

**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 (dm <sup>3</sup> )	Weight gross/net (kg)
Consumer pack	1	7332430003775			

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

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Packing level	Quantity	GS1 code	WxLxH (mm)	Vol (dm <sup>3</sup> )	Weight gross/net (kg)
Dispenser box	4	7323190024032			
Transport box	24	7323190024025			
Pallet	2016	7323190024018			

## Material

Natural rubber latex : No

## Product Composition Wound Contact Layers

Product Component	Composition
Transferring layer	Polyurethane foam
Wound contact layer	Silicone
Protective release liner	Polyethylene film

## Product Performance Wound Contact Layer Products

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Free Swell Absorptive Capacity	EN 13726-1 part 3:2	T-1069	g/100 cm <sup>2</sup>	Not specified	N/A
Free Swell Absorptive Capacity	EN 13726-1 part 3:2	T-1069	g/g	Not specified	N/A
Conformability-Extensibility, MD	EN 13726-4	T-1086	N/cm	Not specified	N/A
Conformability-Extensibility, CD	EN 13726-4	T-1086	N/cm	Not specified	N/A
Conformability-Permanent Set, MD	EN 13726-4	T-1086	%	Not specified	N/A
Conformability-Permanent Set, CD	EN 13726-4	T-1086	%	Not specified	N/A

## Technical

## Dimension

Dimension text	Dimension value
Product	20 cm x 50 cm

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Dimension text	Dimension value
Product	8 in x 20 in

### Classifications

Regulation type(s)	MDD Class I/IIb	Locally Regulated	Unregulated
CE Certificate Number :	CE 01965		
Notified body medical devices/PPE :	BSI (2797)		
Intended use MDD :	Mepilex Transfer is designed for a wide range of exuding and difficult-to-dress wounds. Mepilex Transfer can also be used as a protective layer on non-exuding wounds and/or large areas of fragile skin. Mepilex Transfer can be used under compression.		
Sales released in :	Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	Algeria, Australia, Bahrain, Canada, China, Israel, Japan, Kazakhstan, Kuwait, Macedonia (the former Yugoslav Republic of), Malaysia, Moldova (the Republic of), New Zealand, Russian Federation, Saudi Arabia, Serbia, Singapore, Taiwan (Province of China), Thailand, Turkey, Ukraine, United Arab Emirates	Belarus, Bosnia and Herzegovina, Hong Kong, Iran (Islamic Republic of), 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

### GMDN Code (Global Medical Device Nomenclature)

46855 Wound - nonadherent dressing, permeable

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**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 (dm <sup>3</sup> )	Weight gross/net (kg)
Consumer pack	1	7332430666642			
Dispenser box	5	7323190126606	26x220x236		
Transport box	35	7323190126590	234x263x215	13.2	1.3 / 0.5

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Packing level	Quantity	GS1 code	WxLxH (mm)	Vol (dm <sup>3</sup> )	Weight gross/net (kg)
Pallet	4200	7323190126583	800x1200x1884		

## Material

**Animal tissues :** No  
**Natural rubber latex :** No  
**Medicinal substances :** No

## Product Composition Non-bordered Foam Products

Product Component	Composition
Backing material	Polyurethane film
Wound pad	Polyurethane foam
Wound contact layer	Silicone
Protective release liner	Polyethylene film

## Product Performance Non-bordered Foam Products

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Free Swell Absorptive Capacity	EN 13726-1 part 3:2	T-1069	g/100 cm <sup>2</sup>	Not specified	N/A
Free Swell Absorptive Capacity	EN 13726-1 part 3:2	T-1069	g/g	Not specified	N/A
Fluid Handling Capacity	EN 13726-1 part 3:3	T-1068	g/10 cm <sup>2</sup> /24 h	Not specified	7.3
Absorbency	EN 13726-1 part 3:3	T-1068	g/10 cm <sup>2</sup> /24 h	Not specified	1.82
Moisture Vapour Transmission Rate (MVTR)	EN 13726-1 part 3:3	T-1068	g/10 cm <sup>2</sup> /24 h	Not specified	5.5
Moisture Vapour Transmission Rate (MVTR) of a wound dressing when in contact with water vapour	EN 13726-2 part 3:2	T-1070	g/m <sup>2</sup> /24 h	Not specified	2282

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Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Moisture Vapour Transmission Rate (MVTR) of a wound dressing when in contact with liquid	EN 13726-2 part 3:3	T-1075	g/m <sup>2</sup> /24 h	Not specified	4617
Waterproofness	EN 13726-3	T-1083	Pass/Fail	>500 mm H <sub>2</sub> O for 300 s	N/A
Conformability-Extensibility, MD	EN 13726-4	T-1086	N/cm	Not specified	0.6
Conformability-Extensibility, CD	EN 13726-4	T-1086	N/cm	Not specified	0.5
Conformability-Permanent Set, MD	EN 13726-4	T-1086	%	Not specified	0.3
Conformability-Permanent Set, CD	EN 13726-4	T-1086	%	Not specified	2.7
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6	N/A
Viral penetration	ASTM F 1671	N/A	Pass/Fail	29 out of 32 samples	N/A

#### Technical

#### Dimension

Dimension text	Dimension value
Product	17.5 cm x 17.5 cm
Product	6.9 in x 6.9 in

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**Classifications**

Regulation type(s)	MDD Class IIb	Locally Regulated	Unregulated
MDD Classification Rule :	4		
CE Certificate Number :	CE 01965		
Notified body medical devices/PPE :	BSI (2797)		
Intended use MDD :	Mepilex Lite is designed for the management of a wide range of non to low exuding wounds, such as leg and foot ulcers, pressure ulcers, partial thickness burns, radiation skin reactions and Epidermolysis Bullosa. Mepilex Lite can also be used as protection of compromised and/or fragile skin.		
Sales released in :	Bulgaria, Croatia, France, Greece, Hungary, Martinique, Poland, Portugal, Romania, Slovakia, Slovenia, Spain	Bosnia and Herzegovina, Israel, Moldova (the Republic of), Pakistan, Serbia, Turkey	Macedonia (the former Yugoslav Republic of)

**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

**GMDN Code (Global Medical Device Nomenclature)**

46854 Wound - nonadherent dressing, absorbent, sterile

**UNSPSC**

42311510 Foam dressings

**Commodity Code**

3005100000 Wadding, Gauze, Dressings, drapes singlepacked - adhesive articles, Sets mainly consisting thereof

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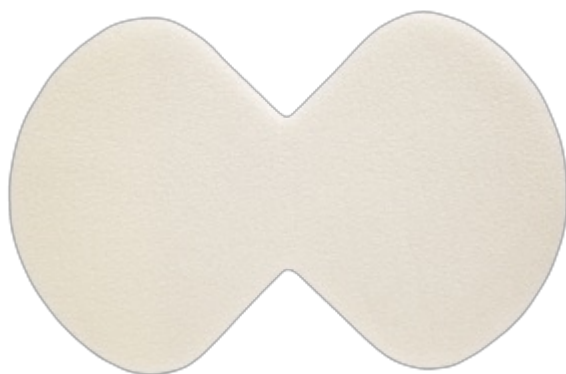
**288100 Mepilex Heel**

Soft silicone foam dressings

## Product details

**Size :** 13cm x 20cm  
**Descriptive feature :** Foam, Non-border, Soft silicone  
**Sterile :** Sterile  
**Brand :** Mepilex

## Images



## Delivered items

288100-02

**Sales released in:** Argentina, Australia, Austria, Belgium, Bolivia (Plurinational State of), Brazil, Canada, Chile, China, Colombia, Czechia, Denmark, Ecuador, Faroe Islands, Finland, Germany, Hong Kong, Hungary, India, Ireland, Italy, Japan, Kazakhstan, Korea (the Republic of), Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Peru, Poland, Portugal, Puerto Rico, Russian Federation, Singapore, South Africa, Spain, Sweden, Switzerland, Thailand, United Kingdom of Great Britain and Northern Ireland, United States of America

**Country of origin:** Finland

**Shelf life:** 3 years

**Sterilization method:** EtO

**Production Responsibility:** Mölnlycke Health Care Oy, PO Box 76, Saimaankatu 6, FI-50101 Mikkelä 10, Finland

**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 / UDI-DI	Width x Length x Height	Vol	Weight gross / net
Piece	1	7332430680822			

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Packing level	Quantity	GS1 Code / UDI-DI	Width x Length x Height	Vol	Weight gross / net
Consumer pack	1	7332430718785			
Dispenser box	5	7323190271405			
Transport box	25	7323190271399	228x387x230 mm	20.3 dm3	1.4 / 0.4 kg
Pallet	1750	7323190271382	800x1200x1872 mm		

## Material

Animal tissues :	No
Human blood derivatives :	No
Natural rubber latex :	No
Medicinal substances :	No
Phthalates :	No
Polyvinyl chloride :	No

## Product Composition Non-bordered Foam Products

Product Component	Composition
Backing material	Polyurethane film
Wound pad	Polyurethane foam
Wound contact layer	Silicone
Protective release liner	Polyethylene film

## Product Performance Non-bordered Foam Products

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Free Swell Absorptive Capacity	EN 13726-1 part 3:2	T-1069	g/100 cm <sup>2</sup>	Not specified	77.9
Free Swell Absorptive Capacity	EN 13726-1 part 3:2	T-1069	g/g	Not specified	12.5
Fluid Handling Capacity	EN 13726-1 part 3:3	T-1068	g/10 cm <sup>2</sup> /24 h	Not specified	33.07
Absorbency	EN 13726-1 part 3:3	T-1068	g/10 cm <sup>2</sup> /24 h	Not specified	6.81
Moisture Vapour Transmission Rate (MVTR)	EN 13726-1 part 3:3	T-1068	g/10 cm <sup>2</sup> /24 h	Not specified	26.26

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Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Waterproofness	EN 13726-3	T-1083	Pass/Fail	>500 mm H <sub>2</sub> O for 300 s	Pass
Conformability-Extensibility, MD	EN 13726-4	T-1086	N/cm	Not specified	1.3
Conformability-Extensibility, CD	EN 13726-4	T-1086	N/cm	Not specified	1.0
Conformability-Permanent Set, MD	EN 13726-4	T-1086	%	Not specified	0.4
Conformability-Permanent Set, CD	EN 13726-4	T-1086	%	Not specified	0.3

## Technical

### Dimension

Dimension text	Dimension value
Product	13 cm x 20 cm
Product	5 in x 8 in

### Classifications

Regulation type(s)	MDD Class IIb	CFR Class I	Locally Regulated	Locally Regulated
CE Certificate Number :	CE 01965			

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# 292005 Mepitel

Soft silicone wound contact layer

## Product details

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<b>Product group name :</b>	Mepitel
<b>Size :</b>	20cm x 30cm
<b>Descriptive feature :</b>	Soft silicone wound contact layer
<b>Sterile :</b>	Sterile
<b>Brand :</b>	Mepitel®

## Images

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## Delivered items

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292005-15

**Sales released in:** Argentina, Australia, Austria, Azerbaijan, Belgium, Bolivia (Plurinational State of), Brazil, Bulgaria, Canada, Chile, China, Colombia, Croatia, Czechia, Denmark, Ecuador, Estonia, Faroe Islands, Finland, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Korea (the Republic of), Latvia, Lithuania, Luxembourg, New Zealand, Norway, Peru, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Taiwan (Province of China), Turkey, United States of America

**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.

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**Is suitable for Tray:** No

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7332430090829		295x395x157 mm	0.6 cm <sup>3</sup>	73.2 g / -
Consumer pack	1	07333350930073	07333350930073			
Dispenser box	5	07333350227838	07333350227838	22x283x361 mm		
Transport box	30	07333350579074	07333350579074	295x395x157 mm	18.3 dm <sup>3</sup>	2.2 / 1.0 kg
Pallet	2640	7313661256482		800x1200x1877 mm	1801.9 dm <sup>3</sup>	218.2 kg / -

292005-14

**Sales released in:** Argentina, Australia, Austria, Azerbaijan, Bahrain, Belarus, Belgium, Bolivia (Plurinational State of), Bosnia and Herzegovina, Brazil, Bulgaria, Canada, Chile, China, Colombia, Croatia, Czechia, Denmark, Ecuador, Estonia, Faroe Islands, Finland, France, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, Iraq, Ireland, Israel, Italy, Kazakhstan, Korea (the Republic of), Latvia, Lithuania, Luxembourg, Macedonia (the former Yugoslav Republic of), Mexico, New Zealand, Norway, Pakistan, Peru, Poland, Portugal, Puerto Rico, Romania, Russian Federation, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Taiwan (Province of China), Trinidad and Tobago, Turkey, Ukraine, United Arab Emirates, United States of America, Uzbekistan

**Country of origin:** Finland**Shelf life:** 3 years**Sterilization method:** EtO**Production Responsibility:** Mölnlycke Health Care Oy, PO Box 76, Saimaankatu 6, FI-50101 Mikkeli 10, Finland**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	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7332430090829			609.8 cm <sup>3</sup>	73.2 g / -
Consumer pack	1	7310792920053	7310792920053			

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Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Dispenser box	5	7332551585303	7332551585303	22x283x361 mm		
Transport box	30	7332551585297	7332551585297	295x395x157 mm	18.3 dm <sup>3</sup>	2.2 / 1.0 kg
Pallet	2640	7332551585280		800x1200x1877 mm		218.2 / -

## Material

<b>Animal tissues :</b>	No
<b>Human blood derivatives :</b>	No
<b>Natural rubber latex :</b>	No
<b>Medicinal substances :</b>	No
<b>Phthalates :</b>	No
<b>Polyvinyl chloride :</b>	No

## Product Composition Wound Contact Layers

Product Component	Composition
Transferring layer	Polyamide tricot textile net
Wound contact layer	Silicone
Protective release liner	Polyethylene film

## Product Performance Wound Contact Layer Products

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Conformability-Extensibility, MD	EN 13726-4	T-1086	N/cm	Not specified	1.7
Conformability-Extensibility, CD	EN 13726-4	T-1086	N/cm	Not specified	N/A
Conformability-Permanent Set, MD	EN 13726-4	T-1086	%	Not specified	2.1
Conformability-Permanent Set, CD	EN 13726-4	T-1086	%	Not specified	N/A
Adhesion to steel	ASTM D3330/D3330M-04, method F	T-261	N/25 mm	Not specified	0.28

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Technical

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## Dimension

Dimension text	Dimension value
Product	20 cm x 30 cm
Product	8 in x 12 in

## Classifications

Regulation type(s)	MDR Class IIb	CFR Class I	Locally Regulated	Locally Regulated
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CE Certificate Number :

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# 2438 Tubifast

Elasticated viscose tubular bandage

## Product details

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<b>Size :</b>	Blue
<b>Descriptive feature :</b>	Tubular bandage
<b>Sterile :</b>	Non-sterile
<b>Brand :</b>	Tubifast garments

## Images

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## Delivered items

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2438-03

**Sales released in:** Algeria, Andorra, Argentina, Australia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Brazil, Brunei Darussalam, Bulgaria, Canada, Chile, China, Colombia, Croatia, Cuba, Cyprus, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Kazakhstan, Korea (the Republic of), Kuwait, Latvia, Lithuania, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovenia, Spain, Sweden, Switzerland, Taiwan (Province of China), Thailand, Turkey, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United States of America, Uzbekistan, Viet Nam

**Country of origin:** United Kingdom of Great Britain and Northern Ireland

**Shelf life:** 5 years

**Sterilization method:** Non-sterile

**Production Responsibility:** Mölnlycke Health Care Ltd, Tubiton House, Medlock Street, Oldham, OL1 3HS, United Kingdom

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**Packing information:** First packaging layer is a cardboard dispenser box. Second layer is a corrugated board transport box.

