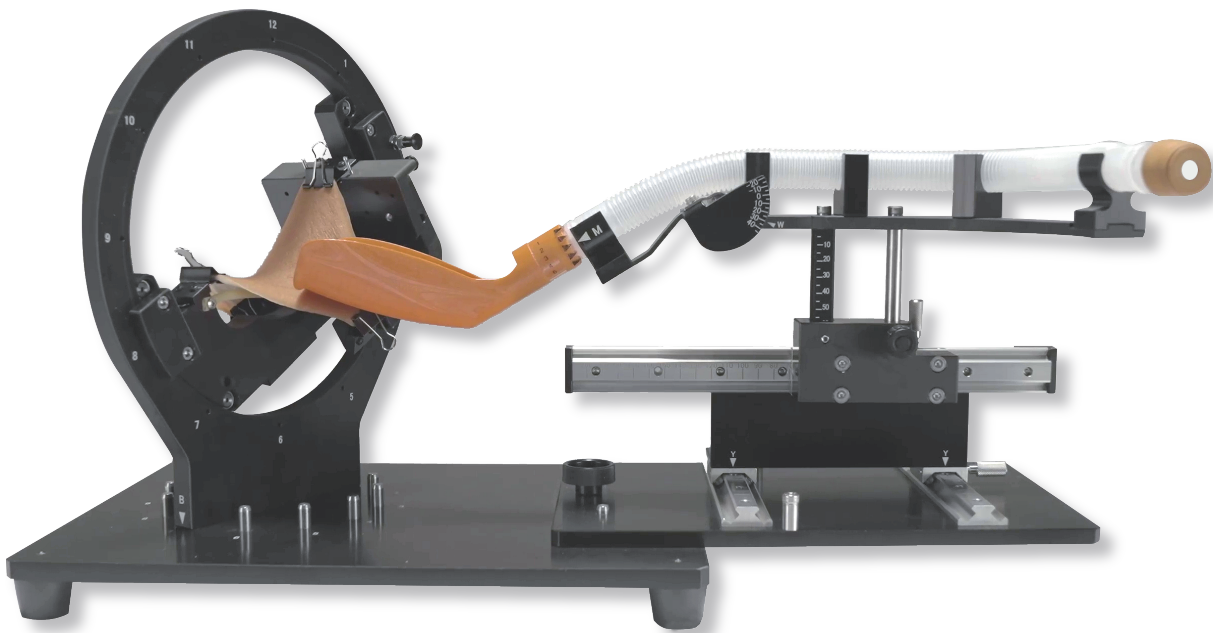


KOTOBUKI
Medical

G-Master ESD Training System User Manual

Product Number GM0001

Warranty Card Included



KOTOBUKI Medical, Inc.

GETTING STARTED

Thank you for purchasing KOTOBUKI Medical's ESD training system, the G-Master. In order to fully understand our product and use it effectively, please read this instruction manual carefully before use. Be sure to store this manual in a safe place that can be accessed when needed. For troubleshooting, please refer to this manual before contacting our support team.

The G-Master was developed jointly by KOTOBUKI Medical and the National Cancer Center Hospital East. The "G" stands for "Gastric", as this product was designed to help its users master gastric ESD surgery. We hope you will benefit from using the G-Master.

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PURPOSE AND FEATURES

Purpose

The G-Master was designed to realistically simulate an endoscopic submucosal dissection, or ESD surgical technique. Utilizing an open-air and fully adjustable training platform, the G-Master is an ethical and hazard-free alternative to porcine models.

The G-Master can accurately recreate common gastric cancer sites when used with our plant-based synthetic tissue, VTT. Due to the realism of our VTT products, the G-Master can be used to practice every step of an ESD surgical procedure, from lesion raising to incision and dissection.

We designed the G-Master for interactive training, as the open nature of the machine makes it easy for an instructor to observe all angles of the training procedure.

Features

1. Adjustable mechanized arms for calibrating VTT tissue to recreate gastric cancer sites (can also be used to simulate the loosening of the stomach wall during gassing and degassing)
2. Open-air design for full visualization of the training procedure
3. Plant-based training tissue pads made of VTT are triple-layered to accurately represent mucosa, submucosal, and muscular layering of the gastric wall
4. Injection fluid for lesion raising solidifies into a gel-like substance when in contact with VTT, ensuring that raised lesion areas stay at an ideal height for longer training sessions

Learn more about the G-Master and its features here:



1. SAFETY INSTRUCTIONS



WARNING

Do not forcibly bend, pull, or twist any parts of this product. Keep it away from extreme temperatures.

