

**FIELD SAFETY NOTICE & BATCH RECALL, German market ONLY**  
**Medical Devices**

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| NREF          | CAPA-P-2013-039_FSCA   |
| Action        | Field safety notice informing the users of a batch recall  |
| Date          | 02/04/2014   |
| Destinataires | For the attention of the Hospital Director, the local Medical Device Vigilance Correspondent and any other medical professionals of the concerned departments. |

Products: **L-VARLOCK Instrument / Implant box**  
Reference: **BT0130**  
Batch number: **12815**

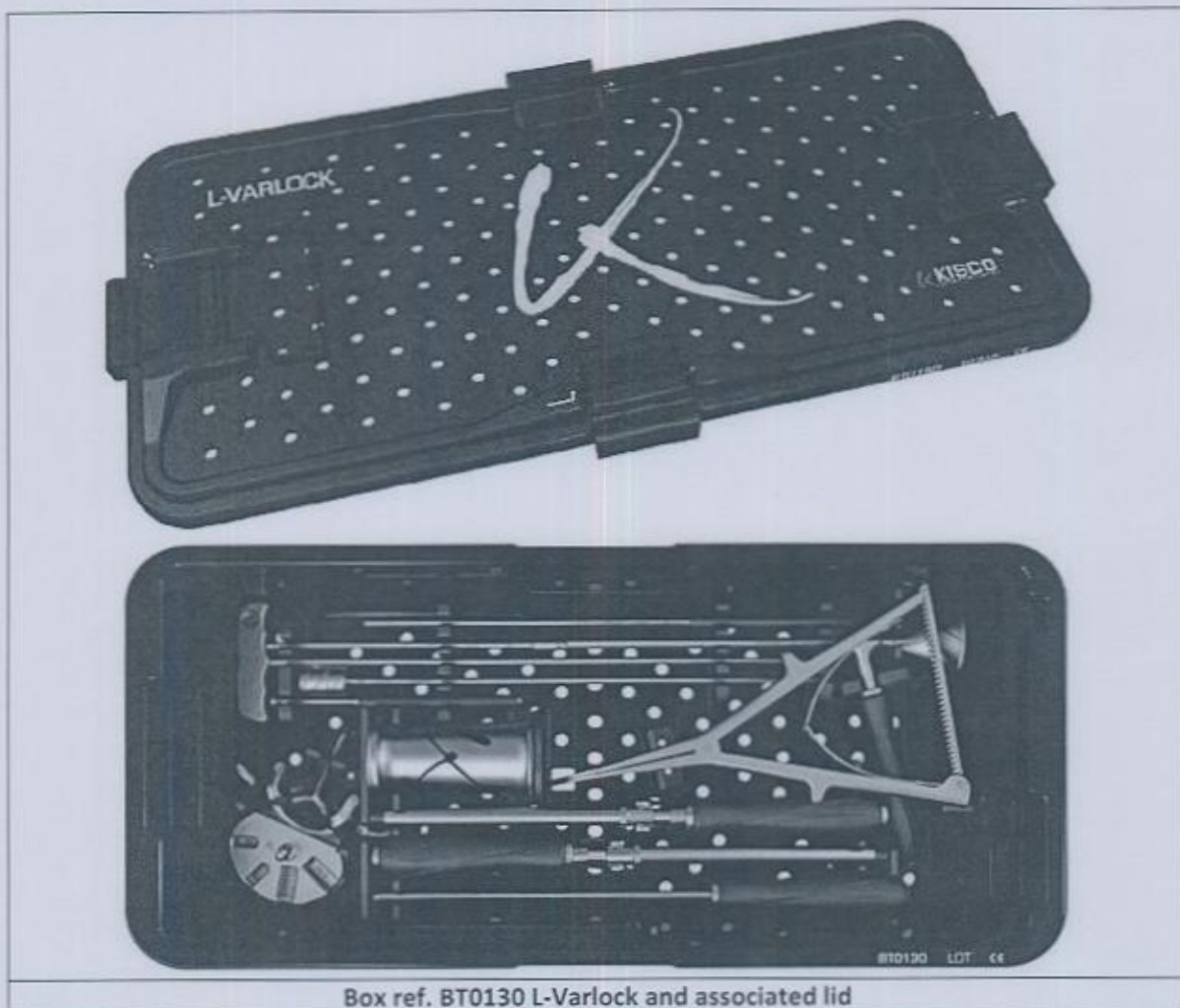
Dear Sir or Madam,

We would like to inform you that KISCO International is initiating a voluntary safety action regarding the above-mentioned medical device on the German market.

**Description**

Since January 2013, implants and instruments of the L-Varlock range are packaged in a box ref. BT0130. These devices are provided non sterile and can be cleaned and then sterilized by the user in this same box, according to the method described in the Instructions For Use.

Further to internal steam sterilization tests, KISCO International recently noticed that this sterilization method could not ensure an acceptable sterility assurance level for the most critical instrument sterilized in this BT0130 box as it was designed and put on the market in January 2013 (batch #12815).



Box ref. BT0130 L-Varlock and associated lid

#### Potential Risk

Steam sterilisation validation tests have not demonstrated the efficacy of this method to sterilize the L-Varlock devices, when sterilized in the BT0130 box of batch #12815. The risk of the non-sterility of one of these devices can therefore not be excluded and consequently the risk of infection of the patients too.

To date, no adverse effects have been reported to Kisco International following the use of L-Varlock devices sterilized in the BT0130 box of batch #12815.

#### Corrective actions taken by KISCO International

KISCO International has performed a design change to this box in order to allow the sterilization of all devices of the range when using the method described in the Instructions For Use. New steam sterilization validation tests with this new version of the BT0130 box demonstrated the efficacy of this method to achieve the minimum Sterility Assurance Level of all L-Varlock devices.

These changes are effective from batch #13532, put on the market in September 2013.



#### **Actions to be taken by the user**

Our records indicate that you have been supplied with L-Varlock implants/instruments box ref. BT0130, batch#12815.

We therefore kindly ask you to follow the below procedure:

- 1) Identify all the concerned devices in your stock and quarantine them. Our Customer Service Department will contact you at the earliest opportunity to organize the return and replacement of the devices.
- 2) Although the risk of patient infection can be reasonably considered as remote, we recommend increased vigilance during periodical post-operative follow-up of patients who have been through a surgery using L-Varlock devices sterilized in the above-mentioned boxes. Particularly, special focus should be given to any signs of infection.
- 3) Please complete and return the attached acknowledgement form.

All surgeries performed with the L-Varlock system sterilized in a BT0130 box of another batch number or not sterilized in a BT0130 box are to be excluded from the scope of this safety notification.

The competent authorities have been informed of this action.

In accordance with MEDDEV 2.12-1 Rev. 8, we remind you that any side effect observed during the use of these devices have to be notified to the concerned competent authorities and/or directly to KISCO International.

Should you have any question, our Quality department can be reached by phone at +33(0)4 78 90 85 59 or by email: [materiovigilance@kisco.fr](mailto: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,

  
**President, KISCO International**  
**Medical Device Vigilance Correspondent**