

## TAXUS™ Express<sup>2</sup>™ Coronary Stent System and Express<sup>2</sup>™ Coronary Stent System Limited Recall

### Patient Q&A

- ***What does the recall mean for me?***

If you have already received a stent, you are not affected by this recall. This recall only addresses stents that have not been implanted in a patient. All recalled product is being removed from hospitals through this recall.

- ***Is my stent being recalled?***

No. Boston Scientific is not recalling any stents that have already been implanted in patients.

- ***What lot numbers are being recalled?***

It is possible that the lot number on your stent is one of the recalled lot numbers, however, it is important for you to understand that this recall does not have any effect on stents that have already been implanted.

- ***Does the recall mean that I have to have my stent removed?***

**No. If your doctor has already placed one of these Boston Scientific stents in your artery, the recall does not affect you.** As described below, the recall addresses a potential problem with the balloon that delivers the stent into your artery during the procedure. After the stent has been implanted in your artery, the delivery balloon is removed from your artery and discarded. This problem can only occur during the procedure, not afterward. It does not have any impact on the stent (or the drug and polymer coating of the drug coated TAXUS Stent) that remains in your artery after completion of the procedure.

- ***If I have already received a TAXUS Express<sup>2</sup> or Express<sup>2</sup> Stent, should I be concerned?***

No. We would like to reassure patients, and family members, that this recall does not affect stents that have already been implanted. If you have already received a Boston Scientific stent, this recall does not affect you.

- ***Does this recall mean that my stent may not work?***

The recall does not have any impact on the effectiveness of your stent. This risk associated with the problem that is being addressed by this recall only impacts the delivery balloon that is used to deliver the stent in your artery during the procedure. If you have already received a stent, this recall does not have any impact on how well your stent is working.

- ***If I received a TAXUS Stent, does the recall affect how the drug works?***

No, the recall does not have any impact on the drug or polymer coating of the TAXUS Stent that remains in your artery after completion of the procedure.

- ***If I am scheduled for angioplasty, should I be concerned about getting a Boston Scientific stent?***

No. Boston Scientific is committed to providing physicians and patients with products that are safe and effective for their intended use. If you are a patient (or family member of a patient) considering a stenting procedure, please be assured, that while there are risks associated with any medical procedure, coronary stenting continues to be a proven, safe and effective treatment for coronary artery disease. By recalling these suspect lots, Boston Scientific is taking appropriate action for patient safety.

- ***What can I do to ensure the long-term effectiveness of my stent?***

You should consult your cardiologist to discuss different behavioral, medical and lifestyle decisions that might improve your cardiovascular health.

- ***Why are the stents being recalled?***

The issue that prompted this recall is referred to as “no deflation.” A “no deflation” complaint occurs when the delivery balloon fails to deflate within one minute after deployment of the stent. **Again, this can only take place during the procedure.**

- ***Is a “no deflation” dangerous?***

It can be. Although the number of patient complications due to “no deflation” events that occur during procedures is extremely low, Boston Scientific recalled specific lots of these products potentially exhibiting a higher possibility of no deflation of the delivery balloon because if a problem does occur during a procedure, it can lead to significant complications during the procedure.

- ***What should I do if I have more questions or concerns?***

Boston Scientific is using all possible channels to proactively and openly communicate and disseminate information about this recall to physicians and patients. Should you have specific questions or concerns, we encourage you to call our **Customer Support Line: (800) 832–7822 or consult your physician.**