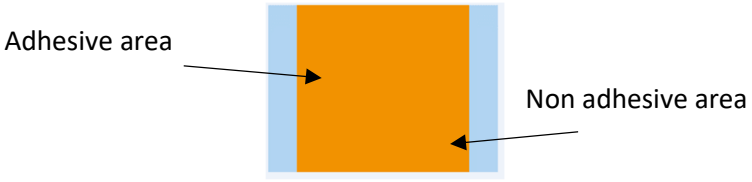
tiaset

TECHNICAL AND SAFETY DATA FOR

DERMADINE PLUS ®

Classe III

BRAND NAME	**DERMADINE PLUS ®**
DESCRIPTION	Sterile single use adhesive surgical drape for incisions with iodized antiseptic
TECHNICAL CHARACTERISTICS	Dermadine Plus ® is a very thin polyurethane plastic resin adhesive drape with a hypoallergenic acrylic adhesive. It is a certified medical grade device using an iodine complex solution with antimicrobial properties that do not interfere with the wound. Dermadine Plus ® is highly elastic and resistant with an optimal mechanical memory that makes it ideal for use in operating theatres for circumscribing areas to be operated on in a range of surgical specializations. The drapes are available in several sizes and shapes and are completely impermeable to liquids and microorganisms, while allowing the skin to breathe thanks to the molecular structure of polyurethane. Dermadine Plus ® is coated on one side with a hypoallergenic acrylic adhesive. It is easily detachable from the protective silicon paper and adheres closely to the skin. Each drape is individually wrapped. The drapes can be supplied with or without secondary packaging.
INDICATIONS FOR CLINICAL USE	Dermadine Plus ® surgical drapes are indicated for use in the preparation and delimitation of the operating area providing a mechanical barrier which protects the skin from microorganisms before incision. Thanks to the antiseptic properties of iodine, as well as acting as a barrier during surgery, Dermadine Plus ® also disinfects the skin. Dermadine Plus ® is suitable for use in all types of surgery including interventional diagnostics and robotic surgery. Dermadine Plus ®® can also be applied to specialist single-use drapes.
AREAS OF USE	Dermadine Plus ® is suitable for use in a range of surgical procedures: It maintains an aseptic barrier covering the area of incision. It safeguards skin prepared for incision from bacterial contamination. It can cover wounds with drainage to optimize the drainage process. Covering of the incision area to prevent bacterial migration and fix in place specialist single-use drapes.
DESIGN	
REF AND DIMENSIONS	

REF	SIZE	TOTAL AREA	ADHESIVE AREA
42020P	**XS**	200X200 MM	1500X200 MM
43525P	**S**	350X250 MM	300X250 MM
44040P	**M**	400X400 MM	350X400 MM
47045P	**L**	700X450 MM	600X450 MM
47060P	**L1**	700X600 MM	600X600 MM
47080P	**XL1**	700X800 MM	700X800 MM
48060P	**XL**	800X600 MM	600X600 MM
48080P	**XXL**	800X800 MM	700X800 MM

CERTIFICATION	Dermadine Plus ® is produced according to production standards ISO 9001 and ISO 13485. The product is certified by Notified Body 0373, with the CE Mark CE 0373
CLASSIFICATION	Dermadine Plus ® is classified according to Directive 93/42 CEE, Rule 13 of attachment IX Directive 93/42/CEE and successive modifications and integrations as a Medical Grade Device Class III as approved by the Autorità Competente del Farmaco Italiana (AIFA). Dermadine Plus ® is produced in conformity with the Essential Requirements specified in Attachment I and according to the criteria outlined in Attachment V Directive 93/42/CEE and successive modifications and integrations.
CND CODE	**T02010102**
RDM CODE	**1977958**

