SpinCare™

PORTABLE WOUND DRESSING SYSTEM

Instructions For Use

Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to injury to the patient and/or care giver.

1. SYSTEM DESCRIPTION

The SpinCare Wound Dressing Device is a portable electrospinning device that produces in-situ personalized, nano-fibrous dressings for the treatment of external burns and wounds using the SpinKit pre-filled syringe containing the wound dressing solution.

CONTENT OF THE SpinCare™
1 SpinCare
1 SpinCare Docking
1 SpinCare Charger
1 Instructions for Use

CONTENT OF THE SpinKit™
1 SpinKit Solution
1 Sterile Cannula
1 Patient Cable
1 Instructions for Use

2. INDICATIONS FOR USE

The SpinCare is intended for the treatment of skin breaches such as partial and full thickness wounds, abrasions, superficial and partial thickness burns, donor site wounds, surgical incisions, after suture removal, skin tears, dermatological lesions or ulcers*.

3. CONTRAINDICATIONS

Known sensitivity or allergy to polyester derivatives.

4. POTENTIAL COMPLICATIONS

Potential complications that may occur with any dressing: bleeding, infection, tear of tissue while removing the dressing etc.

Note: The SpinCare dressing is latex free.

Fig. 1- The SpinCare Device and Docking

5. WORK INSTRUCTIONS

5.1. Charging (see Fig. 1)

- **Use only the SpinCare Docking and Charger to fully charge the device before use; use of other chargers may cause device damage.**
- **The SpinCare can't be operated while charging.**

5.1.1. Place the Docking on a flat surface and plug in the charger.

5.1.2. Place the SpinCare in its Docking for overnight charging. Make sure the ON/OFF button (12) is OFF.

5.1.3. A red LED (4b) will flash during charging, turning to green when the device is fully charged.

5.2. Preparing the SpinCare (see Fig. 2)

5.2.1. Remove the SpinCare from the Docking.

5.2.2. Shift the ON/OFF (12) to ON. The green LED (4b) is turned on.

5.2.3. Open a SpinKit. Insert the Patient Cable into the device Patient Cable socket (13). Connect a standard ECG electrode sticker to the other end.

