

Biosense Webster, Inc.
3333 Diamond Canyon Rd
Diamond Bar, CA 91765
Phone 909 839.8500



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Biosense Webster
a Johnson & Johnson company

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061, 5630 Fishers Lane
Rockville, MD 20854

CITIZEN PETITION

On 9 May 1997, FDA issued a final rule in the Federal Register requiring exposed connectors of certain electrode lead wires and patient cables to be protected. The rule was promulgated to prevent patient electrocution caused by the accidental insertion of an exposed patient-contacting device into an AC power cord or outlet. The rule, later codified at 21 CFR Part 898, requires manufacturers to ensure that affected product shipped subsequent to 9 May 2000 would meet the stipulated performance standards.

Biosense Webster, Inc. ("Biosense") is a California corporation which manufactures diagnostic and therapeutic electrophysiology (EP) catheters and extension cables, some of which were modified recently to comply with the requirements of 21 CFR Part 898. The company's product line includes diagnostic EP catheters (Class II) and therapeutic catheters (Class III). Please refer to the attached list of all product codes and their associated Instructions for Use for further details.

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The undersigned, on behalf of Biosense, submits this petition pursuant to 21 CFR §10.30 to request the Commissioner of the Food and Drug Administration (the “Commissioner”) to take the actions requested as specified below.

A. Action Requested

In follow-up to conversations with the FDA on 17 and 18 August 2000, Biosense requests a two-part variance from the 9 May 2000 deadline to ensure compliance with the final rule that established a performance standard for electrode lead wires and patient cables for its EP catheters and cables terminating in a 0.25 inch diameter Nexus plug. To cover products still in the field and those shipped after the 9 May 2000 deadline, a retroactive variance is requested. In addition, to address those products that have yet to be shipped, Biosense requests a prospective variance. If this two-part variance is granted, Biosense will be fully compliant with the requirements of 21 CFR Part 898 by no later than 30 December 2000.

B. Statement of Grounds

Biosense requests a two-part variance in our effort to meet the following goals:

- a) to provide an adequate and reasonable timeframe to implement and test the design, packaging, and sterilization modifications required to bring the Nexus plug catheter into compliance with the performance standard; and
- b) avoid creating a burden to customers or preventing patient access to EP connectors necessary for diagnostic and therapeutic EP procedures.

We estimate that the validation of these changes across all affected product lines will be completed by 30 December 2000. In our good faith effort to bring this product, previously interpreted as falling outside the mandated criteria, into compliance as quickly as possible, we submit the following items for your consideration:

1. In the final rule, the FDA states that “a performance standard is needed to prevent electrical connections between patients and electrical power sources”

and the environment in which this product is used inherently provides this level of patient safety;

2. The catheter referenced here differs in design, size, and rigidity from examples presented in the final rule as requiring modification by the prescribed deadline; and
3. Conversion of the existing Nexus plug will require sufficient time for validation testing of packaging and sterilization processes.

1. Prevent Electrical Connections Between Patients and Electrical Power Sources

In the final rule, FDA states that “a performance standard is needed to prevent electrical connections between patients and electrical power sources.” The performance standard was developed “to address the risk of patient exposure to macro shock or electrocution due to the inappropriate connection of a patient-connected cable or electrode lead wire to an alternating current (AC) power source.” FDA further stated that “manufacturers have been encouraged to modify their designs to prevent lead wires from being inserted into electrical outlets.” To this end, a performance standard “will eliminate the risk, to the extent possible, of unprotected lead wires and patient cables being inadvertently inserted or manipulated so as to make contact with live parts of an AC power cord or electrical outlet.” Biosense believes that the environment of the EP lab itself contains many features designed to this same end and, thus, concluded that electrical safety issues had already been addressed. In addition, the large size and rigidity of the Nexus plug prevents accidental insertion into an electrical outlet. The diameter of the Nexus plug is 300% greater than 2.0mm tip pin mentioned in the final rule.

The catheter and connector referenced in this petition are indicated for use only by trained staff within the EP lab. This highly controlled environment is shielded – walls, floor, and ceilings – to prevent stray electrical fields from entering and to contain x/ray energy within the room. There are no AC line sockets or exposed metal surfaces and all surfaces are grounded. During an EP procedure, the patient lies on a bed constructed of radiopaque polymeric material. The remaining equipment and tables within the room are

medical devices, with certifications for electrical safety. In addition, hospitals are required to meet various state, city, and internal hospital codes and standards for electrical safety. Given the safety features unique to the EP lab, as well as the level of awareness within the user community, Biosense believed that significant protection from electrical transmission in the case of an accidental contact with the Nexus plug was inherently provided. Pictures of an EP lab have been attached, for the FDA's convenience, to illustrate the aforementioned safety features (see Attachment 3).

