

ADVISORY FIELD SAFETY NOTICE

AZUR CX Detachable 35 Coils and AZUR Detachable 18 Endovascular Embolization Coil

Customer Name and Address

Dear Physician,

We are writing to you because our records show that you may have received product from certain lot(s) of AZUR Endovascular Embolization products where a small number of the devices may be missing the implant coil. The products that may be affected by this issue are certain lots of:

- AZUR Peripheral Coil system Detachable 18
- AZUR Peripheral Coil system Detachable 35

A list of lots that may be affected by this issue is provided in Attachment 1.

The AZUR system is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

MicroVention has received fifteen (15) complaints related to devices missing the implant coil. There has been no adverse events related to missing coils reported to the manufacturer. MicroVention will continue to monitor any adverse events related to the issue.

Product IFU (Instructions for Use) identifies a series of verification steps that must be performed prior to implant coil deployment including checking the product for irregularities or damage and monitoring for radiopaque marker location and implant presence. See Figure 1 below for the Preparation instructions of the AZUR Detachable System provided in the IFU.

16. Hold the device just distal to the shrink-lock and pull the shrink-lock proximally to expose the tab on introducer sheath. See Figure 3.

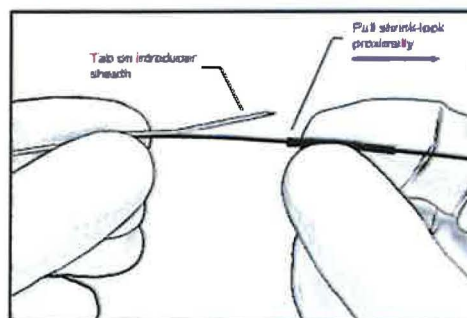


Figure 3 - Pull Shrink Lock Proximally

17. Slowly advance the coil implant out of the introducer sheath and inspect the coil for any irregularities or damage. If any damage to the coil or delivery pusher is observed, DO NOT use the device.

Figure 1 - Preparation instructions of the AZUR Detachable System provided in the IFU

If you follow the pre-deployment instructions during the preparation of the product, you will see whether there is an implant coil present at the end of the delivery pusher. A delivery pusher with an implant coil should look like figure 2 (below) and a delivery pusher that is missing the implant coil will look like figure 3 (below).



Figure 2 – Coil Present



Figure 3 – Coil Missing

A device that has a coil on to the delivery pusher may be used. A device that is missing its implant coil should not be used. A replacement device should be obtained and presence of the coil confirmed per IFU. If the verification steps are not performed per IFU, the user may potentially advance the delivery system without an implant into the peripheral vasculature. Testing shows that the stiffness of the delivery pusher stiffness is not higher than that of regular intravascular guidewire. As a result, the company has concluded that the likelihood of patient harm is improbable.

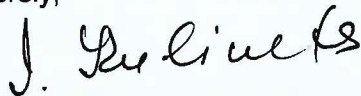
In the event that you encounter a device without a coil, please contact Customer Service to arrange for product return. If you have questions or need assistance, please reach out to the customer service of your local Terumo affiliate.

We ask that you take the following steps immediately:

1. Disseminate the advisory notice to the appropriate personnel.
2. Immediately complete and return the “**MEDICAL FACILITY ACKNOWLEDGMENT FORM**” form provided.

We regret any inconvenience that this action may cause, but we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Sincerely,



Irina Kulinets, PhD, RAC
Sr. Vice President of Regulatory Affairs, Clinical Research and Quality
MicroVention Inc., A **TERUMO** Group Company

Enclosure:

- Attachment 1 – Affected AZUR product lots
- Attachment 2 – Medical Facility Acknowledgment Form

**MEDICAL DEVICE ADVISORY FIELD SAFETY NOTICE
MEDICAL FACILITY ACKNOWLEDGMENT FORM**

MEDICAL FACILITY NAME: _____

ADDRESS: _____

MEDICAL FACILITY CONTACT PHONE #: _____

I have read and understand the Advisory Field Safety Notice issued by MicroVention Inc. regarding the AZUR CX Detachable 35 Coils and AZUR Detachable 18 Endovascular Embolization Coil Products and disseminated the Advisory Field Safety Notice to the appropriate personnel.

