
Urgent Field Safety Notice

Spectra-System®/ Legacy™ Guided Surgery Handle Kit,
2017.05.25 FSCA-identifier
Type of action (Device Exchange).

June XX, 2017

Doctor
Name
Address
Country
Order Number

URGENT: MEDICAL DEVICE FIELD CORRECTIVE ACTION/RECALL

Dear Customer Name:

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 your office.

Through our Regulatory Affairs reporting process we have found that the product may be out of Implant Direct specification. The 2.3mm small drill guide insert through hole is a smaller diameter than Implant Specifications. This discrepancy may lead to the possibility of a delay in procedure for the patient. Our current data indicates the likelihood of risk to the patient is remote. In the event the G-HK 2.3mm drill insert is used the insert will stop the drill from insertion; if there is a delay in procedure, 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

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,

…….
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……..

Doctor
Name
Address
Country

Legacy Full-Contour Abutment 3.5mmD Assembly Acknowledgement and Recall Return Form

Product Description	Part Numbers	Lot Number
Legacy Full-Contour Abutment 3.5mmD Assembly	G-HK	65249

☐ ***We acknowledge receipt of the Legacy Full-Contour Abutment 3.5mmD Assembly 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 Legacy Full-Contour Abutment 3.5mmD Assembly Field Corrective Action/Recall Notification. We have checked our inventory and were <u>unable</u> 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.*

_____	_____
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/customer.claims@implantdirect.com