**Is suitable for Tray:** No

Packing level	Quantity	GS1 Code / UDI-DI	Width x Length x Height	Vol	Weight gross / net
Piece	1	7332430888105			
Consumer pack	1	5055158008724			
Dispenser box	1	5055158008731			
Transport box	30	7332551935511	266x528x356 mm	50.0 dm3	9.1 / 7.5 kg
Pallet	720	7332551935504	800x1200x1574 mm		

#### Material

Animal tissues :	No
Human blood derivatives :	No
Natural rubber latex :	No
Medicinal substances :	No
Phthalates :	No
Polyvinyl chloride :	No

#### Product Composition Compression and Retention Products, Tubigrip and TSSB

Product Component	Composition
Fabric	Viscose, Elastane

#### Product Performance Compression and Retention Products

Characteristics	Internal Test Method	Unit	Requirement	Product Performance
Extensibility Length	SM83	%	Not specified	35<x<65
Extensibility Width	SM2244	%	Not specified	x>300

#### Technical

##### Dimension

Dimension text	Dimension value
Limb measurement	24 cm - 40 cm

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

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Dimension text	Dimension value
Limb measurement	9.5 in - 16 in
Product length	10 m
Product length	10.9 yd
Lay flat width	7.5 cm
Lay flat width	3 in

Classifications

Regulation type(s)	MDR Class I ns	CFR Class I	Locally Regulated	Locally Regulated
Intended Purpose :	Dressing retention, patch wrapping, skin covering and as an undercast stockinette.		Dressing retention, patch wrapping, skin covering and as an undercast stockinette.	Dressing retention, patch wrapping, skin covering and as an undercast stockinette.
MDR Classification Rule :	4			
Conformity Annexes :	IV			
Measuring Function :	No			
Notified body medical devices/PPE :	MPA	FDA CDRH	Local Authority Thailand	Local Authority Kuwait
FDA Regulation Number :		21 CFR 880.5075		
510(k) clearance number :				
Intended use CFR :		Dressing retention, patch wrapping, skin covering and as an undercast stockinette.		

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## 2440 Tubifast

Elasticated viscose tubular bandage

### Product details

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<b>Size :</b>	Yellow
<b>Descriptive feature :</b>	Tubular bandage
<b>Sterile :</b>	Non-sterile
<b>Brand :</b>	Tubifast garments

### Images

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### Delivered items

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2440-03

**Sales released in:** Algeria, Andorra, Argentina, Australia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Brazil, Bulgaria, Canada, Chile, China, Colombia, Croatia, Cuba, Cyprus, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, French Guiana, Germany, Greece, Hong Kong, Hungary, Iceland, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Kazakhstan, Korea (the Republic of), Latvia, Lithuania, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovenia, Spain, Sweden, Switzerland, Taiwan (Province of China), Thailand, Turkey, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United States of America, Uzbekistan, Viet Nam

**Country of origin:** United Kingdom of Great Britain and Northern Ireland

**Shelf life:** 5 years

**Sterilization method:** Non-sterile

**Production Responsibility:** Mölnlycke Health Care Ltd, Tubiton House, Medlock Street, Oldham, OL1 3HS, United Kingdom

**Packing information:** First packaging layer is a cardboard dispenser box. Second layer is a corrugated board

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transport box.

Is suitable for Tray: No

Packing level	Quantity	GS1 Code / UDI-DI	Width x Length x Height	Vol	Weight gross / net
Piece	1	7332430888099			
Consumer pack	1	5055158008762			
Dispenser box	1	5055158008779			
Transport box	12	7332551935542	295x395x246 mm	28.7 dm3	5.4 / 4.5 kg
Pallet	672	7332551935535	800x1200x1872 mm		

Material

Animal tissues : No  
 Human blood derivatives : No  
 Natural rubber latex : No  
 Medicinal substances : No  
 Phthalates : No  
 Polyvinyl chloride : No

Product Composition Compression and Retention Products, Tubigrip and TSSB

Product Component	Composition
Fabric	Viscose, Elastane

Product Performance Compression and Retention Products

Characteristics	Internal Test Method	Unit	Requirement	Product Performance
Extensibility Length	SM83	%	Not specified	35<x<65
Extensibility Width	SM2244	%	Not specified	x>300

Technical

Dimension

Dimension text	Dimension value
Limb measurement	35 cm - 64 cm
Limb measurement	14 in - 25 in

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Dimension text	Dimension value
Product length	10 m
Product length	10.9 yd
Lay flat width	10.75 cm
Lay flat width	4.5 in

Classifications

Regulation type(s)	MDR Class I ns	CFR Class I	Locally Regulated	Locally Regulated
Intended Purpose :	Dressing retention, patch wrapping, skin covering and as an undercast stockinette.		Dressing retention, patch wrapping, skin covering and as an undercast stockinette.	Dressing retention, patch wrapping, skin covering and as an undercast stockinette.
MDR Classification Rule :	4			
Conformity Annexes :	IV			
Measuring Function :	No			
Notified body medical devices/PPE :	MPA	FDA CDRH	Local Authority Thailand	Local Authority South Korea
FDA Regulation Number :		21 CFR 880.5075		
510(k) clearance number :				
Intended use CFR :		Dressing retention, patch wrapping, skin covering and as an undercast stockinette.		

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## 2444 Tubifast

Elasticated viscose tubular bandage

### Product details

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<b>Size :</b>	Purple
<b>Descriptive feature :</b>	Tubular bandage
<b>Sterile :</b>	Non-sterile
<b>Brand :</b>	Tubifast garments

### Images

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### Delivered items

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2444-03

**Sales released in:** Andorra, Argentina, Australia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Brazil, Bulgaria, Canada, Chile, China, Colombia, Croatia, Cyprus, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Indonesia, Ireland, Israel, Italy, Kazakhstan, Korea (the Republic of), Latvia, Lithuania, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovenia, Spain, Sweden, Switzerland, Taiwan (Province of China), Thailand, Turkey, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United States of America, Uzbekistan, Viet Nam

**Country of origin:** United Kingdom of Great Britain and Northern Ireland

**Shelf life:** 5 years

**Sterilization method:** Non-sterile

**Production Responsibility:** Mölnlycke Health Care Ltd, Tubiton House, Medlock Street, Oldham, OL1 3HS, United Kingdom

**Packing information:** First packaging layer is a cardboard dispenser box. Second layer is a corrugated board

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

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transport box.

Is suitable for Tray: No

Packing level	Quantity	GS1 Code / UDI-DI	Width x Length x Height	Vol	Weight gross / net
Piece	1	7332430888075			
Consumer pack	1	5055158008847			
Dispenser box	1	5055158008854			
Transport box	15	7332551935573	395x590x268 mm	62.5 dm3	10.5 / 8.8 kg
Pallet	360	7332551935566	800x1200x1758 mm		

#### Material

Animal tissues :	No
Human blood derivatives :	No
Natural rubber latex :	No
Medicinal substances :	No
Phthalates :	No
Polyvinyl chloride :	No

#### Product Composition Compression and Retention Products, Tubigrip and TSSB

Product Component	Composition
Fabric	Viscose, Elastane

#### Product Performance Compression and Retention Products

Characteristics	Internal Test Method	Unit	Requirement	Product Performance
Extensibility Length	SM83	%	Not specified	35<x<65
Extensibility Width	SM2244	%	Not specified	x>300

#### Technical

##### Dimension

Dimension text	Dimension value
Limb measurement	64 cm - 130 cm
Limb measurement	25 in - 51 in

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Dimension text	Dimension value
Product length	10 m
Product length	10.9 yd
Lay flat width	20 cm
Lay flat width	8 in

Classifications

Regulation type(s)	MDR Class I ns	CFR Class I	Locally Regulated	Locally Regulated
Intended Purpose :	Dressing retention, patch wrapping, skin covering and as an undercast stockinette.		Dressing retention, patch wrapping, skin covering and as an undercast stockinette.	Dressing retention, patch wrapping, skin covering and as an undercast stockinette.
MDR Classification Rule :	4			
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## FEATURE

# An Overview of Neonatal and Pediatric Wound Care Knowledge and Considerations

Mona Mylene Baharestani, PhD, ANP, CWOCN, CWS

*Despite significant technological advances in the care of premature neonates and chronically ill children, the knowledge and evidence base for the management of this population's wound care lag far behind its adult counterpart. Updating antiquated care regimens is an uphill battle. This review of the literature seeks to illuminate key anatomical/structural differences in neonatal skin with particular attention paid to percutaneous absorption and tolerance of adhesives. The article also presents anatomically and physiologically based recommendations for the selection of prevention and treatment modalities, including specific dressing types, appropriate dressing change and securement procedures, and pain management. Commonly encountered wound types (epidermal stripping; surgical wounds; extravasation and thermal injuries; chemical burns; pressure ulcers; diaper dermatitis; and wounds secondary to congenital conditions) are discussed. Opportunities for research abound and are considered.*

**KEYWORDS:** neonatal/pediatric wound care, extravasation injuries, pressure ulcers, diaper dermatitis, epidermolysis bullosa

*Ostomy Wound Management 2007;53(6):34-55*

A paucity of pediatric wound care research is available upon which to guide practice; few wound care products have been studied in this population.<sup>1-3</sup> This problem is compounded further by the ethical and litigious issues involved in carrying out research in this vulnerable population, leaving clinicians without an evidence base from which to render care. In fact, it is not unusual for skin care regimens to be based on individual or institutional preference and routine.<sup>4</sup> Most papers on wound care in neonates and children are anecdotal or are discussions of wound healing principles and clinical practice guidelines for adults.<sup>1</sup> Research data regarding the safety and clinical efficacy of wound care dressings, drugs, and adjunctive treatments in neonates and children are needed.<sup>3,5</sup>

Although they follow the same wound healing trajectory as adults, wounds in neonates and children typically exhibit faster rates of closure.<sup>6-8</sup> Fibroblasts are present in greater numbers, collagen and elastin are more rapidly produced, and granulation tissue forms more quickly compared to adults.<sup>8,9</sup> In fact, rapid, uncomplicated wound healing requiring limited healthcare professional intervention is the “normative expectation” in pediatrics.<sup>10</sup> This expectation of rapid, uneventful healing and innate age-related integumentary resiliency has, in part, resulted in the lack of wound care knowledge transfer to the pediatric population.<sup>10</sup> Pieper et al's<sup>1</sup> recent study of 13 home care agencies found that while children represented 3% of all visits and 17% of children had wounds, basic

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principles of wound care were not implemented into practice. Pressure ulcers and open surgical wounds among this pediatric population often were cleansed with hydrogen peroxide, household soap, or povidone-iodine — 44% were treated with dry gauze and 19% with normal saline dampened gauze.<sup>1</sup> Yet, more than 90% of the home care nurses interviewed for this study described the pediatric wound care as appropriate.<sup>1</sup> Similarly, a survey<sup>11</sup> among 104 neonatal intensive care units (NICUs) in the US found that less than 25% had wound care protocols in place. A survey of 13 NICUs in the UK reported wound care practices to be wide and varied with neither written policy nor guidelines for staff.<sup>12</sup> In fact, 32% of wounds were either left open to air or covered with dry dressings, with the prevailing view of staff participating in the study that plastic surgery would cure the wound at a later time.<sup>12</sup> Although eight of the units surveyed had access to wound specialists, only one unit reported use of this specialty.<sup>12</sup> Baker et al's<sup>13</sup> US survey of 305 NICUs also reported a lack of consensus on skin care practices, with less than 30% of those interviewed agreeing on how to treat skin breakdown in micro-preemies. As a result, wounds were treated with hydrogen peroxide, exposed to air, or “allowed to heal” without intervention.<sup>1</sup>

The purpose of this overview is to illuminate key anatomical/structural differences in neonatal skin as it pertains to percutaneous absorption, and tolerance of adhesives to foster anatomically/physiologically based inquiry when selecting prevention and treatment modalities; and to review the evidence for commonly encountered wound types.

### Factors Affecting Wound Healing in Neonates and Children

The normally rapid wound healing response of neonates and children is often compromised by protein-calorie malnutrition, hypotension requiring inotropic therapy, edema, infection, and physiological instability that prevents safe redistribution of pressure.<sup>7,9</sup> Possessing minimal to no antigen exposure, neonates are at especially high risk for overwhelming life-threatening sepsis secondary to bacterial proliferation and overgrowth within the wound bed.<sup>14,15</sup> Their decreased epidermal-to-dermal cohesion, deficient



**Figure 1.** Premature neonate of 24 weeks' gestation. Photo courtesy of P. Palmer, RN, BSN.

stratum corneum, impaired thermoregulation, body surface/weight ratio nearly five times greater than the adult, and immature immune system — as well as hepatic and renal function — places neonates at increased risk for epidermal stripping, infection, increased transepidermal water loss with resultant heat loss, and toxicity from percutaneous absorption.<sup>12,14,16</sup>

### Integumentary Milestones: Summarizing Current Knowledge

At 24 weeks gestation, premature neonates have little stratum corneum and attenuated rete ridges. Their skin is red, wrinkled, translucent, and gelatinous in appearance (see Figure 1). They lack subcutaneous tissue; therefore, their dermis is lying directly over the muscle.<sup>17</sup> Consequently, skin stripping secondary to adhesive dressing and/or tape removals can result in full-thickness tissue loss. Between 26 and 29 weeks' gestation, subcutaneous fat deposition begins and skin wrinkling lessens. However, the barrier function of the skin remains poor and at 26 weeks gestation as much as 110 mL of water can be lost in 24 hours.<sup>18</sup>

Ostomy Wound Management 2007;53(6):34-55

#### KEY POINTS

- Despite increased wound healing knowledge and unprecedented advances in neonatal care, the evidence base of pediatric skin and wound care protocols remains limited.
- The author reviews current knowledge about neonatal and pediatric skin, skin problems, and currently recommended skin protection and wound care measures.





**Figure 2.** Premature neonate of 30 weeks' gestation.  
Photo courtesy of P. Palmer, RN, BSN.



**Figure 3.** Premature neonate of 36 weeks' gestation.  
Photo courtesy of P. Palmer, RN, BSN.

At 30 weeks, subcutaneous tissue is evident and the stratum corneum is two to three cell layers thick, compared to 40 weeks when it is 30 layers thick<sup>17</sup> (see Figure 2). Functional integumentary maturity occurs at 33 weeks. The epidermis is fully keratinized and the dermal/epidermal junction is stronger but remains fragile and easily damaged. At 36 weeks (full term), the skin is structurally similar to the adult but the epidermal and dermal layers are up to 60% as thick as an adult<sup>18</sup> (see Figure 3).

