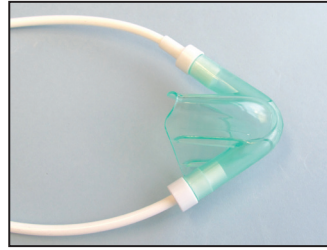
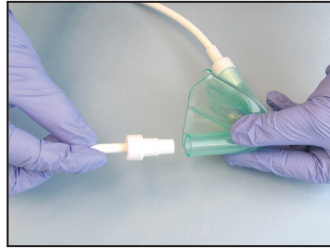
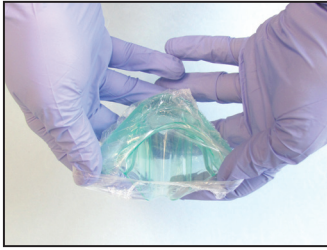


Instructions for use: Axess™ Nasal Masks



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

Mask part numbers:

28534, 53034-9, 53034-12, 53034-16, 53035-9, 53035-12, 53035-16, 53037-9, 53037-12, 53037-16

Used on Axess™ Circuits: 52005, 52006, 53005, 53006 which includes IFU 28904 explaining how to use mask and circuit in a procedure.

Accessories: 53055 capnography fitting (used with mask and circuit per 53055-INS)

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%.

Axess™ Nasal Masks are single use only and to be used with Axess™ 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.

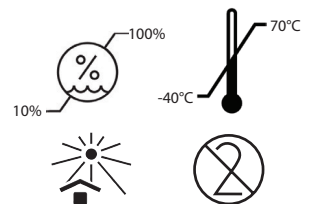
Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.

Cautions:

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

BROWARD A&C
MEDICAL GAS SPECIALISTS
954-725-1470 Ext. 403

CE
0482
MD



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

Made in USA

Part No. 28745 / REV. E - 03/2021

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CROSSTEX
A CANTEL MEDICAL COMPANY

	EN	DE	PT	FR	NL	ES	RU	IT	PL
	Consult instructions for use	Gebrauchsanweisung lesen	Consulte as instruções de utilização	Consulter le mode d'emploi	Raadpleeg gebruiksinstructies	Consulte las instrucciones de uso	См. инструкцию по использованию	Consultare le istruzioni per l'uso	Patrz instrukcja użycia
	Caution	Achtung	Precaução	Avertissement	Opgelet	Precaución	Внимание!	Attenzione	Przeostroga
	Single use only	Nur zum Einmalgebrauch	Utilização única	Usage unique seulement	Uitsluitend voor eenmalig gebruik	De un solo uso	Только для одноразового использования	Monouso	Wyłącznie do użytku jednorazowego
	Manufacturing lot number	Chargennummer	Número de lote de fabrico	Numéro de lot de fabrication	Partijnummer productie	Número de lote de fabricación	Номер производственной партии	Codice del lotto	Numer partii produkcyjnej
	Prescription only (USA)	Verschreibungspflichtig (USA)	Apenas com prescrição médica (EUA)	Sur ordonnance uniquement (États-Unis)	Alleen op voorschrift (VS)	Sujeto a prescripción médica (EE. UU.)	Только по рецепту (США)	Solo su prescrizione (USA)	Wyłącznie na receptę (USA)
 yyyy/mm	Date of manufacture	Herstellungsdatum	Data de fabrico	Date de fabrication	Productiedatum	Fecha de fabricación	Дата производства	Data di fabbricazione	Data produkcji
	Manufacturer	Hersteller	Fabricante	Fabricant	Producent	Fabricante	Производитель	Fabbricante	Producent
	European Representative	EU-Bevollmächtigter	Representante Europeu	Représentant européen	Europese vertegenwoordiger	Representante en Europa	Представитель в Европе	Rappresentante autorizzato nella Comunità Europea	Przedstawiciel w Europie
 0482	Approved for European Union, notified body	In der EU zugelassen, benannte Stelle	Aprovado para a União Europeia, organismo notificado	Approuvé pour l'Union européenne, organisme notifié	Goedgekeurd voor Europese Unie, erkende instantie	Aprobado por la Unión Europea, organismo notificado	Одобрено для применения на территории Европейского Союза, уполномоченный орган	Approvato nell'Unione Europea, organismo notificato	Produkt dopuszczony do stosowania w Unii Europejskiej, jednostka notyfikowana
	Catalog number	Bestellnummer	Número do catálogo	Référence catalogue	Catalogusnummer	Número de catálogo	Номер по каталогу	Numero di catalogo	Numer katalogowy
	Medical Device	Medizinprodukt	Dispositivo médico	Dispositif médical	Medisch apparaat	Producto sanitario	Медицинское устройство	Dispositivo medico	Urządzenie medyczne
	Unique Device Identifier	Eindeutige Produktkennung	Identificação única do dispositivo	Identification Unique du Dispositif	Unieke apparaatidentificatie	Identificador de producto único	Уникальный идентификатор устройства	Identificativo unico del dispositivo	Unikatowy identyfikator wyrobu
	Keep away from sunlight	Vor Sonnenlicht schützen	Mantener afastado da luz solar	Éviter toute exposition à la lumière du soleil	Uit de buurt van zonlicht houden	Manténgase lejos de la luz solar	Хранить в защищенном от света месте	Tenere lontano dalla luce	Chronić przed światłem słonecznym