

EpiFLO^{SD}
TRANSDERMAL SUSTAINED O₂ THERAPY



*...wound healing achieved
with transdermal sustained
oxygen therapy*



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Clinical Users Guide

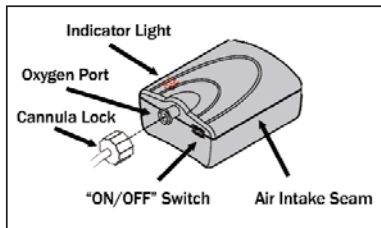


...wound healing achieved with transdermal sustained oxygen therapy

PRODUCT DESCRIPTION

EpiFLO^{SD} is a transdermal sustained oxygen therapy device (TSOT) indicated for the treatment of difficult-to-heal wounds. EpiFLO^{SD} consists of a disposable electrochemical oxygen concentrator with no moving parts weighing four-ounces and measures approximately 6x2.5x5cm (2.5"x1"x2"). It silently delivers 3 mL/hour of oxygen directly into the wound bed providing treatment 24 hours / day, 7 days / week through a 152cm (60") long # 5 Fr. cannula. The oxygen delivery cannula and concentrator are connected via a luer port and lock system. EpiFLO^{SD} has an "ON/OFF" switch and indicator light to show device status. EpiFLO^{SD} 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.

Fig. 1



INDICATIONS FOR USE

The EpiFLO^{SD} 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^{SD} 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

The following warnings and precautions should be observed with the use of the EpiFLO^{SD} system:

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

WARNING: Do not smoke during treatment with this device.

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

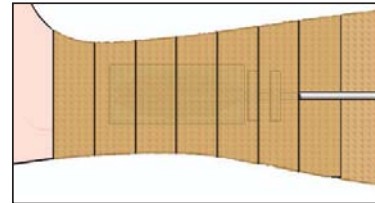
WARNING: Prior to use, read all of the EpiFLO^{SD} package insert instructions and all of the dressing manufacturer's instructions for use. Failure to do so may result in possible infection that could lead to severe patient injury or death.

WARNING: Do not alter the EpiFLO^{SD} system. Do not attempt to open the oxygen concentrator.



...regenerative wound care using oxygen

Fig. 8b



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^{SD} 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 Application
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 Application
Each new, single use EpiFLO^{SD} oxygen concentrator provides transdermal sustained oxygen therapy continuously for 7 or 15 days, as labeled on the device. At the end of 7 days of oxygen delivery, or 15 days for the 15-day device, the

device will begin a rapid flash for 12 hours indicating the need for a new device. After the 12-hour warning period, the indicator light will turn off. When the indicator light stops flashing the device may no longer be generating oxygen. Discard the used system and continue therapy with a new EpiFLO^{SD} system as prescribed. Leave the EpiFLO^{SD} unit switch in the "ON" position to fully discharge the batteries.

11) Troubleshooting

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. For further information contact your local care provider or the Converg Medical Corporation by phone: 1-888-839-6137 or email: Support@convergmedical.com

12) System Disposal

WARNING: Consult the waste management division of your local government for appropriate disposal instructions. The 7-day EpiFLO^{SD} system contains alkaline batteries that cannot be recharged; the 15-day EpiFLO^{SD} system contains lithium batteries that cannot be recharged.

13) STORAGE INSTRUCTIONS

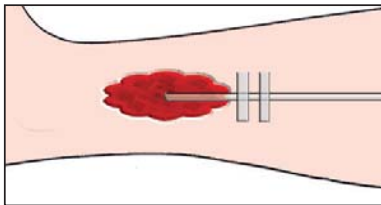
Store the EpiFLO^{SD} system at normal room temperature. Avoid temperatures above 50°C (122°F) or below 13°C (50°F).



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its course is not bent in a way that can impede the flow of oxygen through the cannula.

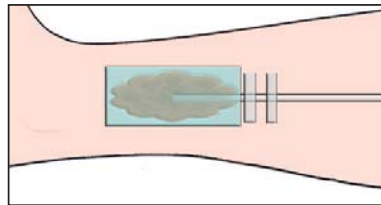
Fig. 6



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

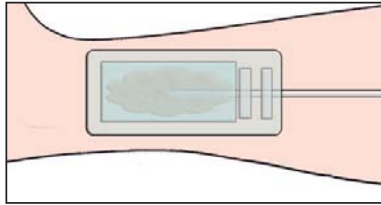


7a) Cover the Wound, Cannula and Absorbent Dressing with Transparent Film Dressing

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^{SD} 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 the flow of oxygen through the cannula.

8) Wearing the Device

The 152 cm (60") long cannula allows for flexibility to wear the device. Plan to position EpiFLO^{SD} in an area on the patient that will be comfortable,



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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.