Do not attempt to modify this product on your own. Should it become damaged, do not attempt to fix it. Please contact our support team.

If there is any abnormality or malfunction, stop using the product immediately.

Do not allow children to use this product unsupervised. Store this product out of reach from children.

Take care not to pinch your fingers or skin when adjusting this product.

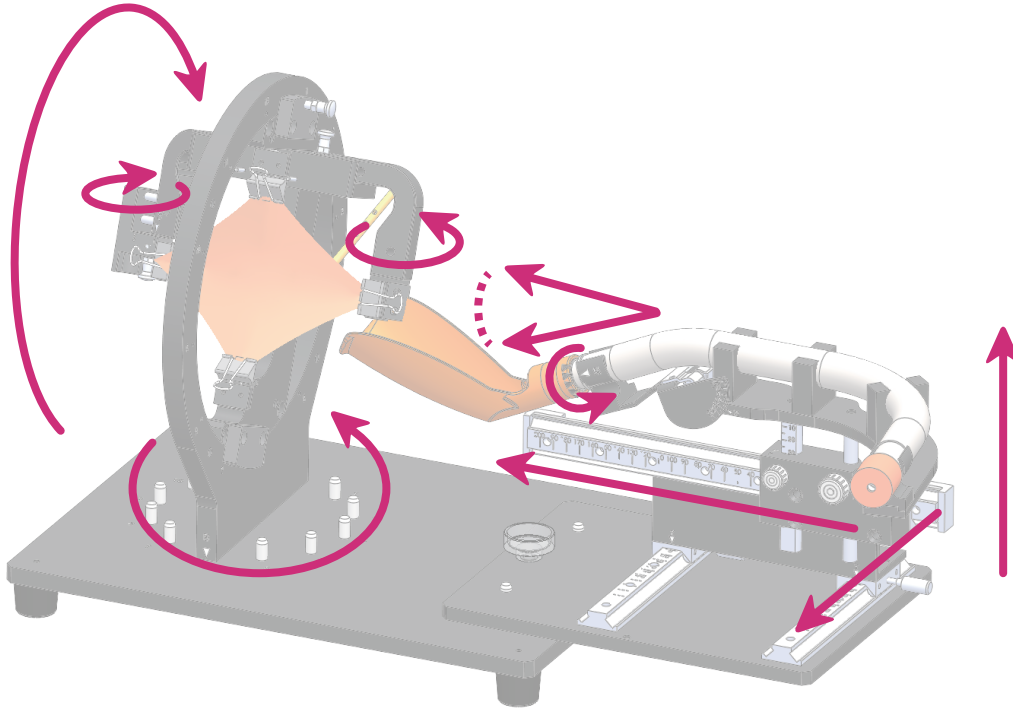
2. PRODUCT INFORMATION

Product Name	G-Master
Product Number	GM0001
JAN Code	4562480971066
Size (main unit)	W 635 x D 300 x H 310 mm
Weight (main unit)	Approx. 9.9 kg
Size (packaged)	W 750 x D 410 x H 430 mm
Weight (packaged)	Approx. 16.7 kg
Product Components	<p>G-Master unit x 1 pc</p> <p>Spatula x 1 pc</p> <p>Polarity cable for VTT x 1 pc</p> <p>VTT Mucosa Type x 3 pcs</p> <p>VTT Injection Solution x 1 pc</p> <p>Cleaning brush 2 types x 1 pc</p> <p>Water-based marker x 1 pc</p> <p>Instruction manual x 1 pc</p> <p>Setting sheets (11 types) x 1 pc</p>
Supervision	National Cancer Center Hospital East
Development, manufacturing	KOTOBUKI Medical, Inc.

