

Medical Devices

Use Infant Heel Warmers with Care

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THE INFANT HEEL WARMER, used routinely in neonatal care settings, is an instant chemical heat pack. It increases capillary circulation in an infant's heel to facilitate blood collection by heel stick. This nonsterile, single-use, disposable device contains a nontoxic material. Device activation results in an exothermic reaction with a maximum temperature of around 104°F (40°C) within the first few minutes before it gradually diminishes.

Although the infant heel warmer is safe and effective when used as intended according to manufacturers' instructions, problems have occurred. The following cases were reported to the FDA's medical device adverse event reporting program. These reports of rare occurrences contain limited information but serve to warn of adverse events associated with the use of infant heel warmers.

Case 1: An infant suffered second to third-degree burns to the heel requiring treatment.

Case 2: Twins with hyperbilirubinemia were being prepared for a heel-stick procedure. The heel warmer ruptured, its contents covered the infants, and they suffered first and second-degree burns.

Case 3: An infant received a second degree burn when the device was reused and reheated contrary to labeling instructions.

Case 4: When the nurse activated the infant heel warmer, it burst open and splashed her in her eyes. The infant wasn't hurt, but the nurse required emergency eye wash and ophthalmic antibiotics.

What went wrong?

The adverse event reports suggest that users may not be following the device manufacturers' instructions for use.

What precautions can you take?

Follow your facility's policies and procedures, the manufacturer's labeling recommendations, and these suggestions:

- Assess and document the patient's skin integrity prior to use. Don't apply a heel warmer to an infant whose skin integrity is impaired in any way. Exercise extra caution when using this device on a premature infant.
 - Activate the heel warmer according to the device's labeling. Don't activate it near the infant or near anyone's eyes.
 - Don't wrap the heel warmer with any additional heat source, such as a warm washcloth.
 - Use the device for 3 to 5 minutes or as directed by the manufacturer and monitor the application site continually, at least every 30 seconds, to avoid burns when using the warmer with premature infants. After removing the heel warmer, inspect the skin for any signs of altered skin integrity, such as blisters or erythema.
 - Don't reuse a device; it's intended for a one-time use only. Using a reheated device could cause a burn.
 - If heel warmer contents leak and come in contact with the skin, wash immediately with mild soap and water. Also change affected clothing and bedding.
 - If contents come in contact with the eyes, flush them thoroughly with water and immediately notify the healthcare provider.
 - If contents are accidentally swallowed, contact the healthcare provider or poison control center.
 - Follow your facility's policies and procedures to document any adverse event, including part of body exposed, treatment, communication, and how the patient was monitored.
 - If you need more information on an infant heel warmer device, contact the manufacturer.
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Although you need to support your health care facility's adverse event—reporting policy, you may voluntarily report a medical device that doesn't perform as intended by contacting MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178) or online at [MedWatch](#). Diane Dwyer, RN, BSN, who coordinates Device Safety, is a nurse-consultant at the Center for Devices and Radiological Health at the Food and Drug Administration in Rockville, Md.