

3M™ Micropore™ Surgical Tapes

7 pirkimo dalis



Gentle, Reliable Securement



Now Available in
Two Adhesion Levels

Popierinis chirurginis pleistras

50 years ago, 3M introduced the industry's first hypoallergenic, breathable tape, a true breakthrough for patient safety and comfort. Today, 3M™ Micropore™ family of surgical tapes remain the #1 brand of surgical tapes globally. Micropore™ paper tapes:

- Offer gentle adhesion for at risk skin
- Are conformable and highly breathable
- Reliably secures dressings and devices to skin
- Are hypoallergenic and latex-free

Suggested applications:

- Securing small to medium dressings, especially on damp skin
Limpa net prie drėgnos odos
- Securing light tubing
- Securing Ostomy pouches

Galima tvirtinti tvarščius ar intrakraujagyslines priemones



Ordering Information:

Catalog No.	NHRIC No.	Size - Standard	Size - Metric	Rolls/Box	Boxes/Case	HCPCS Code*
3M™ Micropore™ Paper Tape Plus 1532 has a higher initial adhesion than the 1530						
1532-1	8333-1532-01	1 in x 10 yd	2,5 cm x 9,1 m	12	10	A4450
1532-2	8333-1532-02	2 in x 10 yd	5 cm x 9,1 m	6	10	A4450
1532S-1	8333-1532-11	1 in x 1 ½ yd	2,5 cm x 1,37 m	100	5	A4450
3M™ Micropore™ Surgical Tape						
Standard:						
1530-0	8333-1530-00	½ in x 10 yd	1,25 cm x 9,1 m	24	10	A4450
1530-1	8333-1530-01	1 in x 10 yd	2,5 cm x 9,1 m	12	10	A4450
1530-2	8333-1530-02	2 in x 10 yd	5,0 cm x 9,1 m	6	10	A4450
1530-3	8333-1530-03	3 in x 10 yd	7,5 cm x 9,1 m	4	10	A4450
Single Use:						
1530S-1	8333-1530-11	1 in x 1 ½ yd	2,5 cm x 1,37 m	100	5	A4450
1530S-2	8333-1530-12	2 in x 1 ½ yd	5,0 cm x 1,37 m	50	5	A4450
Tan:						
1533-0	8333-1533-00	½ in x 10 yd	1,25 cm x 9,1 m	24	10	A4450
1533-1	8333-1533-01	1 in x 10 yd	2,5 cm x 9,1 m	12	10	A4450
1533-2	8333-1533-02	2 in x 10 yd	5,0 cm x 9,1 m	6	10	A4450
Dispenser Pack:						
1535-0	8333-1535-00	½ in x 10 yd	1,25 cm x 9,1 m	24	10	A4450
1535-1	8333-1535-01	1 in x 10 yd	2,5 cm x 9,1 m	12	10	A4450
1535-2	8333-1535-02	2 in x 10 yd	5,0 cm x 9,1 m	6	10	A4450
1535-3	8333-1535-03	3 in x 10 yd	7,5 cm x 9,1 m	4	10	A4450

* HCPCS codes as referenced in the Local Coverage Determination Surgical Dressing Policy.

Disclaimer:

HCPCS codes have been provided to assist you in the preparation of Medicare Part B claims. Please note, however, that the reimbursement information provided by 3M Health Care and its representatives is intended to provide general information relevant to coverage and coding for 3M products. Insurers' reimbursement policies can vary and the use of the codes discussed here does not guarantee that an insurer will cover or pay at any particular level. Health care providers should exercise independent clinical judgment in choosing the codes which most accurately describe the products provided.

Product Content: Nonwoven rayon and hypoallergenic, pressure-sensitive, acrylate adhesive. 3M™ Micropore™ Tape is free of natural rubber latex.

Storage/Shelf Life: It is recommended that 3M™ Surgical Tapes be stored under normal conditions within the temperature range of 59–86°F (15–30°C). 3M™ Micropore™ Tape has a recommended shelf life of five (5) years under these conditions.