SPECIFICATIONS AND CHARACTERISTICS OF MATERIALS	
ACTIVE SUBSTANCE	Iodine complex solution (I_3^-). Iodine is categorized as an antiseptic and disinfectant, code ATC: D08AG03.
MECHANISM OF ACTION	The formation of the polyhalogen polialogen complex, triiodide ion (I_3^-), is due to the presence of species of iodine and iodide that when in equilibrium with one another bond with the polymerized lattice of the acrylic adhesive, conferring antiseptic and antimicrobial properties on the medical device. The alternating equilibrium between these two species, favoured by the weak acidity of the skin, liberates molecules of iodine which interact with the cellular structures of microorganisms present on the skin, deactivating them and reducing the bacterial load. In its free form, iodine acts as an oxidizing and agent which makes it a powerful bacteride and antiseptic. Free molecules bond with the cytoplasmic protein structures of microorganisms, inhibiting the synthesis of proteins and causing cell death.
ANTIBACTERIAL PROPERTIES	In tests Dermadine Plus ® acted as a bacteriostatic agent against all strains tested, hindering bacterial growth by up to 99,99%. Among the strains tested were: Pseudomonas Aeruginosa ATCC15442 Staphylococcus Aureus ATCC6538
BIOCOMPATIBLE	Dermadine Plus ® has passed the biocompatibility tests for this type of product according to International Standards UNI EN ISO 10993-5:2009 and UNI EN ISO 10993-10:2013
PRODUCTION	Production conforms to standards ISO9001 and ISO 13485 with approval of systems for quality guarantee, production quality guarantee and sterilisation according to attachment V and attachment III dir. 93/42 CEE. Production environment and contamination control is class ISO 7 for the transformation and packaging of Sterile Barrier Systems.
PRODUCTION MATERIALS	Polyurethane plastic resin 20±5% microns. Hypoallergenic acrylic adhesive for medical use 30 gr per m^2 tolerance +/- 10%. One side coated or laminated silicon paper or coextruded plastic films, g/m^2 between 90 and 120
TECHNICAL DATA POLYURETHANE FILM	<table><tr><td>Tipo</td><td>caratteristiche</td><td>UM</td><td>Method</td><td>Value</td></tr><tr><td>Fisica</td><td>Densità</td><td>Gr/cc</td><td>ASTM 1238</td><td>1.2</td></tr><tr><td>Colore</td><td>Trasparenza</td><td></td><td></td><td></td></tr><tr><td>Termica</td><td>Intervallo di fusione</td><td>°C</td><td>ISO 11357</td><td>148-152</td></tr><tr><td>Meccanica</td><td>Spessore</td><td>Micron</td><td></td><td>22±1</td></tr><tr><td></td><td>Allungamento: DM/DT</td><td>%</td><td>ISO 527</td><td>>450</td></tr><tr><td></td><td>Resistenza alla rottura DM/DT</td><td>MPa</td><td>ISO 527</td><td>>30</td></tr><tr><td></td><td>Traspirazione del vapore</td><td>g/m^2/24h</td><td>ASTM E 96-53</td><td>670±50</td></tr></table>
CHARACTERISTICS OF POLYURETHANE FILM	Biocompatible film. Water and blood repellent. Completely impermeable to liquids. Uniform antireflection colouring. Product remains stable over time. Breathable. Odourless. Antistatic. Drapable. No peeling Free from: Natural latex, Polyvinyl chloride and Phthalates. Adapts to body contours.
CHARACTERISTICS OF ADHESIVE	Medical grade hypoallergenic acrylic adhesive. Biocompatible 30 gr / m^2 +/- 10% (suitable for industrial coating). Approved by the American Food and Drug Administration 21 CFR 175,105 for use on skin. Optimal cutaneous peel adhesion. Atraumatic removal from skin. Does not leave residues after removal. Technical balance between adhesion and cohesion. Free from natural latex Free from Thiuram-mix Uniform coating
ADHESIVE PROTECTION	The adhesive is protected by a silicon paper of circa gr / m^2 90-120 +/- 5% coated on one side or laminated or medical use polyester. The paper can be printed on with a water-based ink for food or pharmaceutical use.

