75 Corporate Drive
Trumbull, CT 06611
T: 203 601 5200
www.coopersurgical.com

JANUARY 10, 2023

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

17G Wallace Single-Lumen Oocyte Recovery Set

Part Number: ONS1733

Dear Valued CooperSurgical Customer,

CooperSurgical is hereby issuing a Medical Device Field Safety Notice (FSN) for the **lot 619003420** of its **17G Wallace Single-Lumen Oocyte Recovery Set** (herein known as the "Product").

Reason for Field Safety Notice (FSN):

CooperSurgical has become aware of failure reports regarding low or no suction when attempting to use the Product during its normal operation. An investigation is ongoing, and thus far a failure analysis of 60 samples of the same lot was performed in accordance with the Information for Use (IFU), revealing no failures in suction and no formation of bubbles. Based on preliminary investigation findings, CooperSurgical believes that the suction problems may be caused by a clinic's failure to properly check the connections and ensure adequate flow prior to use. Therefore, CooperSurgical strongly recommends that such actions are taken prior to use. This notice is being issued out of an abundance of caution because it has been noted that the Product from this lot specifically (**lot 619003420**) has an elevated reported occurrence of suction failure (sometimes including bubbles), which may ultimately result in a failure to obtain the intended oocyte(s).

Risk to Health:

The potential risk associated with loss of suction includes failure to collect the oocytes as intended, which may result in loss of viability of oocytes or may require additional attempts to properly collect the oocytes as intended. Any time additional attempts are necessary to properly collect the oocytes, there can be an increased risk of bleeding and pain.

Actions to be Taken:

CooperSurgical would like you to confirm receipt of this notice and **requests the completion of the form below** to ensure that all recipients of the Product in **lot 619003420** have been informed of the heightened complaint rate for this specific lot. We would like to take this opportunity again to **reiterate the importance of ensuring all connections are sound and adequate flow can be achieved as per the Instructions For Use. This means:**

1) **Ensure you check the flow rates before you start the OPU procedure, as you may need to adjust your negative pressure settings on your vacuum pump.**
2) **Please also ensure there is a secure seal between the test tube bung and the test tube. If the bung and test tube are incompatible sizes, there may not be a sufficient vacuum achieved.**
3) **Each OPU needle unit/system should always be tested prior to each patient procedure.**

We sincerely apologize for any inconvenience caused by receiving this notice. If you have any questions, please feel free to reach us at **recall@coopersurgical.com** or **+1 203-601-5200** ext. **3300**

Sincerely,

Karen Gienau

Karen Gienau
Sr. Post Market Surveillance Manager

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Customer Acknowledgement Form

IMMEDIATE RESPONSE REQUESTED

Please complete this form and return it via email to **recall@coopersurgical.com** or via fax to +1 **203.601.9870, ATTN: Product Surveillance.**

Customer Account #:	**Account Name:**	
Street Address:	**Town, State, & Zip Code:**	
Contact Name:	**Phone Number:**	**Email address:**

I have read and understand the notice instructions provided in the letter dated January 10, 2023. ☐ Yes ☐ No

Have any adverse events been associated with affected product(s)? ☐ Yes ☐ No

If yes, please explain: _____

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at +1 **203.601.5200** Ext. **3300** or email us at **recall@coopersurgical.com**. Adverse reactions or quality problems experienced with the use of this product may be reported to HPRA Serious Adverse Event Reporting program either online, by regular mail, or by fax.