

October 23, 2008

Sterilization of Ascension Orthopedics Instrument Sets

Ascension Orthopedics, Inc. has completed sterilization validations for our instrument sets. The validations were performed by an outside laboratory, SPS Medical of Rochester, NY. The validation protocols were performed in accordance with AAMI ST79:2006 Steam Sterilization and Sterility Assurance in Health Care Facilities and AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization.

The most complex and worse case Ascension Orthopedics instrument sets have passed steam sterilization validation testing (RadFX, TFS Rearfoot, and HRA sets). All testing was done using the overkill approach with *Geobacillus stearothermophilus* spores. The results confirmed a 10^{-6} Sterility Assurance Level (SAL) for the sets when using the recommended cycles.

In accordance with our validation results, the following cycles are recommended:
Steam Pre-vacuum -4 minutes at 132°C (270°F)
Steam Gravity -15 minutes at 132°C (270°F)

A vacuum drying cycle of at least 30 minutes is also recommended.

These cycles are also valid for smaller, less complex Ascension sets including the DRUJ, PIP, MCP, CMC, PyroDisk, Lunate and MRH as they are easier to sterilize than the worse case sets referenced above. If further information is required, please contact David C. Furr, Sr. VP Quality, Regulatory, and Clinical Affairs at Ascension Orthopedics, Inc. (512)-836-5001 ext. 1516.



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