Customer
Address

URGENT – FIELD SAFETY NOTICE / PRODUCT RECALL
Medical Devices

Commercial name of the affected product(s): L-VARLOCK – Cage holder (reference HD0060)
FSCA-identifier: CAPA-2017-001
Type of action: Recall of the lot 15486

Date: January 09th, 2017

Attention: Hospital Director, the local Medical Device Vigilance Correspondent and any other medical professionals of the concerned departments

Details on affected devices:

Ref.	Designation	Batch #
HD0060	L-VARLOCK Cage holder	15486

Intended use:

Cage holders are used in interbody fusion arthrodesis procedures by posterior approach.

Purpose of the notice:

KISCO International has recorded several complaints involving the use of the cage holder HD0060 from L-VARLOCK range. These incidents involve the breakage of the tip of the cage holder tube during implantation of the cage.

Although this risk has caused at this date, no adverse clinical consequences for the patients, KISCO International has decided to initiate a safety action to remove all the cage holders HD0060 from the batch number 15486.

The cage holder is used to hold the cage during its impaction. Sometimes, the clamp of the cage holder is not correctly engaged on the notches of the cage and during the impaction, the forces are transferred to the tip of the holder tube and cause its breakage.

On the batch number 15486, we have detected that the hardness of the material after heat treatment was at the upper limit of the required specification and made the instrument tip more fragile.

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Breakage of the tip of the holder tube

the clamp of the cage holder engaged on the notches of the cage

Potential associated risks:

Consequences of the breakage of the tip are detailed below:

- Loss of functionality of the instrument : Impossibility of positioning the cage as desired,
- Risk of prolongation of operative time until the use of another instrument contained in the kit,
- Potential risk of leaving the broken piece in the patient.

Actions to be taken by the user:

Our records indicate that you have been supplied with the devices concerned by this recall.
KISCO International kindly requests you to:

1. Identify all the concerned devices in your stock and quarantine them.
2. Return the devices and attach a copy of the acknowledgement form with the products. KISCO International will contact you to organize the return of the products.
3. Complete and return the attached acknowledgement form by which you confirm that you have been aware of this safety notice.

Transmission of this Field Safety Notice:

We ask you to follow the below procedure:

- Pass this information on to all those who need to be aware of it within you organization.
- Retain a copy of this information and make sure that it is regularly circulated in order to avoid any doubt of the medical staff during the use of these products.

The concerned competent authorities have been informed of this action.
According to MEDDEV 2.12-1 Rev. 8, we kindly remind you that it is essential to report to the competent national authority and/or KISCO International all adverse events observed during the use of these medical devices.
Should you have any question, our Quality department can be reached by phone at +33(0)4 69 84 23 38 or by email: materiovigilance@kisco.fr.

We apologize for the inconvenience caused by this safety notice and we thank you for your comprehension and your cooperation.
Yours sincerely,

Mr. Shigeru Shiono
President

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Acknowledgement and return form *Healthcare facility name*

Field Safety Notice CAPA-2017-001_FSCA related to Cage holders HD0060 from the range L-VARLOCK

We kindly ask you to complete and return this acknowledgement form within 7 days:
KISCO International, Quality and Regulatory Affairs Department
By email: materiovigilance@kisco.fr or by fax: +33(0)9 72 46 70 86

With this form, I confirm that:

- **I have received the safety notice from KISCO International**
- **I have passed this information on to all those who need to be aware of it within my organization**
-

Please check the correct answer below:

□ I do not have any device in stock within my facility.

□ I would like to return the devices to KISCO International. The concerned references and batch numbers are listed the Table below:

Reference	Batch #	Quantity
HD0060	15486	

Hospital:

Signatory name:

Function:

Address:

Signature and date:

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