5.2.4. Take the solution syringe. Remove the Luer-lock cover and connect the sterile cannula.

5.2.5. Open the device cover (3) and insert the Solution Syringe (6) into the Syringe Bed (7).

5.2.6. Use the FORWARD (8) button and Roller (10) to move the plunger until it contacts the rubber piston.

5.2.7. Close the cover (3).

5.2.8. The SpinCare is now ready for use.

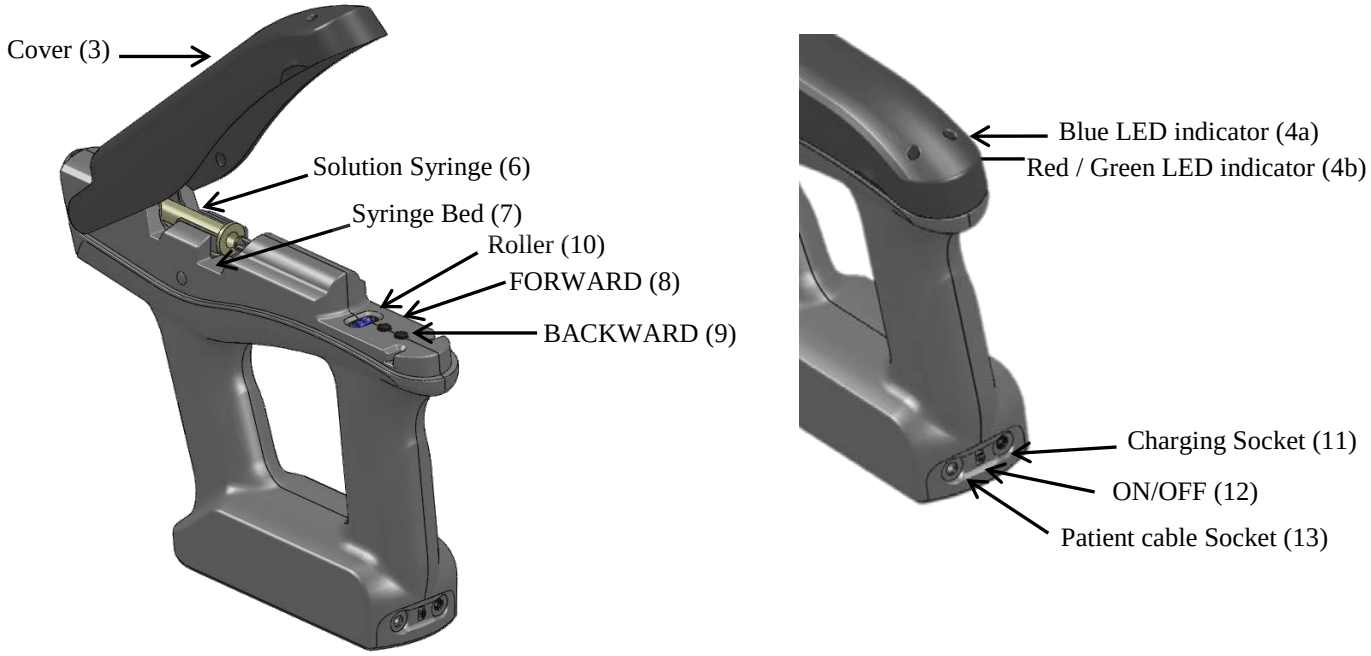

Fig 2: The SpinCare and the loaded syringe

5.3. **Dressing the wound (see Figs. 1-2)**

5.3.1. Clean the wound site according to hospital /clinic standard of care.

5.3.2. Attach the ECG sticker to the patient about 50cm away from the dressing site.

5.3.3. Use the FORWARD (8) button and Roller (10) to move the plunger further until a drop appears at the tip of the cannula.

5.3.4. Wipe the cannula with gauze.

5.3.5. Press the DISTANCE bar (1) to activate the Laser Indicators (4). Adjust the distance from the patient until the two dots overlap (~20cm).

5.3.6. Keep pressing the DISTANCE bar and press the ACTIVATE bar (2) while pointing at the area to be dressed. A BLUE led (4a) will turn on and the formation of the dressing starts.

KEEP PRESSING BOTH BARS DURING THE DRESSING PROCESS.

5.3.7. Once dressing is complete, dispose of the syringe according to section 5.4.

5.3.8. Shift the ON/OFF button (12) to OFF.

5.3.9. Disconnect the Patient Cable and discard.

Note:

- ***Dressing is formed when both DISTANCE and ACTIVATE bars are continuously pressed.***
- ***Optimal operation distance (~20cm) is indicated by the overlap of the two laser dots.***
- ***The thickness of the dressing depends on the duration the device is used.***
- ***If the RED led (4b) is flashing during operation, indicating low device charge, don't stop dressing. Charge the device after finishing the current dressing.***

HIGH VOLTAGE! Avoid contact between the device distal-end and the patient, his surroundings and /or caregiver and /or a third person.

The device has a safety shut down feature that stops operation if the distance to patient is too short. Operation will resume once the system is back to normal operation distance.

5.4. **Disposing of the syringe**

5.4.1. Position the SpinCare on a flat area.

5.4.2. Open the upper cover (3).

5.4.3. Push the BACKWARD button (9) to move the Plunger back.

5.4.4. Wipe off solution drops and pull out the used syringe. Discard according to hospital instructions.

5.4.5. Clean the distal end of the device both on the inner and outer sides.

5.5. **Secondary dressing**

Some wounds may require a secondary dressing per physician decision and standard of care.

6. WEAR TIME

The dressing could remain in place until one or more of the following occurs: tenderness, signs of infection, physician decision, no further clinical need.

6.1. If applicable, carefully remove the secondary dressing and examine the wound.

6.2. If applicable, free one edge of the dressing and slowly remove the entire dressing.

6.3. If applicable, repeat the dressing procedure as described in Section 5.3.

7. STORAGE

The SpinCare should be stored at room temperature.

The SpinKit should be stored at 4°C to 30°C. Avoid excessive heat or cold.

The SpinKit solution must be used before the expiration date printed on the package

8. MAINTENANCE OF THE SPINCARE

8.1. Clean your SpinCare after each use**.**

8.2. Use a dry clean cloth and 70% Alcohol to gently wipe the SpinCare surface.

- **Make sure the ON/OFF button is OFF before cleaning.**
- **Do not use any detergents, organic solvents or chemicals for cleaning the SpinCare.**
- **Never place the SpinCare under running water or immerse it in water for cleaning.**

9. WARNINGS

- The SpinCare can be used only with the SpinKit solution.
- During operation avoid contact of the tip of the SpinCare with patient or other persons.
- For external use only! Do not inject!
- Do not apply in proximity to the face.
- Do not aim the laser distance indicators towards person's eyes.
- Do not open and/or dismantle the SpinCare; No modification of the equipment is allowed.
- Do not use the SpinCare charger if the charger cord is damaged.
- Do not use the SpinCare after device malfunctions, is dropped or damaged.

10. PRECAUTIONS

- Do not use an expired SpinKit Solution.
- Do not use the SpinKit if its package has been damaged or opened.
- Do not sterilize the SpinKit.
- The device should be operated at 4-30^{o}C, with a relative humidity range of 20-70% and atmospheric pressure range of 88-103 kPa.

11. ELECTROMAGNETIC COMPATIBILITY (EMC)

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SpinCare including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of other electrical equipment on or near this system may cause interference. Verify normal operation of equipment in the system before use on patients
- This system is not MRI (Magnetic Resonance Imaging) compatible.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment are not allowed.

12. GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

- The system is suitable for use in the specified electromagnetic environment. The customer and/or the user of the system should assure that is used in an electromagnetic environment as described below:

Electro-magnetic emissions		
The *SpinCare* device is designed to be used in the electro-magnetic environment specified below. The equipment's customer or user must ensure that it is used in such an environment.		
Emission test	**Compliance**	**Recommended electro-magnetic environment**
RF emissions CISPR 11	Group 1	The *SpinCare device* uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	SpinCare system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

13. ELECTRICAL SPECIFICATIONS

Charger input: 100-240Vac; 50/60 Hz; 150-300 mA
Charger output: 10Vdc; 1.2A
Battery: Li-ion rechargeable 7.4V / 2.6Ah
Device operation: 25±2 KV /80 µA max

14. LASER SPECIFICATIONS

Class I
Max output of laser radiation: 0.35mW
Pulse duration: Continuous
Emitted Wavelength: 650nm
Name and publication date of Standard IEC 60825-1:2014

15. TROUBLESHOOTING

PROBLEM	IT'S POSSIBLE THAT	HOW TO TROUBLESHOOT
SpinCare doesn't work	SpinCare is not charged	Charge the SpinCare (section 5.1)
	SpinCare is not operated correctly	Follow IFU (section 5.3)
	SpinCare identified hardware problem and performed shut down	Restart the SpinCare (turn OFF and ON again). If the problem persists please notify NICAST.
	Device malfunction	Please notify NICAST
No Drop appears after activation	SpinCare is not charged	Charge the SpinCare (section 5.1)
	No solution syringe has been inserted into the device	Insert a syringe as described in section 5.2
	Solution syringe is empty	Replace solution syringe (section 5.2)
	Cannula is blocked	Wipe the cannula end If the problem remains, replace the cannula (Section 5.3)
	SpinCare syringe is not well positioned in the Syringe Bed	Correct position following "Preparing the SpinCare " (Section 5.3)
	Device malfunction	Please notify NICAST
The blue LED is on, but nothing happens	Dressing time was too short	Repeat procedure. A visible dressing appears only after about 30 seconds
	No solution syringe has been inserted into the device	Insert a syringe as described section 5.2
	Solution syringe is empty	Replace solution syringe (section 5.2)
	Cannula is blocked	Wipe the cannula end If the problem remains, replace the cannula(Section 5.2)
	SpinCare syringe is not well positioned in the Syringe Bed	Correct position following "Preparing the SpinCare " (section 5.2)
	Patient or device is not connected to the patient cable	Connect patient and device to the patient cable
	Device malfunction	Please notify NICAST
The SpinCare was working properly, but then it stopped working	Either the DISTANCE or the ACTIVATE bars are not pressed correctly	Make sure you press BOTH bars simultaneously using BOTH hands.
	The device needs to be charged.	Charge the SpinCare (section 5.1)
	Patient cable disconnected from patient or device	Make sure patient and device are connected to the patient cable
	SpinCare identified hardware problem and performed shut down	Restart the SpinCare (turn OFF and ON again). If the problem persists please notify NICAST.
	Device malfunction	Please notify NICAST
Liquid is seen in the syringe bed	The cannula is not correctly connected to the syringe	• Clean spillage with a soft dry cloth • Correct cannula/syringe connection. If needed, replace cannula/syringe with a new one.
	The syringe is damaged and leaking	• Discard of the damaged syringe • Clean spillage with a soft dry mat • Replace syringe with a new one
After pressing the DISTANCE bar, no red spots appear on the patient's skin	The device is not adequately charged.	Stop treatment and charge the device
	Device malfunction	Please notify NICAST

16. SYMBOLS

	Use by
	Serial number / Lot number
	Single use only
	Do not resterilize
	Catalog number
	Consult instructions for use
	Laser Class I
	Caution!
	High Voltage *Note: Low energy exposure with very low current*
	Do not use if package is damaged
	Method of sterilization: Aseptic filling
	Keep dry
	Keep away from sunlight
	Temperature limitation
	Authorized representative in the EU
	Manufacturer
	Type BF Applied Part

17. LIMITED WARRANTY

Nicast Ltd. warrants its SpinCare ("Device") to be free from defects in workmanship and materials for a period of two (2) years from the date the Device is delivered to the original purchaser ("Warranty Period"). This Limited Warranty is extended only to the original purchaser and is non-transferable. Nicast's sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device which is defective in either workmanship or material. This is the sole remedy of the Purchaser. This Limited Warranty excludes the batteries, or the solution kits. In addition, this Limited Warranty does not cover any Device which may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of Nicast's instructions, including, without limitation, the instructions contained in the Instructions for Use (IFU). There are no other warranties than those expressly stated herein. To the extent permitted by law, Nicast Ltd. Does not make any implied warranty of merchantability or fitness for a particular purpose as to any product or device, whether or not that product or device is covered by any express warranty contained herein. In no event shall Nicast be liable for any special, incidental, consequential, or indirect damages (including, without limitation, damages for loss of profits, use or time incurred by purchaser or end user). In addition, Nicast ltd. shall not be liable for any exemplary or punitive damages.

** The device was clinically tested on Donor Site Wounds (DSWs), which represent a wide variety of skin breaches.*

Nicast Ltd.
2 Yodfat St, Lod
71291, Israel
Tel. +972 (8) 9153001
Fax +972 (8) 9153002
www.nicast.com

EC REP
MedNet GmbH
Borkstraße 10
48163 Münster
Germany

CE 0482