

Medical Device Retrieval



November 2015

Dear Hospital Administrator:

Boston Scientific is retrieving certain lots of 9Fr ACUITY Pro Coronary Sinus Outer Guide Catheters due to potential for separation of the proximal handle from the shaft.

Background

The ACUITY Pro 9Fr Outer Guide Catheter is designed to provide a pathway into the coronary venous system for implantation of a left ventricular pacing lead. The Catheter has a proximal handle with an integrated hemostasis valve and a shaft with a flexible distal segment. Once the left ventricular lead is placed, the handle and distal segment are cut and removed.

Boston Scientific has received reports of handle separations during the cut and removal process; there have been no reported patient harms. After full investigation, Boston Scientific concludes that if the hub and shaft are aligned off-center in the bonding equipment during manufacturing, the result may be a reduced bond, which may separate during cutting. The affected product listed below was manufactured during the time period when the equipment was likely to be misaligned.

Affected Product

Product Descriptions	Product Models	Lot Numbers
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Extended Hook - 54cm	8104	18279548, 18279734, 18324877, 18329863, 18330946, 18348755, 18351569, 18353214, 18426640, 18461104, 18461521
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Extended Hook - 45cm	8105	18281110, 18315176, 18322343, 18323156, 18323651, 18324468, 18327210, 18327359, 18345738, 18346540, 18346668, 18347522, 18352159, 18354329, 18379847, 18380498, 18393785, 18394034, 18395315, 18408497, 18408902, 18410018, 18428314, 18435809, 18437015, 18437680, 18439474, 18440388, 18444811, 18445630, 18446236, 18462103, 18462459, 18463154, 18466449, 18478544
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Straight Right - 54cm	8106	18286550, 18410783
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Straight Right - 45cm	8107	18285401, 18285605, 18312411, 18312981, 18313754, 18337534, 18338037, 18354248, 18411116, 18413022, 18413155, 18413834
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Right - 54cm	8108	18273724, 18284294, 18338159, 18414856
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Right - 45cm	8109	18285220, 18293137, 18294062, 18313856, 18314250, 18332118, 18337848, 18353117, 18415202, 18415923, 18416945, 18418278, 18419899
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Wide - 54cm	8110	18421013, 18473202

Medical Device Retrieval
of affected lots of ACUITY Pro Coronary Sinus 9Fr Outer Catheter

ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters – Wide - 45cm	8111	18285930, 18351033, 18353540, 18420652, 18468909
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Multipurpose - 54cm	8112	18291473, 18336768, 18355225, 18421690, 18427953
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters – Multipurpose - 45cm	8113	18324876, 18324963, 18332278, 18352696, 18358192, 18371973, 18372577, 18440783, 18441697, 18467134, 18468171, 18471598, 18472178, 18478892, 18479477
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Coronary Sinus Hook - 54cm	8114	18282143, 18284604, 18335173, 18345117, 18441212, 18442550, 18442887
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters – Coronary Sinus Hook - 45cm	8115	18288704, 18328790, 18329233, 18356691, 18357371, 18357372, 18372837, 18373201, 18377504, 18378867, 18446665, 18447045, 18451382, 18451950, 18452785, 18453099, 18464410, 18473932, 18477470, 18483223, 18483940
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters – Amplatz - 54cm	8116	18281865, 18473055
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters – Amplatz - 45cm	8117	18333920, 18334332, 18466601
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Straight - 54cm	8118	18316161, 18336837, 18348081
ACUITY Pro Coronary Sinus 9Fr Outer Guide Catheters - Straight - 45cm	8119	18286265, 18291252, 18332911, 18336838, 18347898, 18480844, 18483020, 18471580

Action: Your local Boston Scientific sales representative is available to support this retrieval

1. Immediately segregate all affected product to ensure that it will not be used
2. Get an Inventory Authorization Number from Boston Scientific
3. Ship product back to Boston Scientific with the Inventory Authorization Number referenced
4. Complete the attached Certificate of Removal and email it to BSCFieldActionCenter@bsci.com

Further information

Boston Scientific wants to ensure the highest quality product for our patients and physicians. The alignment of handle bonding equipment is now confirmed daily and replenishment inventory is available. If you have any questions, please contact your local Boston Scientific representative or a Technical Services representative at one of the numbers listed below.

Sincerely,

[Contact]

[Title]

[Phone]

[Email]

Encl: Sales FAQ

Return of Certificate of Removal from Customer

Certificate of Removal from Customer

Product Family	ACUITY Pro 9 Fr Guide Catheter
Population	Reference attached Hospital Administrator letter
Issue Date	November 26, 2015
Due Date	December 11, 2015

Background

The ACUITY Pro 9Fr outer guide catheter is designed to provide a pathway into the coronary venous system for a left ventricular pacing lead. The catheter has a proximal handle with an integrated hemostasis valve and a shaft with a flexible distal segment. Once the left ventricular lead is placed, the handle and distal segment are cut and removed.

Action

Boston Scientific has identified a potential for the handle and shaft in certain lots of ACUITY Pro Coronary Sinus 9Fr outer guide catheters to separate. The company is retrieving/removing the identified lots of guide catheters

Confirmation of Action (to be completed by Hospital Administrator or Cath Lab Manager)

- U.S. Action: Collect and return all listed lot-controlled devices to Boston Scientific, 4100 Hamline Avenue North, St. Paul, MN 55112 (Attn: Returns) by December 11, 2015
- INTL Action: Collect and return all listed lot-controlled devices to Boston Scientific, Cashel Rd., Clonmel, Co Tipperary, Ireland (Attn: Returns) by December 11, 2015
- Certify actions taken by filling out the below section:

Action	Result (check appropriate box)
I have inspected my facility's inventory and found no affected product	
I have inspected my facility's inventory and have sent affected product back to Boston Scientific	Qty Returned:
Signature	
Print Name	
Title	
Facility Name	
Date	

Email this form to BSCFieldActionCenter@bsci.com,

Boston Scientific
91104690-FA ACUITY Pro 9Fr Catheters Hub Detachment Retrieval
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