

April 2010

Subject: **United States distribution and implantation of COGNIS CRT-Ds and TELIGEN ICDs has resumed**

Dear Doctor:

Boston Scientific has obtained U.S. Food and Drug Administration (FDA) clearance for the two validated manufacturing changes affecting its COGNIS[®] cardiac resynchronization therapy defibrillators (CRT-Ds) and TELIGEN[®] implantable cardioverter defibrillators (ICDs) and will immediately resume U.S. distribution of these devices. Implants of these products may begin immediately. Your local representative will work with your hospital to replenish inventory.

As you know, on March 15, 2010, Boston Scientific voluntarily stopped United States distribution of all CRT-Ds and ICDs and removed these products from U.S. hospital shelves. We took this action after discovering that we had implemented two validated manufacturing changes in our CRT-D and ICD devices without filing the appropriate documentation with the FDA in advance. **No device failures have been associated with these manufacturing changes, nor do we expect any failures in the future related to these changes.** As we communicated to physicians in a letter dated March 22, 2010, there is no indication that there are any patient safety risks associated with these changes, and we are not recommending any modifications to normal follow-up procedure for patients previously implanted with Boston Scientific CRT-D or ICD devices.

We take our responsibility to be fully compliant with all FDA regulations very seriously. When we learned that we had failed to make the required FDA submissions for these changes, we acted swiftly, transparently and appropriately. We provided the FDA with the necessary documentation, and we have now received FDA clearance for these manufacturing changes, which affect all our CRT-Ds and ICDs. Solely on its own initiative, the Company has conducted an internal review of manufacturing and other changes for the products affected by the ship hold and product removal, as well as the associated regulatory submissions. The review found a few additional instances where the Company did not submit the appropriate documentation for validated manufacturing changes for the CONFIENT[™], LIVIAN[™], PRIZM[™], RENEWAL[®] and VITALITY[™] families of products. The Company has now submitted this documentation and is working closely with the FDA to secure clearance that will allow us to return CONFIENT, LIVIAN, PRIZM, RENEWAL and VITALITY -- the earlier generations of the Company's CRT-D and ICD products -- to market as soon as possible in the United States. These products may continue to be implanted in geographies outside the United States.

In addition to looking back, we are looking forward to ensure our internal processes will prevent anything like this from happening again. We have implemented more robust processes, with even more checks and balances, for the preparation and review of all change orders and associated regulatory submissions. Our multi-functional review board will ensure that all change orders are properly processed, reviewed and submitted.

We at Boston Scientific are pleased that you are once again able to provide your patients the benefits of our COGNIS CRT-Ds and TELIGEN ICDs.

If you have questions or we can be of any assistance, please contact your local Boston Scientific representative or U.S. Technical Services at 1.800.CARDIAC (227.3422).

Sincerely,



Hank Kucheman
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