

Be sure to read this instruction manual before using this product.
Keep this manual available for reference when needed.

Instruction for Use

Trade Name: Kerrison Rongeur

Warning

Please read these instructions carefully prior to using this product. Product should be used according to these instructions and pay close attention to the safety of patients. Failure to follow manufacturer's recommendations may cause harm or injury to patient.

For the US market

Do not reuse the device when it is used on a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD) or variant CJD (vCJD).

For markets outside the US

When the device is used on a patient with, or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse. Be cautious of the possibility of secondary infection. Refer to www.a-k-i.org or AAMI Standard ST79 for more information related to cleaning and sterilization.

Contraindication/Prohibition

1. Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
3. Prohibition of secondary processing of this product
Do not apply any secondary processing to this product, for example, do not apply impacts or vibration markings to the surface of this product. Doing so could break this product.
4. Handle with care
Handle this product with care, as it can be deformed or damaged. Rough handling could significantly reduce the service life of tools and appliances.
5. Prohibition of use of polishing powder and wire wool
When cleaning this product, do not attempt to polish its surfaces with rough polishing powder or wire wool. This could cause scratches on the surfaces of this product and result in rust or corrosion.
6. Prohibition of use of household detergents
Use only medical detergents to clean this product. Do not use any household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.
7. Do not use low temperature hydrogen peroxide gas plasma sterilization.
This product is not suitable for sterilization with hydrogen peroxide low temperature gas plasma. It may discolor the surface of the product or affect the feature of the product.

Code No.	Product Description
02-095-41	Tri-D Kerrison Rongeur 150 x 1 mm, 35 deg, Upward
02-095-42	Tri-D Kerrison Rongeur 150 x 2 mm, 35 deg, Upward
02-095-43	Tri-D Kerrison Rongeur 150 x 3 mm, 35 deg, Upward
02-095-44	Tri-D Kerrison Rongeur 150 x 4 mm, 35 deg, Upward
02-095-45	Tri-D Kerrison Rongeur 150 x 5 mm, 35 deg, Upward
02-095-46	Tri-D Kerrison Rongeur 150 x 6 mm, 35 deg, Upward
02-095-47	Tri-D Kerrison Rongeur 150 x 7 mm, 35 deg, Upward
02-095-48	Tri-D Kerrison Rongeur 150 x 8 mm, 35 deg, Upward
02-095-51	Tri-D Kerrison Rongeur 200 x 1 mm, 35 deg, Upward
02-095-52	Tri-D Kerrison Rongeur 200 x 2 mm, 35 deg, Upward
02-095-53	Tri-D Kerrison Rongeur 200 x 3 mm, 35 deg, Upward
02-095-54	Tri-D Kerrison Rongeur 200 x 4 mm, 35 deg, Upward
02-095-55	Tri-D Kerrison Rongeur 200 x 5 mm, 35 deg, Upward
02-095-56	Tri-D Kerrison Rongeur 200 x 6 mm, 35 deg, Upward
02-095-62	Tri-D Kerrison Rongeur 150 x 2 mm, Cvd, 35 deg, Upward
02-095-63	Tri-D Kerrison Rongeur 150 x 3 mm, Cvd, 35 deg, Upward
02-095-64	Tri-D Kerrison Rongeur 150 x 4 mm, Cvd, 35 deg, Upward
02-095-72	Tri-D Kerrison Rongeur 200 x 2 mm, Cvd, 35 deg, Upward
02-095-73	Tri-D Kerrison Rongeur 200 x 3 mm, Cvd, 35 deg, Upward
02-095-74	Tri-D Kerrison Rongeur 200 x 4 mm, Cvd, 35 deg, Upward

Material: Stainless steel

Intended purpose

This product is a surgical device that is used to remove cartilage or bone tissue. Tissue that is grabbed in the opening of the tip of the device can be cut and removed by squeezing the handle.

Intended user

This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

Instructions for use

Before using this product, inspect, wash, and sterilize in accordance with these instructions.

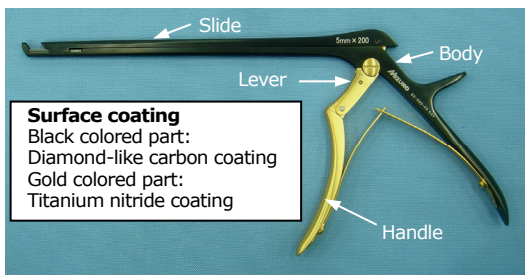
Warning/Caution

1. Important fundamental cautions
 - Device must be sterilized by users in accordance with our recommended sterilization procedures or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.
 - Do not twist or bend the device excessively during use. The tip is extremely thin and may break.
2. Defect/Adverse event
 - Defect
 - Corrosion caused by use of chemicals
 - Damage or malfunction caused by corrosion or pitting
 - Peeling of coating

