

**SMARTRELEASE 81014 HANDPIECE STERILIZATION PARAMETERS**

Steam sterilize using one of the below cycles. The following steam parameters have been found to be successful in demonstrating a sterilization assurance level (SAL) of at least 10<sup>-6</sup>.

| <b>GRAVITY-DISPLACEMENT STEAM</b> | <b>Instrument Only / In Sterilization Case</b>    |
|-----------------------------------|---|
| Exposure Time                     | 35 minute Full Cycle                              |
| Exposure Temperature              | 270-275°F (132-135°C)                             |
| Minimum Dry Time                  | 20 minutes  |
| Materials                         | Double wrapping in a standard central supply wrap |

| <b>DYNAMIC AIR REMOVAL (Pre-Vac)</b> | <b>Instrument Only / In Sterilization Case</b>    |
|--------------------------------------|---|
| Exposure Time                        | 5 minute Full Cycle                               |
| Exposure Temperature                 | 270-275°F (132-135°C)                             |
| Minimum Dry Time                     | 20 minutes  |
| Materials                            | Double wrapping in a standard central supply wrap |

**Note: Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a pre-vacuum steam sterilization cycle for 18 minutes at 134°C (273°F). (WHO/CDS/CSR/2000.3, "WHO Infection Control Guidelines for TSE," March 1999).**

**"Flash" Sterilization:**

Surgical centers that wish to steam sterilize patient care items for immediate use shall at a minimum follow the requirements as outlined in ANSI/AAMI ST79:2010. Reduction of bioburden and removal of gross soil are essential steps in preparing an item for sterilization by any method. Please follow the steps for decontamination of the instrument prior to any sterilization process including "Flash" sterilization. The processed items must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use. There is NO storage or shelf life of flash-sterilized items because of the probability of contamination after the sterilizer door is opened and the items are removed. When performed correctly, flash sterilization is safe and effective for sterilization of medical devices (AAMI ST79:2010).

Re-usable surgical instruments with moving parts require a dry cycle to keep the product functioning appropriately. "Flash" Gravity-Steam sterilization with NO dry time is NOT recommended as a normal process of sterilization.

**OTHER STERILIZATION METHODS**

**CAUTION:** Other sterilization systems have not been tested and are not recommended.