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

May 19, 2016

Doctor
Name
Address
Country
Order Number

URGENT: MEDICAL DEVICE RECALL

Dear Customer Name:

Implant Direct Sybron Manufacturing LLC is recalling 1 lot of the 6534-08N InterActive® Implant Open-Tray Transfer Narrow, some of which was shipped to your office.

Through our Regulatory Affairs reporting process we have found that the incorrect sized product (6534-08W) was packaged instead of a 6534-08N causing a possible issue with the impression. This discrepancy may lead to the possibility of an oversized crown fabrication. Our current data indicates the possibility of occurrence for the part being packaged is probable. However the likelihood of risk to the patient is minimal. In the event the 6534-08W is used; there is a risk of patient discomfort and may cause inflammation of the gingiva.

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

Product Description	Part Numbers	Lot Number
6534-08N InterActive® Implant Open-Tray Transfer Narrow	6534-08N	71664

1. **The proper product - the 6534-08N - is being sent with this notification. Please use this product and not the affected product.**

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

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 and you have any questions contact Implant Direct Sybron Manufacturing LLC Customer Care at 1-888-649-6425. A return label is included with this letter. **This is at no charge.**

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 retrieve their affected product.

If you or your patients have experienced any issues as a result of the affected products noted in this communication, you may voluntarily report the incident to the FDA through the MEDWATCH reporting system at the following:

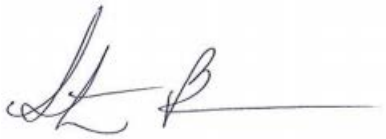
http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm

Implant Direct Sybron Manufacturing sincerely apologizes for the inconvenience this situation causes you and your customers.

Thank you for your patience and support.

Sincere Regards,

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



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

Doctor
Name
Address
Country

6534-08N- InterActive® Implant Open-Tray Transfer Narrow

Acknowledgement and Recall Return Form

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

Product Description	Part Numbers	Lot Number
InterActive® Implant Open-Tray Transfer Narrow	6534-08N	71664

☐ ***We acknowledge receipt of the 6534-08N– InterActive® Implant Open-Tray Transfer Narrow Recall Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product. We will be returning the following quantity to Implant Direct Sybron Manufacturing.***

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

Doctor

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

Name
Address
Country

☐ ***We acknowledge receipt of the 6534-08N– InterActive® Implant Open-Tray Transfer Narrow Recall Notification. We have checked our inventory and were <u>unable</u> 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.*

_____ _____

Contact Person (Please Print) Facility

_____ _____

Signature Date

WE ALSO KINDLY REQUEST YOUR COOPERATION IN FAXING/EMAILING/MAILING (RETURN LABEL INCLUDED) THIS

Implant Direct
Sybron Manufacturing, LLC

3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

Tel: 818-444-3300
Fax: 818-444-3406

ACKNOWLEDGEMENT FORM TO THE FOLLOWING NUMBER/EMAIL ADDRESS TO CONFIRM YOUR RECEIPT OF THIS NOTIFICATION WHETHER OR NOT YOU HAVE ANY AFFECTED PRODUCT.

888-649-6425/customer.claims@implantdirect.com