URGENT – Field Safety Notice

nGEN™ Generator (Catalog No: D-1384-01)

December 23, 2020

Dear Valued Customer,

At Biosense Webster, Inc. we continuously monitor the performance of our products to help ensure patient safety and compliance. We want to make you aware of an issue we have detected involving the use of the QMODE+™ setting on the nGEN™ Generator (Catalog No: D-1384-01) in combination with the QDOT MICRO® Ablation Catheter.

You are receiving this letter because you have been identified as a site that has the nGEN™ Generator and the QDOT MICRO® Catheter.

Initial field experience involving twelve hospitals using the nGEN™ Generator's QMODE+™ setting presented a higher than anticipated number of complaints of char on the ablation catheter tip. Development of char on an ablation catheter is a known hazard of radiofrequency ablation and is the result of excessive temperature at the blood/tissue/catheter interface. Although char formation by itself is not a patient adverse event, in rare circumstances it has the potential to contribute to patient adverse events. No patient adverse events have been reported related to this issue. Biosense Webster is conducting an investigation into this issue.

You are asked not to use the nGEN™ Generator in QMODE+™ with the QDOT MICRO® Catheters.
The use of QMODE+™ and QDOT MICRO® Catheters can continue with the nMARQ® Generator.

Next Steps

1. Please review this letter carefully and share it with anyone in your facility that needs to be informed.
2. Please complete, sign, and ***return the Business Reply Form*** to the following email Address: to be updated per local information & process.

We have communicated this information to the applicable regulatory authorities.
If you have additional questions about this letter, please contact your Biosense Webster Inc. representative.

Sincerely,

Maria Jose Arana

Digitally signed by Maria Jose Arana
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Maria Jose Arana
Sr. Director, Quality & Compliance
Biosense Webster, Inc.
31 Technology Drive, Suite 200
Irvine, CA 92618 USA
www.biosensewebster.com