

Characteristics of an Ideal Laser Fiber



Scientific

#### THE IDEAL LASER FIBER



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.



66 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.



FIBER

<sup>&</sup>lt;sup>1</sup> Knudsen, B. Evaluation of 16 New Holmium: YAG Laser Optical Fibers for Ureteroscopy, Abstract presented at AUA 2013.

#### 1 FIBER CONNECTION

#### Why It is Important to Customers



#### **Definition**

The connection between the laser and the proximal end of the optical fiber<sup>3</sup>

## 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**"<sup>3</sup>

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<sup>2</sup>





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<sup>&</sup>lt;sup>2</sup> Nazif, O., et al. Review of laser fibers: A practical guide for urologists, Journal of EndoUrology, Volume 18, Nov 2004.

<sup>&</sup>lt;sup>3</sup> Teichman, J., et al. HoYag lithotripsy proximal fiber failures from laser and fiber mismatch, Journal of Urology, Volume 71, 1049-1051, June 2008, with permission from Elsevier.

## **1. FIBER CONNECTION**Why We Believe in the Flexiva™ Fiber



## EVALUATION OF A NEW 240- $\mu$ M 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"<sup>5</sup>

## Flexiva 200 Fiber Custom Guided Connector

- Tapered fibers are more prone to failure than similar sized, nontapered fibers<sup>8</sup>. The connector tends to convert off-axis rays into higher order rays that might exceed the fiber NA and cause failure<sup>3</sup>.
- 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<sup>4</sup>.



<sup>&</sup>lt;sup>4</sup> Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.





<sup>&</sup>lt;sup>5</sup> Knudsen, B., et al. Evaluation of a New 240 micron single-use holmium: YAG optical fiber for flexible ureteroscopy, Journal of Endourology, Volume 27, April 2013. The publisher for this copyrighted material is Mary Ann Liebert, Inc. publishers.

<sup>&</sup>lt;sup>8</sup> Mues, A. Evaluation of 24 holmium: YAG laser optical fibers for flexible ureteroscopy, Journal of Urology, Volume 182, 348-354, July 2009.

#### 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**<sup>3</sup>



1 of  $2 \rightarrow$ 

<sup>&</sup>lt;sup>3</sup> Teichman, J., et al. HoYag lithotripsy proximal fiber failures from laser and fiber mismatch, Journal of Urology, Volume 71, 1049-1051, June 2008, with permission from Elsevier.

#### 2 EFFICIENT ENERGY TRANSMISSION

#### Why We Believe in the Flexiva™ Fiber



# 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

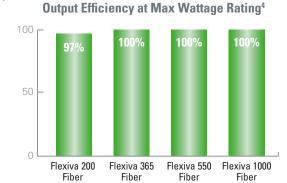
"Of the fibers, Flexiva TracTip and Flexiva 200 were the most flexible and maintained stable energy transmission before and after durability testing in comparison to these new fiber brands of similar core size"

#### FlexShield™ Coating and Cladding

• Designed to handle up to 50W, even in tight bend configurations, such as for lower pole lithotripsy<sup>5</sup>

• 100% output efficiency<sup>4</sup>

• "Fiber performance was consistent in terms of energy transmission and resistance to fracture when activated in bent configuration" 5





<sup>&</sup>lt;sup>1</sup> Knudsen, B. Evaluation of 16 New Holmium: YAG Laser Optical Fibers for Ureteroscopy, Abstract presented at AUA 2013.



<sup>&</sup>lt;sup>4</sup> Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.

<sup>&</sup>lt;sup>5</sup> Knudsen, B., et al. Evaluation of a New 240 micron single-use holmium:YAG optical fiber for flexible ureteroscopy, Journal of Endourology, Volume 27, April 2013. The publisher for this copyrighted material is Mary Ann Liebert, Inc. publishers.

#### 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<sup>8</sup>

## 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."

#### **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





1 of 2 >

<sup>&</sup>lt;sup>6</sup> Mues, A., et al. Evaluation of 24 holmium: YAG laser optical fibers for flexible ureteroscopy, Journal of Urology, Volume 182, 348-354, July 2009, with permission from Elsevier.

<sup>8</sup> Seto, C. Durability of working channel in flexible ureteroscopes when inserting ureteroscopic devices, Journal of Urology, Volume 20, March 2006.

#### 3. FLEXIBILITY

#### Why We Believe in the Flexiva™ Fiber



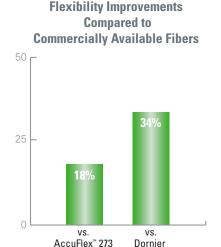
# EVALUATION OF A NEW 240-µM SINGLE-USE HOLMIUM: YAG OPTICAL FIBER FOR FLEXIBLE URETEROSCOPY

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<sup>4</sup>

- Greater flexibility results in greater ability to reach all areas of the renal pelvis to treat stones, potentially reducing the need for secondary procedures.<sup>4</sup>
- Less force required to deflect the scope vs. AccuFlex<sup>™</sup>
   Fiber and Dornier<sup>4</sup>
- "Of the fibers [tested], the Flexiva TracTip Fiber and the Flexiva 200 Fiber were the most flexible"



Flexiva 200 Fiber



DUR270D

<sup>1</sup> Knudsen, B. Evaluation of 16 New Holmium: YAG Laser Optical Fibers for Ureteroscopy, Abstract presented at AUA 2013.

