COOK SOUTH EAST ASIA PTE. LTD.
238A THOMSON ROAD, #12-08 NOVENA SQUARE
OFFICE TOWER A, SINGAPORE 307684
PHONE: +65 6812 7400, FAX: +65 6812 7401
CO. REGN: 198602196G
WWW.COOKMEDICAL.COM

May 3, 2017

URGENT: MEDICAL DEVICE RECALL

ATTENTION:
Risk Management/Recall Administration
Our records indicate that you may have received some of the affected products listed below.

Details on affected devices:

Product Brand Name	Catalog Identifier	Lot Number
LapSac® Introducer	J-LSI-102500	All lots

Note: There is another catalog identifier globally for this product (i.e. 054300). Please contact Cook South East Asia to verify if in any doubt.

Description of the problem:
Cook South East Asia Pte. Ltd. is initiating a voluntary recall of the products listed above. We have identified that the reprocessing instructions do not provide sufficiently detailed information for the cleaning, disinfection, and sterilization of these products. Our preliminary investigation indicates that the validation data related to the reprocessing of these devices do not meet the current guidance.

There have been no reports of adverse reactions related to inadequate cleaning, disinfection, or sterilization associated with these devices.

Potential adverse events that may occur if the products are not adequately reprocessed include localized surgical site infection to deeper organ space infection as well as chemical residual exposure.

Intended use for affected products:

Product Family	Intended Use	Product Image
LapSac® Introducer	Used to aid in the introduction of a LapSac during endoscopic surgical procedures.	

Action to be taken:

1. Examine your inventory immediately to identify and quarantine those affected products.
2. Return the required *Acknowledgement and Receipt Form* indicating quantities, part numbers, and lot numbers of affected products within 30 days.
3. **Return or discard any affected products.** (Instructions regarding product returns are listed in the attached Acknowledgement and Receipt Form.)
4. **Even if you do not have affected products**, you must still complete the *Acknowledgement and Receipt Form* and email to SNG-RegulatoryAffairs@CookMedical.com or return to a Cook South East Asia Pte. Ltd. Representative.
5. Immediately report any adverse events to;
   Cook South East Asia, Regulatory Affairs Department
   Yu Hosokai Tel:+65 6812 7486
   Jennifer Chin Tel:+65 6812 7461
   Email: SNG-RegulatoryAffairs@CookMedical.com
   Fax: +65 6812 7401

Alternatively, healthcare professionals may report the adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at

COOK SOUTH EAST ASIA PTE. LTD.
238A THOMSON ROAD, #12-08 NOVENA SQUARE
OFFICE TOWER A, SINGAPORE 307684
PHONE: +65 6812 7400, FAX: +65 6812 7401
CO. REGN: 198602196G
WWW.COOKMEDICAL.COM

www.hsa.gov.sg/ae_online. Events that are reported to Cook South East Asia will be investigated and subsequently reported to HSA.

Transmission of this notice:
This notice must be shared with appropriate personnel, including down to the user level, within your organization or to any organization where the potentially affected devices have been transferred.

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should you have any medical questions or concerns, please contact Cook South East Asia at +65 6812 7400. We look forward to your response.

Yours Sincerely,

[redacted]

COOK SOUTH EAST ASIA PTE. LTD. SINGAPORE

Yu Hosokai
Regulatory Affairs Specialist
CooK South East Asia Pte. Ltd.

CC: Chairman Medical Board
Relevant Head of Departments