



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2018-043**

14 FEB 2018

TO: THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS

SUBJECT: VOLUNTARY RECALL OF INNOVA™ 180 mm & 200 mm SELF-EXPANDING STENT SYSTEM

All are hereby advised by the Food and Drug Administration (FDA) about the voluntary recall of INNOVA™ stent system with attached sizes distributed by Boston Scientific Philippines, Inc., with business address at Unit 2503 Antel Global Corporate Center, Julia Vargas, Avenue, Ortigas Center, Pasig City 1605 with the following information:

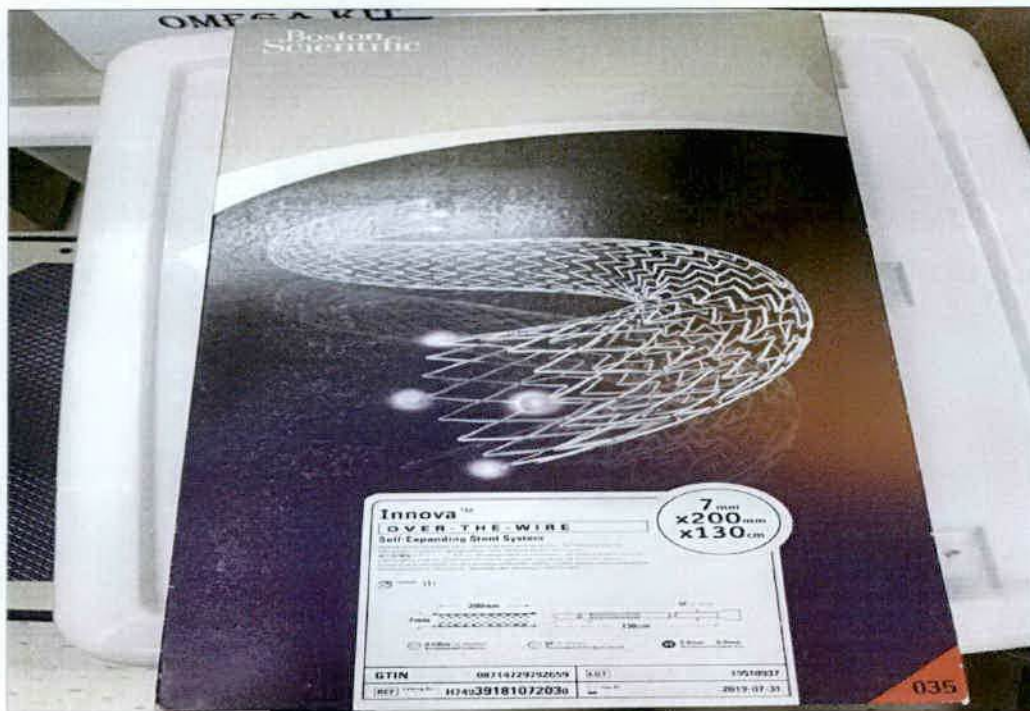
Innova 180mm, 200mm – US, Japan	
Product Description	Material Number (UPN)
Innova 5 x 180 x 75	H74939293051870
Innova 5 x 200 x 75	H74939293052070
Innova 6 x 180 x 75	H74939293061870
Innova 6 x 200 x 75	H74939293062070
Innova 7 x 180 x 75	H74939293071870
Innova 7 x 200 x 75	H74939293072070
Innova 8 x 180 x 75	H74939293081870
Innova 8 x 200 x 75	H74939293082070
Innova 5 x 180 x 130	H74939293051830
Innova 5 x 200 x 130	H74939293052030
Innova 6 x 180 x 130	H74939293061830
Innova 6 x 200 x 130	H74939293062030
Innova 7 x 180 x 130	H74939293071830
Innova 7 x 200 x 130	H74939293072030
Innova 8 x 180 x 130	H74939293081830
Innova 8 x 200 x 130	H74939293082030



Innova 180mm, 200mm – China	
Product Description	Material Number (UPN)
Innova-China 5 x 180 x 75	H74939259051870
Innova-China 5 x 200 x 75	H74939259052070
Innova-China 6 x 180 x 75	H74939259061870
Innova-China 6 x 200 x 75	H74939259062070
Innova-China 7 x 180 x 75	H74939259071870
Innova-China 7 x 200 x 75	H74939259072070
Innova-China 8 x 180 x 75	H74939259081870
Innova-China 8 x 200 x 75	H74939259082070
Innova-China 5 x 180 x 130	H74939259051830
Innova-China 5 x 200 x 130	H74939259052030
Innova-China 6 x 180 x 130	H74939259061830
Innova-China 6 x 200 x 130	H74939259062030
Innova-China 7 x 180 x 130	H74939259071830
Innova-China 7 x 200 x 130	H74939259072030
Innova-China 8 x 180 x 130	H74939259081830
Innova-China 8 x 200 x 130	H74939259082030

Innova 180mm, 200mm - EU	
Product Description	Material Number (UPN)
Innova EU 5x180x75	H74939180051870
Innova EU 5x200x75	H74939180052070
Innova EU 6x180x75	H74939180061870
Innova EU 6x200x75	H74939180062070
Innova EU 7x180x75	H74939180071870
Innova EU 7x200x75	H74939180072070
Innova EU 8x180x75	H74939180081870
Innova EU 8x200x75	H74939180082070
Innova EU 5x180x130	H74939181051830
Innova EU 5x200x130	H74939181052030
Innova EU 6x180x130	H74939181061830
Innova EU 6x200x130	H74939181062030
Innova EU 7x180x130	H74939181071830
Innova EU 7x200x130	H74939181072030
Innova EU 8x180x130	H74939181081830
Innova EU 8x200x130	H74939181082030


The cited medical device was voluntarily recalled by Boston Scientific Philippines, Inc. after partial deployment occurs when the stent is unable to be fully released from the delivery system. Part of the stent can become anchored in the vessel while the rest of the stent remains within the delivery system. The most common reported injury has been additional medical or minor surgical intervention, vessel trauma or prolongation of the implant procedure. In certain cases Boston Scientific Philippines, Inc. received reports of major surgery to retrieve the stent/delivery system or to correct vascular compromise.



Distributors, retailers, hospitals that have any lot of the stated medical device product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots.

Any suspected adverse reaction experienced or any incident of the same cases from the use of the device but not limited to the lots stated above, should be reported immediately to FDA at telephone no. (02) 857-1900 loc. 8301 or email us at cdrrhr_prsdd@fda.gov.ph.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General



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