

February DD, 2019

Name:

Address:

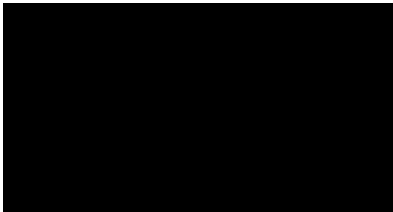
Order Number:

Dear Customer,

In addition to the information already provided to you via the attached field safety notification letter for Interactive Precision IO Scan Adapter Part number 6534-09PT (Lot numbers 104479 and 104963) on November 28, 2018 and Part number 6530-09PT (Lot numbers 104151, 106478, 114914, and 124072) on December 28, 2018, Implant Direct Sybron Manufacturing LLC would like to provide you with new available information: The missing feature decreases retention of the peek part on the titanium base, therefore there is a risk it may come loose during the procedure inside the patient's mouth. If that occurs there is a risk of aspiration or ingestion of a part that may need minor medical intervention.

The field action remains unchanged, however. Please refer to the instructions provided in the field safety notification letter.

Sincere regards,



Implant Direct Sybron LLC
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

Urgent Field Safety Notice

InterActive Precision IO Scan Adapter

FSCA-identifier: 2018.11.DD

Field Safety Corrective Action

November DD, 2018

Name:

Address:

Order Number:

Dear Customer,

Implant Direct Sybron Manufacturing LLC is performing a field corrective action for Interactive Precision IO Scan Adapter Part number 6534-09PT, Lot numbers 104479 and 104963, some of which were shipped to your office. Three (3) customer complaints have been received stating that the Peek part was loose on the Titanium base. QA investigation confirmed these lots were not manufactured to specification. No immediate or long-term health consequences are expected as this product is only used during prosthetic procedures. Only a delay in treatment is expected to occur. Use of this product will not have an adverse consequence.

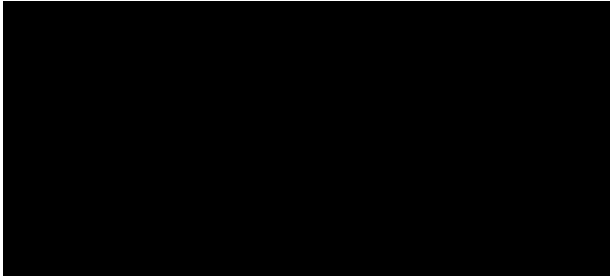
The following table lists the affected part and lot numbers. Please review this table to determine if you have any of the affected product in your inventory.

Product Description	Part Numbers	Lot Numbers
Interactive Precision IO Scan Adapter	6534-09PT	104479 and 104963

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.

Sincere regards,



Return and Contact person:

Cendrine Mikec and Customer Service Team
Implant Direct Europe AG
Kozakkenberg 4,
5951 DL Belfeld - Community of Venlo,
The Netherlands
Phone: 00800 4030 4030
Fax: +41 44 567 81 01

Enclosure:
Response Form

Name:
Address:
Order Number:

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

Product Description	Part Numbers	Lot Numbers
Interactive Precision IO Scan Adapter	6534-09PT	104479 and 104963

- We acknowledge receipt of the InterActive 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 InterActive 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.*



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

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.**

Tel: 00800 4030 4030 / Fax: +41 44 567 81 01 /

Email: customerservice@implantdirect.eu