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INSTRUCTIONS FOR USE

PORTER

Silhouette Disposable Breathing Circuit

Silhouette
LOW PROFILE NASAL MASK

FM-1313 Rev. J 07/22

SECTION 1: SILHOUETTE OVERVIEW

Brief instructional setup and usage videos are available as supplemental information online at: www.porterinstrument.com/silhouette

DESCRIPTION OF BREATHING CIRCUIT

The Silhouette Low-Profile Nasal Mask is intended for single patient use. The Silhouette Nasal Mask and Breathing Circuit are designed with lightweight tubing and conforming mask used to deliver nitrous oxide and oxygen to a conscious, spontaneously breathing patient. The Silhouette Nasal Mask also provides scavenging capability when connected to a vacuum source, to remove excess nitrous oxide from the patient's exhalation. This circuit is designed to offer medical professionals a tool that can be used to deliver analgesia gas with unobstructed access to the oral cavity and scavenging efficiency. The Silhouette Nasal Mask is available in four sizes for proper fit onto a patient's nose. The Silhouette Breathing Circuit is connected to a nitrous oxide and oxygen flowmeter and a vacuum source.

The Silhouette Nasal Mask is placed (adhesive lamination cover removed first) on to the patient's nose. The Silhouette tubing is placed around the patient's ears. The reusable paratubing is attached to the fresh gas and vacuum control device connections. The slide bolo is placed to secure the Silhouette Breathing Circuit at the patient's neck, completing a multi-point secure placement on the patient's face. A fresh gas mixture of nitrous oxide and oxygen is delivered from the flowmeter into the Silhouette Breathing Circuit and into patient's nasal cavity via the Nasal Mask; exhalation is scavenged through the vacuum control device. The disposable Breathing Circuit is disposed after each patient use.

The sight lines from the medical professional to the patient's mouth (work area) created by the low profile allow for manipulation of the patient's mouth without interference to the fit of the Silhouette Breathing Circuit, while the patient can turn their head, without losing the seal.

BIOCOMPATIBILITY

The Silhouette Nasal Mask is made from medical-grade silicone rubber and includes plastic material tubing that connects to reusable silicone tubing. Biocompatibility Testing (data on file) supports the use of these materials and gas pathways on adult and pediatric patients. The patient-contacting materials used are commonly used in similar consumer products.

INTENDED USE / APPLICATIONS FOR USE

The intended use of the Silhouette Low-Profile Nasal Mask is to provide a disposable patient nasal mask and breathing circuit for delivering nitrous oxide / oxygen conscious sedation in a medical health care setting to conscious, spontaneously breathing adult and pediatric patients. The Nasal Mask is intended to be used with a continuous flow flowmeter device.

The device features low-profile mask and breathing circuit that allows high visibility to the medical professional and provides an adhesive-based seal onto the patient's nose, allowing the scavenging system to effectively remove excess exhaled nitrous oxide. The product design includes features to allow etCO_2 capnograph monitoring of patient exhalation.

INDICATIONS FOR USE

The following Indications for Use are associated with the delivery of a mixture of nitrous oxide and oxygen gas to a conscious, spontaneously breathing patient from a continuous flow flowmeter and through the Silhouette Low-Profile Nasal Mask.

The Silhouette Breathing Circuit is to be used in nitrous oxide-oxygen sedation systems for delivering a mixture of nitrous oxide and oxygen gases with a maximum nitrous oxide concentration of 70%.

Rx Only: Silhouette is to be used by a physician or licensed healthcare professional.

CONTRAINDICATIONS

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

1. Some chronic obstructive pulmonary diseases
2. Severe emotional disturbances or drug-related dependencies
3. First trimester of pregnancy
4. Treatment with bleomycin sulfate
5. Methylenetetrahydrofolate reductase deficiency
6. Severe asthma

STORAGE CONDITIONS

Storage conditions for Silhouette are 47° F - 82° F (8° C - 28° C).

PRODUCT EXPIRATION

Silhouette can be used for a maximum of two years after the **date/lot:** XXXX-XX-XX found on the outside packaging (Silhouette box).

