3M™ Electrosurgical Pads

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3M Medical

from the 3M Health Care family

Split-Plate Indemnification Agreement.

Use the 3M split-pad with those brands of electrosurgical generators listed in our indemnification agreement and 3M will indemnify your hospital, and its employees, medical and professional staff. Please contact your local 3M Sales Representative for more details. If your hospital is like most, it has multiple brands of generators. Our broad indemnification may allow your hospital to standardize on one brand of pad.

- Offered to the hospital and its employees, medical and professional staff
- Applies as long as claim is promptly reported to 3M
- Provides that 3M will defend litigation, not just pay back hospital later if hospital is found liable.
- Applies even if hospital is found to be liable and 3M not liable.

3M Education Programs.

3M provides in-depth continuing education to nurses and technicians to help improve patient and staff safety. For example:

- The PAES Electrosurgery Safety Seminar: a program for healthcare professionals that reviews practical safety measures and that has been approved for one continuing education unit (CEU) by the American Nurses Association's Board of Accreditation.
- Posters, literature, and videos that outline proper procedures and safety tips for using patient plates.

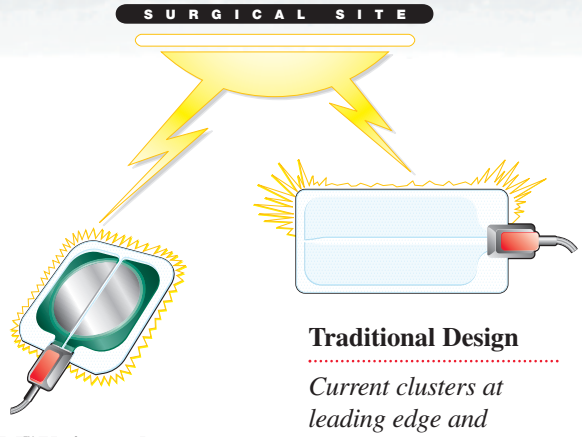
3M™ Universal Electrosurgical Pad 9100 Series with *Safety Ring*. The revolutionary electrosurgical pad is easy to place because of its smaller size.

The 3M™ Universal Electrosurgical Pad 9100 Series with proprietary Safety Ring is a breakthrough in electrosurgical pad technology. This pad is smaller in size — a mere 15 square inches — so it's very easy to place, while maintaining the safety of traditional pads up to 33% larger in conductive surface area.

The Universal Pad demonstrates a maximum temperature rise similar to traditional pads up to 33% larger and meets the performance criteria set forth by the Association for the Advancement of Medical Instrumentation (AAMI) for Maximum Safe Temperature Rise (AAMI Standard HF-18, 2001 Revision, Section 4.2.3.1).

A solution to an old problem.

The tendency of electrosurgical current and heat to cluster at the leading edge of a non-capacitive pad has been a long standing industry-wide design problem. With the 3M Universal Pad, the problem has been solved.



3M™ Universal Electrosurgical Pad with *Safety Ring*

Uniform dispersion of current allows smaller size and universal orientation

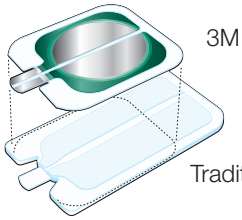
Traditional Design

Current clusters at leading edge and corners, thus requiring placement perpendicular to surgical site

Latex indication: neither natural rubber latex nor dry natural rubber are components in Electrosurgical Pads 9100 Series or their packaging.

Easy to place because it's smaller.

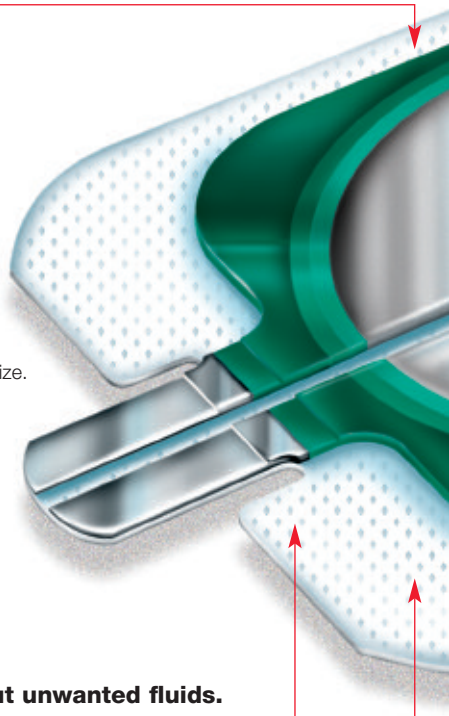
Forget about the limitations of traditional pads (below, left). The smaller-sized 3M Universal Pad will fit a greater number of suitable placement sites on the patient and can be oriented in any direction.



