

NATROX™

Oxygen Wound Therapy

Continuous Diffusion of Oxygen Therapy
delivery system

Oxygen Generator (OG) and
Oxygen Delivery System (ODS)



INSTRUCTIONS FOR USE

Inotec AMD^{LTD}

Notes to user and/or clinician

To achieve maximum benefit from NATROX™ and to avoid potential hazards it is important the patient understands the use of this device and complies with these instructions for use.

This device does not contain chemicals that release oxygen upon activation. No dangerous, explosive or harmful gases (e.g. H₂) are released.

Indications for use

The NATROX™ system is intended for slow-healing or non-healing wounds such as leg ulcers, non-healing surgical and trauma wounds. Pure humidified oxygen is delivered to the wound surface in order to support the natural wound healing processes.

NATROX™ Oxygen Generator (OG)

The OG is a multiple use, battery powered (rechargeable) and used for the duration of the treatment. It is carried in the holster or fitted close to the wound. There are no consumables as the battery is rechargeable. There is no ON/OFF switch, to activate simply fit a fully charged battery, the green light will flash and oxygen is now flowing.



NATROX™ Oxygen Delivery System (ODS)

The ODS is a sterile, single-use oxygen delivery system attached to a 1m long tube which connects to the OG providing oxygen directly to the wound surface, while allowing the free passage of exudate (fluids) away from the wound to a proprietary Wound Dressing which manages the wound environment.



NATROX™ International Battery charger and batteries

For mains connection. One battery must be left on **CONTINUOUS** charge. The other fitted to NATROX™. Always charge batteries before first use or after storage.



NATROX™ Contraindications (should not be used for)

The NATROX™ system is contraindicated for the following:

- Wounds being treated with layers of topical ointments or creams, such as anti-microbial treatments
- Inadequately debrided wounds
- Deep sinus wounds or tracts
- Patients unable to tolerate occlusive/adhesive dressings
- Potentially malignant wounds or ulcers.

Warnings & precautions

The NATROX™ system is to be used and fitted by qualified medical professionals only, or those trained and competent in wound care. The ODS is single use and must be replaced at the same time as the wound dressing.

Do not use if the packaging has been previously opened or is damaged.

Do not expose NATROX™ OG or its battery to excessive heat and keep dry.

If the patient wishes to shower the NATROX™ OG device must be disconnected from the ODS, kept dry and reconnected afterwards.

NATROX™ OG should not be sterilized, autoclaved, or flushed with water or any other fluid. The environment inside the NATROX™ OG in which oxygen is generated does not support bacterial or fungal growth.

NATROX™ OG and ODS are only to be used together and must not be combined with any other devices.

NATROX™ OG is multiple patient, multiple-use and battery powered (rechargeable) and requires no intervention. Wipe-down instructions are within the NATROX™ OG case.

The ODS must not be reused due to a risk of infection. Used ODS may contain exudates (wound fluids).

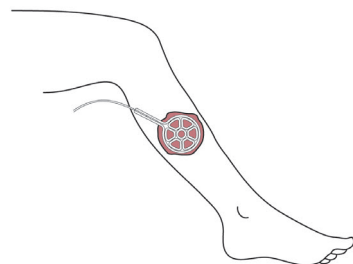
Instructions for use

Prior to Use

Using normal aseptic technique, remove all dressings to expose the wound. Ensure the wound bed is clean and moist. As appropriate, use a wound cleanser and irrigate with sterile normal saline or water. All ointments and creams must be removed from the wound. Prepare the skin around the wound as required. Barrier cream or gel strips may be considered to protect the surrounding skin.

