Apyx MEDICAL
(formerly Bovie Medical)

FA-2020-1
April 23, 2020

URGENT MEDICAL DEVICE FIELD SAFETY NOTIFICATION

Handpiece	Catalog Numbers	Lot Number
Renuvion/J-Plasma Precise Handpiece	BVX-150B, BVX-270B, BVX-330B, BVX-270BPP, BVX-330BPS, APYX-150B, APYX-270B, APYX-330B, APYX-270BPP, APYX-330BPS	All lots within expiration date
Renuvion/J-Plasma Precise Open Handpiece	BVX-044-BPS, BVX-044-BPP, BVX-150-BPP, BVX-150-BPS, APYX-044-BPS, APYX-044-BPP, APYX-150-BPP, APYX-150-BPS	All lots within expiration date

Dear Valued Customer,

This letter is to inform you that Apyx Medical (formerly Bovie Medical) is initiating a voluntary field safety notification related to the clinical use practices of the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	Apyx Medical has recently received four reports of unexpected stress fractures on the shaft of the handpiece resulting in fragmentation during clinical use.
IMPACT:	▪ When a full thickness stress fracture occurs at the distal end of the handpiece shaft, the result can be delamination of the shaft into one or several pieces. ▪ We are aware of four events occurring worldwide, all in Latin America, with two of the four cases leading to additional surgical intervention to remove the fallen fragment from the patient.
ACTIONS REQUIRED BY YOU:	1. **Follow the cleaning instructions provided in the Instructions for Use (IFU)** to remove coagulum/eschar from the blade during clinical use: "*For optimum performance, keep the distal end of the shaft free of debris. A damp gauze pad can be used for cleaning. Do not activate while cleaning the tip*". 2. **Do Not clean the blade with a scratch pad or other abrasive material** as a full thickness stress fracture may result from inadvertently filing down the shaft while cleaning the blade. 3. **Follow the Warnings in the IFU before, during or after clinical use** to avoid breakage, weakness or damage of the handpiece ["*This medical device cannot be effectively cleaned and/or sterilized by the user and therefore cannot be safely reused. It is intended for single use only. Reprocessing (cleaning, disinfection and sterilization) may compromise essential material and design characteristics as well as the structural integrity of the device and lead to device failure, bio-incompatibility, infection, or other risks of device failure to the patient"*]: ○ Do Not clean the handpiece with any chemicals, solvents, cleaning agents, disinfection agents or ad hoc cleaning methods. ○ Do Not reuse the handpiece on other patients as it is intended for single use only; Discard the handpiece after each use on a patient (one handpiece per patient). ○ Do Not reprocess, disinfect, sterilize or clean the handpiece for further reuse. ○ Do Not resterilize the handpiece with steam or gas or any other method whether inside your facility or by a 3rd party. 4. **Do Not modify or alter the tip of the device**. 5. Do Not use a cannula or a skin port that has tight interference with the outer diameter of the shaft of the device.

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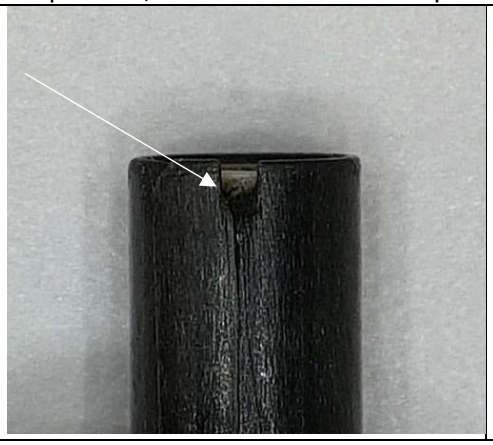
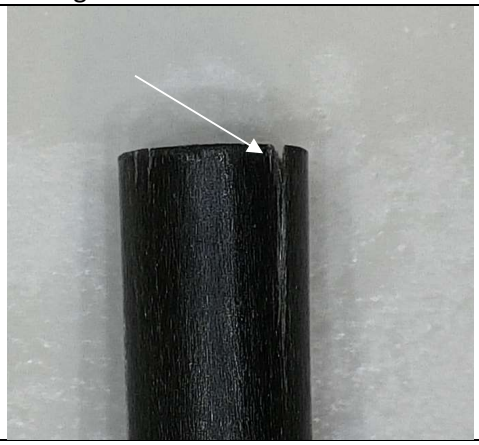
	6. **Discontinue using the handpiece if during clinical use you observe a stress fracture develop as depicted in Figures 1 & 2 below**. 7. Immediately report to us and return any devices that exhibit this issue during clinical use.
RESOLUTION:	Apyx Medical will further update the Instructions for Use to provide warnings and cautions for points 2, 4 & 5 for care the handpiece during clinical use.
FIGURES:	 