QUALITY CONTROL

QUALITY CONTROL

Sample size determined according to Mil. Std 105E: simple-level Grade II-Severity grade ordinary. AQL from 0,10 to 4 according to the level of defect.
For incoming supplies:
Visual control (n. packages, state of packaging, quantity)
During production:
Visual controls (presence of waste, marks, irregular dimensions, colour).
Integrity and functionality (presence of cuts, folds, dimensions).
Physical (gr/m^2, adhesion, thickness).
Correct folding.
Packaged product:
Correct folding of product inside SBS
Control of seal of packaging if present
Correct application of label with control of data (Lot, Ref, Production, Expiry date).
Control of items inside transportation packages.

LABELLING

PRIMARY PACKAGING

SECONDARY PACKAGING

PACKAGING FOR SALES

Each single pack has a label displaying all the information necessary to identify the product (REF, Lot, Production, Expiry Date, Type of Sterilization, Content, Size).

The label conforms to Dir. 93/42 CEE attachment VII. The ink is free from heavy metals. There are two detachable labels with information specific to the product including a bar code, for example GS1-128. This system of double labeling allows each drape to be tracked to the patient on which it is used and referenced to clinical notes and recording information from the operating register.

On the sales packaging there is an identical label, also indicating the number of pieces, without the detachable labels. Inside the sales packaging is a sheet with instructions for use (IFU).
On the transportation packaging there is an identical label. The quantity of the product is also indicated.
An indicator above the label shows whether the product has been sterilized. If it is yellow, the product has not been sterilized. If it is red the product has been sterilized.

PACKAGING

Before being placed in the SBS, the drape is folded and wrapped in a sheet of paper on which instructions for opening and positioning the product on the patient are printed with water-based ink. This packaging is necessary to allow the user to extract the product correctly without contamination from the Sterile Barrier System.

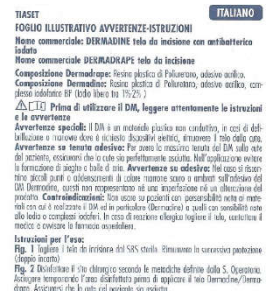
Single Pack:
The drape is inside a Sterile Barrier System (SBS) LATEX FREE, in conformity with l'ISO 11607 /2006 part 1 / 2.
The SBS has a peel-open (Chevron), double fastening. The materials used are PET/ALLUMINIUM/PE peel open suitable for vacuum packing and other packaging types. It is completely impermeable to liquids or microorganisms. To be sterilized by irradiation.

Ink printing present in the SBS is between the plastic films to prevent IT contaminating the user.

Multi packs:
Dermadrape Plus ® is available in packs of 10/15/20/ XX pieces depending on the size. The transportation box can contain several multi-packs. It is sealed with tape and contains a descriptive label. If the indicator is red, the box has been sterilized by irradiation.

REF	Descrizione prodotto	Conf. SBS pz	Dispenser pz	Dispenser Nr	Cartone pz
42020P	Dermadine Plus ®	1	20	6	120
43525P	Dermadine Plus ®	1	20	6	120
44040P	Dermadine Plus ®	1	15	6	90
47045P	Dermadine Plus ®	1	15	6	90
47060P	Dermadine Plus ®	1	10	6	60
47080P	Dermadine Plus ®	1	10	6	60
48060P	Dermadine Plus ®	1	10	6	60
48080P	Dermadine Plus ®	1	10	6	60

