

Instructions for use: PIP+™ Scavenging Circuits

PIP+™ RFST™ Scavenging Circuit (32009, 33008)

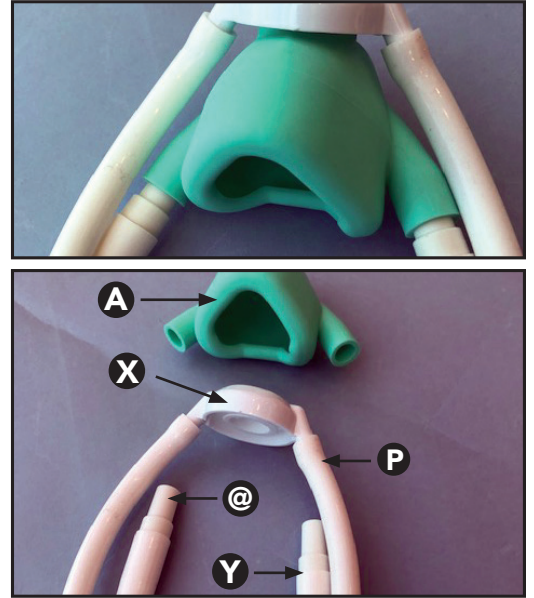
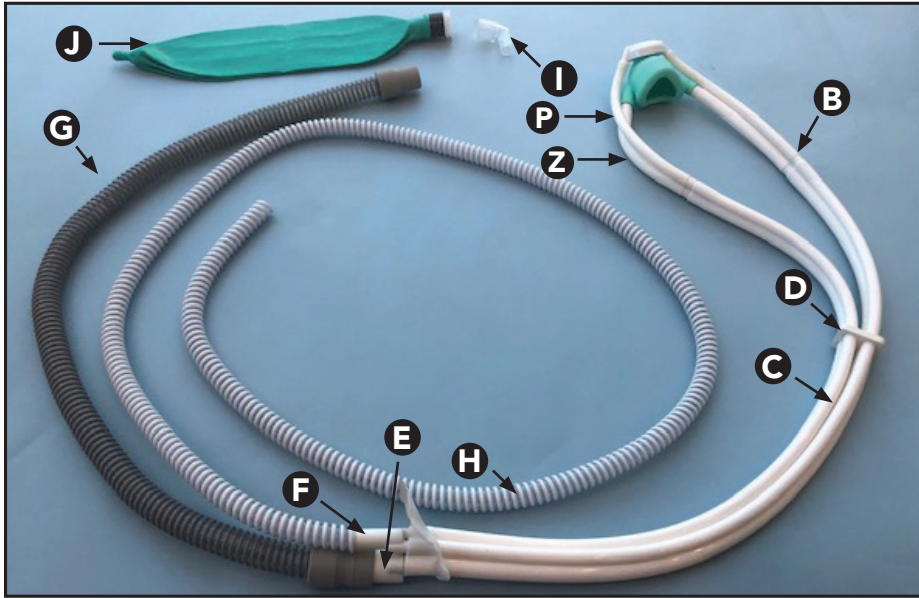


Figure 1

Figure 2

A 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, **B** 21178, **C** 25590, **D** 26253, **E** 21245, **F** 21246, **G** (3ft/.91m) 33014, (6ft/1.8m) 22137-FRU, **H** (6ft/1.8m) 27132, **I** 26255-FRU, **J** (3L) 33025, (2L) 33026, **P**:25594, **X** 22099, **Y** 25593, **@** 21179



Figure 3



Figure 4



Figure 5



Figure 6

PIP+™ Inline Circuit (32007, 33010)

