

## Plastic Instruments

### INTENDED USE:

Key Surgical® Plastic Instruments are designed to secure wires, tubing, catheters, drapes and other accessories in both sterile and non-sterile environments.

### CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

### POINT OF USE CARE:

Clean plastic instruments 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 instrument.

### STERILIZATION:

The plastic instruments 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>
Pre-Vacuum	132° C (270° F)	4 minutes

The plastic instruments have not been validated for immediate-use steam sterilization (IUSS).

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 instruments 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

**LOT** LOT  
NUMBER