3M Universal Electrosurgical Pad

Traditional Pad Size

Illustration shown is actual size.



Unique backing keeps out unwanted fluids.

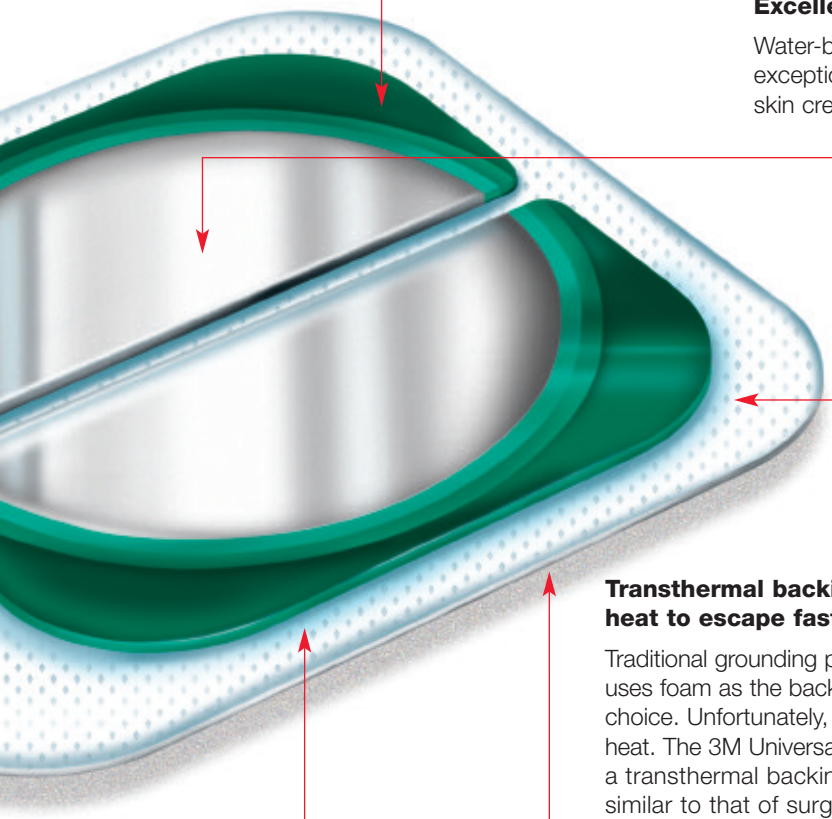
- Backing includes a non-woven laminant and a layer of polyethylene — a construction similar to that of surgical drapes. This material forms a barrier to moisture; it is waterproof and fluid resistant.
- Non-conductive isolation border surrounds the conductive adhesive gel to help seal out unwanted fluids. The pad's border adhesive is similar in properties to the 3M™ Micropore™ Tape.

Stress flaps to prevent dislodging.

Stress flaps play a critical role in holding the tab end of the plate securely to the patient, minimizing dislodging if the cable or cord is inadvertently pulled.

More evenly distributed current because of Green *Safety Ring.*

RF current is reduced at the leading edge and corners, and dispersed more uniformly over the pad's entire surface. This allows the pad to be smaller and easier to place, and still have a thermal performance similar to traditional pads that are up to 33% larger in conductive surface.



Excellent pad-to-skin contact.

Water-based hydrophilic conductive adhesive provides exceptional pad-to-skin contact, flowing uniformly into skin crevices.

Reduced chance of skin stripping.

For patients with fragile skin, our non-aggressive border adhesive reduces possibility of skin stripping.

Transthermal backing permits heat to escape faster.

Traditional grounding pad technology uses foam as the backing material of choice. Unfortunately, foam locks in heat. The 3M Universal Pad employs a transthermal backing material similar to that of surgical drapes, letting heat escape 25% faster than foam and reducing risk of unsafe temperature rise.

A cost-effective, universal solution.