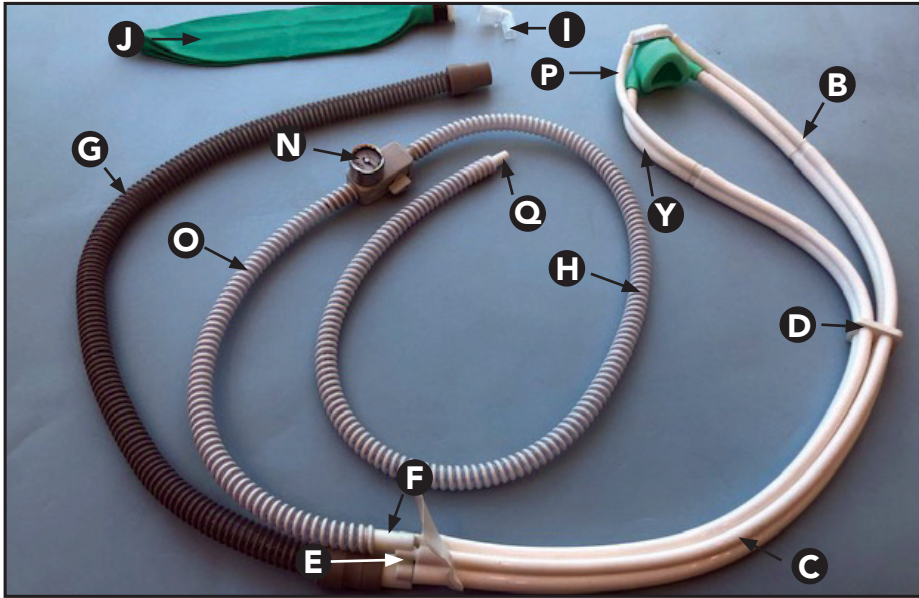


Figure 7

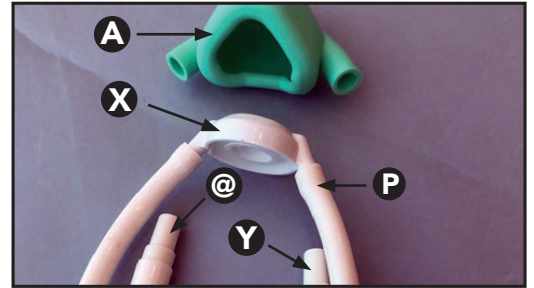
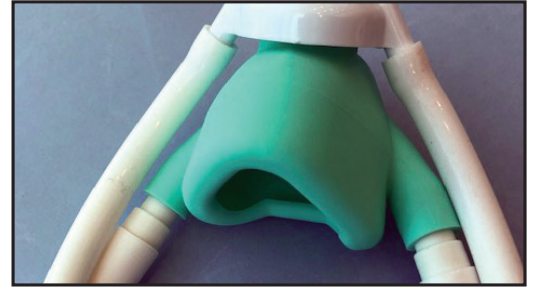


Figure 8

A 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, **B** 21178, **C** 25590, **D** 26253, **E** 21245, **F** 21246, **G** (3ft/.91m) 33014, (6ft/1.8m) 22137-FRU, **I** 26255-FRU, **J** (3L) 33025, (2L) 33026, **P** 25591, **X** 22099, **Y** 25593, **@** 21179



Figure 9

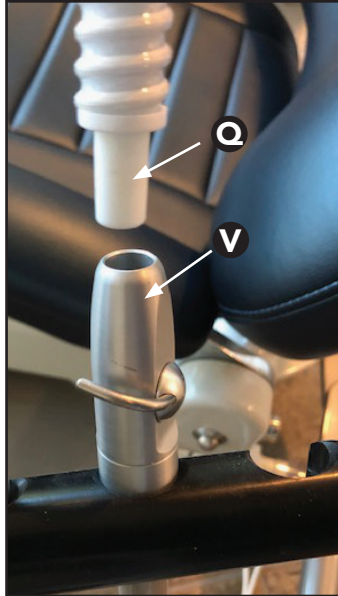


Figure 10



Figure 11

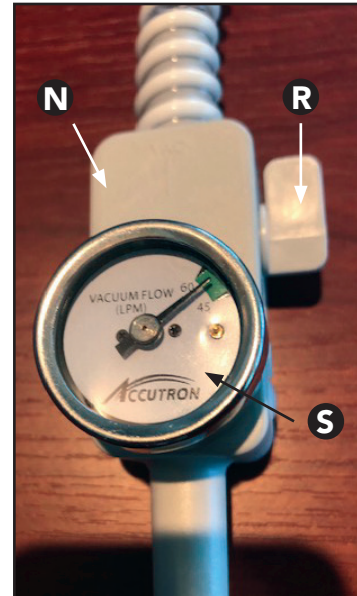


Figure 12

System Setup

PIP+™ RFS™ Scavenging Circuits (32009, 33008)

