

AccuTrac™ Single-Use Holmium Laser Fiber

Flexiva™ TracTip™ High Power Single-Use Laser Fiber



New Product Committee Guide

General Information

Name of product

AccuTrac Single-Use 200 micron Holmium Laser Fiber, Flexiva TracTip High Power Single-Use 200 micron Holmium Laser Fiber and Flexiva ID TracTip High Power Single-Use 200 micron Holmium Laser Fiber

Product codes

Product Code	Description	Unit
M0068404110	AccuTrac 200 micron Holmium Laser Fiber	Single
M0068404112	AccuTrac 200 micron Holmium Laser Fiber	Box 5
M0068403960	Flexiva TracTip 200 micron Holmium Laser Fiber	Single
M0068403961	Flexiva TracTip 200 micron Holmium Laser Fiber	Box 5
M006R8403960	Flexiva ID TracTip 200 micron Holmium Laser Fiber	Single
M006R8403961	Flexiva ID TracTip 200 micron Holmium Laser Fiber	Box 5

Product description

The AccuTrac Laser Fibers are fiber-optic laser energy delivery devices consisting of a SMA-905 connector, strain relief and a silica core fiber jacketed with ethylene tetrafluoroethylene (ETFE). The AccuTrac Fibers are equipped with a polished and reinforced ball-shaped TracTip. These fibers may be used in a variety of laser-based surgical cases as an integral part of laser systems.

The Flexiva TracTip Laser Fibers are fiber-optic laser energy delivery devices consisting of a SMA-905 connector, strain relief and a silica core fiber jacketed with ethylene tetrafluoroethylene (ETFE). The Flexiva TracTip Fibers are equipped with a polished and reinforced ball-shaped TracTip. These fibers may be used in a variety of laser-based surgical cases as an integral part of laser systems.

The Flexiva ID TracTip Laser Fibers are fiber optic laser energy delivery devices consisting of a SMA-905 connector, strain relief, and a silica core fiber jacketed with ethylene tetrafluoroethylene (ETFE). The Flexiva ID TracTip Fibers are equipped with a polished and reinforced ball-shaped output tip. These fibers may be used in a variety of laser-based surgical cases as an integral part of laser systems. An RFID (Radio-frequency identification) feature enables the laser system to recognize the connected laser fiber.

Manufacturer: Boston Scientific Corporation

Distributor federal tax ID: 04 269 5240

Will this product(s) replace or supplement a current in-house product(s) now performing the same function?

The AccuTrac and Flexiva TracTip Fibers will supplement the product line of AccuMax™ and Flexiva™ (End-Firing) Single-Use Holmium Laser Fibers currently on the market.

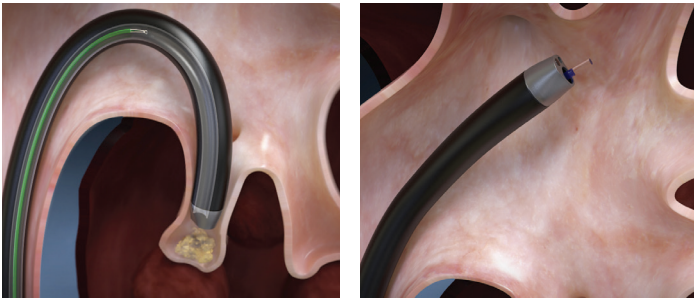
Laser compatibility

AccuTrac Fibers are recommended for use with Ho:YAG laser systems with a standard SMA-905 connector that have been cleared for surgical use. Recommended Ho:YAG lasers are Dornier and New Star. Please refer to the laser system User Manual for complete information regarding applications, contraindications, precautions and warnings.

Flexiva TracTip Fibers are recommended for use with Ho:YAG laser systems with a standard SMA-905 connector that have been cleared for surgical use. Recommended for use with Lumenis manufactured Ho:YAG and Nd:YAG lasers. Please refer to the laser system User Manual for complete information regarding applications, contraindications, precautions and warnings.

Product Usage

Save time and procedural steps



AccuTrac™ & Flexiva™ TracTip™ Fibers vs. Typical Flat Tip Laser Fiber

Flat Tip Laser Fibers

According to the "Endourologic Use of the Holmium Laser": 2001 Demetrius Bagley, Akhil Das.

