URGENT: MEDICAL DEVICE REMOVAL

SOLTIVE™ SuperPulsed Laser Fiber

Product Name	Model Number	UDI-DI	Lot Number
SOLTIVE™ SuperPulsed Laser Fiber	See Attachment 1* Updated Oct. 1, 2026		

Date: September 16, 2026

Attention: Operating Room / Surgery and Risk Management Departments

Dear Healthcare Professional:

Olympus is initiating a Medical Device Removal for the SOLTIVE SuperPulsed Laser Fiber products distributed in the US (Attachment 1). New versions of these devices are being introduced that use a new material for the strain relief component (see Figure 1). These products along with either the SOLTIVE Pro or SOLTIVE Premium laser generator consoles and their accessories (footswitch, interlock connector, etc.) make up the SOLTIVE laser system, which is intended for use in incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Reason for Action:

Olympus identified and is implementing an alternate material for the strain relief component that will more immediately self-extinguish if it were to ignite. Olympus is requesting users transition to products incorporating the new strain relief material and return all existing unopened and unexpired SOLTIVE laser fiber products.

Note 1: Olympus is committed to transitioning users from the existing SOLTIVE laser fiber devices to units incorporating the new device material as quickly as possible. Until you receive the new version, existing devices may continue to be used safely when used in strict accordance with the safety information presented in the IFU and in the supplemental information provided, either within the previous letter (see 'Background') or in the 'SOLTIVE Laser Fiber Aiming Beam Quick Reference' guide provided with all product distributed since that letter was sent.

Note 2: Due to the nature of laser fibers, the safety information in the IFU and the Aiming Beam Quick Reference guide must continue to be followed with the new version of the product as the core material of all laser fibers remain susceptible to fracture (see 'Background') even with these changes to the strain relief component.

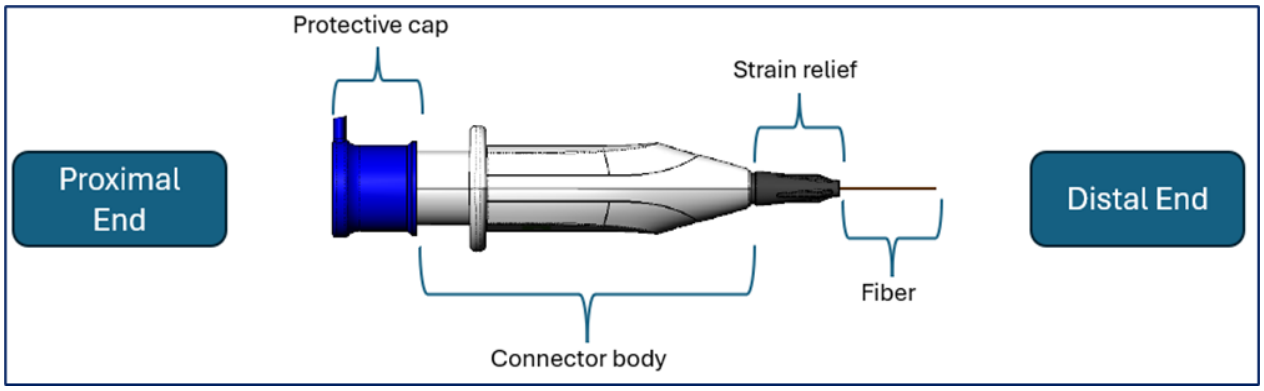

Figure 1. Image showing the components of a SOLTIVE laser fiber device.

Further updates to the product labeling are being developed and will be communicated to users separately.

Background:

In 2025, Olympus identified an increased number of complaints reporting thermal events associated with the use of SOLTIVE laser fiber devices. A known risk associated with these devices is that a break in the core material within the fiber can cause a dispersion of the laser energy at that location which can lead to accidental laser exposure to the patient or operating room personnel or thermal damage to or ignition of adjacent equipment or materials. In some of the reported instances in which the breakage occurred within or near the strain relief, the strain relief component itself ignited and did not immediately self-extinguish.

A previous letter sent in May 2025 informed consignees of 175 malfunctions and two serious injuries that were reported associated with this issue globally, reminded users of the relevant safety information contained in the IFU, and provided supplemental guidance to help identify laser fiber devices with a broken core and prevent their use with the treatment beam, which could cause these types of thermal events. SOLTIVE laser fiber products distributed since the 2025 letter have included a 'SOLTIVE Laser Fiber Aiming Beam Quick Reference' guide which provides comparable information on identifying laser fiber devices with a broken core.

