

SmartRelease™ ECTR

Endoscopic Carpal Tunnel Release System

Instructions for Use



SmartRelease™
Endoscopic Carpal Tunnel Release **ECTR**

MICROAIRE®

TABLE OF CONTENTS

SYSTEM DESCRIPTION AND INTENDED USE	PAGE 1
SMARTRELEASE™ ECTR SURGICAL INSTRUMENTS AND ACCESSORIES	PAGE 2
SAFETY INFORMATION	PAGE 2
ENVIRONMENTAL PARAMETERS	PAGE 3
DEFINITIONS	PAGE 3
GENERAL WARNING AND CAUTIONS	PAGE 3
PRECAUTIONS	PAGE 3
INSTRUMENTATION ASSEMBLY	PAGE 4
ADJUSTING LIGHT AND FOCUS	PAGE 6
ENDOSCOPE FOCUS AND ALIGNMENT	PAGE 7
CAMERA-TO-ENDOSCOPE SET-UP GUIDE AND SUGGESTED SURGICAL SET-UP	PAGE 7
CLEANING OF INSTRUMENTATION	PAGE 8
TROUBLESHOOTING GUIDE FOR FOGGING	PAGE 12
ORDERING INFORMATION	PAGE 13
WARRANTY, SERVICE AND REPAIR	PAGE 14

SYSTEM DESCRIPTION AND INTENDED USE

The MicroAire® SmartRelease™ Endoscopic Carpal Tunnel Release System (ECTR) is comprised of an endoscope and a handpiece that holds a disposable blade assembly. The ECTR attaches to any standard video camera and light source used in endoscopic/arthroscopy procedures. The surgeon introduces the ECTR blade assembly into the carpal tunnel through an incision in the wrist flexor crease.* Viewing the deep side of the transverse carpal ligament (flexor retinaculum) through a window at the tip of the instrument, the surgeon elevates the blade to cut the ligament as the instrument is withdrawn.

When the carpal tunnel is released endoscopically with the MicroAire Endoscopic Carpal Tunnel Release System, clinical results indicate that postoperative morbidity is improved and time away from normal activities and full employment are reduced by as much as 46 percent.¹ The safety of this device has also been documented in a large clinical series involving over 1,000 cases in a 63 multicenter study.² The results of this study showed minimal complications.

For additional information, consult the **MicroAire Surgical Technique** (REF: IM-ECTR-TECH) brochure, the **MicroAire Surgical Technique and Anatomical Dissection** video. Endoscopic release of the transverse carpal ligament (flexor retinaculum) should not be attempted until the surgeon has been trained at a MicroAire-sponsored workshop or qualified training surgeon or trained on comparable device. Operating room staff should thoroughly review the **MicroAire SmartRelease ECTR Instructions for Use** (REF: IM-ECTR-IFU) prior to set up of this system.

Indications: The MicroAire Carpal Tunnel Release System is for use in patients diagnosed with carpal tunnel syndrome that is not associated with, or secondary to, any other known pathology (i.e., “idiopathic” carpal tunnel syndrome). Preoperative x-rays of the wrist, including a carpal tunnel view, are recommended to aid in the diagnosis of associated pathology (i.e., calcific tendonitis, fracture of the hook of the hamate). This device is indicated solely for releasing the transverse carpal ligament (flexor retinaculum).

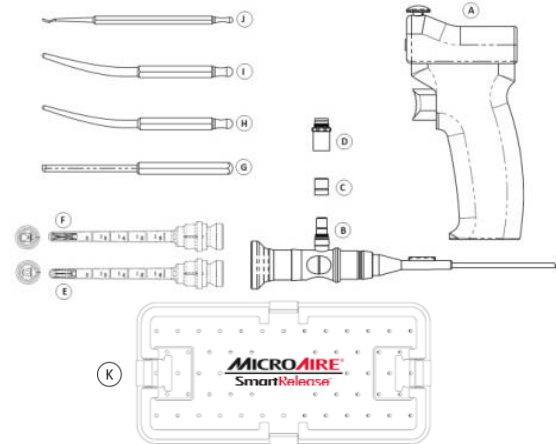

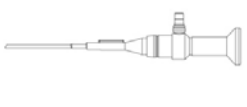
Contraindications: The MicroAire Endoscopic Carpal Tunnel Release System is not intended for use in patients with known abnormalities of their wrist (carpal tunnel), including distal radial deformities, rheumatoid and other synovitis.

* The MicroAire Carpal Tunnel Release System uses a dry procedure. No fluid or gas should be introduced into the carpal tunnel during this procedure.











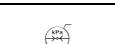



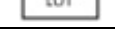
¹ Agee, JM et al. Endoscopic Release of the Carpal Tunnel: A Randomized Prospective Multicenter Study. *Journal of Hand Surgery*. 1992; 17(6):987-995.

² Agee, JM et al. Endoscopic Carpal Tunnel Release: A Prospective Study of Complications and Surgical Experience. *Journal of Hand Surgery*. 1995; 20A (2):165-171.

ECTR SURGICAL INSTRUMENTS AND ACCESSORIES

<p>SMARTRELEASE™ECTR INSTRUMENTS AND ACCESSORIES</p> <p>A) SmartRelease™ Aluminum Handpiece REF 81014 B) 3.0mm Eyepiece Autoclavable Endoscope REF 81025 B) Refurbished 3.0mm Eyepiece Autoclavable Endoscope REF 81025A C) Endoscope Light Post Adapter. Storz® / Olympus® fitting REF 81151 D) Endoscope Light Post Adapter, Wolf® / Dyonics® fitting REF 81152 E) Disposable SlimLine Blade Assembly REF 82020-1 or 82020-6 F) Disposable Blade Assembly REF 81010-1 or 81010-6 G) Hamate Finder Coequal to Disposable Blade Assembly REF 81061 H) Hamate Finder - Small REF 81026 I) Hamate Finder – Medium REF 81027 J) Synovium Elevator REF 81029 K) Instrument Sterilization Tray REF 81040</p>		
<p>OLDER ENDOSCOPES</p> <p>L) Video Endoscope REF 81020N L) Refurbished Video Endoscope REF 81020 M) Refurbished Autoclavable Endoscope REF 81023A (<i>exchange only</i>)</p>	<p>L) 81020 Video Endoscope</p> 	<p>M) 81023A Autoclavable Endoscope</p> 




