



K-Wire & Steinmann Pin Dispenser

INTENDED USE:

Key Surgical® K-Wire and Steinmann Pin Dispensers are designed to hold non-threaded K-Wires and Steinmann Pins during the sterilization process and dispense the wires and pins during a surgical procedure. The dispensers are designed to protect the K-Wires and Steinmann Pins during storage, transportation, cleaning and sterilization.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

INSTRUCTIONS FOR USE:

1. Identify dispenser that will be used.
2. Place K-Wires and Steinmann Pins in dispenser based on size and quantity of wires and pins and wrap according to the sterilization wrap instructions or place in a sterilization pouch.
3. Dispensers should be sterilized according to the parameters detailed below. The perforations alleviate concerns of inadequate steam penetration of wires and pins during sterilization.
4. After sterilization, move dispenser to sterile storage area for storage or transport to point of use location.
5. To use wires and pins during a surgical procedure, turn knob at the bottom of the dispenser and wire or pin should easily dispense.
6. Return dispenser to sterile processing department after use for cleaning and reprocessing.
7. The dispensers are reusable and should be cleaned and decontaminated prior to reuse according to the instructions below.

POINT OF USE CARE:

Clean dispenser 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. Avoid prolonged exposure to saline to minimize the chance of corrosion. 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 dispenser.

STERILIZATION:

The K-Wire and Steinmann Pin Dispensers are provided non-sterile and have been validated for sterilization according to applicable international process standards and guidance for the following methods and parameters:

<i>Cycle Type (Steam)</i>	<i>Temperature</i>	<i>Minimum Time – Full Cycle</i>
Gravity	121° C (250° F)	30 minutes
Pre-Vacuum	132° C (270° F)	4 minutes
Immediate Use Pre-Vacuum	132° C (270° F)	3 minutes

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 K-Wire & Steinmann Pin Dispenser 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.



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