

Product Data Sheet

Drapes and sets

Hand/foot set

REF 1232-01



Page 1 (2)

Version: 02.07.2012, rev. 2

Last modified: 5.7.2012

<p>CE0434 The product complies with legal requirements for medical devices EO sterilized according to valid version of ISO 11135 standard [NATURAL LATEX FREE]</p>	<p>78 x 145 cm 150 x 190 cm</p> <p>230 x 300 cm</p>
<p>Contents</p>	<p>Raw material</p>
<p>1 Mayo stand cover 78 x 145 cm, reinforced</p>	<p>PP nonwoven, plastic laminate/polyethylene film laminate, blue</p>
<p>1 hand/foot drape 230 x 300 cm, elasticated aperture 3,5 cm, absorbent patch 50 x 100 cm, tube holders</p>	<p>PP nonwoven/polyethylene film laminate, blue/PP nonwoven, white, blue absorbent patch PP nonwoven, elastic material styrene/butadiene/styrene</p>
<p>1 instrument table cover 150 x 190 cm</p>	<p>PP nonwoven/polyethylene film laminate, blue</p>
<p>Features:</p>	<p>As a sterile draping set for hand/foot operations.</p>
<p>Shelf life:</p>	<p>5 years</p>
<p>Pack count, carton weight:</p>	<p>1 pc/bag, 6 pcs/dispenser box, 12 pcs (2 x 6) transport carton</p>
<p>Sales unit:</p>	<p>Transport carton (2 dispensers of 6 pcs)</p>
<p>Unit pack:</p>	<p>White Tyvek/plastic pouch polyethylene/polyester film</p>
<p>Dispenser box</p>	<p>Carton, totally chlorine free, size 285x287x485 mm</p>
<p>Transport carton:</p>	<p>Carton, totally chlorine free, size 300x590x500 mm</p>
<p>Packing tape:</p>	<p>Transparent, PVC-free</p>
<p>Compliance with legal requirements:</p>	<p>Medical Devices Directive 93/42/EEC, Class 1</p>
<p>Compliance with product standards:</p>	<p>EN13795</p>
<p>Quality standards:</p>	<p>The product is manufactured in compliance with ISO9001, ISO13485</p>
<p>Label information:</p>	<p>In accordance with EN980 and EN1041</p>
<p>Storage recommendation:</p>	<p>Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone</p>
<p>Disposal recommendation</p>	<p>Energy recovery or mixed waste</p>
<p>Risk if reused:</p>	<p>The product is single use. If reused performance of product may deteriorate, cross contamination may occur</p>

<p>Barcodes: Unit pack</p>	<p>Dispenser</p>	<p>Transport carton</p>
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Page 2 (2)

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<p>6438129110173 1232 single</p>  <p>6 438129 110173</p>	<p>6438129310177 1232 dispenser</p>  <p>6 438129 310177</p>	<p>6438129510171 1232 carton</p>  <p>6 438129 510171</p>
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ONEMED

 evercare[®]

Produktų katalogas

Chirurginiai apklotai & rinkiniai

2017



Surgical Drapes & Sets

Infection Control

evercare® drapes are designed for patient safety to provide an impermeable barrier against microbial penetration.

evercare® drapes provide effective fluid control across the entire surface and have highly absorbent reinforcements placed where most needed.

The drape material has been developed to ensure minimal particle release (low linting).

User Friendliness

evercare® drapes are easy to unfold and conform to the patient's body contours.

The low reflection of the drape material will not disturb the operating theatre personnel in what is otherwise a stressful environment (the blue/grey color is easy on the eyes).

The soft inner lining of evercare® drapes provides patient comfort and also prevents slipping.

The specially designed adhesive edges are easy to open up even if they adhere to each other due to a draping failure. With evercare® adhesive edges there is no chance that gloves will get stuck to the adhesive.

The adhesives used are known for their skin friendliness: there will be no damage to the skin when the drapes are removed from the patient post-surgery.

