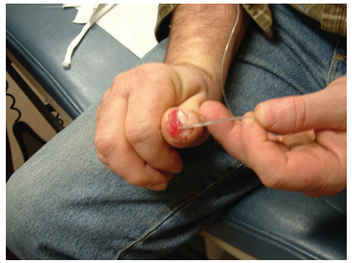
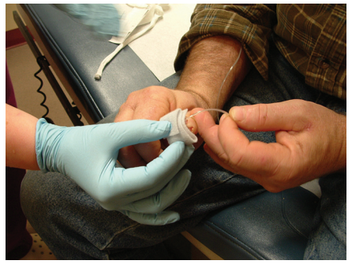
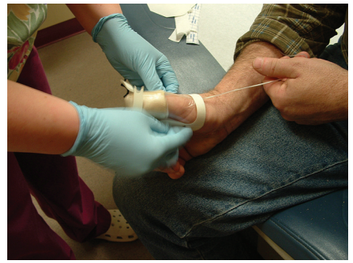
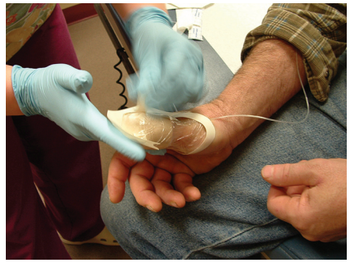
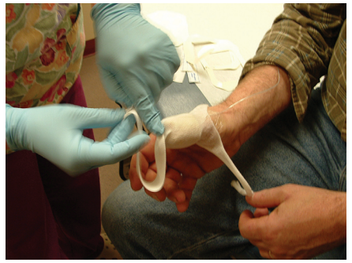
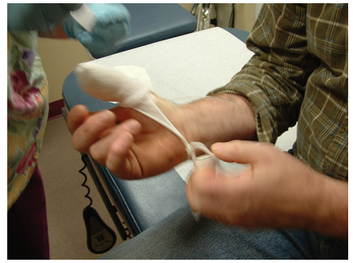
APPLICATION GUIDANCE

EPIFLO is a versatile wound healing device that can be use almost anywhere on the body.

Here EPIFLO® is applied to a wound on the thumb. The cannula is covered with a primary and secondary dressing and then sealed with a thin film transparent dressing.

DRESSING LISTS

SMITH & NEPHEW
Allevyn™, Allevyn Cavity™, Iodosorb, Intrasite Gel, Opsite, Profore

COLOPLAST
Biatain®

CONVATEC
Versiva®, Lyofoam®, Aquacel®, Aquacel Ag®, Kaltostat®, Duoderm®, Duoderm® Hydroactive® Gel, Duoderm® Extra Thin CGF® Dressing, CombiDERM®

MOLNYCKE
Mepilex®, Mepilex Thin®, Mepilex® Border, Mepilex® Silver, Mepitel®, Duoderm®, MeFilm®, Lyofoam

MMM
Tegaderm™, Tegaderm™ Foam, Tegaderm™ Matrix, Tegaderm™ Alginate, Tegaderm™ Hydrocolloid, Tegaderm™ Alginate Ag, Tegaderm™ Transparent Film Dressing, Coban™

COVIDIEN
Kendall™ AMD Antimicrobial Foam Dressings

JOHNSON & JOHNSON
Silvercel™

EC REP MDSS GmbH Schiffgraben 41 30175 Hannover, Germany CE 0086

MK005-BR REV C

OGENIX CORPORATION 3401 ENTERPRISE PARKWAY SUITE 340 BEACHWOOD, OHIO 44122 T : 781 702 6732 WWW.OGENIX.COM

EPIFLO®

TRANSDERMAL CONTINUOUS O_2 THERAPY

CLINICAL USERS GUIDE

PRODUCT DESCRIPTION

EPIFLO® is a transdermal continuous oxygen therapy device indicated for the treatment of chronic or difficult-to-heal wounds. EPIFLO® concentrates oxygen from atmospheric air and delivers the concentrated oxygen to the region of the wound bed creating an oxygen-enriched environment intended to promote the healing process in chronic wounds as an adjunct to standard wound care in wound management and treatment (See indications for use). EPIFLO® consists of a disposable electrochemical "fuel cell based" oxygen concentrator with no moving parts weighing four ounces (figure 1). It silently delivers 3 ml/hour of oxygen directly into the wound bed providing treatment 24 hours per days 7 days per week through a 91 cm –36 in (3 ft) long cannula. The oxygen delivery cannula and concentrator are connected via a port and Luer lock system. EPIFLO® has an ON/OFF switch and indicator light to show device usage status. EPIFLO® is currently available as a 28 day device. A new device is applied every 28 days until the wound is healed or closed by secondary intention.

