Sterilization Parameters for Wrapped or Containerized Items

NSI Instruments are reusable, unless otherwise marked, and meet ANSI standards for sterilization. Steam autoclave sterilization is recommended. Thoroughly clean instruments of all debris, tissue, and foreign matter prior to sterilization. It is recommended to follow the NSI General Instrument Instructions For Use (NSI IFU); Document #NSI-IFU-001-RevB, for all NSI surgical instruments.

Steam sterilization cycles typically used in health care facilities include the gravity-displacement cycle and two types of dynamic-air-removal cycles. One type of dynamic-air-removal cycle, removes air from the chamber and load by means of pressure and vacuum excursions. The other type, the steam-flush pressure-pulse (SFPP) cycle, removes air with a series of steam flushes and pressure pulses above atmospheric pressure. The sterilizer manufacturer's operator's manual should be consulted for specific exposure times, temperatures, and drying times. However, Tables 5 and 6 describe the most common temperatures and time parameters for various types of loads.

The sterilizer manufacturer's written instruction for cycle parameters should be followed. Programmed cycle selections should be used. Any differences between the programmed cycle parameters and the cycle parameters recommended by the medical device manufacturer should be investigated and resolved before the items are sterilized. Procedures for correct cycle selection should be developed and implemented and process audits should be conducted to ensure compliance. Procedures for cycle modification should specify use of an appropriate process device (PC), i.e., one that provides an adequate challenge in a cycle with extended exposure time: also, the user should ensure that the packaging material can withstand an extended cycle.

If a rigid sterilization container system or sealed containment device for flash sterilization is used as packaging, the container system manufacturer's written recommendations regarding exposure time should be consulted and reconciled with those of the sterilizer manufacturer. The correct cycle parameters should be selected and verified based on the results of product testing.

Rationale: Sterilizers vary in design and performance characteristics, so cycle parameters should always be verified against the sterilizer manufacturer's instructions for the specific sterilizer and load configuration used. The use of rigid sterilization container systems or sealed containment devices designed for flash sterilization could affect come-up and exposure times in steam sterilizers, depending on the efficiency of air removal from and steam penetration into the container systems. Therefore, it is important to verify that containerized devices can be effectively sterilized by the cycle parameters selected. The design of some medical devices will itself hinder air removal and steam penetration, making sterilization more difficult. The device manufacturer is in the best position to specify the conditions necessary for steam sterilization of a particular device.

Table 1 – Minimum Cycle Times for Gravity-Displacement Steam Sterilization Cycles

Item	Exposure Time at 121˚ (250˚F)	Exposure Time at 132˚ (270˚)	Drying Times
Wrapped Instruments	30 minutes	15 minutes	15-30 minutes
Textile Packs	30 minutes	25 minutes	15 minutes
Wrapped Utensils	30 minutes	15 minutes	15-30 minutes
Unwrapped Nonporous Items		3 minutes	0-1 minutes
Unwrapped Nonporous and Porous Items in Mixed Load		10 minutes	0-1 minutes

Table 2 – Minimum Cycle Times for Dynamic-Air-Removal (prevacuum) Steam Sterilization Cycles

Item	Exposure Time at 121˚ (270˚F)	Drying Times
Wrapped Instruments	4 minutes	20-30 minutes
Textile Packs	4 minutes	15-20 minutes
Wrapped Utensils	4 minutes	20 minutes
Unwrapped Nonporous Items	3 minutes	0-1 minutes
Unwrapped Nonporous and Porous Items in Mixed Load	4 minutes	0-1 minutes

NOTE -- These tables represent the variation in sterilizer manufacturer's recommendations for exposure at different temperatures. For a specific sterilizer, consult that manufacturer's recommendations. NSI-IFUSP-001-Rev B 03.15