STERIS

Instrument Management Services

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Semi-Detachable Kerrison Rongeur - Washing, Decontamination & Sterilizing instructions – INS009 iss 004

Intended Use and features

The Semi-Detachable Kerrison Rongeur is indicated for use by suitably trained, medical professionals for cutting or biting bone during surgery. The Semi-Detachable Kerrison Rongeur differs from other Kerrison Rongeurs in that it has the ability to be partially opened which provides the advantage of efficient cleaning and decontamination between uses and prior to sterilisation of the whole instrument compared to a non-detachable version.

Product characteristics

The Semi-Detachable Kerrison Rongeur is available with bite sizes between 1 and 5mm in 45 degree or 90 degree upward cutting versions. They have a working length of 180mm, 200mm or 210mm and have either a reflection reducing or black finish.

Item #	Product Description
PH654950 to PH654954	Semi-Detachable Kerrison Rongeur Upper Cut / 180mm - 45 Degree 1mm to 5 mm
PH654955 to PH654959	Semi-Detachable Kerrison Rongeur Upper Cut / 180mm - 90 Degree 1mm to 5mm
PH654960 to PH654964	Semi-Detachable Kerrison Rongeur Upper Cut / 200mm - 45 Degree 1mm to 5mm
PH654965 to PH654969	Semi-Detachable Kerrison Rongeur Upper Cut / 200mm- 90 Degree 1mm to 5mm
PH654970 to PH654974	Semi-Detachable Kerrison Rongeur Upper Cut / 210mm - 45 Degree 1mm to 5mm
PH654975 to PH654979	Semi-Detachable Kerrison Rongeur Upper Cut / 210mm - 90 Degree 1mm to 5mm
PH654980 to PH654984	Semi-Detachable Kerrison Rongeur Upper Cut / 180mm - 45 Degree / Black / 1mm to 5mm
PH654985 to PH654989	Semi-Detachable Kerrison Rongeur Upper Cut / 180mm - 90 Degree / Black / 1mm to 5mm
PH654990 to PH654994	Semi-Detachable Kerrison Rongeur Upper Cut / 200mm - 45 Degree / Black / 1mm to 5mm
PH654995 to PH654999	Semi-Detachable Kerrison Rongeur Upper Cut / 210mm - 45 Degree / Black / 1mm to 5mm
PH655000 to PH655004	Semi-Detachable Kerrison Rongeur Upper Cut / 200mm - 90 Degree / Black / 1mm to 5mm
PH655005 to PH655009	Semi-Detachable Kerrison Rongeur Upper Cut / 210mm - 90 Degree / Black / 1mm to 5mm

⚠ Correct bite size selection based on the surgical discipline is of utmost importance to prevent overloading which could cause damage to the instrument.

⚠ Device proper functionality including assurance of full assembly shall be verified prior to each use.
The lifetime of the Semi-Detachable Kerrison Rongeur is determined by proper functionality and careful care during use. End of lifetime is determined by wear and damage due to use. Improper functioning, damaged or excessively worn Semi-Detachable Kerrison Rongeur should not be used.

⚠ Contra-Indications

The Semi-Detachable Kerrison Rongeur is contra-indicated for use in contact with the heart, central circulatory system and central nervous system.

Cleaning & User Instructions

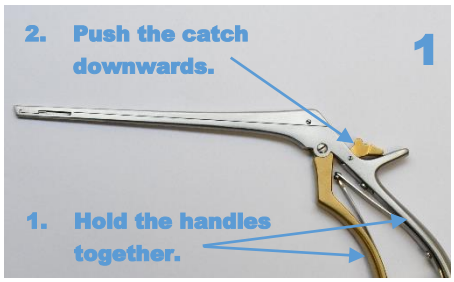
⚠ This device is supplied NON-STERILE: To be sterilized before use. The device can be damaged due to inappropriate cleaning, disinfection and/or sterilization.
Physical removal of gross debris and bioburden, through soaking and wiping of instrumentation with water should be initiated immediately after the procedure, at the point of use. In order to keep instrumentation moist while preventing organic soils from drying prior to washing and decontamination, spray the instrument with enzymatic solution.

