



**Medical Device Field Safety Notice from Manufacturer**

July 9, 2015

[Distributor Name]  
[Distributor Address]

**RE: Field Safety Notice from Manufacturer on Use of TurnPike™ Spiral and TurnPike Gold catheters, Models 5621, 5630, 5640, 5641**

Dear [Doctor's Name or Distributor Contact],

Initial customer feedback regarding use of the TurnPike Spiral catheter has made us aware that TurnPike Spiral and TurnPike Gold catheters should not be used in vessels smaller than 1mm, as the catheter could become lodged and result in vessel injury upon removal. There have been no reported patient injuries associated with this use of the TurnPike Spiral and TurnPike Gold catheters. However, to minimize risk, Vascular Solutions, Inc. is adding the following contraindication and warning to the Instructions for Use of the TurnPike Spiral and TurnPike Gold catheters:

Contraindication – The TurnPike Spiral and TurnPike Gold catheters are contraindicated for use in vessels with an effective diameter smaller than 1mm.

Warning – Never advance the TurnPike Spiral or TurnPike Gold catheters into a vessel with an effective diameter smaller than 1mm. The catheter could become lodged and result in vessel injury.

These statements apply to use of TurnPike Spiral (Models 5640 and 5641) and TurnPike Gold (Models 5621 and 5630) catheters shipped to your facility to date, and will be included in the Instructions for Use that accompany the products in the future.

Please complete the following steps within one week of receipt of this notice:

- (1) Identify customers who have received units of TurnPike Spiral or TurnPike Gold to date.
- (2) For each of these affected customers: fill in the **green** highlighted sections of the attached notification.
- (3) Provide the attached notification to each affected customer (please translate if needed).
- (4) Confirm by reply email to [regops@vasc.com](mailto:regops@vasc.com) that all affected customers acknowledged the notification.

We appreciate your attention to this matter and apologize for any inconvenience. Please don't hesitate to contact me with questions or for further information.

Sincerely,

A handwritten signature in cursive script, appearing to read "Carrie Powers".

Carrie Powers  
Vice President of Marketing  
Vascular Solutions, Inc.  
6464 Sycamore Court North  
Minneapolis, Minnesota 55369  
(763) 656-4300 (Tel.) | [www.vasc.com](http://www.vasc.com)

[Distributor Letterhead]

**Medical Device Field Safety Notice from Manufacturer**

[Date]

[Customer Name]  
[Customer Address]



**RE: Field Safety Notice from Manufacturer on Use of TurnPike™ Spiral and TurnPike Gold catheters, Models 5621, 5630, 5640, 5641**

Dear [Insert Name of Customer Contact],

Initial customer feedback regarding use of the TurnPike Spiral catheter has made the manufacturer, Vascular Solutions Inc., aware that TurnPike Spiral and TurnPike Gold catheters should not be used in vessels smaller than 1mm, as the catheter could become lodged and result in vessel injury upon removal. There have been no reported patient injuries associated with this use of the TurnPike Spiral and TurnPike Gold catheters. However, to minimize risk, the manufacturer is adding the following contraindication and warning to the Instructions for Use of the TurnPike Spiral and TurnPike Gold catheters:

Contraindication – The TurnPike Spiral and TurnPike Gold catheters are contraindicated for use in vessels with an effective diameter smaller than 1mm.

Warning – Never advance the TurnPike Spiral or TurnPike Gold catheters into a vessel with an effective diameter smaller than 1mm. The catheter could become lodged and result in vessel injury.

These statements apply to use of TurnPike Spiral (Models 5640 and 5641) and TurnPike Gold (Models 5621 and 5630) catheters shipped to your facility to date, and will be included in the Instructions for Use that accompany the products in the future. At your earliest convenience, kindly confirm receipt of this communication with [Distributor Contact Information]. If there are other physicians at your facility who will likely use a TurnPike Spiral or TurnPike Gold catheter in your inventory today, please also share this information with them.

Please don't hesitate to contact me below with questions or for further information.

Sincerely,



[Signature]

[Name] [Title]  
[Organization]  
[Contact Information]

Attachment

Confidential

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