Kent Surgical Industries L.L.C Plot No.12, 54th Street, Companies Camp, Al Ain, Abu Dhabi, United Arab Emirates	This IFU Cover The following products: From REF: 2-xxx-xx - 70-xxx-xx	Ph.: +971 3 753 2555 Email:support@kentsurgical.com Website: www.kentsurgical.com

Symbols Using in Labeling:

Symbol	Symbol Title	Description of symbol
	**Catalogue number**	Indicates the manufacturer's catalogue number.
	**Consult instructions for use.**	Indicates the need for the user to consult the instructions for use.
	**Date of manufacture**	Indicates the date when the medical device was manufactured.
	**Do not use if package is damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.
	**Caution**	Indicates that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	**Manufacturer**	Indicates the medical device manufacturer.
	**Batch code**	Indicates the manufacturer's batch code.
	**Non-sterile**	Indicates a medical device that has not been subjected to a sterilization process.
	**Use-by date**	Indicates the date after which the medical device is not to be used.
	**Keep dry**	Indicates a medical device that needs to be protected from moisture.

	**Keep away from sunlight**	Indicates a medical device that needs protection from sunlight.

The following recommendations are for the processing of Kent Surgical®:

- Reusable Stainless Steel surgical instruments, trays, and cases.

Kent Surgical® instruments must be cleaned and sterilized before initial use for reusable surgical instruments, trays, and cases. Immediately upon receipt, the goods must be verified as complete and correct.

Please follow the validated hospital processing procedure (handling, cleaning, disinfecting, sterilization) for the Kent Surgical® instrument.

General Safety Information:

- Read and follow these instructions for use and keep them accessible to the staff working with the device.
- If this product is used on a patient with Creutzfeldt-Jakob Disease (CJD) or even if CJD is only suspected, the product must not be re-used and must be destroyed.
- The instruments should be used and sterilized ONLY by trained and qualified personnel.
- All instruments must be cleaned, disinfected, and sterilized each time they are used; this also applies particularly to the first time they are used after delivery, as all instruments are supplied unsterile (All new instruments have to be washed at least three times before they can be included in the instrument cycle).
- Effective cleaning and disinfection are an indispensable prerequisite for effective sterilization.
- When using instruments, please ensure that, as part of your responsibility for the sterility of instruments, only methods for cleaning/disinfection and sterilization, which have been adequately validated for the equipment and products, are implemented, that the equipment used (disinfector, sterilizer) is regularly maintained and tested, and that the validated parameters are maintained for each cycle.
- All Instruments supplied by Kent Surgical® are Latex Free including their packaging.

- Please observe the legal regulations applicable in your country as well as the hygiene regulations of the medical practice or hospital.
- All devices must be thoroughly cleaned.
- The sterilization parameters are only valid for devices that are adequately cleaned.
- The products must be used exclusively for the intended purpose by appropriately trained and qualified personnel.
- Application period: Temporary (< 60 min. under normal conditions) according to Directive 93/42/EEC.
- Intricate parts with blind holes or long, narrow cannulation require particular attention during cleaning.
- The following information is only valid for properly installed, maintained, calibrated, and compliant reprocessing equipment.

Warning:

- Do not use steel wool, wire brushes, or abrasive cleaners.
- Avoid solutions containing bleach or corrosive cleaners. Only place Kent Surgical® instruments with similar metallic composition together in an ultrasonic cleaner.
- Possible danger to the life of patient, user, and third parties if these Instructions for Use are not observed.
- Possible danger to the life of others by shipping contaminated products.
- In case of return shipments, send only clean and disinfected products in sterile packaging.
- Non-sterile handling can result in danger to the life of the patient. Products supplied in non-sterile condition must be cleaned, disinfected, and sterilized before the first application.

Limits On Reprocessing:

- Repeated processing cycles that include ultrasonic, mechanical washing, and sterilization have minimal effect on **Kent Surgical®** reusable instruments.
- **Kent Surgical®** recommends the use of neutral pH detergents.
- Other detergents must be qualified to be compatible with surgical instruments and trays.

