


Insufflation Filters

REF PS3600NS, PS3601NS, PS3602NS, PS3603NS

 The following should be thoroughly read before use.

IMPORTANT NOTES

This document is designed to provide instructions on how this product/s is used. It is not a reference to surgical techniques. This product should only be used by a qualified person or clinician.

INDICATIONS

The Purple Surgical Insufflation Filter & Tubing Sets allow the passage of carbon dioxide gas from the insufflator to the patient, enabling intra-abdominal insufflation and preventing cross contamination.

PRODUCT CHARACTERISTICS

The Purple Surgical Insufflation Filter provides 99.99% filtration efficiency, to prevent cross contamination of gas borne pathogens between the patient and insufflator. Each model has a luer lock fitting one end of the set to connect to the patient via luer fitting on a cannula or veress needle. The other end of the device is attached to the insufflator, either by a further luer lock connector, attached to a small piece of tubing (PS3600NS) or an O ring adapter (PS3601NS), a push fit adapter (PS3602NS), or a 15mm connector built into the filter (PS3603NS) If the insufflator machine has a small diameter push fit gas outlet, the luer lock connector may be cut off a PS3600NS model and the tubing applied directly to this fitting.

HOW SUPPLIED

Supplied in Non sterile format to Kit packer, for sterilisation as part of a kit prior to market release to intended user.

INDICATIONS FOR STERILISATION PROCESSING:

Method	Indicated	Contraindicated	Process limitations
ETO	x		Maximum Temp - 60°C Deepest Vacuum - 50mbar Absolute Maximum No. of Cycles: x2
Irradiation	x		> 25kGy - < 40kGy
Steam / Other		x	Not Applicable - Unqualified

Note It is the responsibility of the kit packer to validate the sterilisation process employed, with respect to the conditions of their presentation of the packaging system.*

COMPATIBILITY AND CONNECTIVITY

The Insufflation filter / tubing set output is standardized with male ISO 594-2 luer lock fitting. Input fittings are available with either the standard ISO 594-2 compliant male luer-lock fitting, push fit connection, O Ring connection, 22mm connection or 15mm connection to suit the model of insufflator unit for use.

CONTRAINDICATIONS

DO NOT use when Laparoscopic techniques are contraindicated.

PRECAUTIONS / WARNINGS

- (1) DO NOT use if package is received opened or damaged.
- (2) Procedures should be performed only by clinicians with adequate training and knowledge. Medical literature should be consulted for techniques, hazards, contraindications and complications prior to the procedure.
- (3) The filter may block if fluid from the peritoneal cavity inadvertently enters the filter via the evacuation line.
- (4) The user should review the instructions for use of all devices, being used in conjunction with these product/s.

ADVERSE REACTIONS

No known issues.

DIRECTIONS FOR USE

- (1) Using sterile technique, remove the product/s from its packaging. To avoid damage to instruments on the sterile table, do not flip the device into the sterile field.
- (2) Pass the input end of the tubing set out of the sterile field for connection to the insufflator.
- (3) Connect the output luer lock end of the tubing set to the gas tap of a Veress Needle or cannula port to enable abdominal insufflation.

SINGLE USE PRECAUTIONS

This product/s are designed and sold for single use only. Re-processing and, or, re-sterilisation is not permitted. The effects of any unauthorised re-processing or re-sterilisation can result in the following complications:

- 1. Cross contamination due to ineffective re-processing/re-sterilisation.
- 2. Mechanical fatigue, and associated failure, due to the effects of the re-processing / re-sterilisation method.

DISPOSAL

Discard after single use, DO NOT re-sterilise. This product/s is to be disposed of as controlled medical waste according to national guidelines.



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en: LABELLING SYMBOLOGY - Standard EN980 unless otherwise stated
 es: SIMBOLOGÍA DEL ETIQUETADO - Norma EN980 salvo que se indique lo contrario
 pt: SÍMBOLOS UTILIZADOS NO RÓTULO - Norma EN980 excepto indicação em contrário
 de: KENNZEICHNUNGS SYMBOLOGIE - Standardmäßig laut EN980, falls nicht anders vermerkt
 fr: SYMBOLES D'ÉTIQUETAGE - Norme EN980, sauf indication contraire
 it: SIMBOLI SULL'ETICHETTA - Standard EN980, se non diversamente specificato
 pl: SYMBOLE NA ETYKIĘCIE - norma EN980, chyba że podano inaczej
 nl: LABELSYMBOLLEN - Standaard EN980 tenzij anders vermeld
 sv: MÄRKNINGSSYMBOLGI - Standard EN980 om inget annat anges
 tr: ETIKETLEME SİMGELERİ - Aksi belirtilmedikçe EN980 Standardı doğrultusunda



en: Manufacturer
 es: Fabricante
 pt: Fabricante
 de: Hersteller
 fr: Fabricant
 it: Produttore
 pl: Producent
 nl: Fabrikant
 sv: Tillverkare
 tr: Üretici



en: Keep dry
 es: Mantener en un lugar seco
 pt: Manter seco
 de: Trocken aufbewahren.
 fr: À conserver dans un endroit sec
 it: Conservare all'asciutto
 pl: Chronić przed wilgocią
 nl: Droog houden
 sv: Förvaras torrt
 tr: Kuru tutun



