

Urgent FIELD SAFETY NOTICE

Device: Titan™ Stabilizer and Titan™ 360 Stabilizer: Suction Tubing Clip
Reference: FSN1406 2015-02
Action: Device Removal

Attention: Chief of Perfusion, Department of Cardiovascular Surgery, Director of Operating Room Services

DESCRIPTION

Terumo Cardiovascular Systems (Terumo CVS) is voluntarily recalling certain lots of Titan™ Stabilizers and Titan™ 360 Stabilizers because the Suction Tubing Clip may break when it is being attached to the Hercules™ 3/360 Universal Stabilizer Arm. Although the clip is for convenience purposes and is not required for device operation, there is potential for broken Suction Tubing Clip fragments to fall into the surgical site.

Five reports have been received of Suction Tubing Clips breaking when the surgeon attempted to attach the clip to the Stabilizer Arm.

Note: part of the affected population is distributed by Estech prior to Terumo CVS acquiring the product line.



POTENTIAL HAZARD

There are no reported injuries or illnesses as a result of this issue.

A broken Suction Tubing Clip could delay a surgical cardiac procedure as the surgeon replaces the unit or secures the suction tubing away from the surgical site by other means.

If a Suction Tubing Clip breaks and fragments fall into a patient's body cavity during surgery, the event could lead to a delay in the procedure as the surgeon retrieves the component. This could be complicated by the fact that the clip fragments may have sharp edges and are not radiopaque.



Titan Stabilizer attached to Hercules™ 3 Universal Stabilizer Arm (Suction Tubing Clip on right).

DETAILS ON AFFECTED DEVICES

Reference	Description	Lot Number
401-231	Titan™ Stabilizer Attachment	052R
401-231U	Titan™ 360 Stabilizer Attachment	020R, 024R, 026R, 029R, 030R, 034R, 035R, 037R, 040R, 048R

CORRECTIVE ACTION

Terumo CVS' investigation determined that the Suction Tubing Clip material weakened during a re-sterilization process that occurred for the affected lots listed. Terumo CVS' current sterilization process mitigates this risk.

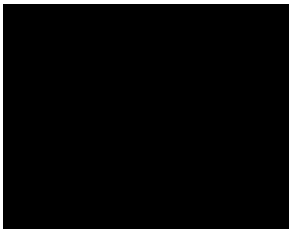
Terumo CVS advises users to stop using Titan Stabilizers and Titan 360 Stabilizers from the affected lot numbers and return all affected product to Terumo.

CUSTOMER INSTRUCTIONS

- (1) Review this Field Safety Notice and assure that all users are aware of this notice.
- (2) Discontinue use of affected product.
- (3) Indicate the number of affected Titan™ Stabilizers and Titan™ 360 Stabilizers in inventory from the referred population on the related reply form and return this form as quickly as possible to the fax number or email address indicated on the form.
- (4) A local Terumo representative will contact you to organize pick-up of return(s), compensation and/or suitable replacement.

We confirm that this Field Safety Notice has also been notified to your national Competent Authorities. We encourage you to contact us or your local Terumo representative with any questions or concerns:

Organisation (to be completed by the sales or dealer)
Contact name (function)
Contact phone, mobile, email



MD Vigilance Specialist
Regulatory Affairs
Terumo Europe NV
Leuven, Belgium

Device: **Titan™ Stabilizer and Titan™ 360 Stabilizer: Suction Tubing Clip**

Reference: **FSN1406 2015-02**

Please complete, sign and fax or email this back: To:
Telefax / e-mail:

Hospital Name	
City	
Country	

Our records indicate that you have received affected unit(s).

By completion and return of this form, I am confirming receipt, reading and acting on this Safety Notice:

- We have no physical inventory from the affected population.
- We have the following affected unit(s) ready to return:

Reference	Lot Number	Number of units ready to return

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN1406A [EN]