Paul, Minnesota 55144 Unites States	BSI Kitemark Court Milton Keynes MK5 8PP UK	FM 68740
93/42/EEC (MDD) Annex V & VII	3M Company 3M Health Care 2510 Conway Ave, Bldg. 275-5W-06 Saint Paul, Minnesota 55144 Unites States	BSI Kitemark Court Milton Keynes MK5 8PP UK	CE 00493

Additional information:

The information provided in this technical data sheet related to material content represents 3M's knowledge and belief as of the date it is provided, which may be based in whole or in part on information provided by suppliers to 3M.

This Technical Data Sheet is approved by 3M Regulatory Affairs:
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