**Address of recipient**

# FIELD CORRECTIVE ACTION
# MEDICAL DEVICE BATCH RECALL – EXTENSION

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|---|---|
| NREF | FSCA 2301-39 |
| Action | Medical Device Batch recall – **In2Bones I.B.S Compression screw** |
| Manufacturer | In2Bones SAS – 28 chemin du petit bois – bâtiment 2 – 69130 Ecully – France<br>SRN : FR-MF-000005246 |
| Date | March 20th, 2023 |
| 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 extends the Recall of I.B.S Compression screws initiated on February 22nd, 2023 to include the following batches:

| Part number | Description | UDI-DI | UDI-PI | |
|---|---|---|---|---|
| | | | Batch | Expiration date |
| S30 ST128 | I.B.S® 3.0-C Compression screw - diam 3.0mm lg28mm | 3760225710265 | 2209116* | 30/SEPT/2027 |
| | | | 2208068 | 31/AUG/2027 |
| | | | 2206257 | 31/JUL/2027 |
| S25 ST024 | I.B.S® 2.5-C Compression screw diam 2.5mm lg24mm | 3760225710159 | 2209042 | 30/SEPT/2027 |
| | | | 2206249 | 30/JUN/2027 |
| | | | 2208066 | 31/AUG/2027 |
| | | | 2210338 | 31/OCT/2027 |
| S25 ST026 | I.B.S® 2.5-C Compression screw diam 2.5mm lg26mm | 3760225710166 | 2207037 | 31/JUL/2027 |
| | | | 2210288 | 31/OCT/2027 |

* Batch involved in the initial batch recall, communicated on February 22nd, 2023

## 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 mis-labelling between I.B.S Compression screws diameter 3.0mm length 28mm and I.B.S Compression screws diameter 2.5mm length 24mm or 26mm.
The screws of the batches concerned by the recall may have different diameters and lengths from those issued on their label.

## Associated risks

Several possible health outcomes have been identified and analyzed for the patients:

- **Scenario 1** – Most probable scenario: If the surgeon detects intraoperatively the slightly different screw diameter and length before implantation and replaces it by one of the correctly selected diameter and length: minor extension of the surgery duration without clinical consequences.
  This scenario is considered to be the most probable scenario. Indeed, 2.5mm and 3.0mm diameter screws are not intended to be implanted using the same screwdriver: a T7 screwdriver should be used for 2.5mm diameter screws implantation while a T8 screwdriver should be used for 3.0mm diameter screws.

- If the surgeon does not detect the slight difference of screw diameter and 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:

a. The screw implanted is too small for the patient anatomy: Bone fusion failure that could lead to pseudarthrosis (*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*);

b. The screw implanted is too big for the patient anatomy: Soft tissues lesions that may be associated to bone damages.

This scenario is considered to be the worst-case scenario, and has never been reported to date;

. **Scenario 4** – If the surgeon has difficulties to implant the screw and detects its slightly different diameter and length during the implantation: significant increase of the surgery duration.

## 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 S30 ST128, S25 ST024 and S25 ST026
# March 2023

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 that needs to be returned to In2Bones |
|---|---|---|---|
| S30 ST128 | I.B.S® 3.0-C Compression screw - diam 3.0mm lg28mm | 2209116 | |
| | | 2208068 | |
| | | 2206257 | |
| S25 ST024 | I.B.S® 2.5-C Compression screw diam 2.5mm lg24mm | 2209042 | |
| | | 2206249 | |
| | | 2208066 | |
| | | 2210338 | |
| S25 ST026 | I.B.S® 2.5-C Compression screw diam 2.5mm lg26mm | 2207037 | |
| | | 2210288 | |

| | |
|---|---|
| **Facility:** | **Date:** |
| **Name, Surname:** | **Signature, Stamp** |
| **Function:** | |