### Common Wound Etiologies among Neonates and Children

Epidemiological studies and empirical evidence suggest that the most commonly encountered wound types among hospitalized neonates and children include epidermal stripping, extravasation injuries,

surgical wounds, incontinence-associated dermatitis, chemical and thermal injuries, wounds secondary to congenital abnormalities, and pressure ulcers in variable rates of prevalence.<sup>1,6,9,19-23</sup>

**Epidermal stripping.** Epidermal stripping secondary to tape and adhesive dressing removal is most common in neonates born before 27 weeks' gestation and is the primary cause of skin breakdown in the NICU.<sup>3,24</sup> Given the neonate's attenuated rete ridges, adhesive products typically bond more aggressively to the epidermis than the epidermis does to the dermis.<sup>25</sup> Epidermal stripping is not only a source of discomfort, but also can lead to other morbidity in very low birthweight neonates and those who are immunocompromised.<sup>16</sup> Interventions to help prevent epidermal stripping include using an alcohol-free liquid skin barrier on the skin under adhesive dressings in neonates >30 days of age and clear film dressings to secure intravenous sites.<sup>16,26-28</sup> Using pad splints and padded Velcro™ straps over splints rather than tape<sup>26,29</sup> and using soft silicone dressings to treat areas of denudation secured with tubular latex-free stretchy gauze netting can offset the stripping phenomenon.<sup>24,29</sup> Staff should be taught to remove adhesives gently using the horizontal stretch method<sup>30</sup> and to avoid use of adhesive removers and bonding agents in the neonatal population because these products can potentiate the risk of epidermal stripping and result in toxic percutaneous absorption. Neonates and those with edematous skin should be handled with extreme care.<sup>26</sup> Mepitac® or Mepiform (Molnlycke Health Care, Inc, Norcross, Ga), soft silicone dressing can be used as a tape in those with blistering disorders (eg, epidermolysis bullosa).<sup>26</sup>

**Extravasation injuries.** Extravasation injuries occur as a result of inadvertent leakage of vesicant fluid from a vein/cannula into the surrounding soft tissue<sup>29,31,32</sup> (see Figure 4). The reported incidence of extravasation injury in neonates and children is 0.1% to 15%<sup>23,33</sup> and occurs most frequently in neonates of <26 weeks' gestation given the fragility and small caliber of the peripheral veins.<sup>32</sup> Staging of infiltrates/extravasation is described in Table 1.<sup>34</sup>

To prevent and manage this type of skin injury, experts recommend using sterile transparent dressings to secure intravenous lines to allow for at least hourly



**Figure 4.** Extravasation injury in a 3.5-week-old newborn.

site inspections.<sup>25,29</sup> Although there is no consensus on best practice for extravasation wound treatment, experts recommend application of hydrogels covered with silicone dressings, applying a hydrogel-filled glove or boot to the affected site or using a hydrofiber covered by a thin hydrocolloid.<sup>21,30-32,35</sup> Potential problems with using the hydrogel-filled glove or boot include periwound maceration, the infant's inability to move the affected extremity secondary to the gel weight, and trauma when removing securement tapes/film dressing.<sup>30</sup> The periwound skin can be protected against maceration through use of an alcohol-free liquid skin barrier in neonates >30 days of age.<sup>27,28</sup> If necrotic tissue is present, surgical consultation should be obtained, coupled with use of autolytic debridement.

**Surgical wounds.** In a 2005 prevalence audit (n = 252),<sup>22</sup> 43% of hospitalized children were noted to have an open surgical wound and/or closed incision, 71% required daily nursing observations, 22% received twice daily dressings, 5% received complex dressing care, and 2% received negative pressure wound therapy (see Figure 5).

Care protocols should include frequent monitoring for signs and symptoms of infection. While antimicrobial dressings containing cadexomer iodine and sustained-release silver have been successfully utilized in adult populations to manage wound malodor and reduce bacterial load, similar neonatal and pediatric data are lacking.<sup>9</sup> Reports of a case series of burn wounds and a dehisced surgical wound managed with silver dressings suggest these products may be safe and effective alternatives to traditional dressings.<sup>14,36</sup> Simon et al<sup>37</sup> similarly reported positive clinical outcomes

over a 3 year period during which Manuka Medihoney™ (Derma Sciences, Princeton, NJ) was used on dehisced surgical wounds and infected port-explantation sites in pediatric patients receiving chemotherapy.

In full-thickness wounds with large amounts of drainage, ostomy pouches, wound drainage collectors, and negative pressure wound therapy (NPWT) may be appropriate. Hydrogel, hydrofiber, foams, and soft silicone dressing use in the management of non-infected open surgical wounds has been reported anecdotally<sup>9</sup>; experts suggest that the periwound skin of children and neonates >30 days of age should be protected with a liquid barrier film.<sup>27,28</sup>

**TABLE 1**  
**STAGING OF IV**  
**INFILTRATES/EXTRAVASATION<sup>34</sup>**

Stage	Characteristic
0	Absence of redness, warmth, pain, swelling, blanching, mottling, tenderness or drainage Flushes with ease
1	Absence of redness, swelling Flushes with difficulty Pain at site
2	Slight swelling at site Presence of redness Pain at site Good pulse at site 1- to 2-second capillary refill below site
3	Moderate swelling above or below site Blanching Pain at site Good pulse below infiltration site 1- to 2-second capillary refill below infiltration site Skin cool to touch
4	Severe swelling above or below site Blanching Pain at site Decreased or absent pulse Capillary refill >4 seconds Skin cool to touch Skin breakdown or necrosis



**Figure 5.** Dehisced surgical wound in a 13 year old.

**Incontinence-associated dermatitis (diaper dermatitis).** The prevalence of diaper dermatitis among hospitalized neonates and children has been reported to be between 16% and 42%.<sup>22,23</sup> In fact, diaper dermatitis is one of the most common dermatological conditions encountered among neonates and children who are diapered.<sup>22</sup> Diaper dermatitis can be staged according to the integrity of the epidermis and the presence/absence of *Candida albicans* skin infection<sup>22</sup> (see Table 2).

Interventions to prevent and manage this condition include diaper changes at least every 3 to 4 hours or sooner if needed and use of diapers containing absorptive gels.<sup>24</sup>

It is generally recommended that commercial diaper wipes be avoided in neonates and that a petrolatum-based ointments and/or zinc oxide based barrier product be used to protect the skin.<sup>24</sup> In the presence of *C. albicans*, an antifungal ointment should be applied. The use of powders and products containing dyes and fragrances should be avoided in the nursery.<sup>24</sup> Cavilon™ No-Sting Barrier (3M, St. Paul, Minn) is approved for use in infants >30 days of age.<sup>27,28</sup>

**TABLE 2**  
**TYPES OF DIAPER DERMATITIS<sup>22</sup>**

<b>Type 1:</b> Epidermis intact and no candidal infection present
<b>Type 2:</b> Epidermis intact and candidal infection present
<b>Type 3:</b> Epidermis not intact and no candidal infection present
<b>Type 4:</b> Epidermis not intact and candidal infection present

**Chemical burns.** Experts suggest that chemical injuries may occur secondary to the application of adhesive removers, bonding agents, betadine, and alcohol-based prep solutions.<sup>25,29</sup> If betadine or alcohol-based prep agents are used before insertion of lines or drains or procedures, the amount used should be limited and rinsed immediately with sterile water.<sup>29</sup> The undersides of patients always should be checked to ensure they are not lying on linens soaked in prep solution. It is best to totally avoid the use of these agents and instead use aqueous-based skin preparations.<sup>29</sup> In pre-term neonates, percutaneous toxicity from alcohol and betadine-based solutions is an additional concern.<sup>38</sup>

**Thermal injuries.** In neonates, thermal injuries may be secondary to heat from monitoring electrodes or less commonly from use of cold light for identifying veins and arteries for line insertions.<sup>25,29</sup> The most common cause of community acquired thermal injuries in children is associated with fire.<sup>39</sup> To prevent neonatal burns from heat, temperatures of monitoring devices should be reduced and application time should be limited as is feasible.<sup>29</sup> To prevent neonatal burns from cold light, exposure time should be minimized and a protective guard used.<sup>29</sup> A literature review<sup>40</sup> on the use of Biobrane (Bertek Pharmaceutical Inc., Research Triangle, NC), a biosynthetic dressing consisting of a layer of peptides derived from porcine dermal collagen incorporated into silicone and nylon, has demonstrated clinical efficacy over conservative treatment in terms of pain control, wound healing, and hospital length of stay in children with partial-thickness burns. Further randomized controlled trials are required to examine the incidence of hypertrophic scarring and to compare clinical outcomes to other skin substitutes.<sup>40</sup>



When Mepitel® (Molnlycke), a silicone dressing, was compared to silver sulfadiazine in a prospective, randomized study of 63 children with partial-thickness scald burns, wounds of children treated with the silicone dressing healed faster, were less painful, exhibited less eschar formation, and required fewer dressing changes.<sup>41</sup> As a result, the silicone treatment group required fewer analgesics and had lower hospital charges.<sup>41</sup> As with all wounds, the selection of an age-appropriate wound cleansing agent and dressing to address wound needs is needed (see “Best Practices in Wound Care Principles”).

#### Wounds secondary to congenital conditions.

*Aplasia cutis congenita.* Aplasia cutis congenita, which occurs in 0.03% of births, is a defect of the skin manifested by absent areas of epidermis and subcutaneous tissue.<sup>9,42</sup> Wounds are partial- or full-thickness; 80% occur on the scalp.<sup>30</sup> Life-threatening bleeding and infection have been reported in the literature.<sup>9,43,44</sup> Lesions of the skull require imaging to assess the depth of involvement.<sup>9,43</sup> Small partial-thickness areas (<1 cm<sup>2</sup>) usually reepithelialize well with the use of atraumatic moisture-retaining dressings and topical antibiotics but larger or full-thickness wounds require dermatology, plastic surgery, and neurosurgical intervention.<sup>9,43</sup>

*Epidermolysis bullosa.* Epidermolysis bullosa (EB) is a heterogeneous, genetic group of mechano-bullous disorders characterized by skin and mucosal blistering in response to minor friction or trauma.<sup>9,45</sup> Inherited EB is grouped into three major types based on the depth of blister formation: simplex, junctional, or dystrophic.<sup>45</sup>

Commonly suggested interventions based on expert opinions include using gentle handling techniques to minimize friction and shear forces to the skin<sup>30</sup> and avoiding adhesives and tapes. Instead, dressings can be secured by stretchy non-latex tubular gauze netting.<sup>9</sup> Only flat-seamed clothing or clothing turned inside out should be used<sup>30</sup> and tight clothing and non-padded shoes should be avoided.<sup>45</sup> Each finger and toe should be wrapped individually with non-adherent dressings to prevent digitary fusion.<sup>45</sup>

Cardiac monitoring and pulse oximetry devices must be secured with non-adhesive products. Exposure to humidity and heat should be decreased — they can increase blistering.<sup>30</sup> Cloth diapers should

be used; the elastic edges of disposable diapers should be cut out because they can cause blistering.<sup>45</sup> Using non-adherent dressings, tailoring use of absorptive dressings when exudate is high, and providing for moisture when drainage is minimal are other strategies.<sup>9</sup> Soft silicone dressings provide an excellent atraumatic dressing option. Large blisters must be lanced or aspirated with a sterile hypodermic needle without removing the roof.<sup>9</sup>

In one open-label, uncontrolled study<sup>46</sup> of 15 patients with 78 wounds, Apligraf™ (Organogenesis Inc, Canton, Mass) was found to induce rapid healing in children with acute and chronic wounds secondary to EB without side effects. Large controlled studies with longer follow-up are needed before greater widespread use is advocated.

A case report<sup>47</sup> demonstrated the success of Integra™ Bilayer Matrix Dressing (Integra Lifespan Corp, Plainsboro, NJ) to cover the wound followed by Apligraf™ for epidermal coverage after surgical correction of pseudosyndactyly (mitten deformity of the hand). Further controlled studies are needed.

**Pressure ulcers.** Pressure ulcer rates as high as 27% in pediatric intensive care units, 23% in neonatal intensive care units, and 20% to 43% among outpatients with spina bifida have been reported.<sup>48-51</sup> Lack of pressure redistribution measures and the presence of friction/shear-related forces result in micro-vascular soft tissue damage and resultant partial- to full-thickness pressure ulcers. Stage I to Stage IV ulcers, unstageable ulcers, and suspected deep tissue injuries should be documented in accordance with the National Pressure Ulcer Advisory Panel’s (NPUAP) updated definitions<sup>52</sup> (see Table 3). In children, unlike adults, more than 50% of pressure ulcers are related to sustained pressure from equipment and devices<sup>51</sup> (see Figure 6).

Experts recommend performing risk assessments at least daily utilizing an age-appropriate valid and reliable pressure ulcer risk assessment scale.<sup>9,24</sup> Preventive skin care practices such as those outlined by Lund<sup>16,21,25,27,29,30</sup>; the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN)<sup>24</sup>; Baharestani and Ratliff, Curley and Quigley, and Irving<sup>3,5,12</sup>; Malloy<sup>4,20</sup>; Garvin<sup>7</sup>; and Baharestani and Pope<sup>9</sup> must be provided and frequent skin assessments

### TABLE 3 PRESSURE ULCER STAGING SYSTEM<sup>52</sup>

**Suspected Deep Tissue Injury (DTI):** Purple or maroon localized area of discolored skin due to damage of underlying soft tissue as a result of ischemia from pressure and/or shear. This area initially presents as intact skin or a blood-filled blister and may rapidly evolve to expose additional layers of tissue even with optimal treatment. Variations in skin pigmentation may change visual presentation and thus early deep tissue injury may be difficult to discern. Other characteristics of the area may include pain, firmness, softness, or a difference in temperature as compared to adjacent tissue

**Stage I:** Persistent redness of a localized area of intact skin usually over a bony prominence. Other characteristics of the area may include delayed capillary refill, pain, firmness, softness, or a difference in temperature as compared to adjacent tissue. Usually a minor and resolvable condition. Variations in skin pigmentation may change visual presentation

**Stage II:** Partial-thickness loss of epidermis or dermis presenting as a shallow open ulcer without slough. May present as an intact or open/ruptured serum-filled blister

**Stage III:** Full-thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle are not exposed. Slough may be present, but does not obscure the depth of tissue loss. Other characteristics may include undermining and tunneling. Rolled edge of dermis may be seen

**Stage IV:** Full-thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Other characteristics often include undermining and tunneling

**Unstageable:** Full-thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, gray, green, or brown) and/or eschar (tan, brown, or black) in the wound bed. Blood blisters are not débrided and therefore placed in the DTI group



**Figure 6.** Pressure ulcer in an 8-year-old secondary to a plaster cast.

performed, particularly under blood pressure cuffs, pulse oximetry devices, tracheostomy plates, oral and nasal gastric tubes, nasal prongs and masks of continuous positive airway pressure (CPAP) devices, arm boards, traction boots, and plaster cast edges.<sup>53</sup> Protective padding (eg, hydrocolloids, thicker silicone

dressings, or foam dressings) is needed under devices as feasible<sup>9,54</sup> and pressure redistributed by using only support surfaces on cribs, isolettes, incubators, and beds that are age- and weight-appropriate. Patients should be turned and repositioned at least every 2 hours as is medically feasible. Unique to the neonatal and infant population, being held by healthcare professionals and parents also offloads pressure. Tapes and clothing should be loosened in the presence of edema and friction and shear forces should be minimized.<sup>26</sup> If an ulcer develops, the wound should be cleansed as needed (refer to “Best Practice in Wound Care Principles”), necrotic tissue débrided, bacterial colonization and infection managed, nutritional status maximized as is consistent with overall goals of care, and appropriate local wound care modalities selected. Maintaining a quality monitoring program will ensure standardized ongoing assessments of staff education, guidelines, and the effectiveness of care delivery processes as measured by the occurrence and management of facility-acquired skin breakdown.

**Organogenesis inc.**

LIVING TECHNOLOGY

The persistence of Apligraf cells on the wound and the safety of this device in venous ulcer patients beyond 1 year and diabetic foot patients beyond 6 months have not been evaluated. Apligraf is indicated for use with standard therapeutic compression for the treatment of noninfected partial- and full-thickness skin ulcers due to venous insufficiency of duration greater than 1 month that have not adequately responded to conventional therapy. Apligraf is also indicated for use with standard diabetic foot ulcer care for the treatment of full-thickness neuropathic diabetic foot ulcers of greater than 3 weeks' duration that have not adequately responded to conventional ulcer therapy and that extend through the dermis, but without tendon, muscle, capsule, or bone exposure. Apligraf should not be used on infected wounds or on patients with hypersensitivity to any components of Apligraf or the shipping medium. Please consult complete prescribing information for a description of epidermal and dermal elements contained in Apligraf.

