

HyperGrip® Series Product Sterilization

White Paper



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HyperGrip® (HG) Connector Series

Product Sterilization



Transmission of disease in a healthcare setting is a major concern among medical professionals. Specifically, any medical device which is used within the sterile field in a surgical setting must be sterile prior to its introduction to the patient.

Sterilization is more than just Disinfection. Whereas Disinfection *reduces* the number of infection causing microorganisms, Sterilization is an unconditional process, assuring that there are *no* microorganisms on the device, by either killing or removing them. According to the CDC (Centers for Disease Control and Prevention), “*Any item, device, or solution is considered to be sterile when it is completely free of all living microorganisms and viruses. The definition is categorical and absolute (i.e., an item is either sterile or it is not). A sterilization procedure is one that kills all microorganisms.*”

Typical Sterilization processes used for medical devices include: Autoclaving, EtO sterilization, and hydrogen peroxide gas plasma technology.

Autoclaving

An autoclave is like a pressure cooker, which locks and sterilizes with steam under high temperature and pressure. The word “autoclave” is a combination of the Greek for ‘self’ (auto) and the Latin for ‘key’ (clavis) – or a ‘self-locking’ device. Autoclaving is widely used to sterilize medical devices because it’s quick, cost effective, and relatively safe. But, some devices might not be able to withstand the heat and may degrade due to its accelerated aging effects.

EtO Sterilization

Another popular method of sterilization for medical devices is exposure to Ethylene Oxide (EtO) gas (chemical formula: C_2H_4O). As a low temperature process, EtO can be used on heat sensitive products, and since the gas can penetrate through the packaging material, it can be used after single use devices have been packaged. But its use as a sterilization method in hospitals is declining, partly due to the long processing time required, as well as safety concerns with EtO, since it’s highly flammable, explosive, toxic and carcinogenic (the EPA classifies EtO as “a Group B1, probable human carcinogen”).

Sterrad®

Advanced Sterilization Products (“ASP”, a division of Ethicon Inc., a Johnson and Johnson Company) manufactures Sterrad® sterilization systems, which “*use low temperature hydrogen peroxide gas plasma technology to sterilize instruments and medical devices safely and effectively, protecting the instruments, users, patients, and environment*” – ASP. Sterrad® has distinct advantages over both autoclaving and EtO, as a low temperature process with shorter cycle times than EtO. As a strong oxidant, however, hydrogen peroxide might not be compatible with some devices and can leave a sticky residue. But, care should be taken because it’s a strong skin irritant, and can be harmful to the eyes and respiratory system.

Note:

Sterrad® is a trademark of Advanced Sterilization Products

Tests on HyperGrip® connectors

Smiths Connectors HyperGrip® (HG) series connectors were designed to meet the stringent requirements of the Medical Device market, therefore must be compatible with commonly used sterilization protocols. Independent tests were therefore performed on the HG2 (12 position), HG3 (19 position), and HG4 (33 position) connectors to determine whether they can withstand typical sterilization procedures to which medical devices, that would incorporate these connectors, might be subjected.



Testing with standard Autoclaving, EtO, and Sterrad® methods was undertaken, after which all connectors must still meet the design requirements for connector retention and mating cycle life (ref: Smiths Connectors test report #TR-045-13). All connectors passed the following tests at the indicated test facilities:

Autoclave Sterilization (performed at *Nelson Laboratories*):

- ▶ Type: Gravity / Flash / Steam Autoclave
- ▶ Sample size: 3 mated pair of each size (HG2, HG3, HG4)
- ▶ Number of Cycles: 20
- ▶ Temperature: 135°C ± 1 °C
- ▶ Full cycle time: 10 minutes
- ▶ Dry Time: 0 minutes

EtO Sterilization (performed at *Nelson Laboratories*):

- ▶ Sample size: 3 mated pair of each size (HG2, HG3, HG4)
- ▶ Number of Cycles: 20
- ▶ Preconditioning:
 - ▶ Temperature: 43.3°C
 - ▶ Relative humidity: 55%
 - ▶ Time: 18 hours per cycle, average
- ▶ EtO Exposure:
 - ▶ Temperature: 54.44 °C
 - ▶ Initial vacuum: 1.30 psia
 - ▶ Steam addition: 0.49 psia rise (23% RH)
 - ▶ Steam dwell time: 30 minutes
 - ▶ EtO gas concentration: 590mg/L (of 100% EtO)
 - ▶ EtO gas dwell time: 2 hours
 - ▶ Air washes: 3 repeats
- ▶ Aeration:
 - ▶ Temperature: 43.3°C +/- 5°C
 - ▶ Time: 24 hours min.

Sterrad® testing (performed at *Advanced Sterilization Products®*):

- ▶ Using the Sterrad® ST100NX system, 'standard' cycle
- ▶ Sample size: 3 mated pair of each size (HG2, HG3, HG4)
- ▶ Number of Cycles: 20
- ▶ Temperature: Ambient
- ▶ Exposure holding time: 55 min +/- 5 min
- ▶ Dwell time between cycles (cool down): 30 min +/- 5 min
 - ▶ No more than 2 cycles were performed per day

Note:

All HG series samples used in these tests were fully loaded and assembled, mated pairs

Conclusion

HyperGrip connectors are suitable for applications in medical devices which are subjected to autoclave, EtO, and Sterrad sterilization before use in a sterile surgical environment.



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