_____	_____	_____
Representative Name (Print Name)	Signature	Date

PLEASE EMAIL THE COMPLETED FORM TO [[DISTRIBUTOR to PROVIDE CONTACT INFORMATION](#)]

ATTACHMENT 1

Affected AZUR Product Lots

ProductDescription	Catalog Number	LotID	GTIN
AZUR 18 CX DETACHABLE 10MM x 32CM	45-781032	1903065Z8	00810170018350
		1903085Z8	00816777024374
		1903155Z8	00810170018350
		1903205Z8	00810170018398
		1903225Z8	00810170018398
		1904015Z8	00810170018350
		1904055Z8	00810170018350
		1904085Z8	00810170018350
		1904155Z8	00810170018350
		1904245Z8	00816777024367
		1904265Z8	00810170018350
		1904295Z8	00810170018350
AZUR 18 CX DETACHABLE 12MM x 38CM	45-781238	1905155Z8	00810170018350
		1903115Z8	00810170018367
		1903135Z8	00810170018367
		1903205Z8	00810170018398
		1904105Z8	00810170018367
		1904155Z8	00810170018350
		1904295Z8	00810170018350
AZUR 18 CX DETACHABLE 14MM x 34CM	45-781434	1905065Z8	00810170018367
		1903115Z8	00810170018367
		1903155Z8	00810170018350
		1904015Z8	00810170018350
		1904105Z8	00810170018367
		1904155Z8	00810170018350
AZUR 18 CX DETACHABLE 16MM x 39CM	45-781639	1905155Z8	00810170018350
		1903155Z8	00810170018350
		1903185Z8	00810170018381
AZUR 18 CX DETACHABLE 18MM x 36CM	45-781836	1904015Z8	00810170018350
		1903065Z8	00810170018350
		1903115Z8	00810170018367
		1903205Z8	00810170018398
		1903225Z8	00810170018398
		1904085Z8	00810170018350
		1904155Z8	00810170018350
		1905155Z8	00810170018350
AZUR 18 CX DETACHABLE 20MM x 40CM	45-782040	1904015Z8	00810170018350
		1903045Z8	00810170018404
		1903115Z8	00810170018367
		1903185Z8	00810170018381
		1904055Z8	00810170018350
		1904155Z8	00810170018350
		1905035ZA	00810170018404

ProductDescription	Catalog Number	LotID	GTIN
		1905065Z8	00810170018367
		1905085Z8	00816777024374
		190515571	00810170018404
		1905155Z8	00810170018350
AZUR 18 CX DETACHABLE 2MM x 2CM	45-780202	1903115Z8	00810170018367
		1903135Z8	00810170018367
		1903185Z8	00810170018381
		1904055Z8	00810170018350
		1904085Z8	00810170018350
		1904175ZA	00816777024367
		1904225Z8	00816777024367
		1904245Z8	00816777024367
		1904265Z8	00810170018350
		1904295Z8	00810170018350
		1905135Z8	00816777024367
		1905205Z8	00816777024367
		AZUR 18 CX DETACHABLE 2MM x 4CM	45-780204
1903085Z8	00816777024374		
1903115Z8	00810170018367		
1903135Z8	00810170018367		
1904015Z8	00810170018350		
1904035Z8	00816777024374		
1904085Z8	00810170018350		
1904105Z8	00810170018367		
1904155Z8	00810170018350		
1904175Z8	00810170018299		
1904225Z8	00816777024367		
1904245Z8	00816777024367		
1904265Z8	00810170018350		
1904295Z8	00810170018350		
1905025Z8	00816777024374		
1905035Z8	00816777024374		
1905065Z8	00810170018367		
1905085Z8	00816777024374		
1905105Z8	00816777024374		
1905105ZA	00816777024374		
1905135Z8	00816777024367		
1905205Z8	00816777024367		
AZUR 18 CX DETACHABLE 3MM x 4CM	45-780304	1903085Z8	00816777024374
		1903115Z8	00810170018367
		1903135Z8	00810170018367
		1903135ZA	00810170018299
		1904035Z8	00816777024374
		1904035ZA	00816777024381

