Syntellix AG • Aegidientorplatz 2a • DE 30159 Hannover

To whom it may concern

Subject:
Urgent safety information - medical device recall
Product concerned: MAGENZIX® CS
Art. No. 1027.014, CS 2.7 x 14mm Lot Number 197553
Art. No. 1032.014, CS 3.2 x 14 mm Lot Number 197557

August 24, 2020

Dear Sir or Madam,

Herewith we inform you that Syntellix AG has detected exchanged labels for the above mentioned items and has therefore initiated a field safety corrective action for voluntary withdrawal.

For this reason, we kindly ask you to isolate the implants of the above-mentioned affected lots and lock them for further use. A Syntellix sales representative will immediately get in touch with the appropriate contact person in your organization to discuss the return and the modalities of the exchange.

In our risk assessment, we determine the following (only applies to patients who may have been treated with the affected products):

- It is technically impossible to insert an implant with a too small diameter (2.7 mm) from a package labelled with a diameter of 3.2 mm with the supplied instruments (guide wire, screwdriver).
- It is possible that an implant with a diameter that is minimally too large (3.2 mm) was used although the packaging was labelled with the diameter 2.7 mm. However, this has no negative affect on the healing process of the osteotomy/fracture.

Please ensure in your organisation that all users of the above mentioned products will be informed and are aware of this letter. If you have sold the products to third parties, please forward a copy of this information or inform the contact person listed below. Please retain this information at least until the action has been completed. The Federal Institute for Drugs and Medical Devices (BfArM) in Germany has received a copy of this letter.

Contact person:
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The goal of Syntellix is and always will be to supply you with medical devices of the highest quality standards. Therefore, we sincerely apologize for any inconvenience arising for you or your employees in connection with this measure, but we also ask for your kind understanding and cooperation.

With best regards
Syntellix AG

Prof. Martin H. Kirschner, MD
Chief Technology Officer (CTO)
Safety Officer

Kristin Forssmann, MD
Medical Director
Deputy Safety Officer