Hogan Healthcare Ltd.
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FIELD CORRECTIVE ACTION

MEDICAL DEVICE BATCH RECALL

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 SRN : FR-MF-000005246
Date	February 28th, 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 initiates a Batch Recall for the following I.B.S Compression screws, diameter 3.0mm, length 28mm:

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

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 labelling non-conformity on the packaging of I.B.S Compression screws - reference S30 ST218 from batch 2209116.
Indeed, the screws of batch 2209116 have been mis-labelled as I.B.S Compression screws diameter 3.0mm length 28mm whereas they are I.B.S Compression screws diameter 2.5mm length 24mm.
Only batch 2209116 is affected by this mislabeling.

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 smaller screw diameter and length (i.e. 2.5mm diameter, 24mm length) before implantation and replaces it by one of

the correctly selected diameter and length (i.e. 3.0mm diameter, 28mm 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: if the surgeon wants to implant a 3.0mm screw, he/she will use a T8 screwdriver but if the screw inside the packaging is a 2.5mm diameter screw instead, it won't be able to be correctly assembled on the screwdriver

- If the surgeon does not detect the slightly smaller 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 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*). 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 slightly smaller 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 diameter 3.0mm length 28mm, reference S30 ST128, batch 2209116 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 diameter 3.0mm length 28mm, reference S30 ST128, batch 2209116 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.

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

Fax back form
BATCH RECALL – I.B.S Compression screw Diameter 3.0mm, Length 28mm
Reference S30 ST128 – Batch 2209116
February 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 diameter 3.0mm, length 28mm, reference S30 ST128, batch 2209116**
- **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	

Facility:	**Date:**
Name, Surname:	**Signature, Tampon**
Function:	