SECTION 2: USING SILHOUETTE

USING SILHOUETTE WITH OR WITHOUT A BAG TEE

Refer to photos below of reusable vacuum and fresh gas attachments to Porter and Matrx flowmeters.

Matrx

Porter with AVS (and without Bag Tee)

The Silhouette Breathing Circuit may be used with or without a Bag Tee. Brief instructional setup, how to retrofit, and usage videos are available as supplemental information online at:
www.porterinstrument.com/silhouette

When used with a Bag Tee (including those of most brands of flowmeters) the 3-Liter Breathing Bag should be capped off using the Cap (62905510W) found in the Flowmeter Connection Kit (SIL-CONN-KIT). The fresh gas Adapter (PA-1629-000) in the kit provides a 22mm adapter to 5 - 7 mm taper for the Reusable paratubing hose (B-5581-001).

Note: The 4 holes featured in every Silhouette Nasal Mask provide air intake. Patient inhalation through the Silhouette Breathing Circuit (with Total Flow delivery of approximately 5 L/min or lower) will open the Emergency Air Intake (EAI) valve on a Bag Tee for supplemental air intake. **Do not block these 4 holes during procedure.**

USING SILHOUETTE AND VACUUM WITH BAG TEE

Refer to Figure 1 and the item (#) list on the next two pages when reading this section

1. Existing Bag Tee assembly: Detach the 3 L bag from the bottom of the bag tee (#16).

2. Fit the Silhouette Cap to the Bag (bottom) port and the Adapter to the 22mm port.

3. The Silhouette Breathing Circuit design contains Disposable and Reusable sections (connected to flowmeter and vacuum source). Use Silhouette Reusable Connector Kit (SIL-CONN-KIT). Attach smaller ID hose end to flowmeter Adapter. Attach larger ID hose end to AVS or other vacuum source.

4. Attach Vacuum Hoses (#15): Refer Figure 1

5. *Automatic Vacuum Switch*: Attach one end of the Reusable vacuum hose (#15) to the Union of the Silhouette Disposable Breathing Circuit (diameter indexed) and the other end to the MASK port (labeled on body) of the AVS (#1). Attach a second vacuum hose (#15) to the VAC port (labeled on body) of the AVS (#1), then insert straight end of adapter (#20) into the other end of the vacuum hose and the tapered end of the adapter into the High Volume Evacuation (HVE) Line.

