Improving ureteroscopy outcomes

Enhancing the treatment of nephrolithiasis.

Nephrolithiasis is a prevalent condition, commonly treated via minimally invasive procedures. During a ureteroscopy, a catheter is inserted into the body to facilitate the extraction of renal calculi, or 'kidney stones'. Although this procedure is routine, medical device manufacturers are constantly striving to enhance the performance and safety of extraction devices to further improve patient outcomes and reduce recovery times.

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Market:	Medical Devices
Sub-Market:	Urology
Procedure:	Ureteroscopy
Category:	Catheters
Zeus Product:	Reinforced Polyimide Tubing

Nephrolithiasis: Formation and Risk Factors

Nephrolithiasis, or 'kidney stones', are hard, crystalline deposits that form inside the urinary tract. These stones consist of minerals and salts, which can combine and crystallize, particularly when urine becomes concentrated. The condition results in the formation of **renal calculi** ranging in size from < 1 mm to > 1 cm.

Diseases such as high blood pressure, diabetes and obesity all increase the risk of kidney stone formation, which is also exacerbated by dehydration.

Early diagnosis and dietary changes can significantly improve patient outcomes, however, passing renal calculi can be extremely painful. Consequently, more than half a million people will visit the emergency room with kidney stone problems every year.

It is estimated that one in ten people will experience problems with renal calculi during their lifetime, with an elevated risk of developing the condition in males (19%) than females (9%).*

Historically, treatment for this prevalent condition involved general surgery, leading to hospitalization and protracted recovery periods. In recent years, however, treatment for nephrolithiasis has been radically transformed by the introduction of **minimally invasive surgical procedures.**

Advances in medical device technology have facilitated less invasive procedures for stone extraction that can be performed on an outpatient basis, resulting in shorter hospital stays, fewer complications, and faster recovery times.

>500,000

Over half a million people visit the emergency room with kidney stone problems every year.*

* kidney.org/atoz/kidneystones

Ureteroscopy and Kidney Stone Extraction

Following the diagnosis of renal calculi, a urologist can perform a **ureteroscopy** (URS) to view, ablate and remove crystalized deposits. This procedure can be used to treat small to medium-sized stones located throughout the urinary system.

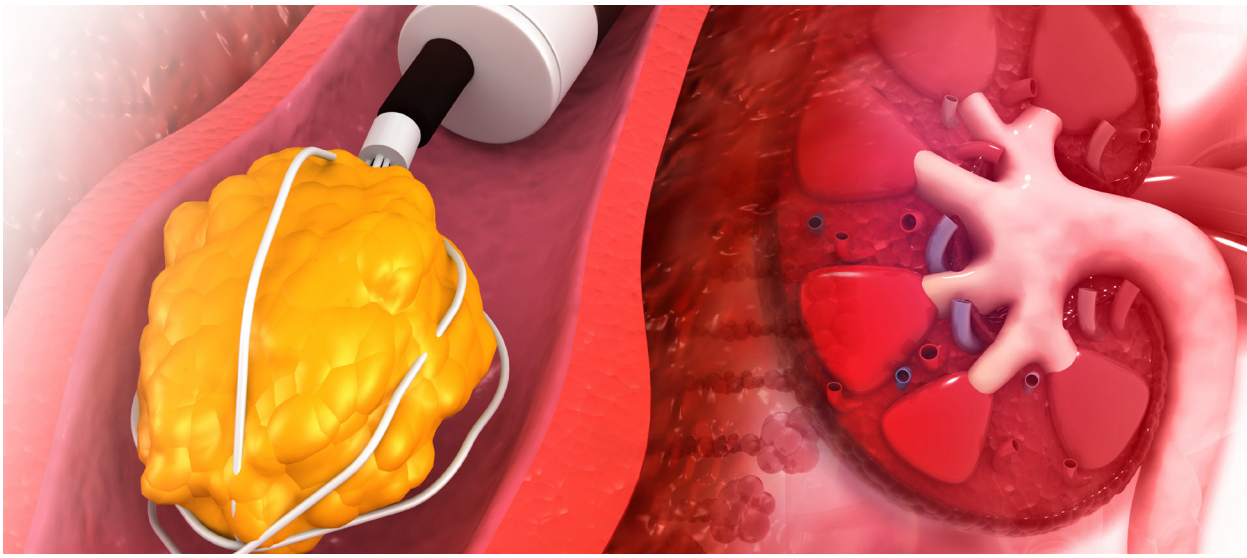
During treatment, a ureteroscope is inserted through the urethra. It then passes through the bladder, into the ureter, and finally the kidney.