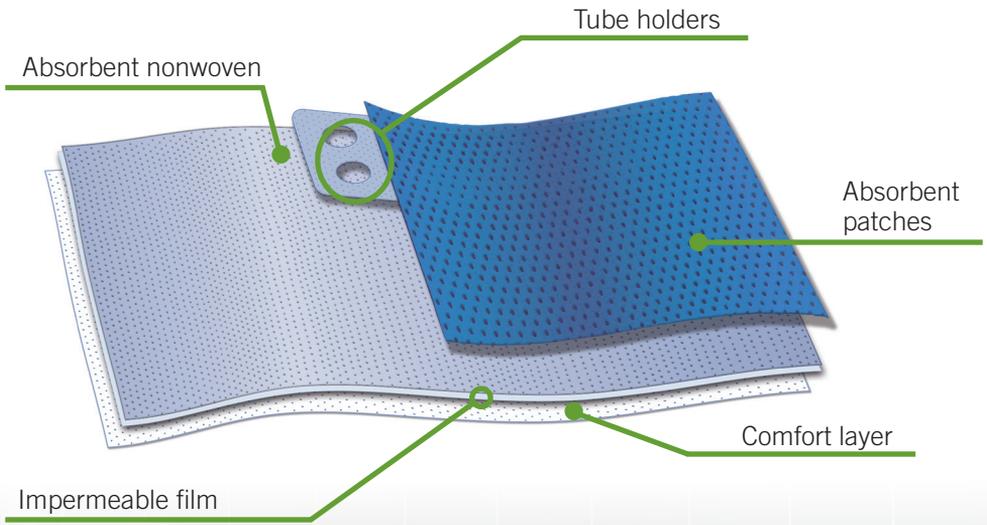
Cost Effectiveness

The development of evercare® drapes was driven by innovation.

The material is based on the latest polymer technology and is very cost effective.

Designs contain many unique features that help to reduce the set-up time and also provide extra support during surgery.

Material Chart



Complies to EN 13795.

- | | | | |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------|
|  | Absorbent and impermeable multilayer material |  | Polyethylene film |
|  | Absorbent and impermeable 2-layer material |  | Elastic material |
|  | Absorbent and impermeable reinforcement material (absorbent patch) |  | Adhesive edge |

Label information in accordance with EN ISO 15223-1 and EN 1041

evercare® is a registered trademark of OneMed Group Oy

Article number

Contents & Size

Barcode

UNDER BUTTOCK DRAPE

REF 1741-01

ONEMED

OneMed Group Oy
Metsäläntie 20, FI-00320 Helsinki, Finland

STERILE EO

2460

[NATURAL LATEX FREE]

Legal manufacturer's contact information

Symbols in use

	Sterilization method: – ethylene oxide EO
	Use before
	Batch number
	CE mark: certifies that the product complies with the European legal requirements for medical devices
2460	Identification number of the notified body

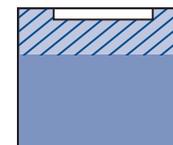
	Single use
	Does not contain natural rubber latex
	Keep away from sunlight
	Recommended storage temperature
	Keep dry

210x120 mm

Antrinio įpakavimo (dėžutės) lipdukas



REF 1465-02
SIZE 180 x 180 cm
PCS 8



180 x 180 cm

LOT



DE Abdecktuch selbstklebend
 FR Champ opératoire adhésif
 SE Operationslakan, självhäftande
 FI Liimareunainen leikkauslakana
 DA Operationslagen
 NO Operasjonslaken
 EE Kleepribaga lina
 LV Pašlīpošs pārklājs
 LT Apklotas su lipnių kraštu, vidutinis
 PL Serweta przyklejana średnia
 RU Простыня адгезивная
 SK Růško dvojvrstvé samolepiace
 CZ Rouška dvouvrstvá samolepící
 PT Campo operatório auto-adesivo
 ES Campo quirúrgico adhesivo

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ADHESIVE DRAPE
Medium

REF 1465-02

ADHESIVE DRAPE Medium

ONEMED



OneMed Group Oy
Metsäläntie 20, FI-00320 Helsinki, Finland

DECLARATION OF CONFORMITY

replaces version dated: 12.06.2017

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

declare under our sole responsibility that following products, all belonging to class I (sterile) according to Annex IX of the Directive 93/42/EEC for medical devices,

Name, type or model:

1001	Universal set
1003	Essentia Universal set
1005-02	Universal set w. Mayo stand cover
1006-01	Universal set w. Mayo stand cover
1007	Universal set
1010-02	Universal set w. Mayo stand cover
1011-02	Universal set w. Mayo stand cover, abs. patch 25x60 cm
1014-02	Universal set w. Mayo stand cover and fluid collection pouch
1015-02	Universal set without Mayo stand cover
1030-02	Paediatric universal set
1050-02, 1050-50	Split sheet set
1051-02	Split sheet set
1205-01	Hip set
1210-02	Hip set Standard
1215-02	Hip set Large
1220-02	Hip set Special
1225-02	Vertical drape set, small
1226-02	Vertical drape set, large
1230-02	Extremity set
1231-02, 1231-100	Extremity set
1232-02, 1232-50	Hand/foot set
1233-02	Extremity set
1234-01	Extremity set bilateral
1235-02, 1235-50	Knee arthroscopy set
1236	Shoulder split sheet set with pouch
1246	Aorta set
1248-50	Abdominal-perineal set
1250-01, 1250-50	Gynae/Cyst set
1251-02	Gynaecology set
1252	Gynaecology and urology set
1253-01	Gynaecology set
1255-01	Delivery set
1260-02	C-section set, incision film with hole
1261-02	C-section set, incision film
1262	C-section set, incision film
1267-02	Laparoscopy set
1288-01	Dental set
1290-02	Dental set
1291-02	Head/neck drape
1292	Craniotomy set