- You can standardize on the 3M Universal Pad, eliminating SKUs. As long as 100% of the pad makes full contact with the patient at a suitable placement site without overlap, there are no limitations on age or weight. A separate inventory of "infant" pads may not be necessary.
- This pad has been specifically designed to be compatible with most major brands of generators.
- Three-year shelf life allows for efficient inventory management.

3M™ Electrosurgical Patient Plates 1100 Series. Low impedance, low current density connection with minimal skin irritation and trauma.

The 1100 Series of electrosurgical patient plates has a soft, gel-like, conductive adhesive surrounded by an isolation border on foam backing. Product benefits include:

- **Stress flaps to secure tab end of pad**
- **3M water-based (hydrophilic) conductive adhesive readily flows into skin crevices, providing exceptional pad to skin contact**
- **Non-conductive border adhesive**
- **Available in split and solid styles, and with or without pre-attached cord**

3M™ Electrosurgical Patient Plate 1100 Series, Small

3M™ Electrosurgical Patient Plate 1100 Series, Large

Ordering Information

3M™ Universal Electrosurgical Pads with *Safety Ring* 9100 Series				
Catalog Number	**Description**	**Conductive Adhesive Area**	**Pads/ Pouch**	**Pads/ Shipper**
9130	Standard (non-split), uncorded,	15 sq. in.	1	100
9130F	Standard (non-split), uncorded,	15 sq. in.	5	200
9135	Standard (non-split), with pre-attached cord	15 sq. in.	1	40
9160	Split, Uncorded	15 sq. in.	1	100
9160F	Split, Uncorded	15 sq. in.	5	200
9165	Split, with pre-attached cord,	15 sq. in.	1	40
9165L	Split, with pre-attached 15' cord,	15 sq. in.	1	40

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3M™ Electrosurgical Patient Plates 1100 Series				
Catalog Number	**Description**	**Conductive Adhesive Area**	**Pads/ Pouch**	**Pads/ Shipper**
1179	Large split pad with pre-attached cord	20 sq. in./129cm^2	1	40
1180	Large split pad without cord	20 sq. in./129cm^2	1	100
1180F	Large split pad without cord	20 sq. in./129cm^2	1	100
1181	Small split pad with pre-attached cord	10 sq. in./64.5cm^2	1	40
1182	Small split pad without cord	10 sq. in./64.5cm^2	1	100
1149C	Large solid pad with pre-attached cord	20 sq. in./129cm^2	1	40
1149	Large solid pad without cord	20 sq. in./129cm^2	1	100
1149F	Large solid pad without cord	20 sq. in./129cm^2	1	100
1148	Small solid pad with pre-attached cord	10 sq. in./64.5cm^2	1	40
1146	Small solid pad without cord	10 sq. in./64.5cm^2	1	100

3M™ Electrosurgical Pads 7100 Series				
Catalog Number	**Description**	**Conductive Adhesive Area**	**Pads/ Pouch**	**Pads/ Shipper**
7179	Large split pad with pre-attached cord	20 sq. in./129cm^2	1	40
7180	Large split pad without cord	20 sq. in./129cm^2	1	100
7180F	Large split pad without cord	20 sq. in./129cm^2	5	100
7149C	Large solid pad with pre-attached cord	20 sq. in./129cm^2	1	40
7149	Large solid pad without cord	20 sq. in./129cm^2	1	100
7149F	Large solid pad without cord	20 sq. in./129cm^2	5	100

Also available:

3M Electrosurgical Grounding Pad and Accessory Guide.

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

3M

Health Care

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1 800 228-3957
healthcare@3M.com
www.3M.com/healthcare

3M Canada Inc.

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London, Ontario N6A 4T1
Canada
1 800 563-2921

40% Pre-consumer waste paper
10% Post-consumer waste paper

70-2009-7119-3

3M Health Care Business

3M Center
2510 Conway Ave, Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Company
3M Health Care
2510 Conway Ave
St. Paul, MN 55144 USA

hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

3M™ Electrosurgical Plates
Product Numbers
1149, 1149C-LP, 1179, 1180, 1181, 1182, 8149F, 8180F, 9130, 9130F, 9135-LP, 9160, 9160F, 9165, 9165L

is classified,
per Rule 9 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as a Class IIb device
and

is in accordance with Annex II 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 devices fulfill the applicable provisions of the Directive 93/42/EEC, as amended per 2007/47/EC.