Risk to Health:

Harms associated with accidental laser exposure or fires may lead to patient or user pain or burns. Burns as a result of operating room fires could potentially pose critical or life-threatening risks if they occur in the presence of oxygen, other flammable gases/substances, or combustible fabrics. Additionally, reports have indicated that this issue has caused delays or cancellations of procedures to acquire replacement devices.

Actions Required:

Our records indicate that your facility has received one or more of the affected products. Olympus therefore requests that you take the following actions:

1. Examine the carton labels of all SOLTIVE laser fiber products in your inventory for the affected model numbers, UDI-DI numbers, manufacturing dates and lots in Attachment 1. If you have the affected versions of these products in your inventory, transition to the new versions of the products as soon as possible by placing an

order through Customer Service or using your usual ordering process. The new versions of these products will have a manufacturing date after that indicated in Attachment 1.

Note: Different catalog numbers have different manufacturing dates indicated.

2. Until you receive the new versions of these products, you can continue using the affected versions while strictly following the safety information presented in the IFU and in the Aiming Beam Quick Reference guide.

3. Once you have received the new versions of these products, stop using the affected versions and set them aside for return.
    a. Contact Olympus Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Please have your lot number and, if necessary, PO#. Olympus will issue a credit to your facility upon return of the previous design.

4. Olympus requests that you acknowledge receipt of this letter through our recall web portal:
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number: "0510"
    c. Complete the form as instructed.

    Note: This request applies even if you no longer have any affected product in your inventory.

5. If you have further distributed them, forward this letter to other users who may have affected products.

Olympus requests you to report any complaints, including fiber damage/breaks, smoke, sparks, flare, burning of a device or equipment, unsteady flames, steady flames and burns to a clinician or supporting staff occurring while using the SOLTIVE Laser Systems and SOLTIVE Laser Fibers. Please report complaints to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me by phone at (484) 553-1029 or by e-mail at ashley.troiani@olympus.com.

Sincerely,

Ashley Troiani

Ashley Troiani
Senior Manager, US FCA Lead

Attachment 1: Affected Products List

Product Name	Model Number	Primary (Pouch-Level) UDI-DI[a]	Package (Carton-Level) UDI-DI[b]	Manufactured On or Before
5-pk of 150-µm Single-Use SOLTIVE™ SuperPulsed Laser Fiber Devices w/ a Ball Tip	TFL-FBX150BS	00821925043923	00821925043916	2026-04-29
Lot Numbers: KH508505, KH508506, KH508509, KH508513, KH509538, KR266808, KR340624, KR374613, KR381654, KR448669, KR448670, KR448781, KR448782, KR450039, KR466842, KR472651, KR481662, KR486136, KR488903, KR491198, KR497541, KR500036, KR500328, KR502973, KR502974, KR503072, KR504027, KR504168, PW310824, PW311238, PW311239, PW311330, PW311331				
5-pk of 200-µm Single-Use SOLTIVE™ SuperPulsed Laser Fiber Devices w/ a Ball Tip	TFL-FBX200BS	00821925043985	00821925043978	2026-06-03
Lot Numbers: GK506619, KH509547, KH509552, KH509554, KH509555, KH509558, KH509974, KH510402, KH510515, KH510661, KH510662, KH510666, KH510671, KH510688, KH510713, KH510718, KH511482, KH511888, KH511930, KH511931, KH512543, KH513143, KH513157, KH513158, KH513528, KH513529, KH513530, KH513769, KH513770, KH513771, KH513772, KH513773, KH513774, KH513775, KH513776, KH513777, KH513778, KH513779, KH513780, KH513781, KH513819, KH514067, KH514068, KH514069, KH514074, KH514075, KH514080, KR365625, KR365632, KR373721, KR373818, KR374609, KR374610, KR374616, KR374620, KR381671, KR381673, KR387734, KR387762, KR391646, KR391660, KR391665, KR401619, KR401651, KR401652, KR402615, KR403617, KR403620, KR403624, KR403635, KR436704, KR436705, KR436707, KR436709, KR436710, KR436711, KR436714, KR436715, KR436716, KR436717, KR436718, KR436719, KR436721, KR436722, KR442769, KR442793, KR442857, KR443861, KR448054, KR448055, KR448056, KR454649, KR454651, KR454654, KR454656, KR454658, KR454662, KR454665, KR455701, KR455718, KR455729, KR455785, KR455984, KR455986, KR455988, KR461700, KR461809, KR461887, KR462766, KR462773, KR466687, KR466840, KR466911, KR466932, KR466937, KR467804, KR467807, KR467809, KR467827, KR468835, KR468847, KR468848, KR470936, KR470976, KR470981, KR472646, KR472659, KR472677, KR472691, KR474687, KR474689, KR474703, KR476822, KR476823, KR476828, KR478759, KR478763, KR478766, KR481950, KR481970, KR481972, KR481978, KR485823, KR485883, KR485900, KR485983, KR485985, KR486138, KR486160, KR488695, KR488697, KR488825, KR488841, KR488844, KR489663, KR489731, KR490988, KR490992, KR490993, KR491004, KR491005, KR491009, KR491055, KR491057, KR491072, KR491074, KR491076, KR495227, KR495250, KR495256, KR495268, KR496921, KR496987, KR497000, KR497006, KR500038, KR500041, KR500043, KR500046, KR500047, KR500071, KR500076, KR500078, KR500086, KR500087, KR500088, KR500860, KR500866, KR500872, KR500877, KR500878, KR502748, KR502749, KR502750, KR502751, KR502752, KR502753, KR503297, KR503331, KR503896, KR503898, KR504296, KR504311, KR504598, KR504636, KR504661, KR504696, KR504703, KR504709, KR504789, KR504959, KR504961, KR505546, KR505643, KR506155, KR506170, KR506171, KR506558, KR506619, KR507404, KR507482, KR507483, KR507885, KR507913, KR507914, PW308877, PW308878, PW308879, PW309870, PW309871, PW309872, PW309873, PW310825, PW310826, PW310827, PW311242, PW311279, PW311280, PW311281, PW311282, PW311283, PW311341, PW311342				

