

0039-DOC Instructions For Use, English

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Instruction for Use of Repositionable probe fixation device

Warning:

1. In accordance with the 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 is made of XXX, do not use them on a patient who is severely allergic to XXX. Otherwise, allergic symptoms may occur.

Caution:

1. This instruction manual contains essential information on using this instrument safely and effectively. Before use thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments 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 and expressed his/her acceptance for the details of the operation/procedure and all the potential risks and complications, which may lead to injury, illness or death of the patients.
3. Please read this instruction manual entirely before use.
4. Do not use this device when probes with dimensions other than those stated to be usable are used.
5. Do not use this device with biteblocks with dimensions other than those stated to be usable.

Warranty:

EchoVice warrants that reasonable care and prudence has 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 expressed 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 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, expressed or implied, including (but not limited to) merchantability or fitness for intended use, with respect to such device.

Name

Echo M

Intended Use

The intended use of EchoVice is to stabilize transesophageal(TEE) ultrasound probes used during examinations, procedures and operations. EchoVice is a hardware solution implemented in the patient’s bite block. The device removes movements of transesophageal ultrasound probes in the transverse plane but retains the rotational functions. The device uses a control unit to lock clamps around the probe, which fixates the devices. The device is intended to be used by trained clinical personnel.

Structure

Echo M mainly includes closing component, fixation component, wire tube component and trigger component (Fig. 1)

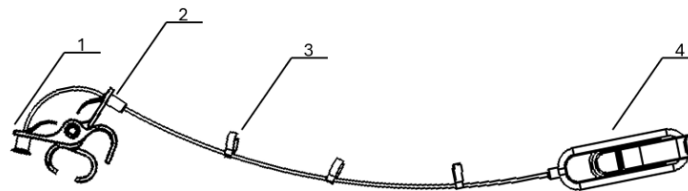


Fig.1 Schematic diagram of **Echo M**

- 1. Closing component
- 2. Fixation component
- 3. Wire tube component
- 4. Trigger component

Specification

The specifications of the device are represented by channel width and working length, as indicated in table 1.

Channel width(mm)	Tolerance (mm)	Maximum outside diameter	Working length (mm)	Tolerance (mm)
			1050	

applicaple TEE probe diameter: $\varnothing 11\text{mm} \pm 1\text{mm}$

Indications

- Examination or procedure involving TEE ultrasound probes
 - where a bite block is used.

Contraindications

- no use of bite block, the device is intended to be inserted into a biteblock and should not be placed directly in the mouth of the patient.
- Other devices in the patients bite block and/or oral cavity obstructing the placement of the device in the biteblock

Potential complications

- Damage to the patients teeth or oral cavity.
- Infection.
- Complications which are not currently known or observed may be present.

Clinical benefit

- EchoM does not provide a direct diagnostic or therapeutic effect. Its clinical benefit is derived from its ability to stabilize the transesophageal echocardiography (TEE) 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 decisionmaking, thereby supporting safe and effective use of transesophageal echocardiography.

Preparative check and preparation

- Check whether there is any damage on the packaging before use. Do not use the device if the packaging is damaged.
- After the shelf life is confirmed, unpack and take the device out of the package;
- Do not use the device if there are any function abnormality or questions.

Instructions for use

1. The device is compatible with transesophageal echocardiography probes with insertion tube diameters of $\varnothing 11\text{mm} \pm 1\text{mm}$, ensure that the probe used fits this specification.
2. Ensure that the sticker have not been damage before use (See Fig. 2).