STERILIZATION STERILE R	To be sterilized by irradiation. The sterilization process is validated by ISO 11173 parts 1 and 2. The product must not be sterilized by EtO as a chemical reaction could occur between the sterilizing agent and the iodine that could result in the formation of substances, such as ethylene iodide, which may have side effects.
EXPIRY DATE	The medical device is valid for 2 years from the date of sterilization.
ADDITIONAL SAFETY INFORMATION	
TRANSPORT AND STORAGE	Dermadine Plus ® drapes are transported and stored in ways that will not alter the properties of the product or damage the packaging. The cardboard packaging does not deteriorate over time and can withstand reasonable jolts and normal environmental conditions of humidity and temperature. Dermadine Plus ® should be kept at room temperature, in a dry place away from direct sunlight. Transport is by box truck to protect the products from the elements. Shipping companies are certified ISO 9001. Boxes are positioned in euro pallets cm 80x120 or 100x120 or loose.
DISPOSAL	The products are not dangerous but are nonetheless used in operating theatres. After use they can be incinerated by controlled thermo combustion according to relevant laws and hospital procedures. The product does not generate toxic or harmful gases or residues during combustion.
DISPOSAL OF PACKAGING	The packaging protects the medical device from damage that could occur during transport. Packaging materials are selected to be ecological and recyclable. Recycling allows for a reduction in the use of primary materials and reduces waste. Dispose of packaging according to local laws and regulations.
CONDITIONS OF USE	
	Single use product. The product is intended for single use, on one patient. DO NOT REUSE OR RE-STERILIZE.
LATEX	The medical device does not contain natural latex.
PHT	The medical device not contain phthalates
	The medical device does not contain Thiuram-mix in the adhesive
PRECAUTIONS AND WARNINGS	Single use. The product is sterile only if the packaging is intact. Open the packaging so as not to contaminate the drape. Use the medical device immediately after opening. Discard without using if the packaging is damaged or the seal is not intact. The product is intended exclusively for external use and MUST BE USED ONLY BY MEDICAL PROFESSIONALS. The user is responsible for the correct use of the product.
SPECIAL WARNINGS	As the drape is made from a non-conductive plastic material, it must be removed before defibrillation or other interventions using electrical devices.
CONTRAINDICATIONS	Do not use on patients with allergies to the materials present in the medical device. In the event of an allergic reaction, seek medical advice and advise the clinic's or hospital's pharmacy.
WARNING	Before using the medical device make sure that the indicator on the box or packaging is RED. If the indicator is YELLOW, the device has not been sterilized and MUST NOT BE USED. Contact Tiaset or our local agent if the indicator is yellow. STERILE. SAFE TO USE NON-STERILE. DO NOT USE

