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Urgent Field Safety Notice

Commercial name of the affected product: Zilver PTX Drug-Eluting Peripheral Stent

FSCA-identifier: 2012C0005

Type of action: Labelling modification

Date: Dec 19, 2012

Details on affected devices:

Catalogue Number: ZIV6*****PTX

Lot Number: All Lots

Dear Doctor,

This letter is to inform you of labeling enhancements that will be implemented as a result of feedback received following use of the Cook Medical Zilver PTX Drug-Eluting Peripheral Stent. Cook Medical has received reports on a small number (n=4; occurrence rate of 0.017%; one serious adverse event) of delivery system catheter fractures resulting in tip separation after stent deployment. In response to these reports, Cook Medical is carrying out an in-depth investigation to better understand the root cause of these tip separations.

Our records indicate your facility has received Zilver PTX Drug-Eluting Peripheral Stents. **Please note that this is an information notice to you. Please do not return any product in response to this letter.**

During the ongoing investigation two observations have been made that could prove helpful to clinicians in the rare event they experience a Zilver PTX delivery system tip separation. These observations are discussed below and will be incorporated into updated Instructions for Use (IFU).

Observation 1: To prevent any unrecognized tip/inner catheter separation, it is recommended to check the delivery system after removal from patient to make sure the tip is intact (maintain wire guide access until this check is completed). This device's delivery system includes an inner catheter loaded within an outer (Flexor) sheath. A 2 cm white tip extends from this inner catheter, and is visible beyond the distal end of the Flexor sheath. The reported delivery system separations have included this white tip and an adjoining segment of inner catheter ranging from approximately 8 to 15 cm in length. Since only the white tip itself is radiopaque, it is important to understand there could possibly be a larger fragment *in situ* than is evident from x-ray images.

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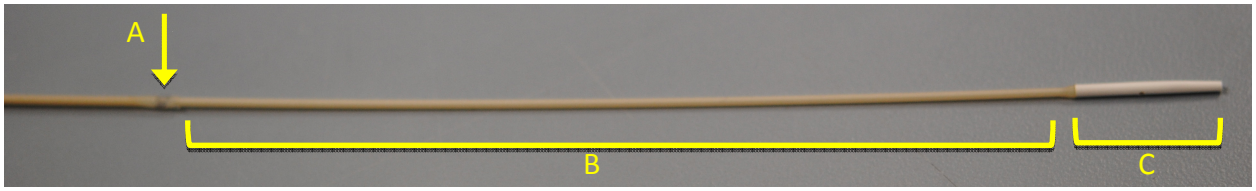

Figure 1 - Zilver PTX inner catheter, A - pusher band B - stent retention area (length correlates to stent length) C – white tip, radiopaque (length = 2 cm). Inner catheter separation observed immediately proximal or distal to pusher band (A).

Observation 2: It is important to use the wire guide types recommended in the IFU (extra or ultra stiff 0.035 inch (0.89mm) wire guides). The recommended wires provide enhanced pushability of the stent delivery system and a more uniform pathway than other guide wires. In addition, the inner lumen of the Zilver stent delivery system is sized to match these wire guides. As such, they provide a structure that reduces the likelihood of kinking in the inner catheter, reducing the risk of inner catheter separation. It should be noted that in the use of hydrophilic wire guides, regular activation of these wires is important. Upon drying, these wires are substantially less lubricious than similarly-sized wires that are uncoated, and can therefore introduce increased stress on the inner catheter of the delivery system.

We will keep you informed should any additional information arise during our investigation that can affect the use of the Zilver PTX stent when treating your patients.

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The Irish Medicines Board (IMB) has been informed of this action.

Should you have any questions, please feel free to contact us at Cook Ireland Ltd. for more information (**Tel** +353 61 334440, **fax** +353 61 334441, **e-mail** european.complaints@cookmedical.com)

We regret the inconvenience this may cause you. Thank you.

Contact reference person:

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