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

3rd July 2018

MEDICAL DEVICE RECALL

QCR-86, RC-2018-RN-00835-1 DE0009663

Chorion Villus Biopsy Needle Set (K-CVNS-1821-Robinson-ET)

Attention: Chief Executive Officer, Director of Nursing, Operating Theatres,

Purchasing Officers/Stores Manager and OBGYN Department.

Our records indicate that you may have received some of the affected product.

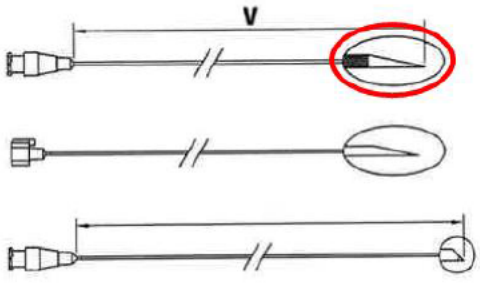
Details of Affected Product:

PRODUCT BRAND NAME	CATALOGUE IDENTIFIER	ORDER NUMBER	LOT
CHORION VILLUS BIOPSY NEEDLE SET	K-CVNS-1821-ROBINSON-ET	G26661	All lots with **expiry date** between **3 July 2018 to 4 June 2021**

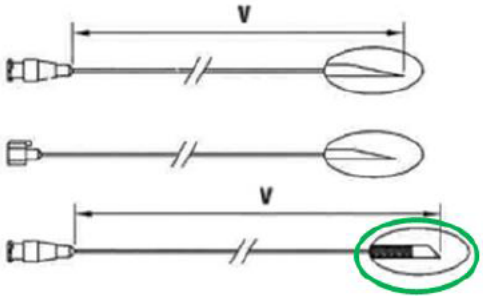
Description of the Problem:

Cook Medical is initiating a medical device recall of the Chorion Villus Biopsy Needle Set (K-CVNS-1821-Robinson-ET). The diagram on the product label is incorrect. It shows that the 18GA needle has an echotip, and the 21GA needle does not, whereas the product is designed such that the 21GA needle has the echotip and the 18GA needle does not.

INCORRECT LABEL



CORRECT LABEL



The tip of the larger gauge guide needle is likely to be visible on the ultrasound regardless of a non-echogenic tip. Therefore the risks associated with the labelling error are extremely low. In the event that the labelling error resulted in a clinician expecting the echogenic tip to be present on the guide needle, instead of the sampling needle, the clinician may not be able

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to adequately identify the tip of the inserted access needle. It is unlikely that use of the mislabelled product will result in occurrence of an adverse event.

There are no factors that may contribute to the risk associated with the use of K-CVNS-1821-ROBINSON-ET containing a misrepresentation of echotip on the label. Manufacturing needle echotipping procedures are not impacted by label graphics. There is no effect on product, it is only a label error.

Action to be Taken:

1. Examine inventory immediately to determine if you have affected product.

2. **If you have affected product in your inventory**, please quarantine the affected product/s.
   Once your affected product has been quarantined, please complete the Acknowledgement and Receipt Form within **5 business days** and send it via fax (65) 6812 7401, or
   email: SNG-RegulatoryAffairs@CookMedical.com

3. If you no longer have affected product in your inventory, complete the Acknowledgement and Receipt Form and return it via fax (65) 6812 7401, or email: SNG-RegulatoryAffairs@CookMedical.com

4. **Even if you do not have affected products**, you must still complete the *Acknowledgement and Receipt Form* and send it via fax (65) 6812 7401 or email to SNG-RegulatoryAffairs@CookMedical.com

5. **Once acknowledgement form is received, Cook Medical will arrange for collection of affected products and product credit.**
   NOTE: Unaffected products that are returned will not be credited

6. Report 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 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:

Please pass this notice on to the appropriate personnel, including down to the user level, within your organisation or to any organisation where the potentially affected devices have been transferred.

Please retain this letter in a prominent position for one month should there be any product in transit.

Thank you for your immediate attention to this matter. We recognise this disrupts your normal operations and for this, we sincerely apologise. Should you have any questions or concerns, please contact Customer Service (email:

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CO. REGN: 198602196G
WWW.COOKMEDICAL.COM

CookSEA.CS@CookMedical.com phone: 6320 7678/ 7677) or your local field representative at Cook Medical for more information.

Yours Sincerely

[redacted]

[redacted]

Jennifer Chin
Regulatory Affairs Officer
Cook South East Asia Pte Ltd

WILLIAM A. COOK AUSTRALIA PTY. LTD.
95 BRANDL STREET, BRISBANE TECHNOLOGY PARK
EIGHT MILE PLAINS, BRISBANE, QLD 4113, AUSTRALIA
PHONE: +61.7.3434.6000 FAX: +61.7.3434.6001
WWW.COOKMEDICAL.COM
ABN 79 005 526 723

27th June 2018

MEDICAL DEVICE RECALL

QCR-86, RC-2018-RN-00835-1 ARTG:138806

Chorion Villus Biopsy Needle Set (K-CVNS-1821-Robinson-ET)

Attention: Chief Executive Officer, Director of Nursing, Operating Theatres, Purchasing Officers/Stores Manager and OBGYN Department.