The ureteroscope is designed to pass smoothly though the urinary tract system. It consists of a long, narrow, flexible device equipped with a light source and a miniature fiber optic camera. This enables the urologist to visualize the urinary system and to view and assess any renal calculi.

The device also features an additional lumen through which instruments can be introduced for the safe extraction of stone deposits.

If the stone is small enough, **a stone retrieval** device containing a nitinol wire basket may be inserted through the ureteroscope lumen to entrap and remove the stone. For larger stones, intracorporeal lithotripsy is first performed to fragment the stone into smaller pieces, followed by removal using the stone retrieval device.

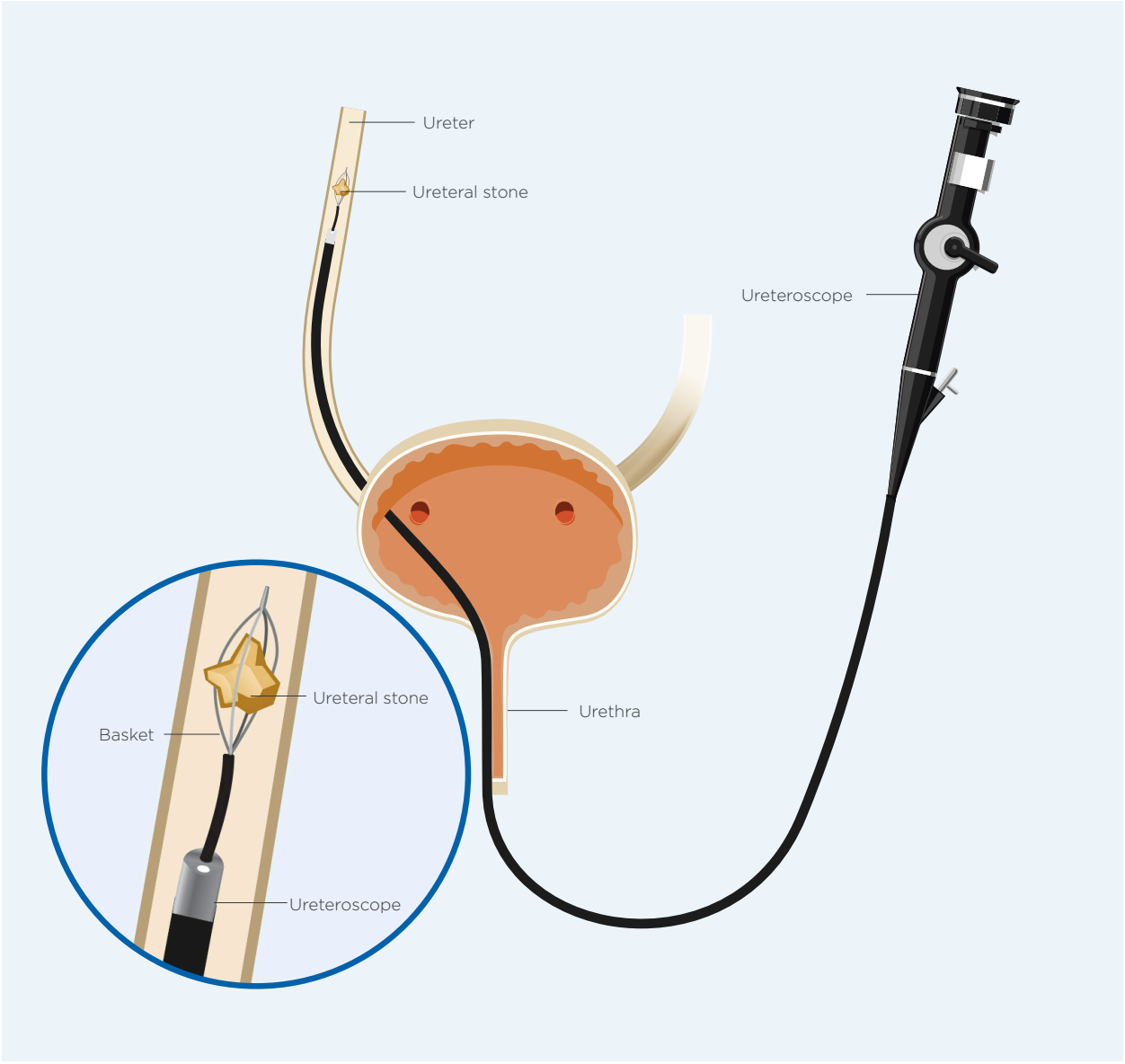
A tipless basket configuration helps to reduce tissue trauma during stone manipulation. To further diminish soft tissue damage, baskets also remain retracted in a sheath until close to the targeted stone, when they are extended, expanded, and subsequently withdrawn to successfully enclose and remove renal calculi.