[a] This UDI-DI number appears on the pouch label and corresponds to a single individually pouched SOLTIVE laser fiber device.
[b] This UDI-DI number appears on the carton label and corresponds to a carton of five individually pouched sterile devices.
* Manufacturing date corrected on October 1, 2026. No changes to list of lot numbers.

SOLTIVE™ SuperPulsed Laser Fiber

Product Name	Model Number	Primary (Pouch-Level) UDI-DI[a]	Package (Carton-Level) UDI-DI[b]	Manufactured On or Before
5-pk of 150-µm Single-Use SOLTIVE™ SuperPulsed Laser Fiber Devices	TFL-FBX150S	00821925043886	00821925043879	2026-06-07*
Lot Numbers: GK508270, KH508270, KH509563, KH510723, KH511414, KH511421, KH511439, KH514236, KR365626, KR369791, KR374615, KR403612, KR403628, KR448671, KR448672, KR448673, KR449938, KR449949, KR449983, KR450008, KR450027, KR488743, KR489519, KR489984, KR491900, KR497822, KR497826, KR500350, KR500354, KR500861, KR502744, KR502745, KR504030, KR504793, KR504957, PW310662, PW311234				
5-pk of 200-µm Single-Use SOLTIVE™ SuperPulsed Laser Fiber Devices	TFL-FBX200S	00821925043947	00821925043930	2026-06-08*
Lot Numbers: GK508268, KH508268, KH509548, KH509995, KH510430, KH511429, KH511433, KH511441, KH511463, KH511475, KH511480, KH511487, KH511503, KH511583, KH511929, KH511932, KH511933, KH512538, KH513142, KH513848, KH514072, KH514073, KH514076, KH514083, KH514088, KH514090, KH514095, KH514099, KH514100, KH514102, KH514104, KH514105, KH514106, KH514107, KH514108, KH514109, KH514110, KH514115, KR340630, KR349640, KR365724, KR365725, KR365726, KR365728, KR372610, KR372614, KR372617, KR372618, KR381637, KR381664, KR381688, KR393719, KR395636, KR395637, KR400985, KR400990, KR401031, KR401104, KR401135, KR401620, KR401625, KR401628, KR401653, KR401654, KR403607, KR403608, KR403609, KR403610, KR403613, KR403615, KR403616, KR403619, KR403621, KR403622, KR403625, KR403626, KR403627, KR403632, KR403633, KR403637, KR403638, KR426631, KR426638, KR426641, KR426662, KR426663, KR426673, KR426683, KR426688, KR426731, KR426758, KR426762, KR426767, KR426769, KR426791, KR426800, KR427623, KR427624, KR455678, KR455712, KR455727, KR455738, KR455832, KR461016, KR461019, KR461989, KR461990, KR461991, KR462507, KR462510, KR462749, KR466893, KR466931, KR466942, KR466950, KR467954, KR467999, KR468788, KR468798, KR470038, KR470041, KR470941, KR470942, KR470956, KR470970, KR472665, KR472667, KR472668, KR472682, KR472688, KR474664, KR474676, KR474681, KR477654, KR477818, KR478975, KR478982, KR478983, KR478996, KR479019, KR482120, KR482123, KR482133, KR482135, KR482695, KR482757, KR482776, KR482782, KR485097, KR485126, KR485156, KR485840, KR485859, KR485894, KR486125, KR486139, KR486146, KR486155, KR487724, KR488690, KR488691, KR488970, KR488972, KR488973, KR488974, KR488975, KR491178, KR491179, KR491180, KR491181, KR491182, KR491976, KR492058, KR492059, KR492060, KR492061, KR492062, KR492064, KR492067, KR492070, KR492071, KR495323, KR495324, KR495475, KR495479, KR495480, KR495481, KR497065, KR497070, KR497142, KR497147, KR500034, KR500042, KR500068, KR500069, KR500070, KR500072, KR500074, KR500077, KR500079, KR500080, KR500082, KR500083, KR500084, KR500859, KR500862, KR500864, KR500865, KR500867, KR500868, KR500869, KR502791, KR502792, KR502793, KR502794, KR503298, KR503843, KR503845, KR503846, KR503905, KR504344, KR504364, KR504365, KR504366, KR504633, KR504648, KR504650, KR504701, KR504702, KR504708, KR505045, KR505065, KR505066, KR505369, KR505581, KR505644, KR506548, KR506620, KR506621, KR507422, KR507484, KR507485, KR507874, KR507915, KR507916, PW308880, PW308881, PW308882, PW308883, PW308884, PW308885, PW308886, PW308887, PW310663, PW310723, PW310728, PW310730, PW310802, PW310803, PW310804, PW310805, PW310806, PW310828, PW310829, PW310830, PW310831, PW310832, PW310833, PW310868, PW310869, PW310870, PW310871, PW310872, PW310873, PW311240, PW311241, PW311274, PW311275, PW311276, PW311277, PW311278, PW311337, PW311338, PW311339				