**Apligraf® Essential Prescribing Information** Numbers in parentheses () refer to sections in the main part of the product labeling. **Device Description:** Apligraf is supplied as a living, bi-layered skin substitute manufactured using neonatal foreskin keratinocytes and fibroblasts with bovine Type I collagen. (1) **Intended Use/Indications:** Apligraf is indicated for use with standard therapeutic compression in the treatment of uninfected partial and/or full-thickness skin loss ulcers due to venous insufficiency of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy. Apligraf is indicated for use with standard diabetic foot ulcer care for the treatment of full-thickness foot ulcers of neuropathic etiology of at least three weeks duration, which have not adequately responded to conventional ulcer therapy and extend through the dermis but without tendon, muscle, capsule or bone exposure. (2) **Contraindications:** Apligraf is contraindicated for use on clinically infected wounds and in patients with known allergies to bovine collagen or hypersensitivity to the components of the shipping medium. (3, 4, 5, 8) **Warnings and Precautions:** If the expiration date or product pH (6.8-7.7) is not within the acceptable range DO NOT OPEN AND DO NOT USE the product. A clinical determination of wound infection should be made based on all of the signs and symptoms of infection. (4,5) **Adverse Events:** All reported adverse events, which occurred at an incidence of greater than 1% in the clinical studies are listed in Table 1, Table 2, and Table 3. These tables list adverse events both attributed and not attributed to treatment. (6) **Maintaining Device Effectiveness:** Apligraf has been processed under aseptic conditions and should be handled observing sterile technique. It should be kept in its tray on the medium in the sealed bag under controlled temperature 68°F - 73°F (20°C - 23°C) until ready for use. Apligraf should be placed on the wound bed within 15 minutes of opening the package. Handling before application to the wound site should be minimal. If there is any question that Apligraf may be contaminated or compromised, it should not be used. Apligraf should not be used beyond the listed expiration date. (9) **Use in Specific Populations:** The safety and effectiveness of Apligraf have not been established in pregnant women, acute wounds, burns and ulcers caused by pressure. **Patient Counseling Information:** VLU patients should be counseled regarding the importance of complying with compression therapy or other treatment, which may be prescribed in conjunction with Apligraf. DFU patients should be counseled that Apligraf is used in combination with good ulcer care including a non-weight bearing regimen and optimal metabolic control and nutrition. Once an ulcer has healed, ulcer prevention practices should be implemented including regular visits to appropriate medical providers. **Treatment of Diabetes:** Apligraf does not address the underlying pathophysiology of neuropathic diabetic foot ulcers. Management of the patient's diabetes should be according to standard medical practice. **How Supplied:** Apligraf is supplied sealed in a heavy gauge polyethylene bag with a 10% CO<sub>2</sub>/air atmosphere and agarose nutrient medium, ready for single use. To maintain cell viability, Apligraf should be kept in the sealed bag at 68°F - 73°F (20°C - 23°C) until use. Apligraf is supplied as a circular disk approximately 75 mm in diameter and 0.75 mm thick. (8) **Patent Numbers:** 4,485,096; 5,106,949; 5,536,656

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Integral to this process is the initiation and maintenance of continuous feed-back loops.

## Best Practice in Neonatal and Pediatric Wound Care: Examining the Principles

When selecting a wound care dressing, drug, or adjunctive therapy for use in neonatal and pediatric populations, it is important to consider the goals of therapy, the practice environment, resource availability, patient age/degree of integumentary maturity, skin condition, product concentration and adherence, potential for skin sensitization, impact of product absorption, and need for avoidance of products containing dyes, fragrances, and preservatives.<sup>4,55,56</sup> Knowledge of product safety and manufacturer's recommended use data in the neonatal/pediatric population are essential.<sup>55</sup>

**Patient assessment.** As with adults, a thorough assessment should include but is not limited to the following<sup>9</sup>: current medical issues, clinical stability, age, medical history, surgical history, allergies and skin sensitivities, medication history, review of laboratory results and diagnostic tests, height and weight, social history, family support systems, pain status (using a tool validated for use within the patient's age group),<sup>57</sup> nutritional history, history of previous wounds, treatment and healing outcomes, pressure ulcer risk assessment score (using a valid and reliable tool such as: Braden Q, Braden, or Glamorgan)<sup>55</sup> and a targeted physical examination. Examples of validated pediatric pain assessment tools are listed in Table 4.

**Dressing selection criteria.** Ideally, a dressing should protect the wound, facilitate atraumatic removal and application, not require frequent changes, remain in place in a humidified environment, and be the correct size or have the capability to be cut to fit the area.<sup>29</sup> In addition, cultural and religious sensitivity is important when selecting dressings. For example, some dressings contain animal-derived products. While a complete review of dressing safety and effectiveness is beyond the scope of this publication, clinicians need to ascertain that the products selected have been shown to be safe and effective for the intended indication and population.

Commonly used products include soft silicone dressings, liquid barrier films, hydrocolloid dressings.

**TABLE 4**  
**VALIDATED NEONATAL PAIN ASSESSMENT TOOLS**

<b>Tool</b>	<b>Age Tested</b>
PIPP (Premature Infant Pain Profile)	28 to 40 weeks
CRIS (Crying, Requires Oxygen Saturation, Increased Vital Signs, Expression, Sleeplessness)	32 to 36 weeks
NIPS (Neonatal/Infant Pain Scale)	28 days to <1 year old
N-PASS (Neonatal Pain Agitation and Sedation Scale)	0 to 100 days
NFCS (Neonatal Facing Coding System)	Preterm and term neonates, infants at 4 months of age
PAT (Pain Assessment Tool)	Neonates
SUN (Scale for use in Newborns)	Neonates
EDIN (Neonatal Pain and Discomfort Scale)	25 to 36 weeks (preterm)
BPSN (Bernese Pain Scale for Neonates)	Term and preterm neonates
Oucher	3 to 12 years old
FLACC (Face, Legs, Activity, Crying, Consolability Scale)	2 months to 7 years old
CHEOPS (Children's Hospital of Eastern Ontario)	1 to 7 years old
Wong-Baker Faces Scale	3 to 7 years old
Bieri-Modified	Children >3 years old
CHIPPS (Children and Infants Postoperative Pain Scale)	Children up to 4 years old

(Adapted from: *The American Academy of Pediatrics and the Canadian Paediatric Society*)

**Silicone dressings.** Silicone dressings are available as contact layers, absorbents, antimicrobials, exudate transferrants, gel sheets for scar management, and as fixation tapes. They are commonly used in neonatal and pediatric wound management because they are versatile and lack adhesives. Their use should be avoided in patients with known silicone allergy.

**Non-alcohol-based liquid barrier films.** Non-alcohol-based liquid barrier films are applied to the skin to prevent epidermal stripping secondary to adhesive removal and to protect against chemical erosion from wound fluid.<sup>9,27,28</sup> Cavilon™ No-Sting Barrier film (3M, St. Paul, Minn) is approved for neonates >30 days of age to prevent skin stripping from adhesive removal.<sup>24,27,28</sup>

**Hydrocolloids.** The neonatal and pediatric literature<sup>24,25,58-62</sup> contains multiple references to the successful use of hydrocolloids in maintaining wound bed moisture, providing autolytic debridement, and providing a waterproof and bacterial barrier, as well as a barrier for other adhesives.

Specific benefits provided by thin hydrocolloids in the treatment of neonatal and pediatric wounds include prevention of tissue damage, reduction of

epidermal water loss, allowance of full limb range-of-motion, easy application to small body surfaces, sterile dressing delivery, suitability for use in incubators/humidified environments, and provision of a barrier to viral and bacterial transmission.<sup>63</sup>

**Hydrogels.** Hydrogels are available in two basic forms: solid sheet and amorphous gels. The primary components are cross-linked polymers and water.<sup>9</sup> Neonatal and pediatric case studies describe use of hydrogels in the management of toxic epidermal necrolysis, wound dehiscence, extravasation injuries, pressure ulcers, fungating lesions, and burns.<sup>35,36,63-65</sup>

**Foam dressings.** Foam dressings are polymeric materials with hydrophilic contact layers and hydrophobic outer layers. These dressings vary in thickness and may be impregnated with surfactants, glycerine, charcoal, or silver. Anecdotal pediatric case studies document successful use of these products.<sup>9</sup>

**Composite dressings.** Composite dressings are multilayered superabsorbent dressings designed for the management of moderate to heavily draining wounds. Successful use of composite dressings was reported anecdotally in the management of an extravasation injury in a 27-week gestational age neonate.<sup>66</sup>

**Semipermeable films.** Semipermeable films are versatile, transparent, thin, polyurethane moisture-vapor permeable dressings designed to maintain a moist environment. These dressings facilitate epithelialization of minimally exuding partial-thickness wounds and provide autolysis of non-infected wounds. Film dressings also can be used to secure primary dressings while promoting a moist environment.

**Hydrofiber dressings.** Hydrofiber dressings are composed of carboxymethylcellulose hydrofibers. Highly absorbent, these dressings transform into solid sheet gels once in contact with fluid. Anecdotal success has been reported in pediatric case studies.<sup>9</sup>



*Negative pressure wound therapy.* Negative pressure wound therapy involves application of sterile hydrophobic, open-pore reticulated polyurethane foam or hydrophilic, polyvinyl alcohol foam dressings (KCI, San Antonio, Tex) cut to the appropriate wound geometry, covered with a transparent film drape, and fitted with a T.R.A.C.® Pad (KCI) attached to a computerized, calibrated microprocessor unit to deliver controlled NPWT. Patient age, exposed structures within the wound, bacterial load, and treatment goals influence selection of dressing type, pressure setting, dressing change frequency, and use of interposing layer(s). A clinical series of 51 children with acute and chronic wounds successfully treated with NPWT was reported by Caniano et al.<sup>67</sup>

*Alginates.* Alginates are seaweed-based dressings designed for the management of moderately draining wounds. In adults, these dressings usually are used to control light bleeding; this has not been studied in the pediatric patient population.<sup>9</sup> Calcium alginates are not recommended for use in neonates secondary to calcium absorption concerns.<sup>19,30</sup>

*Topical enzymes.* While the safety and efficacy of topical enzymes in the pediatric population has not been studied, successful use in the management of pediatric burns and extravasation injuries has been anecdotally reported.<sup>39,68</sup> Although not specifically contraindicated, topical enzyme preparations have not been tested for safety or efficacy in the neonatal and pediatric populations. The manufacturer's recommended use of these drugs is only for persons >18 years of age.<sup>9</sup>

**Dressing change procedure and securement.** Although manufacturer guidelines for dressing changes must be followed, some dressing change procedures are unique to the pediatric population. For neonates and small children, it is ideal to have two people present (one to provide comfort and one to change the dressing).<sup>29</sup> As appropriate, family members can be involved, assisting with dressing changes and observing or cuddling/holding their child.<sup>29</sup> Patient distraction techniques can be used; when appropriate, a Child Life Specialist can be involved. Stress can be tempered by decreasing noise, bright lights, and excessive handling.<sup>29</sup> Dressing changes should be kept to a minimum consistent with the

needs of the wound, the need for monitoring, and manufacturer recommendations. Preparing dressings before uncovering the wound can help limit wound exposure time and resultant thermoregulatory stress and pain receptor exposure.<sup>29</sup>

As feasible, the use of tape on premature infant's skin should be avoided. When needed, dressings can be secured with latex-free stretchy tubular gauze netting materials. When a wound is over a joint, proper positioning should be ensured to prevent contracture development during wound healing.<sup>10</sup>

Also, collaborative treatment goals and wound healing outcomes should be established (eg, higher incidence of hypertrophic or keloid formation in those with darkly pigmented skin).<sup>10</sup>

**Irrigation procedures.** Because cold irrigants will increase patient stress and decrease wound bed temperature (thereby, ceasing polymorphic and macrophagic activity until restoration of normothermia occurs), only warm fluids should be used.<sup>29</sup> Aseptic techniques should be maintained.<sup>29</sup> Sterile water and normal saline are the most commonly recommended cleansing agents for pediatric wounds<sup>68</sup>; sterile water is preferred for neonates.<sup>24</sup> Among neonates, cleansers should be warmed to body temperature and normal saline diluted 1:1 with sterile water.<sup>24,60</sup> A 20-mL syringe with a blunt needle or a polytetrafluoroethylene (Teflon™) catheter should be used to gently flush away wound exudate.<sup>24</sup> Antiseptics should be avoided given their potential for tissue damage and absorption.<sup>24,60</sup>

**Pain assessment and management.** Pain assessment should be integral to every wound assessment.<sup>69-72</sup> Behavioral characteristics (crying, facial expressions, motor response, restlessness, or undue quietness) should be considered.<sup>69-72</sup> A valid and reliable pain assessment scale (eg, CRIES, CHIPPS, NIPS) can be used in conjunction with patient assessment.<sup>29,57,70-72</sup> (see Table 4). Institutional pain management guidelines should be followed.<sup>29</sup> Soft silicone-based dressings, hydrocolloid pastes, hydrocellular foams, and hydrogels coupled with analgesics, distraction, and guided imagery may be beneficial in pain management.<sup>9</sup> Where clinically appropriate, autolytic debridement can be facilitated through the use of hydrogels, hydrocolloids, foams, and pre-activated polyacrylate

with Ringer's solution dressings.<sup>2</sup> Securement devices such as tubular stretchy latex-free gauze netting can securely maintain dressing placement while allowing for atraumatic non-adhesive dressing removal.<sup>2</sup>

**Education.** Integral to education in pediatrics is recognition of each child's uniqueness, the developmental characteristics of each age group, and the psychological and psychosocial factors children face.<sup>70</sup> These young patients should be involved as feasible in care and allowed to make choices (eg, what they want to eat, selection of special stickers on their dressings). Peer-related activities should be encouraged as feasible and play therapy as age/developmentally appropriate.<sup>70</sup> If the child is of school age and returning to class, resources, education, and contact information should be provided to teachers and the school nurse.<sup>55</sup> Communication techniques/language used should be age-appropriate for the learner. For example, education of teenagers is best provided on a one-to-one basis with respect for their privacy. Educational materials that are concise and focused are best received.<sup>70</sup> The clinician needs to assess how much the patient and/or parent(s)/caregivers want to know and involve the family as feasible and when consistent with their wishes and that of their child. The patient and/or parent(s)/caregiver's level of understanding, expectations, coping skills, and access to sources of support should be assessed.<sup>70</sup> The patient and family's possible feelings of guilt associated with the cause of the wound and level of anxiety require consideration.<sup>29</sup>

**Wound assessment.** Wound assessment documentation in children generally follows those established for adults<sup>9</sup> and includes etiology, phase of healing, wound type (acute or chronic), location/distribution, dimensions (length, width, depth) measured in centimeters, presence of tunneling, undermining, sinus tracts measured in centimeters, tissue types (granulation, slough, eschar, epithelialization), exudate (amount, color, consistency, odor) and the presence of infection. The status of surrounding skin (intact, erythematous, hyperkeratotic, indurated, fluctuant, crepitant, candidal overgrowth, denudation secondary to adhesive stripping), level of pain, overall goals of care, patient/family goals of care, and previous treatments and outcomes also must be assessed and documented.

