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Philips Image Guided Therapy Corporation

March 26, 2020

Urgent Field Safety Notice (FSN)

Bridge Occlusion Balloon 590-001

<Contact Name>
<Customer Name>
<Street Address>
<City, State, Zip Code>

Dear Healthcare Professional,

The purpose of this letter is to advise you that Philips Image Guided Therapy Corporation is issuing a voluntarily notice for all lots of the Bridge Occlusion Balloon which is indicated for:

The Bridge Occlusion Balloon catheter is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage. Any use for procedures other than those indicated in the instructions is not recommended.

Reason for the Field Safety Notice:
The purpose of this letter is to provide you with an update regarding the Bridge occlusion balloon. We recently were made aware of an unpublished physician study that suggests potential formation of thrombus on the Bridge occlusion balloon when staged in patients for an extended period of time.

Risk to Health:
The preliminary study results suggest that intravascular balloon staging with prolonged dwell times (average of 176 ± 118 minutes) may be associated with an increased risk of thrombus formation. This study had one reported pulmonary embolism identified 3 days post procedure, which has not been attributed to the device. The rate of occurrence of the risk of harm is deemed to be remote (0.0108%), as no additional complaints for thrombus formation have been reported over the lifetime of the device outside of this preliminary study. This rate is within the expected range for lead extraction per HRS guidelines.[1]

The safety of the Bridge occlusion balloon has been well-proven among thousands of lead extractions over the last several years[2] and remains effective in occluding SVC tears, significantly reducing the probability of mortality when used properly.[3] Due to the rapid rate of blood loss associated with SVC tears, the Bridge device may be staged prophylactically to limit the time to occlusion.[3]

Actions to be taken by the Healthcare Professional:
Inform potential users of the product in your organization of this notification and ensure awareness.
At this time, the recommendation from our Medical Advisory Board is; when utilizing Bridge prophylactically, consider deployment after lead preparation is complete, and before the extraction sheath is inserted into the patient. Once extraction is complete and there are no hemodynamic stability concerns, remove Bridge from the vasculature.

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Recommendations for Bridge preparation[3] remain the same: place a 0.035" stiff guidewire to any internal jugular, subclavian, or brachiocephalic vein before every lead extraction procedure, and all patients should have a 12F femoral vein introducer sheath inserted.

Best practice protocol[3] encourages prophylactic use of Bridge for high-risk cases, low-volume or new extractors, intra-procedure perceived increase risk, and physician familiarity or preference. Several dozen patient rescues have been reported with prophylactic use of the balloon, and prophylactic use may limit >700cc of incremental blood loss[3] compared to emergent use. At this time, the benefits of prophylactically staging the Bridge occlusion balloon outweigh the risks[4].

Type of Action by the Company:
In order to correct this issue Philips Image Guided Therapy Corporation will be updating the IFU with these instructions.

Contact Information:
Patient safety and transparency of data are paramount at Philips. Philips values the trust you place in us for the delivery of safe, effective, high-quality products. This voluntary field safety notice is consistent with our commitment to you and your patients. If you have any questions, please contact your local Philips sales representative or reach out to us directly using the contact information below.

Philips Image Guided Therapy Corporation:
Address: Plesmanstraat 6, 3833 Leusden, Netherlands
Email: IGTD_INTL_FieldSafety@philips.com

As always, adverse reactions or quality problems experienced with the use of this product may be reported to vecomplaints@philips.com or IGTD.customerinquiry@philips.com

Sincerely,

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1. Kusumoto, FM. et al "2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction." Heart Rhythm. 2017 Dec;14(12):e503-e551. doi: 10.1016/j.hrthm.2017.09.001. Epub 2017 Sep 15.
2. Date on file, Philips Lead Management case log. 2016-2020.
3. The Endovascular Occlusion Balloon for Treatment of Superior Vena Cava Tears During Transvenous Lead Extraction: A Multi-Year Analysis and An Update to Best Practice Protocol. Circ Arrhythm Electrophysiol. 2019;12(8):e007266.
4. Tsang DC, Azarrafiy R, Pecha S, Reichenspurner H, Carrillo RG, Hakmi S. Long-term outcomes of prophylactic placement of an endovascular balloon in the vena cava for high-risk transvenous lead extractions. Heart Rhythm. 2017;14:1833–1838.

Customer Response Form

Mandatory fields are marked with *

1. Field Safety Notice Information	
FSN Reference Number	D05573

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FSN Date	26th March 2020
Product Name	Bridge® Occlusion Balloon
Product Code/ Model	590-001

2. Customer Details	
Healthcare Facility/Hospital Name*	
Distributor Name (if applicable)	
Address*	
Country*	
Contact Name*	
Title/ Function of Contact	
Telephone Number*	
Email*	

3. Action undertaken on behalf of Healthcare Facility/Distributor;

☐ I confirm receipt of the Field Safety Notice and that I read and understood the content

Print Name*	
Signature*	
Date*	

4. Please return acknowledgement to sender;

Email	IGTD_INTL_FieldSafety@philips.com
Postal Address	Plesmanstraat 6, 3833 Leusden, Netherlands

Deadline for acknowledgement: **30th September 2020**

It is important that your organization acknowledge receipt of this FSN. Your organizations reply is the evidence required to monitor the progress of the corrective actions