

## **Boston Scientific Receives FDA Clearance And CE Mark Approval For Direxion™ Torqueable Microcatheter**

NATICK, Mass., Nov. 19, 2013 [/PRNewswire/](#) -- Further bolstering its market-leading portfolio of peripheral embolization technologies, Boston Scientific Corporation (NYSE: BSX) has received U.S. Food and Drug Administration clearance and CE Mark approval for its [Direxion™ Torqueable Microcatheter](#).

Peripheral embolization is a technique used primarily by interventional radiologists to treat liver cancer, uterine fibroids and other challenging conditions. It involves deliberately blocking a blood vessel to prevent blood flow to an area of the body, which can effectively shrink a tumor or block an aneurysm.

"The Direxion Microcatheter's unique handling characteristics are intended to enable physicians to efficiently access difficult to navigate vessels across many types of peripheral embolization procedures," said Riad Salem, M.D., MBA, professor of Radiology and director of Interventional Oncology at Northwestern Memorial Hospital.

"Combined with a range of tip shape offerings and selection of pre-loaded systems, the Direxion Microcatheter offers an attractive portfolio that opens up a whole new dimension in microcatheter technology," said Robert Lewandowski, M.D., associate professor of Radiology at Northwestern Memorial Hospital.

Salem and Lewandowski were the first users of this platform worldwide.

The Direxion Torqueable Microcatheter is designed to facilitate selective access and delivery of diagnostic, embolic and therapeutic materials into the peripheral vasculature. The product, offered in either a 0.021" or 0.027" inner diameter microcatheter, features a slotted, nitinol hypotube technology. This technology is designed to maximize torque transmission in the catheter shaft, giving the Direxion Torqueable Microcatheter the best-in-class handling physicians need in order to reach the most challenging anatomy. The Direxion Torqueable Microcatheter is available in six tip configurations as well as pre-loaded configurations designed to suit a range of peripheral embolization procedures. These configurations include the physician's choice of the Fathom™-16 guidewire, Transend™-14 guidewire, or Transend-18 guidewire.

[Click here](#) to view or download an image of the Direxion Torqueable Microcatheter.

"Boston Scientific is committed to supporting interventional radiologists with innovative technologies designed to improve outcomes for patients suffering from challenging conditions such as liver cancer and uterine fibroids," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "The Direxion Torqueable Microcatheter adds a completely new technology to our market-leading peripheral embolization portfolio, and its unique slotted nitinol hypotube technology will provide physicians with unrivaled handling characteristics."

### **About Boston Scientific**

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit [www.bostonscientific.com](http://www.bostonscientific.com) and connect on [Twitter](#) and [Facebook](#).

### **Cautionary Statement Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans, new product launches, regulatory approvals, product performance and importance, and competitive offerings. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in

Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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