Implant Direct
Sybron Manufacturing, LLC
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362
Tel: 818-444-3300
Fax: 818-444-3406

July 12, 2016

URGENT: FIELD Correction Notification Safety Notice

Dear Customer:

Implant Direct Sybron Manufacturing LLC is performing a Field Safety Corrective Action (FSCA) for 3 lots of the of RePlant® Angled Abutment, some of which were shipped to your office.

Through our internal Regulatory Affairs evaluation (Health Hazard Evaluation) process, we have found a possible issue with the design specification, manufactured outside of specifications. Specifically, some consignees received product that may have been out of specifications set by the company. Our current data indicates the possibility of this occurring is remote (<0.10%). In the event the consignee has this product in their inventory, the product will not fit into the implant as indicated. This discrepancy may lead to the screw loosening and the patient would need to return to the Doctor for an additional non-surgical procedure. In worst case scenario crown could come loose and patient could swallow it. This would not cause a long term health consequence. Our current data indicates the possibility of this occurring is remote (<0.1%). If the product has been used with no issues no further action is necessary.

The following table lists the affected part and lot numbers (located on the vial in which the product was shipped). Please review this table to determine if you have any of the affected products in your inventory.

Product Description	Part Numbers	Lot Number
RePlant® Angled Abutment	6050-52-60	50174, 39799, 49364

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1. **Please review your inventory for the affected product.**
2. **Please complete and return the Acknowledgement and Recall Return Form within 48 hours.**
3. **If you are an authorized Implant Direct Sybron Manufacturing 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 in order to provide the customers with the correct tool.**

If you have any of the affected product listed above, we will send you a replacement part. If you have any questions contact Implant Direct Europe AG, Customer Care at toll free number: 00800 4030 4030.

Implant Direct Sybron Manufacturing sincerely apologizes for the inconvenience this situation may cause you. The appropriate Competent Authorities has been notified.

Sincere Regards,

Contact reference person:
Stephanie Bergeron
Regulatory Affairs Supervisor
Implant Direct
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362
818-444-3393
818-444-3406 Fax

Return and Contact person:
Maida Wright

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Implant Direct Europe AG
Hardturmstrasse 161
8005 Zürich
Switzerland
00800 4030 4030 /info@implantdirect.eu

Doctor
Name
Address
Country

RePlant® Angled Abutment Acknowledgement and Recall Return Form

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☐ ***We acknowledge receipt of the RePlant® Angled Abutment Field Corrective Action Notification. We have checked our inventory and were able to locate one or more units 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.*

Quantity Returned

☐ ***We acknowledge receipt of the RePlant® Angled AbutmentField Corrective 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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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.