

INDICATIONS FOR USE

Surgical Instruments are designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, or suturing. Surgical Instruments may also be used to facilitate the insertion of surgical implants.

All reusable instruments are subject to care instructions supplied by Speedway, unless separate instructions are provided with the instruments.

WARNING

Instruments should not be used for anything other than their intended use. Speedway Instruments are supplied **non-sterile**, unless otherwise noted and must be cleaned, lubricated, and sterilized prior to use according to hospital protocol and procedures as required by country specific norms.

- Inappropriate use of instruments may result in patient injury, damaged or broken instruments.
- Proper cleaning, handling, sterilization, and standard routine maintenance (if applicable) will ensure that the instruments perform as intended and will extend their useful life. Delicate surgical instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilization.

PRECAUTIONS

Sterilize the instruments prior to use.

MANUFACTURING

Surgical Instruments are made from different metals or with special coating, therefore should be processed separately to avoid electrolytic action between the different metals. Before use, inspect the instruments for damage, wear and tear or any non-functioning parts. Carefully inspect the critical, inaccessible areas, joints, and all movable parts. Damaged or defective instruments should not be used or processed.

STERILIZATION PROCEDURES

- EN ISO 17665-1:2006, "Sterilization of Health Care Products - Moist Heat - Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices"
- AS/NZS 4187:2014, "Reprocessing of reusable medical devices in health service organizations"
- ANSI/AAMI ST79: 2017, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities."

We recommend the sterilization parameters listed below.

Phase	Time	Temperature
Pre-Wash	3 minutes	30°C (86°F)
Wash	10 minutes	40°C (104°F)
Wash	10 minutes	30°C (86°F)
Rinse	3 minutes	30°C (86°F)
Heated Rinse	15 minutes at 80° C (176°F) or 10 minutes at 90°C (196°F)	
Drying	BY Observation. Do not exceed 110°C (230°F)	

WASHING & CLEANING PROCEDURES

- Wash the instruments with distilled water and do not allow blood and/or bodily fluids to dry on the instruments.
- Remove gross contaminants with steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.
- Hard water should be avoided for rinsing.

PRECLEANING

- Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations.
- Instruments having more than one part or piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.
- Separate sharps and delicate surgical instruments.
- Avoid processing instruments of different metallic composition together.

RINSE:

- Rinse instruments thoroughly under warm distilled or demineralized water.

CLEANING PRECAUTIONS:

- If appropriate, disassemble surgical instruments prior to cleaning and sterilization. Do not soak instruments in hot water, alcohol, disinfectants, or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution. Do not use steel.
- Wool wire brushes, pipe cleaners or abrasive detergents to remove soil as these will damage the instrument and lead to corrosion.
- Micro surgical, plated and delicate instruments should be cleaned manually and should not be processed in an ultrasonic cleaner. Carefully protect the tips of delicate micro surgical instruments throughout the entire cleaning and sterilization process.
- Color anodized instruments may lose their color through the use of conventional, mechanical treatment processes.

RETURN / EXCHANGE POLICY:

- Contact Speedway or the local distributor for return policy.
- Return the product with proper identification and reason for return.

DISCLAIMER OF LIABILITY:

Speedway, accepts no liability for the choice or use of its instruments.