

Plastic Sterilization Trays

INTENDED USE:

Key Surgical® Plastic Sterilization Trays are designed to store and protect delicate instruments during sterilization. These trays are not intended for use with immediate-use steam sterilization (IUSS). The trays feature holes and additional slots in the lid and base to increase the circulation of steam and air. Holes in the silicone mat inserts align with the base to ensure adequate drying and prevention of wet packs. The use of the plastic trays may prolong the life of surgical instruments by protecting the items during storage, transportation, and sterilization.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

PREPARATION:

Plastic Sterilization Trays are reusable and must be cleaned and disinfected prior to initial use and subsequent reuse.

INSTRUCTIONS FOR USE:

1. Configure the tray and mat properly to where the mat pins point upward and the holes in the tray base and mat align to accommodate the instruments that will be sterilized. The mat is used to help stabilize, separate, and protect instruments. Instruments should be arranged in a single layer with adequate spacing to prevent them from contacting each other.
2. An approved sterility assurance device (i.e. chemical indicator) should be placed inside and on each level of the tray in a location easily visible to the user.
3. Cover the tray with the lid and press down until the side tabs click shut, securing the lid.
4. Wrap the plastic tray with an approved non-woven textile wrap. Do not wrap more than one tray per wrap.
5. The tray should always be placed flat on the sterilizer rack prior to sterilization. Stacking of trays inside the sterilization chamber is not recommended.
6. Sterilize the loaded wrapped tray in accordance with the instrument device manufacturer's IFU.
7. After sterilization, move wrapped tray to a sterile storage area for storage or transport to the point of use location.
8. Return plastic tray to the sterile processing department after set has been used.
9. The plastic trays are reusable and should be cleaned and decontaminated prior to use according to the instructions below.

POINT OF USE CARE:

Clean plastic tray as soon as possible after use. If cleaning must be delayed, immerse in an enzymatic solution or water to prevent drying and encrustation of surgical soil. Remove excessive soil with a disposable wipe.

MANUAL CLEANING:

1. Pre-rinse under cold tap water for one (1) minute to remove gross debris
2. Soak for a minimum of two (2) minutes in a pH neutral detergent, prepared in accordance with the manufacturer's instructions for use.
3. Rinse under cold tap water for one (1) minute.
4. Ultrasonically clean for a minimum of five (5) minutes in a neutral pH detergent, prepared in accordance with the manufacturer's instructions for use.
5. Rinse under cold tap water for one (1) minute.

AUTOMATED CLEANING:

It may be necessary to manually clean prior to automated processing to improve the removal of adherent soil. Follow the previous instructions for manual cleaning.

1. Run the automatic wash cycle – minimum cycle parameters:
 - 1 minute cold pre-rinse
 - 5 minute enzyme wash at 43° C minimum temperature
 - 1 minute cold rinse
 - 7 minute dry at 90° C minimum temperature

CLEANING INSPECTION:

Visually inspect before sterilization or storage to ensure the complete removal of soil from surfaces. If soil is still present, re-clean the plastic tray.

STERILIZATION:

Follow the instructions for use of the sterilization packaging manufacturer, the enclosed device manufacturer and the sterilizer manufacturer.

The plastic tray has been validated for sterilization according to applicable international process standards and guidance for the following methods and parameters:


Cycle Type (Steam)	Temperature	Minimum Time – Full Cycle
Gravity	121° C (250° F)	30 minutes
Pre-Vacuum	132° C (270° F)	4 minutes
Pre-Vacuum	134° C (273° F)	3 minutes

STERRAD® System and Cycle within the United States	STERRAD® System and Cycle outside United States
STERRAD® 100S	STERRAD® 100 Short cycle
STERRAD® NX Standard cycle	
STERRAD®100NX Standard cycle	

It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

DISPOSAL:

Plastic sterilization trays have a life span and will require replacing if there are any signs of deterioration or loss of functionality. Dispose of product following facility policy for disposal.

 MANUFACTURER: KEY SURGICAL LLC
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 REF CATALOG NUMBER

 EC  REP

MDSS GMBH
SCHIFFGRABEN 41, D-30175 / HANNOVER, GERMANY



 LOT  LOT NUMBER

 CONSULT INSTRUCTIONS FOR USE

BROC-3095, Rev K, 2019