Insufflation Filters

REF: PS3600NS, PS3601NS, PS3602NS, PS3603NS

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:

<table>
<thead>
<tr>
<th>Method</th>
<th>Indicated</th>
<th>Contraindicated</th>
<th>Process Limitations</th>
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</thead>
<tbody>
<tr>
<td>ETO</td>
<td>x</td>
<td></td>
<td>Maximum Temp - 60°C</td>
</tr>
<tr>
<td>Irradiation</td>
<td>x</td>
<td></td>
<td>Deepest Vacuum - 50mbar Absolute</td>
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<tr>
<td>Steam / Other</td>
<td></td>
<td>x</td>
<td>Maximum No. of Cycles: x2</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>≥ 2.5KgY - ≤ 40KgY</td>
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<td></td>
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<td>Not Applicable - Unqualified</td>
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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 S04-2 luer lock fitting.
Input fittings are available with either the standard ISO S04-2 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 open 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.