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FIELD SAFETY NOTICE – InterAtrial Shunt Device (IASD) System II

Corvia Medical FSCA-02-2020-09-28

Change to the Instructions for Use:
IFU Part Number 00453AW Rev 06 - Advice given by manufacturer regarding the use of the device.

The Instructions for Use (IFU) labeling for the IASD System II medical device has been updated and reissued to all medical device inventory in Europe.

There is more emphasis on avoiding device mal-deployment. The revised IFU language is a component of the action plan to reduce risk, following a procedure with maldeployment previously filed as a vigilance report to the Dutch competent authority under the reference IT 2031396. The following changes to the IFU are associated with this action:

1) Warnings – "Avoid mal-deployment of the device" is elevated to be a heading within the Warnings section. In the prior version of the IFU there were no headings within the warnings section.

2) Potential Adverse Events – to the already existing potential risk: "Device embolization, whole or partial," added a description of the potential consequences: "Intervention or surgery to remove an embolized or mal-deployed device".

3) Procedural Cautions – (new) "Caution: Do not place the guidewire in the LV or allow the guidewire to migrate into the left ventricle."

The revised IFU also includes updates to address requirements of the EU Medical Device Regulation. The revised IFU was reviewed and approved by the Notified Body. The FSCA is provided to the National Competent Authorities of the countries where the device is distributed.

Users are instructed of labeling changes by a company representative prior to use. Training records for this action are on file with the company. All product inventory is within the control of the company, so all devices made available to the user have the revised Instructions for Use.

Please complete the attached form by which you confirm that 1) you have received this notification and 2) have distributed this Field Safety Notice to whom it may concern.

Contact person for this notification:

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Acknowledgement of Receipt Instructions

Please complete this acknowledgement of receipt and return it to Corvia Medical within 7 days. *Confirmation text below may be copied/paste into an email message or printed, hand-filled scanned and attached to email or faxed*:

Email to: kstohlman@corviamedical.com

Or FAX to: Kate Stohlman, +1 (978) 654-6130

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Acknowledgement of Receipt

Hospital/Company Name:	
Address (city/country):	
Responder Name:	
Function:	
Phone number:	
Email:	
Date of confirmation:	

I confirm that I have received the Field Safety Notice from Corvia Medical regarding the update in Instructions for Use of the InterAtrial Shunt Device (IASD) System II and have distributed the notification to whom it may concern.

End of Response

Corvia Medical follows the EU requirements for confidentiality of personal information.

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