To: whom it may concern Relevant Head of Departments Cc: Chairman Medical Board Name/name: Hejie Wang Abtlg./Dept. QM/RA Tel./phone: +65 6572 6056 Email: <u>asiaregulatory@dornier.com</u> Datum/date: 11.04.2019

Urgent Field Safety Notice (FSN):

Shelf Life Issue of Dornier Standard Diode and Nd:YAG Lightguides

Dear Valued Customer,

The purpose of this letter is to advise you that Dornier MedTech, the manufacturer of the Dornier Diode and Nd:YAG Laser Fibers, is voluntarily issuing a Medical Device Recall regarding the laser fibers listed in the table below. Distribution records indicate that you have received one or more of these products that are the subject of this action.

During a routine re-evaluation of the packaging design for the diode fibers conducted to confirm a 5year shelf life, test results indicated that the current package design, paper/poly pouch, of the products with the article numbers as listed below, showed pin hole package failures. The samples tested were units retrieved from the field during the aforesaid routine re-evaluation. Dornier has not received any customer complaints regarding this issue. Although further testing is underway, out of an abundance of caution, Dornier has stopped shipping all fibers that have this package design and has initiated this action. Accordingly, Dornier MedTech is issuing this Field Safety Notice as a precautionary measure to prevent the use of product where the sterility barrier may have been compromised.

The Dornier Diode Laser Fibers are intended to be used as an accessory for Dornier Medilas D Family of Lasers, as well as the Nd:YAG Family of General Surgical Lasers.

Article No	Name
K1008084	LL-E D01-6100-BF-0 10ST BAREFIBER
K1009920	LL-E D01-6180-D-0 10ST DUESE 1.8MM
K1009922	LL-E D01-6100-B-0 10ST BAREFIBER SPUEL
K1009924	LL-E D01-6210-D-0 10ST DUESE 2.1MM
K2010292	LL-E D01-4070-BF-1 10ST BAREFIBER HCL
K2010710	LL-E D01-4070-BF-0 10ST BAREFIBER HCP
K2011577	LL-E S01-4070-BF-0 10ST BAREFIBER HCP
K2011580	LL-E S01-6100-BF-0 10ST BAREFIBER
K2011594	LL-E S01-6180-D-0 10ST DUESE 1.8MM
K2011596	LL-E S01-6210-D-0 10ST DUESE 2.1MM
K2011822	LL-E D00-4079-BF-0 10ST BAREFIBER
K2011824	LL-E D00-6109-BF-0 10ST BAREFIBER

The table below lists the affected products:

Article No	Name
K2012393	LL-E D01-6080-BF-0 10ST BAREFIBER
K2012867	LL-E S00-4079-BF-0 10ST BAREFIBER
K2012870	LL-E S00-6109-BF-0 10ST BAREFIBER
K2013073	LL-E S02-6080-BF-1 10ST BAREFIBER
K1001291	LL-EINM ND E-6210-D 10ST DUESE 2.1MM
K1001292	LL-EINM ND E-6180-D 10ST DUESE 1.8MM
K1001295	LL-EINM ND E-6100-B 10ST BAREFIB SPUEL
K1001296	LL-EINM ND E-4070-B 10ST BAREFIB SPUEL
K1010498	LL-EINM ND E-4070-BF 10ST BAREFIBER
K1001293	LL-EINM ND E-6220-G 10ST GEWINDE
K1001294	LL-EINM ND E-6180-G 10ST GEWINDE 1.8MM
K1010500	LL-EINM ND E-6100-BF 10ST BAREFIBER

