

**Product Advisory – Important Medical Device Information**

**Imager™ II Angiographic Catheter**

Dec 16, 2016

Dear Materials Manager/Field Action Contact:

Boston Scientific is initiating a Product Advisory for a subset of Imager™ II Angiographic Catheters. Following a field report, Boston Scientific has determined that some units within a single lot were missing the bottom pouch seal. This was caused by an alternate label reprint process which resulted in the units missing a step in the packaging process. Although Boston Scientific has confirmed that only one batch was missing a bottom seal, as a precautionary measure, we are notifying all customers of this issue that received batches processed through this alternate label reprint process.

The compromised seal is completely missing and is obvious to the user. The device can be readily exchanged resulting in an insignificant prolongation in procedure. To date there have been no reports of patient injury associated with a missing pouch seal.

See attached table for affected Material/Lot information; this advisory does not include any products other than what is listed in the table.

**Affected Product Listing**

Product Description	Material Number (UPN) #	Lot/Batch #	Expiration date range
Imager™ II Angiographic Catheter	See attached product listing		01Apr2018-31July2018

**PLEASE NOTE:** We are aware that hospitals often remove products from the outer carton and store on the shelves in the inner-pouch only. If this is a practice at your facility, **it is very important that you carefully use the product table and consider both the inner and outer packaging UPN codes when searching for affected product, as the UPN numbers on the inner and outer labelling are different.**

If you identify any inventory missing a bottom pouch seal, segregate the product immediately and return it to Boston Scientific in accordance with the enclosed instructions. **If you are a distributor, please note that the depth is to the hospital level and this notification should be forwarded to your customers.**

Affected worldwide regulatory authorities are being notified of this product advisory as required.

Please read carefully through the instructions included with this notification. Your local Sales Representative can answer any questions that you may have regarding this notification.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

Carol Attieh  
Regulatory Affairs & Quality Assurance Manager  
Boston Scientific

Encl: Advisory Instructions  
Acknowledgement Form

## Advisory Instructions

The Acknowledgment Form enclosed with this notification must be completed and returned **even if you no longer have any of the affected products.**

1. **Immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.**
2. **If you identify any inventory missing a bottom pouch seal:**
  - a. Immediately discontinue use of and segregate product.
  - b. Immediately remove all affected product from your inventory.
  - c. Segregate this product in a secure location for return to Boston Scientific.
  - d. Contact Boston Scientific immediately to obtain a Returned Goods Authorization (RGA) Number. When contacting BSC, please include your account number, UPNs and batch(es) affected, and quantities:  
**Email: [MENA-ExportServices@bsci.com](mailto:MENA-ExportServices@bsci.com) and copy [attiehc@bsci.com](mailto:attiehc@bsci.com)**

3. **Complete and return the Acknowledgment Form.**

Complete the enclosed Acknowledgment Form (even if you no longer have any of the products), following the directions on this page and on the form.

Return the Acknowledgment Form to:

**Email: [attiehc@bsci.com](mailto:attiehc@bsci.com)**

## Imager™ II Angiographic Catheter Product Advisory

Table 1: Affected Product Listing

Outer package 5-pack UPN	Inner package single unit UPN	Batch
M001314001	M001314000	'00112546
M001314001	M001314000	'00112772
M001314011	M001314010	'00114197
M001314021	M001314020	'00111844
M001314021	M001314020	'00112480
M001314021	M001314020	'00113939
M001314031	M001314030	'00111843
M001314031	M001314030	'00112732
M001314041	M001314040	'00112428
M001314041	M001314040	'00112757
M001314041	M001314040	'00114188
M001314041	M001314040	'00114458
M001314041	M001314040	'00114740
M001314051	M001314050	'00111855
M001314051	M001314050	'00111856
M001314051	M001314050	'00112295
M001314051	M001314050	'00112427
M001314051	M001314050	'00112743
M001314051	M001314050	'00113050
M001314051	M001314050	'00113902
M001314051	M001314050	'00113903
M001314051	M001314050	'00114178
M001314051	M001314050	'00114179
M001314051	M001314050	'00114590
M001314051	M001314050	'00114734
M001314051	M001314050	'00114744
M001314061	M001314060	'00111806
M001314061	M001314060	'00112175
M001314061	M001314060	'00112460
M001314061	M001314060	'00112711
M001314061	M001314060	'00113917
M001314061	M001314060	'00114155
M001314061	M001314060	'00114472
M001314071	M001314070	'00112461
M001314071	M001314070	'00113072
M001314071	M001314070	'00113918