## Conclusion

Adult-based wound care practices provide a rudimentary foundation for neonatal and pediatric wound care but do not negate the need for developmentally specific evidence-based guidelines.<sup>9</sup> Most currently available guidelines and information are based on expert opinions and case studies. However, given the wide variation in percutaneous toxicity potential and developmental and integumentary maturity spanning from the very low birth weight premature infant through adolescence, clinicians desperately need age-appropriate, safe, and effective products, educational tools and research based guidelines from which to deliver safe and effective wound care practice.<sup>9</sup> - OWM

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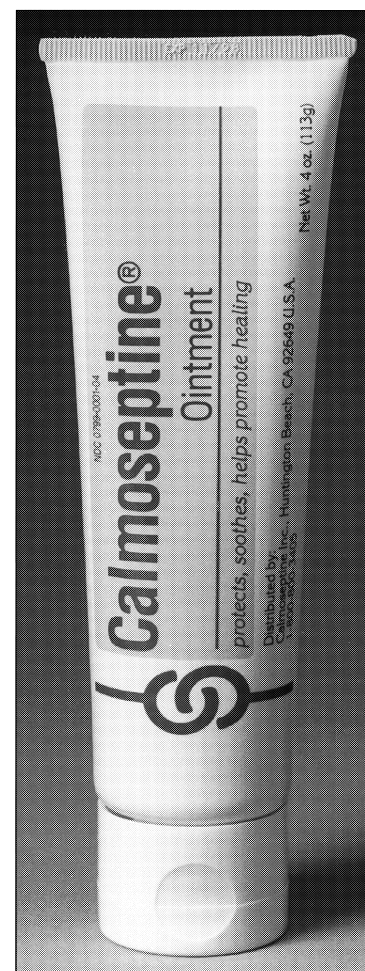
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# Inpatient management of children with recessive dystrophic epidermolysis bullosa: A review

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## Abstract

Recessive dystrophic epidermolysis bullosa is a disorder marked by skin and mucosal blistering after minimal trauma. Even the most routine procedures in the hospital, if done incorrectly, can precipitate extensive skin loss, pain, and scarring. Most providers have little experience working with patients with this degree of skin fragility. When a person with recessive dystrophic epidermolysis bullosa is admitted to the hospital, there are multiple considerations to keep in mind while strategizing an effective care plan: avoidance of new blisters with a “hands-off” approach; careful consideration of all indwelling devices; symptomatic management of pain, itch, and anxiety; coordination of dressing changes; aggressive treatment of skin infections; environmental and staffing considerations; and awareness of other chronic complications that affect care, such as anemia, malnutrition, and chronic pain. To minimize discomfort for patients with recessive dystrophic epidermolysis bullosa during the hospital stay, inpatient care teams should understand these considerations and modify the care plan accordingly. Prior preparation by the hospital facility and inpatient care team will facilitate the delivery of safe and effective care and greatly improve the overall patient experience.

## KEYWORDS

epidermolysis bullosa, health care delivery, immunobullous disease, quality of life

## 1 | INTRODUCTION

Inherited epidermolysis bullosa (EB) is a heterogeneous group of chronic skin disorders characterized by fragility and blistering of the skin and mucous membranes. EB is complex and multisystemic in severe subtypes. For individuals with recessive dystrophic EB (RDEB), even the most routine procedures, such as moving the patient or measuring vital signs, can precipitate blistering and extensive skin loss.

Most providers outside of EB specialty centers have limited knowledge about the accommodations and specific handling techniques that these individuals require. Although there are guidelines for the general care of children with RDEB, there are none specifically for care in the inpatient setting.<sup>1,2</sup> The purpose of this review is to provide a practical resource to help facilitate inpatient

admissions and safe and effective day-to-day treatment on the hospital floor for this vulnerable group.

The first half of this review will provide an overview of the clinical presentation of RDEB and commonly associated complications. The second half will review general inpatient management, including safe patient handling, initial patient assessment, and inpatient wound care for individuals with RDEB.

## 2 | PATHOGENESIS

Mutations in the gene that encodes collagen VII weaken the structural adhesion within the skin, allowing the skin layers to separate with only minimal trauma, resulting in blisters and erosions.<sup>3</sup>

### 3 | CLINICAL PRESENTATION AND ASSOCIATED COMPLICATIONS

Wounds can occur anywhere on the body. Blistering is often worse in areas subject to repeated trauma, such as the hands, feet, and bony prominences (Figure 1).<sup>4</sup> Chronic wounds can lead to scarring, joint contractures, pseudosyndactyly (mitten hand deformity), and greater risk of cutaneous squamous cell carcinoma.<sup>5</sup>

#### 3.1 | Pain and itch

Pain is an almost constant symptom in RDEB patients and can severely affect quality of life and complicate daily activities.<sup>6</sup> Acute pain results from the formation and expansion of bullae and the irritation of erosions, in addition to anal fissures and reflux.<sup>6</sup> Sources of chronic pain include chronically inflamed wounds, joint contractures, bone pain, and constipation.<sup>6</sup>

Individuals with RDEB can experience severe and debilitating itching, which can originate from healing wounds or intact skin.<sup>7</sup>

The mechanism underlying the itch in RDEB is poorly understood, but it is likely that it is due to the disease itself, as well as certain triggers such as inflammation, concurrent opioid use, heat, sweating, and stress.<sup>7</sup> Controlling itch is particularly important because chronic scratching can result in trauma and blister formation.

#### 3.2 | Infection

The bacterial burden of a wound exists on a spectrum, starting at one end as contamination, with the potential to progress to colonization, critical colonization, and ultimately frank infection.<sup>8</sup> Contamination and colonization are normal states and require no treatment, but critical colonization, a state in which the bioburden is enough to impair wound healing, should be treated with topical antimicrobials.<sup>8</sup> To minimize antimicrobial resistance, systemic antibiotics are typically reserved for frank infections. The diagnosis of infection and appropriate treatment are discussed in a later section in this review.



**FIGURE 1** Clinical presentation of recessive dystrophic epidermolysis bullosa: (A) right lateral back, (B) buttocks, (C) left arm, (D) right knee. Diffuse erosions and scarring typical of a patient with recessive dystrophic epidermolysis bullosa. Blistering can be worse in areas subjected to repeated trauma including the (B) buttocks, (C) elbows, and (D) knees

The most common culprit organisms are *Staphylococcus aureus*, *Streptococcus* species, and *Pseudomonas aeruginosa*.<sup>1,8</sup> Wound infection is generally diagnosed clinically according to wound size, exudate, odor, pain, surrounding erythema, and edema,<sup>8</sup> but these classic signs of inflammation can be diminished or obscured in chronic EB wounds.<sup>8</sup>

Systemic infections are less common than cutaneous infections but can be lethal because of chronic malnutrition and a weakened immune system and most often arise from cutaneous infection.<sup>2</sup>

### 3.3 | Nutrition

Maintaining adequate nutrition is paramount because malnutrition can impair wound healing,<sup>9</sup> but management of nutrition is complicated in EB because of high caloric demand secondary to accelerated skin turnover, blood and protein loss through wounds, recurrent infections, and chronic inflammation.<sup>2,9</sup> Low intake secondary to dysphagia and constipation compounds the risk of malnutrition.<sup>2,9</sup> Iron; zinc; selenium; folate; and vitamins A, D, and B6 deficiencies have been observed in association with EB.<sup>2</sup> Some of these deficiencies have been implicated in impaired wound healing, osteoporosis, and cardiomyopathy.<sup>2</sup> Mixed anemia secondary to iron deficiency and chronic inflammation is frequent in individuals with EB and may also contribute to impaired wound healing.<sup>9,10</sup>

### 3.4 | Gastrointestinal

The gastrointestinal tract is one of the most common sites of extracutaneous complications in EB.<sup>11</sup> Wounds in the oral cavity and esophagus can lead to odynophagia, dysphagia, unwillingness to eat, and reflux.<sup>11</sup> Dental caries and premature loss of teeth can complicate oral hygiene and feeding.<sup>12</sup> In the small and large bowel, wounds can cause protein and blood loss, contributing to anemia, hypoalbuminemia, hypoproteinemia, and malabsorption.<sup>11</sup> Anal erosions and fissures result in painful defecation and constipation, further decreasing willingness to eat.<sup>11</sup> Chronic blistering can lead to strictures and cause ankyloglossia, microstomia, dysphagia, chronic constipation, and megacolon.<sup>11</sup>

### 3.5 | Ocular

Corneal abrasions and blistering may occur because of the fragility of the conjunctiva and cornea.<sup>13</sup> Chronic corneal wounds can precipitate scarring. In the operating room, skin contractures may prohibit complete closure of the eyes, putting the person at risk of corneal damage.<sup>14</sup>

### 3.6 | Cardiac

Dilated cardiomyopathy is a rare complication of EB and is probably due to multiple factors, including micronutrient deficiencies (especially selenium and carnitine), chronic anemia, iron overload from transfusions, and viral myocarditis.<sup>15</sup>

## 3.7 | Renal and genitourinary

Blistering along the genitourinary mucosa can lead to dysuria.<sup>16</sup> Chronic blistering can lead to strictures and urethral meatus stenosis, which can result in urinary retention, bladder distention, hydroureter, and hydronephrosis.<sup>16</sup>

## 3.8 | Psychiatric

Depression is common in individuals with EB, who at times can have suicidal ideations or gestures.<sup>17</sup> They may also experience anxiety and posttraumatic stress disorder secondary to painful dressing changes. Social isolation secondary to the visibility of their skin involvement is common.<sup>18</sup>

## 4 | OVERVIEW OF INPATIENT MANAGEMENT

Successful inpatient management of an individual with RDEB requires a multipronged approach to care. Avoidance of new blisters is critical and is best done with a hands-off approach to patient handling. The use of any indwelling medical devices should be carefully considered, because insertion and removal can precipitate trauma. Symptoms of pain, itching, and anxiety are common in individuals with RDEB and should be regularly assessed and treated. Caring for an individual with RDEB can be a significant time commitment and may require certain staff members to become “specialized” in dressing changes. Dressing changes should be carefully coordinated to minimize discomfort. Skin infections are common and should be treated aggressively, as they can lead to life-threatening systemic infections. The team should be aware of the chronic complications commonly associated with RDEB that can affect care, such as anemia, malnutrition, and chronic pain.

## 5 | EMERGENCY DEPARTMENT CONSIDERATIONS

When an individual with RDEB is received in the emergency department, the most appropriate service to admit them to needs to be considered. In the United States, hospitalist services, for example, are likely to be the most experienced in coordinating inpatient care among consultants and tend to have more availability on the unit. Depending on the reason for admission and the severity of the illness, individuals with RDEB may be admitted to intensive care units, surgical services, or specialty services. Furthermore, this decision will differ for different countries according to the typical distribution of specialty trainees within ward services. Second, although we review general handling procedures below, patients will benefit from carrying a letter or card that outlines individualized care instructions to help facilitate and orient new caregivers.

## 6 | AVOIDANCE OF NEW BLISTERS

A major portion of inpatient care for RDEB is dedicated to preventing new blisters. Although completely preventing new blisters is impossible, adhering to the following suggestions can minimize the risk of developing new wounds and greatly increase patient comfort throughout the hospital stay (Figure 2).

### 6.1 | Pressure relief

Pressure areas are particularly at risk of rapid wound development.<sup>4</sup> A pressure-redistributing mattress should be used for the duration of the stay (Repose, Frontier Medical Group, Blackwood, Caerphilly, UK; AccuMax Quantum, Hill-Rom, Batesville, IN; Rest-Q, Comfortex, Winona, MN).<sup>4</sup> If the person is scheduled for surgery, a padded operating table should be used or the table should be lined with sheepskin.<sup>19</sup> Any furniture that will support the person's weight at any point during the hospital stay should also be padded, including the toilet seat, bath chair, and bed railing.<sup>4</sup> Egg crate padding can be cut to cushion these items.

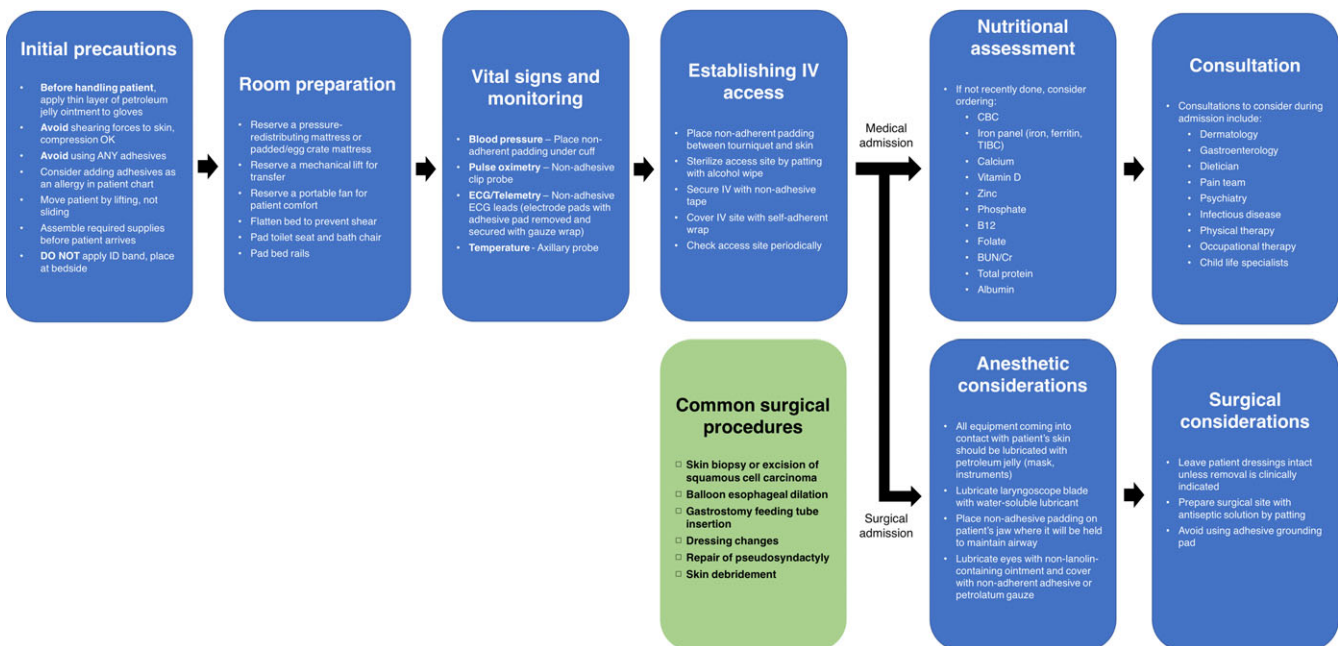
### 6.2 | Patient handling

Given the skin fragility and propensity to form blisters in individuals with RDEB, handling can be a challenge; a hands-off approach is advised whenever possible.<sup>4</sup> This is not to say that the person should be ignored. Essential care needs to be provided, potentially in a consolidated manner. When handling is unavoidable, several general management principles should be followed to minimize trauma (Figure 2):

- Before handling the person, apply a thin layer of ointment on gloves and medical devices that will have direct contact with patient skin.<sup>20</sup>
- Apply firm but gentle pressure; avoid shearing forces.<sup>20,21</sup>
- When moving the person, lift instead of sliding.<sup>20,21</sup>
- Avoid applying any kind of adhesive directly on the person's skin. If adhesives are accidentally used or are required to secure access, they can be removed safely using medical adhesive remover (Niltac, ConvaTec, Deeside, Flintshire, UK; Uni-Solve, Smith & Nephew, London, UK; Detachol, Ferndale Labs, Ferndale, MI).<sup>20,21</sup>
- Avoid rubbing of the skin.<sup>21</sup>

### 6.3 | Patient monitoring

Many of the aforementioned principles should be applied to modify the monitoring setup (Figure 2). Electrocardiographic lead adhesive pads should be removed and leads secured with gauze wrap or non-adhesive dressing (Mepitel, Mölnlycke Health Care, Gothenburg, Sweden; Silflex, Advancis Medical, Nottinghamshire, UK; Adaptic, Acelity, San Antonio, TX).<sup>2,21</sup> An oximeter clip probe should be used instead of an adhesive sensor.<sup>2</sup> Before taking blood pressure, several layers of nonadherent padding should be placed between the blood pressure cuff and skin as a cushion.<sup>2</sup> If monitoring of temperature is required, axillary probes are preferred because oral probes may cause oral blistering.<sup>20</sup> Indwelling urinary catheters should be avoided if possible because of the risk of developing urethral strictures. If urinary catheters are necessary, they should be well lubricated before insertion.



