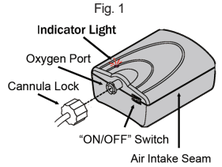
EPIFLO®

TRANSDERMAL CONTINUOUS O_2 THERAPY

PRODUCT DESCRIPTION

EPIFLO® is a transdermal continuous 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 directly into the wound bed providing treatment 24 hours per day, 7 days per week through a 36 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. This model of EPIFLO is a 28-day device. A new device is applied every 28 days until the wound is healed or closed by secondary intention.

Fig. 1



INDICATIONS FOR USE

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

- Skin ulcerations due to diabetes, venous stasis, and pressure ulcers
- Gangrenous lesions

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.

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

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

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.

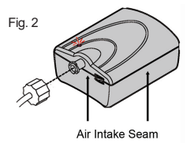
WARNING: Do not alter the EPIFLO system. Do not attempt to open the oxygen concentrator. Attempting to open the unit may pierce or rupture the battery case and severe burns could result from exposure to the battery chemicals.

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

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

Fig. 2



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 or fungi in the unit is expected or has ever been seen, the unit has not been tested to validate its inability to support such growth.

CAUTION: Intended operator is a medical professional - Nurse, physician/surgeon, PA or physical therapist and other trained clinical personnel.

CAUTION: 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 information sheet with the patient and caregiver.

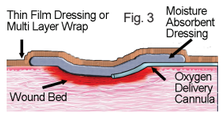
The following **PRECAUTIONS** should be observed with the use of the EPIFLO system:

- Therapy should be initiated only after the wound bed has been properly debrided and prepared.
- Wounds that present with a heavy bioburden should be treated to reduce contamination.
- Therapy is most effective when used on wounds that are generally free of necrotic tissue.
- 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 continuous oxygen therapy.
- 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.
- Do not use lotions, oils, emulsions, ointments, topical creams or amorphous 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 resting directly on top of the wound bed (Fig. 3). The wound and cannula are covered with a primary moisture absorbent dressing and then covered with a secondary film dressing or multi layer wrap.

Fig. 3



Interruptions in therapy are strongly discouraged. This oxygen concentrator does not contain chemicals that release oxygen upon activation.

INSTRUCTIONS FOR USE

This document provides detailed Application Instructions and suggestions on dressing choices etc. A tutorial video is available on our website: www.ogenix.com for training purposes. Clinician or hospital groups can also request in-service training on a prior appointment basis. It is recommended that clinicians review the video or request in-service training if there has been an interruption of more than 3 months in their use of EPIFLO.

1) Gather Supplies

The 28-day EPIFLO model comes with one 28-day oxygen concentrator and six sterile oxygen 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 prior 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 indicator light will rapidly flash green 4 times and then flash green once every 5 seconds to indicate that the oxygen concentrator is functioning (Fig.4). If the indicator light stays off, stays on without flashing, blinks erratically, or shows red, contact your care provider for a new device.

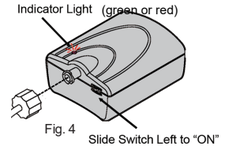


Fig. 4

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.

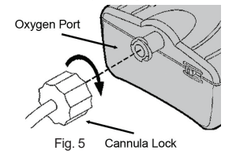


Fig. 5

5) Cannula Placement

Position 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.

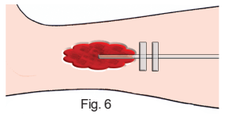


Fig. 6

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.

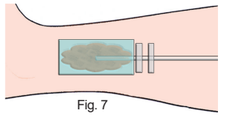


Fig. 7

7a) Cover the Wound, Cannula and Absorbent Dressing with Transparent 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 between the skin and the transparent film dressing must be completely sealed to achieve maximum benefit from the EPIFLO system. If necessary, use additional transparent film to close any openings or improve poor seals of the secondary dressing.

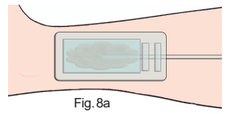


Fig. 8a

7b) Cover the Wound, Cannula and Absorbent Dressing with Multi Layer Wrap.

For wounds that require a multi layer compression wrap, apply the compression dressing over the primary moisture absorbent dressing and cannula. Do not use a transparent film dressing as a secondary dressing; the multi layer wrap can provide enough oxygen barrier to maintain an oxygen rich environment at the wound site. Apply the compression dressing according to the dressing manufacturer's instructions for use. During dressing application, weave the delivery cannula up and out of each layer of the dressing (Fig. 8b). Ensure that the delivery cannula is not kinked and that its course is not bent in a way that can impede oxygen flow through the cannula.