Dressing Application & Connection

1. Remove the sterile ODS from its packaging.
2. Position the ODS centrally to the wound, **FLESH COLOURED SIDE UPPER**, white side down. The ODS can be trimmed to suit varying wound sizes and shapes using sterile scissors or blade.
3. Fix and support the tube with a short length of 'micropore' tape close to the dressing.
4. Apply an absorbent wound dressing over the top ensuring that the ODS is completely covered.
5. For wounds **NOT** requiring compression make further fixings along the leg where it is comfortable and apply a tubular bandage. With less mobile or moribund patients, ensure they do not sit or lie on the tubing for extended periods.
See Compression bandage information right.
6. Direct the oxygen tube where it is comfortable and connect to the NATROX™ OG unit via the twist lock system. Ensure the tube is tidy and not kinked. For tall patients an extension tube (NA042) 1000mm is provided in the case lid.



7. Fit a freshly charged battery to the OG, after a short time the green light will flash indicating Oxygen is now flowing. To disconnect or stop oxygen flow, simply slide the battery out.

Encourage the patient to wear loose fitting clothes. A holster is supplied to allow the OG to be positioned in various locations for patient comfort. As NATROX™ takes oxygen from air, ensure the small slits around the sides of the OG are not obstructed.

8. ODS should be left in place for a maximum of seven days. Red oxygenated tissue may be seen following the outline of the ODS. A temporary increase in the volume of exudate is a normal feature of the start of the healing process. When replacing the ODS rotate it so that it covers previously uncovered areas of the wound. The ODS should be replaced at the same time and frequency as the absorbent wound dressing.
9. For disposal, treat the ODS as clinical waste.

Compression bandage

When the NATROX™ system is used in conjunction with compression bandaging it is important that the oxygen tube is not compressed against fragile skin where it may leave a mark. If this seems likely place a small gauze pad under the tube. As soon as possible weave the tube out of each layer of the bandaging and finally secure it with 'micropore' tape to the top layer of bandage in the normal way. Check that the tube is not kinked and that its course does not restrict the flow of oxygen.

Battery removal

Hold NATROX™ OG and placing thumb and finger at the end, slide it out.

Battery charging

Two batteries (**Green** and **Blue**) are provided plus a charger for mains 240V AC electricity. **A battery must be left on continuous charge at all times.** When fully charged NATROX™ produces oxygen for around 30 hours. A fully charged battery must be fitted every 24 hours.

As soon as possible connect the charger to a mains supply where it must be left undisturbed. Connect the **Green** battery to the charger, the yellow light will flash while charging and stays ON when fully charged. Set a routine and change the battery each morning or evening. As batteries are **Green** and **Blue** a simple record can be kept on a diary.

Now connect the **Blue** battery to NATROX™ OG and see the small green light flash showing that oxygen is now flowing.

Fault Conditions:

1. If the yellow light on the battery does not flash when charging and stays on when fully charged.
2. If the green light on NATROX™ OG does not flash when a fully charged battery is fitted.

In both cases: Do not use and report to your Clinician or Inotec AMD, or the distributor.

Batteries may be left on charge without concern. A battery should always be on charge ready to use. Always charge batteries before first use or after storage.

Recycling

If, for any reason, the device has become non-functional (e.g accidental damage) it should be wiped down with an antimicrobial agent, placed in the blue carrying case, packed and returned to the manufacturer for recycling of batteries and Oxygen generator cell with a description of the fault. The return address is shown on the back of this leaflet.

Pack contents

The NATROX™ pack contains:



NATROX™ Oxygen Generator (NA034)



2 x Rechargeable batteries (NA035-1&2)



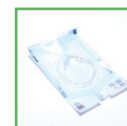
1 x Recharging unit (NA006 International) (NA057 UK)



NATROX™ Oxygen Delivery Systems (NA058 1000mm) are supplied separately in boxes of 25 (NA064) or 50 (NA065)



1 x Holster (NA032)



1 x Extension tube 1000mm (NA042)



1 x Instructions for use (NA021)



1 x Quick Start Guide (NA059).

If any item is missing, please contact Inotec AMD or your local distributor.

NATROX™

Oxygen Wound Therapy

NATROX™ OG



NATROX™ ODS



Additional information can be found on our website at www.inotecamd.com

For questions or comments on this device or on the information supplied in this instruction booklet, please call Inotec AMD on +44 (0)1763 209007

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