SAFETY INFORMATION

MARKINGS DEFINITION	
	Attention, See Instructions For Use
	European Conformity Mark with MicroAire’s Notified Body Number
	DO NOT Lubricate
	DO NOT Immerse
	Lock
	Unlock
REF	Product Catalog Number
SN	Product Serial Number
	Date of Manufacture YYYY-MM
	Temperature Limitations
	Humidity Limitations
	Atmospheric Limitations
	Authorized European Representative
	Single Use
	Lot Number <i>Example: (1010175891)</i>
	Expiration Date YYYY-MM
	Latex Free

ENVIRONMENTAL PARAMETERS




OPERATING CONDITIONS

Device has been tested and proven to operate within the following conditions:

 <p>50° F/10° C 104° F/40° C</p>	 <p>0 91%</p>	 <p>86 106</p>
Temperature	Humidity	Atmospheric

SHIPPING AND STORAGE CONDITIONS

Device has been tested and proven to operate after repeated exposure to the following conditions:

 <p>0° F/18° C 120° F/49° C</p>	 <p>0 91%</p>	 <p>86 106</p>
Temperature	Humidity	Atmospheric

The materials and components used in the construction of this device were selected to ensure that the device could be shipped by any standard commercial method without special handling conditions.

DEFINITIONS

- **NOTE:** Used to point out the easiest means of carrying out techniques.
- **CAUTION:** Used to point out special procedures or precautions that must be followed to avoid damaging the system instrumentation.
- **WARNING:** Used to indicate that the safety of the patient and hospital personnel could be involved.

⚠ GENERAL WARNINGS AND CAUTIONS

- **WARNING:** Failure to lock the ECTR Blade Assembly in place may cause the ECTR Blade Assembly to separate from the ECTR Handpiece, which may injure the patient or damage the instrument.
- **WARNING:** Do not over-tighten screw-lock on blade; this may result in blade not retracting, which may injure the patient.
- **WARNING:** The blade is sharp; handle with care. Blade assembly should be properly disposed. **DO NOT re-sterilize blade assembly – it is designed for single use only.**
- **WARNING:** The MicroAire ECTR uses a dry procedure. No fluid or gas should be introduced into the carpal tunnel during this procedure. Fogging will occur as a result and visualization will be compromised.
- **CAUTION:** If the O-ring is not compressed, it does not form a moisture-proof seal and fogging will occur at the camera/endoscope interface.
- **CAUTION:** Do not use clamps or forceps when handling the endoscope.
- **CAUTION:** Do not handle the endoscope at the distal end. Grasp the camera mount end only.
- **CAUTION:** Do not place other items on top of the endoscope.
- **CAUTION:** Do not ultrasonically clean the endoscope or use solvents other than isopropyl alcohol.
- **CAUTION:** Other sterilization systems that are not listed have not been tested and no recommendations can be made.
- **CAUTION:** Do not steam autoclave the Video Endoscope.
- **CAUTION:** Soaking the Video Endoscope for longer than two hours may damage the Endoscope.
- **CAUTION:** Federal Law (USA) restricts this product sale by or on the order of a physician or hospital.

⚠ PRECAUTIONS

- Universal precautions for handling contaminated materials should be observed at all times.
- **DO NOT** lubricate or oil the handpieces.
- **DO NOT** immerse the handpiece in any fluid.
- **DO NOT** use high pH cleaning solutions unless they are approved for use with anodized aluminum and surgical instruments.
- **DO NOT** use cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.

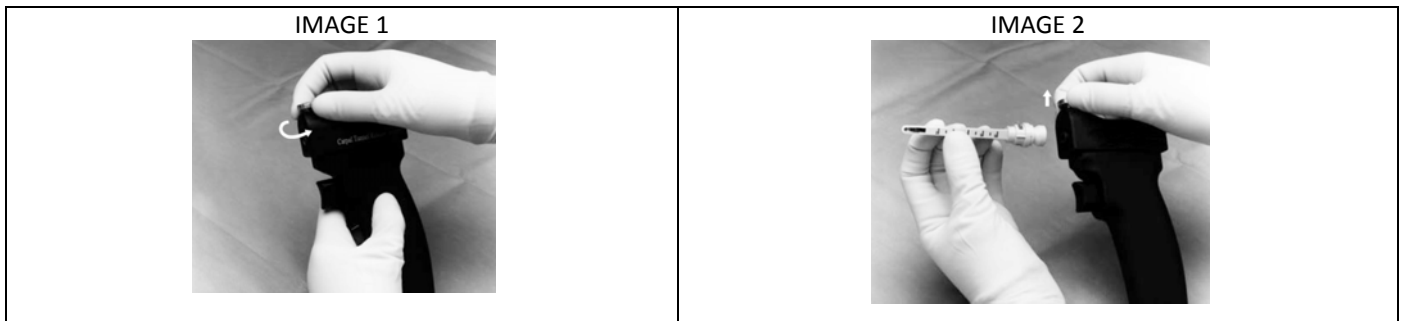
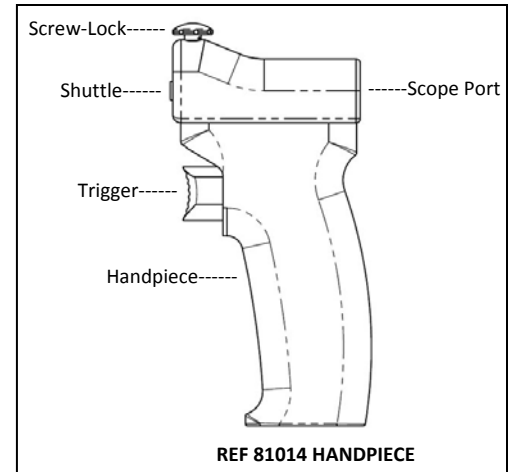
INSTRUMENTATION ASSEMBLY

The endoscope should always be protected when transported and stored. Dropping or bending the endoscope may damage the imaging system, which is costly to repair. The endoscope and ECTR Disposable Blade Assembly are not designed to be used as a lever or probe.

