URGENT FIELD SAFETY NOTIFICATION
Bovie® J-Plasma® Handpieces

February 8, 2018

Product Name	Catalog Numbers
J-Plasma Precise® OPEN	BVX-044-BPP, BVX-044-BPS, BVX-150-BPP, BVX-150-BPS
J-Plasma Precise®	BVX-150B, BVX-150N, BVX-330B, BVX-330N, BVX-450B, BVX-450N
J-Plasma® Handpiece	BVX-270B
J-Plasma Precise 360®	BVX-330BR, BVX-330NR, BVX-450BR, BVX-450NR
J-Plasma Precise® FLEX	BVX-500BF
J-Plasma® Handpiece with Cable	GS-018C, GS-270C

Dear Customer,

Bovie Medical is initiating a voluntary field safety correction for all J-Plasma® Handpiece products on the market (catalog numbers listed above). This letter contains important information that needs your immediate attention.

ISSUE: Bovie Medical has become aware of an issue caused by incomplete insertion of the J-Plasma® handpiece cable plug into the generator receptacle. There have been no patient injuries reported as a result of this issue.

IMPACT: When the J-Plasma® handpiece with generator is used during surgical procedures without the cable plug being completely inserted into the generator, the green indicator light to the left of the receptacle will illuminate even with an incomplete cable plug insertion (green light indicates electrical connection resulting in handpiece activation but does not indicate a complete helium gas path seal).

The lack of a complete helium seal at the cable plug connection could result in:

- Patient body fluid back flowing into the handpiece, up the cable to the connector, and into the generator receptacle. The resulting risk is the potential cross-contamination when the generator is used again for subsequent patients. The likelihood of this risk has been determined to be low.
- Possible loss of the helium plasma stream which may cause an unintended tissue effect to the treatment area or a delay in the surgical procedure. The likelihood of this risk has been determined to be moderate.

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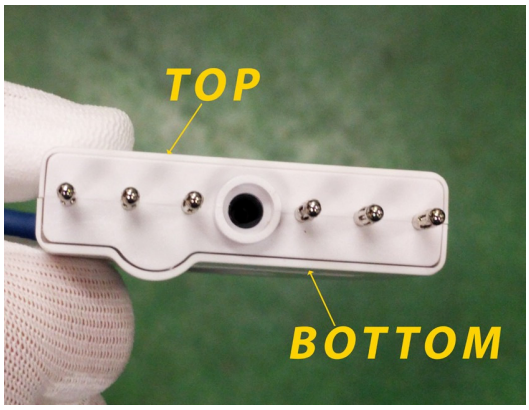
ACTIONS:

At the end of each procedure, inspect the handpiece cable plug and generator receptacle for the presence of fluids. If fluids are present, immediately discontinue use of the generator.

In addition to following the J-Plasma® handpiece Instructions for Use, immediately begin to follow the supplemental instructions provided below to ensure that the J-Plasma® handpiece cable plug is properly and completely inserted into the generator receptacle prior to use-

STEP ONE - Ensure handpiece cable plug orientation is in line with generator receptacle.



STEP TWO - Identify landmarks on generator receptacle (yellow arrow) and handpiece plug (green arrow).

Instructions Continued on Following Page...

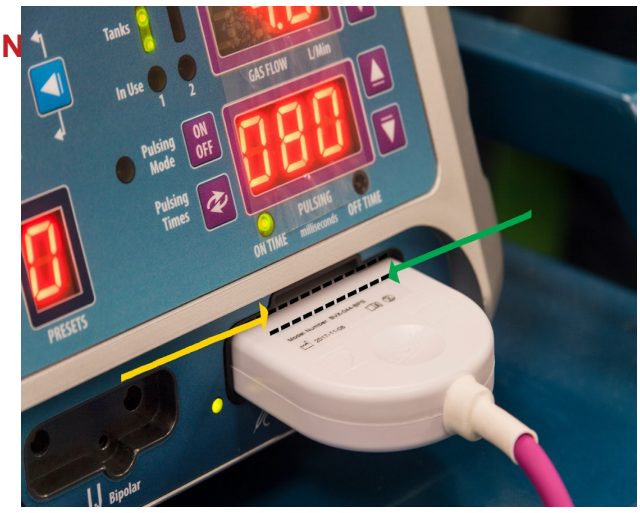
STEP THREE -

- Place one hand on the back of the generator while inserting the cable plug firmly with your opposite hand.
- Considerable force may be required to ensure proper connection to the generator.

STEP FOUR - Align edge of rectangular indentation on plug with edge of generator receptacle as pictured.

INCOMPLETE PLUG INSERTION
Edge of rectangular indentation on plug does NOT align with edge of generator receptacle as pictured.

- If cable plug is not completely inserted, rectangular indentation will be visible.
- **DO NOT** use until inserted correctly.
- Seek assistance if plug can not be inserted correctly.



STEP FIVE - You may continue using the devices that you have in your inventory following the above instructions.

RESOLUTION: This issue will be resolved with a design change to the plug for the J-Plasma® handpiece in the coming months.

Please share this information with your surgical staff and retain this notification as part of your facility 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.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

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

- Email: complaint.coordinator@boviemed.com
- T oll free call 1-800-537-2790, Monday through Friday, 8:00 AM to 5:000 PM, Eastern Time.

We apologize for the inconvenience that this has caused your facility.

Sincerely,

Dr. Topaz J. Kirlew, MBA, MT(ASCP)
Director Regulatory Affairs

Enclosure: Response Form