CLASS OR REACTION WITH FIRE Incendio 	The product cannot be classified into any of the classes outlined by DM 339/83 and 234/84. From an analysis of risks relating to the product (technical dossier) the product does not present a fire hazard. Resistance of the material to sources of heat (ignition) is limited by the melting point of the material (<148 °C-152 °C >). In the event that the material ignites, use appropriate methods of extinction.
IFU  TIASET ITALIANO FOGLIO ILLUSTRATIVO AVVERTENZE-ISTRUZIONI Nome commerciale: DERMADINE tela da incisione con antibatterico legato Nome commerciale DERMADRAPE tela da incisione Composizione Dermadrape: Resina plastica di Poliuretano, adesivo acrilico. Composizione Dermadine: Resina plastica di Poliuretano, adesivo acrilico, complesso iodofarico RF (iodio libero tra 1%-2%). Prima di utilizzare il DM, leggere attentamente le istruzioni e le avvertenze Avvertenze speciali: il DM è un materiale plastico non conduttivo, in caso di defibrillazione o riscrivere dove è richiesto dispositivi elettrici, rimuovere il telo dalla cute. Avvertenze su tenuta adesiva: Per avere la massima tenuta del DM sulla cute del paziente, assicurarsi che la cute sia perfettamente asciutta. Nell'applicazione evitare la formazione di pieghe o bolle di aria. Avvertenze su adesivo: Nel caso si riscontrino piccoli punti o addensamenti di colore marrone scuro o ambrati sull'adesivo del DM Dermadine, questi non compromettono né una imperfezione né un alterazione del prodotto. Controindicazioni: Non usare su pazienti con pregressibilità nota ai materiali con cui è realizzato il DM ed in particolare (Dermadine) a quelli con sensibilità note allo iodio o composti iodoferi. In caso di reazione allergica togliere il telo, contattare il medico e ovviare la farmacia ospedaliera. Istruzioni per l'uso: Fig. 1 Togliere il telo da incisione dal SBS sterile. Rimuovere la corrosiva protezione (lembo scuro) Fig. 2 Disinfettare il Sito chirurgico secondo le metodiche definite dalla S. Operativa. Asciugare temporaneo l'area disinfettata prima di applicare il telo Dermadine/Dermadrape. Assicurarsi che le aree del materiale non aderite	Inside each pack is an instructions sheet in various languages for the correct use of the product, its characteristics, precautions and warnings. READ THE MANUFACTURER'S INSTRUCTIONS BEFORE USE
INSTRUCTIONS FOR USE 	**Step 1** Remove the Dermadine Plus ® from its Sterile Barrier System without contaminating it and discard the outer protective wrapping. **Step 2** Disinfect the area for incision according to the protocol of the operating theatre. Dry the area before applying the drape. It is important that the skin is completely dry for the drape to stick. **Step 3** Hold the non-adhesive edge of the drape and unroll it. Holding the edge on both sides, remove the inner protective pulling from the centre, slowly and maintaining a 90° angle with the film. Avoid using abrupt movements or pulling horizontally. **Step 4** Hold the drape taught a few cm from the skin and apply to suit the needs of the surgeon. **Step 5** Using sterile gauze, smooth out the drape over the area of incision, taking care not to stretch it excessively and moving from the centre outwards. Take care to avoid the formation of air bubbles. **Step 6** Remove the drape by delicately detaching it, pulling it at an angle of 180° with the skin, folding it back on itself. Hold the drape near the skin to avoid excess tension **Note**: Dermadine Plus ® is folded in such a way that it can be opened, applied and removed by one person, or by two.
IMPORTANT WARNING ABOUT THE ADHESIVE	As the adhesive property of Dermadine Plus ® is adversely affected by water, the patient's skin must be completely dried after it has been disinfected and before the drape is placed in position. Be careful that folds or air bubbles do not form when the drape is applied.
WARNING ABOUT THE DRAPE'S COLOUR	It is possible that small spots of a brown or amber colour will form on the adhesive of the drape. These are due to the aggregation of iodine molecules on the acrylic adhesive. They in no way compromise the correct functioning of the device and do not represent a defect.
ADVERSE REACTIONS TO ACTIVE SUBSTANCE	Side effects of iodine: do not use Dermadine Plus ® on patients with a known allergy to iodine or to iodophor complexes. The interaction of iodine and acetone can result in the formation of compounds that may irritate the skin. Dermadine Plus ® is biocompatible but adverse reactions may nevertheless occur, including burning, iododerma, acneiform eruptions, slower tissue healing and irritation of the mucous membranes. If an allergic reaction occurs, remove the drape, contact a doctor and advise the hospital pharmacy.
	READ THE PRODUCT INFORMATION BEFORE USE
PHOTOSENSIBILITY	None. The primary packaging of the product protects it with an aluminumized film from natural and artificial light

CONTAMINATION 	None
CHEMICAL – PHYSICAL IMCOMPATIBILTY 	Not verifiable
SAFETY NOTE 	With reference to D.Lgs 626/94, products awarded the CE mark according to directive 93/42 CEE (D. Lgs 46/97) are safe for the uses as specified by the manufacturer. The medical device does not contain dangerous substances other than those listed under precautions and warnings, special warnings and contraindications.
PRODUCER'S CONTACT DETAILS	
MANUFACTURER'S CODE	**13865**
INTERNAZIONAL ELECTRONIC PEPPOL CODE	**9906:IT01999370511**
PRODUCER	**TIASET, CARRESI LORENZO**
SITE OF PRODUCTION	**VIA BOTRIOLO71, 52026 CASTELFRANCO PIANDISCÒ (AREZZO)**
INFORMATION AND CONTACTS 	**ADDRESS: VIA BOTRIOLO71, 52026 CASTELFRANCO PIANDISCÒ (AREZZO)** **TELEPHONE: 055 9149122** **FAX: 055 0691080** **MOBILE: 328 4634811-3345301493** **EMAIL: INFO@TIASET.COM** **EMAIL: TIASET.CARRESI@GMAIL.COM** **EMAIL PEC: TIASET@LEGALMAIL.IT** **WEBSITE : WWW.TIASET.COM**
FISCAL CODES 	**P.IVA 01999370511** **CF CRRLNZ84B20F656W** **REA 154836** **AA 54010**

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