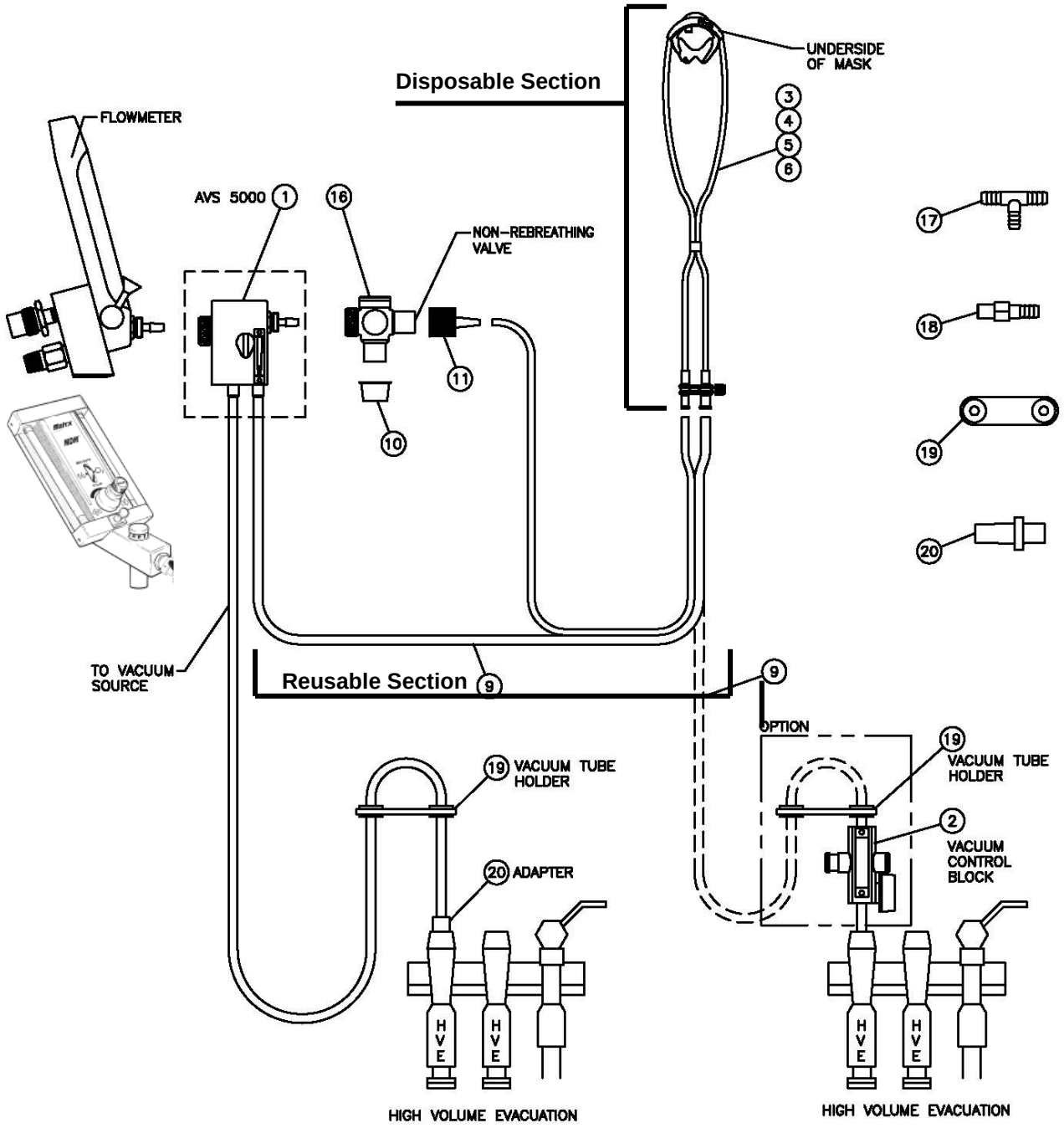
6. *Vacuum Control Block*: Attach one end of the Reusable vacuum hose (#9) to the Union of the Silhouette Disposable Circuit (diameter indexed) and the other end to the vacuum control block (#2).

   The vacuum control block can then be inserted directly into the High-Volume Evacuation (HVE) Line; or may be placed “in line” by cutting the vacuum hose and attaching the cut ends of the tubing to both ends of the vacuum control block.

   Note: To properly read vacuum levels, the vacuum control block must be held upright with the on/off switch above the control valve.

FIGURE 1

NITROUS OXIDE CONSCIOUS SEDATION DELIVERY SYSTEM



ITEM	PART NUMBER / REF	DESCRIPTION (Refer to Figure 1 for Assembly)
1	AVS 5000	Automatic Vacuum Switch (AVS)
2	5501-RK	Vacuum Control Block Kit (Optional)
3	SIL-PEDO-12	Silhouette Circuit, Pediatric, 12 Pack **(Disposable)**
4	SIL-SM-12	Silhouette Circuit, Small, 12 Pack **(Disposable)**
5	SIL-MED-12	Silhouette Circuit, Medium, 12 Pack **(Disposable)**
6	SIL-LG-12	Silhouette Circuit, Large, 12 Pack **(Disposable)**
7	SIL-START-PK	Starter Pack: 3 Circuits **(Disposable)**, Paratubing, Cap, Adapter **(Reusable)**
8	SIL-VAR-4X3	Mask Variety Pack, 3 Circuits of each size **(Disposable)**
9	SIL-CONN-KIT	Connector Kit; Paratubing, Cap, Adapter, Strap **(Reusable)**
10	62905510W	Cap, White **(Reusable)**
11	PA-1629-000	Tubing Adapter, 22mm x 5-7 taper **(Reusable)**
12	B-5581-001	Paratubing, 6 ½ ft. **(Reusable)**
13	FM-1312	Silhouette Mask Instruction for User Insert
14	FM-1313	Silhouette User's Instructions
15	5059	Vacuum Hose (8 ft.)
16	P1407A (US)	Bag Tee (REF P1407E for European)
17	5063	1/2" 'T' Adapter for In-line Vacuum Block (See Figure 2)
17a	5068	5/8" 'T' Adapter for In-line Vacuum Block (See Figure 2)
18	5064	"Straight" Adapter for In-line Vacuum Block (See Figure 2)
19	5065	Vacuum Tube Holder
20	A-3679-000	Adapter, Black, ¾" Round (VAC/MASK)
21	PA-1630-000	Clip Strap
22	SIL-SIZER-4	Silhouette Sizers, 4 pack **(Reusable)**

