GUIDANT

Abbott GmbH & Co. KG, Wingertshecke 6, 35392 Gießen

Gießen, 8. Juni 2006

Update on ABSOLUTE™ .035 Peripheral Stent System

Dear Doctor

As part of our commitment to keep you updated on important information in the area of peripheral stenting, Abbott Vascular (the new owner of the former Guidant Endovascular Solutions) is issuing this letter to update you on situations that can lead to difficulties deploying the ABSOLUTE .035 Peripheral Stent. As you are aware, the device labeling includes information regarding resistance during deployment. Abbott would like to emphasize this information and inform you of new information being incorporated into the Instructions For Use. In addition, should you encounter resistance during deployment we would like to present options you may consider.

Background:

On April 3, 2006, the 135cm catheter length of the ABSOLUTE .035 Peripheral Stent System was recalled due to an increase in deployment difficulties. While the 80cm catheter length is not part of that action, and is performing acceptably, Abbott is taking steps to apply learning from the investigation of the 135cm length device performance.

Important information from current IFU:

Abbott advises you to use the ABSOLUTE .035 Peripheral Stent System in accordance with the Instructions For Use. In particular you should note the following information:

- Should unusual resistance be felt at any time during lesion or stricture access or Delivery System removal, the introducer sheath / guiding catheter and stent system should be removed as a single unit
- Applying excessive force to the Stent Delivery System can potentially result in loss or damage to the stent and Delivery System components
- The stent is not designed for repositioning or recapturing
- Do not attempt to pull a partially expanded stent back through the sheath or guiding catheter; dislodgement of the stent from the delivery System may occur

Additional Information being incorporated:

Removal of the entire system -- the catheter together with the introducer sheath or guiding catheter as a single unit – in the event that unusual resistance being felt is an important point and will be repeated in appropriate procedural steps. In addition, Abbott intends to incorporate new information in the IFU including the following:

- Once the stent is apposed to the vessel or duct wall, it is not recommended to remove the stent with the delivery system.
- The stent is not designed for re-sheathing.
- Do not unlock the handle prior to positioning the stent at the intended location.
- If the thumbwheel moves prior to unlocking, do not use.

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- If the thumbwheel moves freely in both directions after unlocking, remove the device together with the introducer sheath or guiding catheter as a single unit; unintentional deployment may occur.
- Failure to follow these instructions could result in failure to deploy, difficulties with deployment, partial stent deployment or deployment in an unintended location.
- Potential Adverse Events includes Intervention due to:
    - Stent migration
    - Unintentional placement of stent
    - Partial stent deployment
    - Stretched and / or damaged stents

Next steps:

Abbott Vascular will be taking steps to insure that the new information provided to you in this letter is incorporated into the IFU. As a matter of course, if you encounter problems with the product or its usage, you should report them immediately to your Abbott/Guidant Representative or directly to Abbott GmbH & Co. KG, Betriebsstätte Gießen, Wingertshecke 6, 35392 Giessen, phone 0641 - 92221-0 (Mo. - Fr. form 8:00 to 17:00 Uhr).

Please contact your Abbott/Guidant Representative should you have any further questions about this notice.

Sincerely,
Abbott GmbH & Co. KG
Betriebsstätte Gießen