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RE: Cleaning and Sterilization instructions for Lenstec re-usable surgical instruments

Dear Lenstec Customer,

The following instructions have been validated to adequately cleanse, sterilize and dry Lenstec's re-usable surgical instruments.

CLEANING INSTRUCTIONS (MANUAL)

- Immediately after every surgery rinse the injector and lens loader with deionized water and then clean the device and its crevices using a soft surgical/laboratory brush moistened with alcohol. Care should be taken to avoid damage to the extreme tip.
- Inspect the instrument under magnification (10x) to check for gross contamination, wear or damage. Do not reuse if wear or damage are apparent.
- Be sure to clean any contamination prior to sterilization as this could cause wear or damage to injector.
- NOTE: Should any other type of cleaning method be used (ie. Ultrasonic, detergent cleaner, etc), the user must verify its effectiveness prior to sterilization and subsequent use.

STERILIZATION AND RESTERILIZATION OF THE INJECTOR

After the injector and lens loaders have been properly cleaned, it is recommended that they be sterilized in accordance with one of the following standards:

- AAMI ST79 A1 2008; A2 2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- Local national standards.

STERILIZATION CYCLE PARAMETERS

UNWRAPPED ITEMS:

- Gravity displacement vessel: The recommended minimum exposure time and temperature for injectors and lens loaders is **three (3) minutes at 135° C (270° F)**, with a load size of three (3) Lenstec reusable surgical instruments in those autoclaves common to healthcare facilities.

- NOTE: This validated cycle represents a 'worst case' scenario representing the shortest duration sterilization cycle which effectively sterilizes the instruments.

WRAPPED ITEMS:

- Gravity displacement vessel: The recommended minimum exposure times and temperatures validated for injectors and lens loaders with a load size of three (3) Lenstec reusable surgical instruments are:
 - **Thirty (30) minutes at 121° C (250 ° F)**
 - **Fifteen (15) minutes at 132° C (270 ° F)**

DRYING TIMES

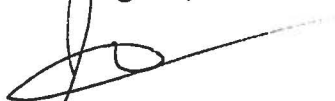
WRAPPED:

- For 30 minutes at 121°C cycle DRY TIME: minimum 15 – 30 minutes
- For 15 minutes at 132°C cycle DRY TIME: minimum 15 – 30 minutes

UNWRAPPED- FLASH Sterilization

- For 3 minutes at 132°C cycle DRY TIME: minimum 0 – 1 minutes

Best regards,



Jimmy Chacko
Vice-President, Regulatory Affairs
Lenstec Inc.