



REUSABLE SURGICAL ASSIST ATTACHMENTS
INSTRUCTIONS FOR USE

Catalog Number	Description
RAA-91126	Valve Assist Blade, Reusable, Stainless Steel, 11mm x 26mm
RAA-91526	Valve Assist Blade, Reusable, Stainless Steel, 15mm x 26mm
RAA-91826	Valve Assist Blade, Reusable, Stainless Steel, 18mm x 26mm

RAR-91924	Atrial Rake, Reusable, Stainless Steel, 19mm x 24mm
RAR-91924L	Atrial Rake, Reusable, Stainless Steel, 19mm x 24mm, Knurled, Long
RAR-92930	Atrial Rake, Reusable, Stainless Steel, 29mm x 30mm
RAR-93934	Atrial Rake, Reusable, Stainless Steel, 39mm x 34mm
RAR-93944	Atrial Rake, Reusable, Stainless Steel, 37mm x 46mm



Reusable Valve Assist Blade



Reusable Atrial Rake

Product Description:

The Reusable Surgical Assist Attachment is a stainless steel, manual positioning device for use with a Reusable Surgical Arm. This attachment is designed to provide access and exposure for a variety of surgical procedures.

Non-sterile, Reusable.

Indications For Use:

The Reusable Surgical Assist Attachment is used during surgery intended for atraumatic positioning and exposure of anatomical structures.

Contraindications:

- This device is not intended for use other than as indicated above.

Warnings:

- 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 device 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.

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.
- This device is packaged non-sterile and is steam sterilizable.
- This device is a temporary device and cannot be implanted.
- This device does not contain latex.

Cautions:

- Normal repeated use has minimal effect on these instruments. End of life is normally determined by wear and damage due to use or three years, whichever comes first.
- The World Health Organization recommends the longest exposure times when there is concern regarding HIV, TSE, CJD, etc. contamination. It is the user's responsibility to determine what contamination exists and what procedure is appropriate to ensure proper sterilization.

Adverse Effects:

- None known.

Instructions For Use:

1. Carefully read instructions prior to use.
2. Inspect device for damage prior to use.
3. Clean and steam sterilize the Reusable Surgical Assist Attachment prior to and after each subsequent use.
 - Chase Medical has no control over the conditions or contaminants the user will subject the instruments to, therefore it is the ultimate responsibility of the user to determine what cleaning and sterilizing methods and additional steps might be needed to properly remove all known and unknown organisms or contaminants. In all circumstances the user should closely follow the recommendations provided by the manufacturers of the cleaning/sterilizing products and equipment used.
 - **Never** allow organic materials or other contaminants to dry or get encrusted on the instrument.
 - **Always** process dissimilar metals separately including different grades of the same metals. Do not allow instruments to stand while touching each other.
 - **Always** wear appropriate safety protection and observe applicable safety procedures when handling, cleaning, and sterilizing surgical instruments.
 - **Pre-cleaning/Holding** – Thoroughly rinse instruments with warm distilled water immediately after use. If not possible to start the cleaning process immediately after use, apply a neutral-pH enzymatic solution for holding following the manufacturer's instructions, then rinse thoroughly before continuing disinfecting and cleaning. The manufacturer recommends Ruhof products.
 - **Disinfecting** – Immerse instruments in a suitable disinfectant approved for use on surgical instruments following the manufacturer's instructions. Rinse instruments thoroughly after disinfecting.
 - **Cleaning** – Instruments must be thoroughly cleaned before sterilization and have all organic materials, stains, rust, corrosion, and other contaminants completely removed. Regardless of the cleaning method used, stubborn particles will need to be removed manually by soaking in a suitable enzymatic cleaner following the manufacturer's instructions and then brushing with a Whisk'R Brush.
 - **Sterilization** – The most common method of sterilization is by autoclaving following the manufacturer's instructions. Some facilities use ethylene oxide gas sterilization which is not recommended, but if used, great care must be exercised with this hazardous chemical and the manufacturer's instructions followed closely. Cold sterilization is not recommended because of the risk of potential damage to the instruments resulting from the lengthy chemical action required.
 - **Industry Recommended Minimum Parameters for Wrapped Steam Sterilization:**
 - a) Pre-vacuum Type; 132°C (270°F); 3bar (28.5psi); 4-18 min exposure; 30+ min dry time.
 - b) Gravity Displacement: 121°C (250°F); 30-60min exposure; 45+ min dry time.
 - c) Load size, atmospheric, and other conditions may alter specifications. If stricter specifications are required by the user then those specifications should be used.
 - d) Instruments should be open and/or disassembled and carefully prepared in accordance with the sterilization equipment manufacturer's guidelines.
 - e) Equipment and procedures used for sterilization should be in compliance with ANSI/AAMI ST79, AST-MF1744 and ISO 17665, www.a-k-i.org.
 - f) It is the user's responsibility to validate the sterilization process used.