ProductDescription	Catalog Number	LotID	GTIN
		1904175Z8	00810170018299
		1904175ZA	00816777024367
		1904225Z8	00816777024367
		1904245Z8	00816777024367
		1904265Z8	00810170018350
AZUR 18 CX DETACHABLE 3MM x 8CM	45-780308	1903015Z8	00816777024398
		1903045Z8	00810170018404
		1903115Z8	00810170018367
		1903135Z8	00810170018367
		1903155Z8	00810170018350
		1903185Z8	00810170018381
		1904055Z8	00810170018350
		1904105Z8	00810170018367
		1904155Z8	00810170018350
		1904175Z8	00810170018299
		1904225Z8	00816777024367
		1904245Z8	00816777024367
		1904265Z8	00810170018350
		1904295Z8	00810170018350
		1905035Z8	00816777024374
		1905065Z8	00810170018367
		1905085Z8	00816777024374
		AZUR 18 CX DETACHABLE 4MM x 13CM	45-780413
1903045Z8	00810170018404		
1903115Z8	00810170018367		
1903135Z8	00810170018367		
1903135ZA	00810170018299		
1903155Z8	00810170018350		
1904105Z8	00810170018367		
1904155Z8	00810170018350		
1904175Z8	00810170018299		
1904225Z8	00816777024367		
1904265Z8	00810170018350		
1904295Z8	00810170018350		
1905025Z8	00816777024374		
1905085Z8	00816777024374		
1905105Z8	00816777024374		
1905135Z8	00816777024367		
1905205Z8	00816777024367		
		1903115Z8	00810170018367
		1903135Z8	00810170018367

ProductDescription	Catalog Number	LotID	GTIN
AZUR 18 CX DETACHABLE 5MM x 16CM	45-780516	1903205Z8	00810170018398
		1904055Z8	00810170018350
		1904085Z8	00810170018350
		1904225Z8	00816777024367
		1904265Z8	00810170018350
		1904295Z8	00810170018350
		1905025ZA	00810170018305
		1905035Z8	00816777024374
		1905035ZA	00810170018404
		1905065Z8	00810170018367
		1905105Z8	00816777024374
		1905135Z8	00816777024367
		1905205Z8	00816777024367
AZUR 18 CX DETACHABLE 6MM x 20CM	45-780620	1903045Z8	00810170018404
		1903115Z8	00810170018367
		1903135Z8	00810170018367
		1903135ZA	00810170018299
		1903155Z8	00810170018350
		1903185Z8	00810170018381
		1904055Z8	00810170018350
		1904085Z8	00810170018350
		1904105Z8	00810170018367
		1904155Z8	00810170018350
		1904225Z8	00816777024367
		1904245Z8	00816777024367
		1904265Z8	00810170018350
		1904295Z8	00810170018350
		1905025Z8	00816777024374
		1905035Z8	00816777024374
		1905065Z8	00810170018367
		1905085Z8	00816777024374
		1905105Z8	00816777024374
1905105ZA	00816777024374		
1905135Z8	00816777024367		
1905205Z8	00816777024367		
AZUR 18 CX DETACHABLE 7MM x 24CM	45-780724	1903045Z8	00810170018404
		1903185Z8	00810170018381
		1904085Z8	00810170018350
		1904105Z8	00810170018367
		1904265Z8	00810170018350
		1904295Z8	00810170018350
		1905025Z8	00816777024374
		1905035Z8	00816777024374
1905085Z8	00816777024374		

