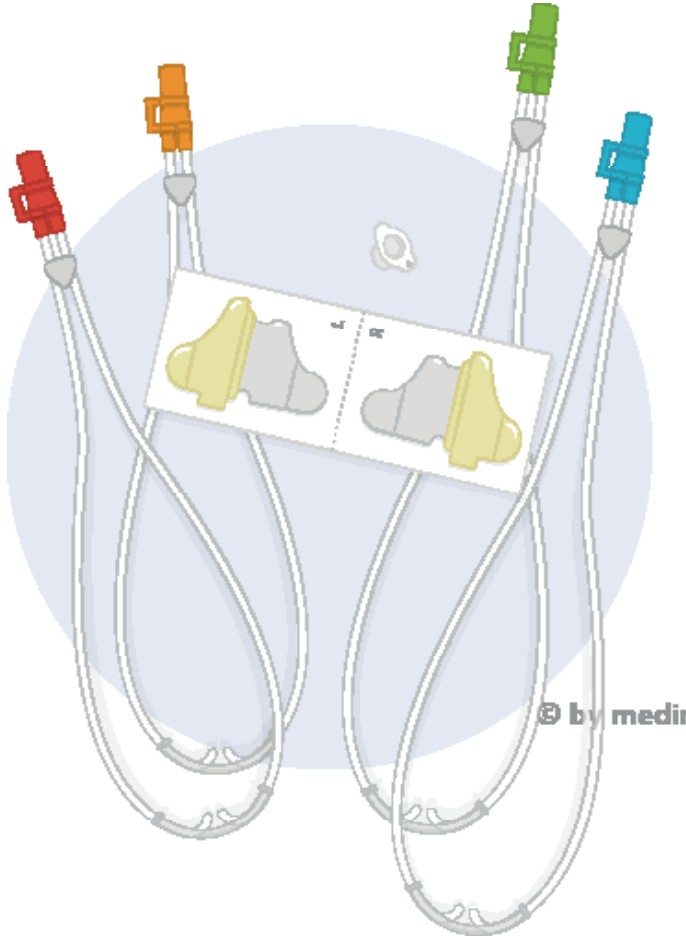
Nuflow®

High flow Nasal Cannula



medin®
A Hamilton Medical Company

Classification:

— Nuflow: class IIa CE 0483

medin Medical Innovations GmbH
Adam-Geisler-Str. 1
82140 Olching
Germany

☎ +49 8142 448 460
info@medin-medical.com
www.medin-medical.com

OP Nuflow
REV02
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EN (US)

Warning:
Read these instructions for use before using the products, and follow the instructions closely.
The Nuflow Nasal Cannula may only be used by individuals with a thorough knowledge of and in accordance with these instructions for use for the purpose described under the section headed "Intended use".
The warnings and information must be observed.
The use of devices (such as a ventilator) used in combination with the Nuflow Nasal Cannula is described in the respective instructions for use of the devices. Users must also comply with these instructions for use.

1. Intended use

The medin Nuflow Nasal Cannula is a single-use product which is intended for nasal oxygen therapy in premature infants, newborns, infants and young children.
The medin Nuflow Nasal Cannula can be used in combination with medin devices with suitable mode or other ventilators with suitable mode and internal overpressure protection or in combination with a blender with additional overpressure protection.
The medin Nuflow Nasal Cannula must be used by and under the supervision of qualified medical or expert staff who have been trained in the use of the Nuflow Nasal Cannula, in a clinical setting, and with simultaneous monitoring of the patient's oxygen saturation.

Warning:
The Nuflow Nasal Cannula may be used only in combination with a device for suitable nasal oxygen therapy and corresponding patient monitoring.

- For clinical use only.
- The oxygen saturation in the patient's blood must be continuously monitored during use.
- The product should be used only by trained personnel.
- The Nuflow Nasal Cannula (REF 1320, 1330, 1340, 1350) is a single-use product. It may be used only on a single patient and may not be reprocessed.
- Overpressure protection (e.g. an overpressure valve) must always be present in the system.
- The Nuflow Nasal Cannula may be used only in combination with a suitable device and suitable tubing. Otherwise the proper function of the Nuflow Nasal Cannula cannot be guaranteed.
- Please check the patency of the Nuflow Nasal Cannula before using it on the patient by setting a flow on your oxygen therapy device.
- If the Nuflow Nasal Cannula does not work properly, it should not be used.
- US legislation stipulates that this device may only be sold to or on the instructions of a doctor (for USA: Rx only).

