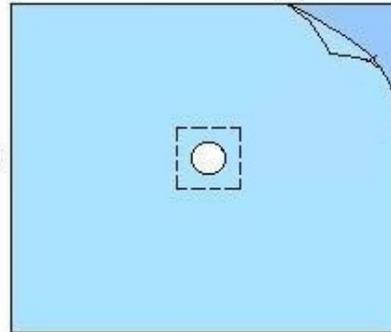


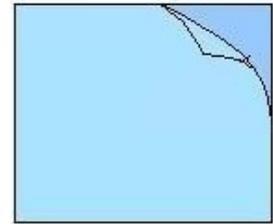
ITEM CODE
SE4200SE

ITEM DESCRIPTION
SPINAL PUNCTURE KIT STERILE

01 drape 45x45cm
01 drape 75x90cm with adhesive hole diam. 10cm
05 gauze non woven 4ply 7.5x7.5cm
01 dressing 8x10cm
01 tweezers



75



45

45

dressing



tweezers



gauze non woven
7.5x7.5 4ply



Betatex S.p.A. products are identified by a lot number to refer to

Packing: Boxes of 40 piece
Sterilization: ETO sterilization
Class: Ila sterile

Intended use: Indicated for general surgery in order to create a barrier against liquids and bacteria and consequently avoid contamination to the patient

QUALITY ASSURANCE

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Specific system requirements must be agreed upon when defining the contract

Data sheet nr °	Date of issue	revision n.	Date of revision	Created by	Product Engineering Manager	Pag.
947.619	21/04/2022	0	21/04/2022	Valeria Busti	Simona Sambuchi	1 of 4
Betatex S.p.A. – Viale Europa – 06083 Ospedaliccchio di Bastia Umbra (PG) – Italia Tel. +39 (075) 8004872 – Fax +39 (075) 8004972					www.betatex.com info@betatex.com	

ITEM CODE
SE4200SE

ITEM DESCRIPTION
SPINAL PUNCTURE KIT STERILE

Tolerance: $\pm 3\%$

MATERIALS CHARACTERISTICS

Characteristics	Value
DRAPE 45X45CM	
ALLERGENICITY	PP+PE: allergens free
LENGTHWISE ELONGATION	PP+PE: (DRY) 55.5%; (WET) 48%(UNI EN 29073-3, EN 13795)
CROSSWISE ELONGATION	PP+PE: (DRY) 47 %; (WET) 46.5 % (UNI EN 29073-3, EN 13795)
ANTISTATICITY	PP+PE: antistatic
ABSORBENCY TIME	PP+PE: 5.4 s (UNI EN ISO 9073-6:2004 par4)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION DRY	PP+PE: 0 UFC (UNI EN ISO 22612, EN 13795)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION WET	PP+PE: IB 6 (UNI EN ISO 22610, EN 13795)
BURSTING STRENGTH	PP+PE: (DRY) 237 kPa; (WET) 240 kPa (UNI EN ISO 13938-1, EN 13795)
ABSORPTION CAPACITY	PP+PE: Absorbent layer about 580%
FLAMMABILITY	PP+PE: Class I (CFR 1610)
CLEANLINESS - MICROBIAL	PP+PE: 0 (CFU/cm ²) (UNI EN 11737, EN 13795)
HYDRO HEAD	PP+PE: 144 cm H ₂ O (UNI EN 20811, EN 13795)
COLOR	PP+PE: Uniform color no reflective
DRAPABILITY	PP+PE: draping coefficient 91.1% (UNI EN ISO 9073-9)
WEIGHT	PP+PE: 58 GR/M ²
NATURAL LATEX FREE	PP+PE: yes
LINTING	PP+PE: CL 1.8 LOG 10; IPM 1.8 (UNI EN ISO 9073-10) (EN 13795)
AIR PERMEABILITY	PP+PE: no apply
RESISTANCE TO BLOOD PENETRATION	PP+PE: penetrazione sangue assente (ISO 16603:2004/UNI EN 14126:2004)
RESISTANCE TO PERFORATION	PP+PE: 9.58 N (UNI EN 863:1997)
DISPOSAL	PP+PE: Usefull for incinerator
PRESENCE OF TOXIC SUBSTANCES	PP+PE: phtalathes free
LENGTHWISE TENSILE STRENGTH	PP+PE: (DRY) 81.2 N; (WET) 79.2 N (UNI EN 29073-3, EN 13795)
CROSSWISE TENSILE STRENGTH	PP+PE: (DRY) 46.7 N; (WET) 46.5 (UNI EN 29073-3, EN 13795)
DRAPE 75X90CM WITH HOLE DIAM. 10CM	
ALLERGENICITY	PP+PE: allergens free
LENGTHWISE ELONGATION	PP+PE: (DRY) 55.5%; (WET) 48%(UNI EN 29073-3, EN 13795)
CROSSWISE ELONGATION	PP+PE: (DRY) 47 %; (WET) 46.5 % (UNI EN 29073-3, EN 13795)
ANTISTATICITY	PP+PE: antistatic
ABSORBENCY TIME	PP+PE: 5.4 s (UNI EN ISO 9073-6:2004 par4)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION DRY	PP+PE: 0 UFC (UNI EN ISO 22612, EN 13795)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION WET	PP+PE: IB 6 (UNI EN ISO 22610, EN 13795)

