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Surgical Instrument Company to Pay Brain-Injured Man \$12.75M

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Of the Legal Staff

A surgical equipment company has agreed to pay \$12.75 million to a man who suffered brain damage when the tip of one of its laser probes broke off during surgery.

Plaintiff Michael Brassloff, injured during an operation to remove a benign brain tumor, has settled his case with Monteris Medical, maker of the NeuroBlate 2.2 mm SideFire device, according to the settlement papers.

Brassloff alleged that the carbon dioxide-cooled laser probe that was inserted through a hole in his skull broke off, forcing pressurized carbon dioxide directly into Brassloff's brain. He went into a coma, and when he regained consciousness, found he had trouble walking and speaking, and developed seizures and Parkinson's disease-like symptoms.

"The family is gratified by settlement with Monteris Medical, which helps address



SPECTER



BALDWIN

many of Mr. Brassloff's deficits. We intend to report the settlement to the FDA so they may consider regulatory and enforcement action," lawyers Shanin Specter and Kila Baldwin of Philadelphia-based Kline & Specter said in a joint statement.

Patrick Sardino of Cozen O'Connor in New York represents Monteris and did not return a call seeking comment.

According to the plaintiff's pretrial memorandum, Brassloff suffered a post-op intracranial hemorrhage, for which he had to have another surgery to correct.

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"Subsequent testing of the probe by Monteris revealed that a defect in the lens caused it to fracture consistently when exposed to an environment consisting of pure blood during laser energy delivery," the plaintiff's memorandum said.

Court papers said that Monteris notified the Food and Drug Administration of the incident and voluntarily removed the device from the market. The plaintiff's memorandum said that the FDA concluded that the device was not adequately tested prior to release.

In its court papers, Monteris argued it was not responsible for Brassloff's brain damage.

"There is no evidence showing that the tip of the probe fractured during plaintiff's

surgery," Monteris said in its pretrial memorandum. "There is no evidence that even if the tip of the probe fractured, that there was any resulting injury to the plaintiff. Other than a software signal issue during plaintiff's surgery, there were no objective indications that plaintiff sustained a traumatic brain injury as a result of the surgery."

Monteris continued, "The injuries and/or damages sustained by plaintiff were in the range of potential expected outcomes for

which informed consent was obtained. The diagnostic tests, MRIs and CTs, performed after the procedure, showed expected findings and were within normal range of bleeding; The post-incident analysis of the imaging demonstrates that the probe's properties during the procedure were consistent with other non-incident procedures."

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