2. Principles of function and technical specification

The Nuflow Nasal Cannula is a patient interface (interface between the patient and a suitable device) for nasal oxygen therapy. The Nuflow Nasal Cannula is connected to the suitable device via a ventilation tube (single or double tubing system). The required flow and required oxygen concentration are adjusted on the device. If the Nuflow Nasal Cannula is used on a ventilator with suitable mode, the adapter for the Y-piece (OD 15 mm/ID 10 mm) of the tubing system may be needed.
The size of the Nuflow Nasal Cannula is selected according to the size of the patient's nose. The Nuflow Nasal Cannula is secured to the patient's skin either with the hydrocolloid fixation provided or it must be secured directly to the skin using a suitable self-adhesive medium (e.g. fixation gauze/viscose gauze).

Nuflow Nasal Cannula	REF
small	1320
medium	1330
large	1340
xlarge	1350
Nuflow hydrocolloid fixation	REF
Fixation patch, small (for use with Nuflow size REF 1320 or REF 1330)	1380
Fixation patch, large (for use with Nuflow size REF 1340 or REF 1350)	1381
Tube connections available	
OD 10 mm or OD 15 mm	
Weight of Nuflow Nasal Cannula incl. nasal bandage and adapter (without packaging)	
Nuflow size 1320 and 1330	13 g
Nuflow size 1340 and 1350	19 g

3. Nuflow Nasal Cannula material

The prongs and tubes of the medin Nuflow Nasal Cannula are made of silicone. The fixation of the Nuflow Nasal Cannula contains a hydrocolloid portion.

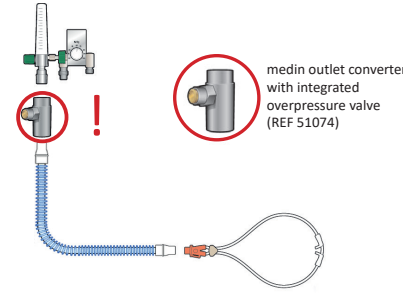
4. Equipment:

Warning:
The Nuflow Nasal Cannula may be used only in combination with a suitable device and suitable tubing. Otherwise the proper function of the Nuflow Nasal Cannula cannot be guaranteed.

The oxygen therapy can be performed with various devices. The following equipment is needed in the configuration options below:

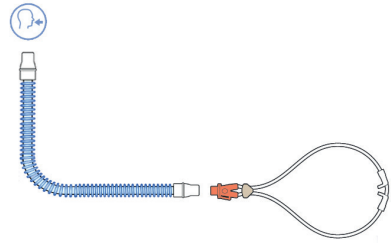
- **Combination with a blender/gas mixing unit:**

(1) Nuflow Nasal Cannula incl. hydrocolloid fixation
(2) Blender/gas mixing unit with flow meter and scaling in 0.5 L/min increments and overpressure valve (pressure in the tube not more than 60 mbar); flow range must be selected in accordance with the size of the Nuflow Nasal Cannula
(3) Appropriate tubing system, incl. inspiration tube with patient-side connection, ID 10 mm



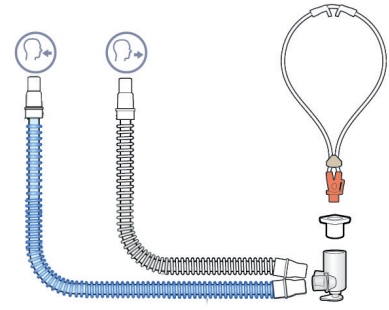
- **Combination with a medin nCPAP driver with suitable mode or oxygen therapy driver:**

(1) Nuflow Nasal Cannula incl. hydrocolloid fixation
(2) Driver with suitable mode and overpressure protection
(3) Appropriate tubing system, incl. inspiration tube with patient-side connection, ID 10 mm



- **Combination with a ventilator:**

(1) Nuflow Nasal Cannula incl. hydrocolloid fixation
(2) Ventilator with suitable mode and overpressure protection
(3) Appropriate tubing system, single or double tubing system with patient-side connection, ID 10 mm or ID 15 mm (Y-connection)



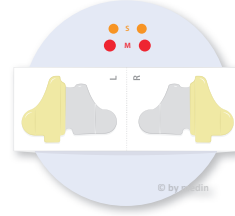
5. Structure and set-up of the system

Warning:
If the packaging of a part is damaged or if the products themselves are damaged, these parts should not be used and instead should be disposed of. In addition, check the channels of the Nuflow Nasal Cannula for patency. If the Nuflow Nasal Cannula is not patent, it should not be used.