<sup>&</sup>lt;sup>4</sup> 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 stone**<sup>7</sup>

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 deflected**<sup>8</sup>







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

<sup>&</sup>lt;sup>7</sup> Das, A. Endourologic Use of the Holmium Laser. Copyright 2001, Teton NewMedia.

<sup>8</sup> Seto, C. Durability of working channel in flexible ureteroscopes when inserting ureteroscopic devices, Journal of Urology, Volume 20, March 2006.

## **4. TRACK-ABILITY**Why We Believe in the Flexiva™ Fiber



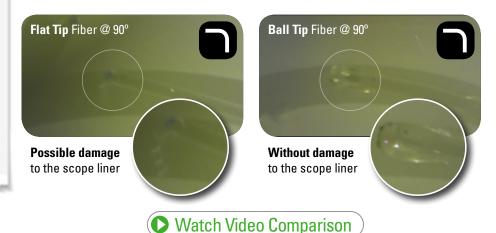
#### BALL-TIP HOLMIUM LASER FIBER MAY REDUCE FLEXIBLE URETEROSCOPE DAMAGE

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.<sup>9</sup>

## 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 site<sup>4</sup>
- Designed to pass through a scope without puncturing scope liner or damaging scope optics<sup>4</sup>



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



<sup>&</sup>lt;sup>4</sup> Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.

<sup>&</sup>lt;sup>9</sup> Lipkin, M. Ball-Tip Holmium Laser Fiber May Reduce Flexible Ureterosope Damage, Journal of Urology, Volume 191, e197, May 2014.

#### 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<sup>5</sup>

## 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<sup>5</sup>



<sup>&</sup>lt;sup>5</sup> Knudsen, B., et al. Evaluation of a New 240 micron single-use holmium: YAG optical fiber for flexible ureteroscopy, Journal of Endourology, Volume 27, April 2013. The publisher for this copyrighted material is Mary Ann Liebert, Inc. publishers.



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#### 5. DURABILITY

#### Why We Believe in the Flexiva™ Fiber



## 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"<sup>10</sup>

#### **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)<sup>4</sup>
- "Flexiva 200 and TracTip 200 did not fracture during durability testing"<sup>1</sup>
- "No fibers failed at bend diameters greater than 0.5cm"<sup>5</sup>





<sup>&</sup>lt;sup>1</sup> Knudsen, B. Evaluation of 16 New Holmium: YAG Laser Optical Fibers for Ureteroscopy, Abstract presented at AUA 2013.

<sup>&</sup>lt;sup>4</sup> Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance.

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<sup>&</sup>lt;sup>10</sup> Knudsen, B. 2014 Optimizing Use of the Holmium:YAG Laser for Surgical Management of Urinary Lithiasis, Curr Urol Rep April, 2014, With kind permission from Springer Science+Business Media.

#### 6. REPAIR SAVINGS

#### Why We Believe in the Flexiva™ TracTip Fiber



#### **Definition**

Measurement and evaluation of the real spending and procedural costs per treated individual<sup>11</sup>

## 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.<sup>13</sup> **Approximately half of these pertinent costs result from ureteroscope damage**.<sup>14</sup>





<sup>11</sup> Roehrig, C., et al. The Growth in Cost Per Case Explains Far More of US Health Spending Increases Than Rising Disease Prevalence. Health Affairs, September 2011.

<sup>&</sup>lt;sup>12</sup> Market research study conducted by Boston Scientific, results on file.

<sup>&</sup>lt;sup>13</sup> Landeman, J., et al. Evaluation of overall costs of currently available small flexible ureteroscopes, Journal of Urology, Volume 62, 2003.

<sup>&</sup>lt;sup>14</sup> Sung, J., et al. Location and etiology of flexible and semirigid ureteroscope damage, Journal of Urology, Volume 66, 2005

#### 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" <sup>15</sup>

## 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<sup>15</sup>
- 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<sup>15</sup>

Ball-Tip Fiber Repair Costs Related to Damaged Working Channels Compared to Blunt-Tip Fibers\*15



<sup>\*</sup>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.



<sup>&</sup>lt;sup>15</sup> Guise, A., et al. The impact on cost and frequency of ureteroscope repairs using a ball-tipped laser fiber for ureteroscopy, Journal of Urology, Volume 191, e948, April 2014, with permission from Elsevier.



Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

Refer to package insert provided with these products for complete Indications for Use, Contraindications,
Warnings, Precautions, Adverse Events, and Instructions prior to using these products.

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Ordering Information 1.888.272.1001

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