Mauguio, 26 February 2020

URGENT - SAFETY NOTICE

Affected Medical Devices: Total hip prosthesis implant:

- Ceramic liner from the SYMBOL CUP NA range
- Ceramic head from the SYMBOL STEM range

Manufacturer: **DEDIENNE Santé,** Le Mas des Cavaliers, 217 rue Nungesser, 34130 Mauguio, France

Affected batches:

Range	Name	Size	Reference	Batch number
SYMBOL CUP NA	DELTA CERAMIC LINER	32 B	3700502202496	197379010A
		36 C	3700502202533	197379030A 204478030A 204478030B
		36 D	3700502202540	189811030A 197379040A 204478042A
SYMBOL STEM	DELTA CERAMIC FEMORAL HEAD	28C	3700502203226	189919070A 197367090A
		28M	3700502203233	189919090A 204143750A
		28L	3700502203240	197356210A
		32M	3700502203264	189919100A
		32L	3700502203271	189913100A
		36C	3700502203288	197367150A
		36M	3700502203295	197356230A
		36L	3700502203301	197356220A

Identification: FSN No. MV_2020-001_FSN_20200226

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
SIMPLIFIED JOINT-STOCK COMPANY WITH CAPITAL OF €506,032. SIREN 339 138 638 RCS MONTPELLIER. NAF 3250A. VAT FR95 339 138 638

Dear Client,

DEDIENNE Santé hereby informs you that you are in possession of the medical devices affected by this safety notice.

Context:

As part of the monitoring program for medical devices produced by DEDIENNE Santé, a high bioburden result was recorded for some implants sampled from a production batch for testing. As this result could potentially call the sterility of the medical devices into question, and as the results of the ongoing investigations are not yet available, DEDIENNE Santé is voluntarily recalling this batch and, as a preventative measure, several other medical device batches.

Risk to patients:

The medical devices in question are likely to be non-sterile, so implantation could cause an infection, if the bacteria is not sensitive to gamma sterilization and is pathogenic to humans. The ongoing investigations will soon determine the actual risk to patients, and determine the actions to take, if any.

Action to take

1. Check the medical devices in your possession. Only those listed above are affected.
2. Inform anyone to whom you have sold or given these medical devices.
3. If you have any of the medical devices in question, please quarantine them in anticipation of the recall.

Actions to take for medical devices that have already been implanted

In light of the information available to date, there are no specific recommendations to follow.

In the context of materiovigilance, please remember to report any adverse events.

Keep a copy of this document in the medical record of implanted patients.

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

Emilie LOREAU
Quality and Regulatory Affairs Manager

Attachment: Acknowledgement of Receipt

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DEDIENNE SANTÉ

ACKNOWLEDGEMENT OF RECEIPT (Return as soon as possible)

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		36C	3700502203288	197367150A
		36M	3700502203295	197356230A
		36L	3700502203301	197356220A

Please fill in this form and return it by fax or email

Fax: +33(0) 4 66 28 06 92
Email: accueil@dedienne-sante.com, subject line: "AR_MV_2020-001_20200225"

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 .....

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