

**Brugermanual for repositionerbar probe
fikseringsenhed.**

**Instructions for use of repositionable probe
fixation device**

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WARNING:

1. In accordance with applicable laws and regulations, the product is intended for use by trained clinical personnel only.
2. The product is intended for single use only! **DO NOT reuse**, reprocess, or resterilize the device. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also create a risk of cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
3. Do not use this device for any purpose other than the stated indications.
4. As the device contains polycarbonate/acrylonitrile butadiene styrene (PC/ABS), thermoplastic elastomer (TPE), polyamide 6/6.6, and polyamide 11, do not use the device in patients with known hypersensitivity to any of these materials, as allergic reactions may occur.

CAUTION:

1. This instruction manual contains essential information on using this device safely and effectively. Before use, thoroughly review this manual and the manuals for all equipment that will be used during the procedure, and use the device as instructed. Keep this and all related instruction manuals in a safe, accessible location. If you have any questions or comments about any information in this manual, please contact EchoVice.
2. Patients should be informed of and express their acceptance of the details of the operation/procedure and all potential risks and complications, which may lead to patient injury, illness, or death.
3. Please read this instruction manual in its entirety before use.
4. Do not use this device with probes that have dimensions other than those stated as usable.
5. Do not use this device with bite blocks that have dimensions other than those stated as usable.

WARRANTY:

EchoVice warrants that reasonable care and prudence have been exercised in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness.

Handling, storage, and cleaning of this device, as well as factors related to the patient, diagnosis, treatment, surgical procedures, and other matters beyond EchoVice's control, directly affect the device and the results obtained from its use. EchoVice's obligation under this warranty is limited to the replacement of this device, and EchoVice shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device.

EchoVice neither assumes nor authorizes any other person to assume for it any other or additional liability with respect to devices reused, reprocessed, or resterilized and makes no warranties, express or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such devices.

NAME

EchoM

INTENDED USE

The intended use of EchoM is to stabilize transesophageal (TEE) ultrasound probes used during examinations, procedures, and operations. EchoM is a hardware solution implemented in the patient's bite block. The device prevents movement of transesophageal ultrasound probes in the longitudinal axis but retains circumferential movement. The device uses a control unit to lock clamps around the probe, which fixate the device. The device is intended to be used by trained clinical personnel.

STRUCTURE

EchoM mainly includes end cap, fixation unit, tube, clips, and trigger unit (Fig. 1)

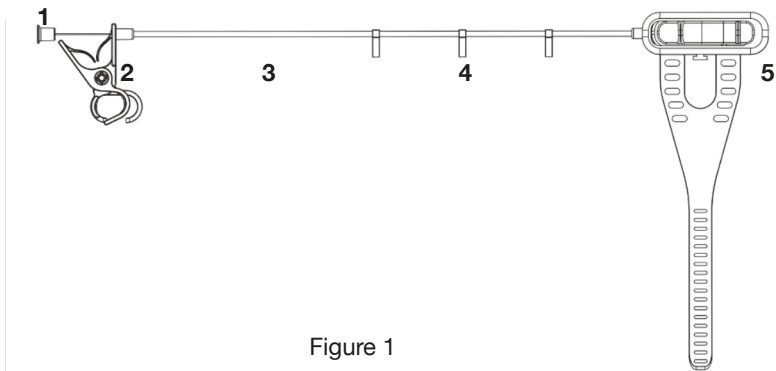


Figure 1

1. End cap, 2. Fixation unit, 3. Tube, 4. Clips, 5. Trigger unit

SPECIFICATIONS

Applicable TEE ultrasound probe diameter: $\text{Ø}11.5\text{mm} \pm 1.5\text{mm}$

INDICATIONS

Examinations or procedures involving TEE ultrasound probes where a bite block is used.