Sterilization: 3M™ Micropore™ Tape is sold non-sterile. The following methods were tested and proven reliable for sterilization and stable adhesion performance, with ethylene oxide residuals well within U.S. FDA guidelines. Procedure used: 1) Tape rolls kept intact up to the full 10-yard length, OR 2) Strips of tape arranged over a suitable release surface, e.g. glass, stainless steel, silicone-treated paper, 3) Tape sealed in appropriate sterilization pouch or wrapper, 4) ETO sterilized warm cycle 55°C (130–145°F), minimum 1 hour exposure time (50% RH - 600 mg/liter, or equivalent), 5) Warm cycle aeration (temperature not to exceed 55°C (130–145°F) for a minimum 20 hour cycle before use.

It is the responsibility of an individual health care organization to confirm sterility when product is sterilized in its facility.

Application recommendations: 1) Always apply to clean dry surface, 2) To maximize adhesion, gently press or rub from center out to edges of tape, 3) To promote skin health, do not stretch or apply with tension over areas where tape will be adhering directly to skin, 4) Refer to "3M Trouble-free Taping" brochure for additional usage recommendations.

For more information contact your 3M Health Care Sales Representative or call the 3M Health Care Customer at **1-800-228-3957**. These products can be ordered from your local distributor. Outside the United States, contact the local 3M subsidiary.



Skin & Wound Care Division
3M Health Care
 3M Center, Building 275-4W-02
 St. Paul, MN 55144-1000
 USA
 1-800-228-3957
www.3M.com/healthcare

3M Canada Company
 P.O. Box 5757
 London, Ontario N6A 4T1
 Canada
 1-800-364-3577
www.3M.com/ca/healthcare

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 70-2010-8114-1

How to Differentiate 3M™ Surgical Tapes

All 3M surgical tapes have adhesives that are hypoallergenic and natural rubber latex free. This table describes their characteristics in relationship to each other.

Characteristics	3M™ Blenderm™ Tape	3M™ Cloth Adhesive Tape	3M™ Durapore™ Tape	3M™ Medipore™ Tape	3M™ Medipore™ H Tape	3M™ Microfoam™ Tape	3M™ Micropore™ Tape	3M™ Transpore™ Tape	3M™ Transpore™ White Tape
General category	Plastic	Cloth	*Silk*	Soft cloth	Soft cloth	Foam/elastic	Paper	Perforated plastic	Blend
Backing	Transparent Polyethylene	Woven cotton	Taffeta acetate	Polyester	Polyester	Closed cell PVC	Nonwoven rayon	Transparent Polyethylene	Polyester-rayon blend
Adhesion – initial*	Dry – moderate Moist – low	Dry – very high Moist – high	Dry – high Moist – high	Dry – moderate Moist – moderate	Dry – high – moderate	Dry – low low	Dry – low – high	Dry – high moderate	Dry – high Moist – moderate
Adhesion – after 48 hrs*	Low	High	Very High	High	Very High	Moderate	Moderate	Moderate	Moderate
Conformability	High	Moderate	Moderate	High	High	High	Moderate	Moderate	Moderate
Stretch	Moderate in all directions	Diagonal	Diagonal	Crosswise & Diagonal	Crosswise & Diagonal	Crosswise, Lengthwise & Diagonal	Diagonal	Moderate, more stretch if narrow strips	Diagonal
Breathability <i>MVTR = moisture vapour transmission rate & porosity</i>	None	High	Low	High	High	None	Very High	Low	High
Tearability	Easy, but ruffled edge	Easy, bi-directional	Easy, bi-directional	Easy at perforations, not lengthwise	Easy at perforations, not lengthwise	Easy	Easy	Very easy, directional	Easy, bi-directional
Water resistance	Waterproof	No	Water Resistant	Water Resistant	Water Resistant	Water Resistant	No	Water Resistant	Water Resistant
Gentleness <i>repeated taping on adults</i>	Less Gentle	Less Gentle	Less Gentle	Less Gentle	Very Gentle	Gentle	Very Gentle	Less Gentle	Gentle
Residue <i>Depends on length of wear, temperature, characteristics of surface (increases with oil, plastic tubing)</i>	None – small amount	Small amount	Small amount	None – small amount	None – small amount	Small amount	None – small amount	Moderate amount	Small amount
Shelf life	5 years	2 years	5 years	3 years	3 years	3 years	5 years	3 years	3 years