SILHOUETTE PART NUMBERS (4 SIZES OF MASK)

Silhouette sizes:

-Pediatric, -Small, -Medium, -Large

Reorder Part Numbers:

- SIL-PEDO-12 (Case of 12 Circuits)
- SIL-SM-12 (Case of 12 Circuits)
- SIL-MED-12 (Case of 12 Circuits)
- SIL-LG-12 (Case of 12 Circuits)
- SIL-PEDO-24 (Case of 24 Circuits)
- SIL-SM-24 (Case of 24 Circuits)
- SIL-MED-24 (Case of 24 Circuits)
- SIL-LG-24 (Case of 24 Circuits)
- SIL-VAR-4x3 (Case of 3 of Each Circuit)

Disposable Breathing Circuit is for use with SIL-CONN-KIT with Reusable Paratubing (B-5581-001), Cap (62905510W), Adapter (PA-1629-000; 22 mm x 5-7 taper), and Clip Strap (PA-1630-000)

The Breathing Circuit provides a luer lock sample line connection to allow etCO_2 capnography monitoring during the administration of nitrous oxide / oxygen conscious sedation to a patient.

Warning:
If not monitoring capnography, the luer lock must be capped (included) to avoid nitrous oxide from leaking into the room.

Single Patient Use

Not made with natural rubber latex

Contents Not Sterile

SECTION 3: BASIC OPERATION OF VACUUM CONTROL FOR SILHOUETTE

FOR PORTER AVS OR VACUUM CONTROL BLOCK

Note: Use one or the other, not both

1. AVS will **automatically** open upon the delivery of 1.5 to 3.5 L/min of gas flow. The vacuum control block is manually operated and must be opened by pushing "on/off" toggle to "on" position.
2. **Adjusting vacuum flow using vacuum control knob position:** Highest scavenging flow: For AVS: knob is horizontal; for 5501-RK: knob is vertical. To lower flow, rotate knob up to 45° from full open position.
3. Use vacuum control knob and acrylic sight glass on side of AVS or vacuum control block. Vacuum flow with ball float within the green bar area is effective; ball high within (or even above) green bar is for highest vacuum flows.
4. **Adjusting vacuum flow with Silhouette Breathing Circuit attached:** Temporarily remove luer lock cap on union of Disposable Section and adjust using control knobs.
5. Start 5501-RK knob in vertical position (highest flow) and adjust flow down. Ball float position indicates higher and lower relative flows (exact position of ball dependent on strength of vacuum pump). Start AVS knob in horizontal position (highest flow).
6. **Best "clock face positions"** for the control knobs are listed in the table below. Set knobs at the designated clock face position ranges for best scavenging vacuum flow. Ball float may be above the green bar if vacuum pump vacuum is strong (high vacuum inches Mercury).

   Set knobs at the designated clock face position ranges for best scavenging vacuum flow

	5501-RK	**AVS**
Highest Flow	Knob Vertical	Knob Horizontal
Best Flow Range	11 o'clock to 1 o'clock	8 o'clock to 10 o'clock

7. Remember to replace the luer cap again after adjustment.
8. Monitor the vacuum conditions during the procedure by observing the sight glass. Repeat Steps 2 through 7 to adjust vacuum flow as necessary.

   Note: Vacuum is indicated with Silhouette Circuit attached and ball "pegged high" in sight glass. Ball float at bottom indicates no vacuum flow.

