

---

**Urgent Field Safety Notice****Legacy™ Implant Closed-Tray Transfer-Concave Profile 3.5mmD Platform****FSCA-identifier : 2018.05.DD****Field Safety Corrective Action**

---

May DD, 2018

Name:

Address:

Order Number:

Dear Customer,

Implant Direct Sybron Manufacturing LLC is performing a field safety corrective action for Legacy™ Implant Closed-Tray Transfer-Concave Profile 3.5mmD Platform part number 8735-05 lot number 90212, some of which were shipped to your office. We have found that the labeling of part number 8735-05 lot number 90212 may be out of specification in that the cap may not be labeled with the correct part number. QA inspection of a sealed returned vial associated with a US complaint confirmed that the cap was labeled with incorrect part number 824210U (simply Legacy™2 Implant), although the correct part number 8735-05 is on the main vial label. The probability of health consequences occurring is remote (<0.1%). This is a part only used temporarily during impressions for the prosthetic procedure. However, if cap vial stated an implant part number, clinician or staff could have mistaken the part as an implant to use during a surgery. While preparing for surgery, clinician and staff would have noticed the mislabeling issue. If issue only noticed during surgery and there wasn't any other optimal implant for that surgery in stock, patient may need a new surgical intervention. Except for this incorrect information, all products within this lot are according to specification and safe for use.

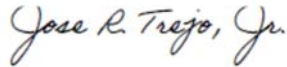
The following table lists the affected part and lot number. Please review this table to determine if you have any of the affected products in your inventory and follow the instructions provided below for correcting the potential cap mislabeling.

Product Description	Part Number	Lot Number
Legacy™ Implant Closed-Tray Transfer Concave Profile 3.5mmD Platform	8735-05	90212

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. If you find a mislabeled cap, please replace the mislabeled cap label with the correct label provided and indicate on the Acknowledgement Form you return.
4. 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.

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 LLC sincerely apologizes for the inconvenience this situation may cause.

Sincere Regards,

A handwritten signature in black ink that reads "Jose R. Trejo, Jr." in a cursive script.

Signature

Quality Systems 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  
PO Box  
8058 Zurich-Airport  
Switzerland  
Phone: 00800 4030 4030  
Fax: +41 44 567 81 01

Enclosure:  
Response Form  
Correct cap label(s)

Name:  
Address:  
Order Number:

**Legacy™ Implant Closed-Tray Transfer-Concave Profile 3.5mmD Platform  
Field Action Acknowledgement Form**

Product Description	Part Number	Lot Number
Legacy™ Implant Closed-Tray Transfer Concave Profile 3.5mmD Platform	8735-05	90212

- We acknowledge receipt of the Legacy™ Implant Closed-Tray Transfer-Concave Profile 3.5mmD Platform Field Action Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product. **If we locate an incorrect cap label, we will write the quantity and incorrect part number below. Please return the incorrect label.***

Total Quantity

Incorrect part label and quantity mislabeled (if applicable)

**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 the Legacy™ Implant Closed-Tray Transfer-Concave Profile 3.5mmD 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.*

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***