

K-Wire Rack (KI-71-RACK-46)

INTENDED USE:

Key Surgical® K-Wire Rack (KI-71-RACK-46) is designed to hold and protect K-Wires (4 to 6 inches in length) during washing, sterilization and storage and is able to serve as a table-top stand for dispensing during procedures. The K-Wire Rack is provided non-sterile.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

INSTRUCTIONS FOR USE:

1. Identify K-wires to be used.
2. Open rack top first and then open bottom of rack so that the etched pin diameters are facing upward from back of rack.
3. Place wires in rack with corresponding diameter etchings.
4. Wrap according to the sterilization wrap instructions or place within a sterilization pouch.
5. Rack should be sterilized according to the parameters detailed below.
6. After sterilization, move rack to sterile storage area for storage or transport to point of use location.
7. Return rack to sterile processing department after use for cleaning and reprocessing.
8. The rack is reusable and should be cleaned and decontaminated prior to reuse according to the instruction below.

POINT OF USE CARE:

Clean K-Wire Rack 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 K-Wire Rack.

STERILIZATION:

Validated for sterilization efficacy using the following cycle parameters:

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



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