



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

**The Spectra System/Legacy Guided Surgery Handle Kit,
FSCA-identifier : 2017.06.26
Type of action (Device Exchange).**

June 26, 2017

Doctor
Name
Address
Country
Order Number

URGENT: Safety Alert/Advisory Notice

Dear,

Implant Direct Sybron Manufacturing LLC is performing a field corrective action for one lot of The Spectra System/Legacy Guided Surgery Handle Kit inserts product code G-HK Lot # 65249, some of which were shipped to [REDACTED]

Through our Regulatory Affairs reporting process we have found that the product may be out of Implant Direct specification. The inside diameter of the 3.4mm small drill guide inserts have a smaller diameter than Implant Direct Specifications. This discrepancy may lead to the possibility of a delay in procedure for the patient if the drilling sequence is discontinued. Our current data indicates the likelihood of risk to the patient is remote. In the event the G-HK 3.4mm drill insert is used, the insert will stop the drill from insertion; if there is a delay in procedure and site is closed, there is a risk of infection, and may lead for the need of additional patient care.

The following table lists the affected part and lot number(s) (located on the vial in which the product was shipped). Please review this table to determine if you have any of the affected products in your inventory. Additionally you will receive replacement product in conjunction with this notification.

Product Description	Part Numbers	Lot Number
The Spectra System/Legacy Guided Surgery Handle Kit	G-HK	65249

888-649-6425 | www.implantdirect.com

FORM – 344 REV



Implant Direct
Sybron Manufacturing, LLC

3050 E. Hillcrest Drive
Thousand Oaks, CA 91362

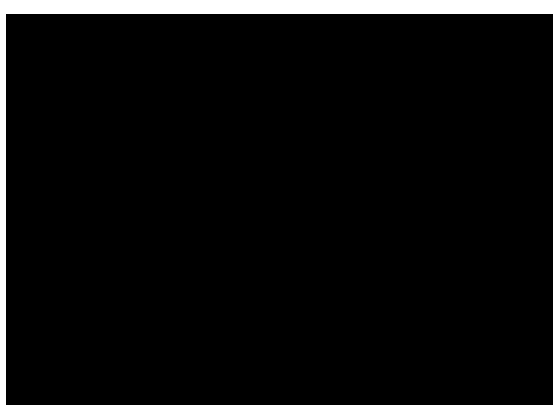
Tel: 818-444-3300
Fax: 818-444-3406

1. Please review your inventory for the affected product.
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 replacement product.

If you have any of the affected product listed above, we will send a padded return envelope with replacement product please return affected product in the padded envelope. If you have any questions contact Implant Direct Sybron Manufacturing LLC Customer Care at 1-888-649-6425.

Implant Direct Sybron Manufacturing sincerely apologizes for the inconvenience this situation may cause you.

Sincere Regards,



Return and Contact person:
Hans Scheepens
Implant Direct Europe AG
Hardturmstrasse 161 8005 Zurich, Switzerland
Phone: 41 44 567 8100

Doctor

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
Country
Order Number

Spectra-System® / Legacy™ Guided Surgery Handle Kit Acknowledgement and Recall Return Form

Product Description	Part Numbers	Lot Number
Spectra-System®/ Legacy™ Guided Surgery Handle Kit	G-HK	65249

We acknowledge receipt of the Spectra-System®/ Legacy™ Guided Surgery Handle Kit Field Corrective Action/Recall 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 in order to recover their affected product.

Quantity Returned

We acknowledge receipt of the Spectra-System®/ Legacy™ Guided Surgery Handle Kit Field Corrective Action/Recall 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

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

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 THIS 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](tel:888-649-6425)/customer.claims@implantdirect.com

customer.support@implantdirect.eu