Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Date: February 4, 2019

RE: Position Statement on Clinical Account Specialist Case Support of Reprocessed Single Use Devices (SUD)

Dear Valued Customer,

This letter is to inform you of Biosense Webster, Inc.'s position regarding case support of reprocessed Single-Use-Devices (SUD) distributed by third parties. Biosense Webster's commitment to providing high-quality products and services requires that we properly train all Clinical Account Specialists on the capabilities, limitations, and proper functioning of all our devices and equipment. Electrophysiologists ask Clinical Account Specialists to assist with reconstructing cardiac anatomy using our technology and interpreting maps and providing insight on the images generated by the CARTO® 3 System. It is critical that our personnel possess a competent base of knowledge of the design intent of each device feature and a thorough understanding of how each device is designed to work with our capital equipment to help achieve the best possible outcome for each patient. This base of knowledge is especially important when it comes to providing product technical support for the CARTO® 3 System, and troubleshooting the CARTO® 3 System in the midst of a procedure, which requires accurate inputs from diagnostic mapping and ultrasound catheters. Most hospital facilities also recognize the critical nature of vendor product competency as it relates to patient safety and consequently require vendor representatives to provide documentation attesting to their competency with their company's products as part of the vendor credentialing process.Reprocessing is a manufacturing process regulated by the U.S. Food and Drug Administration, and reprocessed single use devices generally require a new regulatory submission before they can be distributed. The regulatory clearance for reprocessed devices is owned by the reprocessing company that manufactures and distributes the devices, not the original equipment manufacturer. Therefore, once Biosense Webster's single use devices are subjected to the reprocessing process of another company, those devices are no longer our products.

To offer our customers a portfolio of both new and reprocessed devices, Biosense Webster has partnered with a reprocessing company that is also a member of the Johnson & Johnson Family of Companies. We have shared our calibration methods and product testing methods with our affiliated reprocessing company, and we distribute those products along with new Biosense Webster devices. We are confident that the reprocessed devices we distribute meet our quality standards. However, we have no knowledge of the manufacturing operations or specifications of reprocessed devices manufactured by third parties with which we are not affiliated. As such, Biosense Webster cannot attest to the safety, effectiveness, and accuracy of these devices.

Accordingly, our Clinical Account Specialists can only provide product technical support in cases that use diagnostic mapping and ultrasound catheters distributed by Biosense Webster. Our Clinical Account Specialists understand the capabilities, limitations, and proper functioning of these devices and are able to deliver on our commitment of high-quality support for these products.

For any questions related to the information contained in this letter, please contact your local Biosense Webster, Inc. representative.

Thank you for your continued partnership and for choosing the Biosense Webster, Inc.

Sincerely,

Biosense Webster, Inc.

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