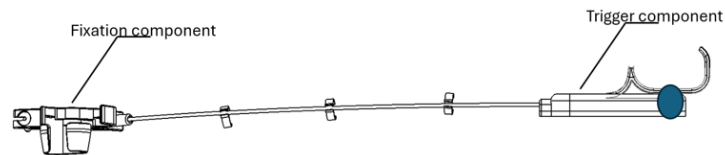


Fig.2

3. Strap Trigger component on TEE ultrasound probe handle (see Fig. 3).

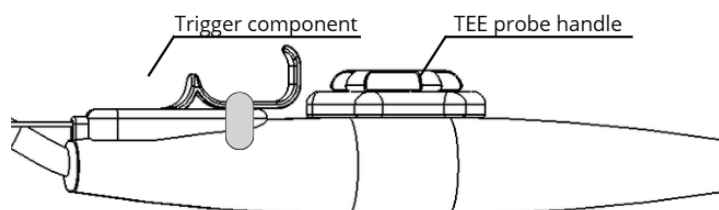


Fig. 3

4. Break the sticker by pushing the trigger forward (See Fig. 4).

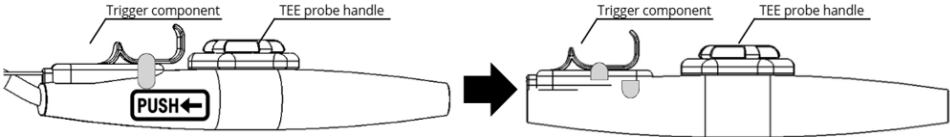


Fig. 4

4. Connect Wire tube component on to TEE ultrasound probe tube (see Fig. 5).

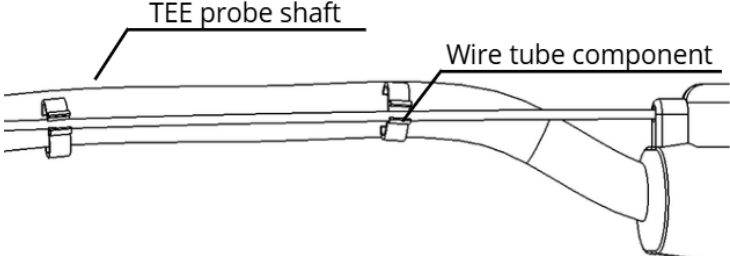


Fig. 5

5. Insert TEE probe into the biteblock and place Fixation component in the bite block (see Fig. 6).

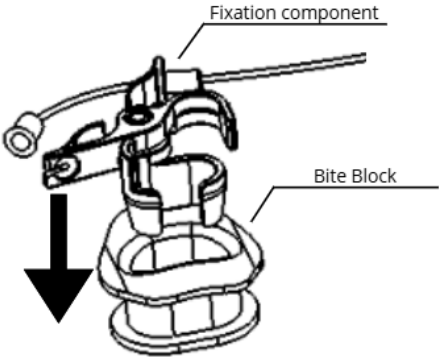


Fig. 6

6. Insert TEE probe (see Fig. 7)

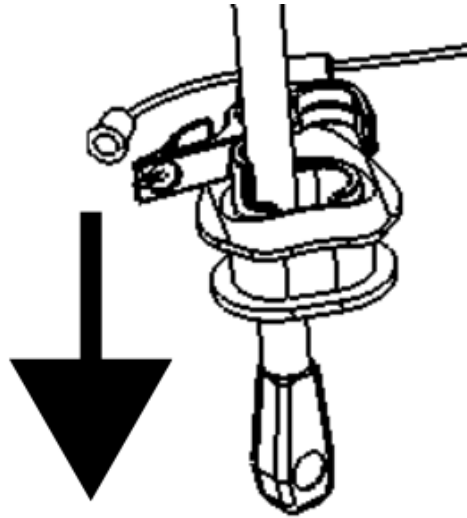


Fig. 7

7. Put closing component in place. (See Fig. 8).

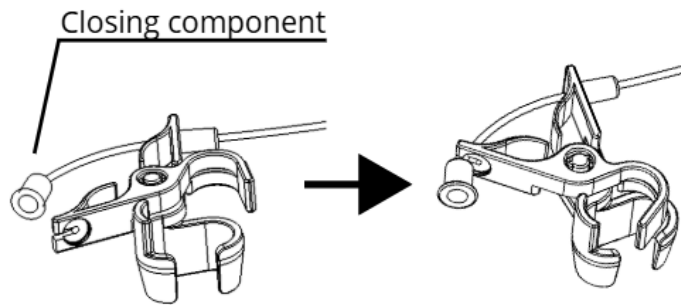


Fig. 8

8. Pull the trigger until fixation of the TEE probe is indicated, You will hear a click (See Fig. 9). Ensure fixation before further use.

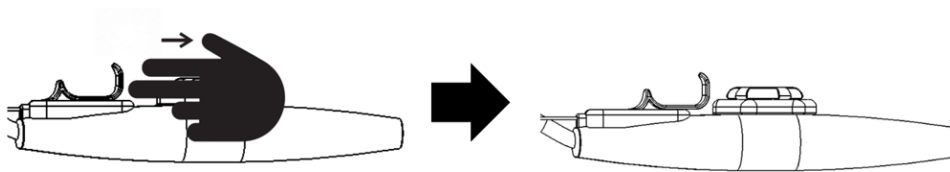


Fig. 9

9. Pull the trigger to release the TEE probe, you will hear a click. Manipulate the probe until the desired location and image is obtained. Pull the trigger to fixate the TEE probe in the desired location, you will hear a click. Repeat as needed throughout the procedure.

10. Remove device from TEE probe. Ensure that the device is not fixating the TEE probe and that the closing component have been released. Trigger component is unstrapped from the probe handle and the wire tube component and Fixation component are removed from the probe tube and 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 on pediatric cases.
5. Do not operate Fixation component, Wire tube component or Trigger component with excessive force in case of any damage to the device.
6. Do not test fixation whilst inserting the TEE probe. Testing must be done before or after the probe has been inserted.
7. Please confirm fixation of TEE 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		Nonsterile
	Use by Date		Manufacturer
	Batch Code		Date of Manufacture
	Catalogue Number		Use by Date
	Serial Number		Medical Device

			
	Unique Device Identifier		Damaged Pack
	Keep Dry		Sunlight Away
	Temperature Limit		Repackaging
	CE marked		

[Package] Packed in **XXX**

[Production date] See packing

[Cleaning] cleaned with **xxx**