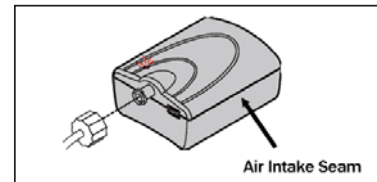
WARNING: Do not expose the oxygen concentrator to excessive heat. Store the system at normal room temperature. Avoid temperatures above 50°C (122°F) or below 13°C (50°F).

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 (the seam where the lid attaches to the base see Fig. 2). If all four air intake seams are obstructed, the device may not produce oxygen properly

Fig.2



CAUTION: Do not sterilize, or autoclave the EpiFLO^{SD} 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: Patient wound care must be directed by personnel trained in wound care. In order to achieve maximum benefit from EpiFLO^{SD} 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^{SD} 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.
- 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 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.
- Do not use lotions, oils, emulsions, ointments, topical creams or amorphous gel dressings



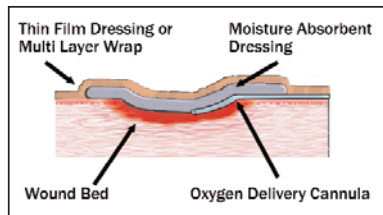
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and/or any other products containing petrolatum or petrolatum based products in and around the treated wound. These products are not compatible for use with EpiFLO^{SD}.

HOW EPIFLO^{SD} WORKS TO HELP HEAL A WOUND

- The tip of the oxygen delivery cannula is placed in the middle of the wound margins resting directly on top of the wound bed (Fig. 3).
- The wound and cannula are first covered with a primary moisture absorbent dressing to manage the increase in exudate.
- The cannula, wound and moisture absorbent dressing are then covered with a secondary thin film dressing or multi layer wrap.
- The secondary occlusive dressing traps the oxygen over the wound site to maintain an oxygen rich wound healing environment.
- EpiFLO^{SD} bathes the wound in oxygen and can stimulate epithelialization, granulation tissue, glycosaminoglycan production, and collagen synthesis.

Fig. 3



DRESSING SELECTION

Application of the EpiFLO^{SD} oxygen concentrator and cannula system requires a moist wound healing environment utilizing a primary and secondary dressing system in order to maximize the

therapy. The simplicity of the therapy and device allows great flexibility in dressing selection in order to meet individual patient needs.

The primary dressing should be moisture absorbent. Typically, during the first few days of transdermal sustained oxygen therapy, wound drainage will greatly increase. Therefore, it is recommended that the dressing selected is one that can handle a large amount of exudate. Wounds that are thought to have a heavy bioburden or are clinically infected may be dressed with an exudate absorbent dressing that contains silver or other non-petrolatum-based antimicrobials.

Primary moisture absorbent dressing options:

- Alginates with or without silver
- Foam dressings with or without silver
- Hydrofiber with or without silver
- Island dressings

An occlusive dressing should be used as a secondary dressing. The critical function of the occlusive dressing is to trap the oxygen over the wound site to maintain an oxygen rich wound healing environment. The dressing should be selected to allow a 5 cm (2") margin between the edge of the wound bed and the edge of the dressing. Transparent film dressings allow for easy visual inspect of the moisture absorbent dressing. In some cases when an adherent occlusive dressing is not appropriate and/or when compression is recommended, alternative dressings may be used to maintain an oxygen rich environment.

Secondary occlusive dressing options:

- Transparent film dressing
- Hydrocolloid dressings
- Multilayer compression bandage system



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- Self-adherent wrap

contain chemicals that release oxygen upon activation.

INSTRUCTIONS FOR USE

1) Gather Supplies

The EpiFLO^{SD} system comes as either a

- 7- day oxygen concentrator with 2 delivery cannulas or as a
- 15- day oxygen concentrator with 4 delivery cannulas.

Additional supplies needed are as follows:

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

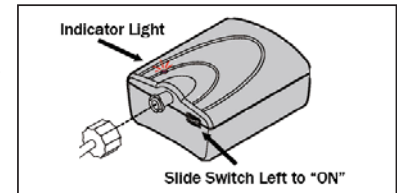
2) Clean the Wound

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

3) Activate the Oxygen Concentrator

Remove the EpiFLO^{SD} 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. If therapy is to be interrupted for more than eight hours, the device can be turned off and restarted when therapy resumes. Interruptions in therapy are strongly discouraged. This oxygen concentrator does not

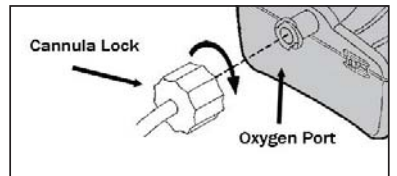
Fig. 4



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