



Peel Pouch Sterilization Rack

INTENDED USE:

Key Surgical® Peel Pouch Sterilization Rack is a stainless-steel rack designed to keep peel pouches/packs on edge. The rack prevents over stacking to facilitate sterilant contact and aids in drying of pouches after steam sterilization.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

INSTRUCTIONS FOR USE:

1. Place pouched instruments one per slot into rack.
2. Sterilize using parameters outlined below.

PREPARATION:

Sterilization racks are reusable and must be cleaned using the following parameters:

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 according 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 sterilization rack.

STERILIZATION:

The peel pouch sterilization rack 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


100% Ethylene Oxide (EtO)	
Concentration	725 mg/L
Temperature	55° C
Exposure Time	60 minutes
Humidity	50-80%

STERRAD® System and Cycle within the United States	STERRAD® System and Cycle outside United States
STERRAD® 50	STERRAD® 50
STERRAD® 200	STERRAD® 200 Short cycle
STERRAD® 100S	STERRAD® 100S Short cycle
STERRAD® NX Advanced cycle	STERRAD® NX Advanced cycle
STERRAD® NX Standard cycle	STERRAD® NX Standard cycle
STERRAD® 100NX 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:

The peel pouch sterilization rack has 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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