⚠ **CAUTION:** Small-diameter endoscopes are fragile.

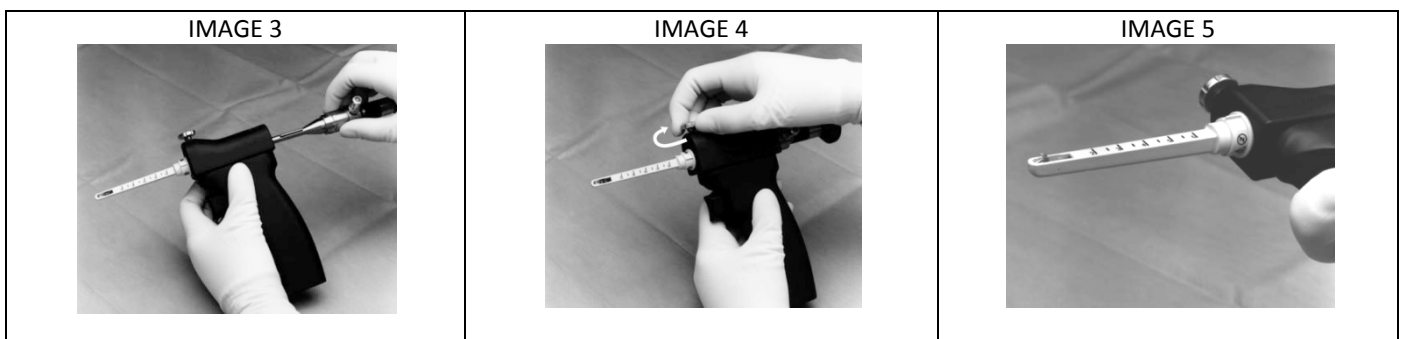
1. ASSEMBLY – DISPOSABLE BLADE ASSEMBLY INTO HANDPIECE

1. Turn the blade screw-lock on the top of the handpiece counterclockwise until it stops to ensure that it is unlocked (Ref: IMAGE 1).
2. Pull up and hold the screw-lock while aligning the disposable blade assembly with the shuttle inside the nose of the handpiece (Ref: IMAGE 2).
3. Insert the blade assembly onto the shuttle inside the handpiece, slight rotation of the blade assembly might be required in order to make the blade assembly seat properly. The blade assembly is keyed to the shuttle/handpiece.
4. Once blade has been inserted, release the screw-lock and turn clockwise until finger tight. **DO NOT** over-tighten.



2. ASSEMBLY – ENDOSCOPE TO HANDPIECE

1. Align the endoscope light post with the window on the Blade Assembly's tip. Carefully insert the endoscope into the rear of the handpiece (Ref: IMAGE 3). Blade assembly and scope are all keyed together, allowing for optimal endoscopic view.
2. Once the scope has been properly lined-up with the blade, push the scope into the seated position. An audible click indicates that the endoscope is properly seated. If the scope does not insert easily, rotate it until the unit slides in without resistance. **NOTE:** Do not force the endoscope into the handpiece and do not hit the distal end of the endoscope on the ECTR Handpiece.
3. If rotation is required due to right or left handed operation, simply loosen the screw-lock and rotate the blade assembly/endoscope to desired position.
4. Once desired position is achieved, release the screw-lock and turn clockwise until finger tight. (Ref: IMAGE 4).
 - ⚠ **WARNING:** Failure to lock the ECTR Blade Assembly in place may cause the ECTR Blade Assembly to separate from the ECTR Handpiece, which may injure the patient or damage the instrument.
 - ⚠ **WARNING:** Do not over-tighten screw-lock on blade; this may result in blade not retracting, which may injure the patient.
5. Check system, by activating trigger to check for smooth extension and retraction. Blade should extend about 3.5 mm above the flat surface, when trigger is released blade should retract. (Ref: IMAGE 5).
 - ⚠ **WARNING:** The blade is sharp; handle with care.



3. ASSEMBLY - ENDOSCOPE TO CAMERA

EYEPIECE ENDOSCOPE ASSEMBLY

If you are using the 81025, 81025A or 81023A endoscope, reference the following:

Attach the eyepiece endoscope to the camera coupler according to the recommendation of the camera manufacturer.

⚠ PRECAUTIONS

CAUTION: Do not use clamps or forceps when handling the Endoscope.

CAUTION: Do not handle the Endoscope at the distal end. Grasp the camera mount end only.

CAUTION: Do not place other items on top of the Endoscope.

VIDEO ENDOSCOPE ASSEMBLY

If you are using the 81020N or 81020 endoscopes, reference the following:

C-MOUNT THREADS

Assemble the Video Endoscope and Camera with C-Mount Threads. The Video Endoscope screws onto a camera with C-mount threads, after the C-mount lens coupler has been removed. *The ocular lens adapter (C-mount lens coupler) must be removed before attaching the camera to the Video Endoscope. The lenses in the ocular endoscope adapter will distort viewing if it is not removed, and it will not mechanically attach.*

V-MOUNT THREADS

On camera with V-mount threads, a V-mount adapter needs to be attached to the camera before attaching the Video Endoscope.

Turn the camera lock screw on the Video Endoscope counterclockwise until it stops to ensure that it is unlocked. (Ref: IMAGE 6)
Turn the knurled disc at the end of the Video Endoscope, threading the Endoscope into the camera until it is tight. (Ref: IMAGE 7)

⚠ **CAUTION:** If the O-ring is not compressed, it does not form a moisture-proof seal and fogging will occur at the camera/Endoscope interface.