ProductDescription	Catalog Number	LotID	GTIN
		1905135Z8	00816777024367
AZUR 18 CX DETACHABLE 8MM x 28CM	45-780828	1903045Z8	00810170018404
		1903065Z8	00810170018350
		1903085Z8	00816777024374
		1903115Z8	00810170018367
		1903135Z8	00810170018367
		1903155Z8	00810170018350
		1903205Z8	00810170018398
		1903225Z8	00810170018398
		1904055Z8	00810170018350
		1904085Z8	00810170018350
		1904155Z8	00810170018350
		1904265Z8	00810170018350
		1904295Z8	00810170018350
		1905035Z8	00816777024374
		1905155Z8	00810170018350
		1905155ZA	00810170018336
AZUR 18 CX DETACHABLE 9MM x 28CM	45-780928	1903045Z8	00810170018404
		1903115Z8	00810170018367
		1904055Z8	00810170018350
		1904155Z8	00810170018350
AZUR 18 Framer DETACHABLE 10MM x 26CM	45-681026	1904295Z8	00810170018350
		1903085J5	00810170017766
		1903155J5	00810170017742
AZUR 18 Framer DETACHABLE 14MM x 34CM	45-681434	1904035J5	00810170017766
		1903015J5	00810170017803
AZUR 18 Framer DETACHABLE 20MM x 50CM	45-682050	1903155J5	00810170017742
		1904155J5	00810170017742
		1903085K5	00810170017742
		1903135J5	00810170017834
		1904175J5	00810170017834
		1905105K5	00810170017834
AZUR 18 Framer DETACHABLE 8MM x 20CM	45-680820	1903155J5	00810170017742
		1904015J5	00810170017742
		1903085K5	00810170017742
		1904035J5	00810170017766
		1904155J5	00810170017742
AZUR 18 HYDROCOIL DETACHABLE 10MM x 15CM	45-481015	19031155A	00810170018008
AZUR 18 HYDROCOIL DETACHABLE 10MM x 20CM	45-481020	19031355E	00810170018015
		190424567	00810170018015

ProductDescription	Catalog Number	LotID	GTIN
AZUR 18 HYDROCOIL DETACHABLE 12MM x 15CM	45-481215	19031154K	00810170018022
		19041554Z	00810170018022
AZUR 18 HYDROCOIL DETACHABLE 12MM x 20CM	45-481220	19051357G	00810170018039
AZUR 18 HYDROCOIL DETACHABLE 15MM x 15CM	45-481515	19041554W	00810170018046
		19041556Q	00810170018046
AZUR 18 HYDROCOIL DETACHABLE 15MM x 20CM	45-481520	19032053A	00810170018053
AZUR 18 HYDROCOIL DETACHABLE 20MM x 20CM	45-482020	190320539	00810170018077
		19040855Y	00810170018077
AZUR 18 HYDROCOIL DETACHABLE 20MM x 30CM	45-482030	19040855X	00810170018084
		190515578	00810170018084
AZUR 18 HYDROCOIL DETACHABLE 2MM x 2CM	45-480202	19032054J	00810170017841
		190506581	00810170017841
AZUR 18 HYDROCOIL DETACHABLE 2MM x 4CM	45-480204	19051357N	00810170017858
AZUR 18 HYDROCOIL DETACHABLE 3MM x 10CM	45-480310	19031154N	00810170017889
		19031355G	00810170017889
		190401554	00810170017889
		19050657X	00810170017889
AZUR 18 HYDROCOIL DETACHABLE 3MM x 2CM	45-480302	19050657V	00810170017865
		19051357P	00810170017865
AZUR 18 HYDROCOIL DETACHABLE 3MM x 5CM	45-480305	19031154L	00810170017872
		19031354G	00810170017872
		19031355F	00810170017872
		19042254K	00810170017872
		19042453J	00810170017872
		19050657W	00810170017872
		19051357L	00810170017872
AZUR 18 HYDROCOIL DETACHABLE 4MM x 10CM	45-480410	19031154G	00810170017902
		19031155B	00810170017902
		19031354H	00810170017902
		19031355H	00810170017902
		19032054N	00810170017902
		190415553	00810170017902
		19042254L	00810170017902
		19051357K	00810170017902
AZUR 18 HYDROCOIL DETACHABLE 4MM x 15CM	45-480415	19041554V	00810170017919
		19050657U	00810170017919
AZUR 18 HYDROCOIL DETACHABLE 4MM x 20CM	45-480420	190506582	00810170017926
		19051357H	00810170017926
AZUR 18 HYDROCOIL DETACHABLE 4MM x 5CM	45-480405	190424568	00810170017896
AZUR 18 HYDROCOIL DETACHABLE 6MM x 10CM	45-480610	19041554Y	00810170017933
		19051357J	00810170017933
AZUR 18 HYDROCOIL DETACHABLE 6MM x 15CM	45-480615	19042254G	00810170017940
		19031354J	00810170017957

