

Wound Management
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Product Safety Data Sheet for PICO (dressing and associated secondary fixation strips, L91 batteries and pump device)

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Product Safety Data Sheet for PICO (dressing and associated secondary fixation strips, L91 batteries and pump device)

SPECIFICATION

1. Product Name:

PICO Negative Pressure Wound Therapy system (NPWT).

The product safety datasheet for the energizer, lithium-iron disulfide batteries (L91) can be found in the attached document.

2. Intended uses:

PICO is indicated for patients who would benefit from the application of a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of wound exudates and infectious material.

Examples of appropriate uses are; acute wounds, chronic wounds, flaps and grafts, incision sites, partial thickness burns, sub-acute and dehiscent wounds, traumatic wounds and ulcers.

3. Composition;

Dressing: Laminate of silicon/acrylic adhesives coated polyurethane films to polyethylene layer and polyacrylate/cellulose airlaid layer. A polyurethane port and an acrylic copolymer/nylon filter membrane are bonded to the laminate using an acrylic adhesive. PVC tubing is also bonded to the polyurethane port using an acrylic adhesive. Laminate is placed on HDPE handles.

Secondary fixation strips: Laminate of acrylic adhesive coated on polyurethane film placed between polyethylene, polypropylene and paper carriers.

Pump: Internal components consist of PCBA (Printed Circuit Board Assembly consisting of multiple electronic components, PCB and soldered joints), electric motor driven diaphragm pump, air manifold of Santoprene, wiring and connections and steel battery contacts. External components consist of 2 case halves in ABS, air inlet connection in ABS, button in Santoprene, lenses in polystyrene and battery cover in ABS.

4. Physical and chemical properties

Combustible solid.

5. Hazard information

No health hazard is anticipated during normal handling of this product.

Document Number: 2003126
Document Version: 03

Document Part: 000
Document Status: Released

6. First aid

- a) Inhalation: Not applicable.
- b) Ingestion: Do not induce vomiting. Seek medical help.
- c) Contact with eyes: Not applicable.
- d) Contact with skin: Not applicable.

7. Fire and emergency measures

The product is a combustible solid which gives off toxic fumes, mainly carbon monoxide, carbon dioxide and hydrogen cyanide – when ignited. In case of fire, any standard fire extinguisher may be used; wear self contained breathing apparatus.

8. Accidental release measures

Not applicable

9. Handling and storage precautions

Store in a cool, dry place < 25°C. Keep away from sources of ignition and strong light sources.

10. Exposure controls/personal protection

Not applicable

11. Stability and reactivity

Product should not be stored above 25°C or in direct sun light

12. Toxicological information

See information given in hazard information.

13. Ecological information

Not applicable

14. Disposal

Material should be considered as medical waste after use. Dispose of according to local guidelines. Pump should be disposed of in compliance with local WEEE regulation.

Document Number: 2003126
Document Version: 03

Document Part: 000
Document Status: Released

15. Transport precautions

Not applicable

16. Regulatory information

Not applicable

17. Additional information

Not applicable

18. Name, address and telephone number of supplier

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This information is provided in accordance with the requirements of the UK Health and Safety at Work Act 1974, and specifically in order to assist users of the product to make their 'assessment of health risks' as required by the UK Control of Substance Hazardous to Health Regulation 2002 (COSHH assessments). Provision of this information does not preclude users from seeking advice from other sources as indicated in the COSHH guides. This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra indications, and precautions for the treatment of patients.

Document Number: 2003126
Document Version: 03

Document Part: 000
Document Status: Released

REASON FOR CHANGE

Document Version	Section/Paragraph Changed	Change Made	Date
01	N/A	First issue	24 th June 2010
02	Attached document Title	Addition of data for the batteries Change of name from Poole (Project) to PICO (Product)	27 th Jan. 2011
03	Title Product name Intended use Composition Disposal	Addition of pump device Removal of project reference Re-wording in line with IFU Addition of Pump details Addition of comment regarding pump disposal	17 th March 2011

Document Number: 2003126
Document Version: 03

Document Part: 000
Document Status: Released

RE-VERIFICATION OF DOCUMENT SUITABILITY

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Document Number: 2003126
Document Version: 03

Document Part: 000
Document Status: Released

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None

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Document Number: 2003126
Document Version: 03

Document Part: 000
Document Status: Released