15. October 2014

Safety Notice – Voluntary Product Recall

Endo-Model® SL® – Connection Component, small

Product	REF / Item number	Date of manufacture
Endo-Model® SL® – Connection Component, small	16-2840/02 16-2841/02	01/2014 to 08/2014 (see Figure 2)

Problem description:

The mechanical stop of the Endo-Model® SL® - connection component, size: small is too long (see figure 1, red arrow) and protrudes too far from the axis due to a manufacturing fault. Under certain circumstances, the PE plateau cannot be inserted into the tibial component.

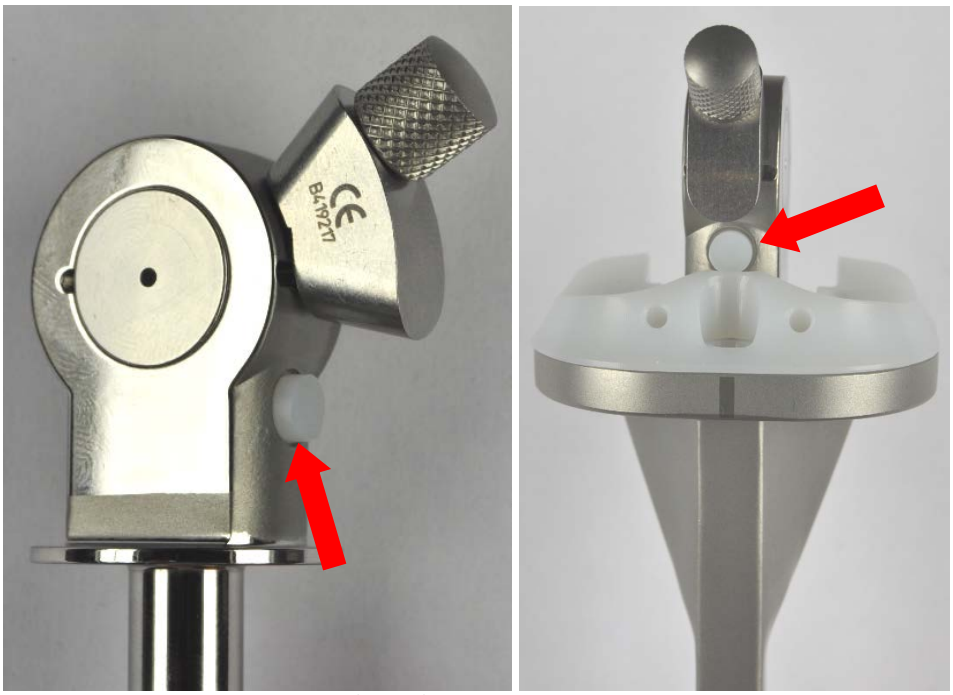

Figure 1: Endo-Model® SL® – Connection Component, small

Figure 2 shows how the manufacturing date can be identified on the affected products.

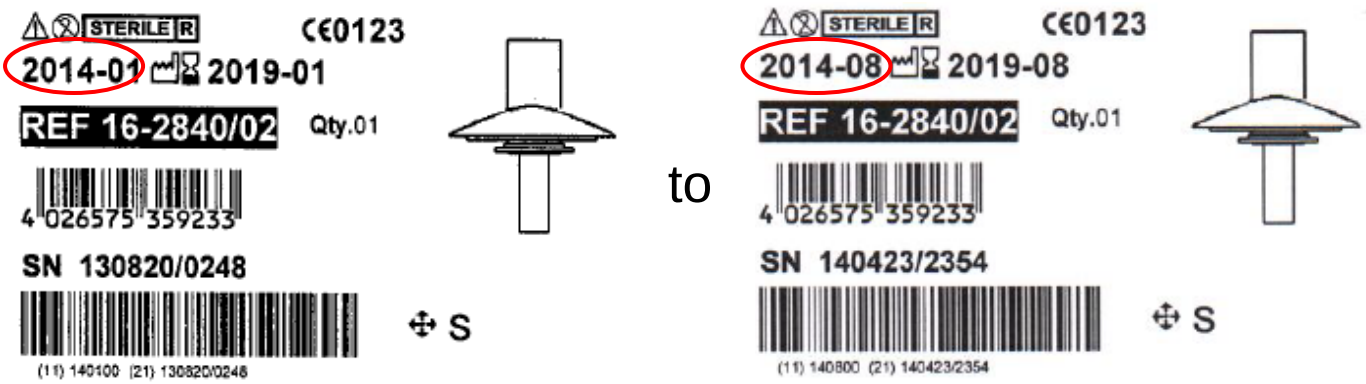

Figure 2: Manufacturing period of the affected products

Clinical consequences

- Due to insufficient clearance between t-part and the tibial plateau, the PE plateau cannot be inserted into the tibial component. The mechanical stop would have to be shortened before use.
- Surgery time may be extended if a manual reduction, which is possible, is carried out. It is not expected that this will affect the functionality of the implant.
- Worst case scenario, the surgeon aborts the operation due to incompatible components. A new operation must be carried out.

Corrective action

Recall of all affected products.

Immediate actions:

- Should you have any of the affected Endo-Model® SL® - Connection Components, small in your inventory, please send the products back to Waldemar Link GmbH & Co. KG.
- Products affected by this recall are the item numbers (REF 16-2840/02 and 16-2841/02) listed in the reply fax together with manufacturing period 01/2014 – 08/2014.
- Replacement of the affected connection components 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 31th of October 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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