**Smith and Nephew Medical**
101 Hessle Road
Hull
HU3 2BN
www.smith-nephew.com

# Product Safety Data Sheet

**1a) PRODUCT NAME(S):**

RENASYS™ TOUCH - Negative Pressure Wound Therapy (NPWT) 66801280, 66802134 and 66801281

**1b) INTENDED USE(S):**

RENASYS™ TOUCH NPWT is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.

Appropriate wound types include: Chronic, Acute, Traumatic, Sub-acute and dehisced wounds, Ulcers (such as pressure or diabetic), Partial thickness burns, Flaps and Grafts

**1c) Details of Supplier of the Product Safety Data Sheet:**

Smith & Nephew Medical
101 Hessle Road
Hull
HU3 2BN

Telephone: 01482 225181 (24 hours)
Email: QACompliance.Hull@smith-nephew.com

**2. HAZARD INFORMATION:**

**2.1 Classification of the substance or mixture:**

The device is considered to cause no adverse effects on health or the environment during normal handling and use. The product contains a Lithium-Ion battery that if compromised the contents are classified as Hazardous – See transport Information.

**2.2 Label Elements:**

See Transport Information, Section 14

**2.3 Other Hazards**
Contains a Lithium-Ion battery

**3. COMPOSITION / INFORMATION ON INGREDIENTS:**

The RENASYSTM TOUCH NPWT system is comprised of the device, canisters (300ml available with and without solidifier or 800ml with solidifier), clamp, carry bag and carry strap. RENASYS TOUCH is compatible with various RENASYS Foam and Gauze Wound dressing kits. This PSDS is intended for the Pump device only.

RENASYSTM TOUCH NPWT Pump Device: The device includes a vacuum pump, printed circuit boards, LCD display, electrical wiring, a Lithium-Ion Battery, vinyl foam tape, silicone tubing, nylon tubing clip, porex Filter, polycarbonate and silicone check valve, and an rubber o-ring. All of the above are housed or attached to the outer case which is manufactured from LEXAN EXL9134 (polycarbonate siloxane copolymer), a flame retardant material, and fastened together by steel screws.

**4. FIRST AID:**

**4.1 First Aid General Information:** N/A

**4.2 Most important symptoms and effects, both acute and delayed:** N/A

**4.3 Indication of any immediate medical attention and special treatment needed:** N/A

| | |
|---|---|
| **a) Inhalation** | Not applicable |
| **b) Contact with skin** | Not applicable |
| **c) Contact with eyes** | Not applicable |
| **d) Ingestion** | Not applicable |

**5. FIRE AND EMERGENCY MEASURES:**

**5.1 Extinguishing media**

**Suitable extinguishing media:** A dry chemical carbon dioxide and foam is required for extinguish due to the Lithium-Ion batteries.

**Unsuitable extinguishing media:** Water should not be used if installed into the mains electricity.

**5.2 Special hazards arising from substance or mixture**

If ignited toxic fumes may be expelled including ammonia, aromatic and aliphatic hydrocarbon fractions, carbon monoxide, carbon dioxide, and hydrogen cyanide. Therefore, appropriate self-contained breathing apparatus should be worn when

fighting a fire. Keep all personnel away from the fire.

**5.3 Advice for firefighters**

Protect skin from contact.

If fire is in a confined space, self-contained breathing apparatus should be worn.

**6. ACCIDENTAL RELEASE MEASURES:**

**6.1 Personal precautions, protective equipment and emergency procedures (for non-emergency and emergency personnel)**
Not Applicable

**6.2 Environmental precautions**
Not Applicable

**6.3 Methods and material for containment and cleaning up**
Not Applicable, manual clean up will apply

**6.4 Reference to other sections**
Not Applicable

**7. HANDLING AND STORAGE PRECAUTIONS:**

**7.1 Precautions for safe handling**

Do not puncture, crush, incinerate or expose the battery to temperatures exceeding 100°C.
Avoid using around flames or ignition.
Use only the AC power cord provided with the device.

**7.2 Conditions for safe storage, including any incompatibilities**

Store in a dry place out of direct light. Short term storage and transport temperature should be -25 to 70°C (-13 to 158°F) and long term storage should be 5 to 40°C (41 to 104°F). If the device has been stored at temperatures below freezing, it must be brought to room temperature prior to use or the device may be damaged.

Do not puncture, crush, incinerate or expose the battery to temperatures exceeding 100ºC. Avoid using around flames or ignition. Use only AC power cord provided with the device.

