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

MES-CK07-008-23EN-0
PREPARED: (2017-08-22) (Version 1)

Instructions for Use

Trade Name: Dural Elevator

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.

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 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.
8. 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.

Shape / Structure

Code No	Product Description
07-008-23	Dural Elevator, Flexible Shaft

Material: stainless steel, aluminum alloy

Intended Purpose

This device is intended for use in the surgical setting to separate or elevate tissues.

Instructions for Use

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

Caution

1. Warning
   1.1 Prior to use the device must be sterilized under the standard sterilization conditions or the validated sterilization conditions which validity is proven by medical organizations in each country or region.
   1.2 Do not use hydrogen peroxide gas plasma sterilization.
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 events may happen when exposing or processing the device with chemicals not defined within these instructions
   Chemicals may damage this product, cause corrosion and may harm the patient or healthcare worker.

Storage/Life

1. Please store the device in normal ambient 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 / Processing

1. Inspect prior to and after each use
   Operational and functional inspection is required to ensure functionality and condition.
2. Processing and inspection after each use
   2.1 It is recommended to use a washer-disinfector for this device
   2.2 Immediate wash with distilled or deionized water.
   If exposed to bleach or antiseptic solutions, immediately wash and rinse with clean water in case of exposure to solutions that may contain chlorine or iodine. Remove all contaminated matters manually, ultrasonic-cleaner and/or soft nylon brush.
   2.3 Use fully deionized water (reverse osmosis) for final rinse.
   2.4 Fully dry this product immediately after washing.
   2.5 After cleaning, fully rinse for more than 5 minutes, with warm or cold water without any additives.
   2.6 Thoroughly dry this product immediately after washing it. Do not leave wet as condensation may cause staining and/or deterioration of device.
   2.7 If the device has moving parts, the lubrication has been completely removed by washing. Only use a water-based anticorrosive lubricant, do not use without lubricant oil on sliding or moving parts as galling or performance issues could occur.

After washing this product, apply a water-based anticorrosive lubricant prior to sterilization.

3. Sterilization

3.1 Device must be sterilized by users in accordance with validated sterilization procedures, that are regulated by medical organizations in each country or region.
Do not use hydrogen peroxide gas plasma sterilization.

3.2 Sterilization of the device is accomplished by steam sterilization. The recommended sterilization parameters are as follows,

ISO/TS 17665-2	
Temp.	Minimum exposure time
121°C / 249.8°F	15 Min
126°C / 258.8°F	10 Min
134°C / 273.2°F	3 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 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.

Packing

1 unit per package

Matters related to warranty period

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 damage on purpose. All other warranty terms and conditions are subject to regulations of MIZUHO Corporation.

Name and address of manufacturer

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