* See adhesion charts

3M™ Micropore™ Surgical Tape Tan



Details

- Conformable and highly breathable Priglunda prie kūno formų ir leidžia odai kvėpuoti
- Reliably secures dressings and devices to skin for at least 10 hours Tvirtai prilimpa prie odos ir priemonių bent 10 val.
- Hypoallergenic and not made with natural rubber latex Hipoalergiškas, sudėtyje nėra latekso
- Minimal potential to stick to gloves Nelimpa prie piršinių
- Easily unwrapped from the roll and easily tears by hand Lengvai išvyniojamas ir atplėšiamas nenaudojant žirklių
- Leaves no adhesive residue Nepalieka klijų likučio
- 1,25 cm x 9,1m, 2,5 cm x 9,1m, 5 cm x 9,1m

3M™ Micropore™ Surgical Tape is part of the Multi Purpose Tape Category that offers gentleness to skin yet adheres appropriately for general securement needs.

Suggested Applications

- Securing small to medium dressings
- Securing lightweight tubing



EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss
Germany

hereby declare under our sole responsibility that the following CE marked device(s)

Trade Name	Micropore™
Intended Purpose	3M™ Micropore™ Surgical Tape is a general-purpose gentle tape used to secure dressings, lightweight tubing, and devices to skin.
Reference	1530-0, 1530-1, 1530-2, 1530-3 1530-0S, 1530-1S, 1530-2S, 1530-3S
Basic UDI-DI	0608223276101000000006CP

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

Date

Manager Regulatory Affairs and
Quality Management System
Health Care Business EMEA
3M Deutschland GmbH

3M is a trademark of 3M.

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3M™ Micropore™ Surgical Tape

General Description

3M™ Micropore™ Surgical Tape (1530, 1533 and 1535 materials)

3M™ Micropore™ Surgical Tape is general purpose gentle tape used to secure dressings, tubing and devices to patients. Also available in tan color and a convenient dispenser.



Micropore 1530 white tape is manufactured at:

3M Deutschland GmbH
Plant Kamen
Edisonstrasse 6
59157 Kamen, Germany

Micropore 1533 tan tape is manufactured at:

3M Company
601 22nd Ave. South
Brookings, South Dakota 57006 United States

Micropore 1535 are dispensers which are packed at:

3M Poland Manufacturing SP. ZO.O
Site Wroclaw
Ul. Kwidzynska 6
Wroclaw, Poland 51-416

Micropore Surgical Tape is CE marked as a Class 1 medical device and fulfils the essential requirements of the Medical Device Directive.

Product Composition

Materials Kamen Manufactured Micropore 1530 Reference Numbers

Component	Raw Material
Backing	Viscose Fiber
Binder	Acrylate
Adhesive	Acrylate
LAB	Acrylate
Core	Paper material

*LAB = Low Adhesion Backsizing; coating that prevents the tape from sticking to itself when on the roll

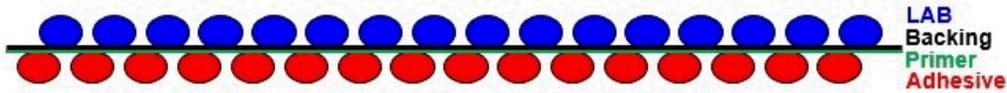
Materials Brookings Manufactured Micropore Tan 1533 Reference Numbers

Component	Raw Material
Backing	Rayon Fiber
Binder	Acrylate
Adhesive	Acrylate
LAB*	Urethane Coating
Core	Paper Material

*LAB = Low Adhesion Backsizing; coating that prevents the tape from sticking to itself when on the roll

Note: Where applicable, the dispenser is made of high impact polystyrene

Schematic drawing: Product Cross Section



Packaging Composition

Micropore Surgical Tape rolls are packaged into a primary box. Then several primary boxes are placed in a corrugated shipper carton

Micropore Packaging	Material
Primary Box:	Paperboard
Shipper Carton:	Corrugated box

The primary box and shipper are labelled with the product name, catalogue number, and symbols required satisfying regulatory needs. The labeling also indicates tape dimensions (width and length) and number of rolls per box/master carton. The box labeling features the different languages based on the markets sold.

Units per primary are shown in the table above, for all references there are 10 primary boxes packed in a shipper carton.

