

HEART ASSIST FINGERS INSTRUCTIONS FOR USE

Catalog Number	Description
HAF-2LGS	Heart Assist, Single Use, 2 Finger Long, Malleable 36mm W X 90mm L
HAF-2SHS	Heart Assist, Single Use, 2 Finger Short, Malleable 36mm W X 54mm L
HAF-3LGS	Heart Assist, Single Use, 3 Finger Long, Malleable 60mm W X 90mm L
HAF-3SHS	Heart Assist, Single Use, 3 Finger Short, Malleable 60mm W X 54mm L



Product Description:

The Heart Assist Finger is a textured silicone, over-molded accessory device for use with a Reusable Surgical Arm. This attachment provides atraumatic positioning and stabilization. The malleable metal design with textured silicone coating allows the surgeon to bend the attachments to conform to anatomical structures allowing for a greater field of vision. The attachment is provided in a double barrier, sterile package.

Sterile, Disposable, Single use only.

Indications For Use:

The Heart Assist Finger is a manual positioning device used during surgery intended for atraumatic positioning and stabilization of anatomical structures.

Contraindications:

- This device is not intended for use other than as indicated above.
- The Heart Assist Finger is contraindicated for use in patients with local or systemic infection.
- Do not position the Heart Assist Finger on newly infarcted tissue, aneurysmal tissue, fragile tissue, or directly over a coronary artery.

Warnings:

- Protect from extreme temperature and humidity.
- **DO NOT REUSE OR RESTERILIZE**. Reuse 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 or resterilization may also create a risk of contamination of the device and/or cause patient infection or 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.
- Proper surgical procedures and techniques are the responsibility of the medical professional. The surgical team must evaluate the appropriateness of the procedure based on their experience. The outcome is dependent on many variables, including patient anatomy, pathology, surgical technique and anesthesia management.
- Although the device has been carefully designed, manufactured and inspected or tested prior to sale, the product may fail to perform its intended function satisfactorily for a variety of reasons. Warnings contained in the product labeling and in this document provide more detailed information and should be read by the user prior to use of product.

Precautions:

- Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.
- The Instructions for Use are furnished for information purposes only.
- Product is Ethylene Oxide sterilized.

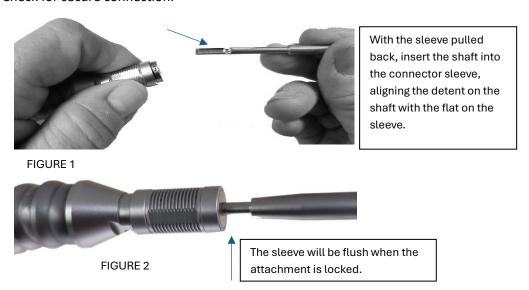
- Sterile unless package is opened or damaged.
- This device is a temporary device and cannot be implanted.
- This device does not contain latex.

Adverse Effects:

None known.

Instructions For Use:

- 1. Carefully read instructions prior to use.
- 2. Inspect package and product for damage and expiration date prior to opening the package.
- 3. If undamaged and unexpired, open the package and transfer the product onto the sterile field utilizing aseptic technique.
- 4. Attach the Heart Assist Finger to a Reusable Surgical Arm.
 - > Slide the sleeve of the Reusable Surgical Arm back towards the arm and insert the shaft of the Heart Assist Finger into the connector sleeve/quick connect with the detent on the shaft (of the attachment) facing the flat area on the sleeve of the Reusable Surgical Arm (see Figure 1).
 - Release the sleeve to its original position to lock in the Heart Assist Finger. The sleeve must be completely forward and flush with the connector (see Figure 2).
 - Check for secure connection.



- 5. The Heart Assist Finger can be bent to conform to anatomic requirements.
 - Note: Repeated bending of the malleable zone of the shaft will eventually cause the shaft to break. Slowly bending the malleable zone will increase the allowable range of deformation of the shaft.
 - Excessive flexing of the malleable zone may cause breakage.
- 6. Position the Heart Assist Finger as required. Turn the main handle of the Reusable Surgical Arm clockwise until the gap between the compression links closes. For further instructions refer to the instructions for use of the Reusable Surgical Arm.
- 7. Disengage the Heart Assist Finger from the Reusable Surgical Arm.
 - > Turn the main handle counter-clockwise to loosen the links of the arm.
 - Slide the sleeve of the Reusable Surgical Arm towards the arm and remove the shaft of the Heart Assist Finger from the connector sleeve/quick connect.
- 8. When finished, discard the Heart Assist Finger according to approved hospital procedures.

LIMITED WARRANTY AND DISCLAIMER OF LIABILITY

Chase Medical products ("Product") are manufactured under carefully controlled conditions and Chase Medical warrants the Product will perform in accordance with its labeling and will be free from defects in material and workmanship under normal use for one year from the date of shipment.

Chase Medical's sole liability shall be limited to replacement of, or credit for, any Product returned to Chase Medical and which Chase Medical determines, in its sole discretion, to have been defective in either material or workmanship at the time of shipment.

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Explanation of Symbols on Packaging Label

STERILE EO	Sterilized using Ethylene Oxide
	Double Sterile Barrier System
	Use-by Date
2	Do Not Re-Use
	Do not use if package is damaged and consult instructions for use

REF	SKU / Catalog Number
LOT	Lot Number
RONLY	Prescription only / Caution: Federal (US) law restricts this device to sale by or on the order of a physician
[]i	Consult Electronic Instructions for Use
LANEX	Natural Rubber Latex is Not Present

Manufactured for:



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900720, Rev 1

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