Décines-Charpieu, on September 28, 2023

URGENT – FIELD SAFETY NOTICE – RECALL NOTIFICATION
BI-MENTUM™ PRESSFIT cup 51

From: Vigilance Officer SERF

To: Local BI-MENTUM™ distributor

FSCA Ref: **R2023-2** (to be quoted in all correspondence)

Dear Sir/Madam,

SERF is voluntarily recalling lot 2207420A of *BI-MENTUM™ PressFit cup 51* devices due to a product reference printing error.

Context

Following two complaints received, with no impact on the patient or user, SERF has identified a printing error in the *BI-MENTUM™ PressFit cup 51* device reference on batch 2207420A.

Other regulatory information and traceability data (batch number/expiration date/UDI code) are correct.

This printing error appears on external (box), internal (blister) and traceability (patient) labels.

The part number appearing after the REF pictogram is incorrect: RM52120051 instead of DS45320051.

Reference RM52120051 corresponds to the internal reference used during manufacture.

Information on affected devices

BI-MENTUM™ PressFit cup 51 cementless cups and dual mobility inserts are intended for hip arthroplasty, which aims to improve quality of life and reduce pain, as a replacement for a pathological joint.

The batch concerned by this recall is described below:

Reference correct	Reference incorrect	Designation	Batch
DS45320051	RM52120051	BI-MENTUM™ PressFit cup 51	**2207420A**

UDI code (Unique Device Identifier) of the device concerned

UDI-DI (01)03662200013746

UDI-PI (17)280229(10)2207420A

UDI
(01)03662200013746
(17)280229(10)2207420A

Safety rationale

The UDI code remains correct, ensuring full traceability of the product, but users/healthcare establishments could be misled if they do not yet use an automatic UDI code reading solution.

This error could result in healthcare establishments failing to identify this product in the event of a safety advisory or corrective action if the automatic reading of the UDI is not yet in use.

Batch number traceability remains valid and sufficient.

No risks have been identified in connection with the use of the product, the device being *BI-MENTUM™ PressFit cup 51*.

Patient care information

No special patient care is required in the frame of this corrective action. No communication to patients is needed, as the purpose of this recall does not affect clinical performance and device safety.

Action to be taken by healthcare facilities

According to our traceability information, you are identified as a customer with affected devices in your inventory.

Please comply with the following instructions to ensure the immediate return of the devices.

1- Please check your inventory and traceability records to determine if you are in possession of any *BI-MENTUM™ PressFit cup 51* affected by this recall notification or if you have sent any to your customer healthcare facilities.

Reference incorrect	Designation	Batch
RM52120051	BI-MENTUM™ PressFit cup 51	**2207420A**

You can also use one of the UDI code formats available below

UDI-DI (01)03662200013746

UDI-PI (17)280229(10)2207420A

UDI

(01)03662200013746
(17)280229(10)2207420A

2- If you are in possession of one or more *BI-MENTUM™ PressFit cup 51* affected by this recall notification:
   - Please remove the device(s) from your inventory immediately and place them in quarantine.

3- If you have distributed one or more *BI-MENTUM™ PressFit cup 51* affected by this recall notification to one or more customer healthcare facilities:

- Please forward this recall notification immediately to the customer(s) concerned.
- Recall the product(s) and place them in quarantine.

4- Once you have completed the audit of your inventory and traceability records, please complete the acknowledgement of receipt form and return it as soon as possible as indicated, **even if you do not hold any stock of the batch concerned by this recall.**

As soon as we receive this form, our customer service department will contact you as soon as possible to exchange any devices concerned.

Receipt of the acknowledgement form ensures that SERF has effectively communicated this recall notification to its affected distributors.

We recommend that you keep a copy of this reminder notification, as well as a signed copy of the acknowledgement of receipt.

The competent authorities may carry out corrective action audits to verify that our customers have been informed and have understood the nature of this document.

Please note that the ANSM (legal manufacturer's National Competent Authority) as well as your National Competent Authority have been notified of this recall notification.

We would like to thank you for your cooperation in this action, and for returning the enclosed acknowledgement of receipt.

For further information, please contact Jean-Charles MONCENIS at j.moncenis@serf.fr.

Please accept, Sir or Madam, the assurance of our highest consideration.

Jean-Charles MONCENIS
Deputy Vigilance Officer
Regulatory & Clinical Affairs Manager

RECALL NOTIFICATION ACKNOWLEDGEMENT FORM

R2023-2 - BI-MENTUM™ PressFit cup 51

Please complete and return this form by email as soon as possible to: j.moncenis@serf.fr

☐ I have received, read and understood the information contained in this safety notice regarding the recall of *BI-MENTUM™ PressFit cup 51* medical devices.

I confirm that I have received the recall notification and that I have complied with the instructions contained therein.

Establishment: .....

Name & function of signatory: .....

Address: .....

Phone number: .....

E-mail: .....

At our facility, we have the following medical device(s) (*please complete the quantity column and information below*):

Reference incorrect	Designation	Batch	Quantity
RM52120051	BI-MENTUM™ PressFit cup 51	**2207420A**	

☐ The device(s) will be returned to you.

☐ The device(s) will not be returned:

- ☐ Damaged or discarded devices: .....
- ☐ Other reason to be specified .....:

Date & signature :