

**PRODUCT SPECIFICATION**

<b>Product name</b>	Polyfield Patient Pack
<b>Product codes</b>	6075AF (Small) 6076AF (Medium) 6077AF (Large)
<b>Range</b>	Premier®
<b>Type</b>	Sterile
<b>Sterilization method</b>	EO



<b>Primary use</b>	Polyfield patient packs are ideal for the use in assisting the control of infection and minimising the risk of cross infection during the management of the wound.
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<b>Labelling</b>	Product name, Premier Logo, Code Ref, lot number, Expiry Date, Single use, sterility symbol and CE Marking
<b>Packing</b>	20 packs per inner box / 80 packs per outer carton

**6075AF Polyfield Patient Pack (Small)**

PACK CONTENT			
Component Code	Description	Qty	Material
Y20058	Blue Small Nitrile Gloves (accelerant free)	1 Pair	Nitrile
B02213-0280	White Non Woven swabs 10x10cm 4ply 25g/m2 ± 10%	7	50% Polyester 50% Viscose
Y22042	White Laminated sterile field 40x40cm	1	Laminated crepe paper
P449428	White disposal bag 27 x 46 cm	1	PE
Y22010	White Dressing Towel 38x43cm	1	Wood pulp fibre 43g/m2; film 15g/m2
Y22040	Dressing Towel 38x37cm	1	Wood pulp fibre
Y25011	White apron 69x 135cm	1	PE
Y33020	Measuring tape 10cm	1	Paper

**6076AF Polyfield Patient Pack (Medium)**

PACK CONTENT			
Component Code	Description	Qty	Material
Y20059	Blue Medium Nitrile Gloves (accelerant free)	1 Pair	Nitrile
B02213-0280	White Non Woven swabs 10x10cm 4ply 25g/m2 ± 10%	7	50% Polyester 50% Viscose
Y22042	White Laminated sterile field 40x40cm	1	Laminated crepe paper
P449428	White disposal bag 27 x 46 cm	1	PE
Y22010	White Dressing Towel 38x43cm	1	Wood pulp fibre 43g/m2; film 15g/m2
Y22040	White Dressing Towel 38x37cm	1	Wood pulp fibre
Y25011	White apron 69x 135cm	1	PE
Y33020	Measuring tape 10cm	1	Paper

The information provided within this Data Sheet is correct as of last revision but it is subject to change without notice.

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6077AF Polyfield Patient Pack (Large)			
PACK CONTENT			
Component Code	Description	Qty	Material
Y20060	Blue Large Nitrile Gloves (accelerant free)	1 Pair	Nitrile
B02213-0280	White Non Woven swabs 10x10cm 4ply 25g/m <sup>2</sup> ± 10%	7	50% Polyester 50% Viscose
Y22042	White Laminated sterile field 40x40cm	1	Laminated crepe paper
P449428	White disposal bag 27 x 46 cm	1	PE
Y22010	White Dressing Towel 38x43cm	1	Wood pulp fibre 43g/m <sup>2</sup> ; film 15g/m <sup>2</sup>
Y22040	White Dressing Towel 38x37cm	1	Wood pulp fibre
Y25011	White apron 69x 135cm	1	PE
Y33020	Measuring tape 10cm	1	Paper

**NITRILE GLOVES SPECIFICATION**

Dimensions –BS EN 455-2	Small	Medium	Large	Force at break (BS EN 455-2)	≥ 6.0 N (during shelf life)
Palm width (mm)	85± 5	95± 5	106± 5		≥ 6.0 N (after challenge testing)
Length (mm)	240min	240min	240min		
Residual powder (BS EN 455-3)	< 2 mg/glove				
Residual protein	< 20 ug/g				
<b>Freedom from holes (BS EN455-1)</b>					
Water tight test	General inspection level I, AQL 1.5				

**QUALITY STANDARDS**

Quality certification	ISO 13485:2003
CE Classification	Class 1s - Medical Device Directive 93/42/EEC
Conformity to standards	The gloves confirm to BS EN455-1, 2,3 &4 The sterilization process is validated according to BS ISO11135
Storage conditions	Store in a cool dry place away from heat and direct sunlight
Shelf life	3 Years if stored as recommended above
Additional information	The product is Latex free, powder free and accelerator free. The pack remains sterile unless opened.
<i>Medical Device and Reporting System: According to the official criteria of MDD, incidents caused by this device must be reported immediately to our offices.</i>	

REVISION:	6.0	DATE	17/11/2015	AUTHOR	F Li
NOTES:	Periodic review, DSN format and Shermond logo updated.				
REVISION:	7.0	DATE	09/11/2017	AUTHOR	F Li
NOTES:	Sterilization method changed from Gamma to EO sterilization Swabs weight change from 30 g/ m <sup>2</sup> to 25g/ m <sup>2</sup>				
REVISION:	8.0	DATE	18/05/2018	AUTHOR	A Gidley
NOTES:	Updates to include: addition of component codes to specifications/change of layout				

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