24. November 2014

Safety Notice – Voluntary Product Recall

MIT-H® Offset Cup Impactor

Product	REF / Item number	Lot-No
MIT-H® Offset Cup Impactor, angled, for BetaCup® and T.O.P.®, 410 mm	291-302/30	All lots

Problem description:

Figure 1 shows the affected MIT-H® Offset Cup Impactor.

Figure 1: MIT-H® offset cup impactor

The OEM manufacturer “Greatbatch” informed the customers about a Field Safety Corrective Action (see BfArM reference 0694/14) that for the affected MIT-H® Offset Cup Impactor, the minimum sterility assurance level (SAL) of 10^{-6} cannot be achieved if the instrument is exposed to the steam sterilization cycles and the associated drying times which are specified in their current instructions for use. The cup impactor is supplied non-sterile and must be sterilized prior to use in the surgery.

Based on sterilization parameters (e.g. drying time > 20 min.), which cannot be met in Germany resp. Europe, the sterilization instructions mentioned in the FSCA (see table 1) are not appropriate to address the problem.

Cycle	Temperature °Celcius (Minimum)	Exposure time (Minimum)	Drying time (Minimum)
Prevacuum	135°C	3 Minutes	60 Minutes
Prevacuum	134°C	18 Minutes	30 Minutes

Table 1: Recommended sterilization parameters from Greatbatch

The proposed solution has been found to be impractical after a technical evaluation. Therefore LINK has decided to recall the product.

Clinical consequences (see FSN from Greatbatch, BfArM incident reference 0694/14)

- There is a risk that the reprocessing cycle is not working and the device will be used non-sterile after completion of reprocessing.
- If a non-sterile MIT H® offset cup impactor in is used during a surgical procedure for implanting an acetabular cup, in the worst case an infection may occur to the patients that can lead to death.
- Starting from the fact that Greatbatch received no complaints to the present, the current occurrence rate is 0%. Greatbatch has not received any reports of deaths, illnesses, injuries or other negative incidents in connection with this topic.

Corrective action

Recall of all affected products.

Immediate actions:

- Should you have any of the affected MIT-H® offset cup impactor in your inventory, please send the products back to Waldemar Link GmbH & Co. KG.
- Products affected by this recall are the item numbers (REF 291-302/30, all lot numbers) listed in the reply fax.
- Replacement of the affected cup impactors will not incur any costs to you. Should you have any question on acquiring replacements for forthcoming surgeries, please contact your local sales representative or customer service for Link products.
- We would be grateful if you could return the fax reply to us in any event until the 12th of December 2014, as documentation of the recall, even if you have none of the listed products in stock or if these products do not exhibit the defect in question.
- Please ensure that all users of the above products within your organization and other relevant persons have been notified of this **safety information**. If you have transferred the products to third parties, please pass on a copy of this information or notify the contact person indicated below.
- The responsible Competent Authorities have been notified of this Field Safety Corrective Action.

Contact persons at Waldemar Link GmbH & Co. KG:

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