**FIGURE 2** Medical and surgical admissions flowchart. Medical and surgical admissions begin with similar preparatory steps but diverge after establishment of intravenous access



## 6.4 | Indwelling medical devices

Finding and maintaining vascular access can be particularly challenging in individuals with RDEB. Visualization and palpation of their veins can be extremely difficult. The most experienced providers are often needed to secure intravenous (IV) access; consultation with anesthesia or vascular access teams may be necessary. It is important to wrap multiple layers of nonadhesive padding around the limb before placing any tourniquet device.<sup>22</sup> The access site should be sterilized by patting rather than rubbing with an alcohol wipe. The line should be secured with nonadhesive tape and covered with self-adherent wrap.<sup>20</sup> IV lines tend to dislodge easily in individuals with EB, which can be emotionally and physically distressing for the patient and staff, so periodic monitoring is required.<sup>20</sup> When IV placement becomes a problem, finding oral alternatives to medications, if possible, should be attempted.

Central venous access may be preferable in cases in which a long-term hospital stay is anticipated and IV access is necessary. The benefits of establishing central venous access, including less potential trauma from repeated skin puncture and provision of a convenient access site, should be weighed carefully against the greater likelihood of systemic infection. As with peripheral access, central lines in individuals with RDEB are prone to catheter migration and dislodgement. In addition to securing the line with nonadhesive tape and self-adherent wrap, anchoring sutures can be placed for further support.<sup>23</sup> Placing sutures through the full thickness of the skin, deep to the cleavage plane, may minimize secondary trauma. It has been reported that a cuffed line is more secure than an uncuffed line in individuals with RDEB.<sup>23</sup> Tunneled lines are also safe to use, although femoral access should be avoided if possible.<sup>2</sup> Percutaneous IV central catheters are an alternative that allow for long-term access by securing on an extremity instead of a central location.

## 6.5 | Operating room considerations

Cutaneous dressings should be left in place unless removal is necessary (Figure 2).<sup>20</sup> To protect the eyes, a non-lanolin-containing ointment can be used as lubrication.<sup>24</sup> The eyes should then be covered with nonadherent adhesive or petrolatum gauze.<sup>25</sup> While preparing the surgical site with antiseptic, patting motions should be used instead of the typical rubbing motions.<sup>20</sup>

## 6.6 | Airway management

Microstomia, limited neck mobility, and ankyloglossia can all complicate airway management in RDEB.<sup>24,25</sup> Noninvasive ventilation should be avoided because it can precipitate facial trauma. Intubation using a fiberoptic bronchoscope is preferred because it can be less traumatic to the oral mucosa than direct laryngoscopy.<sup>25</sup> Endotracheal tubes should be half to one size smaller than predicted to avoid overinflation and trauma.<sup>25</sup> All equipment coming into contact with the person's skin or mucosa, including the facemask and

laryngoscope blade, should be well lubricated.<sup>14,25</sup> Nonadhesive padding should be placed on the jaw before manipulation.<sup>14</sup> Endotracheal tubes should be secured using cotton tape.<sup>17</sup> For a more comprehensive overview regarding anesthetic and surgical considerations, refer to the referenced articles.<sup>14,20,25</sup>

## 7 | INITIAL ASSESSMENT

### 7.1 | Pain and itch

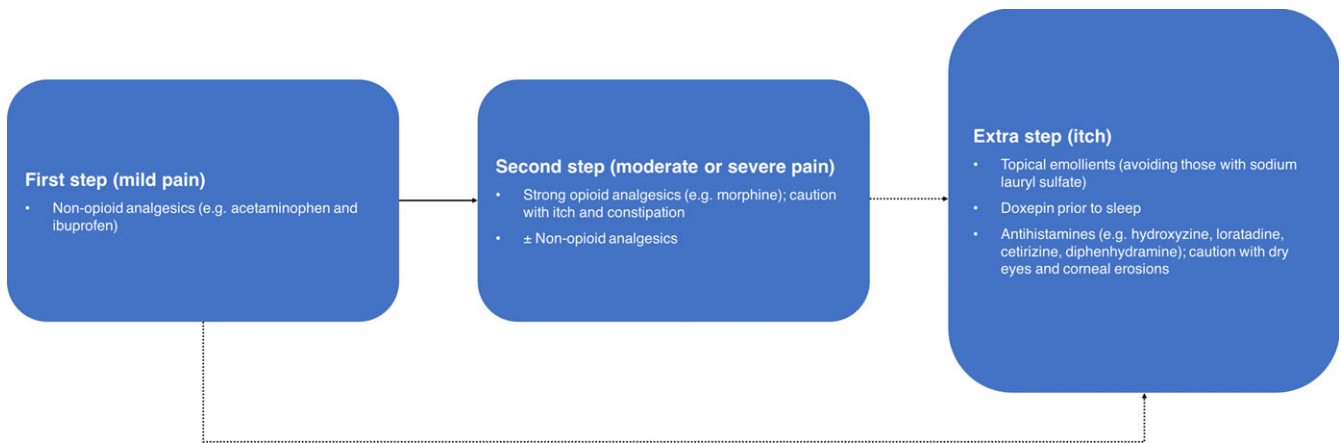
A modified version of the World Health Organization approach to pediatric pain management can be used to treat acute pain in individuals with RDEB (Figure 3).<sup>26</sup> With small wounds or minor pain, nonopioid analgesics (eg, acetaminophen, ibuprofen) can be used alone or together.<sup>26</sup> For moderate or severe pain, an opioid analgesic (eg, morphine) should be used,<sup>26</sup> although opioids can worsen pruritus and constipation.<sup>11</sup> Anxiety can exacerbate anticipatory pain, so anxiolytics such as diazepam and lorazepam taken before a painful procedure may be helpful.<sup>27</sup> When possible for painful or frightening procedures such as biopsies, provide adequate anxiolysis (eg, oral midazolam), local anesthesia, or other forms of conscious sedation (moderate or deep). Conscious sedation, with appropriate bedside monitoring, can be effective and timely, helping avoid general anesthesia and minimizing time in the operating room.

For chronic pain, many individuals with RDEB use long-acting opioids to maintain a base level of comfort.<sup>6</sup> Tricyclic antidepressants and gabapentin have been used successfully in managing chronic wound pain in EB.<sup>6,28</sup> Additionally, nonpharmacologic therapies, including distraction, visualization, and other forms of cognitive behavioral therapy, have been recommended.<sup>6</sup>

For itch, topical emollients may be useful.<sup>2</sup> Topical corticosteroids have been used with some degree of success, but providers should be wary of the greater systemic absorption in individuals with EB because of impaired barrier function.<sup>2,29</sup> Although it is not thought that histamines cause the itching in EB, antihistamines such as doxepin can be tried for their sedative properties, especially before sleep,<sup>1</sup> although they should be used with caution because they can exacerbate dry eyes and corneal erosions.

### 7.2 | Nutrition

As mentioned previously, individuals with RDEB are at risk of developing malnutrition, which in turn will impair wound healing.<sup>9</sup> Because of the gastrointestinal complications associated with RDEB, many children will have had gastrostomy tubes placed for long-term nutritional supplementation.<sup>7</sup> If the person has not had nutritional laboratory tests performed in the last 6 months, the team should consider ordering those listed in Figure 2. If the results suggest underlying malnutrition, supplementary nutrition with nasogastric or gastrostomy tube feeding is recommended. Consultation with a nutritionist is important for each hospital admission.



**FIGURE 3** Pain and itch management flowchart. This approach is based on the World Health Organization's approach to pediatric pain management, which was modified to include an additional step for itch management. The dashed lines indicate that itch management does not necessarily have to follow pain management in a stepwise fashion

### 7.3 | Consultation

Care for individuals with EB requires a multidisciplinary team.<sup>2,30-32</sup> Consultation with the inpatient teams outlined in Figure 2 should be considered during every admission. The child life specialists, in particular, are an important team to consult. They play a crucial role in the care team, explaining indwelling devices to patients and parents, providing nonpharmacologic pain relief through distraction or relaxation techniques, and providing much-needed companionship.

## 8 | GENERAL WOUND CARE

In individuals with RDEB, proper wound care and dressing technique are important for several reasons. Dressings protect the skin as a physical barrier, reduce the risk of wound infection, and promote an environment conducive to wound healing.<sup>21</sup> A properly dressed, noninfected wound will typically heal gradually over time. Any non-healing wound lasting longer than 6 months should be assessed for squamous cell carcinoma.<sup>30</sup>

### 8.1 | Dressing regimen

The specific aspects of a wound care regimen, such as frequency of dressing changes and types of dressings used, vary from person to person depending on several variables, including extent of disease involvement, wound location and characteristics, patient preference, and the presence or absence of infection (Figure 4). Most regimens will include a nonadhesive primary dressing, which provides the contact layer (Mepitel, Molnlycke Health Care, Gothenburg, Sweden; Urgotul, Urgo Limited, Shepshed, Loughborough, UK; Silflex/Siltac, Advancis Medical, Nottinghamshire, UK; Adaptic Touch, Acelyty, San Antonio, TX). Secondary dressings can be placed over primary dressings to provide additional cushion and to

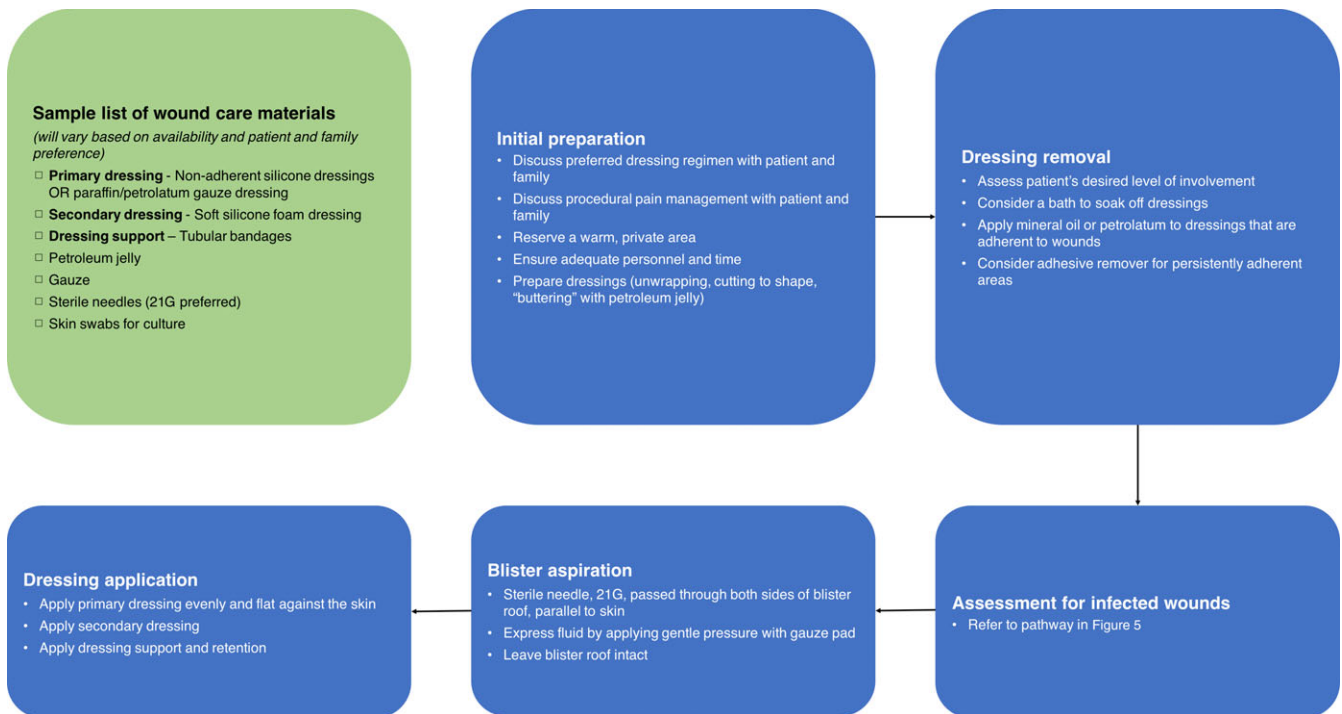
absorb exudate (Mepilex, Tefla, Medtronic, Minneapolis, MN; Polymem, Ferris Mfg. Corp., Fort Worth, TX). Lastly, the dressings are typically reinforced with tubular bandages or self-adhering wrap. Details regarding specific dressing types are outside the scope of this article but can be found in other comprehensive references.<sup>1,21</sup> In adapting a wound care regimen to the inpatient setting, it is important to solicit patient and family preferences. Individuals with RDEB and their caregivers have had a lifetime of experience optimizing their wound care regimen to best prevent injury and maximize comfort,<sup>4</sup> but in certain situations it will be necessary to make changes to a person's preferred wound care regimen to optimize wound healing. In these cases it is important to engage the person and family in dialogue to negotiate a wound care plan that is acceptable to them and the care team.

### 8.2 | Gastrostomy tube site care

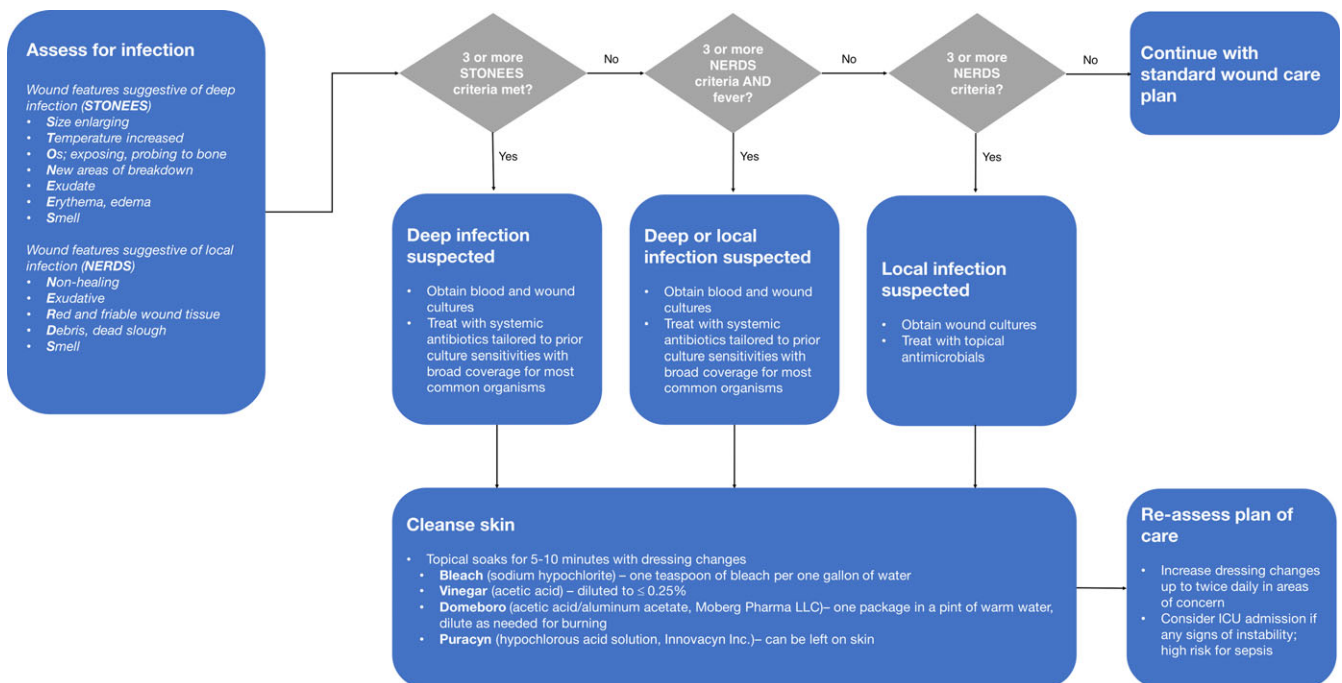
Gastrostomy tube sites should be dressed in a fashion similar to that of the rest of the skin. In the case of leakage from the gastrostomy site, sterile saline should be used for cleaning and a topical barrier applied to minimize further irritation.<sup>21</sup> A superabsorbent secondary dressing can help contain leakage and allow the site to heal gradually.<sup>21</sup>

### 8.3 | Patient comfort

Procedural pain management is an important topic to discuss with the person and caregivers because dressing changes can be a major contributor to discomfort.<sup>6</sup> Providers can further contribute to comfort by maintaining a warm room temperature and taking precautions to ensure privacy.<sup>4</sup> Preparing dressings beforehand by unwrapping them, cutting them to shape, and adding petroleum jelly ("buttering") will also facilitate the dressing process. To preserve patient autonomy, the care team should discuss with the individual how much



**FIGURE 4** General inpatient wound care flowchart. General inpatient wound care begins with preparation of the person and the environment, followed by dressing removal, assessment of infected wounds, blister aspiration, and dressing application. Assessment of a potentially infected wound is further elaborated upon in Figure 5



**FIGURE 5** Wound infection management flowchart. Treatment of an infected wound will depend on whether a superficial skin infection or a deep skin infection is suspected. If wound infection is suspected, the skin should be cleansed after cultures are obtained. ICU, intensive care unit

involvement he or she wants in the dressing changes. In academic settings, privacy and clinical care must be carefully balanced with the unique learning opportunity that the person could provide to learners of all levels.