9. To adjust vacuum flow with Matrx vacuum control block with Silhouette Circuit attached**:** Set to 5 minimum.
10. For Silhouette Breathing Circuit attached for other brand vacuum control blocks: Set middle to high end settings.
11. Follow good work practices recommended by the National Institute for Occupational Safety and Health (NIOSH). Please refer to the below activities
    - 11.1. Caution the patient not to talk unnecessarily or breathe through the mouth.
    - 11.2. The Silhouette Nasal Mask must be fitted properly to avoid leaks.
    - 11.3. 100% Oxygen should be administered while the mask is being placed. Flowing Nitrous Oxide while fitting the mask will significantly increase N_2O ppm (parts per million) exposures.
    - 11.4. All Silhouette Nasal Masks feature 4 holes in the front for supplementary air intake
    - 11.5. Flow only the volume of gas required by the patient. Excessive gas flow could increase N_2O ppm exposures.
    - 11.6. 100% Oxygen should be administered for several minutes at the end of the procedure. This will flush the Nitrous Oxide from the patient. Failure to follow this procedure will result in higher N_2O ppm exposure in the operatory.

SECTION 4: ATTACH SETUP SEQUENCE

Note: Refer to the Product Insert (FM-1312, supplied with each Circuit Pack) for additional information.

Brief instructional setup and usage videos are available as supplemental information online at: www.porterinstrument.com/silhouette

1. Use scavenging and set vacuum flow for Silhouette per instructions in Section 3.

   Note: Refer to the **Warning** on minimizing Nitrous Oxide exposure to the dental worker (Page 7).

2. Use disposable Silhouette Breathing Circuit with Reusable Flowmeter Connector Kit (SIL-CONN-KIT). Attach the smaller diameter hose end to attachment barb or flowmeter adapter. Attach the larger diameter hose end to Porter AVS or other vacuum control device.

3. Place colored sizer masks over the nose to determine appropriate mask size for the patient. Follow the cleaning and sterilization instructions in Section 5 for cleaning and sterilizing the reusable Sizers.

4. The disposable Silhouette Breathing Circuit is packaged in a color-coded box and is first removed from the box for placement on the patient.

5. Prepare for placement of the mask on the patient's nose by removing the adhesive cover tab from the mask.

6. Pull the slide bolo down to create a loop large enough to place behind the patient's ears.

7. Place nasal barb fully into the right nostril, flexing the mask as needed.

8. Rotate the mask down over the nose until contact is made.

9. Compress the mask adhesive at the bridge of the nose. Verify good seal is achieved around the entire mask.

10. Place the tubing over the top of the left and right ear.

11. Move the slide bolo up until the circuit is snug against the patient's neck.

12. Connect disposable section union (diameter indexed) to gas and vacuum reusable hoses (SIL-CONN-KIT).

13. Observe overall position of the patient, mask, and circuit for proper positioning with good mask seal and no evidence of tubing kinking. Use Clip Strap on Reusable Hose to side of chair or to patient.

14. If End tidal CO_2 ($EtCO_2$) monitoring is being used, disconnect the cap at the end of the disposable breathing section and attach the $EtCO_2$ male Luer lock sample line.

15. You are now ready to turn on your nitrous oxide flowmeter.

Note: After completing a patient's treatment, dispose of the Silhouette breathing circuit (36" disposable section only).

PORTER SUGGESTED FLOW INSTRUCTIONS

1. Use scavenging and set vacuum flow for Silhouette per the instructions in Section 3.

   Note: Refer to the **Warning** on minimizing Nitrous Oxide exposure to the dental worker at the bottom of this page.

2. Follow Flowmeter directions for use.

3. **Recommended total flow to start**: General determination is the "4-5-6 Rule" where 6 is the liters per minute (lpm) for an average male, 5 is the lpm for the average female, and 4 is the lpm for a child. Values represent Minute Breathing Volume. Typical procedure begins with 100% O_2 and then moves to a chosen N_2O mixture percentage.

4. Increase flow or percentage as needed based on patient observation.

5. Always remind the patient to refrain from mouth breathing.

Warning:

Dental workers may be exposed to Nitrous Oxide during administration of Nitrous Oxide / Oxygen conscious sedation analgesia.

