



GLOBAL SOLUTIONS FOR MEDICAL INDUSTRY

康健生醫科技股份有限公司
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承認書

SPECIFICATION For APPROVAL

MODEL NO.: AVN-

PART NO.: MVN-E001-A-00000

DESCRIPTION: 英文公版 IFU Ver. J、CE2460 (新增符號資訊)

SUPPLIER NO.: AMD / 皓瀚 (37173)

SPECIFICATION: 顏色：黑白； A4 單面



SUPPLIER	
APPROVED	CHECKED

AMD		
DCC	DMR Document No.: <u>DMR131001</u>	
QA	APPROVED	CHECKED
		2022.05.26
Responsible Department	APPROVED	CHECKED
	5/26/2022	Brian 2022.05.26.

Instruction for Use

Product: Veress Needle

The Following information should be read before using this device.

Description:

The Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

Contraindications:




















This device is not intended for use when endoscopic techniques are contraindicated.

Preparation:

1. Remove the product from the package tray.
2. To hold straight and insert into abdominal, the inner shaft will engage shield and protect to damage internal organ
3. To connect Insufflation generator with luer lock adaptor into needle or Trocar's gas port for insufflation gas into patient's abdominal.
4. Please follow instructions provided by Insufflation pump manufacturer.

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.
- Contents sterile unless enclosed package has been opened or damaged. Store at 15°C~25°C.
- Dispose used product following local state or federal guidelines.
- Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a physician.

 Caution	 Sterilized using Ethylene Oxide	 Consult instructions for use
 Do not use if package is damaged	 Batch code	 Do not reuse
 Keep away from sunlight	 Date of manufacture	 Keep dry
 Catalogue number	 Manufacturer	 Authorised representative in the European community
 Do not re-sterilize	 Use by	 Temperature limitation: 15°C~25°C
 Medical device	 Single sterile barrier system	 Single sterile barrier system with protective packaging outside
 Notified body: DNV Product Assurance AS, with CE2460		

If further information is required, please contact:



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