ProductDescription	Catalog Number	LotID	GTIN
AZUR 18 HYDROCOIL DETACHABLE 6MM x 20CM	45-480620	19041554X	00810170017957
		19042453K	00810170017957
AZUR 18 HYDROCOIL DETACHABLE 8MM x 10CM	45-480810	19032053E	00810170017964
AZUR 18 HYDROCOIL DETACHABLE 8MM x 15CM	45-480815	19040853U	00810170017971
		190415552	00810170017971
AZUR 18 HYDROCOIL DETACHABLE 8MM x 20CM	45-480820	19031355J	00810170017988
		19032053C	00810170017988
		19032252U	00810170017988
AZUR 35 CX DETACHABLE 10MM x 19CM	45-751019	1903045J2	00812636021072
		1903065J2	00812636021027
		1903085J2	00812636021034
		1904155J2	00812636021072
		1904175J2	00812636021072
		1904265J2	00812636021027
		1904295J2	00812636021027
		1905035J2	00812636021041
		1905085J2	00812636021058
		1905105K2	00812636021072
		1905135J2	00812636021072
AZUR 35 CX DETACHABLE 13MM x 24CM	45-751324	1903045J2	00812636021072
		1903155J2	00812636021089
		1903205J2	00812636021089
		1903225J2	00812636021089
		1904155J2	00812636021072
		1904225J2	00812636021089
		1904265J2	00812636021027
		1904295J2	00812636021027
		1905065J2	00812636021041
AZUR 35 CX DETACHABLE 16MM x 32CM	45-751632	1903045J2	00812636021072
		1903065J2	00812636021027
		1903205J2	00812636021089
		1903225J2	00812636021089
		1904175J2	00812636021072
		1904265J2	00812636021027
		1904295J2	00812636021027
		1905035J2	00812636021041
		1905065J2	00812636021041
AZUR 35 CX DETACHABLE 20MM x 39CM	45-752039	1903045J2	00812636021072
		1903205J2	00812636021089
		1904265J2	00812636021027
		1905035J2	00812636021041

ProductDescription	Catalog Number	LotID	GTIN
		1905065J2	00812636021041
		190515574	00812636021102
AZUR 35 CX DETACHABLE 4MM x 7CM	45-750407	1903045J2	00812636021072
		1903065J2	00812636021027
		1903085J2	00812636021034
		1903115J2	00812636021010
		1903155J2	00812636021089
		1904175J2	00812636021072
		1904175K2	00812636021010
		1904225J2	00812636021089
		1904245J2	00812636021010
		1904265J2	00812636021027
		1904295J2	00812636021027
AZUR 35 CX DETACHABLE 5MM x 11CM	45-750511	1903045J2	00812636021072
		1903065J2	00812636021027
		1903085J2	00812636021034
		1903155J2	00812636021089
		1904175J2	00812636021072
		1904175K2	00812636021010
		1904225J2	00812636021089
		1904245J2	00812636021010
		1904265J2	00812636021027
1904295J2	00812636021027		
AZUR 35 CX DETACHABLE 6MM x 17CM	45-750617	1903045J2	00812636021072
		1903065J2	00812636021027
		1903085J2	00812636021034
		1903155J2	00812636021089
		1904055J2	00812636021041
		1905035J2	00812636021041
		1905065J2	00812636021041
		1905085J2	00812636021058
AZUR 35 CX DETACHABLE 6MM x 9CM	45-750609	1903045J2	00812636021072
		1903065J2	00812636021027
		1903085J2	00812636021034
		1904035J2	00812636021034
AZUR 35 CX DETACHABLE 8MM x 12CM	45-750812	1903045J2	00812636021072
		1903085J2	00812636021034
		1905035J2	00812636021041
		1905065J2	00812636021041
		1905085J2	00812636021058
AZUR 35 CX DETACHABLE 8MM x 21CM	45-750821	1903045J2	00812636021072
		1903065J2	00812636021027
		1903155J2	00812636021089
		1904055J2	00812636021041