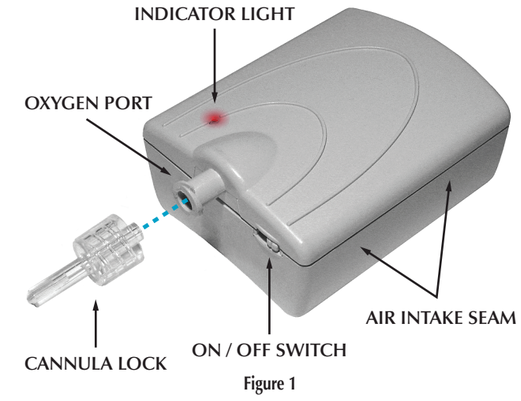


Figure 1

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, post surgical infections, and gangrenous lesions
- Pressure Ulcers
- Amputations/infected residual limbs
- Skin grafts
- Burns
- Frostbite

CONTRAINDICATIONS FOR USE

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: US Federal law restricts the device to sale by or on order of a order of a physician. Please check regulations in other countries as they may vary.

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

CAUTION: Do Not sterilize, or autoclave the EPIFLO® unit. Do not flush the EPIFLO® unit 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 medical 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 cleansed, debrided if necessary and prepared.

—Wounds that present with a heavy bioburden should be treated using best practice to reduce contamination and/or infection.

—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 2 – 7 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. Leaving an exudate saturated dressing in the wound bed beyond the manufacturer's instructions may lead to exudate leaking and maceration (skin break down) and a possible infection. If the increased exudate is controlled though proper dressing changes, it should not inhibit the wound healing process.

—It is necessary to achieve a complete seal with the recommended secondary dressing or the primary dressing (if only one dressing will be used). Any gaps or breaks in the dressing seal will allow oxygen to leak out from the dressing and can affect the efficacy of the transdermal continuous oxygen therapy.

—Do not use lotions, oils, emulsions, ointments, topical creams or amorphous gels and/or any other products containing petrolatum or petrolatum (petroleum) based products in and around the treated wound. These products are not compatible for use with EPIFLO®.

WARNING: Do not smoke during treatment with this device.

WARNING: Avoid going near open flames or other sources of heat (such as a radiator or heater vent) during treatment with this device.

WARNING: Prior to use, read all of the EPIFLO® package insert instructions and all dressing manufacturers' 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. The EPIFLO® should be disposed of after use by the method approved by the associated hospital, facility, nursing home, municipality and/or state, province or country.

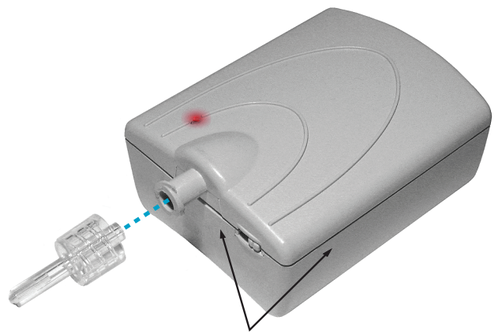
WARNING: DO NOT use if package has been previously opened or damaged or if the unit itself is damaged, even if the package is sealed.

WARNING: DO NOT expose the oxygen concentrator to excessive heat. Store the EPIFLO® system at normal room temperatures. Avoid temperatures above 122 degrees F or below 50 degrees F.

WARNING: DO NOT reinstall the delivery cannula if it is removed from the wound dressing. As a general rule it is best to replace the cannula at the same time as each dressing change.

WARNING: Avoid exposing the EPIFLO unit to water and fluids. Make sure to remove the unit and place it in a dry, safe location during bathing and/or showering.

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 of produce oxygen properly. (Figure 2).



AIR INTAKE SEAM

Figure 2

NOTE: IT IS IMPORTANT TO ENSURE THAT WHATEVER DRESSINGS ARE USED THAT THE OXYGEN IS SEALED IN SO THAT IT IS BLANKETING THE WOUND AND NOT ESCAPING INTO THE ATMOSPHERE.

