# URGENT FIELD SAFETY NOTICE
# REF: FCA-141

**Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System (SAPIEN 3 Ultra Delivery System)**
**Models: 9630TF20, 9630TF23, 9630TF26, 9630TF29**

## ACTION REQUIRED

<MM DD, YYYY>

**<Customer #>**
<Contact name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

**ATTENTION:** Risk Management and Users of the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System

**Details on affected device:**
**Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System (SAPIEN 3 Ultra Delivery System)**
**Models: 9630TF20, 9630TF23, 9630TF26, 9630TF29**

Dear Customer,

Since the recent commercial availability of the SAPIEN 3 Ultra System, Edwards has received reports of burst balloons which have resulted in significant difficulty retrieving the SAPIEN 3 Ultra delivery system into the sheath and withdrawing the system from the patient.

The overall observed complaint rate for balloon burst is approximately 1.0% based on the limited experience with the device of which approximately 0.5% had clinical implications for the patient such as difficulty removing the Delivery System, vascular injury, bleeding, and/or need for surgical intervention. Valve deployment was successful in these cases. Following investigations into these events, Edwards has not identified any evidence of devices that did not conform to specifications.

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**Edwards investigation has determined two factors that influence the frequency of balloon burst: excess inflation volume and fast inflation conditions. The guidelines and instructions provided in the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System IFU and training materials for device use are highlighted below:**

- When deploying the valve, inflate the balloon slowly and continuously throughout deployment. Hold for 3 seconds at full inflation.
- The delivery system requires a prescribed volume for THV deployment and proper function (11 mL, 17 mL, 23 mL, 33 mL).

The following warning will also be added to the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System IFU:

- Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, difficulty retrieving the delivery system, and may require subsequent conversion to surgical intervention.

**Further investigation has also identified a new method for retrieving a burst SAPIEN 3 Ultra balloon through the sheath. It should be noted that this technique may not resolve all retrieval scenarios.**

Edwards is in the process of updating the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System training materials to provide the following recommendations to improve the likelihood of procedural success when balloon bursts occur.

**If a balloon burst is suspected, do not attempt to pull back the delivery system into the sheath until you are prepared to conduct the following technique:**

1. Close stopcock to the delivery system and remove inflation device from stopcock.

2. Continuously twist the handle in a clockwise direction (full 360º rotations) while gently pulling back the delivery system into the sheath tip. Verify delivery system tip has entered the sheath tip under fluoroscopy.
   i. DO NOT FORCE if resistance is met near or at the sheath tip. Forcing retrieval when meeting resistance could result in additional balloon material tearing or tip dislodgement. Consider utilizing other interventional techniques for retrieval (e.g. a snare).

3. If successful in pulling the entire balloon into the tip of the sheath, withdraw the delivery system and sheath as a single unit completely from the arteriotomy while maintaining guidewire position. DO NOT attempt to pull the delivery system through the remaining length of the sheath.

4. If resistance is still encountered, convert to surgery for device removal. Based on medical assessment of the size, tortuousity, and extent of calcification of the peripheral vessels, evaluate the risks and tradeoffs of carefully withdrawing the system into a more peripheral anatomy in order to allow a more localized procedure. Consider use of an occlusion balloon to mitigate bleeding risks.

Please review the acknowledgment form, sign and date it, and return it to your Edwards Representative or FAX/email it as instructed on the form attached. There is no further action necessary regarding this Field Safety Notice.

This notice should be provided to all users of the SAPIEN 3 Ultra system within your organization. If you have any questions or concerns regarding this Urgent Field Safety Notice, please do not hesitate to contact your Edwards Representative.

Sincerely,

[redacted]
[redacted]
Edwards Lifesciences

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

Edwards

## Acknowledgment Form

**URGENT FIELD SAFETY NOTICE**
**REF: FCA - 141**

**Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System**
**(SAPIEN 3 Ultra Delivery System)**
**Models: 9630TF20, 9630TF23, 9630TF26, 9630TF29**

I acknowledge that I have read and understand the information provided in the Urgent Field Safety Notice dated [DATE OF LETTER] regarding Edwards SAPIEN 3 Ultra Transcatheter Heart Valve Systems (SAPIEN 3 Ultra Delivery System), Models 9630TF20, 9630TF23, 9630TF26 and 9630TF29

Hospital / Location (Print):

_____

Name (Print):

_____

Title and Department:

_____

Contact Information
Tel.No/Fax No /Email:

_____

Signature: _____

Date: _____

Please email or fax this acknowledgement form to the attention of:
Customer Service
[insert local EW company name]
[insert local EW company address]
[insert local Customer Service email address]
[insert local Customer Service fax number]