Warning:
The use of chin straps or films to actively close the mouth is not permissible.
The use of creams can have a negative effect on the fixation of the Nuflow Nasal Cannula. Likewise, a continuously moist environment can soften the skin and lead to skin damage.

Please note:
The Nuflow Nasal Cannula does not necessarily need to be secured with the hydrocolloid fixations provided. A suitable self-adhesive medium can also be used (e.g. fixation gauze/viscose gauze).

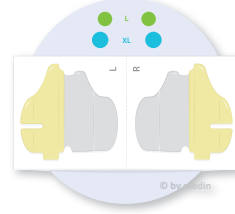
(1) Connect the tubing set to a suitable device for oxygen therapy.
(2) Connect the Nuflow Nasal Cannula to the ventilation tube. Use the adapter provided, if necessary.
(3) Prepare the hydrocolloid fixation provided for size small and medium or for size large and xlarge. Before the fixation is adhered to the skin, it should be at body temperature.
(4) The skin should be dry and clean to ensure an optimal hold.



Fixation bandage for small and medium

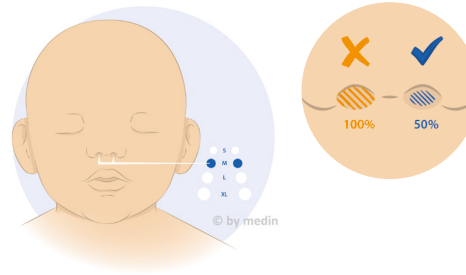
Please note:
When securing the hydrocolloid fixation, ensure that it is not adhered to the eye area, in particular not to the area of the lower eyelids. Scissors can be used to slightly adapt the hydrocolloid fixation to the patient's anatomy.

Be aware that trimming the hydrocolloid fixation can decrease the adhesive strength.



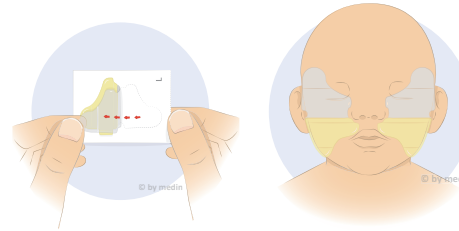
Fixation bandage for large and xlarge

(5) Select the size of the Nuflow Nasal Cannula such that the prongs fill a max. of 50% of the respective nostril!



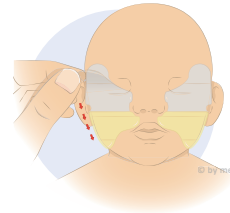
Warning:
The prongs of the Nuflow Nasal Cannula should not fill the nostril; at least 50% of the nostril should remain clear to avoid uncontrolled pressure increases which can harm the patient.

(6) Release the hydrocolloid fixation from the backing film. Secure this to the patient's left and right cheeks. Take note of the information on the backing of the fixation indicating the correct side (L = left; R = right; the sides indicated are from the patient's perspective).



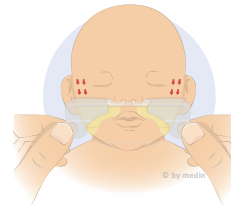
(7) There is a thin removable film on the inner side of the hydrocolloid fixation. Remove this before you position the Nuflow Nasal Cannula.

(8) Open the tube fixation of the Nuflow Nasal Cannula and pull the cannula over the patient's head. Ensure that the fixation tabs which secure the Nuflow Nasal Cannula are open.



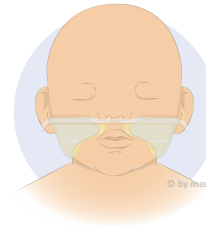
(9) Guide the prongs of the Nuflow Nasal Cannula into the nose. Close the upper part of the hydrocolloid fixation by gently pulling downwards.

(10) Then gently push the tube fixation in the direction of the head until stable guidance of the tubes is ensured.



(11) Using gentle pressure, press the fixation tabs of the fixation bandage with your finger in the direction of the Nuflow Nasal Cannula to ensure optimal contact of the adhesive surface with the Nuflow Nasal Cannula.

(12) The fixation tabs of the hydrocolloid fixations can be opened and closed multiple times. The hydrocolloid fixations can remain on the patient's skin during pauses/interruptions in the oxygen therapy.