PRIMARY DRESSINGS

The primary dressing should be moisture absorbent. Typically during the first few days and sometimes up to a week of transdermal continuous oxygen therapy, wound drainage will greatly increase. Therefore, it is recommended during the first week of treatment 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 another non-petrolatum based antimicrobial. This should be determined by a qualified wound care professional.

Primary moisture absorbent dressing options have included:

The brands listed have been used successfully —it should be noted that no brand has had any issues, however, due to the product breadth, not all brands have been used to date.

- Alginates with or without silver —Tegaderm Alginate, Kaltostat, NU-DERM, Silvercel
- Foam dressing with or without silver —this has included Allevyn, Allevyn cavity, Biatain, Vervisa, Lyofoam, Tegaderm Foam,Mepilex, Mepilex Thin, Mepilex, border, Mepilex Silver
- Hydrofiber with or without silver —Aquacel, Aquacel Ag

SECONDARY DRESSINGS

Secondary dressings should be occlusive or at least semi-occlusive if being used with a primary dressing. The critical function of this dressing is to trap the oxygen over a wound site to maintain the oxygen rich wound healing environment. The dressing should be selected to allow a 5 cm margin between the edge of the wound bed and the edge of the dressings. Secondary dressing options include:

- Transparent film dressings —3M Tegaderm, MeFilm, Opsite
- Hydrocolloid dressings —Duoderm , Duoderm Extra, Duoderm CGF Duoderm thin, 3M Tegasorb
- Composite —CombiDERM
- Foam dressing with or without silver —Allevyn, Allevyn Cavity, Biatain, Vervisa, Lyofoam, Mepilex, Mepilex Thin, Mepilex, Border, Mepilex Silver (note that Mepilex has also been used as a primary dressing)
- Multilayer compression dressing system —Profore, Coban 2
- Self adherent wrap —Coban
- Gauze —Kendall (although not occlusive, if wrapped around a primary dressing and the wound enough times and covered with transparent film, it can be made occlusive).

ANTIMICROBIALS

- Silver —Acticoat, Actisorb
- Others —Iodosorb, KENDALL AMD

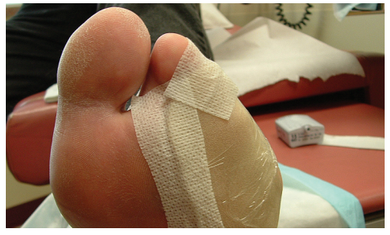
OTHER DRESSINGS

- Non adherent porous dressings —Mepitel, Tegaderm Matrix (used to separate the primary dressing from the secondary dressing or against the skin to ensure the primary dressing does not stick to the skin).
- Hydrogels —Duoderm Gel , Intrasite Gel

APPLICATION GUIDANCE

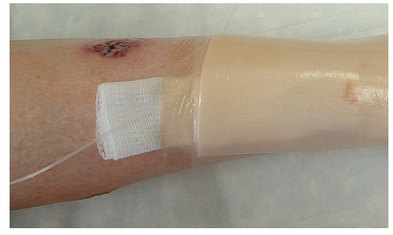
Tenting a Wound on the Toes

When a wound appears on a toe, a primary dressing should be placed over the ulcer on the toe. Then the entire area should be 'tented' with a secondary dressing. Finally, the entire dressing should be covered with a thin film dressing, ensuring that the edges of the thin film form a seal to the skin so that the oxygen will not escape from beneath the dressings. In this way, blood flow will not be restricted to the affected toe and a continuous oxygen supply will be available. Care should be taken to make sure that the cannula is off-loaded with foam , so that it will not pit into the surrounding skin.



Using Gauze or Foam to Off-load a Cannula

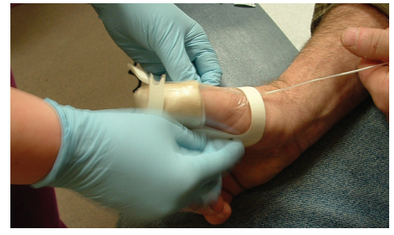
Gauze can be used to off load the cannula so that it does not pit into the skin. The gauze is placed beneath the cannula and then the cannula is adjusted so that the tip is directly over the centre of the wound. The gauze should be placed so that it does not come too close to the wound, but rather begins in the periwound area. Where heavy drainage or purulent exudate is present, it is better to use a foam dressing that will absorb more fluid; the foam should be changed along with the other dressing and cannula. Also note the transparent film application 1 inch beyond the border of the primary dressing —this ensures the oxygen is trapped above the wound.



