

Boston Scientific

FDA Approves 18-Month Shelf Life for TAXUS® Stent System

New U.S. shelf life is longer than any competing drug-eluting stent product

PRNewswire-FirstCall

NATICK, Mass.

(NYSE:BSX)

NATICK, Mass., Jan. 18 /[PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved extending the shelf life of its TAXUS® Express(2)™ paclitaxel-eluting coronary stent system in the United States to 18 months from the current shelf life of 12 months. The decision was based on data submitted by Boston Scientific to the FDA that demonstrated the performance of the TAXUS Stent -- in particular the drug content, drug degradation profile and drug-release -- was maintained within FDA-approved specifications at 18 months. The newly approved TAXUS Stent U.S. shelf life is longer than any competing drug-eluting stent product.

The extended expiration date applies to all available sizes of the TAXUS Stent for sale in the United States. The Company said it would immediately begin updating labels to reflect the 18-month expiration date. The shelf life for the TAXUS Stent outside the United States remains unchanged at 18 months.

"We are very pleased the FDA has approved an extended shelf life for the TAXUS Express(2) Stent, which may help facilitate inventory management for hospitals concerned with product expiration of drug-eluting stents," said Hank Kucheman, Senior Vice President and Group President of Boston Scientific's Interventional Cardiology Group. "The 18-month shelf life for the TAXUS Stent is three times longer than the Cypher Stent, which has FDA approval for a six- month shelf life."

TAXUS and Express(2) are trademarks of Boston Scientific Corporation or its affiliates. Cypher is a trademark of Cordis Corporation.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: <http://www.bostonscientific.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 product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, 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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