



Urgent

August 17, 2021

In2Bones SAS
ATTN: Morgane Grenier
28 Chemin du Petit Bois – Bat N2
Ecully, France 69130

MEDICAL DEVICE RECALL

Action	Medical Device Recall – CoLink® Bone Graft Harvester, 8mm
Recall Initiation Date	August 2, 2021
Recipient	To the attention of Agents / Medical Facilities with impacted product

To Whom It May Concern,

We hereby inform you that In2Bones, USA initiated a voluntarily Lot Recall for the following CoLink® Bone Graft Harvester, 8mm – G05 S1008:

Description	Part Number	Lot Number
CoLink® Bone Graft Harvester, 8mm	G05 S1008	992921
CoLink® Bone Graft Harvester, 8mm	G05 S1008	1018971
CoLink® Bone Graft Harvester, 8mm	G05 S1008	1046581
CoLink® Bone Graft Harvester, 8mm	G05 S1008	1070081

The distribution or use of the parts that are the scope of this recall should cease immediately.

Device Description:

The In2Bones CoLink® Bone Graft Harvester, 8mm is an instrument for harvesting bone.

Indications:

The In2Bones USA LLC, CoLink® Bone Graft Harvester is a general instrument intended for assisting surgeons in the manipulation of bone during surgical procedures.

Issue Description:

Two complaints were received on July 9th, 2021 from the field of CoLink® Bone Graft Harvesters breaking at the outer tube weld site.



Associated Risks:

A Health Hazard Evaluation was conducted for CoLink® Bone Graft Harvester and concluded that there is not significant increased patient safety risk. The risk of product failure is increased when patients have hard bone, which is uncommon based on the intended use and anatomical locations the device is usually used in. The potential patient adverse health outcome, however, is a leftover portion of the cutting tip could be left in the patient if the tube tip breaks and cannot be removed from the site. This is unlikely since the tube tip has it's drilled hole leading up to it for easy access. This could result in a required surgical intervention (similar to a drive tip or drill tip being left in the patient). The tube tip portion is 8mm in diameter and 18 mm long.

Recommended Actions:

Our records indicate that In2Bones USA LLC has delivered CoLink® Bone Graft Harvester, 8mm that are the subject of this recall to you. Follow the instructions below:

1. Inform and distribute this Recall Notification to all relevant persons within your organization / medical facility.
2. Identify the number of CoLink® Bone Graft Harvester, 8mm that are the subject of this recall that are in your inventory and quarantine and/or return them. Also, identify all product that has been purchased, but not used by a medical facility and collect and return the product that is in scope.
3. Indicate this number in the attached acknowledgement form.
4. Fill in and return the acknowledgement form. With this form, you will certify that you have received this Recall Notification and intend to comply with the recommendations listed. This acknowledgement form will enable In2Bones to account for all inventory.
5. Return remaining inventory to In2Bones as soon as possible via Federal Express using the In2Bones USA FedEx customer number.

This recall is being made with the knowledge of the Food and Drug Administration. For any questions, please contact our Quality and Regulatory Affairs Team at 901-260-7931 or by email at kbuchannan@i2b-usa.com or cscifert@i2b-usa.com.

Sincerely,

Christine Scifert
VP, QA & RA