Outer package 5-pack UPN	Inner package single unit UPN	Batch
M001314071	M001314070	'00114473
M001314081	M001314080	'00111858
M001314081	M001314080	'00112298
M001314081	M001314080	'00112300
M001314081	M001314080	'00112457
M001314081	M001314080	'00112458
M001314081	M001314080	'00112748
M001314081	M001314080	'00113111
M001314081	M001314080	'00113956
M001314081	M001314080	'00113957
M001314081	M001314080	'00114490
M001314081	M001314080	'00114825
M001314091	M001314090	'00112177
M001314091	M001314090	'00112178
M001314091	M001314090	'00112462
M001314091	M001314090	'00112463
M001314091	M001314090	'00112713
M001314091	M001314090	'00112714
M001314091	M001314090	'00112715
M001314091	M001314090	'00113919
M001314091	M001314090	'00114158
M001314101	M001314100	'00112296
M001314101	M001314100	'00112297
M001314101	M001314100	'00112448
M001314101	M001314100	'00112449
M001314101	M001314100	'00112746
M001314101	M001314100	'00112747
M001314101	M001314100	'00113108
M001314101	M001314100	'00113110
M001314101	M001314100	'00113955
M001314101	M001314100	'00114441
M001314101	M001314100	'00114487
M001314101	M001314100	'00114488
M001314101	M001314100	'00114489
M001314111	M001314110	'00113127
M001314121	M001314120	'00111845

Outer package 5-pack UPN	Inner package single unit UPN	Batch
M001314121	M001314120	'00112734
M001314141	M001314140	'00112429
M001314141	M001314140	'00113052
M001314141	M001314140	'00114498
M001314151	M001314150	'00111817
M001314151	M001314150	'00113925
M001314191	M001314190	'00111818
M001314211	M001314210	'00113118
M001314221	M001314220	'00112308
M001314221	M001314220	'00112761
M001314221	M001314220	'00113053
M001314221	M001314220	'00114191
M001314221	M001314220	'00114500
M001314221	M001314220	'00114742
M001314231	M001314230	'00112184
M001314231	M001314230	'00112468
M001314231	M001314230	'00113084
M001314231	M001314230	'00114845
M001314241	M001314240	'00112540
M001314241	M001314240	'00113119
M001314241	M001314240	'00113973
M001314241	M001314240	'00114791
M001314251	M001314250	'00113085
M001314301	M001314300	'00112769
M001314311	M001314310	'00111841
M001314311	M001314310	'00112477
M001314311	M001314310	'00114460
M001314321	M001314320	'00112430
M001314321	M001314320	'00113054
M001314321	M001314320	'00113979
M001314321	M001314320	'00114505
M001314331	M001314330	'00111840
M001314331	M001314330	'00112187
M001314331	M001314330	'00112476
M001314331	M001314330	'00113935
M001314341	M001314340	'00112544
M001314341	M001314340	'00113126
M001314351	M001314350	'00111842
M001314351	M001314350	'00112478

Outer package 5-pack UPN	Inner package single unit UPN	Batch
M001314351	M001314350	'00112731
M001314351	M001314350	'00113093
M001314351	M001314350	'00113937
M001314361	M001314360	'00112545
M001314371	M001314370	'00113938
M001314501	M001314500	'00113080
M001314521	M001314520	'00112754
M001314561	M001314560	'00112304
M001314561	M001314560	'00112536
M001314561	M001314560	'00112753
M001314561	M001314560	'00113129
M001314581	M001314580	'00112756
M001314581	M001314580	'00113964
M001314591	M001314590	'00111815
M001314591	M001314590	'00112466
M001314591	M001314590	'00113079
M001314621	M001314620	'00112303
M001314621	M001314620	'00112749
M001314631	M001314630	'00111811
M001314631	M001314630	'00113075
M001314631	M001314630	'00113920
M001314641	M001314640	'00112750
M001314661	M001314660	'00111860
M001314661	M001314660	'00113113
M001314661	M001314660	'00113114
M001314661	M001314660	'00113959
M001314661	M001314660	'00114492
M001314671	M001314670	'00112180
M001314671	M001314670	'00112465
M001314671	M001314670	'00112717
M001314671	M001314670	'00113076
M001314671	M001314670	'00113921
M001314761	M001314760	'00112764
M001314761	M001314760	'00113974
M001314771	M001314770	'00111820
M001314771	M001314770	'00113930
M001314771	M001314770	'00114481
M001314781	M001314780	'00112538
M001314781	M001314780	'00113116