**7.3 Specific End Use**
See section 1b

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION:**

**8.1 Control Parameters**
Not Applicable

**8.2 Exposure Controls**
Not Applicable

**8.3 Personal Protective Equipment**
Not Applicable

**9. PHYSICAL AND CHEMICAL PROPERTIES:**

**9.1 Information on basic physical and chemical properties**

See Product Description.

**10. STABILITY AND REACTIVITY:**

**10.1 Reactivity**
Product is stable and non-reactive

**10.2 Chemical Stability**
Product is stable and non-reactive

**10.3 Possibility of Hazardous Reactions**
Product is stable and non-reactive

**10.4 Conditions to avoid**
Product should be stored in a dry place, at a temperature between 5 to 40°C and out of direct sunlight

**10.5 Incompatible Materials**
Not Applicable

**10.6 Hazardous Decomposition Products**
Product is stable and non-reactive

**11. TOXICOLOGICAL INFORMATION:**

**11.1 Information on Toxicological Effects**

Not applicable.

**12. ECOLOGICAL INFORMATION:**

**12.1 Toxicity –** Not Known

**12.2 Persistence and Degradability –** Not Known

**12.3 Bio accumulative potential –** Not Known

**12.4 Mobility in soil –** Not Known

**12.5 Results of PBT and vPvB assessment –** Not Known

**12.6 Other Adverse Effects –** Not Known

**13. DISPOSAL CONSIDERATIONS:**

**13.1 Waste Treatment Methods**

Dispose of in accordance with local/ national environmental waste guidelines for electrical medical devices containing Lithium-Ion battery. In European countries this product should be separated and sent to a designated collection point for recycling of Waste Electrical and Electronic Equipment (WEEE).

Disposal of battery: follow local guidelines and battery label for proper disposal. Do not puncture, crush, incinerate or expose the battery to temperature exceeding 100°C. Improper disposal of Lithium-Ion battery may result in fire explosion and burns.

**14. TRANSPORT INFORMATION:**

**14.1 UN Number -** 3481

**14.2 UN Proper Shipping Name -** Lithium Ion Batteries Contained In Equipment

**14.3 Transport Hazard Classes -** 9
The lithium battery in the Renasys Touch & Renasys Go are not restricted as they meet the following listed below, and are properly packaged and are classed as a battery installed in equipment

1. For batteries, the Watt Hour rating is not more than 100 Wh.
2. Each battery has been successfully tested and complies with the UN Manual of Test and Criteria, Part III, subsection 38.3
3. Each battery has been manufactured under a quality management program as specified in 2.9.4 of the UN Model Regulations.

These products meet the requirements for transportation under:

- UN Model Regulations Special Provisions 188 and 230
- International Civil Aviation Organization (ICAO) Technical Instructions and the
- International Air Transport Association (IATA) Dangerous Goods Regulations Packing

  Instruction:

  - 967 Section II (UN3481, Lithium ion batteries contained in equipment)
- International Maritime Organization (IMO) Special Provisions 188 and 230
- European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) Special Provisions 188 and 230
- U.S. Department of Transportation (DOT) 49 CFR 173.185 and 173.185(c)
- Canadian Transport of Dangerous Goods Regulations (TDGR) Special Provision 34

Batteries when installed in equipment shall be protected from damage and short circuit, and the equipment shall be equipped with an effective means of preventing accidental activation. When Lithium batteries are installed in equipment, the equipment shall be packed in strong outer packaging constructed of suitable material of adequate strength and design in relation to the packaging's capacity and its intended use unless the battery is afforded equivalent by protection by the equipment in which it is contained.

**14.4 Packaging Group**
Not Applicable

**14.5 Environmental Hazards**
Not Applicable

**14.6 Special Precautions for the user**
Packaging should be handled with care. Rough handling may result in batteries being short circuited or damaged. This may cause leakage, explosion, or fire

**DAMAGED LITHIUM BATTERIES ARE FORBIDDEN FOR TRANSPORT IN ANY MODE**

**15. REGULATORY INFORMATION:**

**15.1 Safety, Health and Environmental Regulations / Legislation specific to the substance or mixture**

*EU Legislation:*
*Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.*

*Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and*

*Restriction of Chemicals (REACH).*

*Safety Data Sheet requirements of Regulation EC no 1272/2008'*

*Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Directive 2011/65/EC*

*Guidance:*
*ECHA Guidance on the compilation of safety data sheets (Version 2.1: February 2014)*

**15.2 Chemical Safety Assessment**
Not Applicable

**16. ADDITIONAL INFORMATION:**

**Full text of H statements referred to in other sections**

**Full text of P statements referred to in other sections**

| | |
|---|---|
| **17a) REFERENCE NUMBER** | 2009694 |
| **17b) DATE OF ISSUE** | **August 2023** |

*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 Substances 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. The 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 patient.*