"The fiber (flat) tip can damage the channel within a flexible endoscope. Therefore, they must be passed only when the channel is straight. For example, to reach calculus within the lower pole of the kidney with a flexible ureteroscope, the tip should be straightened within the renal pelvis and the fiber passed. The fiber is advanced into the field of view and then withdrawn until it is just no longer visible. At that point, it will be located approximately ½ mm beyond the tip of the ureteroscope. The tip can then be deflected and placed into the lower pole for treatment. The fiber can then be advanced."¹

TracTip Laser Fibers

The ball shape tip is designed to reduce procedure steps associated with initial advancement of a deflected laser fiber to the treatment site. One-step passage eliminates the need to re-access challenging stone locations.²

May reduce the risk of flexible endoscope damage

According to "Evaluation of a New 240 micron Single Use Holmium:YAG Optical Fiber for Flexible Ureteroscopy" – "No (Flexiva) fibers fractured during 100 consecutive ureteroscopy procedures. The lack of fiber fracture during clinical use may reduce the risk of flexible endoscope damage due to fiber failure."³

May reduce the risk of laser fiber connector failure

According to "Evaluation of a New 240 micron Single Use Holmium:YAG Optical Fiber (Flexiva) for Flexible Ureteroscopy" – During 100 consecutive ureteroscopy procedures, "No (Flexiva) fibers failed at the connector end."³

Improved scope flexibility

With a 242 micron core size, the AccuTrac and Flexiva TracTip Laser Fibers are designed to improve scope flexibility over larger core fibers (273 micron & 365 micron).²

"The Flexiva 200 Laser Fiber only limited the deflection angle of the scope by 5°, which compares favorably to previously tested sub-200 micron fibers."³



According to the "Evaluation of 24 Holmium:YAG Laser Optical Fibers for Flexible Ureteroscopy":

"We advocate using as flexible a fiber as possible to increase the likelihood that the stone can be reached and promote endoscope longevity."⁴

"Flexible ureteroscope longevity directly correlates with time spent in the lower pole. Working in the lower pole results in stress and fatigue of the deflection mechanism, which leads to a loss of scope deflection and in some cases to scope failure. Therefore, fiber flexibility is an important variable in terms of accessing the stone and improving scope longevity. We advocate using as flexible a fiber as possible to increase the likelihood that the stone can be reached and promote endoscope longevity. While the difference between some fibers may be small, the benefit over multiple procedures may be cumulative."⁴

Documentation on studies conducted with product

Shore DM, Antiporda M, Teichman JM, et al. Evaluation of a new 240-µm single-use holmium:YAG optical fiber for flexible ureteroscopy. *J Endourol.* 2011;Nov (Suppl 1): A118-9.

Shin RH, Lautz JM, Cabrera FJ, et al. Evaluation of Novel Ball-Tip Holmium Laser Fiber: Impact on Ureteroscope Performance and Fragmentation Efficiency. *J Endourol.* 2016 Feb;30(2):189-94.

Akar EC, Knudsen BE. Evaluation of 16 New Holmium:Yttrium-Aluminum-Garnet Laser Optical Fibers for Ureteroscopy. *Urology.* 2015 Aug;86(2):230-5.

Johnson S, Lew D, Davis C, et al. The Impact on Cost and Frequency of Ureteroscope Repairs Using a Ball-tipped Laser Fiber for Ureteroscopy. *J Urol.* 2014 April;191(4):e948.

What quality or safety improvements to patient care could this product potentially provide?

The TracTip Laser Fiber is designed to reduce procedure steps associated with initial advancement of a deflected laser fiber to the treatment site. One-step passage eliminates the need to re-access challenging stone locations.

Cost / Utilization

Is this item/technology on contract with GPOs and/or IDNs? Please speak to your Boston Scientific sales representative for the contract status of specific GPOs and IDNs.

Ship unit: Box/1 or Box/5 **UOM:** Each

Mode of transportation: FedEx™ Delivery

Minimum order quantity? No

Lead time in working days? 2 days

What are the dimensions of the product carton? The product carton for the fiber is 16" x 12"

What is the list price per each unit or unit of utilization?

M0068403960	Flexiva 200 TracTip Laser Fiber	(Box 1)	\$644
M0068403961	Flexiva 200 TracTip Laser Fiber	(Box 5)	\$3217
M0068404110	AccuTrac 200 Laser Fiber	(Box 1)	\$644
M0068404112	AccuTrac 200 Laser Fiber	(Box 5)	\$3107
M006R8403960	Flexiva ID TracTip 200 Laser Fiber	(Box 1)	\$644
M006R8403961	Flexiva ID TracTip 200 Laser Fiber	(Box 5)	\$3217

Method of purchase: The purchase would be an outright purchase

Does this item require special storage considerations? No, store in a cool, dry, dark place

Regulatory

Is this product FDA cleared for this intended use?