NOTE: On cameras where the Endoscope O-ring does not press snugly against a flat surface on the camera face, another O-ring in addition to the current O-ring must be added to prevent fogging. Position the O-ring over the threads of the Video Endoscope and push down until the O-ring fits snugly around the base of the Endoscope's threads. When properly placed, the O-ring assures contact with the camera body threads to create a moisture-proof seal. (Ref: IMAGE 8)

⚠ PRECAUTIONS

CAUTION: Do not use clamps or forceps when handling the Endoscope.

CAUTION: Do not handle the Endoscope at the distal end. Grasp the camera mount end only.

CAUTION: Do not place other items on top of the Endoscope.

IMAGE 6



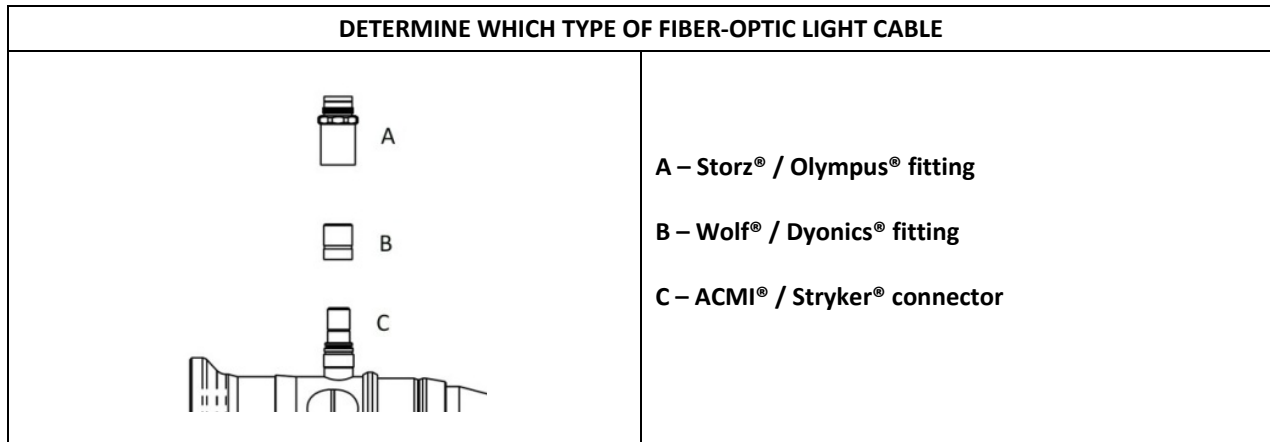
IMAGE 7



IMAGE 8



3. ASSEMBLY – ATTACHING LIGHT CABLE AND FINE-TUNING OPTICAL SYSTEM



ATTACHING THE FIBER-OPTIC LIGHT CABLE

1. Determine which type of endoscope fitting is installed on the fiber-optic cable, and choose one of the following options.
 - a. Adapter is not needed for the ACMI®/Stryker® light cable
 - b. If the light cable is a Storz®/Olympus® REF: 81151 will be required
 - c. If the light cable is a Wolf®/Dyonics® REF: 81152 will be required
 - d. If the fitting on the light cable is **none of the above**, adapters may be available from the light cable manufacturer.
2. Attach the fiber-optic cable to the endoscope.

⚠ **WARNING:** Do not use system without light cable properly attached.

NOTE: Tape or tie the light source and camera cables together to prevent tangling.

ADJUSTING LIGHT AND FOCUS

ADJUSTING WHITE BALANCE, FOCUS AND LIGHT INTENSITY

- a. Select automatic or manual mode to obtain optimal illumination. White balancing the system sets the color balance of the camera. This is usually accomplished by pressing the white balance button on the camera while focusing on a white surface placed on top of the ECTR Blade Assembly window. A white linen or gauze sponge may be used. You may see reflections in the background of the video image, usually when the light is at high intensity (e.g., when the light source is set in the automatic mode). These reflections disappear when tissue or another colored surface is placed over the window of the ECTR Blade Assembly. These reflections should not have an impact on the clarity of the video image during normal operation.
- b. To fine tune the illumination, a light-colored cloth towel may be placed over the viewing window. In automatic mode, the light source should compensate correctly for the camera needs.
- c. When working in the manual mode, adjust the light intensity until details of the cloth fibers are well defined.
- d. If the image is not clear, the endoscope should be replaced. If the view is obstructed, the ECTR Blade Assembly should be replaced. If the view remains unclear, the instrument should not be used. Return it for service.

ENDOSCOPE FOCUS AND ALIGNMENT

1. ADJUSTING THE EYEPiece ENDOSCOPE AND CAMERA

Turn the Eyepiece Endoscope in the coupler until the view is in correct alignment, so the “V” is at the bottom of the screen. Tighten the coupler lock screw and focus the camera coupler according to the recommendation of the camera manufacturer. Adjust the focus by using the focus ring on the coupler of the camera to focus the Endoscope.

2. ADJUSTING THE VIDEO ENDOSCOPE AND CAMERA

Adjust the camera and Video Endoscope by turning the camera until the view on the monitor is aligned so the “V” is at the bottom of the screen. Turn the camera lock screw on the Endoscope clockwise until tight to hold the view in place. Adjust the focus of the camera by turning the focus disc on the Endoscope until the desired clarity is achieved.

NOTE: If the image is not clear, the endoscope should be replaced. If the view is obstructed, the ECTR Blade Assembly should be replaced. If the view remains unclear, the endoscope should not be used. Return it for service.

NOTE: TROUBLESHOOTING GUIDE FOR FOGGING – Reference Page 13

CAMERA-TO-ENDOSCOPE SET-UP GUIDE

Please follow the guide below to determine the appropriate solution for connecting the camera to the endoscope. Depending on which type of camera and endoscope you use, this may vary.

