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Regulatory Affairs & Quality Assurance

March 19, 2018

## MEDICAL DEVICE RECALL- 5 mm Apple-Hunt Secondary Cannula

Dear Valued Customer:

CooperSurgical is recalling a single lot of the 5 mm Apple-Hunt Secondary Cannula (P/N: 900-840 Lot: 223333). The products were identified to have been packaged with the wrong Trocar length type. This discrepancy does not meet the product release specifications. Our records indicate that one or more of the affected products list below may have been distributed to your facility.

PART NUMBER	PART DESCRIPTION	LOT NUMBER		
900-840	5 mm Apple-Hunt Secondary Cannula/Pyramidal Tip	223333		
	Trocar - extended length (5/Box)			

The Apple-Hunt Secondary Cannulas are indicated for use in laparoscopic surgical procedures to provide a pathway for the introduction of endoscopic surgical instruments and allow for maintenance of pneumoperitoneum. The product package contains 5 individually Tyvek-sealed clear plastic trays. The device lot number and expiration date is located on the front Tyvek lid as well as on the side of the external packaging.

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Apple-Hunt Secondary	Cannuda ** Pyraminiati Tip + 5 mms + 6 Cannot have Constant from Constant from	And the second s	(	Apple-Hunt S Mar 900-940 GT 228337 GT 228337 GT 228337 GT 28837 GT 28857 GT 28857 GT 288	Caller Free Caller Free Caller Free ATTENTION ATTENTION ATTENTION ATTENTION Caller Cal	ramidal Tip Coper Surgeon An 100 Rd 9405 Hennes He

The event was discovered internally during a complaint investigation. No adverse events or injuries have been reported to date in connection with the use of the 5 mm Apple-Hunt Secondary Cannula. 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 supplied or transferred any potentially affected product to another facility or organization, please let them know of the recall by providing a copy of this letter. If you have any further questions, please feel free to contact CooperSurgical at <u>recall@coopersurgical.com</u>.

Sincerely,

