TECHNICAL BULLETIN

ON-Q*
PAIN RELIEF SYSTEM

ON-Q* Tunneler (reusable)
Gravity Displacement Steam Sterilization Validation

Purpose

To determine a process that is appropriate for routine gravity displacement steam sterilization of the ON-Q* Tunneler, microbiological validation of gravity displacement was conducted. Studies followed practices recommended in ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Recommendations for a routine minimum sterilization time were based on evaluation of microbial survivors following sterilization of the ON-Q* Tunneler. The ON-Q* Tunneler consists of a medical grade stainless steel shaft and handle.

Conclusion

Gravity displacement steam sterilization is an acceptable method of routine re-sterilization of the ON-Q* Tunneler using the following parameters:

Parameters for Gravity-Displacement Steam Sterilization Cycles

	Wrapped Instrument
Temperature	132°C (270˚ F)
Exposure Time	15 min.
Drying Time	15 to 30 min.

ON-Q* Tunnelers have been functionally tested up to 30 sterilization cycles.

Refer to the ON-Q* Tunneler Directions For Use for more information on decontamination and sterilization of this device.

It is the responsibility of the processing facility to ensure that processing is performed using equipment, materials and personnel to achieve the desired results. This requires validation and routine monitoring of the process.

There are inherent risks in all medical devices. Please refer to the product labeling for **Indications, Cautions, Warnings** and **Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to www.iflo.com for additional product safety *Technical Bulletins*.

Please contact the Clinical Services Department at 800-448-3569 or 949-923-2400 if you have questions regarding this information.

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