Constraints of Stone Retrieval Devices

Thanks to its minimally invasive nature, low morbidity, and high efficacy, ureteroscopy has become a highly advantageous treatment option for nephrolithiasis. For most small- to medium-sized stones it realizes an excellent success rate with **minimal postoperative discomfort.**

Despite its versatility, however, ureteroscopy does have some limitations. For larger stones, and for patients with complex anatomy, alternative treatment options may need to be considered. Additionally, the design and performance attributes of the **stone retrieval device**, which must pass through the scope to reach the treatment site, may be a significant limiting factor.



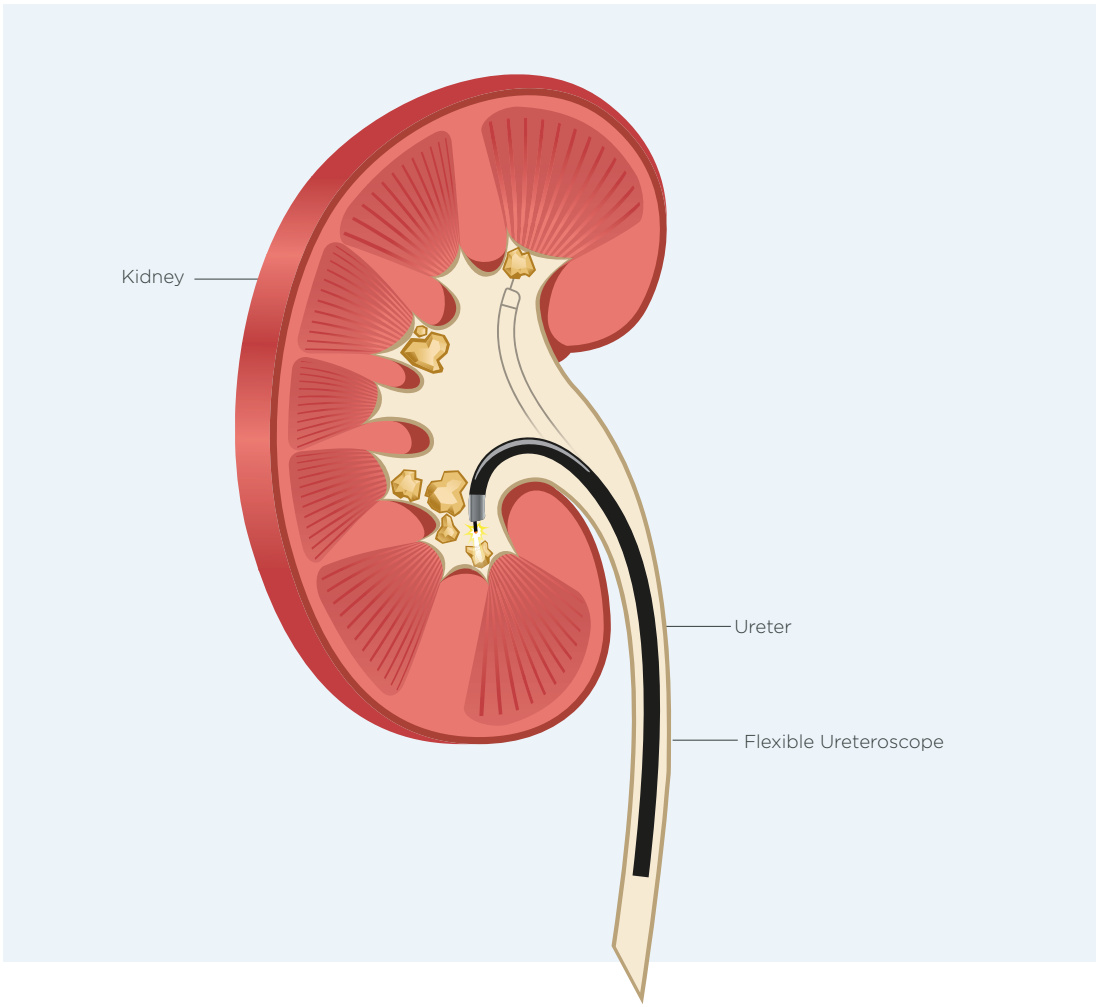
The challenge for device engineers