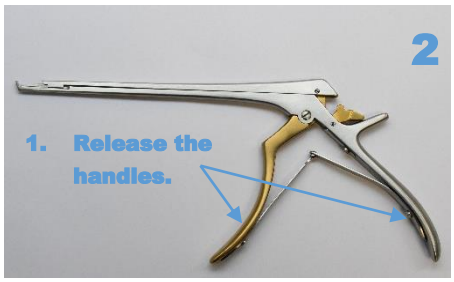
⚠ Care should be taken during use to avoid twisting / turning or levering motions which could lead to damage of the instrument.

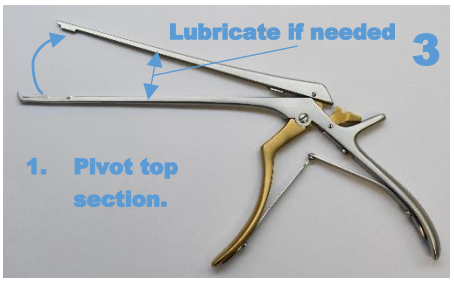
⚠ Using the Semi-Detachable Kerrison Rongeur to cut material other than as defined in this instruction could lead to damage of the instrument.

Disassembly and Assembly Instructions

- **Disassembly for washing and decontamination**

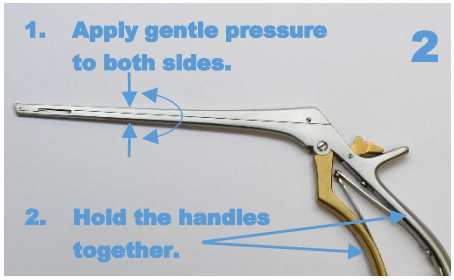


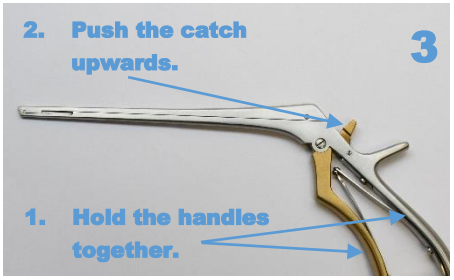


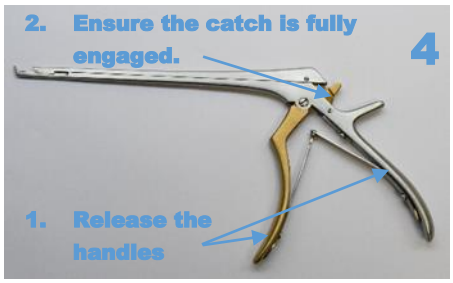


1. Whilst gently holding the handles fully together, push the catch downwards.
2. Release the handles slowly and fully.
3. The top section of the instrument can now be pivoted upwards to allow for effective cleaning.