3. PRODUCT SCHEMATICS

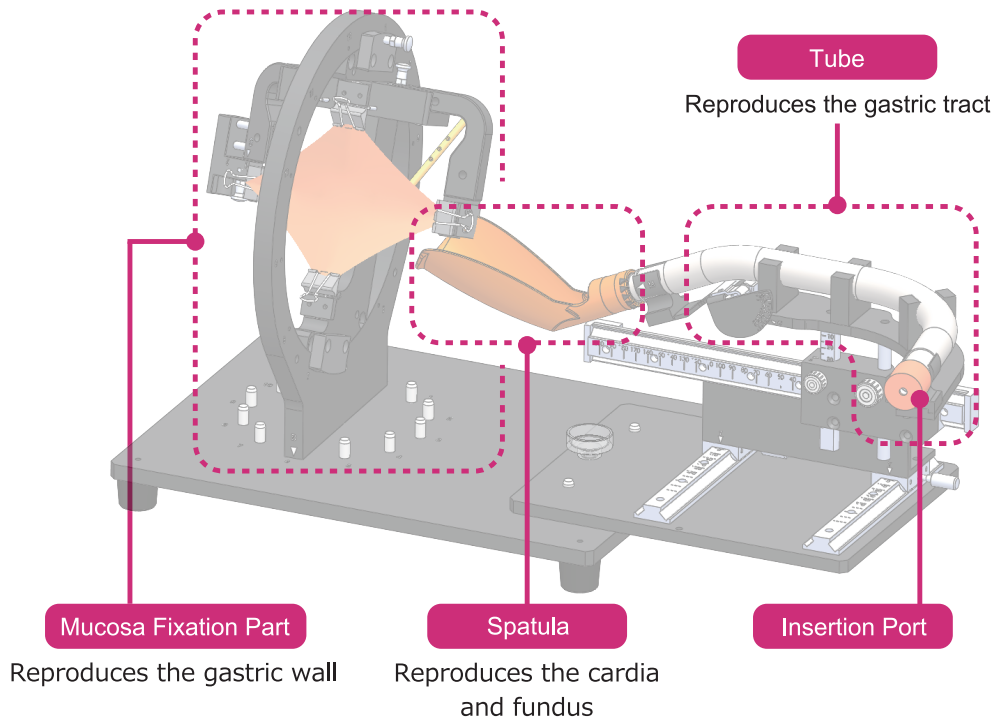
Movable Parts

Adjustable mechanisms reproduce various parts of the gastrointestinal wall.



Structure

The main wheel of the unit has four setting clips for the tissue sheet and two arms that can be used for gassing and degassing simulation. One soft, adjustable tube can be positioned to simulate gastric ridges (rugae). The spatula is removable.

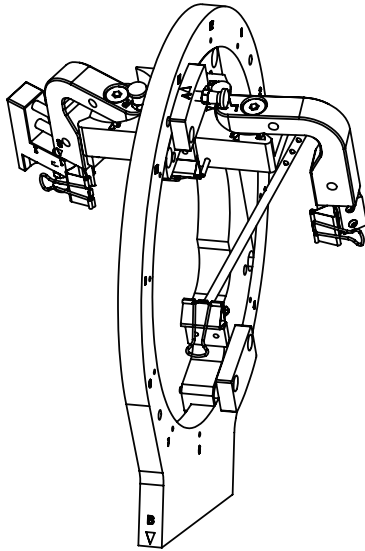


Parts of the Main Unit that Can Be Disassembled

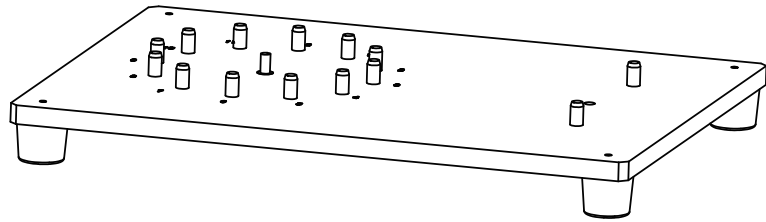
- 1. Mucosa Setting Wheel
- 2. Base
- 3. Insertion Port

*Please only wash the tube and spatula with water, as the rest of the standing parts have bearings that can rust