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ITEM CODE	ITEM DESCRIPTION
SE4200SE	SPINAL PUNCTURE KIT STERILE
BURSTING STRENGTH	PP+PE: (DRY) 237 kPa; (WET) 240 kPa (UNI EN ISO 13938-1, EN 13795)
ABSORPTION CAPACITY	PP+PE: Absorbent layer about 580%
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COLOR	PP+PE: Uniform color no reflective
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WEIGHT	PP+PE: 58 GR/M ²
NATURAL LATEX FREE	PP+PE: yes
LINTING	PP+PE: CL 1.8 LOG 10; IPM 1.8 (UNI EN ISO 9073-10) (EN 13795)
AIR PERMEABILITY	PP+PE: no apply
DISPOSAL	PP+PE: Usefull for incinerator
PRESENCE OF TOXIC SUBSTANCES	PP+PE: phtalathes free
LENGTHWISE TENSILE STRENGTH	PP+PE: (DRY) 81.2 N; (WET) 79.2 N (UNI EN 29073-3, EN 13795)
CROSSWISE TENSILE STRENGTH	PP+PE: (DRY) 46.7 N; (WET) 46.5 (UNI EN 29073-3, EN 13795)
ATOXICITY	ADHESIVE: Free of phtalates, colophonium, PVC and SVHC
CITOTOSSICITA' (CYTOTOXICITY)	ADHESIVE: Not citotoxic (ISO 10993-5)
COMPOSITION	ADHESIVE: hot melt acrylic based adhesive polymer
COMPOSITION	ADHESIVE: Polyester membrane with both sides coated with adhesive polymer
INDEX OF SKIN IRRITATION	ADHESIVE: Non irritant, non sensitizing (ISO 10993-10)
NATURAL LATEX FREE	ADHESIVE: Latex free
ADESIVITY TO SKIN	DRESSING: maximum adherence to the skin
ALLERGENICITY	DRESSING: hypoallergenicity
ABSORBENCE	DRESSING: high absorbency of the central pad
ABSORBENCY TIME	DRESSING: central compress <1 sec
COMPOSITION	DRESSING: coating in virgin paper 100% coated resin
COMPOSITION	DRESSING: central tablet in viscose-perforated polyethylene film and PP
COMPOSITION	DRESSING: perforated support in non-woven fabric (100% polyester)
COMPOSITION	DRESSING: hypoallergenic acrylic adhesive mass
STORAGE	DRESSING: do not expose to direct sunlight, avoid dusty environments
STORAGE	DRESSING: temperature between 0 ° C and 50 ° C
DIMENSION	DRESSING: 8x10 cm
AIR PERMEABILITY (PERMEABILITA' ARIA)	DRESSING: permeability to air and transpiration
WATER VAPOR PERMEABILITY	DRESSING: support in NWF 3500 g/m ² /24ore
RADIOTRASPARECE	DRESSING: radiotrasparent
STERILIZATION	DRESSING: EO
COMPOSITION	FORCEPS: plastica ABS
DIMENSION	FORCEPS: 13cm
NATURAL LATEX FREE	FORCEPS: latex free

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TECHNICAL DATA SHEET



ITEM CODE
SE4200SE

ITEM DESCRIPTION
SPINAL PUNCTURE KIT STERILE

PRESENCES OF TOXIC SUBSTANCES

FORCEPS: PVC and phthalates free

QUALITY ASSURANCE

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