Stone retrieval devices with insufficient **lubricity** or **pushability** may not pass easily through the scope en route to the treatment site. This may require excessive force to be applied to overcome friction within the lumen, which can result in damage to the device, injury to the patient, or both.

A device with inadequate **flexibility** or **kink resistance** may prevent full scope deflection during the procedure. This limited range of motion may inhibit or entirely prevent retrieval efforts deep within complex renal cavities.

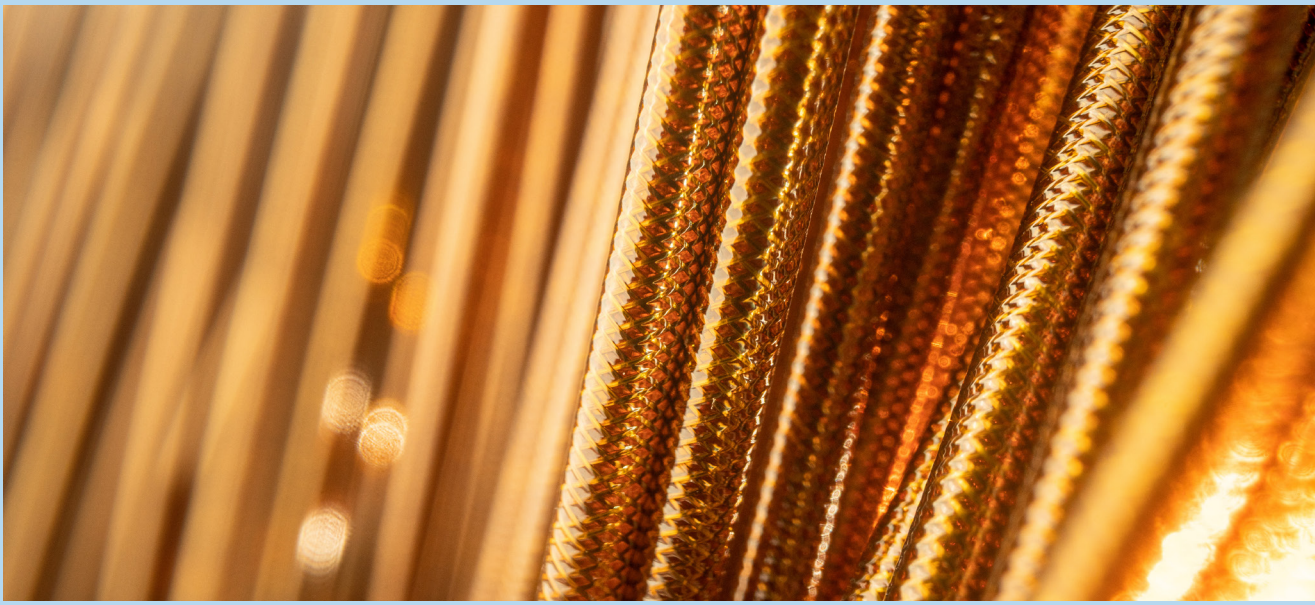
Finally, stone retrieval devices must have **high burst resistance** to withstand the radial force of the basket being deployed and expanding around stone fragments. Insufficient strength may limit radial dilation of the basket, consequently hindering performance when manipulating and capturing stones.

