

SCILO Vertriebs GmbH, Raiffeisenstraße 25, 40764 Langenfeld, Germany

To the Medical Device Safety Officers

22.03.2023

Important customer information:

Incision instrument, 70 mm - possibility of contamination on incision template and wire

Dear Sir or Madam,

SCILO has currently received a complaint from a user about soiling or discolouration on the round, transparent incision template. Please find enclosed some photos showing the error pattern.

The error pattern has been narrowed down to the following 3 batches, whose templates were manufactured in one production:

Lot no. 1137-6410

Lot no. 1140-6436

Lot no. 1151-6511

The soiling/discolouration was only detected in isolated cases. The error patterns occur both on the surface and within the transparent plastic. Both of these abnormalities are firmly attached to the material of the instrument and do not fall off.

The soiling/discolouration can be explained as follows:

Any black spots that may appear are particles of an ear funnel produced in parallel and made of the same material. The brownish, honey-coloured inclusions inside or even caked on the top of the incision template are residues of a machine lubricant from the H1 quality range (food grade).

The two error patterns were classified by SCILO, with the help of its manufacturer, as "no patient hazard" in a risk analysis.

A test in which the instruments were immersed in a liquid and then rubbed on a cotton cloth showed that the discolouration had not settled on the cloth.

SCILO reacted immediately with corrective and preventive measures, including informing all customers who had ordered this item in the past.

If customers still have unproduced quantities of the 3 batches mentioned, we have informed the customers in this case that we would be happy to replace them with goods from a more recently produced batch.

Each potentially affected customer has received an overview with which delivery note and date SCILO delivered the affected batch to the customer. The customers have been asked to please check their stock and send SCILO the available batch quantities of the item.

With best regards,