TYPE OF ENDOSCOPE	SET-UP GUIDE
Eyepiece Endoscope*	Compatibility Tips
Camera cord orientation is 45° or 90°	Raise patient’s hand by placing rolled towel underneath to keep camera cord from hitting the forearm
Endoscope rotates within coupler	For Stryker® camera, add spacer (Stryker® Cat. #280-121) to coupler. Tighten locking mechanism
Picture size too small	Use a camera with coupler of longer focal length

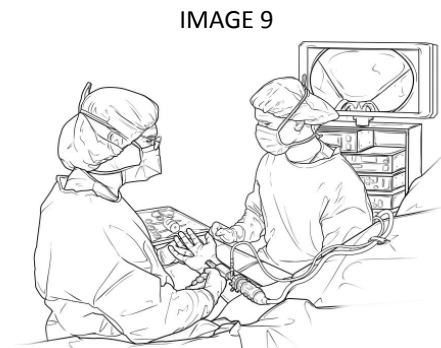
Video Endoscope**	Connecting Camera to Endoscope
C-mount camera	Screw on Endoscope directly (no adapters necessary)
V-mount camera	Use camera manufacturer-supplied V-C mount adapters

* Eyepiece Endoscope is compatible with most manufacturers’ cameras.

** If coupler cannot be removed or camera manufacturer advises against coupler removal, use the Eyepiece Endoscope.

SUGGESTED SURGICAL SET-UP

The surgeon’s orientation with respect to the video monitor and the patient’s operative hand. The surgical suite should be set up to offer the surgeon the best view of the video monitor. The surgeon should be able to easily shift his/her gaze upward from the surgical field to the video image. (Ref: IMAGE 9)



INSTRUMENT CLEANING AND STERILIZATION INSTRUCTIONS *per ISO 17664:2004 & AAMI ST 81:2004*

⚠ **WARNING:** READ GENERAL WARNINGS

LIMITATIONS ON INSTRUMENT REUSE

Many of MicroAire's Instruments and Accessories are reusable; however, they have a limited life span. Prior to and after each use, the instruments must be inspected where applicable for sharpness, wear, damage, proper cleaning, corrosion and integrity of the connecting mechanisms. Particular care should be paid to rigid endoscope; these instruments are fragile and require special care.

1. DISASSEMBLY

1. Disconnect the light cable from the endoscope.
2. Carefully detach the endoscope/camera from the ECTR Handpiece by grasping the exposed portion of the endoscope and pushing against the ECTR Handpiece with the thumb and index finger until the endoscope is released. Pull the endoscope straight out, taking care not to bend the endoscope lens.
3. Detach the endoscope from the camera.
4. Loosen the blade lock screw. Pull up and hold the blade lock screw while pulling out the ECTR Disposable Blade Assembly.
5. Blade assembly should be properly disposed of in appropriate container. **DO NOT re-sterilize blade assembly – it is designed for single use only.**

2. POINT OF USE

1. Excess blood or debris should be wiped off to prevent it from drying onto the surface.
2. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning (MAXIMUM 30 minutes).
3. Blade assembly should be properly disposed of in appropriate container. **DO NOT re-sterilize blade assembly – it is designed for single use only.**

3. PREPARATION FOR DECONTAMINATION

1. Decontamination of reusable instruments or accessories should occur immediately after completion of the surgical procedure.
2. Disassemble endoscope from handpiece and disassemble light-post adapters from endoscope.

CLEANING OF INSTRUMENTATION

INSTRUMENTS: REF 81014, REF 81025, REF 81025A, REF 81151, REF 81152, REF 81061, REF 81026, REF 81027, REF 81029, REF 81040, and REF 81023A.

To avoid contact between devices utilize the MicroAire sterilization case REF: 81040 (Ref: IMAGE 10)



CLEANING: MANUAL

1. Clean the ECTR Handpiece, Hamate Finders, and Synovium Elevator thoroughly with warm (> 60°C / 140°F) water, pH-neutral enzymatic detergent, and a soft brush. Scrub the ECTR Handpiece with the brush, paying close attention to instrument crevices.
2. Scrub the endoscope and adapters with a soft brush in a solution of mild soap and water. Rinse and dry thoroughly.

CAUTION: Do not ultrasonically clean the endoscope or use solvents other than alcohol.

NOTE: Clean the lenses of the endoscope at the tip, camera-mount, and fiber-optic light ends with a cotton swab moistened in isopropyl alcohol to assure a clear endoscopic view.

NOTE: Do not use hard brushes, abrasives or strong chemical solutions to clean the ECTR Handpiece or instruments.

NOTE: Video Endoscope disinfectant cleaning instructions on page 12.
3. Rinse all items thoroughly under running (< 50°C / 122°F) water for a minimum of 2 minutes if possible, use distilled water for the final rinse.

CLEANING: AUTOMATED

⚠ **WARNING:** Do not use automated cleaning for the Video Endoscope REF 81020 or 81020N.

⚠ **WARNING:** READ GENERAL WARNINGS

1. Load the medical devices into the Washer Disinfector.
 - a) Avoid contact between devices (movement during washing could cause damage and washing action could be obstructed).
 - b) Arrange medical devices so that cannulations are not horizontal (to assist drainage).
2. The minimum recommended Washer/Disinfector cycle is below:

#	Title	Detergent	Minutes	Temp
1	Pre-Wash	Mild pH Enzymatic *	4	< = 50 °C (122 °F)
2	Rinse	None	1**	< = 50 °C (122 °F)
3	Wash	Mild pH	4	> = 60 °C (140 °F)
4	Drain for 1 minute minimum			
5	Rinse	None	2**	> = 60 °C (140 °F)
6	Drain for 1 minute minimum			
7	Thermal Disinfect	None	10	> = 93 °C (200 °F)
8	Drain for 1 minute minimum			

* Detergent can be omitted at the pre-wash stage if the equipment does not have this ability.

** If not using mild pH detergent, extend rinse time if possible to reduce possible degradation.

NOTE: Washer/Disinfectors should comply with the requirements of ISO 15883 (in preparation). They should be properly installed and be regularly tested in accordance with ISO 15883

NOTE: Video Endoscope REF 81020 or 81020N disinfectant cleaning instructions on page 12.

DISINFECTION

Disinfection is only acceptable as an adjunct to full terminal sterilization for reusable surgical instruments. See sterilization section.