Warning:
This product is Intended to be used for a maximum of 7 days.

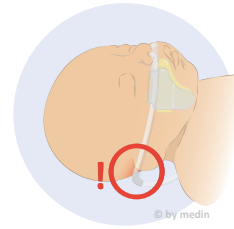
Please note:
Hydrocolloid fixations which loosen at the edges (e.g. at the nose) do not necessarily need to be replaced. If the hydrocolloid continues to adhere and the Nuflow Nasal Cannula is still secure, the hydrocolloid can remain on the skin.

During pauses in the therapy, please place the Nuflow Nasal Cannula in a clean and dust-free environment. Dirt can reduce the ability of the hydrocolloid fixation to adhere and it increases the likelihood of microbial contamination.

Please ensure that the Nuflow Nasal Cannula does not completely slide into the nose. This can cause the nostrils to become sealed and at the same time cause redness of or even injury to the skin due to excessive pressure on the skin!

Warning:
Ensure that the weight of the ventilation tube does not pull on the Nuflow Nasal Cannula or the patient's head. Use cushioning to support the tubing system (towel or similar).The nursing staff should perform a daily skin check in order to promptly detect any redness or pressure points. Areas which come into contact with the Nuflow Nasal Cannula in special positions, such as the cheeks and back of the head, should also be monitored. This also includes regularly checking for the presence of secretions as well as the removal of secretions, if applicable.
The tubing system should slope away from the patient to prevent condensation from running in the direction of the patient.

Warning:
Ensure that the patient does not lie on the tube fixation. This can lead to redness of or injury to the skin.



Warning:
If the adapter included with the Nuflow Nasal Cannula is not used, this should not be kept within the patient's reach (small part which can be swallowed)!

Please note:
The optimal positioning of the supply tubes of the Nuflow Nasal Cannula is close to the patient's skin.

Warning:
The Nuflow Nasal Cannula is a single-use product and should not be reprocessed or sterilized. A reprocessed Nuflow Nasal Cannula can harden and injure the patient.

(13) Technical flow limits of the different sizes of the Nuflow Nasal Cannula

- Size 1 small: Max. 10.0 l/min
- Size 2 medium: Max. 14 l/min
- Size 3 large: Max. 23 l/min
- Size 4 xlarge: Max. 27 l/min

Please note:
The cannula design is based on systems with 60 mbar overpressure valves. The above stated maximum flow (basis of measurement according to DIN 1343 based on 0°C, 1013.25 mbar and 0% air humidity (0/1013)) usually generates a backpressure of approx. 60 mbar in these systems. Whether this maximum flow can be achieved in practice depends on the flow source used, the actual overpressure protection, leakage at the nostril and the tubing system used.

6. Compatible/connectible devices*

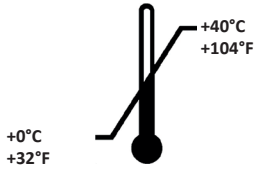
Devices and CPAP drivers which can be connected to the Nuflow:
- medinSINDI®
- medinCNO®mini
- medin-NC3®
- medinBLENDER
- Ventilators with suitable mode

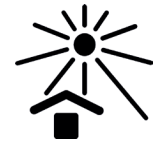
Warning:
A precondition for combining a ventilator and the medin Nuflow Nasal Cannula is the presence of a suitable mode and overpressure protection! The overpressure protection should protect against pressures over 60 mbar.

*not available in all markets

7. Use, storage and disposal

The Nuflow Nasal Cannula must be stored in a clean and dry room and protected from direct sunlight. A brief drop in the storage temperature down to 0°C or an increase up to 40°C do not have any negative effect on the Nuflow Nasal Cannula. However, for long-term storage of the Nuflow Nasal Cannula, a temperature of 21°C and 50% air humidity are recommended, since the adhesive properties of the bandage are best preserved under these conditions.
The Nuflow Nasal Cannula and its packaging can be discarded with regular household waste.





8. Symbols

Symbol	Meaning	Symbol	Meaning
CE	Declaration of conformity according to 93/42/EEC	LATEX	Product does not contain any latex
	Do not use product if packaging is damaged		

History of changes

Revision	Validity date	Changes
01	2018-10-01	Creation
02	2019-03-21	Design changes Changed formulation

Notes

Notes

medin Medical Innovations GmbH
Adam-Geisler-Str. 1
82140 Olching
Germany

☎ +49 8142 448 460
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