1307	Adhesive split sheet 120x180 cm, split 15x50 cm, transparent
1308	Adhesive split sheet 150x183 cm, split 7x70 cm
1309	Adhesive split sheet, bilateral 230x290 cm, splits 6x90 cm
1310-02	Adhesive split sheet 150x250 cm, split 7x70 cm
1315-01	Adhesive split sheet 230x260 cm, split 20x100 cm
1316-01	Adhesive split sheet 230x260 cm, split 20x100 cm
1317-01	Lower vascular drape, 230x260 cm, split 20x100 cm, integrated genital cover
1318-01	Adhesive split sheet 200x260 cm, split 7x100 cm
1319	Beach chair shoulder drape 400 x 230 cm, with pouch
1320-01	Hand/foot drape 150x180 cm, aperture 3,5 cm
1324-02	Hand/foot drape 230x300 cm, aperture 3,5 cm
1325-01	Extremity drape 230x300 cm, aperture 7 cm
1328	Knee arthroscopy drape 230x320 cm
1330-02	Vertical drape, small
1332-02	Vertical drape, large
1355	Gyn-abdominal drape 220/240x335 cm
1356-01	Perineal drape
1365-01	Laparoscopy drape 230x300 cm, aperture 25x20 cm, triangle
1366-01	Laparoscopy drape 230x300 cm, aperture 20x31 cm
1375-01	Thoracic drape 200/300x330 cm, aperture 32x40 cm
1398-01	Arm cover
1408	Utility drape 45x75 cm
1410-01	Utility drape 50x60 cm
1415-01	Utility drape 75x90 cm
1418	Universal cover drape 150x240 cm, extra reinforced
1451-01	Adhesive drape sheet 45x75 cm
1452-01	Adhesive drape sheet 50x50 cm
1453-01	Adhesive drape sheet 100x100 cm
1454-01	Adhesive drape sheet 75x100 cm
1455-01	Adhesive drape sheet 50x60 cm
1456-01	Adhesive drape sheet 37x45 cm
1460-02	Adhesive drape sheet 75x90 cm
1461-01	Adhesive drape sheet 75x75 cm
1463-02	Absorbent drape 60x70 cm
1463-50	Paediatric adhesive absorbent drape 70x60 cm
1464	Adhesive drape Large 254x180cm
1465-02	Adhesive drape Medium 180x180 cm
1466	Adhesive drape 150x170 cm
1470-02	Adhesive drape Large 150x240 cm
1505-01	Adhesive aperture drape 50x60 cm, aperture 6x8 cm
1510-01	Epidural drape 75x80 cm, aperture 6x15 cm
1511	Paediatric adhesive aperture drapes variable 37x65 cm
1512-01	Adhesive aperture drapes variable 50x75 cm
1513-01	Adhesive aperture drapes variable 75x100 cm
1515-01	Adhesive aperture drape 75x90 cm, aperture 6x8 cm
1516	Adhesive aperture drape, transparent 80x130 cm, aperture 15x6 cm
1517	Adhesive aperture drape 100x125 cm, aperture 11 cm
1520-01	Adhesive aperture drape 120x150 cm, aperture 5x7 cm
1525-01	Adhesive aperture drape 120x150 cm, aperture 5x7 cm
1530-01	Adhesive aperture drape 150x180 cm, aperture 6x15 cm
1535-02	Adhesive aperture drape 230x250 cm, aperture 12 cm
1537-01	Adhesive aperture drape 200 x 280 cm, aperture 14x14 cm
1538-01	Adhesive aperture drape 200 x 240 cm, aperture 12 cm

1539-01	Adhesive aperture drape 200 x 280 cm, aperture 15 cm
1555-01	Aperture drape, 50x60 cm, aperture 6x8 cm
1565-01	Aperture drape, 75x90 cm, aperture 6x8 cm
1741-01	Under buttock drape 75x100 cm

to which this declaration relates, are in conformity with the following harmonized standards or other normative documents

EN 13795:2011 + A1:2013	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels
EN ISO 13485:2012	Medical Devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
EN 556-1:2001	Sterilization of medical devices – Requirements for medical devices to be designated "Sterile" – Part 1: Requirements for terminally sterilized medical devices
EN ISO 11135:2014	Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2009 + A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006 + A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

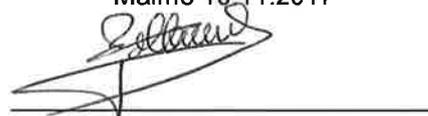
and with the provisions of the laws of Finland and with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of 5 September 2007.

Identification of Notified Body (MDD): DNV GL Nemko Presafe AS, 2460.

Place and date of issue

Malmö 10.11.2017

Name and signature of the authorized person



Julien Rolland
Sourcing Director