Intended Use

Micropore is a general-purpose gentle tape for the hospital and home care patient used to secure most dressings, lightweight tubing and devices to patient's intact skin.

Product Range

Catalog Number	Product Description / Branding	Width x Length	Rolls /Box
1530-0	3M™ Micropore™ Surgical Tape	1,25cm x 9,1m	24
1530-1	3M™ Micropore™ Surgical Tape	2,5cm x 9,1m	12
1530-2	3M™ Micropore™ Surgical Tape	5,0cm x 9,1m	6
1530-3	3M™ Micropore™ Surgical Tape	7,6cm x 9,1m	4
1530-0S	3M™ Micropore™ Surgical Tape	1,25cm x 5,0m	24
1530-1S	3M™ Micropore™ Surgical Tape	2,5cm x 5,0m	12
1530-2S	3M™ Micropore™ Surgical Tape	5,0cm x 5,0m	6
1530-3S	3M™ Micropore™ Surgical Tape	7,6cm x 5,0m	4
1535E-0	3M™ Micropore™ Surgical Tape in blue dispenser	1,25cm x 9,1m	24
1535E-1	3M™ Micropore™ Surgical Tape in blue dispenser	2,5cm x 9,1m	12
1535E-2	3M™ Micropore™ Surgical Tape in blue dispenser	5,0cm x 9,1m	6
1535E-3	3M™ Micropore™ Surgical Tape in blue dispenser	7,6cm x 9,1m	4
	Micropore™ Tan		
1533-0	3M™ Micropore™ Surgical Tape (Tan)	1,25cm x 9,1m	24
1533-1	3M™ Micropore™ Surgical Tape (Tan)	2,5cm x 9,1m	12
1533-2	3M™ Micropore™ Surgical Tape (Tan)	5,0cm x 9,1m	6

GENERAL CHARACTERISTICS

All 1530 & 1535 versions:

Parameter	Product Performance	Test Method (3M internal)	Results (Typical Values)
Adhesion to steel	Good adhesion to stainless steel	EU-TS-05-000055(A)	3.9 N/in
Adhesion to backing	Adheres well to backside of self (overtaping)	EU-TS-05-000055(B)	1.2 N/in

All 1533 versions (Micropore Tan):

Parameter	Product Performance	Test Method (3M internal)	Results (Typical Values)
Adhesion to steel	Good adhesion to stainless steel	TS-208 (A)	3.1 N/in
Adhesion to backing	Adheres well to backside of self (overtaping)	TS-208 (B)	0.9 N/in

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EASE OF USE

All 1530 & 1535 versions:

Parameter	Product Performance	Test Method (3M internal)	Results (typical values)
Mechanical roll unwind	Force to unwind the tape (initial)	EU-TS-000082	2.5 N/in
Tensile strength (tensile force at break)	Tape is strong enough for use and removal	EU-TS-05-000088	43 N/in
Elongation	Tape is conformable	EU-TS-05-000088	14 %

All 1533 versions (Micropore Tan):

Parameter	Product Performance	Test Method (3M internal)	Results (typical values)
Mechanical roll unwind	Force to unwind the tape (initial)	TS-215	2.8 N/in
Tensile strength (tensile force at break)	Tape is strong enough for use and removal	TS-771	37.7 N/in
Elongation	Tape is conformable	TS-771	18.8%

SAFETY AND SKIN TOLERABILITY (1)

All tests conducted according to GLP (good laboratory practice) as described by the FDA (21CFR Part 58) and according respective EU standards

3M™ Micropore™ Surgical Tape is categorized as a surface device having prolonged contact duration (>24 hours to 30 days) with intact skin. As such, the guidance suggests that cytotoxicity, sensitization, irritation, studies be conducted on patient contacting materials

Micropore 1530 & 1535E versions:

Parameter	Test Method	Results
Biocompatibility	ISO 10993-Part 1 (biological evaluation of medical devices- evaluation and testing) ISO 14971 (application of risk management to medical devices)	In compliance In compliance- All document- tation complete
Skin irritation	ISO 10993-10 (Irritation)	In compliance
Gentle to skin	HCIPT (Human Cumulative Irritation Patch Test)	Pass

