

Name of Organization

One Tray Sterilization

PURPOSE/EXPECTED OUTCOME

To establish criteria for use of the One Tray sterilization container system

POLICY STATEMENT

The One Tray system, consisting of sterilization containers, deck plate, and proprietary processing kit, provides an FDA 510(K) cleared process for rapid sterilization temperature-tolerant surgical devices.

- Sterilization can occur via either Pre-Vacuum or Gravity with no cycle dry or cycle cool time. The preferred method is pre-vacuum with a four minute exposure time.
- Do not process One Tray using pulsed "flash" cycles.
Only instrument sets that have instrument manufacturer's instruction for use (IFU) allowing a four minute exposure time, or having been validated for four minute cycle in One Tray, should be processed via rapid sterilization in the One Tray.
- Complex instruments i.e. instruments requiring extended (> 4 min. exposure) sterilization cycles should be prepared and sterilized according to the instrument manufacturer's written instructions.

Items rapidly processed in ONE TRAY have a 30 Day Shelf Life. However in XXX-n, One Tray should only be used for instruments that will be used in the next 48 hours.

DEFINITIONS

Rapid Sterilization- Sterilization with manufacturer's recommended exposure time but without a dry or cooling time

Extended Cycle- An extended sterilization cycle is a sterilization cycle that is extended beyond the sterilizer manufacturer's standard cycle time. For the purposes of this policy this is interpreted to mean any exposure time greater than 4 minutes.

Instructions for Use (IFU)- The written procedure for processing instrumentation as provided by the instrument or equipment manufacturer. IFUs can be located via the One-source Document Management System for Medical And Dental IFUs (<https://www.onesourcedocs.com/member/index.html>)

PROCEDURE

Follow instrument manufactures and One Tray IFU (addendum A) for cleaning processing and storage of processed trays.

REFERENCES

AAMI/ANSI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities (2017).

One Tray User Manual (Addendum A)

One Source Document management system <https://onesourcedocs.com/member/index.html>

ONE TRAY® Sealed Sterilization Container FDA 510K clearance

REQUIRED REVIEW

Perioperative Services

Infection Prevention

ATTACHMENTS: 510K clearance

Addendum A – One Tray IFU

Approval Signatures

Approver
XXXXXXXXXX

Date
XXXXXXX

XXXXXXXXXX

XXXXXXX

XXXXXXXXXX

XXXXXXX

Applicability

Names of Organizations in the Healthcare Organization