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

Urgent Field Safety Notice

RePlant® Precision IO Scan Adapter
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 corrective action for three (3) lots of the RePlant® Precision IO Scan Adapter (part numbers 6035-09PT, 6043-09PT, 6050-09PT), some of which were shipped to your office. We have discovered that the scan adapter may have been assembled incorrectly. The result of the incorrect assembly would be that the clinician would not be able to capture the position and orientation of a dental implant or lab analog during the digital scanning process and the patient may have to be rescheduled, however, no health consequences are expected as this part is only used during prosthetic procedures. Our current data indicates the probability of health consequences occurring is none (0%). Use of this product will not have an adverse health consequence.

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

Product Description	Part Numbers	Lot Numbers
RePlant® Precision IO Scan Adapter	6035-09PT, 6043-09PT, 6050-09PT	104539, 104540, 104511

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.

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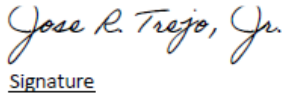
Sincere Regards,



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:

RePlant® Precision IO Scan Adapter Field Action Acknowledgement Form (check one below)

Product Description	Part Numbers	Lot Numbers
RePlant® Precision IO Scan Adapter	6035-09PT, 6043-09PT, 6050-09PT	104539, 104540, 104511

☐ *We acknowledge receipt of the RePlant® Precision IO Scan Adapter 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.*

OR

☐ *We acknowledge receipt of the RePlant® Precision IO Scan Adapter 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