CONTRAINDICATIONS

1. No use of a bite block. The device is intended to be inserted into a bite block and should not be placed directly in the patient's mouth.
2. Other devices in the patient's bite block and oral cavity may obstruct the placement of the device in the bite block.

POTENTIAL COMPLICATIONS

1. Damage to the patients' teeth or oral cavity.
2. Complications which are not currently known or observed may be present.

SERIOUS INCIDENT REPORT

Any serious incident that has occurred in relation to the device should be reported to EchoVice and to the competent authority of the Member State in which the user and/or patient is established.

CLINICAL BENEFIT

EchoM does not provide a direct diagnostic or therapeutic effect. Its clinical benefit is derived from its ability to stabilize the TEE ultrasound probe during examinations and procedures. By reducing unintended probe movement while preserving controlled rotational functionality, the device supports consistent probe positioning and reproducibility of imaging conditions. This helps facilitate the acquisition of clinically relevant images required for diagnostic assessment and intra-procedural decision-making, thereby supporting the safe and effective use of transesophageal echocardiography.

PREPARATIVE CHECK AND PREPARATION

1. Check whether there is any damage to the packaging before use. Do not use the device if the packaging is damaged.
2. After confirming the shelf life, unpack and remove the device from the package.
3. Do not use the device if there are any functional abnormalities or concerns.

INSTRUCTIONS FOR USE

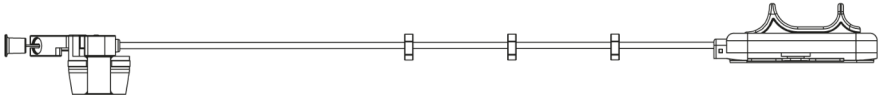
Device Compatibility

The device is compatible with TEE ultrasound probes with insertion tube diameters of $\text{Ø}11.5 \text{ mm} \pm 1.5 \text{ mm}$. Ensure that the probe used complies with this specification before use.

Bite block compatibility must be verified before use. EchoM must be securely positioned in the bite block and must not move or become displaced. If there is any doubt regarding compatibility between EchoM and the selected bite block, do not use the device, and contact EchoVice for guidance before proceeding.

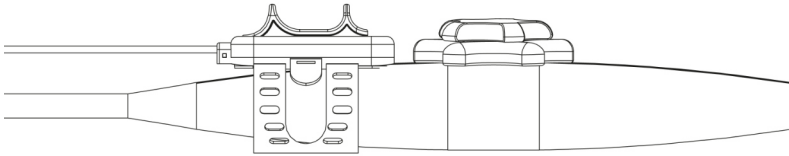
Preparation/Unpacking

1. Remove the trigger unit from the packaging.
2. Remove the tube and fixation unit from the packaging.
3. Visually inspect all units for damage or defects prior to use.

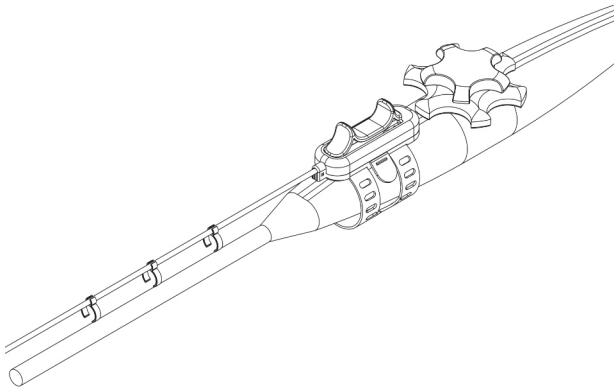


Installation

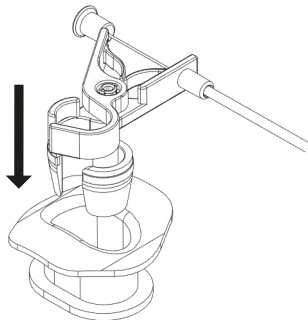
1. Strap the trigger unit onto the handle of the TEE ultrasound probe (see figure 3).



