LUMENIS
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Urgent Medical Device Recall – Immediate Action Required
DuoTome SideLite™ 550 Micron Delivery System

August 29, 2006

Lumenis, as the manufacturer of the DuoTome SideLite™ 550 Micron Delivery System, is initiating a medical device recall. As you may know, the DuoTome SideLite fiber is used in conjunction with the VersaPulse® PowerSuite™ and VersaPulse Select™ holmium laser systems for ablating soft tissue, most commonly with the HoLAP or Holmium Laser Ablation of the Prostate procedure. It has come to our attention that select manufacturing lots of the DuoTome SideLite™ 550 Micron Delivery System devices were shipped without the black indicator markings on the metal tip. The energy exit window is clearly visible and the aiming beam is used to show where the laser energy exits, however the markings assist the surgeon with positioning the fiber within the endoscope and are helpful in that regard. In evaluating this event, we also noted reports of fiber degradation (degradation of the fiber, detachment of the metal cap, and the fiber lasing straight) during use.

Individually these issues are unlikely to cause adverse health consequences. However, we believe this product does not demonstrate the level of performance that we strive to provide to our customers. Therefore, we are initiating a recall of all fibers manufactured since February 1, 2006.

Below is a full list of all recalled DuoTome SideLite™ 550 Micron Delivery System products that were manufactured by Lumenis since February 1, 2006, including Product Description, Catalog Number, and Lot Number. **Further distribution or use of any remaining product affected by this recall should cease immediately.**

Catalog Number: 0641-800-01								
37600206	38030206	38470206	39110306	39660406	40480506	41040506	42110606	42550706
37640206	38120206	38480206	39200306	39670406	40490506	41050506	42120606	42560706
37650206	38150206	38510206	39210306	39680406	40520506	41080506	42200606	42570706
37660206	38160206	38520206	39220306	39690406	40530506	41090506	42210606	42580706
37700206	38170206	38530206	39240306	39770406	40570506	41100506	42280606	42650706
37710206	38200206	38700306	39250306	39800406	40580506	41210506	42290606	42680706
37720206	38210206	38710306	39260306	39810406	40590506	41310506	42300606	42740706
37730206	38230206	38720306	39270306	39820406	40600506	41360506	42310606	42810706
37740206	38240206	38730306	39280306	39830406	40610506	41390506	42320606	42890706
37750206	38300206	38740306	39460306	39840406	40690506	41450506	42330606	43000706
37760206	38310206	38800306	39470306	39880406	40710506	41470506	42350606	43010706
37770206	38380206	38810306	39530306	39890406	40720506	41500506	42360606	43060706
37800206	38390206	38830306	39540306	39900406	40730506	41610606	42380606	43150706
37810206	38400206	38840306	39550306	40180406	40930506	41750606	42410606	43190706
37820206	38410206	38920306	39560306	40200406	40940506	41880606	42420606	43200706
37890206	38420206	38930306	39570306	40340406	40960506	41890606	42430606	43210706
37910206	38430206	38970306	39580306	40390406	40970506	41900606	42460706	43220706
37960206	38440206	38980306	39590306	40430406	40980506	41930606	42490706	43270706
37970206	38450206	38990306	39600306	40460506	41020506	41990606	42500706	43280706
37980206	38460206	39000306	39650306	40470506	41030506	42000606	42540706	43410706
Catalog Number: 0623-703-01								
3889/03/06	4011/04/06	4085/05/06	4088/05/06	4132/05/06	4160/06/06	4272/07/06	4313/07/06	4340/07/06
3912/03/06	4079/05/06	4086/05/06	4095/05/06	4154/05/06	4169/06/06	4273/07/06	4314/07/06	4391/08/06
3939/03/06	4080/05/06	4087/05/06	4116/05/06	4159/06/06	4171/06/06	4307/07/06	4339/07/06	END

Please work with your Lumenis Customer Service Department obtaining RMA for fiber return, checking shipment updates or with questions about specific orders. We regret any inconvenience that this action may cause and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Lumenis.

[redacted], Manager
Regulatory Affairs and Quality Assurance

LUMENIS

Medical Device Recall – TERMINATION
Lumenis DuoTome SideLite™ 550 Micron Delivery System

October 11, 2006

Lumenis, as the manufacturer of the Lumenis DuoTome SideLite 550 Micron Delivery System, is pleased to announce the termination of the voluntary medical device recall for Lumenis labeled fibers (Catalog Number 0623-703-01).

As you know, the DuoTome SideLite fiber is used in conjunction with the VersaPulse® PowerSuite™ and VersaPulse Select™ holmium laser systems for ablating soft tissue, most commonly with the HoLAP or Holmium Laser Ablation of the Prostate procedure.

On August 29, 2006, Lumenis initiated a recall of the Lumenis DuoTome SideLite 550 Micron Delivery System devices that had been manufactured since February 1, 2006. The recall was initiated by Lumenis for the following reasons: absence of the black indicator markings on the metal tip, and fiber degradation (degradation of the fiber, detachment of the metal cap, and the fiber lasing straight) during use. Individually these issues are unlikely to cause adverse health consequences. However, we believe this product did not demonstrate the level of performance that we strive to provide to our customers.

All of the above items were addressed by Lumenis and several refinements to the manufacturing process were made. Additional production instructions and methods were refined, validated, processed and implemented. Lumenis complied and implemented all requirements to satisfy the conditions of the recall. **Therefore, Lumenis terminated the recall for Lumenis labeled DuoTome fibers (Catalog Number 0623-703-01), effective October 5, 2006.**

Please work with your Lumenis Customer Service Department for shipment updates or questions about specific orders.

We regret any inconvenience that this action may have caused you. We are committed to continuing to offer products that meet the highest quality standards that you expect from Lumenis.

Sincerely,

[redacted]

[redacted] Manager
Regulatory Affairs and Quality Assurance