MEDICAL DEVICE RECALL

Dornier Thulio Laser Fibers
February 6, 2023

Dear Valued Customer,

The purpose of this letter is to advise you that Dornier MedTech America, the manufacturer of the Dornier Thulio Laser Fibers, is voluntarily issuing a Medical Device Recall regarding the above-mentioned laser fibers. Distribution records indicate that you have received one or more of these devices that are the subject of this action.

DMTA has become aware of a limited number of instances where the programming of the laser fiber cannot be read by the laser. Accordingly, DMTA is initiating this recall as a precautionary measure to prevent the use of product that may not be fully functional.
The following product and lots are subject to this action:

Part Number	Lot Number
K2016361	F3122S, F4922S, F4722S, F4522S, F4322S, F3522S
K2016363	B3522S, B4322S, B4922S, C4122S
K2016365	C3922S, C4722S, C4522S, C4122S, C4322S
K2016362	F3522S
K2016366	D4522S, D4722S

Note that all units for the above products in your inventory are subject to this action.

Reason for the Voluntary Field Correction:
During routine product reviews, we identified there is a potential issue regarding the programming of some of the RFID chips used in the Thulio fibers. In these cases, the fiber may not be able to be read properly by the Thulio laser which prevents the fiber from being used. If this does occur, by replacing the fiber with a new one, the laser will become fully functional.

Potential Risk to Health:
In the unlikely chance that an unprogrammed fiber is attached to the laser, it would be prior to the fiber being used clinically. If this was to occur, the user would remove the unprogrammed fiber and replace it with a new programmed fiber. Therefore, this issue does not represent any safety related matter.

Actions to be Taken by the Customer/User:
The customer should immediately quarantine all inventory of Dornier Thulio Laser Fibers that are referenced above. Please complete the attached Response form.
Return all product to Dornier by contacting Dornier Customer service at 1-800-831-0859 or contact your local Dornier Sales representative for assistance.

Other Information:
Please contact the DMTA Quality Department if you have any questions regarding this action or any of our products, or if you would like assistance with the action. We regret any inconvenience that this action may cause, but we appreciate your understanding as we take steps to ensure patient and customer satisfaction.

Dornier reminds you that adverse reactions or quality problems experienced with the use of this product may be reported to the Food and Drug Administration (FDA)'s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Thank you for your support. We regret any inconvenience that this action may cause, but we appreciate your understanding as we take steps to ensure patient and customer satisfaction.

Sincerely,

[redacted]

[redacted]

[redacted]

Dornier MedTech America, Inc
1155 Roberts Blvd. N.W., Suite 100
Kennesaw, GA 30144
Phone: 770-514[redacted] Fax: 770-514-[redacted]
[redacted]@dornier.com

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:
Customer Name _____
Street Address _____
Town, State, Zip Code _____

Dornier Thulio Laser Fibers

I have read and understand the recall instructions provided in the February 6, 2023 letter.
Yes _ No_

Any adverse events associated with recalled product? Yes _ No _

If yes, please explain:

_____

_____

_____

Affected Product Information: Include information that is applicable for affected product.

Manufacturer's Product Number/Catalog Number	Lot Number	Quantity in inventory	Quantity returned

PLEASE FAX COMPLETED RESPONSE FORM TO:
Tel. # 770-514-6297, ATTN: John Hoffer

OR MAIL/E-MAIL TO:
Dornier MedTech America Inc., 1155 Roberts Blvd., Suite 100, Kennesaw, GA 30144
ATTN: John Hoffer
e-mail: jhoffer@dornier.com