

HARTMAN MEDICAL GROUP EXTENSION SET INSTRUCTION FOR USE (IFU)

Extension sets (CV100B, CV100R, CVM100B, CV200B, CV300B, CV100Y)

Instructions for Use provides information that promotes the safe use of HMG Distribution extension set products. Failure to fully read, understand and comply may result in an adverse event such as patient injury or even death.













- 1. DESCRIPTION:** Extension set with luer lock needleless connector. Sterile, single use, non-pyrogenic, non-toxic.
- 2. INDICATIONS FOR USE:** The intended use for HMG Distribution Extension Sets CV100B, CV100R, CVM100B, CV200B, CV300B and CV100Y is to provide a pathway for which intravenous fluids, medications, blood and blood products may be administered to a patient's vascular system.
- 3. PRECAUTIONS:** Ensure product is being used prior to expiration. Inspect packaging and product for integrity.
- 4. CAUTIONS:**
 - 4.1 Federal USA law restricts this device to be sold and used only on the order of a physician.
 - 4.2 Needleless valve is not intended for needle puncture access.
 - 4.3 Needleless valve is not intended for use with blunt tip cannula devices.
 - 4.4 This device is intended for single use only. The reuse or re-sterilization of this device is strictly prohibited.
 - 4.5 Do not use if the package is opened or damaged.
- 5. HOW TO USE:**
 - 5.1 Open the individual pouch and carefully remove the extension set. Exercise caution to maintain sterility.
 - 5.2 Remove the distal tip cover.
 - 5.3 Follow local aseptic technique protocol.
 - 5.4 Attach the male luer of the extension set to the female luer of the connecting device.
 - 5.5 Make sure the extension set is patent.
 - 5.6 Follow local protocol for priming.
 - 5.7 Attach administration set or male luer syringe to the needleless connector.
 - 5.8 infusion according to local protocol.
 - 5.9 Remove and discard the extension set per local protocol.
- 6. STORAGE:**

HMG Distribution extension sets should be stored in an environment where the temperature is controlled to a moderate temperature. The environment should also be low in humidity. Take extra care not to place the product too close to light sources. Some light sources are known to produce high local heat and can accelerate the aging of products.
- 7. PRODUCT SPECIFICATIONS:**

Please read the entire label for each HMG Distribution extension set product. The products are unique and differ from one another. On the label you will find specifications regarding approximate priming volumes, overall length, configuration, description and pressure rating. If there is no stated pressure rating, then the product has not been rated for high pressure and should be used accordingly.
- 8. NEEDLELESS CONNECTOR SPECIFICATIONS:**

All of HMG Distribution extension sets allow access through a needleless connector. The needleless connector has neutral displacement, up to 200 activations, alcohol and lipid compatible, flow rate 130-165 mL (gravity feed at approx. 36" head height) and is rated for high pressure.

9. SYMBOL DEFINITIONS:

							
Product reference	Batch/Lot number	Single use only	Sterilized by ethylene oxide	Not made with Latex	Keep dry	Manufactured for	Do not use if package is damaged
							
Physician use only	See instructions for use	Expiry date	Pyrogen free				