Transparent Dressing to Seal Oxygen

Many areas of the body are contoured in a way that make it difficult to seal the dressing to the skin to ensure that oxygen does not escape. In these cases it is essential to use a thin film transparent dressing to cover the area and seal the cannula and oxygen beneath the dressing.

This is an example of a thumb that has been covered with both a primary and secondary dressing and then sealed with a thin film transparent dressing. Note that the transparent dressing extends beyond the secondary dressing. This ensures the seal with be maintained.



15) Cannula and Dressing Change Application

Dressings should be changed according to the manufacturers' instructions for use. The cannula should be changed at the same time as dressings and at least once per week. Constant attention to the amount of exudate is important, especially in the first week of treatment, and the dressing and cannula should be changed accordingly when needed.

16) EPIFLO® Oxygen Concentrator Change Application

28 Day EPIFLO® —The 28 day EPIFLO® unit provides transdermal continuous oxygen therapy for 28 days. The 28 day EPIFLO unit should be changed every 28 days or whenever change out is convenient before the end of 28 days. At the end of the 28day period the EPIFLO indicator a 12 hour rapid flash indicating that the device is due to be changed . At the end of the 28 days or into the 29th day, the indicator light will extinguish indicating the unit is no longer supplying the required oxygen.

EPIFLO® devices are safe for use until the expiry date listed on the device cover.

Continue with a new EPIFLO® system as prescribed. GO back through steps 1–15 above to apply the new EPIFLO®.

17) Trouble Shooting

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 advice please contact your local care provider or Ogenix Corporation at 781-702-6732 or www.ogenix.com.

18) System Disposal

WARNING: Leave the EPIFLO® unit switch in the ON position to fully discharge the batteries before system disposal. The EPIFLO® should be disposed of after use by the method approved by the associated hospital, facility, nursing home, municipality and or state/province or country. The EPIFLO® systems contain batteries that cannot be recharged.

19) Storage Instructions

EPIFLO® should be stored as follows:
approximately 50 – 104 degrees F (10 – 50 degrees C).

20) Potential Risks Associated with use of EPIFLO®

- Dermatological toxicity associated with contact of EPIFLO® and/or its components with the skin;
- Risk of subject discomfort;
- Risk of emotional or psychological distress;
- Risk of maceration, infection, and Cellulitis if the subject is non-compliant with safety instructions and does not follow the dressing change regimen regularly;
- Risk of unit malfunction if EPIFLO® becomes wet, damaged, mistreated or the housing opened.

DRESSING SELECTION

The dressings that are listed in the following "Dressing Section" serve as an exhaustive list of examples of dressings that have successfully been used by physicians with the EPIFLO® device. This is not intended as a list of recommended dressings as these as well as other dressings have been approved by the FDA for wound care. It is the responsibility of the treating physician to choose the dressing that best addresses the need of the patient.

Dressings are also categorized by 2 main types: PRIMARY dressings are the therapeutic or protective covering applied directly to the wound bed. In the case of EPIFLO® usage it should be noted that in almost all applications the cannula makes direct contact with the wound and the primary dressing is placed over the cannula. The primary dressing should be selected to meet the specific requirement for wound condition or exudate control, etc. The SECONDARY dressing (so-called because it is placed second) is placed to either secure the primary dressing , enhance the function of the primary dressing or provide a need for the wound that cannot be met by the primary dressing.

A dressing could be either a primary or secondary depending upon its purpose and therefore where it is placed. At the end of the 90's most dressing were becoming semi-occlusive versus occlusive, because allowing the wound to be relieved of exudate while providing an air exchange promoted a moist wound environment —considered necessary for optimal healing.

Application of the EPIFLO® oxygen concentrator and cannula system requires a moist wound healing environment —today's best practice standard of care in wound healing. This moist wound environment is maintained using proper dressings and can include both a primary and secondary dressing; and a single dressing that has the characteristics of both. The simplicity of the therapy and the device allows great flexibility in dressing selection in order to meet individual needs such as comfort, location of the wound, exudate conditions, material sensitivities, pain levels etc. The choice of dressing is most often determined by the level of exudate or drainage, but in all cases, to maximize results, the dressing manufacturer's instructions for use should be strictly adhered to.