Yes. The AccuTrac™ Laser Fibers are intended for use in laser-based surgical applications, including but not limited to, endoscopic, laparoscopic and open surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary) and surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision of soft and cartilaginous tissue. The AccuTrac Laser Fibers are designed for use with Ho:YAG lasers with a standard SMA-905 connector that have been cleared for surgical use.

The Flexiva™ TracTip™ Laser Fibers are intended for use in laser-based surgical applications, including but not limited to, endoscopic, laparoscopic and open surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary) and surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision of soft and cartilaginous tissue. The Flexiva TracTip Laser Fibers are designed for use with Ho:YAG lasers with a standard SMA-905 connector that have been cleared for surgical use.

What is the FDA classification of this device?

The AccuTrac Holmium Laser Fiber is marketed in the US in accordance with US 21 Code of Federal Regulations 878.4810 as a Laser Powered Surgical Instrument. Laser Fibers are Class II devices and are subject to the premarket notification (510k) process.

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Is this a dated product? Yes, with a 3-year shelf life

Will this product require evaluation by any of the following departments?

- Epidemiology/Infection Control? No
- Bio Engineering Maintenance? No
- Safety and Security? No
- Pathology/Labs? No

Does this product contain metal substances that may affect tests and or procedures performed on patients? No

Does this product/packaging contain detectable latex? No

Is this product reusable? No

What additional waste or recycle costs are anticipated? None

No additional in-house support is required; however, a brief in-service by a Boston Scientific representative is offered at no-charge.

Reimbursement

Is this product reimbursable by insurance?

The procedure for which it is used is reimbursable. A billing guide with respective coding and Medicare reimbursement for ureteroscopy with laser lithotripsy is available upon request. For additional coding and reimbursement information, contact your local Territory Manager or the Urology Reimbursement Help Desk at (508) 683-4022.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)?

There is no applicable Medicare Pass-Through Code for this product.

Is this a patient-chargeable product?

"Patient chargeable" is a colloquial term used by hospitals to convey that a device/supply is appropriately charged to the patient's account (i.e. as a distinct line item on the patient's claim) in the hospital/facility's patient accounting or AR system. It does not mean that the patient is actually charged directly for the device/supply nor would an insured patient ever pay an additional amount "out of pocket" for the device/supply. The fact that a hospital/facility chooses to designate certain devices/supplies (e.g. single-use devices) as "patient chargeable" will not in and of itself result in immediate increased reimbursement for the hospital/facility. It will allow CMS to better factor the true cost of the procedure into future Medicare reimbursement rate setting. It may also help in negotiations with private payers by more clearly demonstrating novel device costs that have been introduced to a procedure.

The designation of a given device/supply as "patient chargeable" is entirely up to the discretion and policy of the individual hospital/facility. Section 2202.8 of the Medicare Provider Reimbursement Manual dealing with Ancillary Services (e.g. operating room) does not specifically address which items are part of the basic (routine) charge and which are charged in addition to the basic charge (non-routine). Medicare is on record that it is up to the individual hospital to determine whether to and how to itemize the charge for a specific device/supply or alternatively, incorporate it into overhead (e.g. via the OR charge). However, Medicare does require that whatever method is chosen be applied consistently. They also require that charges billed on the CMS-1450 form (aka UB-04) be aggregated under the appropriate Revenue Code.

The appropriate Revenue Code is 272 - Medical/Surgical Supplies and Devices-Sterile Supply.



Please consult your sales representative for more information and ordering details.

To learn more visit bostonscientific.com/Urology

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1. Bagley D, Das A. *Endourologic Use of the Holmium Laser*. In: Chapter 7, Teton New Media ISBN:1-83441-43-1, 2001.
2. Bench Testing on file with Boston Scientific. Bench testing not necessarily indicative of clinical performance.
3. Khemees TA, Shore DM, Antiporda M, et al. Evaluation of a new 240-µm single-use holmium:YAG optical fiber for flexible ureteroscopy. *J Endourol*. 2013 Apr;27(4):475-9.
4. Mues AC, Teichman JM, Knudsen BE. Evaluation of 24 holmium:YAG laser optical fibers for flexible ureteroscopy. *J Urol*. 2009 Jul;182(1):348-54.

The fiber should not be re-passed through a deflected scope once laser energy has been applied to the treatment site.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

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