IMPLANT DIRECT™
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362 USA

Urgent Field Safety Notice

InterActive™ Healing Collar
FSCA-identifier : 2018.MM.DD
Type of action (Field Safety Corrective Action)

Month XX, 2018

Name:
Address:
Order Number:

Dear Customer,

Implant Direct Sybron Manufacturing LLC is performing a field safety notification for lot number 98151 of the InterActive Healing Collar part number 6530-15, some of which were shipped to your office. Through an internal investigation we have found that the labeling of the InterActive Healing Collar may be out of specification in that the cap may not be labeled with the correct part number. The cap was labeled with incorrect part number 6530-12N, although the correct part number 6530-15 is on the main vial label. Except for this incorrect information, all products within this lot are according to specification and safe for use. If due to the mislabeling the wrong product is selected for surgery, a two-piece screw-extender or the healing abutment that comes within the implant package can be used to complete the procedure in one stage. No complaints have been reported for this issue.

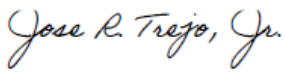
The following table lists the affected part and lot number. Please review this table to determine if you have any of the affected products in your inventory and follow the instructions provided below for correcting the potential cap mislabeling.

Product Description	Part Number	Lot Number
InterActive Healing Collar	6530-15	98151

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 and replace the mislabeled cap label with the correct label provided.
4. 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.

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,



Signature

Jose Trejo
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
Hardturmstrasse 161 8005 Zurich, Switzerland
Phone: 00800 4030 4030

Enclosure:
Response Form & Instructions
Corrected Cap labels

IMPLANT DIRECT™
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Name:
Address:
Order Number:

InterActive Healing Collar Product Acknowledgement Form

Product Description	Part Number	Lot Number
InterActive Healing Collar	6530-15	98151

☐ *We acknowledge receipt of the InterActive Healing Collar Field Safety 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.*

Quantity

☐ *We acknowledge receipt of the InterActive Healing Collar Field Safety Corrective Action Notification. We have checked our inventory and were **unable** to locate any of the above-mentioned products.*

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Name:
Address:
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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.

00800 4030 4030 / customerservice@implantdirect.eu

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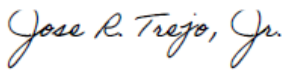

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