



COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN Ref: QCR-110/2021FA0008

FSCA Ref: QCR-110/2021FA0008

Date: 01 September 2021

Urgent Field Safety Notice
Single Lumen and Double Lumen Ovum Pick-Up Needles

For Attention of: Chief Executive Officer, Director of IVF Unit and Purchasing Officers/Stores Manager

Contact details of local representative (name, e-mail, telephone, address etc.)

Cook Medical Europe Ltd.
O'Halloran Road
National Technology Park
Limerick, Ireland
E-mail: European.FieldAction@CookMedical.com
Phone: Please refer to the attached Country Contact List.

For any further information or support concerning the information within this FSN please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.



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Urgent Field Safety Notice (FSN)
Single Lumen and Double Lumen Ovum Pick-Up Needles
Risk addressed by FSN

1. Information on Affected Devices	
1.	<p style="text-align: center;">1. Device Type(s)</p> <p>The Single Lumen Ovum Pick-Up Needles consist of a stainless-steel single lumen needle with a bevelled tip for puncture, an echogenic tip for enhanced visualisation under ultrasound and a manipulation handle. The Double Lumen Ovum Pick-Up Needles consist of a stainless-steel double lumen needle with a bevelled tip for puncture, an echogenic tip for enhanced visualisation under ultrasound, a manipulation handle, aspiration line, a silicone stopper with a luer fitting (to allow connection to a vacuum source) and a flushing line.</p>
1.	<p style="text-align: center;">2. Commercial name(s)</p> <p>Single Lumen and Double Lumen Ovum Pick-Up Needles</p>
1.	<p style="text-align: center;">3. Primary clinical purpose of device(s)</p> <p>The Single Lumen Ovum Pick-Up Needles are intended to be used for ultrasound guided transvaginal aspiration and flushing of ovarian follicles during ovum pick-up procedures. The Double Lumen Ovum Pick-Up Needles are intended to be used for ultrasound guided transvaginal simultaneous or independent aspiration and flushing of ovarian follicles during ovum pick-up procedures.</p>
1.	<p style="text-align: center;">4. Device Model/Catalogue/part number(s)</p> <p>K-OPAA, K-OPS, K-OSN, K-UCI, K-IOPS, K-TIVM, K-OPSD, K-OPSDC</p>
1.	<p style="text-align: center;">5. Affected serial or lot number range</p> <p>As per attached list.</p>

2 Reason for Field Safety Corrective Action (FSCA)	
2.	<p style="text-align: center;">1. Description of the product problem</p> <p>There is no indication of a device defect or problem. In 2021 there has been an increase in the number of incident reports raised due to patients experiencing bleeding (haemoperitoneum) after procedures involving William Cook Australia's Single and Double Lumen Ovum Pick-Up Needles.</p>
2.	<p style="text-align: center;">2. Hazard giving rise to the FSCA</p> <p>Bleeding (haemoperitoneum) incidents reported in 2021 have given rise to this Field Safety Notice. Due to an increase in incidents from France during 2021, William Cook Australia has determined that there is a need to issue a Field Safety Notice to customers within Europe, Switzerland, and Turkey with a "Guidance for use, warnings and precautions".</p>



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2.	<p>3. Probability of problem arising</p> <p>The global incident rate for bleeding (haemoperitoneum) following the use of Single Lumen Ovum Pick-Up Needles is 0.00092% and for Double Lumen Ovum Pick-Up Needles, it is 0.00012%. The probability of the problem arising is unlikely.</p>
2.	<p>4. Background on Issue</p> <p>In 2021, 29 complaints have been received for incidents involving bleeding (haemoperitoneum) after patients were treated with William A. Cook Australia's Single Lumen and Double Lumen Ovum Pick-Up Needles. The incidents occurred between 2019 and 2021. Ovum Pick-Up Needles have been CE marked since 1997 and have a long history of safe clinical use. Bleeding is a well-known and well documented adverse event described in literature which can occur from the use of any ovum pick-up needle during an oocyte collection procedure. To date, a manufacturing defect has not been identified by William Cook Australia which could contribute to these incidents. In Europe, Instructions For Use are not currently supplied with the products. An increase in complaints from France during 2021 has indicated to William A. Cook Australia that a field safety notice, containing a "Guidance for use, warnings and precautions" is necessary.</p>

3. Type of Action to mitigate the risk			
3.	<p>1. Action To Be Taken by the User</p> <p><input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">2. Is customer Reply Required? (If yes, form attached specifying deadline for return)</td> <td style="width: 30%; text-align: center;">Yes</td> </tr> </table>	2. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
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4. General Information															
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4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Reply form List of affected lot numbers Country Contact List Guidance for use, warnings and precautions
4.	6. Name/Signature	Alana Davey Regulatory Reporting Team Leader, Quality Assurance William A Cook Australia

Transmission of this Field Safety Notice	
	<p>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. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>