



# CUROS®

## Port Protector

### Product Effectiveness Studies

#### Purpose

A series of three laboratory studies were conducted at an independent third party testing laboratory to determine if the Curoso® Port Protector was as effective as a properly performed 70% isopropyl alcohol (IPA) swab in disinfecting needleless I.V. luer access valve (LAV) connectors.

#### Scope

The first study measured the population reduction in Staphylococcus aureus on the surface of four different needleless I.V. luer access valves as a result of exposure to the Curoso Port Protector with 70% IPA at time points of five minutes and 96 hours. The four valves chosen represent four different types of valve mechanisms which, according to the Ryder study<sup>1</sup>, represent 15 commercially available and widely used valves.

The second study measured the population reduction of four different microorganism species, 2 gram positive (S. aureus, S. epidermidis) and 2 gram negative (E. coli and P. aeruginosa) on the surface of a needleless access valve at time points necessary to achieve ~5 log reduction.

The third study in the series measured the efficacy of the Curoso Port Protector with 70% IPA aged for one year<sup>2</sup> on a fifth valve (different from the four tested in the first study) on 1 gram positive (S. aureus) and 1 gram negative (P. aeruginosa) organism. The results in the third study were compared to a conventional three second swab method using 70% IPA against the same two organisms, and post swabbing allowing the alcohol on the valve surface to dry for 60 seconds.

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## Luer Access Valves (LAVs) Evaluated in the Product Effectiveness Studies

### Specific Luer Access Valves (LAVs) Utilized in the Test Series:

- **Ultrasite®** B. Braun
- **Securisend®** Halkey-Roberts
- **Clave®** ICU Medical
- **SmartSite®** CareFusion
- **MaxPlus™** Medegen Medical

The CuroS® test results with these five representative LAVs met the extreme criteria for microbial ingress established by the FDA<sup>3</sup>, used to evaluate new needleless luer access valves.



### Conclusions

- CuroS® Port Protectors are effective across a broad range of LAVs, and have been shown to be dramatically more effective than a conventional alcohol swab<sup>4</sup>.
- CuroS, when used in accordance with the Directions For Use, achieved ~5 log reduction across these microorganisms tested: S. aureus, S. epidermidis, E. coli, P. aeruginosa.

### References

Guidance for Industry and FDA Staff Intravascular Administration Sets Premarket Notifications Submissions 510(k) Section 8.0 "Microbial Ingress Testing", "Draft Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", 2007.

- <sup>1</sup> Bacterial transfer through needlefree connectors: Comparison of nine different devices; Marcia Ryder, Steve Fisher, Gordon Hamilton, Martin Hamilton and Garth James, April 2007 Poster Presentation: 2007 SHEA Meeting.
- <sup>2</sup> Aging studies are ongoing and, upon additional testing, further extensions in shelf life stability are expected.
- <sup>3</sup> Guidance for Industry and FDA Staff Intravascular Administration Sets Premarket Notification Submissions [510(k)].
- <sup>4</sup> Testing has shown that conventional 70% IPA swabbing may also achieve ~3 log reduction.



# IVERA™

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