294502 Mepilex Transfer

Soft silicone exudate transfer dressing

Product details

Size : 20cm x 50cm
Descriptive feature : Exudate transfer, Foam, Non-border, Soft silicone
Sterile : Sterile

Images

Delivered items

294502-03

Sales released in: Algeria, Australia, Austria, Bahrain, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Canada, China, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Iran (Islamic Republic of), Ireland, Israel, Italy, Japan, Kazakhstan, Kuwait, Latvia, Lithuania, Luxembourg, Macedonia (the former Yugoslav Republic of), Malaysia, Moldova (the Republic of), Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan (Province of China), Thailand, Turkey, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland
Country of origin: Finland
Shelf life: 3 years
Sterilization method: EtO
Packing information: First packaging layer is a peel-open sterile barrier, plastic/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a cardboard dispenser box. Third layer is a corrugated board transport box.
Is suitable for Tray: No

Packing level	Quantity	GS1 code	WxLxH (mm)	Vol (dm3)	Weight gross/net (kg)
Consumer pack	1	7332430003775			

Find out more at www.molnlycke.com

Mepilex® Transfer

INDICATIONS FOR USE:
- Venous leg ulcers, especially under compression to maximize efficacy on anti-bacterial dressings or protect peri-wound area
- Difficult to dress wounds including metastatic lesions
- Heavily exudating wounds
- Large wounds
- Wounds on difficult to manage areas including those associated with fragile skin

NOTE: Should be used in combination with an absorbent cover dressing. Can be used under compression.

DIRECTIONS FOR USE:
1. Cleanse the wound area and dry the surrounding skin.
2. Apply one side of dressing allowing Mepilex® Transfer to overlap the surrounding skin by at least 5 cm.
4. Remove half of the release film and apply one side of dressing; remove remaining release film and smooth in place. Do not stretch.
5. Apply an appropriate cover dressing according to wound exudate level and fixate in place.

NOTE: Mepilex® Transfer can remain in place for up to 7 days as indicated by wound condition. The absorbent cover dressing may be changed more frequently if required. Mepilex® Transfer can be cut to size if required.

PRECAUTIONS:
- Mepilex® Transfer should not be used with oxidizing agents such as hypochlorite solutions or hydrogen peroxide.
- Mepilex® Transfer should be stored in dry conditions below 35°C (95°F) and be protected from direct sunlight.
- In case of signs of clinical infection, consult a health care professional for adequate infection treatment
- Do not use if inner package is damaged. Sterility is guaranteed if inner package is intact. Do not resterilize.

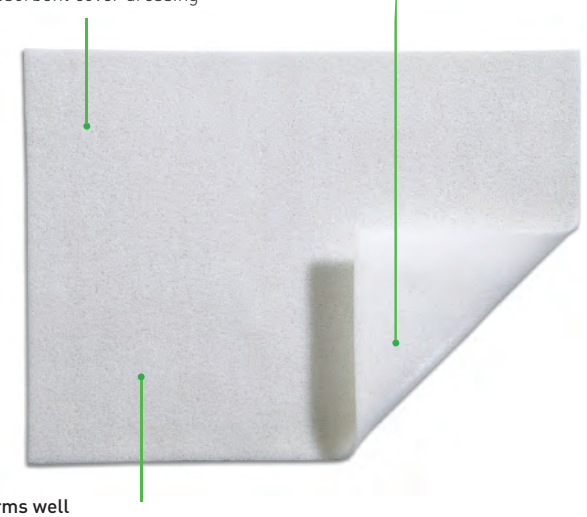
MEPILEX® TRANSFER ASSORTMENT

Art. no	Size cm	Pcs/box	Pcs/case
294600	7.5 x 8.5	5	70
294700	10 x 12	5	50
294800	15 x 20	5	40
294502	20 x 50	4	24

Mepilex® Transfer is packaged sterile in single packs.

