EPISURF Medical

Urgent Field Safety Notice

Commercial names of affected products: Epiguide Condyle Solo, Epiguide Trochlea Solo, Epiguide Femoral Twin, Epidummy Condyle Solo, Epidummy Trochlea Solo, Epidummy Femoral Twin
Field Safety Corrective Action
Date: April 28, 2020
Attention: Episealer Knee Users

Details of affected devices:

Epiguide and Epidummy, which are two instruments of the Episealer Knee Toolkit, shipped to customers between March 5, 2020 and April 1, 2020 with the following Episurf order numbers:
AIA57, EBC26, EBC28, EBC30, EYA92, EYA93, EYB03, EYB04, EYB18, EYB21, EYB27, EYB29, JDA07, JEA58, LTA08, LTA14, NAA01, NJA01, NJA02

Description of the problem:

During an internal inspection, it was discovered that the sealing machine used for sealing the sterile packaging of the Epiguide and the Epidummy did not perform as intended. In some cases, the sealing strength did not conform with the specified requirements. Therefore, the sterility of the affected devices (Epiguide Knee and Epidummy Knee only) cannot be ensured.

Advice on actions to be taken by the user:

In order to use the affected devices (Epiguide Knee and Epidummy Knee only), the devices must be re-sterilised according to the following instructions:

Cleaning:
Disinfector (EN ISO 15883-1:2006); Temperature 90 °C; Exposure time: at least 1 minute.

Sterilisation:
Steam autoclave (EN ISO 17665-1:2006); Temperature 121 °C; Exposure time: 20 minutes; Minimum drying time: 30 minutes; Packaging: Double-Single or without packaging.

If re-sterilisation is not performed, the devices must be disposed of (contact Episurf for new products).

Transmission of this Field Safety Notice:

This notice needs to be passed on to all persons who need to be made aware within your organisation and at any organisation where the potentially affected devices have been transferred.

Contact reference person:
Michael Näsström, Quality Manager, Episurf Operations AB
Karlavägen 60, 114 49 Stockholm, Sweden
+46 (0)70 449 63 55, michael.nasstrom@episurf.com

The undersigned confirms that this information is correct, and that applicable Regulatory Agencies have been noticed.

[redacted]