PRODUCT DESCRIPTION
EpiFLO® is a transdermal sustained oxygen therapy device indicated for the treatment of difficult-to-heal wounds. EpiFLO® consists of a disposable electrochemical oxygen concentrator with no moving parts weighing four-ounces (Fig. 1). It silently delivers 3 mL/hour of oxygen through a 60 inch long cannula. The oxygen delivery cannula and concentrator are connected via a port and lock system. EpiFLO® has an “ON/OFF” switch and indicator light to show device status. EpiFLO® is available as a 7 day or 15 day device. A new device is applied every 7 or 15 days until the wound is healed or closed by secondary intention.

INDICATIONS FOR USE
The EpiFLO® system is intended to provide transdermal sustained oxygen therapy to treat the following:

- Skin ulcerations due to diabetes, venous stasis, post surgical infections, and gangrenous lesions
- Pressure ulcers
- Amputations/infected residual limbs
- Skin grafts
- Burns
- Frostbite

CONTRAINDICATIONS
The EpiFLO® system is contraindicated to treat the following:

- Wounds with inadequate perfusion to support healing
- Ulcers due to acute thrombophlebitis
- Ulcers due to Raynaud’s disease
- Necrotic wounds covered with eschar or slough
- Wounds with fistulae or deep sinus tracts with unknown depth

WARNINGS AND PRECAUTIONS
CAUTION: Federal law restricts the device to sale by or on the order of a physician.

CAUTION: This product is designed for single patient single use only.

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Therapy is most effective when used on wounds that are generally free of necrotic tissue.

Typically there is a marked increase in wound drainage for at least 4 - 6 days, tapering off in subsequent weeks. It is therefore important to inspect the dressing site regularly and change the dressing according to the dressing manufacturer’s instructions when it becomes saturated with exudate. Frequency will vary from patient to patient. Leaving an exudate saturated dressing in the wound bed beyond the dressing manufacturer’s instructions may lead to maceration (skin break down) and a possible infection.

It is necessary to achieve a complete seal with the transparent film dressing. Any gaps or breaks in the transparent film dressing seal will allow oxygen to leak out from the dressing and can affect the efficacy of the transdermal sustained oxygen therapy.

Patient wound care must be directed by personnel trained in wound care. In order to achieve maximum benefit from EpiFLO™ and avoid potential hazards, it is important that the patient and caregiver understand and comply with the instructions for use. The clinician should review this instruction sheet with the patient and caregiver.

The following precautions should be observed with the use of the EpiFLO™ system:

- Therapy should be initiated only after the wound base is clean. As appropriate, prepare the skin around the wound.
- Do not use lotions, oils, emulsions, ointments, topical creams or amor-phous gel dressings and/or any other products containing petrolatum or petrolatum-based products in and around the treated wound. These products are not compatible for use with EpiFLO™.

HOW EPIFLO™ WORKS TO HELP HEAL A WOUND

The tip of the oxygen delivery cannula is placed in the middle of the wound and resting directly on top of the wound bed (Fig. 3). The wound and cannula are first covered with a primary moisture absorbent dressing and then covered with a secondary thin film dressing or multilayer wrap.

Thermosensitive dressing or multilayer wrap.

INSTRUCTIONS FOR USE

1) Gather Supplies

- The EpiFLO™ system comes as either a:
  - 7 day oxygen concentrator with 2 delivery cannulas.
  - 15 day oxygen concentrator with 4 delivery cannulas.

Additional supplies needed are as follows:

- primary dressing - moisture absorbent
- secondary dressing - transparent film or multilayer compression wrap
- surgical tape
- gloves
- wound cleansing supplies per protocol

2) Clean the Wound

- Remove all dressings and expose the wound. Cleanse wound as directed by protocol to use of EpiFLO™. Ensure that the wound base is clean. As appropriate, prepare the skin around the wound.

3) Activate the Oxygen Concentrator

- Remove the EpiFLO™ device from its packaging and activate the oxygen concentrator by sliding the switch left to the “ON” position (Fig. 4). Upon activation, the device indicator light will begin a rapid flash sequence and then flash continuously every 5 seconds to indicate that the oxygen concentrator is functioning (Fig. 4). If the indicator light stays off, or the light stays on without flashing, or blinks erratically, contact your local care provider for a new device. Interruptions in therapy are strongly discouraged. This oxygen concentrator does not contain chemicals that release oxygen upon activation.

4) Assemble the System

- Open the pouch containing the sterile oxygen delivery cannula and remove the cannula. Attach the cannula lock to the device oxygen port (Fig. 5). Firmly twist clockwise to tighten the connector of the cannula to the port fitting on the device.

5) Cannula Placement

- Platen the tip of the oxygen delivery cannula in the middle of the wound margins, resting directly on top of the wound bed (Fig. 6). Secure the cannula to the peri-wound skin (intact skin around the wound) with surgical tape. Ensure that the delivery cannula is not kinked and that its course is not bent in a way that can impede the flow of oxygen through the cannula.

6) Cover the Wound and Cannula with Absorbent Dressing

- Cover the wound and the tip of the delivery cannula with a primary moisture absorbent dressing (Fig. 7). Follow the dressing manufacturer’s instructions for use.

7a) Cover the Wound, Cannula and Absorbent Dressing with Transpar-ent Film Dressing

- Use a transparent film dressing as the secondary dressing covering the wound, cannula and absorbent dressing (Fig. 8a). Follow the dressing manufacturer’s instructions for use. Ensure that the dressing margins are completely sealed to the skin. All openings

CAUTION: Do not sterilize, or autoclave the EpiFLO™ unit. Do not flush it with any washing agent. The environment inside the unit does not support bacterial or fungal growth. While no growth of bacteria in the unit is expected or has ever been seen, the unit has not been tested to validate its inability to support such growth.

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The following precautions should be observed with the use of the EpiFLO™ system:

- Therapy should be initiated only after the wound base has been properly debrided and prepared.
- Wounds that present with a heavy bioburden should be treated to reduce contamination.

WARNING: Do not smoke during treatment with this device.

WARNING: Avoid going near open flames during treatment with this device.

WARNING: Prior to use, read all of the EpiFLO™ package insert instructions and all of the dressing manufacturer’s instructions for use. Failure to do so may result in possible infection that could lead to severe patient injury or death.

WARNING: Do not alter the EpiFLO™ system. Do not attempt to open the oxygen concentrator. Attempting to open the unit may pierce or rupture the battery case and severe burns could result from exposure to the battery chemicals.

WARNING: Do not use if package has been previously opened or damaged.

WARNING: Do not expose the oxygen concentrator to excessive heat. Store the system at normal room temperature. Avoid temperatures above 122°F or below 50°F.

WARNING: Do not reinstall the delivery cannula if it is removed from the wound dressing. Replace with new cannula.

WARNING: Avoid exposing the oxygen concentrator to water or fluids.

WARNING: Do not obstruct the air intake seams in the oxygen concentrator. If all four air intake seams are obstructed, the device may not generate oxygen properly (Fig. 2).

WARNING: Do not reinstall the delivery cannula if it is removed from the wound dressing. Replace with new cannula.