NON-STERILE DELICATE STRIP PLASTER (BOY & GIRL) WITH PAD TREATED WITH ANTIBACTERIAL AGENT
TECHNICAL INFORMATION

Definition

- Delicate strip plaster for boys – in packs.

General characteristics

- Ready-to-use strip plaster, consisting of a nonwoven fabric backing coated with hypoallergenic adhesive with high tolerability for skin and with a central absorbent pad treated with antibacterial agent (0.2% chlorhexidine digluconate) that controls the pad's micro-environment but does not come into contact with the wound.
- It has an extremely conformable adhesive backing that follows the contours of the skin to ensure patient comfort during application.
- The cross-direction extensibility of the nonwoven fabric of the backing makes the dressing suitable for application on joints and moving parts.
- The backing has a good degree of adhesiveness that ensures constant grip in time and a good resistance to changes in temperature.
- Very delicate removal and leaves no adhesive residues on skin.
- The perforated backing and the application of the adhesive in rows allow the proper flow of air and water vapour thus ensuring skin transpiration.
- The central pad is highly absorbent to protect any type of wound and absorb the various levels of exudate. It contains an antiseptic (0.2% chlorhexidine digluconate) that regulates the pad's micro-environment but does not come into contact with the wound.
- The part of the pad that comes into contact with the wound is constituted in a non-adherent net that reduces adhesion to the wound to a minimum.
- The pad and adhesive backing are covered with silicone-coated paper that can be easily removed before use.
- It is radiotransparent, which means that it is invisible to X-rays.
- Available in medium sizes and it is packed in a box containing 24 pieces (see assortment).

Indications

- For the dressing of wounds in hospitals and outpatient clinics.
- In all situations that require dressing the wound with a fast technique not requiring secondary dressings.
- Recommended for dressing wounds on all types of skin and particularly for sensitive skin.
- Ideal for dressings of joints, parts involved in frequent movement or irregular surfaces of the body.

Medical device according to Directive 93/42/EEC, modified by Directive 2007/47/EC Implementation with Legislative Decree no. 37 of 25-01-2010 CE 0373

Class IIb

- Intended use: non-sterile non-invasive surgical dressing device, with absorbent pad treated with antiseptic (0.2% chlorhexidine digluconate) that regulates the micro-environment of the pad in contact with the wound and with adhesive backing in contact with intact skin.

Pikdare S.r.l. - Via Saldarini Catelli 10 - 22070 Casnate con Bernate (CO) - Italy
Tel. 0039 031 7297111 - Fax 0039 031 7297100 - www.picsolution.com

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Compliances

- F.U./F.E. Vigenti - DIRETTIVA CEE 93/42
- ISO 2859 Piani di campionamento
- ISO 10993 Biocompatibilità
- Sistema Assicurazione qualità: certificato secondo UNI EN ISO 9001:2008
- Sistema Assicurazione qualità: certificato secondo EN ISO 13485:2012

Technical specifications

SPECIFICATIONS	METHODS	VALUES
ADHESIVE BACKING		
Composition of adhesive backing		100% polyester nonwoven fabric
Colour of adhesive backing		Printed with coloured drawings
Weight of adhesive backing	EDANA 40-3/90	50 ±5 g/m^2
Thickness of adhesive backing	EDANA 30-5/99	0,46 - 0,60 mm
Machine-direction breaking load (MD)	FU IX ed.	≥ 18N/cm
Machine-direction elongation at break (MD)	FU IX ed.	≤50%
Cross-direction breaking load (CD)	FU IX ed.	≥3.6 N/cm
Cross-direction elongation at break (CD)	FU IX ed.	≤170%
Machine-direction extensibility (MD)	FU IX ed.	Not extensible
Cross-direction extensibility (CD)	FU IX ed.	Extensible
Composition of adhesive mass		Solvent-based synthetic acrylic adhesive
Weight of adhesive mass	M.I.	40 ±2 g/m^2
Weight of adhesive backing	M.I.	90 ±7 g/m^2
Coating of adhesive mass		In rows
Adhesiveness on steel	FU IX ed.	5.0-10.0 N/cm
Moisture vapour transmission rate (MVTR)	FU IX ed.	>3.500 g/m²/24h/37°C
ABSORBENT PAD		
Composition of absorbent part		Non-woven fabric composed of 85% viscose and 15% polypropylene, pad treated with 0.2% chlorhexidine digluconate
Colour of the absorbent part		White
Composition of non-adherent net		Polyethylene film
Colour of non-adherent net		White
Total weight of pad	M.I.	106 ±10 g/m^2
Absorbency	UNI EN 13726-1	6.8±2 g/100 cm^2
PROTECTIVE PAPER		
Composition of protective paper		Silicone-coated paper
Colour of protective paper		White
Weight of protective paper	M.I.	62 ±3 g/m^2

(MD: Machine Direction; CD: Cross Direction)

** According to UNI EN 13726, the moisture vapour transmission rate and conformability of a primary dressing are the result of the combination of the layers composing it. These tests are carried out on the complete dressing: absorbent pad coupled with the adhesive backing.*

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Sterile	**No**
Latex content in the product	**No**
Latex content in the package	**Yes, in the seal of the packaging paper**
Validity	**5 years in proper storage conditions**
Storage and shelf life	**Store in a cool, dry place**

Possibility to sterilise the product
- Sterilisable, in appropriate packaging, by irradiation for a maximum bacterial load of <100 ufc/g.

Number of possible resterilisations
/

Biocompatibility
- The product has passed the biocompatibility tests required by standard ISO 10993: cytotoxicity, allergic sensitisation, skin irritation.
- Compatible with medicines and disinfectants normally used.

Disposal
- In compliance with applicable laws.

Warnings
- Ensure clean and dry hands before using the product.
- Store in a cool, dry place.
- Apply the adhesive backing on clean, intact and dry skin in order not to alter the adhesiveness of the adhesive backing.

Quality testing

- Quality testing is carried out on the raw material, semi-finished product and finished product. Tests are carried out to assess conformity to Pharmacopoeia or internal reference specifications.

Packaging

The labels and/or packaging bear the following information:

Product name
Qualitative and quantitative composition
Dimensions
Instructions for use and warnings
Manufacturer
Date and batch of manufacture
Validity
Storage
Item barcode

Packaging material
- Self-sealing paper pouch (contains natural latex).
- Printed cardboard pack.
- The packaging and materials and inks are certified as non-toxic.

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Manufacturer

- Pikdare S.r.l. - Via Saldarini Catelli 10 - 22070 Casnate con Bernate (Como) - Italy.

Assortment

CODE	DIMENSIONS mm x mm	PACK	UNIT	CARTON
02024090000000	19X72	24 pcs	12 sc	192 sc
02024091000000	19X72	24 pcs	12 sc	192 sc

Other useful information

- Additional information and operating procedures are contained in the technical dossiers filed with the PIKDARE Technical/Quality Assurance Departments.

Technical Director

PIKDARE S.R.L.
Dr. MAURO CASSANI
Medical Devices Department
Technical Director

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