- The use of the instrument for tasks other than those for which it is intended may result in serious damage or failure of the instrument resulting in risk to the patient, and/ or user's health.
- Rongeurs, bone-cutting forceps, osteotomes, and chisels should never be used to cut wire or pin.
- For reusable devices, end of life is normally determined by wear and damage due to use.
- Laser-marked products can fade with phosphoric acid and nitric acid cleaners on treatment. Thus, the marking may be impaired or lost.

Processing Instructions:

- **Point of use Care:**
  - The devices should be covered with a towel dampened with purified water to prevent blood and or debris from drying. Wipe blood and/or debris from the device throughout the surgical procedure to prevent it from drying onto the surface.
  - Wherever possible, do not allow blood, surgical debris, or bodily fluids to dry on the instruments.
  - For best results and to maximize their service life reprocess instruments immediately after use.
  - If transfer to reprocessing is likely to take time, consider covering the instruments with a damp cloth or use an enzymatic foam spray cleaner to help prevent soil from drying.
  - Do not leave instruments soaking in saline or chlorinated solutions.
  - Because of the corrosion risk, long intervals between instrument use and processing for reuse (e.g. overnight or over the weekend) should be avoided, irrespective of the disposal method used (e.g. wet or dry).
  - Avoid mechanical damage during transportation to the processing area (e.g. do not mix heavy devices with delicate items).
  - Pay particular attention to cutting edges to avoid injury and damage to or by the instrument.
  - Separate sharp and delicate surgical instruments.
  - Keep ebonized instruments separate from other stainless-steel instruments to avoid damaging the ebonized coated. ceramic-coated, and Insulated Instruments.

- Keep ceramic-coated instruments separate from other stainless-steel instruments to avoid damaging the ceramic-coated. Insulated Instruments.
- Keep Insulated Instruments separate from other stainless-steel instruments to avoid damaging the Insulated Instruments.

- **Preparation for decontamination:**
  - Reprocess all instruments as soon as is reasonably practicable after use.
  - Open devices with ratchets, box locks, or hinges.
  - Disassemble the device if the device is intended to be disassembled without the use of tools (unless these are specifically provided) to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.
- **Automated Cleaning:**
  Whenever possible automated cleaning methods should be used in preference to manual methods to provide a more consistent and reliable process and, reduce staff exposure to contaminated devices and the cleaning agents used.

Equipment:

- Ultrasonic cleaner.
- FDA/CE-cleared washer.
- Sterile syringes, pipettes, and/or water jets.
- Enzymatic cleaner & neutral detergent.
- Clean lint-free cloths & filtered pressurized air.

Specific Alert for Ultrasonic:

Ultrasonic cleaning may cause further damage to devices that have prior surface damage.

Screws can loosen and back out of an instrument as a result of normal operation and/ or vibration during ultrasonic cleaning.

1. Disassemble devices, if applicable or required.
2. Rinse the devices under cool running tap water for a minimum of 1 minute to remove gross soil. While rinsing, use a clean, brush to aid in the removal of gross soil.
3. Prepare an enzymatic cleaner, such as **Deconex Powerzyme®**, per the manufacturer's recommendations at 5 ml/Liter using 45˚c tap water.
4. Fully immerse the devices in the prepared solution. Allow devices to soak for a minimum of 2 minutes.
5. While the devices are fully immersed, use a soft-bristled brush and/or lumen brush to remove all visible soil from the surface of the devices. Actuate all movable device features

through their full range of motion to ensure all areas of the devices are exposed to the detergent solution.

6. Remove the devices from the solution and rinse under cool running tap water for a minimum of 1 minute.
    - While rinsing, use an appropriately sized syringe to flush lumens, channels, and all hard-to-reach areas.
    - Actuate all movable device features through their full range of motion to ensure all areas are thoroughly rinsed.
7. Prepare a neutral detergent, per the manufacturer's recommendations using lukewarm tap water in an ultrasonic cleaner.
8. Fully immerse the devices in the ultrasonic cleaner and sonicate for 15 minutes.
9. Transfer the disassembled devices into the washer for processing. The following parameters were validated using an FDA-cleared washer:

Phase	Minimum Time (minutes)	Minimum Temperature/Water	Detergent Type and Concentration
Pre-Cleaning	02:00	Cold tap water	N/A
Wash	05:00	45˚c water	Deconex Powerzyme 5 ml/L
Post-Rinse	02:00	Warm tap water	N/A
Thermal Disinfection	05:00	93°C with DI/RO Water	N/A
Drying	10:00	90°C	N/A

10. Remove devices from the washer.
11. Dry the devices using a clean lint-free cloth.
12. Visually inspect each device.
13. Repeat the cleaning process if visible soil remains.
14. Should the user deviate from the specified procedure, the chosen procedure must be validated by the user.

- **Drying:**

If a dry cycle is not included in the mechanical washer or if the device is not processed in a mechanical washer:

- Dry each device thoroughly inside and outside to prevent rust and malfunction.
- Use a clean, soft, lint-free cloth to avoid damage to the surface.
- Pay special attention to threads, ratchets, and hinges or areas where fluid can accumulate.
- Open and close devices so that all areas are reached.
- Dry hollow parts using filtered pressurized air.

- **Manual Cleaning Method:**

Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process:

Equipment:

- Soft-bristled brushes, and lumen brushes.
- Sterile syringes, pipettes, and/or water jets.
- Enzymatic cleaner & neutral detergent.
- Clean lint-free cloths & filtered pressurized air.

1. Disassemble devices, if applicable or required.
2. Rinse the devices under cool running tap water for a minimum of 2 minutes to remove gross soil. While rinsing, use a soft-bristled brush and/or lumen brush to aid in the removal of gross soil.
3. Prepare an enzymatic cleaner, such as **Deconex Powerzyme®**, per the manufacturer's recommendations at 5 ml/Liter using 45˚c tap water.
4. Fully immerse the devices in the prepared solution. Allow devices to soak for a minimum of 10 minutes.
5. Remove the devices from the solution and rinse under cool running tap water for a minimum of 2 minutes.
    - While rinsing, use an appropriately sized syringe to flush lumens, channels, and all hard-to-reach areas.
    - Actuate all movable device features through their full range of motion to ensure all areas are thoroughly rinsed.
6. Fully immerse the devices in the detergent solution. Thoroughly brush the devices for a minimum of 5 minutes using a soft-bristled brush and/or lumen brush to remove all visible soil from the surface of the devices. Ensure to thoroughly brush all lumens, channels, and hard-to-reach areas.

- Actuate all movable device features through their full range of motion to ensure all areas of the devices are exposed to the detergent solution.

7. Thoroughly rinse the devices using reverse osmosis/deionized (RO/DI) water for a minimum of 2 minutes.
   - While rinsing, use an appropriately sized syringe to flush lumens channels and all hard-to-reach areas.
   - Actuate all movable device features through their full range of motion to ensure all areas are thoroughly rinsed.
8. Perform a final rinse on devices using RO/DI water.
9. Dry devices using a clean, soft, lint-free cloth & filtered pressurized air.
10. Visually inspect devices.
11. Repeat the cleaning process if visible soil remains.

- **Lubricate:**

The use of an instrument lubricant, that is compatible with the method of sterilization to be used, is recommended before instruments are sterilized. Be certain that the instrument lubricant is diluted and maintained properly, according to the manufacturer's instructions.

- **Inspection and Functional Check:**

Kent Surgical® instruments must be inspected after processing and before sterilization to ensure proper function.

Further use is confirmed by the successful inspection of the product.

1. Do not use products, which are damaged, incomplete, or show loose parts.
2. Remove for repair or replacement any blunt, worn out, flaking, fractured, or damaged instruments.
3. Do not intend to repair by yourself (3rd party repair may void warranty).
4. Check all instruments for damage, wear staining, and corrosion; cutting edges are free from nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanism (such as ratchets) fasten securely and close easily; long, slender instruments are not distorted.
5. Close instruments with a ratchet lock in the first ratchet position only before sterilization to avoid the risk of thermally-induced stress cracks in the joints.
6. For the device that may be impacted check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves.
7. The operator is responsible for checking the functionality and identifying any damage to the instrument before releasing it to the patient.

