TRIVASCULAR

Important Medical Device Information
Updated Product Instructions for Use (IFU)

for the Ovation Prime™ Abdominal Stent Graft System

February 27, 2014

Dear Clinical Partner,

As part of our commitment to continuous improvement, TriVascular is sending this communication to physician users of the Ovation Prime Abdominal Stent Graft System to provide notification of an update that will appear in a future revision of the product Instructions for Use (IFU). The IFU will be available in your country when the required translations and product registration/notification have been completed. This IFU update does not require rework or return of TriVascular product.

Details on the updated IFU:
TriVascular is incorporating an update to an existing IFU Caution statement in the Deployment Completion Instructions for the optional usage of angioplasty balloons to read as follows (edits indicated):

> ***Caution: It is not recommended to balloon prior to ~~15~~ 20 minutes after completion of the final polymer mix. Ballooning prior to ~~15~~ 20 minutes could damage the sealing rings.***

The change to the current ballooning time (from 15 to 20 minutes) is TriVascular's proactive response to two (2) reports, both in the United States of America, of damage to the sealing rings where ballooning occurred after 15 minutes and before 20 minutes. The two (2) patients experienced transient hypotension that stabilized after treatment in accordance with the current version of the product IFU, and the aneurysms for both patients were successfully excluded. These events represent a very low estimated world-wide incidence rate of less than 0.1%.

The change to ballooning time allows for additional curing of the fill polymer in variable clinical conditions. For example, if a patient has a low core body temperature (below 35°C) an additional minute of cure time per degree below 35°C may be required.

TriVascular commitment:
In our ongoing efforts to provide product education and guidance to physicians and also reduce potential patient safety risks, TriVascular updated the ballooning recommendations in the IFU.

TriVascular is dedicated to dynamically updating worldwide product instructions when new information is received from our Clinical Partners. We appreciate your willingness to work with us and are grateful to partner with you in the care of your patients. If you need additional information, please do not hesitate to contact your local TriVascular representative.

Sincerely,

Shari O'Quinn
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TriVascular, Inc.

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