### 8.4 | Staffing considerations

The time commitment for dressing changes is significant in inpatient care because one-on-one nursing is often required for several hours.

It is our experience that a consistent approach to dressing changes increases compliance and facilitates the dressing process. Thus, asking for dedicated staff who are able to specialize in dressing changes and form a primary nursing team can be helpful. Caring for a patient with RDEB can be distressing not only for the patient, but also the staff involved. As an example, the warm room temperature and wound odor during dressing changes can make for a taxing working environment.<sup>4</sup> Awareness and management of psychological trauma is therefore essential to keep these team members effective.

## 8.5 | Bathing

There is no established standard of care regarding bathing frequency.<sup>21</sup> While in the inpatient unit, we recommend bathing or cleansing every day to every other day during dressing changes.<sup>2,19</sup> Removing dressings during a bath may make the dressing change process more comfortable because the bathwater can help dissolve adherent crusting.<sup>27</sup> Tub water can be supplemented with vinegar (7.5 L of 5% acetic acid or 11.5 L of 3% acetic acid in a full 160-L bathtub) or bleach (120 mL of bleach in a full bathtub) to reduce microbial burden and reduce the risk of infection.<sup>2,7,8</sup> Vinegar and bleach have been shown to have antimicrobial properties for Gram-negative and Gram-positive bacteria, respectively.<sup>33,34</sup> Salt (900-1000 g in a full bathtub) can be added to the water to create an isotonic solution and decrease pain.<sup>7</sup> A whirlpool bathtub, if available, allows for concurrent gentle wound debridement.<sup>19</sup> If a bathtub is unavailable, a shower with a cushioned shower seat is also an acceptable option.<sup>7</sup>

## 8.6 | Blister management

Blisters should be sterilely lanced and drained to prevent blister extension.<sup>1</sup> Using a large-gauge sterile needle, puncture the blister through the blister roof, parallel to the skin. Multiple puncture sites followed by gentle pressure with sterile gauze can be used to facilitate drainage. Leave the blister roof in place to minimize infection risk.<sup>2</sup>

## 8.7 | Managing infection

Patients should be assessed for infection during each dressing change because skin infection impairs wound healing and can lead to life-threatening systemic infection.<sup>1,19</sup> Distinguishing a superficial from a deep skin infection is important because the latter necessitates more aggressive treatment (Figure 5). NERDS (nonhealing, exudative, red or bleeding, debris, smell) and STONEES (size increasing, temperature > 3°F above normal, os [probes to or exposes bone], new areas of breakdown, erythema or edema, exudate, smell) are two mnemonics that may help providers clinically assess for wound infection, as they describe the clinical features of superficial and deep skin infection, respectively.<sup>35</sup> Although these mnemonics have not been validated in wounds related to EB, they have been validated for use in chronic wounds and recommended for use in EB in an expert consensus statement.<sup>1,35</sup>

If three or more of the STONEES criteria are met, the person will require a systemic agent.<sup>1</sup> Similarly, if three or more NERDS criteria are met, and the person exhibits systemic symptoms (fever, malaise), he or she should be treated using a systemic agent.<sup>1</sup> Systemic agents should begin with broad coverage for the most common organisms, including *S. aureus*, *Streptococcal* species, and *P. aeruginosa*.<sup>7</sup> Current and past bacterial culture results should then be used to tailor coverage.<sup>1</sup>

If three or more of the NERDS criteria are met, but the person does not have systemic symptoms, the wound should be treated with topical antimicrobials to decrease microbial burden.<sup>1</sup> Lipid-stabilized hydrogen peroxide cream has broad antimicrobial coverage and is well tolerated in individuals with RDEB.<sup>8</sup> Silver sulfadiazine also has a broad spectrum of activity, although it should be used for only a short period of time because argyria has been reported in individuals with RDEB with prolonged exposure to silver.<sup>8,36</sup> Topical antibiotics, including gentamicin and mupirocin, can be effective in the short term but should also be used cautiously in longer hospital stays to avoid the development of microbial resistance and adverse events from systemic absorption.<sup>22,37</sup>

If infection is suspected, the wound care plan should be modified appropriately. The frequency of dressing changes to the area of concern may need to be increased to prevent irritation secondary to excess wound exudate.<sup>21</sup> The wear time for the specific type of secondary dressing used will dictate how frequently dressings will need to be changed, because some manufacturers recommend changing when exudate is observed on the outer surface of the dressing and some recommend changing when wet or heavy.<sup>21</sup> Additionally, infection can amplify wound pain, so the pain regimen should be adjusted accordingly. Deep sedation with IV propofol and ketamine has been used successfully for dressing changes and deep whirlpool baths in individuals with extensive wound infection.<sup>38</sup>

## 9 | CONCLUSION

Individuals with RDEB experience complications in multiple organ systems, which complicates life inside and outside of the hospital. To minimize discomfort for these individuals during a hospital stay, inpatient care teams will need to factor in the multiple considerations addressed in this text while strategizing the care plan. Prior preparation by the hospital facility and inpatient care team will facilitate delivery of safe, effective care and greatly improve the overall experience of an individual with RDEB.

## ACKNOWLEDGMENTS

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Epidermolysis  
Bullosa practical  
care guidelines

## Adult Surgical Procedures

**DEBRA is the only charity supporting people living and working with EB (Epidermolysis Bullosa) – a rare genetic condition which causes the skin to blister and shear at the lightest friction, or even spontaneously.**

## **Our purpose**

We have a vision of a world where no one suffers from EB.

Until that day, we offer specialist care to those who need it.

We give support to people and families affected.

And we provide real hope for the future by funding pioneering research which will one day find a cure.

## **Our service**

We provide information, practical help and professional advice through our Nursing and Social Care teams.

In partnership with the NHS, DEBRA's Specialist Children's and Adults' Nursing teams work throughout the UK, providing individual specialist healthcare advice and support to both people with EB and their carers, both in the community and in specialist hospital centres in London, Birmingham and Scotland.

DEBRA's Social Care team works with individuals and families, providing information, advice, advocacy and support on issues such as benefits and finance, housing, education and employment, thereby empowering and enabling people with EB to make their own life choices.

Details for the Nursing and Social Care teams, all DEBRA literature, including our 'In Touch' newsletter, information about our Holiday Homes, local or general meetings, are available on our website or through the DEBRA offices.

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These guidelines were originally generated for adult patients under the care of the DEBRA adult EB team & St Thomas' Hospital, London. We would be very happy to offer general advice, however your patient may already be under the care of another EB team. If so, please contact them directly (contact details on back page).

# Guidelines for the practical care of adult patients with Epidermolysis Bullosa during surgical procedures.

## Aim

To provide all staff involved with the care of patients with Epidermolysis Bullosa (EB) undergoing surgical or invasive procedures with clear guidelines and advice to ensure best practice at all times. This is in line with the WHO safe surgical checklist guidance of 2009<sup>(5)</sup>.

## Rationale

EB is a group of rare genetically determined disorders characterised by excessive susceptibility of the skin and mucosa to blister even after trivial shear forces and mechanical trauma. Management of those with EB is often complex and undergoing even routine procedures has the potential to compound their already difficult condition. Whilst in hospital there is a risk of significant skin or mucosal damage and secondary complications as a result of undergoing routine general procedures.

## Introduction to EB

There are 4 main subtypes of EB:

EB Simplex, Junctional EB, Dystrophic EB and Kindler's Syndrome.

It is those affected by Dystrophic EB who will be seen most frequently as they may require, as a consequence of their disease, frequent diagnostic or therapeutic procedures under general anaesthetic.

Common surgical procedures include repair of syndactyly ("mitten glove" deformity), release of contractures, dental extraction, oesophageal dilatation, formation and repair of gastrostomy sites, excision of Squamous Cell Carcinoma, skin grafting and limb amputation.

The EB patient is the expert in managing the condition and will guide health professionals wherever possible. However, they are most vulnerable when asleep as they are unable to self-advocate or advise staff about necessary precautions to be taken<sup>(3)</sup>. Forward planning and communication is the key to a successful outcome.

## Pre-Assessment Guidance

Patients with EB have a number of important issues to address in the pre-operative evaluation. If possible, seeing these patients in consultation a week or two ahead of the operative date is useful because it allows data to be collected and consultation to occur in an unhurried manner that does not risk delaying surgery<sup>(6)</sup>.

Obtain records of previous anaesthesia	Valuable source of information regarding optimal management of the patient with EB undergoing the procedure.
Full Blood Count U&E Clotting Screen	For taking blood samples a gentle pair of hands is often better than a tourniquet.  Iron deficient & anaemia of chronic disease are common.  Renal & cardiac dysfunction may be found in EB.
Assess for possible renal & cardiac complications	May be present in EB & pre-operative echocardiogram should be considered.
BMI	Malnutrition & low body weight & BMI are frequently seen.
MRSA screen Infection control	Treat as per local guidelines.  Infection related to compromised skin integrity & poor immunity related to malnutrition & chronic disease is common in EB.  Treat as per local guidelines & prophylactic antibiotics should be considered.
Gastro-Oesophageal Reflux Disease is common & there is a high risk of aspiration	Patients with EB have a higher risk for gastro-oesophageal reflux <sup>(6)</sup> Antisecretory/mucosal protectant prophylaxis may be required.  Occurrence of oesophageal strictures is common & anatomically these develop high in the oesophageal tract. Those with oesophageal strictures may have pooled secretions & particulate matter that put them at risk of aspiration <sup>(6)</sup> .
Review recent or long term corticosteroid use	Systemic & topical use.
Airway assessment	Microstomia & limited mouth opening, fixed & scarred tongue, limited neck movement due to contractures, poor dentition & oral blistering are all common features.  Dental caries & restorative dental work may be extensive.  For detailed advice please contact the EB nursing team.
Musculoskeletal assessment	Extensive contractures & osteopaenia/osteoporosis may be present. This may result in difficulties achieving optimum procedural positioning.
Psychological preparation	Reassurance & full explanation of the procedure is essential.  Contact the EB Psychotherapist via EB office if appropriate.

## Pre-Operative Preparation and Anaesthetic Management

Contact EB Adult Nursing Team	<p>For specialist advice &amp; support during admission (see details below).</p> <p>In addition Dermatology Outreach Nurses may provide practical help with dressings.</p>
Identity bracelets	Apply with extreme care – ideally over a protective dressing or tubifast.
“Handle with Care” stickers	Available from EB team – ensure these are placed on all patient notes & (if patient consents) they can also be applied to gown as an easy visual reminder.
Anti embolitic management	<p>Avoid TEDS.</p> <p>Flowtron boots are recommended where available.</p>
Supply of suitable dressings & Silicone medical adhesive remover e.g. Apeel® or Niltac® (or a 50/50 preparation) should be taken to theatre with patient	To avoid inappropriate use of adherent dressings & ensure the safe removal of any dressing, tape or monitoring stickers that may be inadvertently applied.
Moving & Handling Issues Pressure Relief	<p>Request assistance &amp; guidance from the patient as appropriate.</p> <p>Minimise the number of transfers.</p> <p>e.g. anaesthetise in operating theatre to avoid at least one episode of patient transfer<sup>(2)</sup>.</p> <p>Transfer using “lift and place” approach<sup>(1)</sup> – never slide.</p> <p>Use of “Pat Slides” is strictly contraindicated.</p> <p>Gloved hands in contact with the skin can cause damage to fragile skin – where feasible gloves should be well lubricated. (Take care to ensure gloves/hands are free from lubrication when handling equipment).</p> <p>EB Nursing team will provide advice appropriate to each individual regarding safest transfer – use of the <i>HoverMatt</i>® is highly recommended for all lateral transfers – contact the EB office or nursing team to arrange use.</p> <p>Use KCI RIK operating table pads for maximum pressure relief.</p>

Skin	Blisters & erosions may be present & dressings should be left in situ wherever possible. If removal of dressings is unavoidable, cling film may be used as a temporary covering to the skin.
Skin preparation	Avoid rubbing or stroking the skin.  Cleansing fluid can be poured over limb & patted dry or a cleansing swab can be placed on skin, gentle downward pressure applied & then removed.
IV access	Use gentle pressure to distend veins & aid cannula insertion. If a tourniquet is used this should be well padded.  Secure cannula with Episil® or Mepitac® tape & k-band®.  In addition, the skin beneath the cannula should be protected from trauma e.g. with Mepilex Transfer®, Mepilex Lite® or similar non-adherent dressing.  To secure central & arterial lines suturing should be considered.
Eyes	Never tape the eyelids – instead close gently & then cover with Geliperm® hydrogel sheet.  Eyelid contractures may be present. There is a risk of corneal abrasion.
Theatre drapes	Secure drapes with a carefully positioned towel clip. Avoid use of sticky tape.
Airway management	After securing the airway, the priority is the avoidance of trauma & further bullae formation – care must be taken when applying face masks, head tilting and lifting chin.  Wrap foam padding around tape ties before securing ET tube to protect the skin on the face & neck.  Cover the areas of face where mask &/or anaesthetist's fingers will rest with a protective layer of suitable non-adherent dressing such as Mepitel One®, Geliperm® or ActiformCool®.  Cricoid pressure is not contraindicated but pressure should be applied evenly and with no sideways movement <sup>(4)</sup> .

Detailed advice & guidance on choice of anaesthesia & airway management (intubation) is available in Guys & St Thomas' NHS Trust Anaesthetic Guidelines<sup>(1)</sup>. Please contact the EB nursing team for more information if required.