Storage/Life

1. Please store the device in normal ambient temperature areas. Do not store in areas of high humidity where the temperature may dramatically vary causing condensation. Do not store on or near chemicals as the chemicals may cause damage to the device.
2. Service life of this product: 5 years
(Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Specifications



Maintenance/Inspection

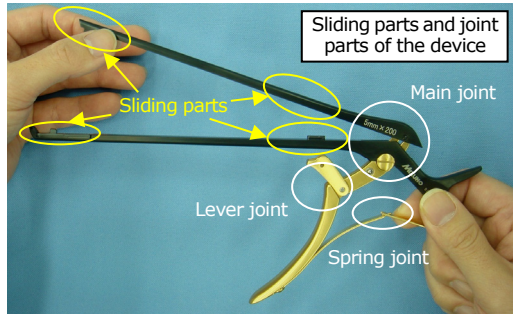
1. Check prior to each use

Operational and functional checks

Conduct daily and pre-operation checks of this product to make sure that it functions properly.

2. Check after each use

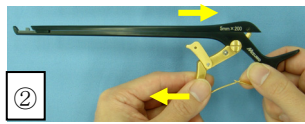
1) Disassembly



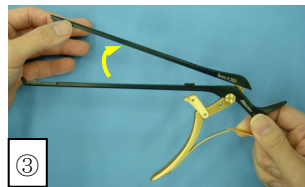
① Grab the handle and pull the lever forward.



② Loosen your grip on the handle, and the slide will move into position for removal from the body.



③ Pull the slide away from the body. (It does not separate completely.)



2) One of the following must be performed immediately after an operation.

Note: Do not use saline or chlorine detergent.

① Immersion cleaning (enzyme)

Use a neutral or weak alkaline enzymatic detergent.

② Spray detergent for preliminary cleaning with a sprayer.

③ Manual cleaning

Use a neutral detergent.

3) Ultrasonic cleaning or jet cleaning (washer-disinfector)

Use a neutral or weak alkaline detergent.

Thermal Disinfection can be used by following the manufacturer's defined parameters: Thermal Disinfection Band:

90-93 °C/194.0-199.4°F, 5-10 minutes (A0 value: 3000-12000) (reference EN ISO 15883-1)

Note: For a weak alkaline detergent, use a product with a pH of 11 or less. Refer to the manufacturer's instructions to dilute the detergent. Refer to the instructions for use of the ultrasonic cleaning machine for its operating conditions.

4) Rinsing

Only use reverse osmosis water for the rinse.

Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.

5) Drying

Fully dry this product immediately after washing it. Do not leave it wet for a longer time than necessary as residual water may damage the instrument. The use of an air blow gun is recommended.

6) Use a water-based anticorrosive lubricant

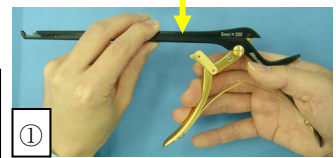
Lubricating oil is completely removed by washing. After washing this product, apply a water-based, anticorrosive lubricant prior to sterilization.

Do not use this product without applying anticorrosive lubricant on its sliding part. [Galling could occur.]

7) Reassembly

① Put the slide on the body and check the fit of the sliding parts.

Note:
To ensure a proper fit, use both hands to put the slide on the body.



② Grab the handle and restore the lever to its original position.



3. Sterilization

Device must be sterilized by users in accordance with validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.

Sterilization of the device may be accomplished by steam.

The recommended sterilization parameters are as follows,

ISO/TS 17665-2	
Temp.	Minimum exposure time
121°C / 250°F*	15 Min
126°C / 259°F*	10 Min
134°C / 273°F*	3 Min

*According to the Guideline for Disinfection and Sterilization in Healthcare Facilities ,2008 (Update:May 2019)

For the US market

FDA has not approved or cleared medical devices, including sterilizers, for the intended use of reducing the infectivity of TSE agents (i.e., prions).

For the markets outside the US

When the device is used on a patient with or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse.

Maintenance and check by agents

For safety use of this instrument, conduct periodic checks by the manufacturer or the agent recognized by the manufacturer. Maintenance and check by other agents could cause the adverse events and the decrease of the performance and the function. To schedule the periodic check, contact your local distributor or the manufacturer.

Packing

1 piece per pack

Warranty

MIZUHO Corporation will repair defective parts of this product without charge for one year from the date of delivery/installment except for cases of damage caused by a third party's repair, act of nature, improper use or intentional damage. All other warranty terms and conditions are subject to regulations of MIZUHO Corporation.

Disposal

This device must be disposed of in accordance with local regulations. Please contact your local distributor for proper disposal.

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in which the user and/or patient is established.

Name and address of manufacturer



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