WARNING: Do not flash sterilize (IUSS – Immediate Use Sterilization in Surgical Settings) these instruments. The instruments have not been designed for flash sterilization. Discard instruments after suspected Creutzfeld-Jakob Disease (CJD) exposure – these instruments have not been designed to withstand the chemical and thermal exposures recommended to eradicate prions.

- **Storage:** Instruments should be stored individually or in a protective tray with partitions in a clean, dry location. Chase Medical’s custom sterilization tray, TRA-9000, sold separately, is designed to store and steam sterilize all Reusable Surgical Assist Attachments.

Marking: Medi-Mark tape may be used to color code instruments. Use caution when applying to not stretch tape or place in a location that inhibits the operation of the instrument.

4. **Attach the Reusable Surgical Assist Attachment to a Reusable Surgical Arm.**

- Slide the sleeve of the Reusable Surgical Arm back towards the arm and insert the shaft of the Reusable Surgical Assist Attachment 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 Reusable Surgical Assist Attachment. The sleeve must be completely forward and flush with the connector (see Figure 2).
- Check for secure connection.

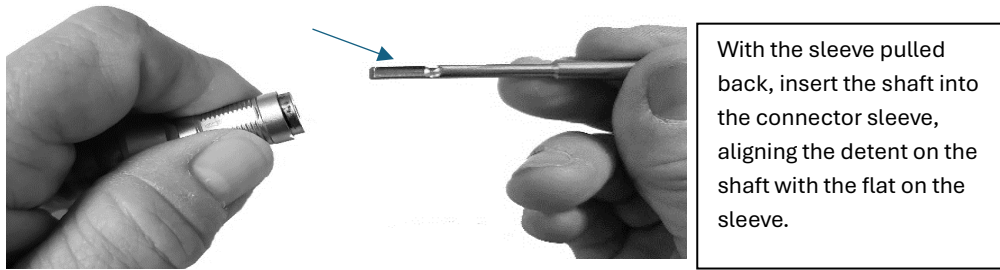


FIGURE 1

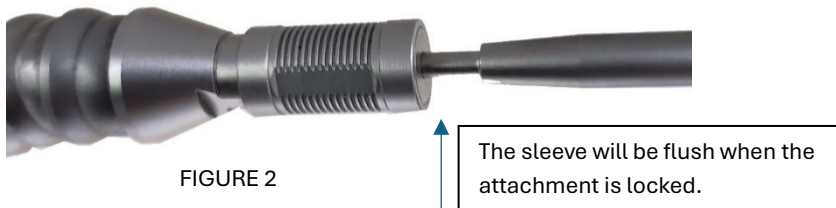


FIGURE 2

5. Position the Reusable Surgical Assist Attachment 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.
6. Disengage the Reusable Surgical Assist Attachment 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 Reusable Surgical Assist Attachment from the connector sleeve/quick connect.
7. When finished, clean and steam sterilize the Reusable Surgical Assist Attachment as shown in step 3.

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Explanation of Symbols on Packaging Label

	Non-sterile		SKU / Catalog Number
	Prescription only / Caution: Federal (US) law restricts this device to sale by or on the order of a physician		Lot Number
	Consult Electronic Instructions for Use		

Manufactured for:



800 E. Campbell Rd.
Suite 252
Richardson, Texas 75081 USA

(972) 783-7005 Tel
(844) 272-6624 Toll Free Fax
Email: info@chasemedical.com
<https://chasemedical.com/IFU>