URGENT FIELD SAFETY NOTICE
REF: FCA-76

ACTION REQUIRED

Edwards Lifesciences LLC: Edwards Commander Delivery System Models 9610TF23, 9610TF26, 9610TF29

May XX, 2016

ATTENTION: Risk Management and Users of the Edwards Commander Delivery System

Details on affected device:
Edwards Commander Delivery System Models 9610TF23, 9610TF26, 9610TF29

Dear Customer,

Edwards has received reports of leaks occurring at the Y connector on the balloon inflation shaft of the Commander Delivery System. Our investigation of these reports concluded the following:

1) The leaks are caused by a crack in the shaft adjacent to the Y connector, under the strain relief tube, at a reflow joint in the shaft and can impact the ability to complete full inflation of the balloon, and full expansion of the valve; and
2) In rare cases, inability to fully deploy the valve in the required location may result in the need for post-dilatation of the valve, deployment of the valve in a non-target location, embolization of the valve, or complications related to the need for surgical removal of the underdeployed valve,
3) The failure may be induced by handling which can occur subsequent to manufacturing, and thus not detected in our 100% manufacturing leak test.

Unfortunately no mitigation measure has been identified which can reliably detect or prevent that issue before use. However, Edwards is aware that there have been occasions when the device deficiency (leakage at the y-connector) has been noticed before using during preparation of the system. Therefore please take special care during the de-airing step of the preparation as occasionally an existing leakage can be noticed here. If that is the case please discard the Commander system and prepare a new one.

We have developed changes to the manufacturing process of the shaft at our supplier which will mitigate these failures and have begun incorporating these changes into finished good manufacturing at Edwards.

The observed complaint rate for this issue is approximately **0.1%** based on our global experience with the device and information available to date. The incidence of serious events is approximately **0.01%**. We have completed a comprehensive Risk/Benefit analysis (provided to BfArM) comparing the risk of this issue occurring on Commander delivery systems, versus removing the SAPIEN 3 System. The analysis shows that the risk to patients presented by removing the device from distribution is higher than the risk presented by this issue.
With that in mind, and in order to assure continued availability of product to support the treatment of TAVI patients, we will replenish field inventory as quickly as possible. Based on our manufacturing capacity for Commander delivery systems, we expect to have enough of the improved Commander inventory to enable a product exchange in German sites starting Aug. 31st, 2016 and we expect the exchange to be completed by Sept. 30th, 2016.

You will be contacted at that time by your Edwards representative, and Edwards will replace any remaining older version of the Edwards Commander Delivery System in your inventory with this new improved version.

An acknowledgment form is included with this Field Safety Notice. Please review the Acknowledgment form, sign and date it, and return it to your Edwards Clinical Representative or FAX/Email it as instructed on the Form attached. At this point in time, no other action is necessary.

If you have any questions or concerns regarding this Urgent Product Notification, please do not hesitate to contact your Edwards Clinical Representative.

Sincerely,

[redacted]
Edwards Lifesciences

This Urgent Field Safety Notice has been communicated by Edwards Lifesciences to the relevant competent authority.

Edwards

Acknowledgment Form

THE URGENT FIELD SAFETY NOTICE
REF: FCA - 76

ACTION REQUIRED
Edwards Commander Delivery System Models 9610TF23, 9610TF26, 9610TF29

I acknowledge that I have read and understand the information provided in the Urgent Field Safety Notice dated XX/XX/XX regarding Commander Delivery Systems, Models 9610TF23, 9610TF26, 9610TF29

Hospital / Location (Print): _____

Name (Print): _____

Title and Department: _____

Contact Information
Tel.No/Fax No /Email: _____

Signature: _____ Date: _____

Please fax/e-mail this form to

Fax : xxx or E-Mail : xxx@edwards.com