

# Frequently Asked Questions (FAQ's)

PROBLEM	IT'S POSSIBLE THAT	HOW TO TROUBLESHOOT
<b>Spincare doesn't work</b>	Spincare is not charged	Charge the Spincare (as explained in the IFU)
	Spincare is "off"	Turn the black switch at the back of the device to "on"
	Device malfunction	Please notify Distributor/Nanomedic
<b>A "drop" does not appear after activation</b>	Setup of the Spincare ampule is not complete	Use the FORWARD button until a drop appears at the tip and start
	No Spincare Kit solution ampule has been inserted into the device	Insert a Spincare Kit Solution ampule as described in IFU
	Spincare Kit solution ampule is empty	Replace Spincare Kit solution ampule (see IFU)
	Cannula is blocked	Wipe the end point of the cannula. If the problem remains, replace the cannula (See IFU) Remember – each ampule is intended for single use
	Spincare Kit solution ampule is not well positioned in the ampule Bed	Correct position following "Preparing the Spincare" (See IFU)
	Device malfunction	Please notify Distributor/Nanomedic
<b>The blue LED is on, but nothing happens</b>	Setup of the Spincare ampule is not complete	Use the FORWARD button until a drop appears at the tip and start
	Procedure/application time was too short	Repeat procedure. A visible whitish layer appears only after several seconds
	No Spincare Kit solution ampule has been inserted into the device	Insert a Spincare Kit solution ampule as described (see IFU)
	Spincare Kit solution ampule is empty	Replace solution ampule (see IFU)
	Cannula is blocked	Wipe the end point of the cannula. If the problem remains, replace the cannula (See IFU) Remember – each ampule is intended for single use
	Spincare ampule is not well positioned in the ampule Bed	Correct position following "Preparing the Spincare" (See IFU)
	Device malfunction	Please notify Distributor/Nanomedic
<b>The Spincare was working properly, but then it stopped working</b>	Either the DISTANCE or the ACTIVATE bars are not pressed correctly	Make sure you press BOTH bars simultaneously using BOTH hands.
	Spincare identified hardware problem and performed shut down	Restart the Spincare (turn OFF and ON again). If the problem persists, please, notify Distributor/Nanomedic.
	Device malfunction	Please notify Distributor/Nanomedic
<b>Liquid is seen in the ampule bed</b>	The cannula is not correctly connected to the ampule	<ul style="list-style-type: none"> <li>Clean spillage with a soft dry cloth</li> <li>Correct cannula/ampule connection. If needed, replace cannula/ampule with a new one.</li> </ul>
	The ampule is damaged and leaking	<ul style="list-style-type: none"> <li>Discard the damaged ampule</li> <li>Clean spillage with a soft dry mat</li> <li>Replace ampule with a new one</li> </ul>
<b>Pressing the DISTANCE bar, no red dots appear on the patient's skin</b>	The device is not adequately charged	Stop treatment and charge the device
	The device is too close to a surface.	Please position the device around 20 cm from the patient (surface)
	Device malfunction	Please notify Distributor/Nanomedic
<b>The green LED is blinking red</b>	Device needs to be charged	Complete current treatment and charge the device
<b>The fibers are dispersed</b>	Patient cable disconnected from patient	Make sure patient and device are connected to the patient cable
	The wound area is partially covered or wet	Make sure the wound area is fully exposed (including a 1-2 cm of margin) and dry

## Usability & General Questions

### **Q: What is the Spincare's current intended use**

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

### **Q: What is electrospinning?**

Spincare is based on a proprietary electrospinning technology, embedded in a portable, light-weight, mobile wound care device. Electrospinning technology uses a polymer solution and electrostatic forces to create a matrix of nanofibers, forming a multi-layer porous skin-like dressing that mimics the structure of the extracellular body tissue (ECM).

### **Q: How does Spincare work?**

Spincare is a portable electrospinning system that applies a protective layer, in real time and from a distance of about 20 cm away from the wound, without touching the wound, causing no pain to the patient. You apply it once and it remains on the wound throughout the healing process. The Spincare System includes a hand-held device and a disposable sterile pre-filled ampule for single patient, single use.