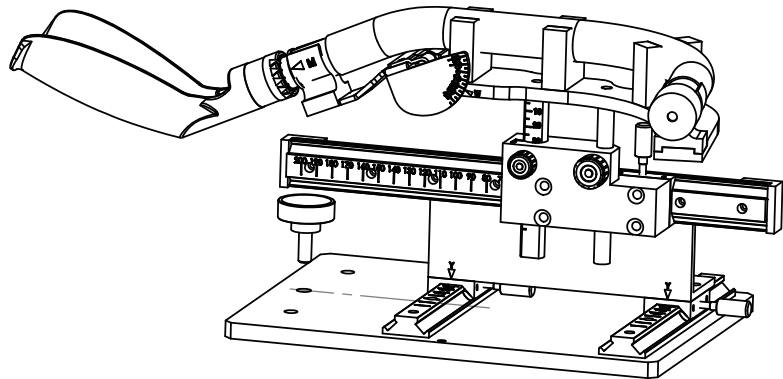
1. Mucosa Setting Wheel



2. Base



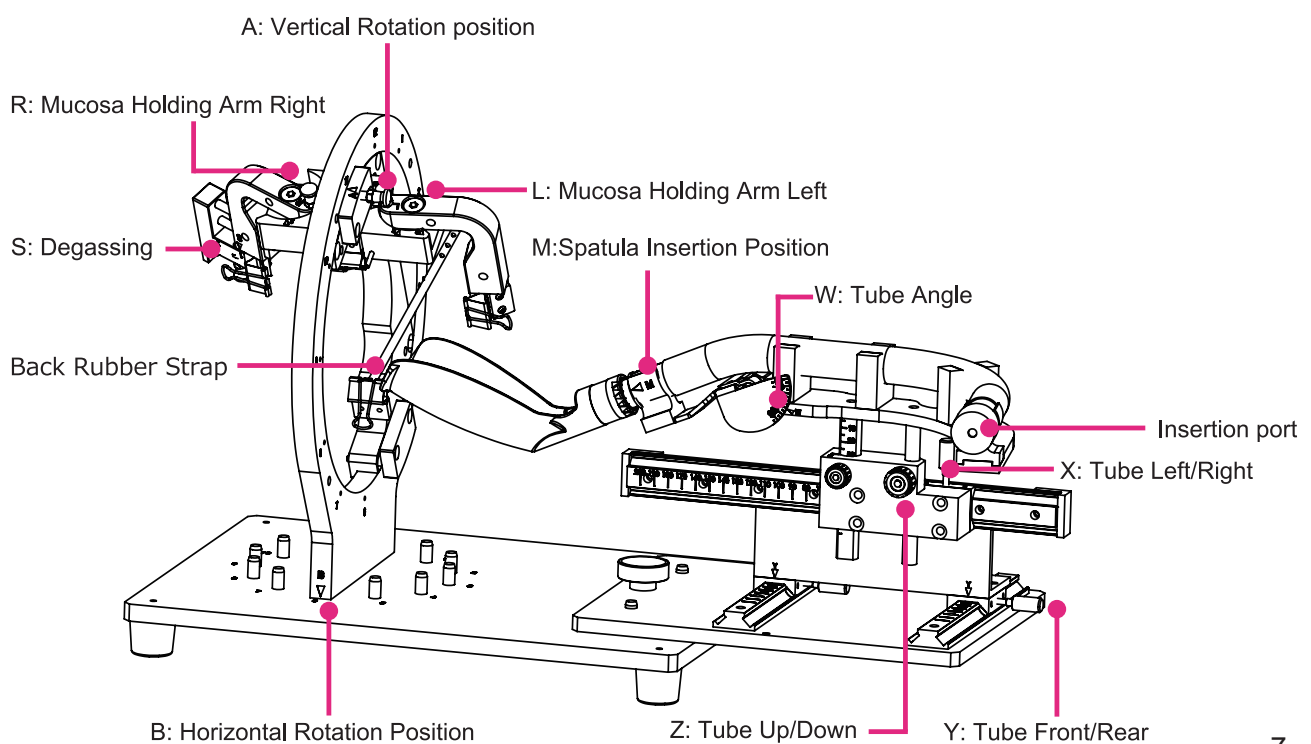
3. Insertion Port
(Tube and spatula can be removed for cleaning)



*To clean the metal part of the Insertion Port, please use a damp towel after removing the tube and spatula.

