

◆Instructions for Use◆

Disposable Insufflation filter with tubing set

◆ Intended Use:

To be used in conjunction with MIS procedure kit for intra-abdominal Laparoscopic surgery and procedure.

◆ Cautions/Warnings:

















This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or re-sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device. Single use only, Sterile (Unless package is damaged or opened). All contents are ETO sterilized.

“Federal (USA) and European Union law restricts the device to sale, distribution and use by or on the order of a physician”

◆ INSTRUCTIONS FOR USE

- 1) Tear off cover to access sterile contents.
- 2) Place contents on sterile field.
- 3) Give the connection fitting closest to filter to the nurse for connection to output insufflation gas port.
- 4) For barbed output, simply cut off fitting and insert over barbed fitting.
- 5) Connect the opposite Luer connector in sterile field to Veress Needle or gas port of Surgical Trocar Cannula.
- 6) Proceed with insufflation.

Glossary of symbols:

| | | | |
|--|--|---|--|
|  | Caution |  | Sterilized using Ethylene Oxide |
|  | Do not use if package is damaged |  | Batch code |
|  | Keep away from sunlight |  | Date of manufacture YYYY-MM-DD |
|  | Catalogue number |  | Manufacturer |
|  | Do not re-sterilize |  | Use by |
|  | Consult instructions for use |  | Do not reuse |
|  | Keep dry |  | Authorised representative in the European community. |
|  | Notified body: DNV Product Assurance AS, with CE2460 | | |
|  | RX ONLY | | |

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