

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

## Instruction for Use

Trade Name: LawtonElite Atraumatic Malleable Suctions

### 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. Failure to follow manufacturer's recommendations may cause harm or injury to the 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 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.

2. Do not bend any more than 30° at 1 point.  
[Broken or damaged pieces may remain in the body making it impossible to insert a mandolin.]
3. Refrain from topical bending and repeated bending at the same location.  
[Broken or damaged pieces may remain in the body.]
4. Do not bend at the tip and base of pipe.  
[Broken or damaged pieces may remain in the body.]

### 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 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.

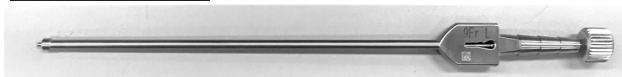
### Symbol mark for labeling

**MD** : Medical Device

### Specifications

Shape

In combination



Main body of suction tube



Mandolin



Code No.	Product Description
07-871-01	LawtonElite Atraumatic Malleable Suction Tube 7.5 cm WL, 3Fr
07-871-02	LawtonElite Atraumatic Malleable Suction Tube 7.5 cm WL, 5Fr
07-871-03	LawtonElite Atraumatic Malleable Suction Tube 7.5 cm WL, 7Fr
07-871-04	LawtonElite Atraumatic Malleable Suction Tube 7.5 cm WL, 9Fr
07-871-05	LawtonElite Atraumatic Malleable Suction Tube 9.5 cm WL, 3Fr
07-871-06	LawtonElite Atraumatic Malleable Suction Tube 9.5 cm WL, 5Fr
07-871-07	LawtonElite Atraumatic Malleable Suction Tube 9.5 cm WL, 7Fr
07-871-08	LawtonElite Atraumatic Malleable Suction Tube 9.5 cm WL, 9Fr
07-871-09	LawtonElite Atraumatic Malleable Suction Tube 11.5 cm WL, 3Fr
07-871-10	LawtonElite Atraumatic Malleable Suction Tube 11.5 cm WL, 5Fr
07-871-11	LawtonElite Atraumatic Malleable Suction Tube 11.5 cm WL, 7Fr
07-871-12	LawtonElite Atraumatic Malleable Suction Tube 11.5 cm WL, 9Fr

Material: Stainless Steel

### Intended purpose

This product is a device connected with the suction device during operation or treatment to control or instruct suction. This product is a reusable universal suction tip.

### 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.
- Bend the pipe manually.
- Inspect the instruments for damage and cracks prior to and after use.  
(Refer to Maintenance / Inspection)

### Warning/Caution

1. Important fundamental cautions  
Prior to use the device must be sterilized under the standard sterilization conditions or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.
2. Defect/Adverse event  
Defect
  - Corrosion or pitting caused by use of chemicals
  - Damage or breakage caused by the corrosion or pitting

Adverse event

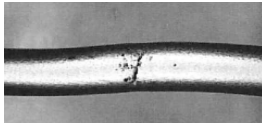
- Broken pieces of metal from the damaged instrument falling into the patient.

**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: 1 years  
(Subject to following manufacturer’s specified maintenance, inspection and proper storage requirements.)

**Maintenance/Inspection**

1. Check prior to each use
  - (1) Operational and functional checks  
Conduct daily and pre-operation checks of this product to make sure that it functions properly.
  - (2) Inspect the instrument for damage, fractures or cracks.



Examples of damage

2. Check after each use
  - (1) Immediately wash with clean water
    - (1)-1 If exposed to bleach or antiseptic solutions, immediately wash:  
Wash and rinse with clean water immediately and immerse in neutral enzyme detergent to remove any bleach or antiseptic solution, which may contain chlorine or iodine and can damage the instrument. Manually remove contaminated matter by hand or with an ultrasonic-cleaner.
    - (1)-2 Further remove any remaining contamination with a plastic brush.
    - (1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.
    - (1)-4 Use a soft towel, a plastic brush or a water jet for cleaning
    - (1)-5 Avoid using metallic brushes or rough polishing agents, applying excessive force, dropping or bumping the device, etc.
    - (1)-6 Reverse osmosis water is recommended to wash this product.
    - (1)-7 Only use reverse osmosis water for the final rinse.
  - ※It is recommended to use a washer-disinfector for this device.  
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)
  - (2) 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.
  - (3) Use distilled water or reverse osmosis water  
Use distilled water or reverse osmosis water to wash and sterilize this product. Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument
  - (4) 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.
  - (5) Maintenance
    - (5)-1 After cleaning, visually inspect under ambient lighting and confirm all dirt and debris has been removed. Confirm whether or not the dirt in the inner lumen could be removed through the attached mandolin.
    - (5)-2 If any dirt or debris is visible, repeat cleaning and lubrication steps.

<Mizuho recommends the following procedures>

(1) Cleaning preparation

- ① When handling devices contaminated with blood or bodily fluids, wear appropriate protective equipment such as masks, gloves, eye protection, and waterproof aprons.
- ② Do not allow blood or bodily fluids on devices to dry.
- ③ The instrument is fragile so handle carefully throughout the cleaning and sterilization process so that the instrument and its tips are not damaged.

(2) Cleaning

<Manual Procedure>

- ① Soak the product in cold tap water for 5 minutes, covering all surfaces, and confirm that the lumen is filled with water.
- ② Rinse with tap water and clean with a plastic brush until all visible residue is removed from the surface of the instrument. Pass the attached mandolin through the inner lumen to remove the dirt and rinse the inner lumen with cold tap water for 20 seconds using a water gun (hydrostatic pressure of 2 bars).
- ③ Place the product into its washing basket and ultrasonically clean at room temperature for 10 minutes in reverse osmosis water with a neutral enzyme detergent dissolved to establish a 0.5% detergent solution.
- ④ Pass the attached mandolin through the inner lumen and rinse with cold tap water for 20 seconds using a water gun (hydrostatic pressure of 2 bars).

<Automated Procedure>

Connect the tool for washing of inner lumen of washer disinfector with this product.

- ① Perform pre-cleaning for 3 minutes using tap water.
- ② Drain the water.
- ③ Clean for 10 minutes in 50°C tap water with 0.3% alkaline detergent solution.
- ④ Drain the water.
- ⑤ Rinse for 3 minutes with distilled or reverse osmosis water.
- ⑥ Drain the water.
- ⑦ Rinse for 2 minutes with distilled or deionized water for the final rinse.
- ⑧ Drain the water.
- ⑨ 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)
- ⑩ Thoroughly dry prior to use or storage

(3) Only use a water-based, anticorrosive lubricant

Lubricating oil is completely removed by washing. Do not use without lubricant oil to any sliding parts, or galling could occur. After washing this product, apply a water-based anticorrosive lubricant prior to sterilization.

3. Sterilization

The device must be sterilized in accordance with the manufacturer’s recommended sterilization procedures or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

The recommended sterilization parameters are as follows,

sterilization method	Pre-vacuum steam sterilization (Autoclave sterilization)	
sterilization conditions	Sterilization temp.	Retention time
	132°C /270°F*	4min
	134°C /273°F*	3min

\*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 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 device, 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.

**Manufacturer**

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