COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
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Urgent Field Safety Notice

Commercial name of the affected product: Sydney IVF PVP
Manufacturer: William A. Cook Australia Pty Ltd
Cook Reference Number: 2015FA0006
Type of action: Field Safety Corrective Action

Date: 10th Oct 2015

Attention: Risk Management/Recall Administration

Details on affected devices:

Product Name: Sydney IVF PVP

Product Code: K-SIPV-200-5

Lot Numbers: Parent Lot # M0615061Z, Sub Lot #'s S19470, S19531, S19246, S19305 & S19382

Description of the problem:
William A. Cook Australia Pty Ltd would like to notify you of a recall of Sydney IVF PVP supplied as a kit of 5 vials (K-SIPV-200-5) parent batch number M0615061Z, Sub Lot #'s S19470, S19531, S19246, S19305 & S19382.

This batch is being recalled because we have evidence that it was formulated with an excess of water, diluting the product outside the design specification. The batch met all of the release specifications, including Mouse Embryo Assay; however, the effect of this dilution is a loss of viscosity, and creation of a hypo-osmotic environment for the sperm. This may make it difficult for the embryologist to capture the sperm, and may lead to swelling of the sperm tail which may render the sperm unusable or less effective in fertilising the oocyte. It is possible that patients may need to undergo additional routine gamete collection procedures.

Our records indicate that your facility has received product that are subject to this field action.

Advise on action to be taken by the user:

1. Please review the attached list of affected products and lot numbers that were shipped to your account, and destroy any affected product that remains unused.

2. Please complete the enclosed Customer Response Form and send via email to European.Complaints@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61 334441).

3. Please report any adverse event to Cook Medical Customer Relations by contacting our Customer Services Department.

Credit will be provided for the destroyed product.

Cook Australia sincerely regrets any inconvenience to your clinic. Please be assured that we will take appropriate action to prevent recurrence of this issue.

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Transmission of this Field Safety Notice:

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.

Contact reference person:

Sinead Burke
Regulatory Affairs Director
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

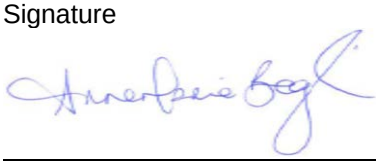
Or

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.Complaints@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

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