This declaration is made on the basis of the quality assurance certificate CE 02242 delivered by BSI, 2797

3M Health Care Business self-declares conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and compliance to the requirements of EN 50581:2012.

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

Signatur[redacted] Date: 13 September 2019

3M Health Care

REG-DOC-05-132198, 3M Electrosurgical Pads, Version 5,
Status: Release, Release Date: 09/12/2019 03:44:20 PM CDT

THIS DOCUMENT WAS PRINTED ON 13-Sep-2019 6:49 AM

DATA SHEET

PROFEEL®

DHD™ Polyisoprene Powder Free

Non-Latex Surgical Gloves

25 pirkimo dalis

Powder Free & Latex Free Surgical Glove

Reorder#/Size		5½ : P3355-56 7½ : P3375-56 6 : P3360-56 8 : P3380-56 Su mikro tekstūra 6½ : P3365-56 8½ : P3385-56 Anatominės konfigūracijos 7 : P3370-56 9 : P3390-56 Rankogalių kraštelis – susuktas
Design and Features		Hand specific, curved fingers, Bisque-Finish and beaded cuff
Type		Powder free, polymer coated – DHD™-technology (damp-hand-donning) – and gamma-sterilized surgical glove
Material		Polyisoprene (latex free) Poliizopreninės Padengtos poliueretanu ir silikonizuotos
Colour		Natural
Surface Treatment		Polymer coating for easy donning
Powder Residues (mg/glove)		≤ 2 (powder free) Be pudros
Dimensions – Palm width (mm)		5½ : 72 ± 4 7½ : 95 ± 5 6 : 77 ± 5 8 : 102 ± 6 6½ : 83 ± 5 8½ : 108 ± 6 7 : 89 ± 5 9 : 114 ± 6
Dimensions - Length (mm)		5½ : min. 305 7½ : min. 306 6 : min. 305 8 : min. 307 6½ : min. 305 8½ : min. 308 7 : min. 306 9 : min. 308
Single wall thickness (mm)	Finger Palm Cuff	0.23 0.20 0.16
Physical Properties	Tensile Strength (MPa) Elongation (%) Force at break (N)	Before aging : 17 After aging : 12 : 490 : 490 : 14 : 12
Packing mode	Inner Wrapper Pouch Dispenser Outer carton	1 pair of gloves 1 inner wrapper 50 pouches 4 dispensers
Glove marking		The cuff of each glove is marked with"PROFEEL" and the respective hand (L/R) & size
Lot number		Lot number structure: YMMPPPPSS Y = year of packing P = internal reference no. MM = month of packing SS = size
Shelf life		5 years from date of manufacture
Pre-shipment Quality Inspection	Dimensions Physical Properties 1000ml Water Leak Major Visual Inspection Minor Visual Inspection Powder Residues	N=13 (EN 455-2) N=13 (EN 455-2) G-I, AQL 0.65 (EN 455-1) G-I, AQL 1.5 G-I, AQL 4.0 N=3 pairs (EN 455-3)
Product Conformance		• Medical Device in compliance with European Medical Device Directive 93/42/EEC (CE Class IIa): EN 455 Parts 1, 2, 3 & 4 • Personal Protection Equipment in compliance with European Regulation (EU) 2016/425 (complex design category III, type tested to EN 420:2003 + A1:2009, EN ISO 374-1:2016 Type B, EN ISO 374-5:2016), CE 2797 • ASTM D3577
Quality Assurance		• BS EN ISO 9001 • BS EN ISO 13485 • US FDA Quality System Regulation (QSR)

Note: The above information is a guideline of typical performance values and characteristics of the product and not to be used as actual product specifications.

EU Type Examination Certificate

This is to certify that:

WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3
Kawasan Perusahaan
Bandar Baru Salak Tinggi
Sepang
Selangor
43900
Malaysia

Holds Certificate Number: CE 724079

In respect of:

Polyisoprene Radiation Attenuation gloves

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

[redacted]

Drs. Dave Hagenaars, Managing Director

First Issued: 2020-12-02
Latest Issue: 2020-12-02

Effective Date: 2020-12-02
Expiry Date: 2025-12-02

PRODUCTS
RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 724079

Product Specification

Model - Radiaxon Polyisoprene Powder Free Radiation Attenuating Surgical Gloves, Sterile
Radiaxon Polyisoprene Sensitive Powder Free Radiation Attenuating Surgical Gloves, Sterile

Classification: Protective glove for use against chemical and micro-organism hazards and radiation.

