



Tuesday, December 7, 2021

Safety Bulletin

" Use of non LISA Laser Fibers"

LISA Laser Products Holmium and Thulium Lasers

Dear Valued Customer:

Patient safety is Omni-Guide Holding, Inc. Lisa Laser Systems highest concern, as such, we need to warn you that it has come to our attention that non validated laser fibers, fibers not manufactured by LISA Laser, are being marketed for use with LISA Laser Products Holmium and Thulium Lasers. Therefore, when using non validated fibers, we are not able to predict fiber and laser performance or failure modes during usage with LISA Lasers. LISA Laser fibers have proprietary designs and calibrations to ensure they meet LISA Laser Products safety and performance standards.

Please be advised and as stated in the lasers instruction for use, the "**only** fibers validated" for use with LISA Laser Holmium and Thulium lasers are LISA Laser fibers. ***WARNING! The use of laser fibers other than those listed in this manual together with this laser device poses a risk of injury to the patient.***

FDA prohibits companies from marketing medical devices for uses that the federal agency has not approved. According to the Agency, "limiting evidence of intended use to only promotional claims would allow manufacturers to circumvent FDA regulation by masking their true intent, either by simply omitting explicit promotional claims or by making claims that are not true." 86 FR 41383 at 41387 (Aug. 2, 2021).

Off-label promotion can be explicit or implicit. Explicit off-label promotion occurs when a manufacturer makes direct claims about a product to promote it for an unapproved use. Implicit off-label promotion occurs when a manufacturer indirectly suggests that a device is appropriate for an unapproved use.

Further, the use of non validated fibers may impair product safety and performance, can cause patient and users harm, and may result in costly damage to the laser optical system and other components

Kind regards,

Carlos O. Acosta

Director Global QA & RA



email CAcosta@omni-guide.com

office 617.551.4400 Ext. 563