HOW EPIFLO WORKS TO HELP HEAL A WOUND

EPIFLO® is a small, portable, silent, disposable, easy to use oxygen concentrator that blankets the wound with 98%–100% pure oxygen. EPIFLO® concentrates oxygen from atmospheric air and delivers the concentrated oxygen to the region of the wound bed. This creates an oxygen-enriched environment intended to promote the healing process in chronic wounds as an adjunct therapy in wound management and treatment. The etiologies of many chronic wounds, including diabetic wounds, are linked to poor oxygen delivery to cells due to impaired circulation. Increasing oxygen concentration above chronic open wounds with the use of transdermal, continuous oxygen delivery promotes healing and may suppress bacterial growth.

By using EPIFLO®, the patient is free to ambulate and can continue normal daily living activities while being treated 24 hours per day for 28 days. The EPIFLO 28 ® stays on for the entire life of the unit, providing continuous oxygen to the patient's wound. The tip of the oxygen delivery cannula is placed in the middle of the wound (Figure 3) resting directly on top of the wound bed. As a general rule nothing should come between the wound and the tip of the cannula.

The wound and cannula are first covered with a primary moisture absorbing dressing and then covered with a secondary dressing or multi layer wrap if needed. The secondary dressing usually serves to keep the primary dressing in place and seal in the oxygen creating an oxygen rich environment. However, sometimes only a primary dressing is required. A list of dressings is located at the end of this guide.

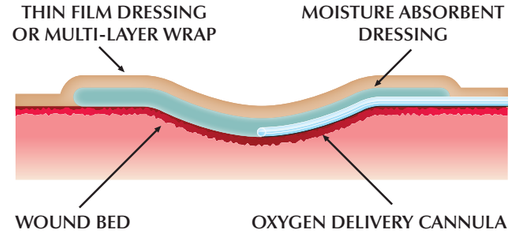


Figure 3

EPIFLO® INSTRUCTIONS FOR USE

1) Gather all dressings and supplies

The EPIFLO® system comes as a 28 day oxygen concentrator with 6 delivery cannulas. Additional supplies needed are as follows:

- Primary dressing —moisture absorbent
- Secondary dressing (or multilayer compression wrap)
- Foam under-padding (to relieve cannula pitting)
- Wound cleansing supplies per protocol
- Other supplies, dressings, gel as per best practice and compatible with EPIFLO® usage.
- Surgical tape, Gloves, Nursing Scissors, EPIFLO® holster

2) Determine best location for device on patient

The EPIFLO® cannula is 91 cm –36 in (3 ft) long, ensuring enough length to wear the device where the patient prefers. The EPIFLO® holster (figure 12) with an adjustable velcro strap gives users the ability to position the EPIFLO® device nearest the wound —on the belt, around the arm, thigh or calf —wherever it is most comfortable and unobtrusive.

3) Remove all dressings and expose the wound

4) Clean 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 (periwound area). Clinical judgement should be used to determine whether debridement is necessary.

5) Activate the EPIFLO® Oxygen Concentrator

Activate the EPIFLO® oxygen device unit by sliding the switch left to the "ON" position (Figure 4). This may take some force as the unit is designed so that it cannot be accidentally turned to the "OFF" position once activated. Upon activation, the device indicator light on top of the device will begin a rapid flash sequence and flash green every 5 seconds to indicate the EPIFLO® unit is functioning correctly. If the indicator light stays off, or the light stays on without flashing or blinks red, contact your local care provider immediately for a new device. Interruptions in EPIFLO® oxygen therapy are strongly discouraged. At this time, place the EPIFLO® unit aside.

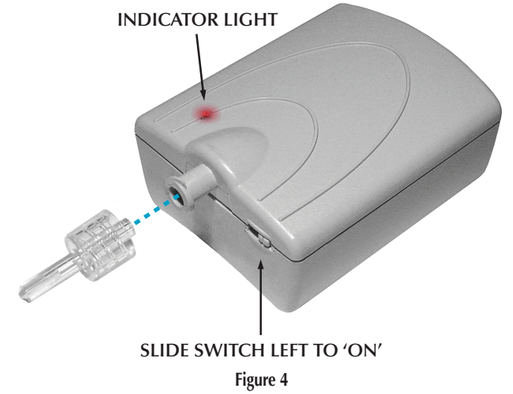


Figure 4

6) Cannula Placement

Open the sterile pouch that contains the cannula and position the tip of the sterile oxygen delivery cannula in the middle of the wound margins, resting directly on top of the wound bed (Figure 6). A small piece of folded gauze or foam should be placed beneath the cannula about 1cm or beyond in the periwound area to off-load the cannula and to avoid pitting or embedding the cannula in the wound or periwound.

