

Single-Use Topical Wound Oxygen Multi-Patch Surgical

Instructions for Use



Caution

Federal law restricts this device to sale by or on the order of a physician. The Single-Use Topical Wound Oxygen Multi-Patch Surgical should be operated by trained personnel under the direction of a qualified medical practitioner.

1.1 Description

The Single-Use Topical Wound Oxygen Multi-Patch Surgical is intended as adjunctive therapy to standard wound care for acute or chronic wounds. Wounds should be cleaned, and debrided if required, per standard wound care protocols, prior to commencing treatment with this device.

The Multi-Patch Surgical can be placed over a wound and when connected to a medical grade oxygen supply (Flow meter or Oxygen concentrator) provides oxygen directly to the wound site at a pressure of 22mmHg. The pressure is pre-set and automatically regulated by the tubing set. It is recommended that a bubble humidifier be used in conjunction with the Multi-Patch Surgical system in order to keep the wound moist during treatment.

1.2 Intended Use

The Single-Use Topical Wound Oxygen Multi-Patch Surgical is intended to be used for the treatment of acute and chronic wounds, such as;

- skin ulcerations due to diabetes, venous stasis, post-surgical infection and gangrenous lesions
- surgical incisional wounds
- decubitus ulcers
- amputations/infected stumps
- skin grafts
- burns
- frostbite

1.3 Preparing the wound

It is recommended to remove all bandages, dressings, creams and ointments from the wound prior to treatment, unless they are gas permeable.

1.4 Recommended Treatment duration

The minimum recommended treatment duration is:

- 60 – 90 minutes per treatment per day

1.5 Infected wounds

It is recommended that all infected wounds (including those infected with antibiotic-resistant strains, such as MRSA) be treated utilizing the institutions' standard operating procedures in conjunction with the therapy.

1.6 Kit Components

Single-Use Topical Wound Oxygen Multi-Patch Surgical case components:

- 30 - Individual Multi-Patch Surgical
- 2 - Foam bands
- 2 - Oxygen supply line sets

NOTE: Bubble jet oxygen humidifier is not included in Multi-Patch Surgical kit

1.7 Treated Protocol

1. Position the patient for comfort and place the *Foam band* under the patient with the wound visible
2. Cleanse the area around the wound and allow it to dry
3. If desired, apply a skin prep of choice around the wound and allow to dry
4. Appropriately size the *Multi-Patch Surgical* opening to the wound by separating appropriate perforation on adhesive strips
5. Peel away backing from the adhesive seal on the *Multi-Patch Surgical*
6. Apply *Multi-Patch Surgical* over wound with the adhesive ring facing down
7. Secure *Multi-Patch Surgical* utilizing the *Foam band*. Allowing approximately 3" of expansion room between *Foam band* and the *Multi-Patch Surgical*
8. Attach bubble jet humidifier bottle (not supplied in kit) to oxygen supply outlet (Flow meter or Oxygen Concentrator)
9. Connect *Oxygen supply line* to the *Multi-Patch Surgical* by attaching the two quick connects at the end of the oxygen tubing
10. Attach the long hose to end of the *Oxygen supply line* to the humidifier bottle
11. Set the Oxygen flow rate to between 3-4 lpm
12. Treat the patient for the duration prescribed therapy
13. At the end of treatment turn off the oxygen supply
14. Disconnect the *Oxygen supply line* set and place it in its reusable packaging
15. Gently remove *Foam band* and place it in its reusable packaging
16. Gently remove *Multi-Patch Surgical* and dispose of appropriately