2nd Notification

JANUARY 6TH, 2020

URGENT: ADVISORY FIELD SAFETY NOTICE
Immediate Action Required

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

MicroVention has included the updated list of affected lots. This updated list includes the same product descriptions, catalog numbers and lot numbers as the previously provided information with correction to some of the GTIN numbers and addition of UDI information (see 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.

There have 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.

2nd Notification

MicroVention TERUMO

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.

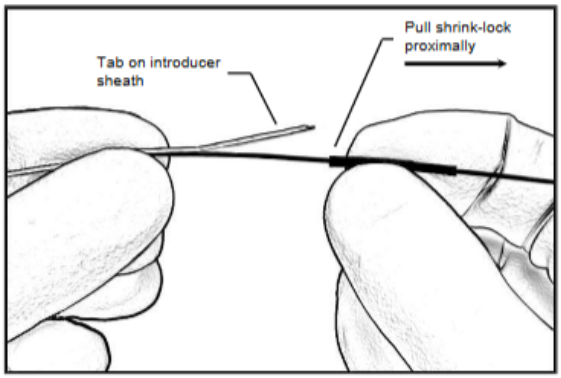

Figure 3 - Pull Shrink Lock Proximally

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).

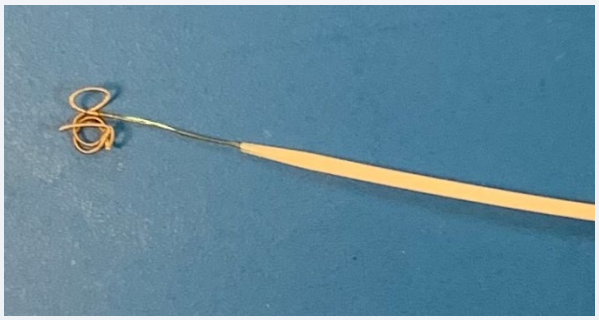

Figure 2 – Coil Present

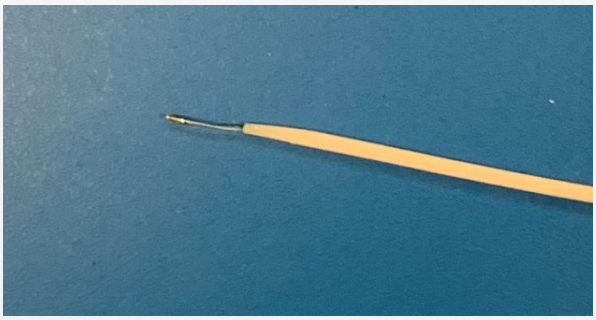

Figure 3 – Coil Missing

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.

2nd Notification

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

2nd Notification

MicroVention TERUMO

Immediate Action Required

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*]