



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

JANUARY 9, 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 it's **17G Wallace Single-Lumen Oocyte Recovery Set**. Hereby 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 or the formation of bubbles. Based on preliminary investigation findings, CooperSurgical strongly recommends following the IFU stressing the importance of checking the connections and ensuring adequate flow prior to use. This notice is being issued out of an abundance of caution because it has been noted that product from this lot specifically (**lot 619003420**) has an elevated reported occurrence of suction failure, bubbles, and 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. There is also a risk of bleeding and pain associated with additional attempts to properly collect the oocytes as intended.

Actions to be Taken:

CooperSurgical would like to confirm receipt of this notice and **requests the completion of the form below** to ensure that all recipients of the **lot 619003420** has 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 IFU. 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 the 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,



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 9, 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 HPRAs Serious Adverse Event Reporting program either online, by regular mail, or by fax.