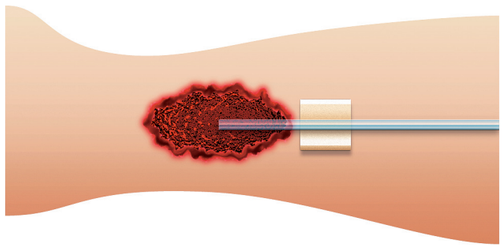


Figure 6

7) Securing the cannula

Once the cannula is centered in the wound it should be secured in the periwound area using surgical tape. The cannula that is placed over the gauze or foam should be taped first (figure 7) so the cannula does not move in the wound bed. It is best to tape the cannula in such a way that the cannula does not touch the skin directly, but rather is trapped in the tape above the skin surface. Hypoallergenic tape may be needed for some patients and is a good rule of practice if possible. It is a good idea to begin taping well outside the wound area if there is any sign of maceration, redness, swelling, or reaction to the adhesive. All of these issues should be dealt with immediately by the attending clinician.

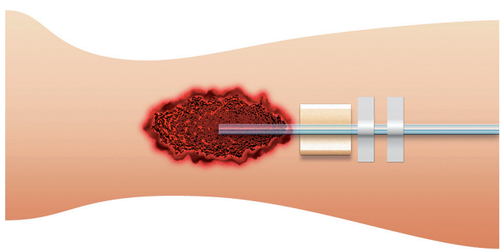


Figure 7

8) Cover the wound and Cannula with Absorbent Dressing (primary dressing-if required)

Cover the wound and the tip of the cannula within the wound with a primary dressing (moisture absorbing), following the dressing manufacturers' instructions for use. (Figure 8)

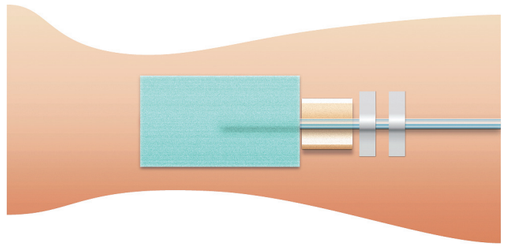


Figure 8

9) Cover the Wound, Cannula and Absorbent Dressing with a Secondary Dressing

Cover, the cannula, wound and primary dressing with a secondary dressing (if needed- Some dressings, for examples, Foams may act as both the primary and secondary dressing), following the dressing manufacturers' instructions. It is important to ensure that the dressing margins are sealed to the skin to create an occlusive environment for the oxygen, so that the oxygen does not escape the dressing (Figure 9). All openings between the skin and the secondary dressing must be completely sealed to achieve maximum benefit from the EPIFLO® system. With some dressings it will be essential to use transparent film dressing or surgical tape around the edges, as some dressings may not seal tight enough to the skin without the extra adhesive.

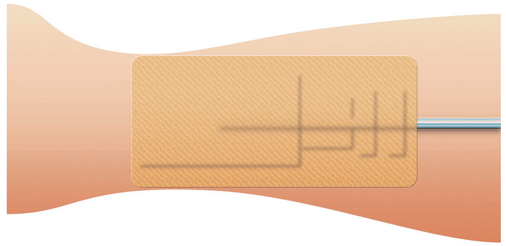


Figure 9

10) (ONLY IF COMPRESSION IS NEEDED) Cover the Wound, Cannula and Absorbent Dressing with Multi Layer Wrap

If compression is needed, it can be placed over the primary dressing, the cannula and the wound, according to the manufacturer's instructions for use. The multi layer compression wrap, if applied correctly, will provide enough of an oxygen barrier to maintain on oxygen rich site for the wound. However, some foam manufacturers allow their products to be used beneath compression wrap and if a foam dressing is needed for any purpose, the manufacturers' instructions for use should be consulted. It is important to make sure that the cannula is not compressed during application of the compression wrap. It is best to place gauze or foam beneath the cannula at its application to the skin and then wrap the compression dressing around the cannula, while holding the cannula perpendicular to the compression wrap direction. This can also be done by weaving the cannula up and out of each layer of the compression dressing (Figure 10). Ensure that the cannula is not kinked and that its course is not bent in a way that can impede the flow of oxygen. Apply the compression dressing according to the dressing manufacturer's instructions for use.

