

Instructions for use: PIP+™ Nasal Masks









Attach the new nasal mask as illustrated here. Remove and replace upon completion of procedure.

Mask part numbers:

33015-3, 33015-9, 33015-14, 33015-15, 33015-16, 33016-1, 33016-2, 33016-3, 33016-9, 33016-10, 33016-11, 33016-12, 33016-13, 33016-14, 33016-15, 33016-16, 33017-1, 33017-9, 33017-10, 33017-11, 33017-12, 33017-17 **Used in adapter asemblies:** 35000, 35100, 35300, 35325, 35350, 35400, 35500, 35600

Used with scavenging circuits: 32007, 32009, 33008, 33010 which includes IFU 28903 explaining how to use mask and circuit in a procedure.

Indications for use:

To be used in nitrous oxide/oxygen sedation systems for delivering to a patient a mixture of nitrous oxide and oxygen gases with a maximum nitrous oxide concentration of 70%.

PIP+[™] Nasal Masks are single use only and to be used with PIP+[™] Scavenging Circuits.

Contraindications:

Contraindications for use of nitrous oxide/oxygen inhalation may include:

- Some chronic obstructive pulmonary diseases
- Severe emotional disturbances or drug-related dependencies
- First trimester of pregnancy
- Treatment with bleomycin sulfate
- Methylenetetrahydrofolate reductase deficiency
- Severe asthma

Whenever possible, appropriate medical specialists should be consulted before administering analgesic/anxiolytic agents to patients with significant underlying medical conditions (e.g., severe obstructive pulmonary disease, congestive heart failure, sickle cell disease, acute otitis media, recent tympanic membrane graft, acute severe head injury.¹ Operator must review patient history with regard to these health issues.

¹ American Academy of Pediatric Dentistry. Clinical Guidelines: Guidelines on Use of Nitrous Oxide for Pediatric Dental Patients. Pediatr Dent 2009;31(6):148-151. Available at: "http://www.aapd.org/media/policies.asp". Accessed February 23, 2010.

Warnings:

To be used only by a professional trained in the use of nitrous oxide, using titration method. Patient should always be closely monitored during nitrous oxide use. If patient has an adverse reaction, reduce or stop the flow of nitrous oxide as needed. The O2 flush button can be used to rapidly purge the lines of N2O. If patient does not show signs of quick recovery, remove nasal hood and treat with pure oxygen from either the O2 resuscitator fitting or an auxiliary oxygen tank using a demand valve, oxygen assisted manual resuscitator, or equivalent. Call for emergency assistance if rapid response is not achieved.

Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.

Cautions:

Federal (U.S.) law restricts this device to sale by or on order of a dentist or physician.





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No expiration date required. Not made with natural latex rubber.



Made in USA Part No. 28743 / REV. E - 03/2021

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