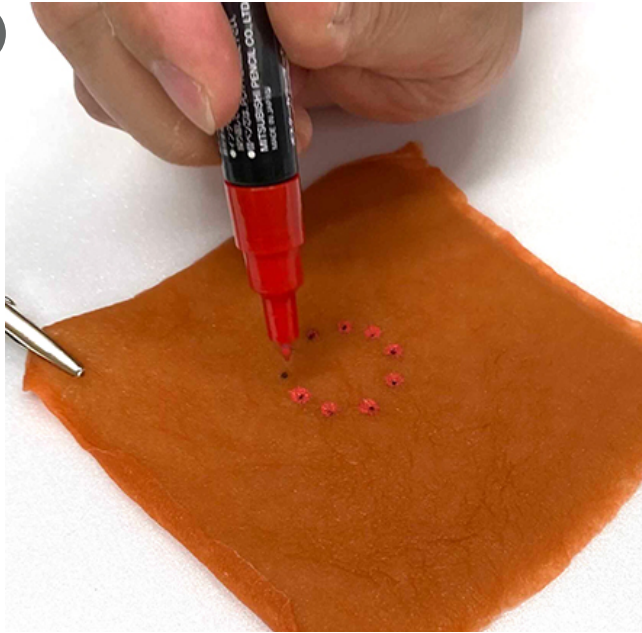
4. DEFINITIONS AND USAGE OF ADJUSTMENT MECHANISMS

Insertion port	Adjust the tube to the desired position. The spatula can also be moved.
R: Mucosa Holding Arm Right	Pull the adjusting knob, turn the arm until it clicks, and release the knob.
L: Mucosa Holding Arm Left	Pull the adjusting knob, turn the arm until it clicks, and release the knob.
A: Vertical Rotation position	Pull and turn the knob. Make sure the bearing clicks into place.
B: Horizontal Rotation Position	Lift the Mucosa Setting Wheel. Turn it as desired and ensure the pegs are securely in place.
Y: Tube Front / Rear	Loosen the knob, slide to the desired position, and tighten the knob.
X: Tube Left / Right	Loosen the knob, slide to the desired position, and tighten the knob.
Z: Tube Up / Down	Loosen the knob, slide to the desired scale, and tighten the knob. *When adjusting Z, please be very careful not to pinch your finger
W: Tube Angle	Hold it by hand and move it to the desired position.
M: Spatula Insertion Position	Move up or down to the desired position.
S: Degassing Knob	Pull and release the knob, turn the arm as desired, and check for the clicking sound. *Reproduces the loosening or tightening of the gastric wall due to gasing/degassing.
Back Rubber Strap	Hook the hole of the rubber string onto the desired knob. Make sure it presses against the white back of the mucosa tissue.



5. SETUP AND DIRECTIONS

1

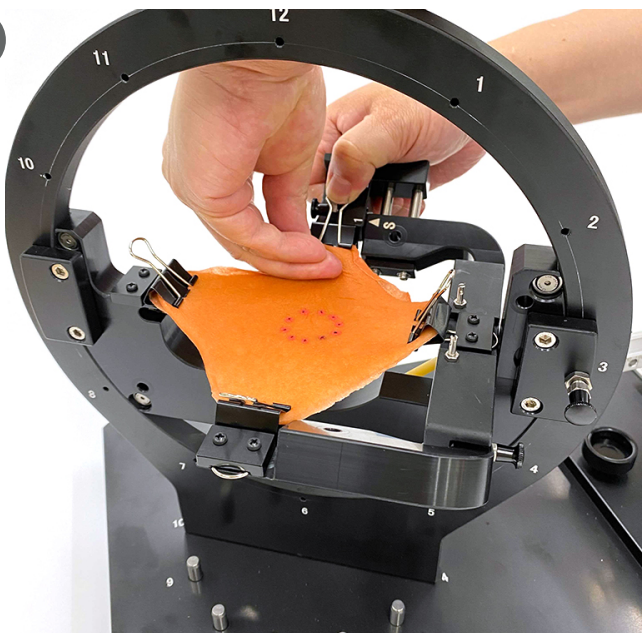


After opening the VTT Mucosa Type, lightly pat down the surface with a cloth or tissue to remove excess moisture. Use an electrode to mark the desired area for the tumor, then use a water-soluble marker to emphasize each marking. This makes it easier to see the procedural area.

Alternatively, you can use a water-based pen to fill in any area on the surface of the VTT Mucosa Type as a possible gastric cancer site, place it in the G-Master, pass the endoscope through the insertion slot, and mark the surrounding area under the endoscope.

