Address of recipient

FIELD CORRECTIVE ACTION
MEDICAL DEVICE BATCH RECALL – EXTENSION

NREF	FSCA 2312-16
Action	Medical Device Batch recall – **In2Bones I.B.S Compression screw**
Manufacturer	In2Bones SAS – 28 chemin du petit bois – bâtiment 2 – 69130 Ecully – France SRN : FR-MF-000005246
Date	January 23rd, 2024
To	**To the attention of the Hospital Director, Recall Coordinator, Risk Manager and all impacted Health Care Professionals**

Dear Sir or Madam,

We hereby inform you that In2bones SAS voluntarily initiates a Batch Recall for the following I.B.S Compression screws, diameter 6.5mm, length 75mm and 80mm:

Part number	Description	UDI-DI	UDI-PI	
			Batch	Expiration date
S65 ST175	I.B.S® 6.5-C Compression screw - diam 6.5mm lg75mm	3760225710685	2306007	31/MAY/2028
S65 ST180	I.B.S® 6.5-C Compression screw - diam 6.5mm lg80mm	3760225710692	2306008	31/MAY/2028

Device Description

I.B.S Compression screws are intended for:

- The fixation of arthrodesis, osteotomies or fractures of longs bones of the upper and lower limbs;
- Osteosynthesis requiring a mono bicortical compression.

The size of the screw should be adapted to the specific indications.
They are sold sterile and are for single-use only.

Non-conformity description

This Field Action is being conducted following the identification of a batch mix-up between I.B.S Compression screws diameter 6.5mm length 75mm and I.B.S Compression screws diameter 6.5mm length 80mm.
The screws of the batches concerned by the recall may have different lengths from those issued on their labels.

Associated risks

Several possible health outcomes have been identified and analyzed for the patients:
- **Scenario 1:** If the surgeon detects intraoperatively the different screw length before implantation and replaces it by one of the correctly selected length: minor extension of the surgery duration without clinical consequences.

- If the surgeon does not detect the different screw length before use,
  . **Scenario 2**: If the screw could have been implanted and fits correctly the patient anatomy: No user nor patient consequences;

. **Scenario 3**: If the screw could have been implanted but is not suitable to the patient anatomy:
In case of screw too long (80mm instead of 75mm) for the patient anatomy: the screw might damage its environment and lead to bones or soft tissues damages.
In case of screw too short (75mm instead of 80mm), the compression of screw might be incomplete and could affect the time for bone fusion leading to pseudoarthrodesis. *As a reminder, failure of fusion is a common result, and may happen due to a myriad of other reasons, including but not limited to failure to comply with post-op instructions, smoking, diabetes and other diseases that compromise vascularity)*.
This scenario is considered to be the worst-case scenario. This hazardous situation has never been reported to date.

. **Scenario 4**: If the surgeon has difficulties to implant the screw and detects its length during the implantation: Minor or significant increase of the surgery duration.
This scenario is considered to be the most-probable scenario.

If one of the screws involved in this recall have already been implanted with no reported incident during the surgery, it is not necessary to modify the postoperative protocol established by the surgon for the patient involved.
It is up to surgeons and healthcare professionals to consider how to inform patients implanted with these devices.

Recommended actions
Our records indicate that In2bones SAS has delivered to you some screws subject of this recall.
We therefore recommend you to follow the instructions here below:

1. **Identify all I.B.S Compression screws of the batches subject of this Field Action that might still be in your inventory and quarantine them.**
2. **Inform and distribute this Recall Notification to all relevant persons within your organization.**
3. ***For distributors only:* Identify all I.B.S Compression screws of the batches subject of this Field Action that were delivered to your customers, and if relevant, instruct them to also follow these instructions (identification and quarantine).**
4. **Fill in and return the fax back form enclosed. With this form, you will certify that you have received this Recall Notification and intend to comply with the recommendations listed. This acknowledge-back form will enable In2Bones SAS to conduct effectiveness checks.**

In order to ensure efficacy of corrective action, please remind final users as necessary to ensure they are well informed.
In2Bones SAS will contact you upon receipt of this fax back form to organize the recall and replacement of the products.

According to the recommendations of Meddev Vigilance Guidance ref. 2.12-1, we confirm this Field Safety Corrective Action has been transmitted to relevant national competent authorities.

For any question, please contact our Quality and Regulatory Affairs team at: +33 4 72 29 26 26 or by email: **qualite@in2bones.com.**

We apologize for any inconvenience created by this Field Action and thank you for your continued cooperation.

Yours faithfully,

In2Bones
Sabina AHADDAD
Quality Assurance and Regulatory Affairs Director

Acknowledge back form
BATCH RECALL – I.B.S Compression screws
References S65 ST175 and S65 ST180
January 2024

We thank you to fill in and return the enclosed fax back form no later than within **7 days**:
In2Bones SAS - Quality and Regulatory Affairs
Email: qualite@in2bones.com
Fax: +33 4 72 29 26 29

I hereby certify that:

- **I have received the Recall Letter issued by In2Bones, related to the batch recall of the I.B.S Compression screws**
- **I have read and understood the Recall Letter and intend to fully comply with the instructions provided**
- **I have checked our inventory for any screws impacted by this Batch Recall**
- ***For distributors only:* I have checked inventories at our customers for any screws impacted by this Batch Recall and have distributed them this Recall Letter so that they comply to it.**

The devices listed below are in our inventory and/or have been returned from our customers. I need In2Bones SAS to organize their recall and replacement.

Part number	Description	Batch	Quantity received	Quantity that needs to be returned to In2Bones
S65 ST175	I.B.S® 6.5-C Compression screw - diam 6.5mm lg75mm	2306007		
S65 ST180	I.B.S® 6.5-C Compression screw - diam 6.5mm lg80mm	2306008		

Facility/Customer:	**Date:**
Name, Surname:	**Signature, Stamp**
Function:	