Description: Powder Free PI Protective Gloves manufactured from polyisoprene.
Inner surface of gloves is smooth surface that assists in donning the gloves without using lubricant such as powder on the glove surface.

The main features of this protective glove are:
- Beaded cuff
- Micro-organisms penetration resistance
- Chemical permeation resistance
- Palm and finger micro-textured (Hand Specific)

Models in range: Radiaxon Polyisoprene Powder Free Radiation Attenuating Surgical Gloves, Sterile

R3560-85	R3565-85	R3570-85	R3575-85	R3580-85	R3585-85	R3590-85

Radiaxon Polyisoprene Sensitive Powder Free Radiation Attenuating Surgical Gloves, Sterile

R3560-86	R3565-86	R3570-86	R3575-86	R3580-86	R3585-86	R3590-86
Sizes	6.0	6.5	7.0	7.5	8.0	8.5	9.0

Category: Category III – complex

Applicable Standards:

EN ISO 21420:2020	General requirements for gloves
EN 421:2010	Protective gloves against ionizing radiation and radioactive contamination.
EN ISO 374-1:2016+A1:2018	Protective gloves again chemicals & micro-organisms
EN ISO 374-2:2019	Resistance to penetration
EN ISO 374-4:2019	Resistance to degradation by chemicals
EN ISO 374-5:2016	Resistance to penetration by blood borne tested
EN 16523-1:2015+A1:2018	Determination of resistance to permeation by chemicals
ISO 16604:2004	Resistance of clothing materials to penetration by blood-borne pathogens
EN 61331-3:2014	Protective devices against diagnostic medical X-radiation. Protective clothing, eyewear and protective patient shields

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EU Type Examination Certificate

No. CE 724079

Product Specification (Continued)

Model – Radiaxon Polyisoprene Powder Free Radiation Attenuating Surgical Gloves, Sterile

Performance

General requirements for gloves to EN ISO 21420:2020.

Characteristic	**Level**
Dexterity:	4

Resistance to penetration to EN ISO 374-2:2019.

Resistance to Water Leak	Pass

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018/Type B
(Test method EN 16523-1:2015+A1:2018)
Resistance to Degradation to chemical protection EN ISO 374-4:2019

Chemical	**Permeation Level**	**Mean Degradation**
		%
40% Sodium hydroxide(K)	6	-32.5
30% Hydrogen peroxide (P)	5	-33.0
37% Formaldehyde (T)	6	-25.6

Resistance to penetration by blood-borne tested to EN ISO 374-5:2016

Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Protective gloves against radioactive contamination to EN 421:2010

kV	**Attenuation % Mean**	**LEV mm Pb Mean**
60	63.02	0.034
80	53.67	0.035
100	48.53	0.035
120	43.11	0.036
150	-	0.036

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EU Type Examination Certificate

No. CE 724079

Product Specification (Continued)

Model – Radiaxon Polyisoprene Sensitive Powder Free Radiation Attenuating Surgical Gloves, Sterile

Performance

General requirements for gloves to EN ISO 21420:2020.

Characteristic	**Level**
Dexterity:	5

Resistance to penetration to EN ISO 374-2:2019.

Resistance to Air & Water Leak	Pass

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018/Type B
(Test method EN 16523-1:2015+A1:2018)
Resistance to Degradation to chemical protection EN ISO 374-4:2019

Chemical	**Permeation Level**	**Mean Degradation**
		%
40% Sodium hydroxide(K)	6	-36.5
30% Hydrogen peroxide (P)	5	-36.5
37% Formaldehyde (T)	6	-3.1

Resistance to penetration by blood-borne tested to EN ISO 374-5:2016

Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Protective gloves against radioactive contamination to EN 421:2010

kV	**Attenuation % Mean**	**LEV mm Pb Mean**
60	68.04	0.039
80	58.00	0.039
100	52.03	0.040
120	47.07	0.040
150	39.55	0.041

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EU Type Examination Certificate

No. CE 724079

Certificate Administration Details

Technical File Reference: TF/PPE/009 – PI RPG

Certificate Amendment Record

Issue date	Comments	BSI Internal report No.
December 2020	First issue.	2797:20:3145132

Note: The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), for the product are referenced in BSI issued Certificate number CE 688305

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