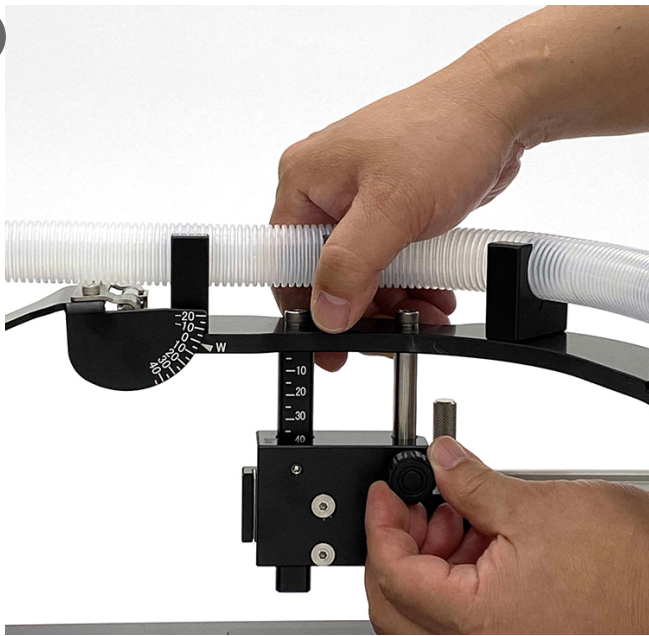


2



Place the Mucosa Holding Arms L and R to the SET position and fix the VTT Mucosa Type with the four clips.

3



Adjust each part according to the desired gastric site, using the Setting Sheet (attached separately) as a reference.

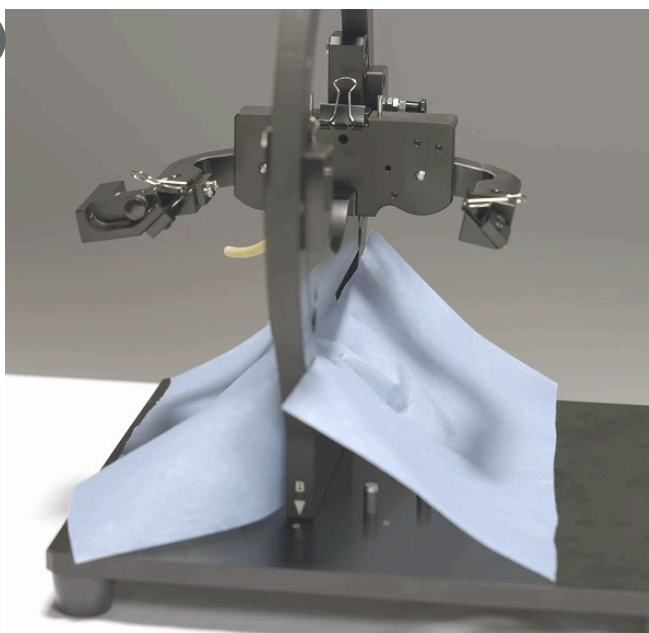
*When adjusting Z Tube Up/Down, hold the part that supports the tube to avoid the risk of pinching your finger

4

Connect the VTT Mucosa Type and the electrocautery pen using the included antipode cable.

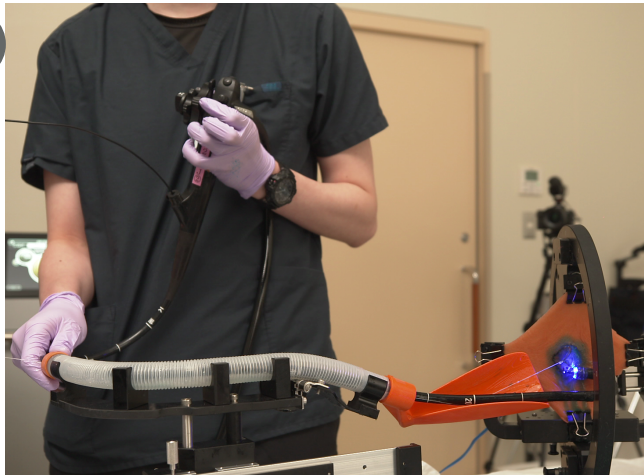


5



Lay a cloth on the lower rim of the rotation unit. This will prevent spillage of the Injection Solution and make cleanup easier after using the G-Master.

