

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

# Instructions for Use

Trade Name: Dura Scissors

**Warning**

1. 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. Not doing so may give rise to serious problems or adverse events.
2. Prohibition of use during contact coagulation  
Never allow the tip of an electrosurgical knife to make contact with this product during contact coagulation or a similar procedure.
3. **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 the market 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](http://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. Use with specified products only  
Use this product only with products specified by Manufacturer. Other products than those specified by Manufacturer could be incompatible with this product due to differences in design and development policies.
3. Prohibition of use of chemicals  
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
4. 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.
5. Handle with care  
Handle this product with care, as it can be deformed or damaged. Rough handling could significantly reduce the service life of devices and appliances.
6. 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 surface of this product and result in rust or corrosion.
7. 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.

Code No.	Product Description
07-815-01	Micro Dura Scissors, Thick Serrated Blade Tokyo Univ Model

Material: Stainless Steel

**Intended Purpose**

This device is a surgical instrument to cut tissue, cloth, suture thread and other materials during surgical procedures. The scissors consist of two pivoted blades and cut the material as the blades close.

**Instructions for use**

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

**Caution**

1. Warning  
Device must be sterilized by users under the standard sterilization conditions or the validated sterilization conditions which validity is proven by medical organizations in each country or region.
2. Cautions on use of other tools in combination with this product
  - Prohibition of use during contact coagulation  
Never allow the tip of an electrosurgical knife to make contact with this product during contact coagulation or a similar procedure.
3. Defect/Adverse event
  - Prohibition of use of chemicals  
Avoid exposing this product to chemicals. Doing so could damage this product and cause corrosion.

**Storage/Life**

1. Do not store the device in high temperature areas. Do not store in areas of high humidity where the temperature may vary wildly causing condensation. Do not store on or near chemicals.
2. Service life of this product: 5 years  
(Subject to the specified maintenance, inspection, and proper storage)

**Maintenance / Inspection**

1. Operational and functional checks  
Conduct daily and pre-operation checks of this product to make sure that it works properly.
2. Immediate washing with clean water  
Wash and rinse with clean water immediately in case the device is exposed to bleach or antiseptic solution, which may contain chlorine or iodine.
3. Dry this product immediately after washing it.  
Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary.
4. Use distilled or deionized water  
Use distilled or deionized water to wash this product. Residual chlorine and organic matters in tap water could cause stains and rust.
5. Use a water-based anticorrosive lubricant  
Lubricating oil is completely removed by washing. Do not use without lubricant oil to sliding part, or galling could occur. After washing this product, apply a water-based anticorrosive lubricant prior to sterilization.
6. 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.

**Shape / Structure**



Sterilization of the device may be accomplished by steam. The recommended sterilization parameters are as follows.

ISO/TS17665-2	
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)

Temp.	Minimum exposure time
134°C / 273°F*	18 Min

#### **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 market 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 safe use of this instrument, inspect device prior to and after each use. Alternative or no review and/or inspection may cause injury to the patient and/or healthcare worker and may decrease the performance and function of this device. Additionally, it is recommended to schedule a periodic inspection through your local distributor or the manufacturer.

#### **Packing**

1 piece per pack

#### **Matters related to warranty period**

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



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