

Date: 4th August 2022

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION- OSCA Obstetric Suction Cup

Model (HK-TTQ-A)

HTKD MEDICAL

Lot Numbers: U2112(2)

Re: Customer Notification regarding the OSCA Obstetric Suction Cup (HK-TTQ-A)

To Whom it May Concern:

This Field Safety Notice is to inform you of a voluntary recall of HTKD Medical's OSCA Obstetric Suction Cup (HK-TTQ-A) involving Lot number U2112(2). The purpose of the recall is to address the potential failure of cable tension when generating vacuum.

HTKD Medical has received reports of OSCA devices that fail to generate or maintain vacuum during use due to a cable failure. HTKD Medical attach great importance to these quality feedbacks. In order to further check the cause of the problem in this lot number U2112(2) and eliminate the safety risks, we are conducting a full investigation as to how this occurred on this Lot Number. We will publish full results of this investigation on completion.

Please provide this information to your hospitals. If you have further distributed this product, please identify your customers and notify them at once of this communication and/or contact HTKD Medical with the contact information so that we can follow-up with the owner of the device.

HTKD Medical is working diligently to resolve this issue. In the meantime, please quarantine any remaining product with this Lot Number U2112(2) in your hospitals. A company representative will contact you and arrange for the return of the product. HTKD Medical, via your local representative, will provide replacement product at no charge. If you have any questions, please call your relevant Distributor Representative.

In accordance with applicable rules, the competent authorities in your country will be notified of this corrective action.

We regret and apologize for any inconvenience that this may cause. We do appreciate your patience and understanding and you can be assured that we will continue efforts to ensure that this product lives up to the high-quality standards expected of all HTKD Medical products.

If you have any further questions regarding this matter, you may contact our European Distribution Manager, Gary Johnson, at gary@ex2medical.com – 00353 86 0480291, or myself at jeffjiang@bj-htkd.com

Yours sincerely,



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