Please share this information with your Operating Room staff and retain this notification as part of your Device Quality documentation. If you have forwarded any of the affected product(s) listed above to another facility, please provide them a copy of this letter.

Apyx Medical has notified the appropriate regulatory agencies and competent authorities of this issue.

Please complete and return the enclosed Response Form as soon as possible but no later than May 1, 2020 so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact:

- By email: CustomerService@ApyxMedical.com
- By phone: 1-800-537-2790 in the United States and Canada, Monday through Friday, 8:00 AM to 5:00 PM, EST.
- Outside the United States and Canada, contact your local Distributor or Representative.

Apyx Medical considers patient safety and customer satisfaction our primary priority. We appreciate your time and attention in reading and acting upon this important notification.

Sincerely,

Dr. Topaz Kirlew, MBA, MT(ASCP)
Vice President, Regulatory Affairs & Quality Assurance

Enclosure: Response Form

URGENT MEDICAL DEVICE FIELD SAFETY NOTIFICATION
Acknowledgement and Receipt Form

Handpiece	Catalog Numbers	Lot Number
Renuvion/J-Plasma Precise Handpiece	BVX-150B, BVX-270B, BVX-330B, BVX-270BPP, BVX-330BPS, APYX-150B, APYX-270B, APYX-330B, APYX-270BPP, APYX-330BPS	All lots within expiration date
Renuvion/J-Plasma Precise Open Handpiece	BVX-044-BPS, BVX-044-BPP, BVX-150-BPP, BVX-150-BPS, APYX-044-BPS, APYX-150-BPP, APYX-150-BPS	All lots within expiration date

Instructions (when returning form via Email):

1. Select option 1 or 2 in the table below, enter the corresponding information and provide comments, as needed.
2. **Return the completed form to the email provided below as soon as possible but no later than May 1, 2020.**

Select Option 1 or 2:	
1. ☐	This does not apply because we no longer own a J-Plasma /Renuvion System Name of person completing the form: Name of facility: Date:
2. ☐	I have read and understood the medical device voluntary field safety notification related to the clinical use practices of the product listed above. • I will share this information with our Operating Room staff and retain this notification as part of our Device Quality documentation. • If I have forwarded any of the affected product(s) listed above to another facility, I will provide them a copy of this letter. Name of person completing the form: Name of facility: Date:

Comments:

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Instructions (when replying by Email):

1. Copy and paste the statement below as a reply to the email received.
2. Add name of person and facility acknowledging the notification and provide comments, as needed.
3. **Send email to email address below As soon as possible but no later than May 1, 2020**

Statement to be copied:
I have read and understood the medical device voluntary field safety notification related to the clinical use practices of the product listed above. I will share this information with the Operating Room staff and retain this notification as part of our Device Quality documentation. If I have forwarded any of the affected product(s) listed above to another facility, I will provide them a copy of this letter. Name of person completing the form: Name of facility: Date:

Comments:

Apyx Medical Contact information:

- By email: CustomerService@ApyxMedical.com
- By phone: 1-800-537-2790 in the United States and Canada, Monday through Friday, 8:00 AM to 5:00 PM, EST.
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