1. Assemble the circuits per Figure 1 and install the mask on the circuit per Figure 2.
2. Connect the reservoir bag and hoses per Figure 3 for RFS Circuits or Figure 5 for Accu-vac™ Circuits.
Caution: The bag must be on the downspout, only one vacuum controller can be used at one time (RFS Circuits or Accu-vac Circuits).
3. Adjust the flow on the RFS Circuit using knob **M** so that the needle is in the green zone of gauge **L** per Figure 4. It is recommended that it be checked periodically during the procedure as facility vacuum pressure can change from time to time.
4. Place mask on patient per Figure 6.
5. Adjust the flow on the Accu-vac Circuit using knob **W** so that the light **K** is green, blue=low flow (check vacuum flow from pump), red=blocked flow (check for kinked hose).

PIP+™ Inline Circuits (32007, 33010)

1. Assemble the circuits per Figure 7 and install the mask on the circuit per Figure 8.
2. Connect the reservoir bag and corrugated hose per Figure 9.
Caution: The bag must be on the downspout, only one vacuum controller **N** can be used at one time.
3. Connect the vacuum line to the vacuum source such as the chair **V** per Figure 10 using installed fitting **C** or connect to wall outlet using fitting T per Figure 11 after cutting off **C**.
4. Place mask on patient per Figure 6.
5. Adjust the flow on the controller **N** per Figure 12 using knob **R** so that the needle is in the green zone of gauge **S**. Gauge can be laid down after initial setting although it is recommended that it be checked periodically during the procedure as facility vacuum pressure can change from time to time.

Gas Flow Operation

Digital Ultra™ Flowmeters: Turn on the unit. It should start at TOTAL FLOW of 5 lpm with 0 %N₂O. Adjust TOTAL FLOW to match the breathing rate of the patient by watching the reservoir bag. At the proper flow it will neither inflate to the max or deflate to the minimum. Gradually increase %N₂O until desired effect is reached. Use the Titration method when adding N₂O to avoid negative patient reactions. At end of procedure, reduce %N₂O to 0 for five minutes to flush N₂O from patient's blood stream.

Ultra PC™ Flowmeters: Turn the unit on and adjust the Total Flow to match the breathing rate of the patient by watching the reservoir bag. At the proper flow it will neither inflate to the max or deflate to the minimum. Gradually increase %N₂O until desired effect is reached. Note that the Oxygen level will need to be reduced by the amount of increase in N₂O to maintain the correct flow rate. Use the Titration method when adding N₂O to avoid negative patient reactions. At end of procedure, reduce %N₂O to 0 and increase O₂ flow by same amount to maintain proper flow. Run for 5 minutes to Flush N₂O from patient's blood stream.

Ultra DC™ Flowmeters: Turn unit on. O₂ flow should start at 3 lpm. Adjust Oxygen flow to match the breathing rate of the patient by watching the reservoir bag. At the proper flow it will neither inflate to the max or deflate to the minimum. Gradually increase N₂O until desired effect is reached. Oxygen flow will need to be decreased by the same amount of the N₂O increase to maintain the proper Total Flow. Use the Titration method when adding N₂O to avoid negative patient reactions. At the end of the procedure, reduce N₂O to 0 for five minutes to flush N₂O from patient's blood stream. The oxygen flow will have to be increased by the amount of N₂O decrease to maintain the same Total Flow.

PIP+™ Circuits can be reprocessed per 26613-INT. Do not exceed recommended temperatures.

UDI Product Tag included for product traceability purposes.

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.

Contraindications:

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

- 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.

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

Warnings:

To be used only by a licensed and trained professional 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.

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

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Made in USA

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	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