

Where is it used:

The EPIFLO system is intended to provide transdermal continuous oxygen therapy to treat the following:

- Skin ulcerations due to diabetes; venous stasis wounds; gangrenous lesions
- Pressure ulcers and post-surgical infections

Contraindications for Use:

EPIFLO is contraindicated to treat:

- Infected wounds (See Warnings)
- 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;
- Venous stasis ulcers and pressure ulcers.

Warnings and Precautions:

Be aware of the risk of or presence of infection for your wound. Contact a doctor immediately if you have any of the following *while using EPIFLO*:

- Increased redness spreading out from the wound.
- Increased pain or swelling.
- Difficulty moving the affected area.
- Pus or odorous drainage.
- Warmth around the wound.
- Fever higher than 100.4 degrees.

How to apply:

1) Gather Supplies

Additional supplies needed are as follows:

- primary dressing - moisture absorbent
- secondary dressing - transparent film
- surgical tape
- gloves are suggested
- wound cleansing supplies per your

EPIFLO-28 comes with one 28-day oxygen concentrator, a pouch and Velcro strap, and six sterile oxygen delivery cannulas. Additional supplies needed include a moisture-absorbant primary dressing, a barrier-film secondary dressing, medical tape, and gloves. Primary and secondary dressings appropriate for use can be purchased with EPIFLO from Ogenix or from a medical supply distributor. **Only use recommended dressings with EPIFLO.**

2) Clean the Wound

Wash hands and don gloves. Remove all dressings and expose the wound. Cleanse wound with soap and water prior to the use of EPIFLO. Ensure that the wound base is clean and dry.

3) Activate the Oxygen Concentrator

Remove the EPIFLO concentrator from its packaging and activate the oxygen concentrator by sliding the switch left to the "ON" position. Upon activation, the indicator light will rapidly flash green 4 times and then flash green once every 5

seconds to indicate that the oxygen concentrator is functioning. If the indicator light stays off, stays on without flashing, blinks erratically, or shows red, contact Ogenix to obtain a new device.

4) Place the Cannula on the Wound

Wash your hands with soap and water. Open the sterile cannula package where indicated (Figure 2) and remove the cannula being careful to avoid touching the plain end (non-luer end) of the cannula (Figure 3).



Figure 2



Figure 3

Determine the best location for application and position the plain end of the oxygen delivery cannula on the edge towards middle of the wound margins resting directly on top of the wound bed (Figure 4).



Figure 4

Secure the cannula to the intact skin around the wound with medical tape (Figure 5).

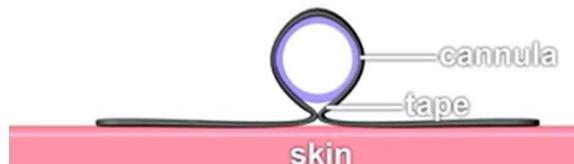


Figure 5

5) Cover the Wound and Cannula with Absorbent Dressing

Cover the wound and the plain end of the cannula (the delivery cannula) with the primary moisture-absorbent dressing. Follow the dressing manufacturer's instructions for use.

6) Cover the Wound with Secondary Film Dressing

Use a barrier film dressing as the secondary dressing covering the wound, cannula, and absorbent dressing (Figure 6). Follow the dressing manufacturer's instructions for use. Ensure that the dressing margins are completely sealed to the skin. All openings between the skin and the film dressing must be completely sealed to achieve maximum benefit from the EPIFLO system. If necessary, use additional film to close any openings or improve poor seals of the secondary dressing. **Make sure the seal is secure to keep oxygen from escaping.**

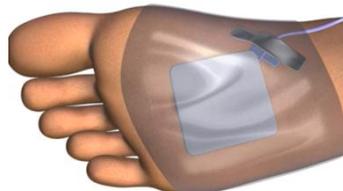


Figure 6

7) Place EPIFLO concentrator in pouch

Place the EPIFLO concentrator in the pouch with the oxygen port extending through the circular opening in the bottom. Ensure the indicator light and ON/OFF switch on the concentrator are visible through the small pouch openings (Figure 7).



Figure 7

8) Attach cannula to EPIFLO concentrator

Discard the paper wrap on the cannula. Extend the cannula and attach the cannula Luer lock to the oxygen port on the concentrator by inserting the lock and turning it clockwise approximately $\frac{3}{4}$ of a turn (Figures 8 and 9). This also secures the concentrator in the pouch. Do not use pliers or other tools when tightening. Finger-tighten only. Overtightening may crack the luer fitting.

