

Urgent FIELD SAFETY NOTICE – Orthopaedic implants – RECALL
Labeling error – Incorrect expiration date

Dear Sir, Madame,

We have identified a possible labeling error regarding one of the lots of one of our medical devices (acetabular screw – total hip prosthesis). We thank you in advance for reading carefully our recommendations regarding the situation:

DM in question: acetabular screw SYMBOL DM compatible → SCREW 4.5 – 68 mm

Reference: 3700502205879

Batch number: 064271220A

Actions to take

1. Verify if one of the devices listed above is/are in your possession.
2. Inform the people to whom you might have sold/given these devices about this recall.
3. If you identify the devices with the labeling error, please contact our sales department to exchange the device. As you can see on the photo below, the error can be detected from the external label.



Labelling error description

Wrong expiration date:
"2020-10"
Correct expiration date:
"2020-09"

Patient risk: If the device has already been implanted, this error has no significance on its sterility, given that the correct expiration date is « 2020-09 ». Therefore, there's no risk for the patient.

The ANSM (French competent authority) and your competent authority are informed of this action.

We thank you again for your time and collaboration.

Mauguio, the 2nd of August 2019

Rafael CHARRA
Regulatory Affairs Manager

**ACKNOWLEDGEMENT OF RECEIPT
(To be returned as soon as possible)**

Medical devices in question:

- Range: **SYMBOL CUP DM**
- Designation: **SCREW 4.5 – 68 mm** (acetabular screw SYMBOL DM compatible)
- Reference: **3700502205879**

Legal manufacturer:

DEDIENNE SANTE
Le Mas des cavaliers, 217 rue de Nungesser
34130 MAUGUIO (FRANCE)

Batch number: **064271220A**

Please complete this form and return it by fax or e-mail:

By fax to: +33(0) 4 66 28 06 92

By e-mail to the address: accueil@dedienne-sante.com

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

- I confirm that I have received the safety notice and that I have complied with the instructions contained in this document;
- I confirm that this safety notice has been communicated to concerned users and to the appropriate staff of my facility;

Please fill in the contact details below:

Facility	Contact name
Address	
Zip code	Town/city
Telephone / Fax	
E-mail	
Date	Signature