Important safety information

GyneFix & GYN-CS

October 6, 2021

SRN no.: BE-MF-000010118

Dear Customer,

The purpose of this message is to inform you that Contrel Europe nv has important safety information about GyneFix & GYN-CS.

Overview of safety information:

The leaflet of GYN-CS states that the product is "MRI safe" and the leaflet GyneFix does not mention MRI. The authorities have pointed out that the classification “MRI safe” is not allowed by law. The correct classification is "MRI Conditional" for implants with metallic parts.

This safety information applies to the following products:

GyneFix 200 (UDI: 8719326937403),

GyneFix 330 (UDI: 8719326937410),

GyneFix 10 (UDI: 8719326937427),

GYN-CS 3 (UDI: 8719326937434),

GYN-CS 10 (UDI: 8719326937441)

Why do we contact you:

You are receiving this letter because our records show that you are distributing one or more of these products.

Problem description:

Contrel Europe nv has become aware that the correct wording has not been used in the leaflet for the GyneFix and GYN-CS.

The leaflet for GYN-CS contains the text “MRI Safe” below the information on “Precautions”. This is currently not the correct terminology for implants containing metal parts (visualization and copper tubes).

The leaflet for GyneFix currently does not contain any text about “MRI safety”.

Why are we sending this safety information about this product?

There is a risk of carbonization, misdiagnosis and/or treatments due to image artifacts. This risk will be further substantiated by Contrel Europe nv by testing.

Contrel Europe nv has not received any reports of damage or injury.

Actions by Contrel Europe nv:

1) Contrel Europe nv will adapt the text of the leaflet (e-IFU) of GYN-CS & GyneFix to “MRI conditional” to comply with current legal standards.

2) Products will be labelled "MRI Conditional".

3) Contrel Europe nv has initiated a labelling correction due to incorrect MRI information in the leaflet and on the packaging.

What we ask you to do:

1) Read this “safety information”.

2) View the list of affected products.

3) Check your inventory to see if you have affected products. Check all storage and usage locations.

4) Report your stock to Contrel Europe nv.

5) Label the packaging of the affected products with the sticker “MRI Conditional”.

6) Keep a copy of this notice with the product.

7) Share this letter with others in your location who need to be notified of this safety alert and with all other facilities that have received the affected product from your location.

8) Please read, complete, sign and return the attached Acknowledgment Form in accordance with the instructions on the form.

9) Please keep the contents of this message current until all affected products have been used up.

Available support:

If you have any questions about this safety information, please contact the CEO, Rina Wildemeersch.

rina.wildemeersch@contrel.be or +32 9234 2433.

We apologize for the inconvenience. We know you value our products and we appreciate your cooperation in this matter.

Contrel Europe nv is committed to maintaining your confidence in the safety and quality of the products.

Kind regards,

Rina Wildemeersch

CEO