DRYING

Wipe off any water from the instrumentation with a soft lint-free towel. Compressed air can also be used to dry the ECTR Handpiece

NOTE: Even surgical instruments manufactured from high grade stainless steel must be dried thoroughly to prevent corrosion. All devices must be inspected for cleanliness of surfaces, joints, and lumens, proper function, and wear and tear prior to sterilization.

MAINTENANCE, INSPECTION AND FUNCTION TESTING

1. Carefully inspect each device to ensure that all visible blood and soil has been removed.
2. Visually inspect for damage and/or wear.
3. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
4. Where instruments form part of a larger assembly, check that the devices assemble with mating components.

NOTE: If concerns are noted that may compromise the function of the device, please contact your MicroAire representative.

PACKAGING

1. Single Instruments – A standard medical grade steam sterilization wrap may be used. Ensure that the wrap is large enough to contain the instrument without stressing the packaging. (ANSI/AAMI ST79-2010)
2. Sets of Instruments – Sets of instruments may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI double wrap method. (ANSI/AAMI ST79-2010)

STERILIZATION

Steam sterilize using one of the below cycles. The following steam parameters have been found to be successful in demonstrating a sterilization assurance level (SAL) of at least 10^{-6} .

⚠ **WARNING:** Do not autoclave the Video Endoscope REF 81020 or 81020N. See Video Endoscope sterilization on page 12.

GRAVITY-DISPLACEMENT STEAM	Instrument / Accessory Only	In Sterilization Case
Exposure Time	30 minute Full Cycle	35 minute Full Cycle
Exposure Temperature	270-275°F (132-135°C)	
Minimum Dry Time	8 minutes	
Materials	Single wrapping in a standard central supply wrap	

PREVACUUM-STEAM	Instrument / Accessory Only	In Sterilization Case
Exposure Time	4 minute Full Cycle	5 minute Full Cycle
Exposure Temperature	270-275°F (132-135°C)	
Minimum Dry Time	8 minutes	
Materials	Single wrapping in a standard central supply wrap	

"FLASH" GRAVITY-STEAM	Instrument / Accessory Only
Exposure Time	11 minute Full Cycle
Exposure Temperature	270-275°F (132-135°C)
Minimum Dry Time	8 minutes
Materials	Single wrapping in a standard central supply wrap

"Flash" sterilization:

Surgical centers that wish to steam sterilize patient care items for immediate use shall at a minimum follow the requirements as outlined in ANSI/AAMI ST79:2010. Reduction of bioburden and removal of gross soil are essential steps in preparing an item for sterilization by any method. Please follow the steps for decontamination of the instrument prior to any sterilization process including "Flash" sterilization. The processed items must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use. There is NO storage or shelf life of flash-sterilized items because of the probability of contamination after the sterilizer door is opened and the items are removed. When performed correctly, flash sterilization is safe and effective for sterilization of medical devices (AAMI ST79:2010).

Re-usable surgical instruments with moving parts require a dry cycle to keep the product functioning appropriately. "Flash" Gravity-Steam sterilization with NO dry time is NOT recommended as a normal process of sterilization.

After steam sterilization, cool down to room temperature without additional cooling. Sudden changes in temperature may damage the endoscope.

⚠ PRECAUTIONS

CAUTION: Do not ultrasonically clean the endoscope or use solvents other than isopropyl alcohol.

CAUTION: DO NOT exceed a temperature of 280° F (138° C).

NOTE: Video Endoscope REF 81020 or 81020N disinfectant cleaning instructions on page 12.

OTHER STERILIZATION METHODS

⚠ **CAUTION:** Other sterilization systems have not been tested and are not recommended.

VIDEO ENDOSCOPE CLEANING

INSTRUMENTS: REF: 81020 OR 81020N

SOAK DISINFECT THE VIDEO ENDOSCOPE

Carefully immerse the Video Endoscope, making sure that the delicate part of the Endoscope is protected during soaking. It is recommended that the endoscope and camera should be cleaned, dried and assembled before soak disinfecting together to avoid fogging of their adjacent lenses. Fogging compromises the quality of the video image during surgery. If the Endoscope and camera are disinfected separately, each instrument must be dried thoroughly before assembling to avoid fogging. Follow the solution manufacturer's recommendations for soaking time, but do not exceed two hours. Always transport the Endoscope with the endoscope protection sleeve locked in place and store the Endoscope in the foam-lined sterilization tray.

NOTES: Soaking solutions are recommended to disinfect only the Video Endoscope REF: 81020 OR 81020N.

⚠ PRECAUTIONS

CAUTION: Do not steam autoclave the Video Endoscope REF: 81020 OR 81020N.

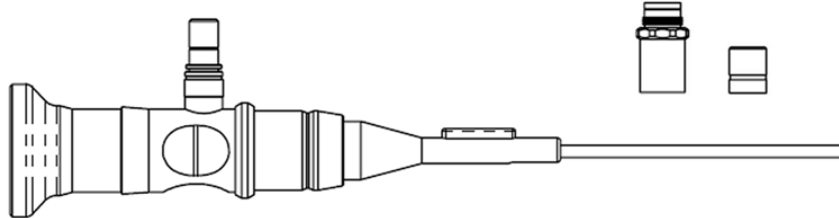
CAUTION: Soaking the Video Endoscope REF: 81020 OR 81020N for longer than two hours may damage the endoscope.

CAUTION: Other sterilization systems such as Sterrad® have not been tested and no recommendations can be made.

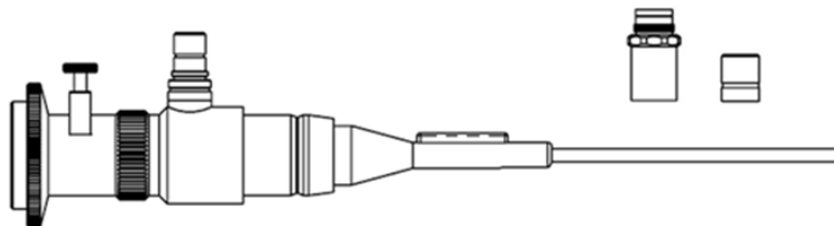
CAUTION: Do not move any of the Video Endoscope's REF: 81020 OR 81020N rotating parts while the Endoscope is immersed.