Our records indicate that you may have received some of the affected product.

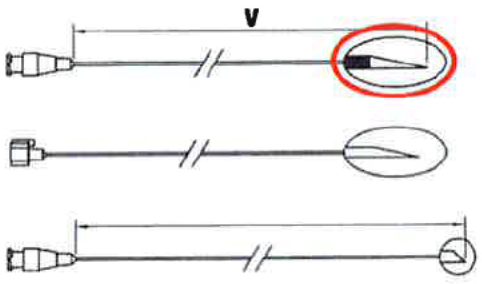
Details of Affected Product:

PRODUCT BRAND NAME	CATALOGUE IDENTIFIER	ORDER NUMBER	LOT
CHORION VILLUS BIOPSY NEEDLE SET	K-CVNS-1821-ROBINSON-ET	G26661	All lots manufactured up to 4 June 2018

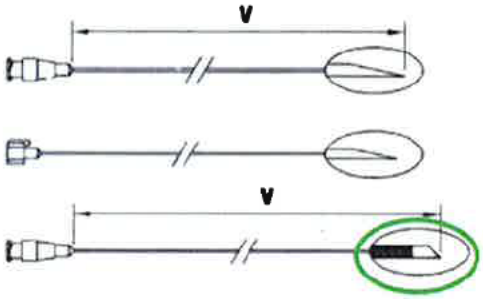
Description of the Problem:

Cook Medical is initiating a medical device recall of the Chorion Villus Biopsy Needle Set (K-CVNS-1821-Robinson-ET). The diagram on the product label is incorrect. It shows that the 18GA needle has an echotip, and the 21GA needle does not, whereas the product is designed such that the 21GA needle has the echotip and the 18GA needle does not.

INCORRECT LABEL



CORRECT LABEL



The tip of the larger gauge guide needle is likely to be visible on the ultrasound regardless of a non-echogenic tip. Therefore the risks associated with the labelling error are extremely low. In the event that the labelling error resulted in a clinician expecting the echogenic tip to be present on the guide needle, instead of the sampling needle, the clinician may not be able to adequately identify the tip of the inserted access needle. It is unlikely that use of the mislabelled product will result in occurrence of an adverse event. There are no factors that may contribute to the risk associated with the use of K-CVNS-1821-ROBINSON-ET containing a misrepresentation of echotip on the label. Manufacturing needle echotipping procedures are not impacted by label graphics. There is no effect on product, it is only a label error.

Action to be Taken:

1. Examine inventory immediately to determine if you have affected product.

2. **If you have affected product in your inventory**, please quarantine the affected product/s. Once your affected product has been quarantined, please complete the Acknowledgement and Receipt Form within **5 business days** and send it via fax (07) 3841 3905, or email: cau.custserv@cookmedical.com or ausrecalls@cookmedical.com.

3. If you no longer have affected product in your inventory, complete the Acknowledgement and Receipt Form and return it via fax (07) 3841 3905, or email: cau.custserv@cookmedical.com or ausrecalls@cookmedical.com .

4. **Even if you do not have affected products**, you must still complete the *Acknowledgement and Receipt Form* and send it via fax ((07) 3841 3905) or email to (cau.custserv@cookmedical.com or ausrecalls@cookmedical.com).

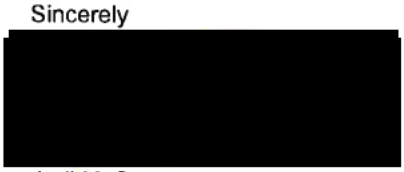
5. **Return affected products to Cook Medical with a copy of the acknowledgement form to receive a product credit.**
   NOTE: Unaffected products that are returned will not be credited

6. Report adverse events to Cook Medical Customer Relations by phone, on 1 800 777 222, or contact your local Cook representative.

Transmission of This Notice:

Please pass this notice on to the appropriate personnel, including down to the user level, within your organisation or to any organisation where the potentially affected devices have been transferred. Please retain this letter in a prominent position for one month should there be any product in transit. Thank you for your immediate attention to this matter. We recognise this disrupts your normal operations and for this, we sincerely apologise. Should you have any questions or concerns, please contact Cook Medical Customer Service or your local field representative at Cook Medical for more information. Please use cau.custserv@cookmedical.com, or call toll free -1 800 777 222. We look forward to your response. This action has been undertaken after consultation with the Therapeutic Goods Administration.

Sincerely



Jodi McCann
Quality Manager
William A Cook Australia Pty Ltd