InVision-Plus® CS™ Chlorhexidine + Silver Ion Engineering with Neutral Advantage™ technology

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

Indications for Use

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ technology is a needleless IV connector system and is intended for single patient use in intravenous and blood administration sets without need for needles, thus eliminating the potential for needle-stick injuries during use.

The InVision-Plus® CS™ is antibacterial, containing silver ions and chlorhexidine, which are intended to inhibit the growth of microorganisms on the treated surfaces of the device, which include the septum and the fluid path.

In vitro testing of the InVision-Plus® CS™ has been shown to be effective for up to 7 days against the following microorganisms: Acinetobacter baumannii, Methicillin-resistant Staphylococcus aureus (MRSA), Staphylococcus aureus, Escherichia coli, Candida albicans, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Staphylococcus epidermidis.

Organism	Log Reduction			
	Day 1	Day 3	Day 4	Day 7
MRSA (clinical isolate)	3.2	5.8	5.5	7.0
E. coli (ATCC #8739)	4.1	4.1	5.2	4.9
S. aureus (ACCT #6538)	3.2	5.2	4.2	4.2
P. aeruginosa (ACCT #9027)	4.3	4.9	4.3	4.5
A. baumannii (ATCC #19606)	3.8	3.8	4.5	5.4
S. epidermidis (clinical isolate)	4.0	5.4	4.0	6.0
K. pneumoniae (ATCC #4352)	5.0	4.2	5.5	5.1
C. albicans (ATCC #38245)	2.6	3.5	3.3	2.9

The subject device is not intended to treat existing infections. The device is not intended to have any effect on contaminated infusion solutions. Correlation between *in vitro* antibacterial activity and any clinical effectiveness has not been tested. The InVision-Plus® CS™ may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec.

Device Description: The InVision-Plus® CS™ is accessed by a standard male-luer syringe or I.V. set connector. A male luer-lock connector should be used with the InVision-Plus® CS™ for a secure connection. The InVision-Plus® CS™ is bi-directional and luer-locking. The InVision-Plus® CS™ will automatically close when the syringe or male-luer I.V. set connector is removed. The InVision-Plus® CS™ may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10mL/sec. Connect only with other devices rated for high pressure with a luer lock connection when performing power injections. The subject device should be changed each use with a low pressure power injector.

The Neutral Advantage™ technology features include a smooth swabbable septum surface, septum seal integrity with no gaps or openings, patented double microbial barrier, straight-through fluid pathway, zero dead space, zero fluid displacement, 0.027mL priming volume, 100% effective blood clearing, saline-only flush option and no clamping sequence or positive pressure syringe technique required.

Contraindications: The InVision-Plus® CS™ is contraindicated for patients with hypersensitivity to chlorhexidine or silver and women who are pregnant. Chlorhexidine has been assigned to pregnancy Category B by the FDA

How Supplied: The InVision-Plus® CS™ is supplied as a standalone device or as part of extension and IV administration sets.

Precautions: Always use aseptic technique. The InVision-Plus® CS™ may not be compatible with every male-luer connector. Some I.V. sets/syringes utilize a male-luer connector with a lumen opening diameter of 0.063" or less which may cause damage to the InVision-Plus® CS™ resulting in septum damage, reduction or loss of fluid flow. DO NOT use any male-luer device unless certain that the male-luer connector opening is 0.064" or larger. Do not use needles with connector. Do not use luer-lock end caps on connector. Do not swab with Chlorhexidine Gluconate (CHG), use 70% Isopropyl Alcohol only. Flush InVision-Plus® CS™ after each use per institutional protocol using normal saline, or normal saline and heparin. Change per CDC guidelines or per validated facility protocol. The CDC recommends that tubing used to administer lipid emulsions and TNA solutions should be changed every 24 hours. The InVision-Plus® CS™ and extension set should also be changed at this time.

Instructions for Use - Needleless IV connectors

1. Wash hands thoroughly with bactericidal soap before each procedure. Use gloves, if required by your institutional protocol.
2. Inspect **InVision-Plus® CS™**. Discard the set if end caps are missing or loose in package.
3. **RYM-7000**: Peel back lid on the "Touch-Free" Package Container. Do not touch the tip of the **InVision-Plus® CS™**. Attach **InVision-Plus® CS™** to the desired vascular access device by rotating the "Touch-Free" Package Container in a clockwise direction until secure. Pull back the Package Container until clear of the port and dispose.

   RYM-7001: Peel back lid on the Blister Package. Remove the male-luer cover. Do not touch the tip of the InVision-Plus® CS™. Attach the **InVision-Plus® CS™** to the desired vascular access device by rotating the **InVision-Plus® CS™** in a clockwise direction until secure
4. Remove protective coverings as assembly progresses.
5. To access the **InVision-Plus® CS™** swab the septum and thread area with 70% Isopropyl Alcohol
6. Position the syringe or I.V. set male-luer connector tip on the **InVision-Plus® CS™** septum.
7. Push forward, rotate syringe or I.V. set male luer-lock connector clockwise until secure.
8. To disconnect the syringe or I.V. set male-luer connector, rotate counterclockwise.

Instructions for Use - Specific to InVision-Plus® CS™ Extension Sets and Administration Sets

1. Open clamp, then prime to expel air from set.
2. Attach set to vascular access device.
3. Ensure that all connections are tightened and secure before use

Product Information: (512) 301-1949 www.rymedtech.com

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