CAUTION: Do not ultrasonically clean the Video Endoscope REF: 81020 OR 81020N or use solvents other than isopropyl alcohol.

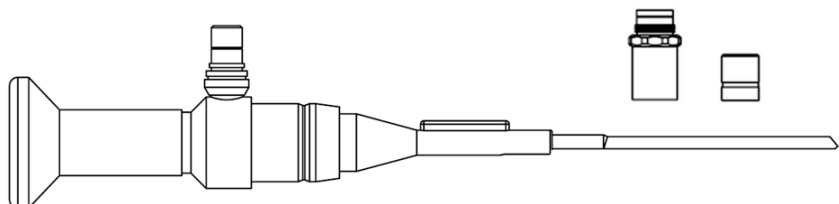
81025 AUTOCLAVABLE ENDOSCOPE & LIGHT POST ADAPTERS



81020 VIDEO ENDOSCOPE & LIGHT POST ADAPTERS



81023 AUTOCLAVABLE ENDOSCOPE & LIGHT POST ADAPTERS



TROUBLESHOOTING GUIDE FOR FOGGING

In order to quickly identify the source of the fogging problem and formulate the appropriate solution:

1. Assemble and pre-warm the system by turning on the camera, light source and monitor, white balance and adjust the focus before the surgeon makes the skin incision to start the procedure (see Note 1 at bottom).
2. Observe for any sign of fogging.
3. Follow the troubleshooting steps below if problems occur.

Condition	Cause	Solution	Prevention
Fogging—before insertion into carpal tunnel	Moisture inside camera coupler and endoscope lens interface. A single drop of moisture can cause fogging at this juncture.	Disassemble and thoroughly dry endoscope lens and camera coupler interface with alcohol or anti-fog agent and sterile cotton swab (see Note 1).	Pre-warm system by connecting light source and camera before surgeon makes the skin incision (see Note 2). Use anti-fog agent to dry before assembly. Thoroughly dry endoscope lens and camera coupler interface with cotton swab before assembly.
	Moisture trapped within endoscope between endoscope lens optics and endoscope eyepiece.	Return to MicroAire Repair Center for repair.	Protect scope in its autoclave case (for Eyepiece Endoscope) or protection sleeve (for Video Endoscope) during processing or when not in use (see Note 3).
Fogging—after insertion into carpal tunnel	Condensation due to temperature difference between endoscope, ECTR Handpiece and patient's tissue.	Attempt to warm scope to patient's tissue temperature: 1. Keep device inside tunnel until scope warms to body temperature, approximately 45 seconds. 2. Dip or wipe scope tip in sterile anti-fog agent and wipe dry.	Pre-warm system by connecting light source and camera before surgeon makes the skin incision (see Note 2). For the Eyepiece Endoscope: If there is sufficient time between processing and the skin incision, allow endoscope to air dry in its autoclave case between procedures.
	Moisture inside camera coupler and endoscope lens interface. A single drop of moisture can cause fogging at this juncture.	Disassemble and thoroughly dry endoscope lens and camera coupler interface with alcohol or anti-fog agent and sterile cotton swab (see Note 1).	For back-to-back cases without sufficient time between processing and the skin incision, place the ECTR Handpiece and instruments into pan of sterile room temperature water/saline immediately following autoclaving (see Note 4).
	Excess fluid inside carpal tunnel.	Soak up fluid with sterile cotton swab.	Avoid injecting anesthetics into the carpal tunnel. Be sure endoscope is completely dry after processing.
	Moisture trapped within endoscope between scope lens optics and scope eyepiece.	Return to MicroAire Repair Center for repair.	Protect endoscope in its autoclave case (for Eyepiece Endoscope) or protection sleeve (for Video Endoscope) during processing or when not in use (see Note 3).
Fuzzy or no picture	Damaged endoscope.	Return to MicroAire Repair Center for repair.	Protect scope in its autoclave case (for Eyepiece Endoscope) or protection sleeve (for Video Endoscope) during processing or when not in use (see Note 3).

OTHER TROUBLESHOOTING TIPS

Condition	Cause	Solution	Prevention
Blade fails to retract	Lock screw over-tightened.	Release blade lock screw, using scope to view blade to ensure blade retraction. If blade remains extended, separate the ECTR Blade Assembly from ECTR Handpiece, leaving the Blade Assembly in carpal tunnel. If blade is still extended, do not remove from tunnel; convert to open procedure.	Tighten blade lock screw until finger tight. Do not over-tighten. May result in blade not retracting.
Sticky trigger	Debris lodged around trigger or handpiece needing maintenance.	Clean device If trigger continues to stick contact MicroAire.	Send handpiece back to MicroAire for maintenance and update.

NOTE:

1. Beware of contamination caused by disassembling the camera and the endoscope in the sterile field.
2. Assembly and pre-warming of the system prior to surgery helps prevent fogging due to temperature difference between the endoscope, ECTR Handpiece, and patient's tissue. In addition, this step serves to check the equipment's functionality and the clarity of the visualization system before the surgeon makes the transverse incision to start the procedure.
3. Proper handling of delicate instruments extends the life expectancy of the endoscope. Always store the endoscope in its autoclave case for processing and between uses.
4. Do not place the endoscope into cool sterile water or saline immediately following autoclave completion. The extreme temperature differences could cause damage to the scope. The scope will quickly cool down on its own following autoclaving.

