



Implant Direct
Sybron Manufacturing, LLC

3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

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

Urgent Field Safety Notice

SwishTapered™ and SwishPlus™ Implant

FSCA-identifier : 2017.12.XX

Type of action (Field Notification for SwishTapered™ and SwishPlus™ Implant extender)

January XX, 2018

Name:
Address:
Order Number:

Dear Doctor,

Implant Direct Sybron Manufacturing LLC is performing a field corrective action notification for 20 lots of the SwishTapered™ and SwishPlus™ Implant, some of which were shipped to your office. Through our Regulatory Affairs reporting process we have found that the extender that is packaged with the SwishTapered™ and SwishPlus™ Implant may have been packaged in the incorrect position. This discrepancy may lead to the possibility of extender not seating properly on the implant. Micro-movements that may result from incomplete sealing can cause possible inflammation of the soft tissue around the implant. Worst case scenario, the screw and extender could come loose and be swallowed or aspirated by patient and medical intervention may be needed. No injuries have been reported.

Enclosed are instructions for placing the SwishTapered™ and SwishPlus™ extender in the correct orientation, in the event that the extender was packaged in the incorrect position (upside down in the plastic retainer). 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(s)
SwishPlus™ Implant	924108	97347
SwishPlus™ Implant	924112	64927, 93563, 98662
SwishPlus™ Implant	924116	70543
SwishPlus™ Implant	924806	99749
SwishPlus™ Implant	924810W	93934
SwishPlus™ Implant	924812W	94204
SwishPlus™ Implant	924814	103199
SwishTapered™ Implant	934106	68075, 69252, 79574

888-649-6425 | www.implantdirect.com

FORM – 344 REV



Implant Direct
Sybron Manufacturing, LLC

3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

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

SwishTapered™ Implant	934112	69101, 80912
SwishTapered™ Implant	934806	68076, 75219
SwishTapered™ Implant	934812	68078, 68889
SwishTapered™ Implant	934814	67980
SwishTapered™ Implant	935712	68077

- 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.**

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,

Stephanie Bergeron
Regulatory Affairs Supervisor
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

888-649-6425 | www.implantdirect.com

FORM – 344 REV



Implant Direct
Sybron Manufacturing, LLC

3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

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

Name:
Address:
Order Number:

SwishTapered™ / SwishPlus™ Implant Acknowledgement Form

Product Description	Part Number	Lot Number
SwishTapered™ / SwishPlus™ Implant		

We acknowledge receipt of the SwishTapered™ / SwishPlus™ Implant Field Corrective Action Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product. We have written the part number(s) and lot number(s) above.

Quantity

We acknowledge receipt of the SwishTapered™ / SwishPlus™ Implant Field Corrective Action Notification. We have checked our inventory and were unable to locate any of the above-mentioned product.

Name:
Address:
Order Number:



Implant Direct
Sybron Manufacturing, LLC

3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

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

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