ProductDescription	Catalog Number	LotID	GTIN
AZUR 35 FRAMER DETACHABLE 8MM x 24CM	45-750024	1905035J2	00812636021041
		1905065J2	00812636021041
		1905085J2	00812636021058
		190515573	00812636021065
AZUR 35 Framer DETACHABLE 10MM x 26CM	45-651026	19030655Y	00810170016103
		19041556W	00810170016103
		19051058A	00810170016103
AZUR 35 Framer DETACHABLE 14MM x 34CM	45-651434	190410564	00810170016127
AZUR 35 Framer DETACHABLE 20MM x 50CM	45-652050	19030654Y	00810170016158
		19041556X	00810170016158
AZUR 35 HYDROCOIL DETACHABLE 10MM x 15CM	45-451015	190410589	00810170014963
AZUR 35 HYDROCOIL DETACHABLE 10MM x 20CM	45-451020	19030456J	00810170014970
		19041056C	00810170014970
		19041756Y	00810170014970
		190422549	00810170014970
		190422573	00810170014970
AZUR 35 HYDROCOIL DETACHABLE 12MM x 15CM	45-451215	190410569	00810170014987
AZUR 35 HYDROCOIL DETACHABLE 12MM x 20CM	45-451220	19040853N	00810170014994
AZUR 35 HYDROCOIL DETACHABLE 12MM x 30CM	45-451230	19041554R	00810170015007
AZUR 35 HYDROCOIL DETACHABLE 15MM x 20CM	45-451520	19030654N	00810170015014
		190408565	00810170015014
		190410588	00810170015014
		190422572	00810170015014
AZUR 35 HYDROCOIL DETACHABLE 15MM x 30CM	45-451530	19030456L	00810170015021
		190408569	00810170015021
		19041056A	00810170015021
		190415571	00810170015021
		19041756Z	00810170015021
		190417599	00810170015021
		19042656G	00810170015021
		19050254X	00810170015021
AZUR 35 HYDROCOIL DETACHABLE 20MM x 20CM	45-452020	19030456N	00810170015038
		19030654L	00810170015038
		19030655W	00810170015038
		19040856A	00810170015038
		19041552H	00810170015038
AZUR 35 HYDROCOIL DETACHABLE 20MM x 30CM	45-452030	19041058A	00810170015045
		19041554U	00810170015045
		19042656H	00810170015045
AZUR 35 HYDROCOIL DETACHABLE 4MM x 10CM	45-450410	19030456C	00810170014895
		19030655V	00810170014895
		19041058F	00810170014895
		190422575	00810170014895
AZUR 35 HYDROCOIL DETACHABLE 4MM x 15CM	45-450415	190422574	00810170014901

ProductDescription	Catalog Number	LotID	GTIN
AZUR 35 HYDROCOIL DETACHABLE 4MM x 5CM	45-450405	19030453C	00810170014888
		19030456B	00810170014888
		19042254B	00810170014888
AZUR 35 HYDROCOIL DETACHABLE 6MM x 10CM	45-450610	19030456E	00810170014918
		19030654W	00810170014918
		190410568	00810170014918
		19041058E	00810170014918
AZUR 35 HYDROCOIL DETACHABLE 6MM x 15CM	45-450615	19030456F	00810170014925
		190401568	00810170014925
		19041058C	00810170014925
		19041556Y	00810170014925
AZUR 35 HYDROCOIL DETACHABLE 6MM x 20CM	45-450620	19030453J	00810170014932
		19030655N	00810170014932
AZUR 35 HYDROCOIL DETACHABLE 8MM x 15CM	45-450815	19030456G	00810170014949
		19030654U	00810170014949
		19050253U	00810170014949
		19050254Z	00810170014949
AZUR 35 HYDROCOIL DETACHABLE 8MM x 20CM	45-450820	19030453K	00810170014956
		19030456H	00810170014956
		19030654R	00810170014956
		19030655G	00810170014956
		19030655H	00810170014956
		19050253V	00810170014956
		19050254Y	00810170014956
		19050657T	00810170014956
		19051058C	00810170014956
AZUR DETACHABLE 35 HYDROCOIL	45-450510	19030453E	00810170014376
		19030655X	00810170014376