DEDIENNE SANTÉ

Mauguio, 27 January 2020

URGENT - SAFETY NOTICE

Affected Medical Devices:
Implants from the SYMBOL CUP DM range (including GYRACUP E and DS EVOLUTION):

- Cementless cup
- Cementless revision cup

Manufacturer: **DEDIENNE SANTE,** Le Mas des cavaliers, 217 rue de Nungesser, 34130 MAUGUIO

Affected batches:

Name	Reference	Size	Batch number
DS EVOLUTION CEMENTLESS	52.34.0904	50	132882380B
SYMBOL CUP DMR HA	3700502204117	50	095858230D
GYRACUP E CEMENTLESS	3700502203561	50	132882400B
SYMBOL CUP DM HA	3700502203561	50	132882380A

Identification: FSN No. MV_2019-012_FSN_20200127

Dear Client,

DEDIENNE Santé has written this document to provide information about implanting the cups in question.

Context:
Cementless cups have a metal back and a single-use gripper. Following tests performed on a batch of grippers, DEDIENNE Santé identified a non-compliance issue in terms of the functional specifications of same. The grippers in question can disconnect from the cup; this event was detected via a client complaint.

Safety rationale:
The main risk is poor cup impaction, as a result of the disconnection during implantation. Given the results of the impaction tests, however, the risk is limited as the problem can be detected and instruments to assist with final impaction are available in the associated ancillary kit. DEDIENNE Santé has nevertheless decided to take a safety action, by notifying its clients of this recall.

Actions to take for in-stock products

1. Check the unused implants in your possession. Only those listed above are affected.
2. Inform anyone to whom you have sold or given these implants.
3. If you have any of the affected products, please return them to DEDIENNE Santé.

Actions to take for products that have already been used
No specific action should be taken for patients who have already had surgery using the implants affected by this safety notice.

We recommend keeping a copy of this safety notice, as well as a signed copy of the acknowledgement of receipt.

Please note that the Competent Authority in your country has been alerted of this safety notice.

Thanks in advance for your collaboration. Yours faithfully,

Emilie LOREAU
Quality and Regulatory Affairs Manager

Attachment: Acknowledgement of Receipt

REGISTERED OFFICE LE MAS DES CAVALIERS. 217 RUE NUNGESSER. 34130 MAUGUIO (France). TEL +33 (0)4 67 99 81 11. FAX +33 (0)4 67 99 81 10
CLIENT SERVICES TEL +33 (0)4 66 28 06 85. FAX +33 (0)4 66 28 06 92
CONTACT@DEDIENNESANTE.COM – WWW.DEDIENNESANTE.COM
LIMITED LIABILITY COMPANY WITH CAPITAL OF €506,032. SIREN 339 138 638 RCS MONTPELLIER. NAF 3250A. VAT FR95 339 138 638

DEDIENNE SANTÉ

ACKNOWLEDGEMENT OF RECEIPT
(Return as soon as possible)

Affected Medical Devices:
Implants from the SYMBOL CUP DM range (including GYRACUP E and DS EVOLUTION):

- Cementless cup
- Cementless revision cup

Manufacturer: **DEDIENNE SANTE,** Le Mas des cavaliers, 217 rue de Nungesser 34130 MAUGUIO

Affected batches:

Name	Reference	Size	Batch number
DS EVOLUTION CEMENTLESS	52.34.0904	50	132882380B
SYMBOL CUP DMR HA	3700502204117	50	095858230D
GYRACUP E CEMENTLESS	3700502203561	50	132882400B
SYMBOL CUP DM HA	3700502203561	50	132882380A

Please fill in this form and return it by fax or email:
By fax to: +33(0) 4 66 28 06 92
By email to: accueil@dedienne-sante.com

I have received, read and understood the information in this safety notice. With this form:

- I confirm that I have received the safety notice and have complied with the instructions contained therein;

- I confirm that this safety notice has been sent to the affected users, as well as to the relevant staff at my facility;

Please fill in the contact details below.

Facility _____ Contact _____

Address _____

Post Code _____ City _____

Telephone/Fax _____

Email _____

Date _____ Signature _____

REGISTERED OFFICE LE MAS DES CAVALIERS. 217 RUE NUNGESSER. 34130 MAUGUIO (France). TEL +33 (0)4 67 99 81 11. FAX +33 (0)4 67 99 81 10
CLIENT SERVICES TEL +33 (0)4 66 28 06 85. FAX +33 (0)4 66 28 06 92
CONTACT@DEDIENNESANTE.COM – WWW.DEDIENNESANTE.COM