### **Q: What are the benefits of the Spincare layer?**

- No contact one-time application; no painful redressing; reduced risk for infection
- Fits any wound size and body contour, no pre-planning, no need for large stock and shelf space and no need for various shapes and sizes
- Fully personalized, completely tailored to patient wound condition, location, geometry
- Ability to conform to hard-to-dress area is first-rate, such as faces, hands, chest and moving parts like elbow and knees
- Allows for free mobility at all times
- Transparent, easy monitoring of healing progress
- Permeable and breathable; it enables cell respiration, oxygen permeation and exudate travel through the layer
- Conforms to all wound and body contours, providing better "coverage" and easy handling of wound dressing; no patching, no stapling, and no fixation require
- Allows for early showers
- Self-peels when healing is complete

### **Q: Are there advantages over commonly used wound dressings?**

The advantages of Spincare over common wound dressings are listed above and are undeniable; patients are spared the pain of the initial dressing and repeated changes of dressings; physicians will be able to view and interact with the wound through the transparent Spincare layer; patients have a greater ability to accomplish activities of daily living by enabling a full range of motion, which thereby might reduce the need for physical therapy often required when a wound dressing inhibits the movement of a body part for several weeks; patients can shower the way they normally do and restore their quality of life!

**Q: Is it possible to inspect the wound after Spincare has been applied?**

Yes, once the temporary Spincare layer has attached itself to the wound it becomes completely transparent.

**Q: How long will it take for me to be allowed to shower?**

24 hours

**Q: How do I remove the temporary Spincare layer if needed?**

There is no need to remove the Spincare layer; it peels off naturally when the wound is healed underneath.

**Q: Can it be used on highly exuding wounds?**

Yes. In such cases you can either wait 24-48 hours before applying the Spincare layer. Or, use a secondary absorbent layer during the first few days. Make sure that the secondary dressing doesn't stick to the Spincare layer by changing the secondary layer frequently.

**Q: What do I do if the wound becomes infected?**

Treat the wound according to hospital standard of care. Sterile wash, antimicrobial solution, ointments or any other treatments can be applied over the layer without removing it.

**Q: Can Spincare be used on a deep wound?**

No. Spincare can be used for superficial and intermediate wounds.

**Q: Can Spincare be used on areas that are subjected to a lot of friction?**

There is a risk that the layer might be peeled off due to the friction. In these cases, it is recommended to use a secondary dressing.

**Q: Can a secondary dressing be used and what is recommended?**

Secondary dressings are not required; if desired, use secondary dressing during the first exuding days. In this case it is recommended to remove the secondary layer on day 3.

When secondary layer is used, it is recommended to either replace it frequently (up to 6 hours), to prevent sticking, or use a silicon interface layer between the Spincare layer and the secondary dressing

**Q: How long will one application last?**

Normally until healing and full epithelialization of the wound. At this point, the Spincare layer peels off naturally. On certain hard to heal wounds reapplication might be needed.

**Q: Can Spincare be re-applied?**

If needed, yes. Make sure to remove any loose residues of the previous Spincare layer by soaking with sterile saline or water, clean the area and reapply.

**Q: How do I know when I have applied enough?**

Start by applying the layer a few cm from the edges surrounding the wound, this will give you an indication of how fast the layer is formed. As soon as a whitish layer is visible the wound is covered.

**Q: Is it possible to use topical treatments such as antibiotic or crèmes prior to application of Spincare?**

No. Topical treatments may be applied above the Spincare layer 24 hours after Spincare has been used. Greasy ointments can prevent the matrix from attaching to the wound.

**Q: Can I apply Spincare on a bleeding wound?**

Yes, for wounds with controlled bleeding such as donor site wounds, post debridement etc.

**Q: What is the Spincare solution made of and does it contain any biological components?**

Spincare solution is biocompatible, purely synthetic with no biological components.

**Q: Can Spincare be used on infants, children and adults?**

Yes.

**Q: How long is the application time?**

The length of the procedure with the Spincare is highly efficient and depends on the size of the wound, normally not more than a few minutes. No cutting, trimming, patching needed, no additional layers are required, no fixation is needed (staples or glue).