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Parameter	Test Method	Results
Sensitization	ISO 10993-10 Sensitization (GPMT)	In compliance
Hypoallergenic	HRIPT (Human Repeated Irritation Patch Test)	Pass
Cytotoxicity	ISO 10993-5 Cytotoxicity (MEM) Elution	In compliance

Micropore 1533 tan version:

Parameter	Test Method	Results
Biocompatibility	ISO 10993-Part 1 (biological evaluation of medical devices - evaluation and testing) ISO 14971 (application of risk management to medical devices)	Partial compliance* In compliance- All documentation complete
Skin irritation*	HCIPT (Human Cumulative Irritation Patch Test)	Pass
Gentle to skin		
Sensitization*	HRIPT (Human Repeated Irritation Patch Test)	Pass
Hypoallergenic		
Cytotoxicity	ISO 10993-5 Cytotoxicity (MEM) Elution	In compliance

*ISO 10993-10: Irritation and Sensitization -- Partial compliance – both irritation and sensitization testing was not conducted per the standard. Instead Human Cumulative Irritation Patch testing and Human Repeat Insult Patch testing was chosen, respectively, to as the preferred methods to test irritation and sensitization at the time this product was designed

SAFETY AND SKIN TOLERABILITY (2)

Parameter	Product Performance	Test Method	Results
Basic safety/ absence of toxic compounds	Contains No health hazard chemical compounds	ISO 10993-18 Biological evaluation of medical devices- Part 18: chemical characterization of materials	Negative- no health hazard compound materials were detected
	<p><i>Free of:</i></p> <ul style="list-style-type: none"> - PVC - Natural rubber latex - Colophony <p><i>No antimicrobial compounds intentionally added.</i></p>	<p><i>Raw Material Information, Formulation, Composition, LCM</i></p>	<p><i>Confirmed</i></p>
Basic safety/ absence of Substances of Very High Concern	<i>The substances of the REACH SVHC candidate list as of December 2014 are not present at or above 0,1%.</i>	<i>Raw Material Information, Formulation, Composition</i>	<i>Confirmed</i>

PACKAGING RELATED INFORMATION

Parameter	Product Performance	Norm	Status
Labeling information supplied by manufacturer	Legally correct labeling	EN1041	In compliance
Symbols used for labeling of medical devices	Legally correct symbols used	EN980 and ISO 15233	In compliance
Sterile Barrier System (SBS)	Product not sterile	N/A	N/A
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

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CERTIFICATIONS

Type of Certification	3M Company Certifications	Certifying Body	Results
<i>Quality Management System Certification</i>	<i>3M Deutschland GmbH, Plant Kamen, is an ISO 13485 certified plant</i>	<i>Certified by DQS</i>	<i>In compliance</i>
<i>FDA Site Registration</i>	<i>3M Deutschland GmbH, Plant Kamen is FDA registered (number available on request)</i>	<i>N/A</i>	<i>In compliance</i>

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 valid until 01 06 2017

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

3M Deutschland GmbH , Health Care Business, Carl-Schurz-Str 1, 41453 Neuss, Germany



Declaration of Conformity

We, 3M Health Care,
hereby declare under our sole responsibility
that the CE marked products to which this declaration relates ,

Micropore™ Surgical Tape
1530-0, 1530-1, 1530-2, 1530-3
Single use
1530S-1 and 1530S-2,
Tan
1533-0, 1533-1, 1533-2
Dispenser
1535-0, 1535-1, 1535-2, 1535-3

are classified, per Rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as a Class I device
and

are in accordance with Annex VII of Directive 93/42/EEC, as amended per 2007/47/EC
on the approximation of the laws of the European Union Member States concerning medical devices.

In addition, we declare that the above mentioned device fulfills the applicable provisions of the Directive
93/42/EEC, as amended per 2007/47/EC.

This certificate is valid for devices originating from the following sites:

3M Health Care
3M Brookings
601 22nd Ave. South,
Brookings, South Dakota USA 57006

EU Representative Address
3M Medica
Zweigniederlassung der 3M Deutschland GmbH
Trading as "3M Health Care"
Hammfeldamm 11
D-41453 Neuss, Germany

Signature: _____

Date: _____

3M Health Care
Regulatory Affairs and Quality Assurance
Skin & Wound Care Division