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: Instrument Stringers with Push-to-open Mechanism (PS), Instrument Stringers with Pull-to-open Mechanism (PL), Instrument Stringers with U-Shaped open Mechanism (US).	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.

Intend of use for Instruments Stringers of Kent Surgical®:

- Instruments Stringer used to expand the instruments for more effective cleaning of hard-to-reach areas containing bioburden, and can also be adjusted to the optimal width for placement of instruments inside a tray.

Product Specification:

- Stainless Steel as per ASTM F-899-20 & ISO 7153-1:2016

General Safety Information:

- Read and follow these instructions 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 or destroyed.
- The Stringers should be used and sterilized by trained and qualified personnel.
- All Stringers 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 stringers are supplied unsterile.
- Effective cleaning and disinfection are an indispensable prerequisite for effective sterilization.
- When using Stringers, 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 (washer-disinfector, sterilizer) is regularly maintained and tested, and that the validated parameters are maintained for each cycle.

- Please observe the legal regulations applicable in your country and the hygiene regulations of the medical practice or hospital.
- 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.
- Visually inspect the stringers before use.
- 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®** Stringers 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®** Stringers.
- **Kent Surgical®** recommends the use of neutral pH detergents.
- Other detergents must be qualified to be compatible with Stringers.
- For Stringers, the 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.

Preparation:

- Stringers are reusable and must be cleaned and disinfected before initial use and subsequent reuse.

Instructions For Use:

A. For Instrument Stringers with U-Shaped open Mechanism (US):

1. String ring-handled instruments in set assembly order onto the stringer by placing one ring on each of the stringer arms. Continue until all instruments are loaded onto the stringer.

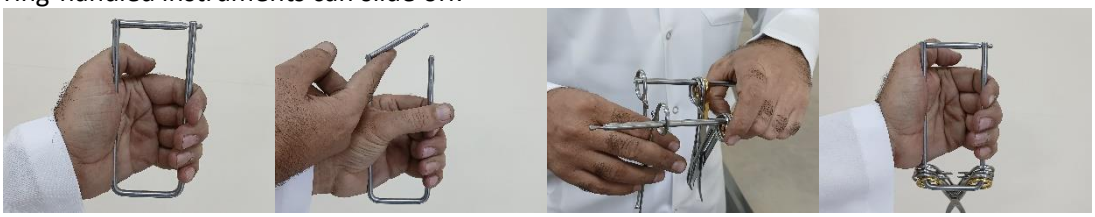
B. Instrument Stringers with Pull-to-open Mechanism (PL):

1. Pull the stringer to the wide position by using both hands.
2. Use your index finger to open the lock.
3. String ring-handled instruments in set assembly order onto the stringer by placing one ring on each of the stringer arms. Continue until all instruments are loaded onto the stringer.
4. Pull the stringer to the wide position by using both hands.
5. Put the lock end inside the hole (Lock Position) to prevent instruments from sliding off.
6. Remove instruments from the stringer by reopening the locks to the straight position so that ring-handled instruments can slide off.

C. Instrument Stringers with Push-to-open Mechanism (PS):

1. Push the stringer to the narrow position by using your hand.
2. Use the other hand to open the lock.

3. String ring-handled instruments in set assembly order onto the stringer by placing one ring on each of the stringer arms. Continue until all instruments are loaded onto the stringer.
4. Push the stringer to the narrow position by using your hand.
5. Put the lock end inside the Lock Position to prevent instruments from sliding off.
6. Remove instruments from the stringer by reopening the locks to the straight position so that ring-handled instruments can slide off.



Manual Cleaning:

1. Pre-rinse under cold tap water for one minute to remove gross debris
2. Soak for a minimum of two minutes in a pH-neutral detergent.
3. Rinse under cold tap water for one minute.
4. Ultrasonically clean for a minimum of five minutes in a neutral pH detergent.
5. Rinse under cold tap water for one minute.

Automatic Cleaning:

It may be necessary to manually clean before automated processing to improve the removal of adhesive 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 (109° F) minimum temperature
- 2-minute cold rinse
- 7-minute dry at 90° C (194° F) minimum temperature

2. Visually inspect to ensure complete removal of soil from surfaces. No visible soil should be observed.
3. If soil is still visible, repeat the above steps until free from visible soil.

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 basket.

Sterilization:

- The stringer has been validated for sterilization efficacy according to applicable international process standards and guidance for the following methods and parameters:

Steam Sterilization			
Cycle Type	Temperature	Minimum holding time	minimum drying time
Pre-Vacuum	(134) ° C	3.5 minutes	10 minutes

- 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.

100% Ethylene Oxide (EtO)	
Concentration	725 mg/L
Temperature	55° C
Exposure Time	60 minutes
Humidity	50-80%
STERRAD® System and Cycle	
STERRAD® 100S/100S Short STERRAD® NX Standard STERRAD® 100NX Standard/Express/DUO/Flex	
STERIZONE® System	STERIZONE® VP4
MMM Hyper (TS-CSD System)	
Easy	

Classic Complex

- 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.

Maintenance:

1. Store away from direct Sunlight and direct sources of water.
2. Inspection before each use.
3. If there are any signs of rusting on the stringer, the stringer needs to be treated with a descaler.

Disposal:

- Stringers have a life span and will require replacing if there are any signs of deterioration or loss of functionality
- For disposal, country-specific laws and regulations must be observed.