ORDERING INFORMATION

81000 SERIES COMPONENTS

Catalog Number	Description
81014	SmartRelease™ Aluminum Handpiece
81026	Hamate Finder- Small
81027	Hamate Finder – Medium
81061	Hamate Finder Coequal to Disposable Blade Assembly
81029	Synovium Elevator
81040	Instrument Sterilization Tray
81025	3.0 mm Eyepiece Autoclavable Endoscope
81020N	Video Endoscope (<i>Non-Autoclave</i>)

DISPOSABLE BLADE

Catalog Number	Description
81010-6	ECTR Disposable Blade Assembly (1 Box with 6 Blades per Box)
81010-1	ECTR Disposable Blade Assembly (1 Blades)
82020-6	ECTR SlimLine Blade Disposable Blade Assembly (1 Box with 6 Blades per Box)
82020-1	ECTR SlimLine Blade Disposable Blade Assembly (1 Blades)

REFURBISHED ENDOSCOPES*

Catalog Number	Description
81025A	Refurbished Eyepiece Autoclavable Endoscope (<i>exchange only</i>)
81020	Refurbished Video Endoscope (<i>Non-Autoclave</i>)

PARTS & ACCESSORIES

Catalog Number	Description
81151	Endoscope Light Post Adapter, Storz®
81152	Endoscope Light Post Adapter, Wolf®

SUGGESTED FIRST TIME ORDER KIT

Catalog Number	Description
81014	– SmartRelease™ Aluminum Handpiece
81025	– 3.0 mm Eyepiece Autoclavable Endoscope (<i>includes light post adapters</i>)
81026	– Hamate Finder- Small
81027	– Hamate Finder- Medium
81061	– Hamate Finder- Coequal to Disposable Blade Assembly
81029	– Synovium Elevator
81040	– Instrument Sterilization Tray

* Refurbished endoscopes are not sold without a core endoscope exchange

WARRANTY, SERVICE AND REPAIR

WARRANTY

MicroAire Surgical Instruments warrants the SmartRelease Endoscopic Carpal Tunnel Release System to be free from defects in material and workmanship in their manufacture for a period of 90 days from the original purchase date by the end customer. The warranty is limited to the repair or replacement of the product without charge.

This warranty is void in the event of abuse, misuse, or use in other than a normal surgical environment, or in the event of disassembly, alteration, or repair of the product not authorized by Manufacturer, or in the event that the product has not been used in a reasonable manner and in compliance with the written instructions furnished by Manufacturer.

All other expressed or implied warranties and all other warranties of fitness or merchantability are excluded here from, and Manufacturer shall have no liability of any kind for incidental or consequential damages.

WARNING: Repairs or alterations to MicroAire products made by anyone other than MicroAire or an Authorized MicroAire Repair Facility will void that product's warranty, and the customer will be responsible for any costs related to returning the product to working condition.

EXTENDED WARRANTY

Extended warranties may be purchased while the equipment is covered by the original warranty. If the equipment is out of warranty, it must first be restored, if necessary, to full serviceable condition before being eligible for a service agreement.

Periodic inspection and service is essential to keep precision MicroAire instruments running properly. If repairs are required, they can be accomplished quickly with a minimal disruption to the hospital's schedule.

REPAIR AND SERVICE

Responsive service comes with every MicroAire product. If a problem with your equipment should arise, contact our Customer Service Department at:

	Telephone:	Fax:	Email:
USA:	800-722-0822	800-648-4309	inquiry@microaire.com
Outside USA:	434-975-8000	434-975-4134	intlsvc@microaire.com

NOTE: Mailing address information located on back cover.

We may be able to help solve the problem quickly without requiring return of the item for service. DO NOT disassemble or attempt to service the equipment. It can only be serviced by MicroAire or an Authorized MicroAire Repair Facility. Unauthorized service will void the warranty.

To return an item for service, follow this procedure:

1. Contact Customer Service for a Return Material Authorization (RMA) number. **NOTE:** DO NOT return equipment without an RMA number. This could cause delays in service, and/or problems tracking your return.
2. Clean and disinfect equipment before sending for repair.
3. Along with the items sent for repair, enclose a detailed description of the problem encountered, the type of use, the place of use, a contact name, and a telephone number. This information is helpful to our repair technicians.
4. If the instrument is out of warranty, enclose a purchase order number with the instrument. If the instrument is under warranty, include the purchase date.
5. In the United States, ship the merchandise by Express Mail, Federal Express, or UPS Blue Label to prevent shipping delays. From outside the United States return goods by Federal Express, UPS, or Air Freight.
6. Return the merchandise prepaid.
7. If an estimate of repair costs is needed before the repair technicians start work, include the name and telephone number of the person to contact.
8. We will repair and reship the item by 2nd Day Air within the United States and by Federal Express or Air Freight outside the U.S. unless specified otherwise.

PERIODIC INSPECTION

Because of the stressful nature of surgical use, decontamination, and sterilization, we recommend that all instruments be returned for routine inspection and service at least once a year. There is no charge for service during the warranty period.

Storz® Registered Trademark of KARL STORZ GmbH & Co.
Olympus® Registered Trademark of Olympus America Inc.
Wolf® Registered Trademark of Richard Wolf Medical Instruments Corporation
Dyonics® Registered Trademark of Smith & Nephew
ACMI® Registered Trademark of Olympus America Inc.
Stryker® Registered Trademark of Stryker
Steris® Registered Trademark of Steris Corporation
Sterrad® Registered Trademark of Advanced Sterilization Products Division of Ethicon, Inc.
These companies are not affiliated with MicroAire Surgical Instruments LLC.




PATENT #: 4,962,770; 4,963,147; 5,089,000; 5,306,284 and Patents pending

Service

Ship instruments to:
MicroAire Surgical Instruments
1641 Edlich Drive
Charlottesville, VA 22911
(1)800-722-0822

Made in USA
Scope Made in Germany

CAUTION: Federal Law (USA) restricts this product sale by or on the order of a physician or hospital.

 MICROAIRE® 1641 EDLICH DRIVE CHARLOTTESVILLE, VA 22911 Phone: (800) 722-0822 (434) 975-8000 International Phone: +001 434 975 8000 Order Fax: (800) 648-4309 or (434) 975-4131 USA +001 434 975 8000 www.microaire.com	 MEDIMARK EUROPE 11, RUE EMILE ZOLA BP2332 F-38033 GRENOBLE CEDEX 2 FRANCE  0086
---	--