

Safety Communication

رسالة سلامة

Advice on the Importance of Following Instructions for the Cold Therapy Mode of Water Circulating Hot-Cold Therapy Devices

Device/ Product Description:	Water-Circulating Hot/Cold Therapy Devices
Affected product:	All
Manufacturer:	All
Problem:	Injuries associated with using the cold therapy mode of these devices, including more serious injuries such as frostbite, second and third degree burns, and cell death requiring medical intervention (for example, skin grafts or amputation).
Recommendation /Actions:	<ul style="list-style-type: none">- Health care provider should consider, Before using the devices, the following parameters:<ul style="list-style-type: none">• The type of therapy (that is, hot, cold, and compression) you should use.• How often and how long therapy should be applied.• The length of breaks between uses.• Total time of treatment.- When applying the device wrap to the skin, apply a barrier (for example, cloth or bandage) between the wrap and the skin, and do not wrap it around the area tightly. No part of the wrap should touch the skin for any period.- Check the skin under the wrap frequently and try to keep the treatment site dry.- Stop using the device if patient experience any negative (adverse) reactions such as:<ul style="list-style-type: none">• Increased pain• Burning• Increased swelling• Itching

- Blisters
- Increased redness
- Discoloration
- Welts
- Other changes in skin appearance

- Determine carefully if you should use these devices on the patients have any of the following conditions,:

- Diabetes.
- Any condition that may decrease the skin sensation, such as peripheral neuropathy, sciatica, stroke, or spinal cord injury.
- Circulatory disorders, including: Raynaud's disease, Buerger's disease, peripheral vascular disease, vasospastic disorders, sickle cell anemia, and hypercoagulable clotting disorders.
- Taking medications that may have a negative effect on peripheral vascular circulation, including: beta adrenergic blockers and local epinephrine use (such as local anesthetics).
- History of cold injury, frostbite, or adverse reactions to local cold application.

For more information, please click [here](#).

If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:

[NCMDR](#)

[Vigilance system](#)

19999 unified call center