

URGENT FIELD SAFETY NOTICE UPDATE
(Update to Field Safety Notice of April 15th, 2014)

Cordis RENLANE™ Renal Denervation Catheter
Catalog No: D135601

All Lot Numbers containing Instructions for Use (IFU) Part Number M-5276-790A
Highest affected lot number 15978181L

August 4, 2014

Dear Valued Customer,

The purpose of the original April 15th, 2014, Field Safety Notice (FSN) communication was to inform you that Cordis Corporation (“Cordis”) is issuing modified labeling for its RENLANE™ Renal Denervation Catheters (catalog number D135601) that include the Instructions for Use (IFU) with part number M-5276-790A (identified in the footer of the IFU document).

In that FSN, Cordis explained that the IFU would be modified to provide supplementary information due to a potential risk that may occur if the affected device is inserted or retracted through a Tuohy-Borst type adjustable hemostasis valve. The RENLANE™ Renal Denervation Catheter Device is manufactured by Biosense Webster, Inc. and distributed by Cordis.

This Update is to provide you with the final IFU modification, which has updated wording relative to compatible arterial access devices along with a copy of the revised IFU. The balance of the information provided in the original FSN is repeated herein. This FSN Update supersedes the original FSN.

Overview:

The original FSN provided important information concerning potential damage that may occur to the helical tip of the RENLANE™ Renal Denervation Catheter (catalog number D135601). As already described in the original IFU, the RENLANE™ Renal Denervation Catheter is a 6F multi-electrode luminal catheter with a 5F shaft. Inadvertent dislodgement or detachment of the rings or of the catheter’s helical tip may occur when the orifice of a Tuohy-Borst type adjustable hemostasis valve is not fully open, especially as the larger French size of the catheter tip is advanced or withdrawn.

This FSN Update clarifies that use of spring-loaded adjustable valves is not recommended, as further discussed in the “Recommendations and Precautions during Clinical Use” section below. Additional wording in that section has been provided to match the final wording incorporated into the IFU. A copy of the updated IFU is included with this FSN.

Details on Affected Device:

The affected product was only distributed in Germany. The highest affected lot number is 15978181L, which is the highest lot number containing the original IFU.

Indications for Use

The RENLANE™ Renal Denervation Catheter and related accessories are used in conjunction with the

RENLANE™ Multi-Channel RF Generator for use in adult patients (> 18 years) with drug resistant hypertension to denervate the renal arteries to reduce blood pressure.

Actions requested on your part:

- Carefully read the “Description of the Problem” and “Recommendations and Precautions during Clinical Use” sections below.
- Complete, sign and return the attached *Customer Acknowledgement Form Update* confirming your understanding of this notice in accordance with the instructions listed on the form.
- Pass on this notice to anyone in your facility that needs to be informed.
- Maintain awareness of this communication until your existing inventory has been depleted. This information has now been incorporated into the updated revision of the RENLANE™ Renal Denervation Catheter (D135601) Instructions for Use (part number M-5276-790B). A copy of the updated IFU is included with this FSN. All lot numbers above 15978181L will have the updated IFU.
- Maintain a copy of this Urgent Field Safety Notice Update with the affected device(s).

Description of the Problem:

A potential risk has been identified through two (2) RENLANE™ Renal Denervation Catheter complaints. Damage to the helical tip of the catheters, including detachment of the rings, was observed. During a failure investigation, analysis showed that use of a Tuohy-Borst type adjustable hemostasis valve, when not fully opened during catheter advancement or withdrawal, caused the catheter damage reported in the received complaints.

Recommendations and Precautions during Clinical Use:

The “Precautions” section of the IFU for the RENLANE™ Renal Denervation Catheter has been updated with the following:

Compatibility of a Tuohy-Borst type spring-loaded valve has not been evaluated with the RENLANE™ Renal Denervation Catheter. Therefore, use of spring-loaded adjustable valves is not recommended as their safety with the catheter has not been established.

Cordis would like to re-emphasize the following wording in the “Catheter Description” section of the IFU:

The catheter is deployed in the renal artery using a compatible arterial access device with a minimum 6.7F inner diameter (0.088”).

Cordis would like to re-emphasize the following wording in the “Precautions” section of the IFU:

- **Do not use excessive force during advancement or withdrawal when resistance is encountered.**

Always follow the IFU for all devices utilized with the RENLANE™ Renal Denervation Catheter during the procedure. If there are any questions regarding compatibility of accessory devices, contact your local Cordis representative.

Available Assistance:

For questions related to this issue please contact your Cordis representative.

Additional Information:

The relevant national Regulatory Agencies and Notified Body have been notified as appropriate and are aware that Cordis is voluntarily taking this action.

Cordis regrets any inconvenience that this communication may cause. We know that you place high value in our products and we appreciate your cooperation in this matter.

Sincerely,



Sr. Director, Quality Engineering, Quality Systems & Compliance
Cordis Corporation

Enclosures: Customer Acknowledgement Form Update
Updated Instructions For Use M-5276-790B