The Pipette Company Pty. Ltd. Unit 13,
22 Ware Street, The Barton, South Australia 5031
Tel: +61-8-8152 0266
Email: tpc@pipetteco.com

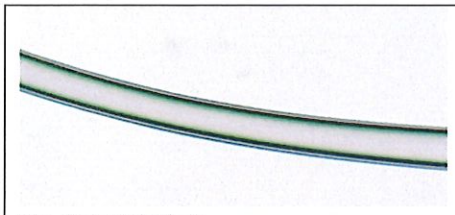
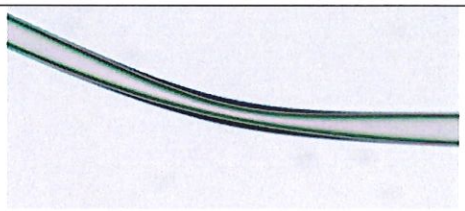
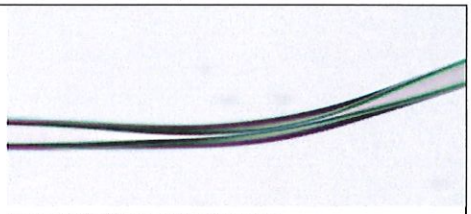
URGENT: Medical Device Recall

May 11, 2017

Dear Valued TPC Customer:

The Pipette Company (TPC) is notifying you of a potential issue with the Injection Pipettes. The affected part number is **LICR-TA35-RT** Lot **S2508T (11129).** The product is being recalled due to a manufacturing defect which may result in a constricted bend.

The products have been identified to have constricted bend due to the internal diameter of the **tip bend** being less than the internal diameter of the **tip.** The release specifications require the internal diameter at the bend to be equal to the internal diameter at the tip of the pipette. The pictures below show variations of the observed nonconformance. Our records show you may have received the affected lot number.

		
No Constriction	Slight Constriction	Constriction <2microns

The product package contains a laminated Tyvek pouch containing 10 Pipettes boxed in a Blue Pipette Holder. The lot number is clearly printed on the product package label.

The Injection Pipette is used to inject sperm into oocytes to fertilize the oocytes. Suction plays an important role as sperm must be freely aspirated into the pipette. Suction should be smooth and responsive to allow control of sperm and cytoplasm within the pipette. The Pipettes are manufactured with bend angles ranging from 20° to 35° to allow the operator to visualize the pipette for a length sufficient to track the position and movement of sperm and cytoplasm.

There have been no reports of any adverse event or patient injury to date. The defect was discovered during a complaint investigation. There is minimal compromised effect on the efficacy or procedural outcomes when Pipettes with extreme constrictions are used. The defect has no significant safety impact on the end user. Complete occlusion at the bend will have unresponsive or no suction and is readily detected by the end user prior to starting a procedure.

The observed non-conformance does not meet the required release specification for these products. We apologize for any inconvenience this may have caused. Please discontinue use of any of the lots listed in the table above and complete the attached **Acknowledgement and Receipt Form** to schedule refund or exchange. If you have any further questions, please feel free to contact TPC at tpc@pipetteco.com.

Sincerely

Nana Banafo, Manager Clinical Product Surveillance

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Acknowledgement and Receipt Form: Response is required

Please complete this form and return in the attached prepaid envelope or email to tpc@pipetteco.com.

Customer Account #:_____ Account Name: _____
Street Address:_____ Town, State, Zip Code: _____
Contact Name:_____Phone Number: _____
Email address: _____

I have read and understand the recall instructions provided in the **May 11, 2017** letter. Yes__No

Any adverse events associated with recalled product? Yes_____No

If yes, please explain:

_____

_____

Affected Product Information: Include information that is applicable for affected product.

Part Number	Part Description	Lot Number	Expiration Date

Part/Lot Number:_____Quantity in inventory:

Quantity returned:_____Quantity used/destroyed: _____

Return Response Box:

Provide any additional information, if applicable.

If respondent has any further questions, a representative at TPC will contact the person responding. Alternatively, you may contact TPC via recall@coopersurgical.com if you have additional questions.

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Acknowledgement and Receipt Form: Response is required

Please complete this form and return in the attached prepaid envelope or email to tpc@pipetteco.com.

For Distributors Only:

Customer Account#: _____Account Name: _____
Contact Name/Title _____Phone Number: _____
Email Address: _____

Affected Product Information: Include information that is applicable for affected product.

Part Number	Part Description	Lot Number	Expiration Date

I have read and understand the recall instructions provided in the **May 11, 2017** letter. Yes__No

I have checked my stock and have quarantined inventory consisting of _____units _____boxes

Part/Lot Number shipped to Customer: _____Quantity shipped: _____

I have identified and notified my customers that were shipped or may have been shipped this product by _____(Specify date and method of notification)

OR

Please notify the attached list of customers who received/may have received this product.
Signature of Receipt: _____

Please complete this form and return in the attached prepaid envelope or email to tpc@pipetteco.com.

If respondent has any further questions, a representative at TPC will contact the person responding. Alternatively, you may contact TPC via tpc@pipetteco.com if you have additional questions.