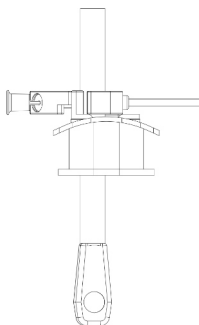
2. Connect the tube with the clips to the TEE ultrasound probe insertion tube (see figure 4).



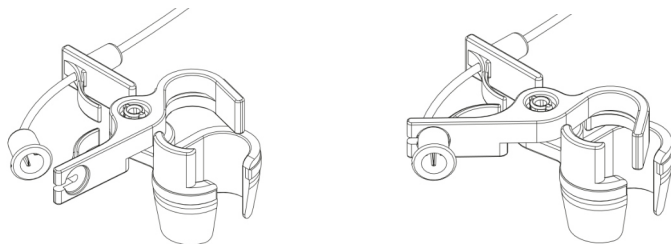
3. Insert the TEE ultrasound probe into the bite block and position the fixation unit within the bite block (see figure 6).



4. Insert the TEE ultrasound probe to the required depth (see figure 7.)

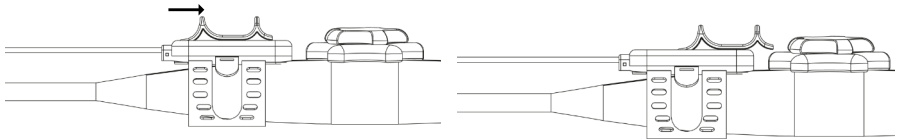


5. Position the end cap in the fixation unit as show in the figure. (see figure 8).

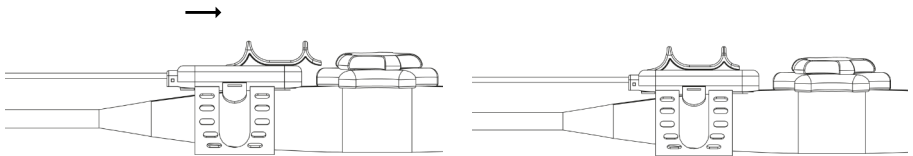


Fixation and Operation

1. Pull the trigger until fixation of the TEE ultrasound probe is achieved. A distinct click will be heard indicating successful fixation (see figure 9). Ensure fixation is secure before proceeding.



2. To release the TEE ultrasound probe, pull the trigger until a click is heard.



3. Manipulate the probe until the desired position is reached.
4. Pull the trigger again to reengage fixation at the desired position. A click will confirm engagement.
5. Repeat release and fixation as needed during the procedure.

Removal/Disposal

1. Ensure the TEE ultrasound probe is not in a fixated state before removal.
2. Remove the device from the TEE ultrasound probe bite block.

NOTE

1. The product must be operated by a trained physician.
2. Please check the shelf life before use. Do not use any device if the shelf life is expired.
3. The product is intended for single use only and one patient only. Do not reuse the device, nor share it between two or more patients.
4. Do not use the device in pediatric cases.
5. Do not operate fixation unit, tube or trigger unit with excessive force in case of any damage to the device.
6. Do not test fixation whilst inserting the TEE ultrasound probe. Testing must be done before or after the probe has been inserted.
7. Please confirm fixation of the TEE ultrasound probe before use.
8. Dispose of the device and packaging in accordance with hospital, administrative and/or local government policy.















STORAGE

Store the device in a cool, dark and dry place, and do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation. Prior to use, check the expiry date on the label of the package.

PRODUCT DISPOSAL

After use, handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

INDICATIONS

	No Reuse		Non Sterile
	Use by Date		Manufacture
	Lot Number		Date of manufacture
	Caution/Destroy after use		CE sign
	Serial Number		Medical Device
	Unique Device Identifier		Damaged package
	Keep dry		Consult instructions for use

[Package] Packed in PETG trays with TYVEK seal.

[Production date] See packaging

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