IMPLANT DIRECT™
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362 USA

Urgent Field Safety Notice

simplyInterActive™ Implant 5.0mmD x 10mmL SBM: 3.4mmD Platform
FSCA-identifier : 2018.MM.DD
Type of action (Field Safety Corrective Action)

Month XX, 2018

Name:
Address:
Order Number:

Dear Customer,

Implant Direct Sybron Manufacturing LLC is performing a field safety notification for lot number 68960 of the simplyInterActive Implant part number 655010U, some of which were shipped to your office. Through our Regulatory Affairs reporting process we have found that the labeling of the simplyInterActive Implant may be out of specification in that the cap may not be labeled with the correct part number. QA inspection of a sealed returned vial associated with a US complaint confirmed that the cap was labeled with incorrect part number 604313U, although the correct part number 655010U is on the main vial label. The probability of health consequences occurring is rare (<1%) since there are at least two stock checks (when the product arrives to the practice and before surgery) where this issue could have been detected. If the mislabeling was only discovered during the surgery after the osteotomy, and another optimal implant was not available, then a new surgical procedure may be needed if the dentist chooses not to use the mislabeled part. Except for this incorrect information, all products within this lot are according to specification and safe for use.

The following table lists the affected part and lot number. Please review this table to determine if you have any of the affected products in your inventory and follow the instructions provided below for correcting the potential cap mislabeling.

Product Description	Part Number	Lot Number
simplyInterActive Implant, 5.0mmD x 10mmL SBM: 3.4mmD Platform	655010U	68960

1. Please review your inventory for the affected product.
2. Please complete and return the Acknowledgement Form within 48 hours.
3. This is a safety notification. You do *not* need to return the product, please follow the instructions enclosed with this letter and replace the mislabeled cap label with the correct label provided.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies. If you have any questions contact Implant Direct Sybron Manufacturing LLC Customer Care at 00800 4030 4030. Implant Direct Sybron Manufacturing sincerely apologizes for the inconvenience this situation may cause.

Sincere Regards,

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…
Implant Direct
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

Return and Contact person:
Berlinde Janssen and Customer Service Team
Implant Direct Europe AG
Hardturmstrasse 161 8005 Zurich, Switzerland
Phone: 00800 4030 4030

Enclosure:
Response Form & Instructions
Correct Cap labels

IMPLANT DIRECT™
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Name:
Address:
Order Number:

simplyInterActive Implant Product Acknowledgement Form

Product Description	Part Number	Lot Number
simplyInterActive Implant, 5.0mmD x 10mmL SBM: 3.4mmD Platform	655010U	68960

☐ *We acknowledge receipt of the simplyInterActive Implant Field Safety Corrective Action Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product.*

Quantity

☐ *We acknowledge receipt of the simplyInterActive Implant Field Safety Corrective Action Notification. We have checked our inventory and were **unable** to locate any of the above-mentioned products.*

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Name:
Address:
Order Number:

Contact Person (Please Print)	Facility
Signature	Date

WE ALSO KINDLY REQUEST YOUR COOPERATION IN FAXING/EMAILING/MAILING THIS ACKNOWLEDGEMENT FORM TO THE FOLLOWING NUMBER/EMAIL ADDRESS TO CONFIRM YOUR RECEIPT OF THIS NOTIFICATION WHETHER OR NOT YOU HAVE ANY AFFECTED PRODUCT.

00800 4030 4030 / customerservice@implantdirect.eu