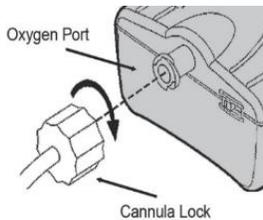


Figure 8



Figure 9

9) Position concentrator and pouch on patient

If the concentrator will be worn on the patient's arm or leg, thread the Velcro band through the loop on the back of the pouch. If the device will be worn on the patient's belt, thread the belt through this loop.

If the band is being used, place it around the limb and tighten only enough to prevent slippage of the device. **Warning - ensure circulation in the limb is not compromised by the band.**

If patient has fragile skin or neuropathy, gauze can be placed under the band to help prevent skin irritation.

10) Assure oxygen flow

Make sure the oxygen flow is not impeded by removing any kinks in the cannula. To prevent snagging, excess cannula can be wrapped and taped to the patient where convenient (Figure 10).



Figure 10

Avoid putting weight or pressure on the wound as this can pinch off the end of the cannula and block oxygen flow. For foot wounds, offload the foot so as to prevent weight being placed directly on the wound.

11) Oxygen Concentrator Change

Each new, single use EPIFLO oxygen concentrator provides transdermal continuous oxygen therapy for 28 days. During this time the indicator light flashes green indicating normal operation. At the end of 28 days of oxygen delivery, the indicator light will rapidly flash red for 12 hours indicating the need for a new device. After the 12-hour warning period, the indicator light will turn off. Discard the used concentrator and replace with a new one as necessary. Leave the used EPIFLO concentrator switch in the “ON” position to fully discharge the batteries.

12) Additional Use Guidelines

- Use only recommended dressings with EPIFLO. These dressings provide the required absorptive capacity and oxygen barrier. Use of other dressings can render EPIFLO ineffective.
- Leave the EPIFLO concentrator switch ON during the entire treatment period.
- Replace the cannula with a new cannula each time the dressing is changed.
- The flashing green indicator light on the concentrator indicates normal operation. A red flashing light, red solid light, or no visible light indicates a problem with the device. Contact Ogenix if a problem is detected.
- Before showering or bathing:
 - Disconnect the cannula lock from the EPIFLO concentrator oxygen port by twisting the lock counterclockwise.
 - Remove the concentrator and pouch to a place where it will not get wet. Leave the switch ON.
 - Cover the cannula lock to ensure that water does not enter the cannula.
 - When finished showering or bathing, reattach the cannula lock to the concentrator oxygen port.
- Do not use petroleum-based gels with EPIFLO.
- Replace the pouch and/or band if they become torn or damaged. New ones are available from Ogenix.
- Discard the pouch and Velcro band at the end of therapy.
- In the event of user questions about the device, contact Ogenix at 216-839-0202 or e-mail at info@ogenix.com

13) Additional Warnings

- **WARNING:** Do not obstruct the air intake seams in the oxygen concentrator. If all four air intake seams are obstructed, the device may not deliver oxygen properly (Figure 11).



Figure 11

- **WARNING:** Do not alter the EPIFLO system. Do not attempt to open the oxygen concentrator. Attempting to open unit may pierce or rupture the battery case. Severe burns could result from exposure to battery chemicals.
- **WARNING:** Do not submerge the EPIFLO device in water.
- **WARNING:** Avoid going near open flames during treatment with this device.
- **WARNING:** Do not smoke when using EPIFLO.
- **WARNING:** Remove before undergoing MRI. EPIFLO is NOT compatible with MRI.
- **CAUTION:** Do not overtighten the cannula Luer lock. Finger tightening is sufficient.
- **CAUTION:** Contact Ogenix if indicator light on the EPIFLO concentrator turns red or is not lit.
- **CAUTION:** In case of emergency, call 911 or visit the emergency department.

EMC Warnings

- **WARNING:** 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 EPIFLO, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- **WARNING:** A risk of increased emissions or decreased immunity may result if any additional cables are attached.
- **WARNING:** 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.
- **WARNING:** RF emitters (e.g., electronic article surveillance devices, security systems, metal detectors, RFID) can affect the device performance. Some of these RF emitters might be hidden (such as RFID). If the device is exposed to fields from RF emitters, the device should be observed to verify that it is operating normally.