2. Differences in Design, Size, and Rigidity

In May of 1999, as part of an industry working group, Biosense and other manufacturers agreed that there was a need to address the performance standards through standardization of connectors for electrophysiology catheters. The industry group decided to voluntarily adopt the International Electrotechnical Commission ("IEC") safety standards for electromedical equipment. In the preamble to 21 CFR Part 898, FDA acknowledges that compliance with the IEC standard was equivalent to compliance with 21 CFR Part 898, and in 21 CFR Part 898.12 adopts the IEC standard. Biosense had already begun its redesign and modification process, so adopting the IEC standards was consistent with its product plan. Those catheters and cables clearly fitting the modification criteria were prioritized for refit, and the phase in of the new design is complete. At that time, Biosense Webster, Inc., made the assessment that the product presented in this petition fell outside of the specifications of the performance standards in three important areas: design, size, and rigidity.

Design

The Biosense catheter is designed to attach to a cable that rests no closer than 12 inches to the patient and is confined to the sterile field during the EP procedure. These catheters, which contain an active electrode lead wire, are intended for use only under the direct control of a doctor or trained medical staff during electrophysiologic mapping or mapping and ablation. Furthermore, the Nexus plug complies with the standards set in the IEC 601-1 Amendment 2, subsection c):

- The said part shall not come into contact with a flat conductive surface of not less than 100 mm diameter (the EP lab is shielded);
- For single-pole connectors, the straight unjointed test finger with the same dimensions as the standard test finger of figure 7 shall not make electrical contact with the said part if applied in the least favourable position against the access openings with a force of $10\text{N} \pm 2\text{N}$ (the connector is multi-poled); and
- If able to be plugged in to a mains socket, the said part shall be protected from making contact with parts at mains voltage by insulation means providing a creepage distance of at least 1.0mm and a dielectric strength of 1500V (supported by design lab testing).

Size

The Performance Standard refers repeatedly to 2.0mm tip pins and the 2.5mm tip pin also is mentioned as being subject to the Standard. In the preamble to the final rule (VII. Summary and Analysis of Comments) and the FDA's Response (Item 12), the rationale applied in determining the applicability of the performance standard to the 2.5mm coaxial pin was given as follows:

“Because it is physically possible to insert a 2.5mm pin into an AC power source, these devices are subject to the performance standard established in this rule.”

In contrast to other cardiac related devices, the Nexus plug has a distal diameter of 0.25 inches. This is approximately 300% larger in diameter than the 2.0mm tip pin. Therefore, as originally stated, Biosense did not interpret the standard as applicable to catheters terminating in the Nexus plug.

Rigidity

The Nexus plug is rigid and cannot be forced an AC outlet, unlike the flexible “banana” plugs (as presented in the *Summary and Analysis of Comments and FDA's Response* section following the final rule), which can be manipulated into an AC power source.

3. Conversion Time

In the short time since being made aware of the applicability of the performance standard to the Nexus plug, Biosense has identified viable design options to ensure compliance of the 209 catheter product codes impacted. These design changes necessitate packaging changes that are still in development and, once completed, may require validation of manufacturing process changes, storage stability and sterilization. Biosense fully expects to begin shipping compliant catheters and cables to customers shortly thereafter. Given the typically rapid turnover of this single-use product in the field, we expect the inventory of non-shielded Nexus plugs to be depleted within 2 months. (Our customers have reported to us that they keep only 1-2 months worth of inventory on hand, due to storage space constraints). Retrofitting the devices in the field is not an option, as product sterility would be compromised.

The foregoing demonstrates that Biosense is committed to making all possible efforts to comply with the performance standards contained in 21 CFR Part 898 by no later than 30 December 2000. If the variance is not granted, and Biosense is required to withhold catheters and cables from distribution, approximately 450 hospitals would be without essential catheters required to perform mapping and therapeutic procedures for critically ill heart patients. The catheter types described in this Citizen's Petition represent 24% (by units) of the US diagnostic EP market and 7% (by units) of the US therapeutic EP market*. The void created by Biosense's inability to ship these products to customers could have a serious impact on the provision of medical services to EP patients. Given the relative market shares, alternate EP catheter manufacturers may not be able to meet the needs of the entire EP community.

*Note: Market data included in a prior petition to FDA indicated that 51% of the EP market would be affected. Although Biosense interpreted the standard to exclude catheters terminating in the Nexus plug, the market data were included in the prior petition because 1) we believed the standard applied to the cables used with these catheters, as the cables did terminate in 2.0mm tip pins, and 2) catheters terminating in the Nexus plug cannot be used without said cables.

C. Environmental Impact

The subject matter of this petition is not within any of the categories of action for which an environmental assessment is required.

D. Economic Impact

No economic impact information will be submitted at this time. Such information shall be submitted at the request of the Commissioner following the Commissioner's review of this petition, pursuant to 21 CFR 10.30.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,



Marcia C. Leatham, MD
Vice President, Clinical, Quality, Regulatory
Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, California
(909) 839-8500

cc: Stewart Crumpler, Office of Compliance, FDA w/o attachments
Lillian J. Gill, Director, Office of Compliance, FDA w/o attachments