ARB Medical, LLC
The Frontier of Innovative Medical Devices

URGENT FIELD SAFETY NOTICE

Field Safety Corrective Action / Recall

Product: Rebound HRD/HRD-V
Reference: MedDev FAGG-AFMPS (Belgium) email, dated September 23, 2018
Type of Action: Product Recall (Removal and Return)

October 4, 2018

Dear Surgeon:

This letter is to inform you that ARB Medical, LLC has initiated a field safety corrective action (FSCA) by voluntarily recalling all the lots of its Rebound HRD/HRD-V product distributed and sold in Europe by DUOMED.

Problem Description: This FSCA/recall is due to complaints of the fracture of the frame (ring) of the product (which is implanted to repair hernias) and also due to suspension of the ARB Medical's CE-mark certificate during the review the product's technical file. As such, the product must not be used until the frame fracture issue is satisfactorily addressed and the CE-mark certificate is reinstated.

Risk(s) to Patient: An injury, pain or discomfort to the patient is associated with the use of the product when its frame fractures. To relieve the patient of the discomfort or pain/injury, a revision surgery (explant of the broken frame and/or its pieces) may be needed. The same risk to patients is associated also with the previous use of the product.

Actions to Be Taken: It is advised to take the following actions:

1) Remove all the lots of Rebound HRD and Rebound HRD-V from the use area and from your stock or supply room or any place of storage.

2) Contact DUOMED (your vendor) for a shipping information and return all these removed lots of the product to DUOMED.

3) For confirmation, send DUOMED a signed letter stating that for the recall, all the lots of the product have been removed and returned while indicating their model numbers, lot numbers and quantities.

4) For a follow-up of patients in whom the product has been already implanted, it is recommended that you perform the following steps:
   - ➢ If a patient complains of a pain or discomfort at the site of the implanted product, take x-ray images and examine the implanted product by studying the images.
   - ➢ If the x-ray images show that the frame is broken, prep the patient for a revision surgery using the standard preoperative procedure.

- With a visual aid and appropriate surgical instruments, perform the surgery by making an incision and creating an access to the implanted product.
- Using an appropriate extraction tool, carefully capture and extract the fractured frame including any fractured frame pieces while making sure that the mesh is not damaged or displaced during the extraction process.
- As appropriate, leave the mesh implanted, intact and in place, and close the surgical wound by using an appropriate wound closure device/tool.

Transmission of the Field Safety Notice: If it is appropriate, the following must be performed: (i) pass on this notice to all those who need to be made aware of within your facility or to any other facility where the potentially affected product has been transferred; (ii) send this notice to other facilities on which this action has an impact; and (iii) maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the field safety corrective action.

Contact Reference Person:

Jamil Mogul
Technical & Regulatory Consultant
ARB Medical, LLC
Cell Phone: +1-408-489-2083
Email: TheMOGULS@aol.com

The undersigned confirms that this field safety notice has been notified to the appropriate Regulatory Agency.

Please feel free to contact the above referenced person if you have any questions regarding this field safety notice.

Best regards,

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