Dornier MedTech GmbH

Argelsrieder Feld 7 D-82234 Wessling Postfach 1113 D-82231 Wessling Tel: +49 (0) 8153 888-0 Fax: +49 (0) 8153 888-665 Sitz der Gesellschaft: Wessling Amtsgericht München HRB 114520 Ust-Id Nr. DE 183642248 Steuer-Nr. 117/115/20580 Vorsitzender des Aufsichtsrats: Phillip Yeo Geschäftsführung: Abel Ang Prokurist: Koo Suay Lan Goh Siew Hoon Bankverbindung: Bayerische Landesbank München Konto: 1211842 BLZ: 700 500 00 SWIFT: BYLA DE MM IBAN: DE70 7005 0000 0001 2118 42 Singapore Registered Office: Regn. No.: T01FC6183C No. 2 Venture Drive #23-18 Vision Exchange Singapore 608526 Tel: +65 6572-6068 Fax: +65 6572-6093

www.dornier.com

K2012146	LL-E S02-6100-BF-0 10ST BAREFIBER					
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Pin hole package failures may lead to fibers being unsterile. Given a contaminated laser fiber was used during a clinical procedure, the health consequences mainly consist of microbial contamination of the surgical site that could lead to surgical site infection. Such events could be result in patient pain and the potential for increased length of hospital stay. Such infection could be treated (e.g., antibiotics). Long-term manifestations, although rare, could include osteomyelitis, soft tissue abscess, and sepsis with worst case being septic shock if not treated. Dornier MedTech is not aware of any clinical incidents related to this packaging issue and no customer complaints have been reported.

What does the user have to do?

- 1. Identify if you have above listed products in stock (article no., lot, quantity).
- 2. If you have above listed products in stock, please immediately quarantine all inventory of Dornier Diode and Nd:YAG laser fibers and do not use these products until further notice to avoid any health risks to the patient.
- 3. We are currently analyzing the situation and will inform you what to do with your quarantined stock of lightguides once that determination has been made.
- If you seek a replacement for your fibers, please check the box on the feedback sheet and send us your affected product. Dornier MedTech will then contact you regarding suitable replacements.
- 5. We further on request you to <u>please fill in the attached form immediately and send it back</u> within 7 calendar days by FAX or e-Mail, to below mentioned contact.

Thank you for your support. Please contact your local sales contact if you have any questions regarding this FSN, any of our products, or would like assistance with the action:

Dornier MedTech Asia Pte Ltd 2 Venture Drive #23-18 Vision Exchange Singapore 608526 Tel.: +65 6572 6068 Mail: infoasia@dornier.com

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

Kind regards Dornier MedTech Asia Pte Ltd

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Dornier MedTech GmbH

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Singapore Registered Office: Regn. No.: T01FC6183C No. 2 Venture Drive #23- 18 Vision Exchange Singapore 608526 Tel: +65 6572-6068 Fax: +65 6572-6093 Klinik/Praxis Stempel - Clinic/Office Stamp

Urgent Field Safety Notice Dornier Standard Diode and Nd:YAG Lightguides Confirmation of receipt by user

- □ We hereby confirm receipt and understanding of the Field Safety Notice
- We confirm that following product(s) is/are located at our facility (Data seen at the Packaging Label):

Article Number	Lot Number	Standard-Lichtleiter mit Düsenspitze 1.8mm / Standard-Lightguide with Nozzle Tip 1.8mm / Fibra-Standard con ugello punta da 1.8mm
		Type K1009920 D01-6180-D-0 1,8mm 600 µm Fazerkern0, 3.5m Länge, Einmallichtleiter DEHP 600 µm Goore fiber, 3.5m length, single use STERILE EO Nucleo della fibra da 600 µm Ø, lunghezza 3.5m, fibra monouso Image: Sterie Boole diffusion Image: Sterie Boole diffusion Sterie Boole diffusion
		Manufacturing Ster Domini Maffelo GmbH Argbineder Fed 7 D-82234 Weshing, Cermany Manufacturing Ster Domini Medica Annon, No. D-82234 Weshing, Cermany Distributed in USA by Domini Medica Annon, No. 1048 Abbert Biol. Cennesari, Cd. 30144 USA. Phane 770-48214 Weshing, Cermany Stels 1. Sevice Information please contact your local distributer at Mp//www.inviewam Catalons Februal (SI). Exercision to device to all by or on the order of a physician (10 Stuck./pcs.) Catalons Februal (SI). Catalons Februal (SI).

 We'd like to send above mentioned products back to Dornier MedTech. Please contact us to provide information about suitable replacements.

Contact Person (block capitals)

Date, Signature

Please send back the filled form at:

asiaregulatory@dornier.com