

Boston Scientific

Boston Scientific Announces FDA Approval of Harmony™ HiResolution® Bionic Ear System

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NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., Sept. 27 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced the approval of its new Harmony™ HiResolution® Bionic Ear System (Harmony System) by the U.S. Food and Drug Administration (FDA). Developed by the Company's Neuromodulation Group, the Harmony System delivers 120 spectral bands, 5 - 10 times more than competing systems, helping to significantly increase hearing potential and quality of life for the severe-to-profoundly deaf.

"The Harmony System represents the next generation of cochlear implant technology," said Jeff Greiner, President of Boston Scientific's Neuromodulation Group. "We have brought together unprecedented advancements in science, design and functionality for the user -- furthering our commitment to restoring hearing and improving quality of life for those living with hearing loss due to permanent inner ear or auditory nerve damage."

Designed to enhance music appreciation and improve hearing in a variety of difficult listening environments, the Harmony System couples revolutionary internal sound processing (with the optional HiRes Fidelity™ 120) with the new Harmony behind-the-ear (BTE) external sound processor. Together, the two key components of the Harmony System are designed to provide significantly enhanced spectral resolution compared to conventional systems for a more natural representation of sound to help improve patient performance.

"With the new Harmony System, we are able to actively steer electrical currents with a high degree of accuracy, increasing the number of spectral bands from 16 to 120," said Greiner. "We are attempting to guide precise pitch information into the cochlea by taking advantage of surviving neural populations to help increase the user's ability to hear in noisy environments and to better appreciate the intricate sounds of music."

Cochlear implant users can access soft whispers and loud sounds without adjusting dials or controls with Harmony's CD-quality processing and sophisticated dual-loop automatic gain control, helping users better appreciate music, hear in noisy environments, use the telephone, and hear sounds that are loud and soft.

In addition to the FDA approval, the Harmony HiResolution Bionic Ear System recently received approval from Health Canada and the CE mark in Europe.

According to clinical evaluation results, approximately 80 percent of the subjects reported a strong preference for the Harmony sound processor with HiRes Fidelity 120, most noting that they had improved clarity of speech and/or that environmental sounds were clearer and easier to distinguish.

The HiResolution Bionic Ear System with optional HiRes Fidelity 120 is approved in the U.S. for adults only at this time and for all patients in Canada and Europe. The product is expected to be available in early 2007.

People interested in bionic ear technology to restore hearing should speak to their physicians and visit <http://www.bionicear.com/> or call 800-678-2575 for more information.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. The Neuromodulation Group is a global leader in the development of implantable, high-technology neurostimulation devices that include treatments for deafness and chronic pain. For more information, please visit <http://www.bostonscientific.com/> or <http://www.bionicear.com/>.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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