OLYMPUS

URGENT: MEDICAL DEVICE REMOVAL

SOLTIVE™ SuperPulsed Laser Fiber

Product Name	Model Number	Primary (Pouch-Level) UDI-DI[a]	Package (Carton-Level) UDI-DI[b]	Manufactured On or Before
5-pk of 365-µm Single-Use SOLTIVE™ SuperPulsed Laser Fiber Devices	TFL-FBX365S	00821925044005	00821925043992	2026-06-03
Lot Numbers: KH509559, KH509562, KH510376, KH510400, KH510408, KH510411, KH510420, KH511505, KH513815, KH513994, KH515696, KR340642, KR342628, KR342638, KR360615, KR401623, KR401629, KR403611, KR403631, KR403639, KR447881, KR447887, KR447917, KR447938, KR447941, KR447944, KR447962, KR447966, KR447968, KR450032, KR450708, KR450715, KR456862, KR456866, KR456867, KR463649, KR467806, KR467811, KR467980, KR471765, KR472664, KR479025, KR479696, KR482031, KR482126, KR485852, KR485855, KR486648, KR488823, KR488831, KR489698, KR489759, KR491020, KR492063, KR495072, KR496317, KR500037, KR500040, KR500048, KR500075, KR500081, KR500085, KR500351, KR501888, KR501889, KR502796, KR502797, KR502798, KR502799, KR502800, KR503315, KR504011, KR504592, KR504615, KR504637, KR505048, KR506159, KR506540, KR507403, KR507888, PW308888, PW308889, PW310586, PW310664, PW311226, PW311227, PW311228, PW311230				
5-pk of 550-µm Single-Use SOLTIVE™ SuperPulsed Laser Fiber Devices	TFL-FBX550S	00821925044043	00821925044036	2026-06-09*
Lot Numbers: GK508271, KH508271, KH509550, KH509553, KH510436, KH511507, KH513151, KH513993, KR269411, KR275838, KR275863, KR349638, KR370615, KR373827, KR381661, KR403614, KR403629, KR403630, KR403634, KR403636, KR448674, KR448675, KR448676, KR448677, KR450724, KR460995, KR461007, KR461012, KR462759, KR465922, KR467974, KR469659, KR469662, KR469675, KR469679, KR469686, KR474658, KR474659, KR487723, KR488698, KR489954, KR491019, KR491028, KR491046, KR492072, KR493972, KR500035, KR500039, KR500073, KR500348, KR500349, KR500352, KR502801, KR502802, KR502803, KR502889, KR503118, KR503619, KR504774, KR504968, KR506530, KR507878, PW311231, PW311232, PW311233, PW311333, PW311334, PW311335				
5-pk of 940-µm Single-Use SOLTIVE™ SuperPulsed Laser Fiber Devices	TFL-FBX940S	00821925044081	00821925044074	2026-06-09*
Lot Numbers: GK508269, KH508269, KH514297, KH516327, KR340638, KR401626, KR403748, KR448678, KR449962, KR450007, KR450036, KR492991, KR502891, KR505371, PW311237				