## Epidural Management

<p>Skin preparation as above.</p>
<p>Avoid use of “sticky drapes”.</p>
<p>Use of adhesive dressings to safely secure the epidural is unavoidable unless suturing (using a tunnelling method) is an option. Use of medical adhesive removal spray is essential when removing the epidural in order to avoid skin damage.</p>
<p>Protect the skin on the spine from potential damage caused by pressure from cannula by applying Mepilex Transfer® to the back underneath the line.</p>
<p>Wherever possible allow the patient/carer to remove dressings when the epidural is removed.</p>

## Intra-Operative Management and Monitoring

<p>Oxygen saturation monitoring</p>	<p>Nail &amp; hand deformity is common &amp; therefore it may not be possible to apply the probe to a digit. It may be necessary to use the ear lobe.</p> <p>If the finger probe is used it is suggested that the finger is well lubricated &amp; then protected with the tip of a glove before the probe is applied<sup>(2)</sup>.</p>
<p>BP</p>	<p>Apply 2-3 layers of soft padding (e.g. soft-band) beneath the cuff.</p>
<p>ECG</p>	<p>Use non-adhesive electrode pads wherever possible.</p> <p>Adhesive electrodes can be used if the adhesive part is removed &amp; the electrode secured in place with Mepitac®. Alternatively the electrode can be placed onto a defib pad sandwiched between two pieces of Mepitel®<sup>(2)</sup> or stuck directly onto Mepitel One® (Note that the readout can be erratic with these methods).</p>
<p>Temperature control &amp; monitoring</p>	<p>Standard tympanic temperature monitoring advised.</p> <p>Avoid tempadots.</p> <p>To maintain patient body temperature during the procedure an adjustable warming system (e.g. Bair Hugger) may be used.</p>
<p>Trolley, bed &amp; equipment</p>	<p>Ensure that all equipment coming into contact with the patient is well padded &amp; lubricated where appropriate.</p>
<p>Incidental pressure</p>	<p>Avoid staff inadvertently leaning on or resting instruments on the patient.</p>
<p>Diathermy</p>	<p>Consider use of bipolar diathermy or harmonic scalpel as adhesive pads should be avoided wherever possible.</p> <p>If unavoidable then the pad should be removed with extreme caution &amp; generous use of silicone medical adhesive remover spray or 50/50.</p>



## Occasional & non-routine intra-operative procedures

Urinary catheterisation	Use a small gauge silicone catheter (10ch or smaller) & ensure that it is well lubricated.  Position catheter tubing with care to avoid potential skin damage.
Naso-gastric tube insertion	Avoid use of rigid NG tube.  Lubricate small gauge tube well before insertion & position with care.
Use of stirrups for positioning during procedure	If required the legs should be well padded for protection first.

## Post Operative Management & Analgesia

Extubation	Awake extubation should be considered to minimise potential airway obstruction & the need for mask pressure on the unprotected face.  Oropharyngeal suctioning can lead to life threatening bullae formation <sup>(4)</sup> .  Post Operative oxygen should be administered via a face mask padded with Mepilex Transfer <sup>®</sup> . Alternatively protect the face with a dressing such as Geliperm <sup>®</sup> .
Pharyngeal suction	Direct vision suction only.  Avoid yanker suckers where possible.
Nutritional requirements	Special diets may be required & the advice of a dietitian with knowledge of EB should be sought (EB dietitian can be contacted via EB office).  Constipation may be a chronic problem.  Many people with EB will have a gastrostomy.
Beds/ mattresses	Continuous pressure relieving system e.g. Repose <sup>®</sup> should be used. The KCI Visio <sup>®</sup> mattress should be used if the patient is at high risk.  Wherever possible the patient should have an electric bed to enable self positioning & reduce the risk of skin damage as result of manual handling.
Analgesia	Consider use of regional anaesthesia as an adjunct to general anaesthesia <sup>(1)</sup> .  Pain management as per WHO analgesic ladder is recommended.  PR analgesia should be used with extreme caution (risk of damage to fragile anal margins).  Use of morphine is NOT contraindicated in EB <sup>(1)</sup> .

## Theatre Essentials

- SpO2 ear probe
- ECG electrodes placed on defib gel pads
- Mepitel One®, Geliperm® and ActiformCool® to protect face from masks
- Silicone medical adhesive remover e.g. Apeel® or Niltac® spray to remove tapes & dressings safely
- Soft band
- Mepilex Transfer® to protect back if Epidural used
- Mepitel®, Mepilex® or Episil® to secure venflon
- Mepitac® to secure ETT or LMA. Alternatively use foam padding around tape ties
- Cling Film to protect skin temporarily if dressings are removed
- Selection of Classic LMAs size 2- 2.5
- Nasal Mask (Goldman)
- Selection of laryngoscopes
- Fibre optic laryngoscope

## To be avoided...

Anything sticky!

But don't panic! If something has been inadvertently applied then remove using silicone medical adhesive remover spray. If this is not available or appropriate please leave in situ and ask the patient to remove it later. Much damage occurs when people panic and try to remove something immediately – unless it is essential that the item is removed it is far better to leave it to the patient or their carer.

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<b>Product</b>	<b>Company</b>
Flowtron Boots	Huntley Healthcare Limited
Apeel	Clinimed Limited
Niltac	Trio Healthcare International Limited
HoverMatt	Hovertech International
KCI RIK	KCI Medical Limited
KCI Visio	KCI Medical Limited
Episil	Advancis Medical
Mepitac	Molnlycke Healthcare
Mepital One	Molnlycke Healthcare
Mepilex Transfer & Mepilex Lite	Molnlycke Healthcare
K band	Urgo Ltd
Geliperm	Geistlich Sons Limited
ActiFormCool	Activa Healthcare Limited
Bair Hugger	Arizant UK Limited
Repose	Frontier Therapeutics Limited

### Further support and advice

Further details of products listed in Guidelines can be obtained from the adult nursing team contacts listed on the back page.

## Contact details

All Nursing & Social Care Services can be contacted Monday to Friday 9am-5pm.

### DEBRA Adult Nursing Service – Linked to St Thomas’ Hospital

Secretary to the EB Adult Nurse team	01527 456968 (8.00am – 2pm Mon – Fri)
Hospital – EB Secretary	0207 188 6399
Out of hours on call dermatologist	0207 188 7188
EB Nurse Consultant (Adults)	07775 688324 (9.00am – 5pm Mon – Thur)

### DEBRA Children’s Nursing Service – Linked to Great Ormond Street Hospital

EB team	0207 829 7808
Emergency on call service	0207 405 9200 (ask for EB Nurse on call)

### Children’s Nursing Service – Birmingham Children’s Hospital

EB team	0121 333 8224
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### Adult Nursing Service – Solihull Hospital

EB team	07846 986987 including out of hours
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### Scottish Nursing Service

Nursing team	01698 477777
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### DEBRA Social Care Managers

South England	01344 771961
Midlands	01299 826999
North England	07920 231271
Scotland	01698 477777
General enquiries	01344 771961
DEBRA Office – Director of Nursing & Social Care	01344 771961



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## Material

Animal tissues :	No
Human blood derivatives :	No
Natural rubber latex :	No
Medicinal substances :	No
Phthalates :	No
Polyvinyl chloride :	No

## Product Composition Fibre, Gauze and Nonwoven Products

Product Component	Composition
Absorption material	Viscose/Polyester nonwoven

## Product Performance Conventional Wound Dressing Products

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Liquid absorbency time	EN 1644-1 (B)	T-214	s	≤ 5	1,85
Liquid absorptive capacity	EN 1644-1 (C)	T-215	%	>700	942
Grammage of material	ISO 9073-1	T-266, WSP 130.1,	g/m <sup>2</sup>	Not specified	39,9
Thickness of material	EN ISO 9073-2	T-267, WSP 120.6	mm	0.53<x<0.65	0,54
Bending length, MD	EN 1644-2 (E) or EN ISO 9073-7	T-307, WSP 90.5	mm	15<x<30	24
Tensile strength, wet CD	ISO 9073-3 or ASTM D5034	T-229	N	>4.5	9,13
Tensile strength, wet MD	ISO 9073-3 or ASTM D5034	T-229	N	>4.5	39,1
Linting, dry	EN 1644-2 (F)	T-1006	particles	<3000	459
pH	EN 1644-1 (F)	T-314	N/A	4.4 ≤ x ≤ 8.2	6,7

## Technical

## Dimension

Dimension text	Dimension value
Product	10 cm x 10 cm

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

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

Regulation type(s)	MDD Class I	Locally Regulated
CE Certificate Number :	CE 01966	
Notified body medical devices/PPE :	BSI (2797)	
Intended use MDD :	Skin cleansing prior to surgical operation, wound cleansing and protection and to absorb wound exudate.	
Sales released in :	Austria, Bulgaria, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden	Moldova (the Republic of), Russian Federation, Turkey

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

EN 1041, EN 556-1, 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 10993-10, EN ISO 10993-18, ISO 14001

## Removable label

No

## GMDN Code (Global Medical Device Nomenclature)

48131 Non-woven gauze pad, sterile

## Reusability

Single use

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# Mepilex® XT

The highly conformable foam dressing with Safetac® technology suitable for all wound healing stages

## Safetac® layer

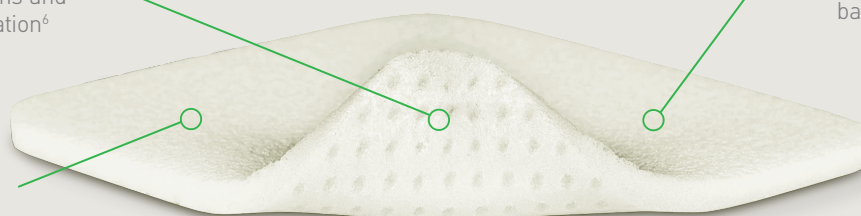
- Reduces pain and trauma at dressing change<sup>3,4</sup>
- Does not adhere to the moist wound bed but to dry skin only
- Seals the wound margins and reduces risk of maceration<sup>6</sup>

## Polyurethane backing film

- Breathable
- Waterproof
- Barrier to viruses and bacteria > 25nm<sup>8</sup>

## Polyurethane foam pad with exudate channels

- Enhanced exudate management capacity
- Absorbs viscous exudate<sup>2</sup>
- Works well under compression<sup>1,2</sup>
- Conformable and flexible foam with a pattern



**Safetac**<sup>®</sup>  
TECHNOLOGY

- Effectively manages a wider range of exudate<sup>1,2</sup> - absorbs viscous exudate<sup>2</sup>
- Non-traumatic to the wound and surrounding skin<sup>3</sup> - fewer disturbances to the wound
- Less painful during dressing changes<sup>4</sup> - less stress for patients<sup>5</sup>
- Enhanced exudate management<sup>1</sup> - reduced risk of leakage and maceration<sup>6</sup>
- Excellent conformity<sup>7</sup> - Promotes patient comfort during wear

## Proven choice for a better outcome

Safetac\*, pioneered by Mölnlycke, delivers above and beyond the ordinary. Proven to help optimize the wound healing journey and even prevent wounds, dressings with Safetac are the safe choice for patients and a champion for higher standards in wound care.

In fact, we have a wealth of evidence that supports the clinical and economic benefits of dressings with Safetac, including Mepilex®, Mepitel®, Mepiform® and Mepitac®. To date, these dressings have helped millions of patients worldwide<sup>7-9</sup>.

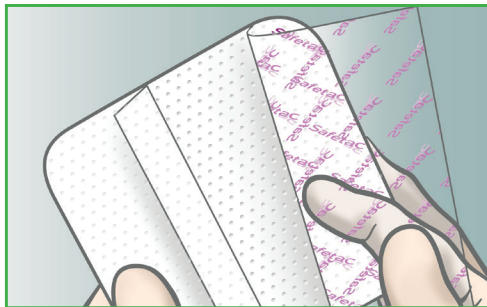
\* A unique proprietary technology exclusive to Mölnlycke Health Care

**Safetac**<sup>®</sup>  
TECHNOLOGY

Mepilex® XT

  
Mölnlycke®

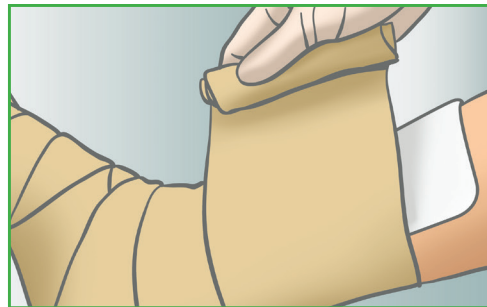
## Directions for use



**1.** Cleanse the wound in accordance with normal procedures. Dry the surrounding skin thoroughly. Remove the release films. For best results, Mepilex® XT should overlap the dry surrounding skin by at least 1-2 cm for the smaller sizes (sizes up to 12.5 x 12.5 cm), and 5 cm for the larger sizes in order to protect the surrounding skin from maceration and excoriation.



**2.** Apply the dressing securely. If required, Mepilex® XT can be cut to size. Do not stretch. Mepilex® XT does not need to be cut to the size of the wound when compression is used.



**3.** When necessary, secure Mepilex® XT with a bandage or other secondary fixation product. Mepilex® XT may be left in place for several days depending on the condition of the wound and surrounding skin.

## How Mepilex®XT works

Mepilex® XT is a soft and highly conformable foam dressing with a pattern on the wound contact side that can effectively manage a wider range of exudate and maintain a moist wound environment.

The Safetac® layer seals wound edges, preventing the exudate from leaking onto surrounding skin, thus minimizing the risk of maceration. The Safetac® layer ensures the dressing can be changed without damaging the wound or surrounding skin, or exposing the patient to additional pain.

## Benefits of Mepilex® XT

- Can be used in all healing stages
- Minimizes pain and trauma during dressing changes
- Minimizes stress caused by pain during dressing changes, to reduce delays in healing
- Minimizes maceration, and effectively manages a wider range of exudate for an optimized wound healing environment
- Stays in place allowing for “hands-free” application to facilitate use of compression or retention bandages<sup>2</sup>
- Well suited for use under compression bandages
- Can be cut to size if required
- Promotes patient comfort during wear
- Can remain in place for several days depending on the condition of the wound<sup>4,9</sup>
- Can be lifted and adjusted without losing its adherent properties
- Non-sensitizing<sup>10</sup>

### References:

1. Fluid handling and retention properties Mepilex XT : Report no. 20130123-006 [SMTL]. 2. Fluid handling and retention properties with Viscous test Fluid Mepilex XT, Report No. 20130104-004/ 20121012-004/20130104-004 [MHC]. 3. White R. et al. Evidence for atraumatic soft silicone wound dressing use. Wounds UK, 2005. 4. White R. A Multinational survey of the assessment of pain when removing dressings. Wounds UK, 2008. 5. Upton D. et al. The Impact of Atraumatic Vs Conventional Dressings on Pain and Stress in Patients with Chronic Wounds. Journal of Wound Care, 2012. 6. Wiberg A.B. et al. Preventing maceration with a soft silicone dressing: in-vitro evaluations. Poster presented at the 3rd Congress of the WUWHS, Toronto, Canada, 2008. 7. Meuleneire F and Foster A. Local treatment of heel pressure ulcers with a silicone foam dressing. Poster presentation. WUWHS, 2008. 8. External Test Lab Report no. 413098 (Nelson Laboratories). 9. Eager CA. Comparison of two foams through the measurement of healing time, frequency of dressing changes and peri wound status. Poster presentation. Advanced Wound Care and Medical Research Forum on Wound Repair, 2001. 10. Biocompatibility Evaluation, Filed in MHC.

## Indications for use

Mepilex® XT is designed for a wide range of exuding acute and chronic wounds in all healing stages.

## Precautions

- Do not use on patients with known sensitivity to the dressing or its components.
- In case of signs of clinical infection, consult a health care professional for adequate infection treatment.
- Do not use Mepilex® XT together with oxidizing agents such as hypochlorite solutions or hydrogen peroxide.



## Mepilex® XT Assortment (Sterile packed)

Art. no	Size cm	Pcs/Box	Pcs/Case
211015	5 x 5	5	40
211100	10 x 10	5	70
211200	10 x 20	5	45
211300	15 x 15	5	25
211500	20 x 50	2	12