- **Assembly prior to sterilization.**



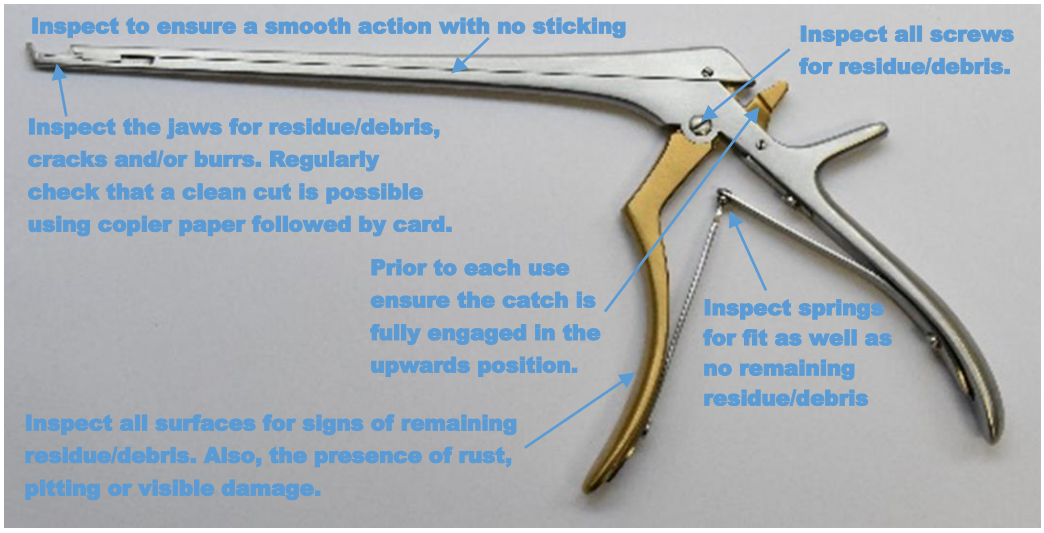




1. With the handles released, close and realign the top section.
2. Whilst applying gentle pressure to the top and bottom halves of the instrument press the handles together ensuring that the jaws are free of any obstructions.
3. Whilst gently holding the handles fully together, push the catch upwards.
4. Gently release the handles. Ensure the catch is fully engaged in the upwards position.
5. The instrument should be checked for smooth operation. If the instrument is found to stick it must be disassembled and a small amount of lubrication added to the sliding surfaces (see disassembly step 3). Lubrication used must be water soluble medical instrument lubricant which is compatible with steam sterilization and meets all local and national guidelines.
6. After step #5 is completed the instrument should be re-assembled, and any excess lubricant removed. The instrument is now ready for sterilization.

Instrument Inspection

Regular inspection of the Semi-Detachable Kerrison Rongeur will ensure it is always in the best condition and ready for use. Carefully inspect the critical, inaccessible areas, joints and all movable parts. Please follow the inspection points as follows:



⚠ **If rust, pitting or visible damage is observed the instrument must be removed from service immediately.**

Washing, Decontamination & Sterilizing instructions

The Decontamination Process is dependent on effective cleaning and washing of instruments by staff appropriately trained to your local procedures for the process. Severe soiling should be removed under running water in a sink draining continually, using brushes and rigid nylon bristles. Attention should be paid to any areas where debris may enter. Staff carrying out decontamination and washing process should operate according to local policy and procedures.

Following manual cleaning the instrument should be washed in a washer-disinfector meeting the requirements of the ISO 15883 series, using a detergent (typically 7-10PH), and incorporating a thermal disinfection cycle (minimum 90^{o}C for 1 minute) using high purity RO water. These instruments should be presented open for the washer, disinfection process.

⚠ Prior to each sterilization, the instrument operation must be checked as it may require lubrication. Lubrication used must be water soluble medical instrument lubricant which is compatible with steam sterilization and meets all local and national guidelines.

The surgical instruments must be sterilized prior to use using high temperature steam. The instrument must be sterilized using validated equipment meeting the requirements of the ISO 17665 series and processed in accordance with national standards and guidelines. The standard parameters of 134-137 degrees centigrade for 3 – 3 ½ minutes are appropriate. A vacuum assisted air removal phase prior to steam admission for sterilisation is recommended.

The parameters above have been validated as appropriate and are effective for the instruments provided with these instructions.

Packaging materials used should conform to EN ISO 11607 or the relevant parts of EN 868-7

For further information, related to the use of these instruments, please contact your STERIS Instrument Management Services Limited representative.

⚠ These instruments must be disassembled in order to be washed, cleaned and decontaminated effectively.

Return of instruments

Before returning any instrument to STERIS Instrument Management Services Limited, please ensure that washing and sterilizing has been carried out in accordance with national standards and guidelines. All equipment used must have a validated cycle. The reference numbers should be entered onto the decontamination certificate.

Damaged Instruments

If any instruments have been damaged or are found to be below your standard of expectation, please supply details so that we may investigate and rectify the situation.

Serious Incidents
Serious incidents that have occurred in relation to this medical device should be reported to a STERIS Instrument Management Services representative and competent authority in the country where the incident occurred.

Disposal after use
The device is made from metal. The device itself does not require special disposal instructions. The device should be cleaned and disinfected to remove any possibility of infection. When disposing of or recycling this device, and its packaging, please follow all national regulations and standards.

Repair Service
STERIS Instrument Management Services are able to offer a repair service for your Semi-Detachable Kerrison Rongeurs. This will ensure your instruments continue to meet all manufacturer specifications. Please contact your STERIS Instrument Management Services representative for details.

Glossary
Please refer to the table below for definitions of the symbols used within the labelling.

Symbol	Meaning
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date when the medical device was manufactured.
	Indicates the medical device manufacturer
	Indicates the authorized representative in the European Community
	Indicates the medical device CE marking.
	Indicates a medical device that has not been subjected to a sterilization process.
	Indicates a medical device that needs protection from light sources.
	Indicates a medical device that needs to be protected from moisture.
	Indicates the need for the user to consult the instructions for use.
	Indicates the need for the user to consult the instructions for use for important cautionary information
	Indicates a Medical Device
	Indicates Unique Device Identifier