Outer package 5-pack UPN	Inner package single unit UPN	Batch
M001314781	M001314780	'00113969
M001314791	M001314790	'00112723
M001314791	M001314790	'00113083
M001314801	M001314800	'00112311
M001314811	M001314810	'00112729
M001314811	M001314810	'00113090
M001314821	M001314820	'00111870
M001314831	M001314830	'00112474
M001314831	M001314830	'00113933
M001314841	M001314840	'00113121
M001314841	M001314840	'00113975
M001314841	M001314840	'00114194
M001314851	M001314850	'00112727
M001314851	M001314850	'00113087
M001314851	M001314850	'00114482
M001314861	M001314860	'00112766
M001314861	M001314860	'00113122
M001314881	M001314880	'00113123
M001314891	M001314890	'00113932
M001314901	M001314900	'00114539
M001315001	M001315000	'00112097
M001315031	M001315030	'00112119
M001315061	M001315060	'00114004
M001315071	M001315070	'00114005
M001315091	M001315090	'00112637
M001315091	M001315090	'00112776
M001315091	M001315090	'00114631
M001315101	M001315100	'00111894
M001315101	M001315100	'00112095
M001315101	M001315100	'00114618
M001315111	M001315110	'00111893
M001315111	M001315110	'00113025
M001315111	M001315110	'00114010
M001315121	M001315120	'00114012
M001315121	M001315120	'00114634
M001315131	M001315130	'00111885
M001315131	M001315130	'00112703
M001315131	M001315130	'00113041
M001315131	M001315130	'00114727

Outer package 5-pack UPN	Inner package single unit UPN	Batch
M001315141	M001315140	'00112125
M001315141	M001315140	'00112646
M001315141	M001315140	'00113042
M001315151	M001315150	'00112123
M001315151	M001315150	'00113040
M001315151	M001315150	'00113998
M001315151	M001315150	'00114436
M001315151	M001315150	'00114470
M001315151	M001315150	'00114548
M001315151	M001315150	'00114550
M001315151	M001315150	'00114551
M001315151	M001315150	'00114600
M001315161	M001315160	'00114661
M001315181	M001315180	'00114629
M001315191	M001315190	'00111878
M001315191	M001315190	'00112116
M001315191	M001315190	'00112551
M001315191	M001315190	'00113989
M001315191	M001315190	'00114645
M001315191	M001315190	'00114730
M001315201	M001315200	'00111880
M001315201	M001315200	'00112698
M001315211	M001315210	'00112552
M001315211	M001315210	'00112696
M001315211	M001315210	'00113033
M001315231	M001315230	'00112115
M001315231	M001315230	'00112694
M001315231	M001315230	'00114644
M001315241	M001315240	'00112697
M001315251	M001315250	'00111891
M001315251	M001315250	'00112092
M001315251	M001315250	'00112650
M001315251	M001315250	'00112775
M001315251	M001315250	'00114007
M001315251	M001315250	'00114662
M001315251	M001315250	'00114731
M001315271	M001315270	'00112649
M001315281	M001315280	'00112549
M001315281	M001315280	'00113028

Outer package 5-pack UPN	Inner package single unit UPN	Batch
M001315291	M001315290	'00113987
M001315291	M001315290	'00114437
M001315301	M001315300	'00112112
M001315301	M001315300	'00112547
M001315301	M001315300	'00113985
M001315311	M001315310	'00111883
M001315311	M001315310	'00112121
M001315311	M001315310	'00112701
M001315311	M001315310	'00113038
M001315311	M001315310	'00113996
M001315311	M001315310	'00114439
M001315311	M001315310	'00114624
M001315321	M001315320	'00112122
M001315321	M001315320	'00113039
M001315331	M001315330	'00113995
M001316021	M001316020	'00111853
M001316021	M001316020	'00112533
M001316061	M001316060	'00112527
M001316061	M001316060	'00112735
M001316061	M001316060	'00113097
M001316061	M001316060	'00113941
M001316071	M001316070	'00111847
M001316071	M001316070	'00112191
M001316071	M001316070	'00113942
M001316071	M001316070	'00114602
M001316071	M001316070	'00114721
M001316091	M001316090	'00112525
M001316091	M001316090	'00112737
M001316091	M001316090	'00114663
M001316131	M001316130	'00113947
M001316331	M001316330	'00113103
M001316351	M001316350	'00112200
M001316581	M001316580	'00111850
M001316581	M001316580	'00113101
M001316581	M001316580	'00113945
M001316631	M001316630	'00113944
M001316671	M001316670	'00111849
M001316751	M001316750	'00113107
M001316791	M001316790	'00113102

Outer package 5-pack UPN	Inner package single unit UPN	Batch
M001316871	M001316870	'00112738
M0064003001	M006400300	'00112587
M0064003021	M006400300	'00112588
M0064003031	M006400300	'00112585
M0064005031	M006400500	'00112999
M001315281	M001315280	'00114642
M001315281	M001315280	'00114773