en: Keep away from sunlight
 es: Mantener alejado de la luz del sol
 pt: Manter ao abrigo da luz solar
 de: Fern von Sonnenlicht aufbewahren.
 fr: À conserver à l'abri de la lumière
 it: Tenere lontano dalla luce del sole
 pl: Chronić przed promieniowaniem słonecznym
 nl: Uit de buurt van zonlicht bewaren
 sv: Förvaras skyddad för solljus
 tr: Güneş ışığından uzakta tutun



en: Do not reuse
 es: No reutilizar
 pt: Não reutilizar
 de: Nicht wiederverwenden
 fr: Ne pas réutiliser
 it: Non riutilizzare
 pl: Nie używać ponownie
 nl: Niet hergebruiken
 sv: Återanvänd inte
 tr: Tekrar kullanmayın



en: Use-by date
 es: Fecha de uso recomendado
 pt: Data de validade
 de: Verfalldatum
 fr: Date limite d'utilisation
 it: Usare entro la data
 pl: Termin przydatności do użytku
 nl: Uiterste houdbaarheidsdatum
 sv: Utgångsdatum
 tr: Son kullanma tarihi



en: Consult instructions for use
 es: Consultar las instrucciones de uso
 pt: Consultar instruções de utilização
 de: Gebrauchsanleitung beachten
 fr: Consulter le mode d'emploi
 it: Consultare le istruzioni per l'uso
 pl: Zapoznać się z instrukcją obsługi
 nl: Raadpleeg de instructies voor gebruik
 sv: Läs instruktionerna före användning
 tr: Kullanma talimatlarına bakın



en: Do not re-sterilise
 es: No reesterilizar
 pt: Não re-esterilizar
 de: Nicht erneut sterilisieren
 fr: Ne pas restériliser
 it: Non risterilizzare
 pl: Nie sterylizować ponownie
 nl: Niet opnieuw steriliseren
 sv: Resterilisera inte
 tr: Tekrar sterilize etmeyin



en: Batch code
 es: Código de lote
 pt: Código de lote
 de: Chargen-Code
 fr: Code de lot
 it: Codice lotto
 pl: Kod partii
 nl: Batchcode
 sv: Batch-kod
 tr: Parti kodu



en: Catalogue number
 es: Número de catálogo
 pt: Número de catálogo
 de: Katalognummer
 fr: Numéro de catalogue
 it: Numero di catalogo
 pl: Numer katalogowy
 nl: Catalogusnummer
 sv: Katalognummer
 tr: Katalog numarası



en: Do not use if package is damaged
 es: No usar si el envase está dañado
 pt: Não usar caso a embalagem esteja danificada
 de: Nicht verwenden, wenn das Paket beschädigt ist
 fr: Ne pas utiliser si l'emballage est endommagé
 it: Non usare se la confezione è danneggiata
 pl: Nie używać, jeżeli opakowanie jest uszkodzone
 nl: Niet gebruiken als de verpakking beschadigd is
 sv: Använd inte om förpackningen är skadad
 tr: Ambalajı hasarlıysa ürünü kullanmayın



en: CE Mark with notified body number
 es: Marcado CE con número de organismo notificado
 pt: Marcação CE com número do organismo notificado
 de: CE-Kennzeichnung mit Nummer der benannten Stelle
 fr: Marquage CE avec numéro d'organisme notifié
 it: Marchio CE con numero dell'ente notificato
 pl: Oznakowanie CE z numerem instytucji notyfikowanej
 nl: CE-markering met number van officiële instantie
 sv: CE-märkning med det anmälda organets identitetsnummer
 tr: Yetkili kurumun numarasıyla birliktCE İşareti



en: Caution
 es: Precaución
 pt: Atenção
 de: Vorsicht
 fr: Avertissement
 it: Attenzione
 pl: Ostrożnie
 nl: Let op
 sv: Försiktighet
 tr: Dikkat

Rx only

en: CAUTION: US Federal Law restricts this device to prescription only.
 es: PRECAUCIÓN: La ley federal de EE. UU. permite el uso de este dispositivo solamente bajo prescripción médica.
 pt: ATENÇÃO: A Lei Federal norte-americana restringe este dispositivo a receita médica.
 de: VORSICHT: Gemäß US-Bundesgesetz ist dieses Gerät verschreibungspflichtig.
 fr: ATTENTION : La législation fédérale des États-Unis limite la vente de ce dispositif sur ordonnance uniquement.
 it: ATTENZIONE: la legge federale degli Stati Uniti limita il presente dispositivo alla sola prescrizione medica.
 pl: PRZESTROGA: zgodnie z prawem federalnym (USA) niniejsze urządzenie może być sprzedawane wyłącznie lekarzom lub na ich zamówienie.
 nl: WAARSCHUWING: Volgens de federale wetgeving van de VS mag dit instrument alleen op voorschrift gebruikt worden.
 sv: VARNING: Enligt federal lag i USA får denna anordning endast lämnas ut mot forskrivning.



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