6 Characteristics of an Ideal Laser Fiber

1. Fiber Connector
2. Efficient Energy Transmission
3. Flexibility
4. Track-Ability
5. Durability
6. Repair Savings
The ideal laser fiber is flexible, thin and durable so that maneuverability is not limited within the collecting system, irrigation flow rate is maintained for visualization and energy is efficiently transmitted with acute deflections without fiber fracture.¹

"Of the fibers, Flexiva™ TracTip and Flexiva 200 were the most flexible and maintained stable energy transmission before and after durability testing in comparison to these new fiber brands of similar core size."¹

1. FIBER CONNECTION
Why It is Important to Customers

Definition
The connection between the laser and the proximal end of the optical fiber.

Why It Matters
Possible Damage to Laser:
“The mismatch of fibers with lasers runs the risk of fiber failure, energy reflected back at the laser and laser damage”.

Possible Damage to Fiber and Scope:
Laser energy may then enter the cladding directly at the connection, possibly causing premature fiber failure or energy leakage into the fiber jacket and scope.

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Evaluation of a New 240-µm Single-Use Holmium: YAG Optical Fiber for Flexible Ureteroscopy

Tariq A. Khemees, MD, David M. Shore, MD, Michael Antiporda, MD, Joel M.H. Teichman, MD, and Bodo E. Knudsen, MD, FRCSC

“Although not tapered, the manufacturer reports the connector guides the energy into the core of this fiber. With no fiber failing during clinical use, including no connector end failures, and with both no connector end failures during bench testing nor any increase in temperature, it appears that this fiber couples well with both the Lumenis VersaPulse™ 100 laser used during clinical procedures and the Dornier Medilas™ H20 laser used during bench testing”

Flexiva 200 Fiber Custom Guided Connector

• Tapered fibers are more prone to failure than similar sized, nontapered fibers. The connector tends to convert off-axis rays into higher order rays that might exceed the fiber NA and cause failure.

• On the other hand, the Flexiva Fiber is designed with a custom guided connector that guides errant laser energy into the core of the fiber without increasing laser deflection angle.

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4 Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.


2. EFFICIENT ENERGY TRANSMISSION
Why It is Important to Customers

Definition

The amount of **energy going into the fiber** versus **coming out of the fiber tip**

Why It Matters

Consistent High Output Efficiency:
Low transmission indicates **energy is being lost** at the **connector**, along the **fiber**, or at the **tip**

This again can lead to **damage** to the **laser console** or **scope**

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Evaluation of 16 New Holmium: YAG Laser Optical Fibers for Ureteroscopy

Erin Akar, MD, and Bodo Knudsen, MD, FRCSC
The Ohio State University Wexner Medical Center

“Of the fibers, Flexiva TracTip and Flexiva 200 were the most flexible and maintained stable energy transmission before and after durability testing in comparison to these new fiber brands of similar core size”¹

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**FlexShield™ Coating and Cladding**

- Designed to handle up to 50W, even in tight bend configurations, such as for lower pole lithotripsy⁵
- 100% output efficiency⁴
- “Fiber performance was consistent in terms of energy transmission and resistance to fracture when activated in bent configuration”⁵

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⁵ Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.


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3. FLEXIBILITY
Why It is Important to Customers

**Definition**
The ability of a small core fiber to **deflect in a flexible scope** with minimal **loss of scope deflection**\(^8\)

**Why It Matters**

**Damage to Flexible Scopes:**
“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.”\(^6\)

**Procedural Success:**
It is recommended to use “as flexible a fiber as possible to increase the **likelihood that the stone can be reached** and promote endoscope longevity”\(^6\)

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3. FLEXIBILITY
Why We Believe in the Flexiva™ Fiber

Evaluation of a New 240-µm Single-Use Holmium: YAG Optical Fiber for Flexible Ureteroscopy

Tariq A. Khemees, MD, David M. Shore, MD, Michael Antiporda, MD, Joel M.H. Teichman, MD, and Bodo E. Knudsen, MD, FRCSC

“The Flexiva 200 fibers demonstrated to be highly deflectable and only limited the deflection angle of the Stryker U-500 endoscope by 5°. This compares favorably to the previously tested nontapered sub-200 micron fibers”

Designed for higher power input at tight bend diameters

• Greater flexibility results in greater ability to reach all areas of the renal pelvis to treat stones, potentially reducing the need for secondary procedures.

• Less force required to deflect the scope vs. AccuFlex™ Fiber and Dornier

• “Of the fibers [tested], the Flexiva TracTip Fiber and the Flexiva 200 Fiber were the most flexible”


4 Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.