Ultra thin foam 'exudate transfer' dressing
- Protects the wound bed while transferring exudate vertically, away from the wound and into an absorbent cover dressing

Safetac® layer
- Non-adherent to moist wound bed
- Ensures removal with minimal trauma and pain
- Prevents maceration



Conforms well
- Conforms well even on difficult-to-dress wounds
- Suitable for large, fragile wounds and difficult to dress areas

Safetac® TECHNOLOGY

EXUDATE TRANSFER DRESSING WITH SAFETAC® TECHNOLOGY

SUPPORTS MOISTURE BALANCE
- Transfers exudate away from the wound bed
- Prevents lateral wicking
- Maintains a optimal moisture balance when used with appropriate cover dressing

THIN AND HIGHLY CONFORMABLE
- Conforms well to body contours
- Facilitates management of difficult to dress wounds

GENTLE ADHESION
- Adheres gently to intact skin
- Does not adhere to moist wound surfaces

MINIMIZES TRAUMA AND PAIN
- Atraumatic to the wound and surrounding skin
- Seals around the wound margins to reduce the risk of maceration
- Does not damage peri-wound area or newly formed granulation tissue

284322 Mepilex EM

Absorbent soft silicone dressing

Product details

Size : 17.5cm x 17.5cm
Descriptive feature : Foam, Non-border, Soft silicone, Thin
Sterile : Sterile

Images

Delivered items

284322-01

Sales released in: Bosnia and Herzegovina, Bulgaria, Croatia, France, Greece, Hungary, Israel, Macedonia (the former Yugoslav Republic of), Martinique, Moldova (the Republic of), Pakistan, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Turkey
Country of origin: Finland
Shelf life: 3 years
Sterilization method: EtO
Packing information: First packaging layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a cardboard dispenser box. Third layer is a corrugated board transport box.
Is suitable for Tray: No

Packing level	Quantity	GS1 code	WxLxH (mm)	Vol (dm3)	Weight gross/net (kg)
Consumer pack	1	7332430666642			
Dispenser box	5	7323190126606	26x220x236		
Transport box	35	7323190126590	234x263x215	13.2	1.3 / 0.5

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.

287321 Mepilex Ag

Technical

Dimension

Dimension text	Dimension value
Product	17.5 cm x 17.5 cm

Classifications

Regulation type(s)	MDD Class III	Locally Regulated	Unregulated
MDD Classification Rule :	4;13		
CE Certificate Number :	CE 01965;CE 514235		
Notified body medical devices/PPE :	BSI (2797)		
Intended use MDD :	Mepilex Ag is an antimicrobial soft silicone foam dressing that is designed for the management of low to moderately exuding wounds such as leg and foot ulcers, pressure ulcers and partial thickness burns. Mepilex Ag may be used on infected wounds as part of a treatment regimen under supervision of a qualified health care professional. Mepilex Ag can be used under compression bandaging.		
Sales released in :	Belgium, Bulgaria, Croatia, Cyprus, Greece, Hungary, Lithuania, Luxembourg, Poland, Romania, Slovakia, Slovenia	Bahrain, China, India, Israel, Japan, Kuwait, Macedonia (the former Yugoslav Republic of), Malaysia, Serbia, Singapore, Sri Lanka, Taiwan (Province of China), Thailand, Turkey, Ukraine, United Arab Emirates, Viet Nam	Belarus, Bosnia and Herzegovina, Hong Kong, South Africa

Applied standards : The standards presented below is a selection of the most essential standards that are adhered to.

EN 1041, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-7, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, EN ISO 10993-11, EN ISO 10993-10, EN ISO 10993-18, ISO 14001