Warning: Attention Care Provider!

Properly tape the cannula length to prevent possible entanglement and/or strangulation hazard.

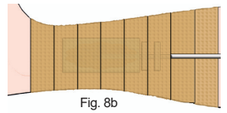


Fig. 8b

8) Wearing the Device

The 36 inch long cannula allows for flexibility to wear the device. Plan to position EPIFLO in an area on the patient that will be comfortable, secure, and not subject to pressure from body weight while the patient walks, sits, or sleeps. The device may be worn in a pocket or in a sock. To affix the device to the patient, place a piece of gauze or foam pad between the device and the patient's skin. Wrap or cover the device with open mesh gauze and/or tape. Do not obstruct the air intake seams in the oxygen concentrator (see Fig. 2). If all four air intake seams are obstructed, the device may not generate oxygen properly. Wear loose fitting clothing over the EPIFLO system. This ensures that air flow into the oxygen concentrator is not obstructed and the delivery cannula is not kinked in a way that can obstruct the flow of oxygen through the cannula.

9) Cannula and Dressings Change

Change dressings as needed according to the dressing manufacturer's instructions for use. Change cannula with each dressing change, and at least once a week.

10) 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 system and continue therapy with a new EPIFLO system as prescribed. Leave the EPIFLO unit switch in the "ON" position to fully discharge the batteries.

11) Trouble Shooting

A slow-flashing red indicator light means that the device has malfunctioned. Remove the device, turn the switch off, and return it to your care provider. A new device will be provided. Additionally, if the indicator does not light, stays on without flashing, or flashes erratically, contact your care provider for a new device. For further information contact your care provider or Ogenix at 216-839-0202.

12) System Disposal

WARNING: Consult the waste management division of your local government for appropriate disposal instructions. The EPIFLO-28 concentrator contains lithium metal batteries that cannot be recharged or replaced.

13) STORAGE INSTRUCTIONS

Store the EPIFLO system at normal room temperature. Avoid temperatures above 122°F or below 50°F.

14) OPERATING RANGE

The optimal operating temperature range for EPIFLO is 10˚C - 40˚C (50˚F - 104˚F). The optimal operating relative humidity range for EPIFLO is 25% - 80%.

EMC ACCOMPANYING DOCUMENT

EPIFLO requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

Portable and mobile RF communications equipment can affect medical electrical equipment.

EPIFLO does not have detachable data cables or transducers.

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.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

EPIFLO is intended for use in the electromagnetic environment specified below. The customer or the user of EPIFLO should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ± 15kV air	+8kV contact + 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.
IMMUNITY to proximity fields from RF wireless communications equipment	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of EPIFLO than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance E = [6/d] √P d = [6/E] √P where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of EPIFLO than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5/10] √P 80 MHz to 800 MHz d = [7/10] √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which EPIFLO is used exceeds the applicable RF compliance level above, EPIFLO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating EPIFLO.

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and EPIFLO

EPIFLO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of EPIFLO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and EPIFLO as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz $d = [3.5/10]\sqrt{P}$	800 MHz to 2.7 GHz $d = [7/10]\sqrt{P}$	710, 745, 780, 5240, 5500, 5785 $d = [6/9]\sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 $d = [6/28]\sqrt{P}$
0.01	0.035	0.070	0.067	0.021
0.1	0.110	0.221	0.211	0.070
1	0.350	0.700	0.667	0.214
10	1.107	2.213	2.108	0.700
100	3.500	7.000	6.670	2.143

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EPIFLO is intended for use in the electromagnetic environment specified below. The customer or user of EPIFLO should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	EPIFLO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are no likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	EPIFLO is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

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.

EPIFLO Label Symbols

Symbol	Meaning
	Non-pyrogenic
	Do not reuse this device, single use only
	Caution: Consult accompanying documents
	Consult instructions for use
STERILE EO	Sterilized by ethylene oxide
	Manufacture date: (year-month)
LOT	Lot number
	Expiration date (use-by date): (year-month)
REF	Reference/model number: (reorder number)
	Type BF Applied Part
	Not made with natural rubber latex
	Keep dry
	Manufacturer
	Storage temperature
	Do not use if package is damaged
	Storage humidity
EC REP	Authorized Representative in the European Community
	WEEE Battery Regulation (EU only)
MR	MR Unsafe

Neogenix, LLC dba Ogenix • 3401 Enterprise Parkway
Suite 340 • Beachwood, OH 44122 USA
216.839.0202 • www.ogenix.com

Manufactured by Neogenix, LLC dba Ogenix • U.S. Pat # 7,429,252

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
CE 2797