



INDICATIONS FOR USE

GEN2 Medical™ surgical instruments are designed to perform specific functions and should be used only for the purpose for which they are intended. Proper surgical technique for the use of instruments is the responsibility of the surgeon.

CONTRAINDICATIONS

Instruments should not be used for any purpose other than their intended use.

WARNING

Consult national infection control/prevention protocols for specific guidance regarding processing medical devices with suspected exposure to Creutzfeldt-Jakob Disease (CJD).

CAUTION

Federal (or United States) law restricts these devices to sale by or on the order of a physician.

Ultrasonic cleaning and repeated use can lead to screws loosening on certain types of instruments, like Kerrison rongeurs. All instruments with screws should be checked for tightness prior to being used in surgery.

All instruments are carefully inspected before shipment. Damage can occur during shipment, and all instruments should be inspected upon receipt and prior to usage.

STERILIZATION AND DECONTAMINATION

All Gen2 instruments are supplied clean but NON STERILE and must be cleaned and sterilized prior to surgery. AORN recommended practices for in hospital sterilization should be followed.

Personnel should follow accepted decontamination guidelines for hand washing and the use of protective attire, etc., as recommended by A.A.M.I. Standards and Recommended Practice, "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Non-Clinical Settings", ANSI/AAMI ST35:2003.

After following the decontamination recommendations, reusable instruments are ready for sterilization. Independent laboratory testing, conducted according to F.D.A. (21 CFR PART 58) and

Good Laboratory Practice Regulations (G.L.P.), has validated steam sterilization as an effective process for reusable instruments. See also, AAMI Standards and Recommended Practices, "Steam Sterilization and Sterility Assurance in Health Care Facilities", ANSI/AAMI ST46:2002; "Flash Sterilization Steam Sterilization of Patient Care Items for Immediate Use", ANSI/AAMI ST37:3ed. AAMI standards recommend that the sterilizer manufacturer's written instructions for cycle parameters should also be followed. Steam sterilization of lumened instruments requires that they be flushed with sterile water just prior to wrapping and sterilization. The water generates steam within the lumen to move air out. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but must never be shorter.

Below are the recommended sterilization parameters:

Sterilizer	Exposure Temperature	Exposure Time	Minimum Dry Time
Pre-vacuum (wrapped)	121° C (250° F)	20 min	20 min
	132° C (270° F)	4 min	20 min
	134° C (273° F)	3 min	15 min
Pre-vacuum (unwrapped)	132° C (270° F)	4 min	
Gravity Steam (wrapped)	132° C (270° F)	18 min	

RETURNED GOODS POLICY

Surgix will accept products for return that are new and in unused condition for 90 days from the date of invoice. The following items are non-returnable, except for defective products or products associated with product complaints.

- Product over 90 days from invoice date
- Sterile product or implants, which have been opened or expired
- Custom or Special order products
- Any product that has been sterilized or used

REPAIRS AND MAINTENANCE

Instruments requiring repair or maintenance can be returned to Gen2 Medical for repair. A statement certifying that each instrument has been thoroughly cleaned and sterilized is required.

WARRANTY

All Gen2 products are guaranteed to be free of defects in workmanship and materials when used properly for their intended surgical purpose. Any product proving to be defective will be replaced or repaired, at Gen2's discretion, at no charge to the customer.



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Made in Germany

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GLOSSARY

	Product has not been sterilized
	Consult instructions for use
	Unique Device Identifier
	Product Manufacturer
	Reference/Reorder Number
	Lot Number
	Quantity
	Use by trained Medical Personal