NIOSH has recommended that exposures should be minimized. Contact NIOSH (1-800-35-NIOSH) to receive NIOSH Publications on *Control of Nitrous Oxide in Dental Operatories.*

Exposure can be minimized by effective controls. National Institute for Occupational Safety and Health (NIOSH) publications state that controls, including System Maintenance, Ventilation and Work Practices can effectively reduce nitrous oxide concentrations in dental operations. Your Porter Scavenger System is an important part of the system of controls.

SECTION 5: VALIDATED METHOD FOR CLEANING AND STERILIZATION

Note: Silhouette Products and Components are shipped Contents Not Sterile.

DISPOSE (NO CLEANING)

Disposable components listed below are Single Use Only:

- Silhouette Disposable Section
- Refer to Figure 1 and Item (#) Table in Section 2

CLEANING ONLY (NOT AUTOCLAVABLE)

Use approved disinfectant for the dental facility environment, warm water wash, for the below listed components requiring cleaning only:

- Vacuum Control Valves

VALIDATED CLEANING AND STERILIZATION

Follow the validated cleaning and sterilization activities described below for the reusable components listed below:

- Silhouette Reusable Section: Flowmeter Connection Kit
  - Reusable Paratubing
    - Clean and Sterilize
  - Sizer Masks (SIL-SIZER-4)
    - Clean and Sterilize
  - White Cap (62905510W)
    - Clean Only
  - Tubing Adaptor (PA-1629-00)
    - Clean Only
- Refer to Figure 1 and Item (#) Table in Section 2

1. Perform Cleaning Procedures below:
   - 1.1. Rinse the reusable section under running water to remove soil and/or contaminants. Ensure lumens are rinsed. Use a syringe to flush all lumens and hard to reach places.
   - 1.2. Prepare detergent bath using Valsure enzymatic solution of ½ oz per gallon using water.
   - 1.3. Immerse the product for 2 minutes
   - 1.4. While immersed scrub the articles using a soft bristled nylon brush until visible soil and/or contaminants are removed. Use an appropriately sized lumen brush to clean lumines. Flush all lumens to ensure contact with prepared detergent throughout.
   - 1.5. Pay particularly close attention to crevices, lumens, connectors, and other hard to clean areas. Allow the product to soak for two minutes.
   - 1.6. Hold the product upright to allow water to drain from the product
   - 1.7. Rinse under running water for three minutes per component. Thoroughly rinse all lumens and internal surfaces.
   - 1.8. **For Manual Cleaning**: Dry product with clean, dry, lint free cloths.
   - 1.9. **For Automated Cleaning**: Place the products onto the washer's rack system and run the washer.
   - 1.10. Visually inspect the product under normal lighting to confirm removal of soil and/or contaminants. **If visual inspection failure occurs**: repeat the entire cleaning process, be sure to pay particular attention to the region that failed. **If visual inspection failure occurs again**: do not re-use, dispose of the product, and replace the product immediately.
2. Perform Steam Sterilization in accordance with the following sterilization set points:
   - Sterilizer type: Prevacuum
   - Preconditioning Pulses: 4
   - Full Cycle: 4 minutes at 270 °F (132 °C), dry time 30 minutes.
   - Full Cycle: 3 minutes at 273 °F (134 °C), dry time 40 minutes.
   - Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (sequential envelope folding)

Warning:

Dry Heat Sterilization and Chemical Disinfectants should not be used. These techniques can leave a residue on the product that can irritate or even chemically burn the patient's skin or mucous membrane

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Parker Hannifin Corporation, Porter Instrument Division warrants that each product or part shall be free from defects in workmanship and materials, under normal use and with appropriate maintenance, for one (1) year from the date of delivery to customer unless otherwise specified in writing. All rubber and plastic parts and accessories are warranted under the same conditions for a period of ninety (90) days from date of purchase.

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CE **0413**

This product complies with the Medical Device Directive (93/42/EEC).
A “Declaration of Conformity” in accordance with the directive has been made and is on file.

EC REP European Communities should contact the Authorized Representative listed below regarding any Medical Device Directive (93/42/EEC) inquiries.

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