IMPLANT DIRECT™
P.O. Box
8058 Zürich-Airport
Switzerland
Infoline 00800 4030 4030

Urgent Field Safety Notice

simply RePlant® Implant 4.3mmD x 13mmL, 4.3mmD Platform
FSCA-identifier: 2018.MM.DD
Field Safety Corrective Action

Month DD, 2018

Name:
Address:
Order Number:

Dear Customer,

Implant Direct Sybron Manufacturing LLC is performing a field safety corrective action for simply RePlant® Implant 4.3mmD x 13mmL, 4.3mmD Platform part number 604313U lot number 108191, some of which were shipped to your office. QA inspection of a sealed returned vial associated with a US complaint confirmed that an InterActive® Plastic Non-Engaging coping part number 6534-46 was packaged instead of the RePlant® Implant. The probability of health consequences occurring is remote (<0.1%). While preparing for surgery, clinician and staff would have noticed the incorrect part. If the condition of the device was only noticed during surgery and there was no other optimal implant in stock, the patient would have to be rescheduled and a potential new surgical procedure would have to be performed.

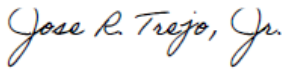
The following table lists the affected part and lot number. Please review this table to determine if you have any of the affected products in your inventory.

Product Description	Part Number	Lot Number
simply RePlant® Implant 4.3mmD x 13mmL, 4.3mmD	604313U	108191

1. Please review your inventory for the affected product.
2. Please complete and return the Acknowledgement Form within 48 hours for the product listed above; Quarantine product and return product listed above.
3. If you are an authorized Implant Direct Sybron Manufacturing LLC distributor, we request that you identify those customers that may have been shipped the affected product lot and contact these customers to inform them of this issue within forty-eight (48) hours of receipt of this notification.

If you have any of the affected product listed above, please return the product and we will send you a replacement part. If you have any questions contact Implant Direct Sybron Manufacturing LLC Customer Care at 00800 4030 4030. The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies. Implant Direct Sybron Manufacturing LLC sincerely apologizes for the inconvenience this situation may cause.

Sincere Regards,



Signature

Quality Systems Supervisor
Implant Direct
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

Return and Contact person:
Cendrine Mikec and Customer Service Team
Implant Direct Europe AG
Basicweg 20
3821BR Amersfoort,
The Netherlands
Phone: 00800 4030 4030
Fax: +41 44 567 81 01

Enclosure:
Response Form

IMPLANT DIRECT™
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Name:
Address:
Order Number:

simply RePlant® Implant 4.3mmD x 13mmL, 4.3mmD Platform
Field Action Acknowledgement Form

Product Description	Part Number	Lot Number
simply RePlant® Implant 4.3mmD x 13mmL, 4.3mmD Platform	604313U	108191

☐ *We acknowledge receipt of the simply RePlant® Implant 4.3mmD x 13mmL, 4.3mmD Platform Field Action Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product:*

Total Quantity Returned

Authorized Implant Direct Sybron Manufacturing LLC Distributors: *Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to recover their affected product.*

☐ *We acknowledge receipt of simply RePlant® Implant 4.3mmD x 13mmL, 4.3mmD Platform Field Action Notification. We have checked our inventory and were **unable** to locate any of the above-mentioned product.*

Authorized Implant Direct Sybron Manufacturing LLC Distributors: *Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to recover their affected product.*

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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