

URGENT: MEDICAL DEVICE RECALL

Page 1 of 2



MicroAire Surgical Instruments, LLC
3590 Grand Forks Boulevard
Charlottesville, Virginia 22911 USA

Phone: 434 975 8000
Fax: 434 975 4131
www.microaire.com

[DATE]

«Customer No: Sold_To»*«Ship To»
«Cust_Name»
«Shipped_Addr1»
«Shipped_Addr2»
«Shipped_Addr3»
«Shipped_City», «Shipped_State» «Shipped_Zip»

Attention: «Contact_Name» or Recall Coordinator

Dear Customer:

This letter is to advise you that MicroAire Surgical Instruments is performing a limited recall of the SmartRelease Endoscopic Carpal Tunnel Release Handpiece (ECTR handpiece), parts 81014/ 83014. We are recalling the ECTR handpieces that were assembled between January – April 2019, because of a higher than normal incidence rate of the blade not retracting, when tightening. Our records indicate your facility has received this product, and we therefore ask that you review this letter and take the action as indicated.

Please note that the associated Instructions for Use (“SmartRelease Endoscopic System, Endoscopic Carpal Tunnel Release, Instructions for Use,” IM-SMARTRELEASE REV E) includes many statements that would already mitigate the problem, e.g.,

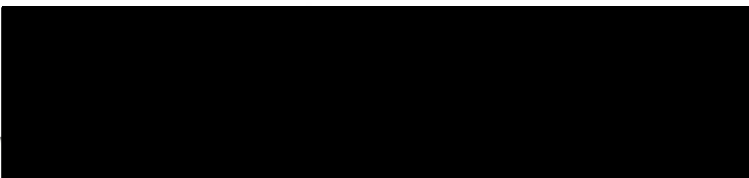
- “Once Blade Assembly has been inserted, release the screw-lock and turn clockwise until finger tight. DO NOT over-tighten.”
- “[after assembly] Check system by activating trigger to check for smooth extension and retraction.... when trigger is released blade should retract.”
- “[Other Troubleshooting Tips] Blade fails to retract [due to] lock screw over-tightened. [Solution is to] Release blade lock screw, using scope to view blade to ensure blade retraction. If blade remains extended, separate the blade assembly from SmartRelease Handpiece, leaving the Blade Assembly in carpal tunnel. If blade is still extended, do not remove from tunnel, convert to open procedure.”
- “[Prevention] Tighten Blade lock screw until finger tight. Do not over-tighten. May result in blade not retracting.”

Regardless of the above IFU information, to be on the safe side, MicroAire is performing this recall and asking that you please complete and send back page two of this letter to notification@microaire.com or via fax at 800-648-4309. We will rework the handpiece (by replacing the handpiece head) and return it to you.

If you have any questions about this Recall, please contact MicroAire Customer Service at 1-800-722-0822 between the hours of 8:30 AM and 5:00 PM (EST) Monday through Friday.

We apologize for this inconvenience and are taking the proper steps to ensure that this will not happen in the future.

Sincerely,



A COLSON ASSOCIATE

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Page 2 of 2



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«Shipped_City», «Shipped_State» «Shipped_Zip»

Attention: «Contact_Name» or Recall Coordinator

SmartRelease Endoscopic Carpal Tunnel Release Handpiece (ECTR handpiece), parts 81014/ 83014.

PLEASE COMPLETE AND RETURN THIS PAGE TO MICROAIRE IMMEDIATELY

Fax: 1-800-648-4309 or Email: notification@microaire.com

As per the Recall, we are requesting that you respond to this letter immediately by placing a ✓ mark in the applicable column for each Serial Number listed:

Part Number	Serial Number	Product is NOT in our inventory	Product is in our inventory & WILL BE RETURNED to MicroAire for service	Product is in our inventory but WILL NOT be returned to MicroAire for service (include reason product will not be returned)

Please fill in the information below:

If the address at the top of the page is not the address where the instrument is located, please provide the correct address below:

Name (print): _____

Facility Name: _____

Signature: _____

Street Address: _____

Date: _____

Address Line 2: _____

Phone: _____

City: _____

Email: _____

State: _____ Zip: _____



A COLSON ASSOCIATE