

## Instructions for Use

Trade Name: NIBS-Es Malleable Instruments Tray

### 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 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 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](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. 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.

This document describes the steps to set up, use, troubleshoot, and maintain NIBS-Es Malleable Instruments Tray. For services and repairs or other matters not described herein, please contact your sales agent.

### Intended purpose

NIBS-Es Malleable Instruments Tray is designed to hold medical devices to be steam-sterilized by healthcare professionals.

Double packaging of the trays with sterile bags or other means enables to maintain the sterility until sterilization of the medical devices placed therein and the use of the instruments.

### 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

Check and clean the tray exterior before use. Improper cleaning may damage anodized aluminum (aluminum oxide film).

### General Precautions

#### 1. Reprocessing Procedure

The trays should be reprocessed immediately after use. Transport them according to the hospital's transport protocols. Instruments should be wiped or rinsed with water immediately after use to remove major dirt. All trays should be separated into lids and caddies.

#### 2. Cleaning Process

This product should be cleaned after each use. As a cleaning agent, use a correctly diluted enzyme or neutral pH agent. The neutral pH value should be aimed at 7. The pH level of the diluted enzyme should be between 5.5 and 8.5.

Note: Use of highly acidic or highly alkaline pH detergents can permanently damage tray's anodized aluminum. Sterilizing the trays

with detergent residue may also damage anodized aluminum. Use a soft brush or similar tool to clean areas where dirt tends to accumulate.

#### 3. Cleaning

(1) Use only a diluted, neutral pH cleaner suitable for anodized aluminum. Highly acidic or highly alkaline detergents will permanently damage tray's anodized aluminum.

(2) Thoroughly rinse and remove the cleaning agent prior to the sterilization process. Any detergent residue may damage anodized protective coating.

(3) Do not use abrasive cleaners, abrasive cleaning pads, or metal brushes on tray surfaces. Use of these abrasives will permanently damage tray's anodized aluminum.

(4) Do not clean the trays by ultrasonic cleaning.

#### 4. Hand-washing

(1) Ensure that the pre-cleaning treatment process has been performed.

(2) Prepare an enzyme or neutral pH detergent. Use tap water at 27–44°C (81–111°F) according to the detergent manufacturer instructions.

(3) Soak all open trays in the cleaning solution. After soaking, move all movable parts. Subsequently, soak for at least 5 minutes.

(4) Use a soft brush to remove all visible dirt. Carefully check that no dirt remains in moving parts, hinges, and hidden areas.

Note: Replace the cleaning solution if it becomes contaminated with blood.

(5) Rinse the trays for at least 30 seconds while completely immersing them in tap water with a water temperature of 27–44°C (81–111°F) to rinse all cleaning solution and dirt.

(6) Dry the trays with a clean, lint-free towel.

(7) Visually check that no dirt remains.

(8) If any dirt remains, start over from the beginning of the cleaning process.

#### 5. Machine-washing

When washing trays with a machine, refer to the washer manufacturer instruction manual.

(1) Ensure that the pre-cleaning treatment process has been performed.

(2) Move the trays skillfully such that the rinse water will flow out.

(3) Visually check for dirt.

(4) If any dirt remains, start over from the beginning of the cleaning process.

(5) If any water droplets remain, wipe the instruments with a clean, lint-free towel.

#### 6. Sterilization

The 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.

#### 7. Cooling

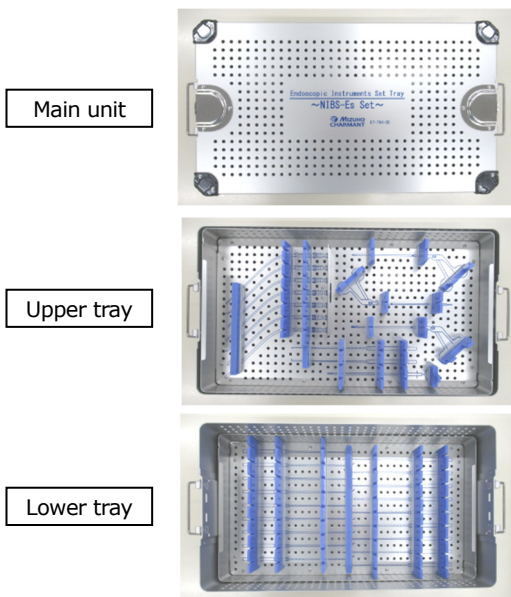
(1) After steam sterilization, cool the trays on a rack until the tray surface can be touched by hand. Cooling should be done properly to prevent condensation and puddling in the trays.

(2) Do not decrease the temperature of the trays rapidly by exposing them directly to air-conditioning breeze. Doing so may cause condensation.

(3) Do not move the trays to the sterile storage area until they are cooled down to the room temperature.

## Product Return/Repair Information

1. Before sending the product for repair or service, clean and sterilize the trays according to the instructions in this document.
2. Parts that become defective owing to problems in the manufacture or materials will be repaired or replaced free of charge.
3. Any problems caused by misuse on the part of customers are not covered by the warranty.
4. Returning of the product for repair or replacement under warranty requires our agreement. Please contact your local sales agent.
5. When returning the trays, please wrap them in such a way that the products will not rub against each other during transportation. Furthermore, please use cardboard boxes as dividers when packing the trays such that they will not contact each other during transportation.
6. Lids and caddies should be shipped under locked condition.
7. Place the trays in plastic bags. Lay a cushioning material or packing paper on the bottom of the cardboard box in which the trays are to be placed. If there are interspaces in the box, please fill them with packing materials.



Code No.	Product Description
07-794-00	NIBS-Es Malleable Instruments Tray

Material : Aluminum alloy, stainless steel, resin

## Packing

1 piece per pack

## 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.



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