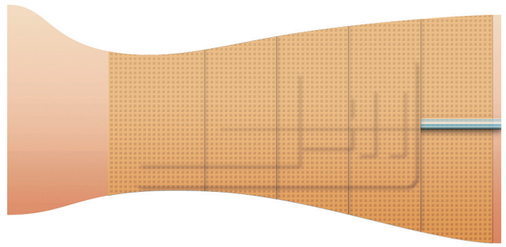


Figure 10

11) Taping the excess cannula length

To reduce the risk of having the cannula pulled from beneath the dressing, it is recommended that prior to assembling the cannula to the EPIFLO® unit, that the cannula is wound several times into a circle and taped above the dressing. In this way, if the cannula is pulled, the excess tubing bears the tension, and the tip of the cannula will not be removed from its place above the wound and beneath the dressing. This insures that the oxygen treatment will be continuous.

12) Assemble the System

Pick up the EPIFLO® unit. Attach the cannula Luer lock end to the EPIFLO® device oxygen port. (Figure 11) Firmly twist the cannula end clockwise to tighten the connector of the cannula to the port fitting on the device —DO NOT USE TOOLS. Care should be taken not to tighten cannula too tight to the Luer lock as it may be difficult to remove and may break off rendering the EPIFLO® unit unusable.

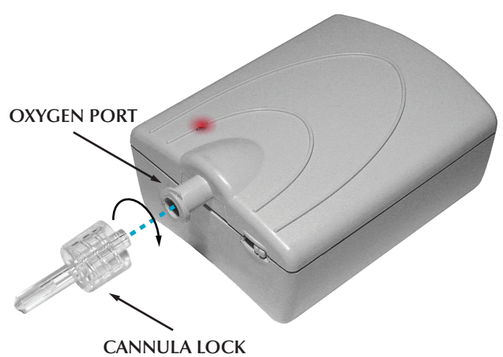


Figure 11

13) Placing the EPIFLO® on the Patient and Wearing the Device

The device should be placed on the patient where it is most comfortable, secure, and not subject to pressure from body weight (or wheelchair, etc) while the patient walks, sits or sleeps. It is important to make sure that at least one of the four intake seams (Figure 2) along the perimeter of the EPIFLO® is unobstructed or the unit will not function properly. The device is typically worn in a pocket, sock, or the EPIFLO® holster (Figure 12) and placed on a belt or around the arm, thigh or calf.

Figure 12

The 91 cm -36 in(3ft) long cannula allows flexibility to wear the device where the patient prefers. The device can also be worn by using open mesh gauze mesh over a foam pad on the patient's body. If the EPIFLO® is worn beneath clothes, it is important to wear loose fitting clothing. This ensures that the oxygen concentrator is not obstructed and the cannula is not kinked in a way that can obstruct the flow of oxygen through the cannula. As the EPIFLO® unit is worn throughout the night as well, it is important to find a secure location for the unit so it is not uncomfortable for the patient or does not move uncontrolled during the night and risk breaking. If the EPIFLO® is being used to treat a plantar ulcer or wound on the bottom of the foot, it is important that the foot be off-loaded and that the cannula is not crushed while stepping on the floor. This could impede the flow of oxygen and/or trap exudate in the cannula. The EPIFLO® unit should not be turned off during the treatment period. The unit should be removed when bathing or showering, but again it should not be turned off. It should be replaced for therapy on the patient ASAP as soon as completing the activity. Do not get the unit wet.

14) Securing the Cannula

The cannula should be taped to the body from the periwound area to the EPIFLO® unit so that it will not become dislodged or be displaced by day to day activities. It is best to loop excess cannula (create a circle) and tape the loop over the top of the secondary dressing after the secondary dressing is secured over the wound. This provides a safety mechanism to maintain the cannula over the wound beneath the dressing; in the event that the cannula is pulled, the excess tubing bears the tension and the tip of the cannula will not be removed from its place above the wound and beneath the dressing.