- **Packing:**

We recommend that instruments be packed in single-use sterilized packaging and/or sterilization containers; They must comply with the legal requirements as follows:

  - Comply with EN ISO 11607 / EN 868.
  - Be suitable for sterilization.
  - Provide adequate protection against mechanical shocks for the instrument and sterilization packaging.

- **Sterilization:**

General Information:

  - Ensure instruments are dry before sterilization.
  - Sterilization cases should be loaded just before the sterilization step.
  - When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer manufacturer's stated maximum load is not exceeded.
  - Use CE-marked, validated vacuum autoclave with a Dynamic Air Removal cycle operating at least 134 – 137C for a minimum holding time of 3.5 minutes and a minimum drying time of 10 minutes at least.
  - Dry times may be highly variable due to the differences in packaging materials (e.g. non-woven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance, and varying cool-down time.
  - The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

The following instructions are recommended for sterile products:

  - Sterile instruments must be stored in their original packaging in a place suitable for storing sterile supplies and may be removed from their packaging only immediately before use. Before use, check the packaging for use-by date and damage.
  - If the expiration date is exceeded or the packaging is defective, do not use the product. Never reuse damaged and contaminated instruments.
  - If the end user chooses to reprocess the opened product originally provided in sterile packaging, we recommend the validated steam sterilization parameters as stated above.
  - For non-sterile products: The product must be sterilized and inspected for damage before use.
  - It remains the responsibility of the processor to ensure that the processing, as 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.

- **Additional Information:**

The cleaning and sterilization information is provided following ANSI/AAMI ST81, ISO 17664, AAMI TIR30, AAMI TIR12, and ANSI/AAMI ST79.

  - The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile **Kent Surgical®** medical device. It remains the responsibility of the processor and/or hospital to ensure that the processing is performed when using equipment, materials, and personnel in the reprocessing facility to achieve the desired result.
  - This requires validations and routine monitoring of the process.
  - Likewise, any deviation by the processor and/or hospital from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.
  - All users should be qualified personnel with documented expertise, competency, and training.
  - Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.
  - Users must wear appropriate personal protective equipment (PPE) when processing devices.

- **Storing:**

To guarantee instrument sterility up to the time of use on the patient, germ-tight packaging is essential.

Furthermore, the sterilized instruments should be stored in dry, clean, dust-free and protected from direct sunlight conditions at moderate temperatures of 5° C to 40° C. Transportation and storage should not adversely affect the features of the reprocessed medical device.

Maintenance and Repair:

Instruments returned to **Kent Surgical®** for repair must be decontaminated, sterilized, and accompanied by the relevant documented evidence.

Failure to supply decontamination/sterilization certification will result in products being returned untouched for re-processing and delayed repairs.

Repairs carried out by **Kent Surgical®** are guaranteed for 6 months to be free of defects in workmanship and parts used to affect the repair when used normally for their intended surgical purpose.

Any workmanship or parts proving to be defective will be replaced or repaired, at our discretion, at no charge to the customer.

Returned Goods Policy:

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by **Kent Surgical®**. Products will not be accepted for replacement if they have been in the possession of the customer for more than 30 days.

Information for validation of reprocessing:

The following testing instructions, materials, and machines were used in the validation:

Cleaning agents pre-cleaning: N/A

Cleaning agents automatic-cleaning: **Deconex Powerzyme®**

Cleaning/disinfecting unit: Belimed WD200.

Additional instructions:

If the above-described chemicals and machines are not available, the user is responsible to validate the relevant procedure.

It is the liability of the user to assure, that the reprocessing treatment resources, materials, and personnel are suitable to achieve the required results.

The state of the technology and national laws require, that the validated processes will be observed.

Disposal:

For disposal, country-specific laws and regulations must be observed.

Guarantee:

We grant you, in case of production and quality faults a full warranty guarantee. For obvious faults, which are caused by errors in the production or use of imperfect materials, the products will be

revised or replaced free of charge. In case of damages or incorrect handling such as mechanical action, fall, overloading, etc. the warranty is excluded. For repairs by unauthorized persons warranty claim will expire.