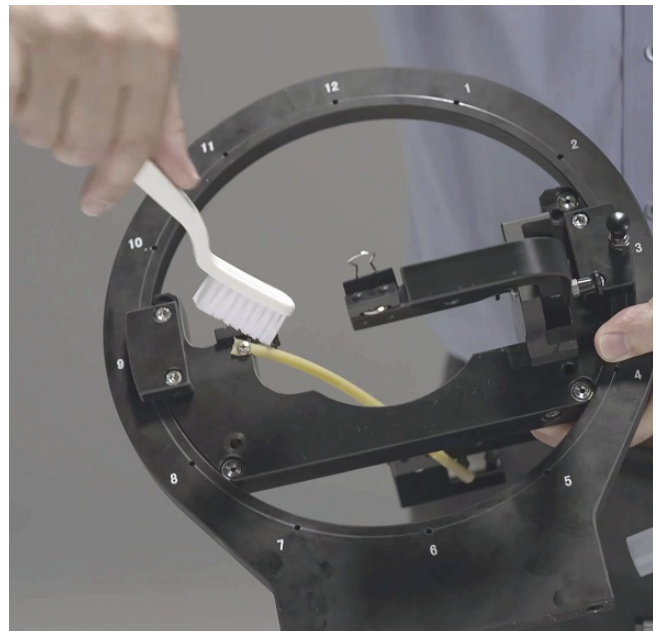
6






Execute the training. The VTT should only be used once, so please treat and dispose of it as combustible/organic waste. If any Injection Solution remains, store it immediately in the refrigerator after opening.

7

If left uncared for, the VTT Injection Solution left on the main unit may harden and cause breakage. After training, be sure to wash the unit with water, wipe clean, and dry before storing it.



6. CARE AND MAINTENANCE

	<p>If left on the machine, the VTT Injection Solution may harden and cause damage. Please use the included brush to thoroughly scrub off any Injection Solution fluid. We highly recommend laying a towel on the base to prevent excess spillage.</p>
	<p>Every part of this device can be rinsed with water except for the Insertion Port. To avoid rust on the Insertion Port bearings and parts, please use a damp towel to clean it. The tube section of the Insertion Port may be detached and rinsed separately.</p>
	<p>Please allow the G-Master to dry thoroughly before storage. This will prevent rust or mold. Once it's dry, store the unit in a dry area.</p>

7. WARRANTY AND SERVICING

Warranty Card

The Warranty Card is located at the back of this manual. Please enter the "Location of Purchase" and "Date of Purchase" correctly on your card. After reading the warranty details carefully, store the warranty and card in a safe place.

The manufacturer's warranty period is one year from the date of purchase (confirmation required). Please keep your receipt of purchase. This warranty does not cover consumables and accessories.

Repair Requests

If any abnormality or malfunction occurs during use of the G-Master, stop using the unit immediately and contact your dealer or KOTOBUKI Medical directly to request inspection and repair.

Please present the Warranty Card, complete with the "Location of Purchase" and "Date of Purchase" information. You must be within the warranty period to request free servicing for this device.

If the warranty has expired but function can still be maintained by repair, servicing can still be requested for a fee upon the customer's request.

After-Sales Services

If you have any immediate questions or concerns, contact your manufacturer or KOTOBUKI Medical.

Free Repair Policy

1. If the product malfunctions within the warranty period, and if the customer has used it according to the instruction manual, this product will be repaired free of charge. Confirmation is required for the Warranty Card, Location of Purchase, and Date of Purchase (confirmation required).
2. To receive free repairs within the warranty period, please present your Warranty Card to KOTOBUKI Medical or to your manufacturer.
3. Repairs within the warranty period will require a fee under the following circumstances:
 - Malfunction or damage due to misuse, modification, or improper repair done by a third party.
 - Malfunction or damage caused by transportation/dropping of the device after purchase.
 - Malfunction or damage caused by fire, flooding, or other natural disasters.
 - Repair requests presented without the Warranty Card.
 - Repair requests made at a store or manufacturer not authorized by KOTOBUKI Medical.
4. The warranty card will not be reissued, so please keep it in a safe place and do not lose it.

Contact

Manufacturer	KOTOBUKI Medical, Inc.
Address	4-7-3 Chuo, Yashio, Saitama 3400816 JAPAN
Tel	+81 (0)48 951 5211
Fax	+81 (0)50 3588 1032
Email	info2@kotobukimedical.com
Web	https://kotobukimedical.com/en/
G-Master Web	https://kotobukimedical.com/en/esd-training/G-master/

8. WARRANTY CARD

ESD Training System "G-Master" Warranty Card

Product Number	GM0001	*Date of Purchase	Warranty Period <small>(From the Date of Purchase)</small>
		MM/DD/YYYY	1 year
*Customer	Name		
	Address		
	Tel		
*Dealer	Name		
	Address		
	Tel		

If the *column is not filled in, the warranty will be invalid.

If not filled in, a receipt or other forms of proof of purchase will be substituted for, so please store in a safe place along with this warranty card.