Removable label

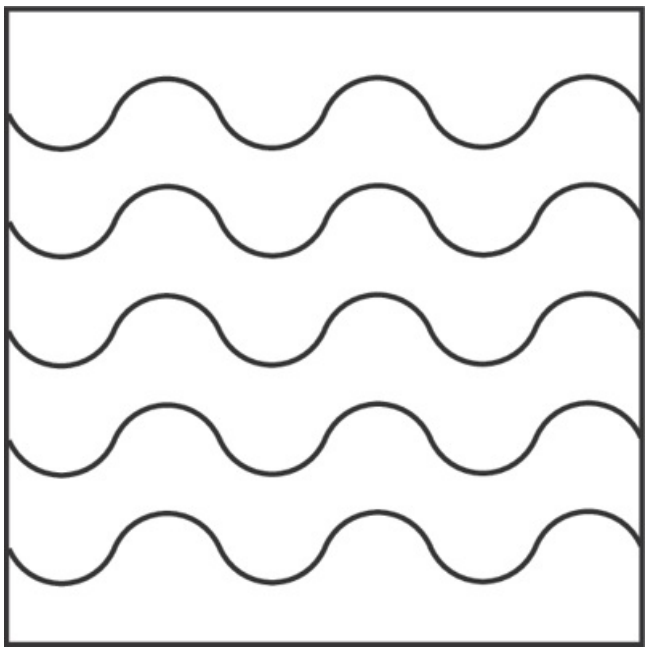
No

187605 Abdominal Swabs, X-Ray Detectable

Product details

Size: 10cm x 60cm
Descriptive feature: 5 pcs, Special nonwoven
Color: White
Sterility: Sterile

Images



Delivered items

187605-08

Sales released in: Austria, Belgium, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Malaysia, Netherlands, Norway, Poland, Portugal, Russian Federation, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland
Country of origin: Belgium
Shelf life: 5 years
Sterilization method: Steam
Packing information: First packaging layer is a nonwoven wrap. Second layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Third layer is a corrugated board box. Fourth layer is a corrugated board transport box.

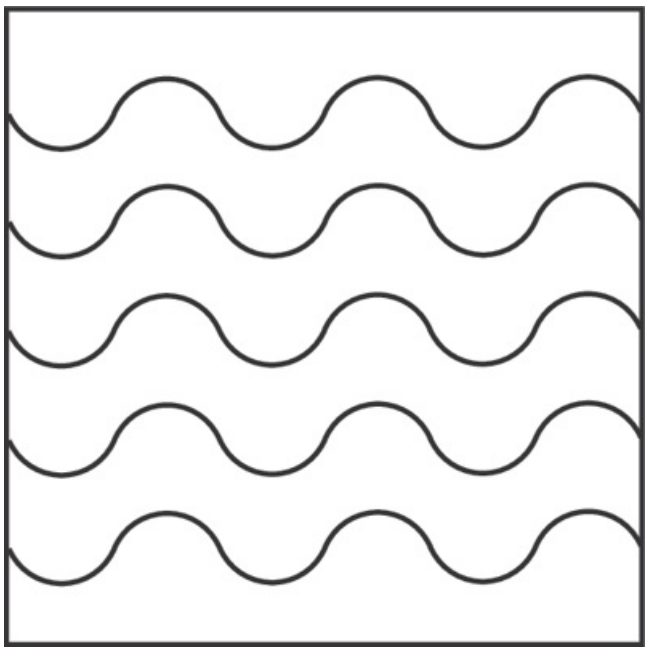
Packaging level	Pack count	GS1 code
Consumer pack	5	7332551372910

187805 Abdominal Swabs, X-Ray Detectable

Product details

Size: 40cm x 40cm
Descriptive feature: 5 pcs, Special nonwoven
Color: White
Sterility: Sterile

Images



Delivered items

187805-08

Sales released in: Austria, Belgium, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Malaysia, Netherlands, Norway, Poland, Portugal, Russian Federation, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland
Country of origin: Belgium
Shelf life: 5 years
Sterilization method: Steam
Packing information: First packaging layer is a nonwoven wrap. Second layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Third layer is a corrugated board box. Fourth layer is a corrugated board transport box.

Packaging level	Pack count	GS1 code
Consumer pack	5	7332551372989

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, SE-402 52 Göteborg, Box 13080, SE-402 52 Göteborg, Sweden being the manufacturer of the following, declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	**Mepilex Transfer**

Product classification: **IIb**

Sterility: **EtO**

Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es: **II**

Certificate number: **CE 01965**

Issued by: **BSI 0086**

For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2010-08-18** Function: **RA Director Operations**

Name: **Anders Edner** Signature:

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:
294502	Soft silicone exudate transfer dressing
294600	Soft silicone exudate transfer dressing
294621	Soft silicone exudate transfer dressing
294700	Soft silicone exudate transfer dressing
294720	Soft silicone exudate transfer dressing
294800	Soft silicone exudate transfer dressing
294920	Soft silicone exudate transfer dressing

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the manufacturer of the following, declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	**Mepilex Lite Products / Mepilex EM Products**

Product classification: **IIb**

Sterility: **EtO**

Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es: **II**

Certificate number: **CE 01965**

Issued by: **BSI 0086**

For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2011-01-04** Function: **RA Director Operations**

Name: **Anders Edner** Signature: 

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:
284000	Absorbent soft silicone dressing
284021	Absorbent soft silicone dressing
284022	Absorbent soft silicone dressing
284040	Absorbent soft silicone dressing
284100	Absorbent soft silicone dressing
284121	Absorbent soft silicone dressing
284122	Absorbent soft silicone dressing
284140	Absorbent soft silicone dressing
284300	Absorbent soft silicone dressing
284321	Absorbent soft silicone dressing
284322	Absorbent soft silicone dressing
284340	Absorbent soft silicone dressing
284500	Absorbent soft silicone dressing

bsi.

By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 514235**

Issued To: **Mölnlycke Health Care AB**
Gamlestadsvägen 3C
Box 13080
Göteborg
SE-402 52
Sweden

In respect of:

Mepilex Ag, Mepilex Border Ag and Mepilex Transfer Ag wound dressings with silver salt

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

Albert Roossien, Regulatory Lead

First Issued: **2007-07-19** Date: **2019-03-05** Expiry Date: **2022-07-18**

...making excellence a habit.™

bsi.

By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 514235

Issued To:

Mölnlycke Health Care AB
Gamlestadsvägen 3C
Box 13080
Göteborg
SE-402 52
Sweden

Product range in EU: Mepilex Ag

Article	Size, cm	Pcs / Shelf container
287021	6 x 8.5	5
287110	10 x 10	5
287050	10 x 10	10
287121	12.5 x 12.5	5
287210	10 x 20	5
287221	10 x 21	5
287310	15 x 15	5
287321	17.5 x 17.5	5
287410	20 x 20	5
287510	20 x 50	2
388100	13 x 20 (Heel)	5
388300	15 x 22 (Heel)	5

First Issued: **2007-07-19** Date: **2019-03-05** Expiry Date: **2022-07-18**

...making excellence a habit.™

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	**Mepilex Ag / Mepilex Heel Ag**

Product classification:	**III**
Sterility Status:	**Sterile**
Measuring function:	**No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	**II**

Certificate number:	**CE 01965;CE 514235**
Issued by:	**BSI (0086)**
For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2019-01-22** Function: **Regulatory Affairs Manager Compliance**

Name: **Karin Darle Olsson** Signature:

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
287021	Antimicrobial soft silicone foam dressing	47042
287050	Antimicrobial soft silicone foam dressing	47042
287110	Antimicrobial soft silicone foam dressing	47042
287121	Antimicrobial soft silicone foam dressing	47042
287210	Antimicrobial soft silicone foam dressing	47042
287221	Antimicrobial soft silicone foam dressing	47042
287310	Antimicrobial soft silicone foam dressing	47042
287321	Antimicrobial soft silicone foam dressing	47042
287410	Antimicrobial soft silicone foam dressing	47042
287510	Antimicrobial soft silicone foam dressing	47042
388100	Antimicrobial soft silicone foam dressing	47042
388300	Antimicrobial soft silicone foam dressing	47042

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	**BARRIER**

Product classification:	**IIa**
Sterility Status:	**Sterile**
Measuring function:	**No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	**II**

Certificate number:	**01965**
Issued by:	**BSI (2797)**
For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2019-07-25** Function: **Regulatory Affairs Manager Compliance**

Name: **Karin Darle Olsson** Signature:

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
187605	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187705	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187722	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187802	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187805	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187812	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187822	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187832	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187835	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187902	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile

Product Reference:	Product Descriptor:	GMDN Code:
187912	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187922	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile
187932	ABDOMINAL SWABS, X-RAY DETECTABLE	39404 Radiopaque non-woven surgical sponge, sterile