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4. TRACK-ABILITY
Why It is Important to Customers

**Definition**
Capability for reliable, one-step passage through a deflected ureteroscope* 

**Why It Matters**

Procedural Efficiency:
Traditional flat tip fibers require the scope to be straightened before passage adding procedural steps and sometimes limiting access to stone7

Possible Damage To Flexible Scope:
Insertion of instruments into the working channel of a flexible scope can nick the lining, especially if the scope is deflected8

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


BALL-TIP HOLMIUM LASER FIBER MAY REDUCE FLEXIBLE URETEROSCOPE DAMAGE

Richard Shin, Fernando Cabrera, Constandi Shami, Zachariah Goldsmith, Nicholas Kuntz, Ramy Youssef, Durham, NC; Andreas Neisius, Mainz, Germany; Charles Scales, Michael Ferrandino, Pei Zhong, Walter Simmons, Glenn Preminger, Michael Lipkin, Durham, NC. Abstract presented at the 2014 AUA.

The Flexiva TracTip Fiber reduced force of insertion in a deflected ureteroscope by approximately 1/3rd without compromising maneuverability compared to a standard laser fiber.9

1st Holmium fiber equipped with polished and reinforced ball-shaped output tip

- Designed to pass through a 270 degree lower pole deflected ureteroscope*
- Designed to reduce procedure steps associated with initial advancement of a deflected laser fiber to treatment site4
- Designed to pass through a scope without puncturing scope liner or damaging scope optics4

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

4 Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.

5. DURABILITY
Why It is Important to Customers

Definition
Small-size fibers have been reported to have an increased failure rate when the laser pulse energy increases.\(^5\)

Why It Matters
Fiber Failure Can Lead to Scope Damage: Failure during clinical procedures could cause endoscope damage leading to high cost of repair. If a portion of the fiber breaks off, extraction of the fiber piece can be very challenging.\(^5\)

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Optimizing Use of the Holmium:YAG Laser for Surgical Management of Urinary Lithiasis

Bodo E. Knudsen, Abhishek P. Patel

In a clinical evaluation of 98 consecutive procedures using Flexiva TracTip “No scope damage related to the fiber was reported, and there were no fractures with deflection. We found that the balltipped fiber does allow for easy first pass through a flexible ureteroscope”

Proprietary FlexShield™ Coating Material

- Designed to reduce scope damage caused by fiber breakage. The Flexiva 200 Fiber and TracTip Fiber can withstand a 1.0cm bend diameter at 2J & 25Hz (50W)
- “Flexiva 200 and TracTip 200 did not fracture during durability testing”
- “No fibers failed at bend diameters greater than 0.5cm”

Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.
The publisher for this copyrighted material is Mary Ann Liebert, Inc. publishers.
### Definition
Measurement and evaluation of the real spending and procedural costs per treated individual \(^{11}\)

### Why It Matters
The healthcare landscape is rapidly evolving, and **cost containment per unit of care has become a major pain point** and top priority for hospitals

The initial flexible ureteroscope purchase price, durability, repair costs and associated warranties all contribute to the cost of performing a flexible ureteroscopy procedure. \(^{13}\) **Approximately half of these pertinent costs result from ureteroscope damage**. \(^{14}\)

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\(^{12}\) Market research study conducted by Boston Scientific, results on file.


6. REPAIR SAVINGS
Why We Believe in the Flexiva™ TracTip Fiber

THE IMPACT ON COST AND FREQUENCY OF URETEROSCOPE REPAIRS USING A BALL-TIPPED LASER FIBER FOR URETEROSCOPY

Scott Johnson, Daniel Lew, Carley Davis, Amy Guise, Milwaukee, WI

“The use of a ball-tipped laser fiber during flexible ureteroscopy with laser lithotripsy may be associated with less frequent working channel repairs, and a modest cost savings”\(^{15}\)

REPAIR SAVINGS
Why We Believe in the Flexiva™ TracTip Fiber

Designed to pass more easily through a fully deflected ureteroscope in an atraumatic manner

• Less Scope Repairs: Reduced incidence of flexible ureteroscope repairs with ball-tip fibers compared to blunt-tip fibers\(^{15}\)

• Lower Cost Per Case: Even after accounting for the increased cost of the ball-tipped fiber, ball-tipped fibers were associated with a net savings of $81 per case\(^{15}\)

Ball-Tip Fiber Repair Costs Related to Damaged Working Channels Compared to Blunt-Tip Fibers\(^{15}\)

- 2 Repairs = $12,408
- 5 Repairs = $28,018

*Data collected over a review period of 58 patients undergoing flexible ureteroscopy with blunt-tip laser fiber and 60 patients with the ball-tip fiber.

Note: Findings based on a retrospective review at one institution. Results may not be representative of all institutions.
