



Sunny Medical Device (Shenzhen) Co., Ltd.

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www.sunnymedical.com.cn

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## **Urgent Field Safety Notice2018-001/01**

**Haemostatic Valves**

**FSCA Dated: June 29, 2018**

**Comments on use**

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Date: **July 24, 2018**

**Attention:** Health Professionals

### **Details on affected devices:**

Sunny Medical Device (Shenzhen) Co., Ltd is sending this communication to notify you of a problem detected in products with the following catalog number:

Product name: Haemostatic Valves

Specification code: SM-HV-7CFLCR-TB

Lot No.: C07180A4

### **Description of the problem:**

Sunny Medical Device (Shenzhen) Co., Ltd has received incidents notifications involving the above mentioned medical devices, and it was reported that:

The click version SM-HV-7CFLCR-TB was causing 6 documented embolies in one hospital, due to air in the system.

Sunny Medical Device (Shenzhen) Co., Ltd has identified as possible root cause the improper use by the doctor, resulting in not all of the gas in the Y connector being discharged. Based on these information, Sunny Medical Device (Shenzhen) Co., Ltd decided to ask the doctor to discharge all the gas inside the device when using the haemostatic valves listed above.

### **Advise on action to be taken by the user:**

To discharge all the gas inside the device when using the haemostatic valves.

### **Transmission of this Field Safety Notice:**

Please make all users and relevant personnel in your organisation aware of this Field Safety Notice. If you have passed the haemostatic valves to third parties, please forward a copy of this information or inform the contact below.



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If you have any question, please don't hesitate to contact Sunny Medical Device (Shenzhen) Co., Ltd or your national sales representative.

**Contact reference person:**

Mr Ulrich Oestreicher  
Andanza International  
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Or

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We apologize for any inconvenience this Field Safety Corrective Action is causing you and thank you for your cooperation.

Sunny Medical

Joanne Zhang  
Sales Manager



Sunny Medical Device (Shenzhen) Co., Ltd.

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## ATTACHMENT I

### Field safety notice

### Business Reply Form

I hereby certify that I have read and understood the Field Safety Notice2018-001/01 and, if appropriate, passed it to my customers.

Product Name	
Product Lot No.	
Product Quantity	
Please check all that applies to the current case	<input type="checkbox"/> We do not have stock of the suspected lots. <input type="checkbox"/> We have notified our clients to do as the notice said
Name (Please block letter)	
Organisation/Company	
Place/Country	
Date	
Signature	

Please return this form by E-mail to [sunnymedical\\_cn@139.com](mailto:sunnymedical_cn@139.com) or by Fax to +86 755 22635989