COOK

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product: Zilver® 518RX Vascular Stent
Manufacturer : Cook Ireland Ltd.
FSCA-identifier: 2015FA0010
Type of action: Recall of product

Date: 17 December 2015

Attention: Risk Management/Recall Administration

Details on affected devices:

Part Numbers:

ZIVX5-125-4-2.0	Zilver® 518RX Vascular Stent
ZIVX5-125-4-3.0	Zilver® 518RX Vascular Stent
ZIVX5-125-4-4.0	Zilver® 518RX Vascular Stent
ZIVX5-125-4-6.0	Zilver® 518RX Vascular Stent
ZIVX5-125-4-8.0	Zilver® 518RX Vascular Stent
ZIVX5-125-5-2.0	Zilver® 518RX Vascular Stent
ZIVX5-125-5-3.0	Zilver® 518RX Vascular Stent
ZIVX5-125-5-4.0	Zilver® 518RX Vascular Stent
ZIVX5-125-5-6.0	Zilver® 518RX Vascular Stent
ZIVX5-125-5-8.0	Zilver® 518RX Vascular Stent
ZIVX5-125-6-2.0	Zilver® 518RX Vascular Stent
ZIVX5-125-6-3.0	Zilver® 518RX Vascular Stent
ZIVX5-125-6-4.0	Zilver® 518RX Vascular Stent
ZIVX5-125-6-6.0	Zilver® 518RX Vascular Stent
ZIVX5-125-6-8.0	Zilver® 518RX Vascular Stent
ZIVX5-125-7-2.0	Zilver® 518RX Vascular Stent
ZIVX5-125-7-3.0	Zilver® 518RX Vascular Stent
ZIVX5-125-7-4.0	Zilver® 518RX Vascular Stent
ZIVX5-125-7-6.0	Zilver® 518RX Vascular Stent
ZIVX5-125-7-8.0	Zilver® 518RX Vascular Stent
ZIVX5-125-8-2.0	Zilver® 518RX Vascular Stent
ZIVX5-125-8-3.0	Zilver® 518RX Vascular Stent
ZIVX5-125-8-4.0	Zilver® 518RX Vascular Stent
ZIVX5-125-8-6.0	Zilver® 518RX Vascular Stent
ZIVX5-125-8-8.0	Zilver® 518RX Vascular Stent
ZIVX5-125-9-2.0	Zilver® 518RX Vascular Stent
ZIVX5-125-9-3.0	Zilver® 518RX Vascular Stent
ZIVX5-125-9-4.0	Zilver® 518RX Vascular Stent
ZIVX5-125-9-6.0	Zilver® 518RX Vascular Stent
ZIVX5-125-9-8.0	Zilver® 518RX Vascular Stent
ZIVX5-125-10-2.0	Zilver® 518RX Vascular Stent
ZIVX5-125-10-3.0	Zilver® 518RX Vascular Stent
ZIVX5-125-10-4.0	Zilver® 518RX Vascular Stent
ZIVX5-125-10-6.0	Zilver® 518RX Vascular Stent
ZIVX5-125-10-8.0	Zilver® 518RX Vascular Stent

Affected Lot Numbers:
All lot numbers.

Description of the problem:

Cook Ireland Ltd has identified potential non-conforming product for the Zilver® 518RX Vascular Stent within our manufacturing facility. Testing demonstrates a process used to manufacture the inner catheter to stylet joint of the delivery system doesn't meet the required specification on a consistent basis and the joint may separate during deployment.
A failure of this joint would represent a device malfunction and were it to occur during a procedure may result in a partial stent deployment. The clinical effect of a partial deployment may be a need for surgical intervention, or may result in vessel trauma or an embolic event.

If this malfunction were to occur in the field the risk of life threatening complications has been quantified as unlikely but possible therefore Cook Ireland Ltd is voluntarily initiating this Field Safety Corrective Action. This potential malfunction applies only to the delivery system prior and during deployment. Stents that are already deployed are not impacted by this Field Safety Corrective Action.

This Field Safety Corrective Action is to inform customers to return any unused products to the address below and to use an alternative device for the intended procedure.

Action to be taken by the user:

1. Please review the the attached list of affected products and lot numbers that were shipped to your account and identify any devices you still have in stock.

2. Immediately collect and return all unused affected products to Cook Medical as soon as possible for credit. Please contact our Customer Services Department to arrange pick up.
   Send the removed products to:

   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

   Credit will be provided for the returned devices where applicable.

3. Please complete the enclosed Customer Response Form and send via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61334441).

Transmission of this Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation or patient 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.

Contact reference person:

Sinead Burke
Director of Regulatory Affairs
COOK Ireland Ltd.
O'Halloran Road, National Technology Park, Limerick, IRELAND

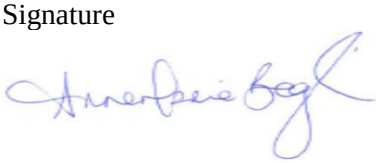
Or

Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.

Signature



Annemarie Beglin
Quality Systems Manager