

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.

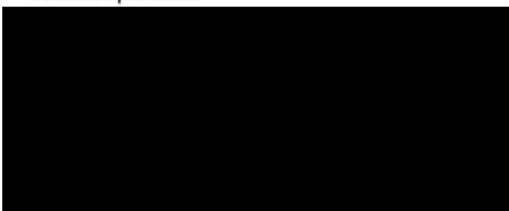
For this reason, we kindly ask you to isolate the implants of the above-mentioned affected lots and lock them for further use. A Syntellix sales representative will immediately get in touch with the appropriate contact person in your organization to discuss the return and the modalities of the exchange.

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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Supervisory Board**  
Annette Claassen

**Registered office of the  
company**  
Hannover  
Hannover Local Court  
HRB 202618

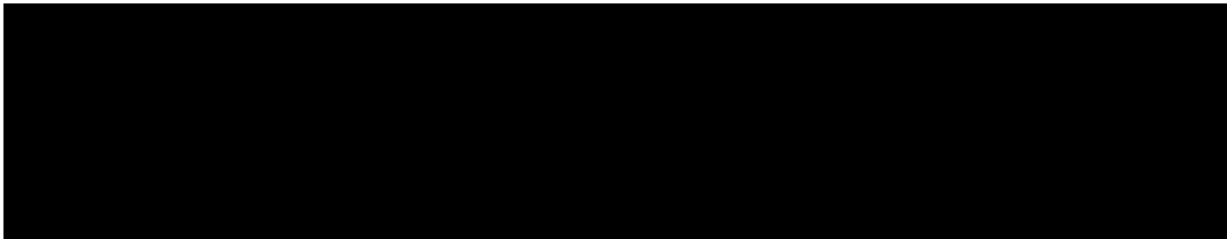
**Bank Account**  
Norddeutsche Landesbank  
IBAN:  
DE8325050000150818177  
SWIFT-BIC:  
NOLADE2HXXX

VAT-ID-No. DE258728980  
Tax ID-No. 25/203/58178





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.



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

Kristin Forssmann, MD  
Medical Director  
Deputy Safety Officer