Attachment 2: Packaging Image

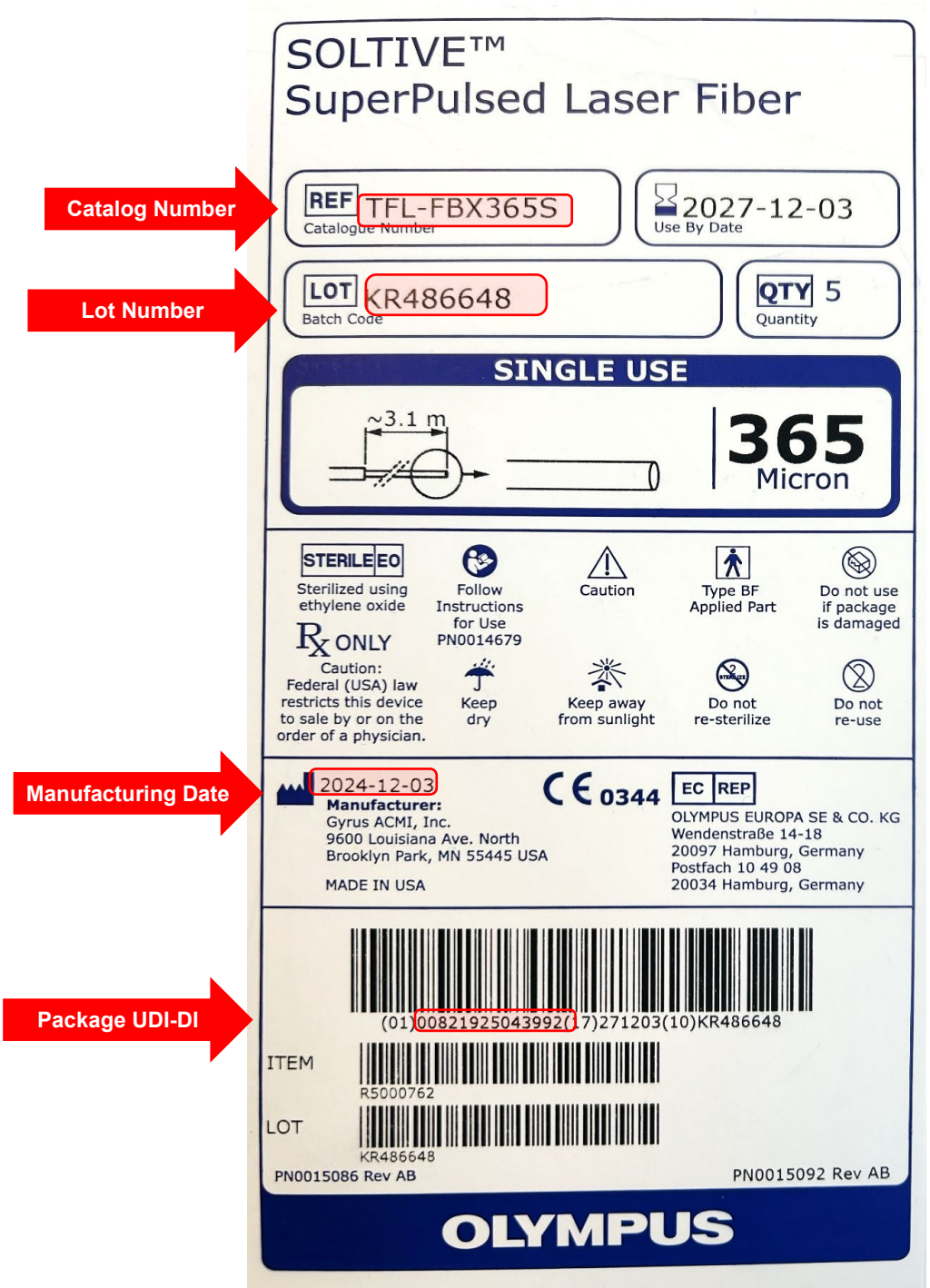

Figure 2. Image showing an example of a carton label for a SOLTIVE SuperPulsed laser fiber product with the location of the identifying elements from the table on Attachment 1.