Medical device engineers are therefore constantly searching for innovative new solutions to facilitate improved construction of stone retrieval tools. They require low-friction, high performance materials to promote **smooth scope passage, enhanced scope deflection, and greater radial dilation**, ultimately resulting in fewer complications and increased procedural success.



IT'S FINALLY HERE

Braid & Coil Reinforced Polyimide Tubing



Reinforced polyimide tubing provides enhanced *flexibility* and *kink resistance*, improved *pushability*, and increased *strength*.

Reinforced braid & coil polyimide tubing provides device manufacturers with more options for **safer, stronger, and more effective stone retrieval components.**

Enhanced Flexibility

Full- or half-load braid patterns can be specified, with higher braid densities facilitating increased **flexibility and kink resistance.**

Superior Strength

Reinforced polyimide tubing can be engineered with various braid densities for optimized **strength** and **pushability.**

Customized Lubricity

PI Glide™, our lubricious PI + PTFE blend, provides a **low coefficient of friction** for easy scope passage.

As an added bonus, Zeus reinforced PI tubing also helps you adhere to REACH and EU MDR guidelines regarding SVHC/CMR restricted substances

Braid & coil reinforced polyimide tubing

Zeus' reinforced polyimide tubing helps medical device engineers optimize equipment and fine-tune key performance characteristics. Engineers can specify the diameter, braid density and coil configuration to their exact requirements, paving the way for more responsive stone retrieval equipment, improved procedural outcomes, and increased patient safety.

Reinforced construction

Thanks to its fortified construction, reinforced polyimide tubing can be formulated to reach the furthest regions of the urinary system with optimum strength, rigidity, and kink resistance. Customers can specify full load and half load braid patterns, in addition to a variety of coil configurations, ensuring high burst resistance, flexibility and pushability.

Customizable configuration

Advanced manufacturing procedures enable Zeus to adjust braid density to individual specifications by increasing or decreasing the picks per inch (PPI). Lower braid densities result in increased pushability, while higher braid densities result in enhanced flexibility and kink resistance. Coil configuration can also be adjusted by altering the wraps per inch (WPI).

Minimal wall thickness

With total wall thicknesses as low as 0.002" / 0.051 mm and internal diameter down to 0.010" / 0.254 mm, the tubing is ergonomic and compatible with different stone basket morphologies.

Offers a targeted approach to meet specific customer and application requirements....

"Unlike the commoditized solutions currently available in the polyimide market, Zeus offers a targeted approach to meet specific customer and application requirements. With our capabilities, we can deliver reinforced polyimide tubing with shorter cut lengths, tighter tolerances, and customized layer structuring. Further illustrating why Zeus continues to be the supplier of choice for leading medical device manufacturers worldwide."

Carl Liebert,
Director – Product Management
Zeus Industrial Products, Inc.

FEATURES

Braid & coil reinforced polyimide tubing

Low Coefficient of Friction

A low coefficient of friction ensures stone retrieval devices pass smoothly and safely through the ureteroscope. PI Glide™, a polyimide and PTFE composite, can be utilized to offer enhanced lubricity, ensuring calculi extraction tools glide easily during extension and retraction.

Flexibility and Kink Resistance

Reinforced polyimide sheath designs provide impressive strength while maintaining flexibility for enhanced scope deflection. These key mechanical properties ensure enhanced kink- and burst-resistance for safer ureteroscopy procedures and optimum patient outcomes.

Tensile Strength

Polyimide products deliver exceptional tensile strength even at very small dimensions. Reinforced tubing extends this capability, providing superior strength to push deep into the body during nephrolithiasis treatment.

Biocompatibility

PI and PI Glide™ tubing products help medical OEMs adhere to REACH and EU MDR* guidelines regarding SVH/CMR restricted substances. Providing essential confirmation that ureteroscopy equipment won't compromise patient safety or vital medical device approvals.

** Our thorough analytical test results indicate that no SVHC/CMR restricted substances are intentionally included in Zeus-supplied polyimide products at levels above the 0.1% threshold outlined by REACH and EU MDR.*

Providing device engineers with more options for optimizing the performance of their designs.

Advances in minimally invasive procedures have brought with them the need for more capable device designs and components. Zeus' reinforced polyimide tubing helps address this need by providing engineers with more options for optimizing the performance of their designs, resulting in safer, stronger, more responsive devices.

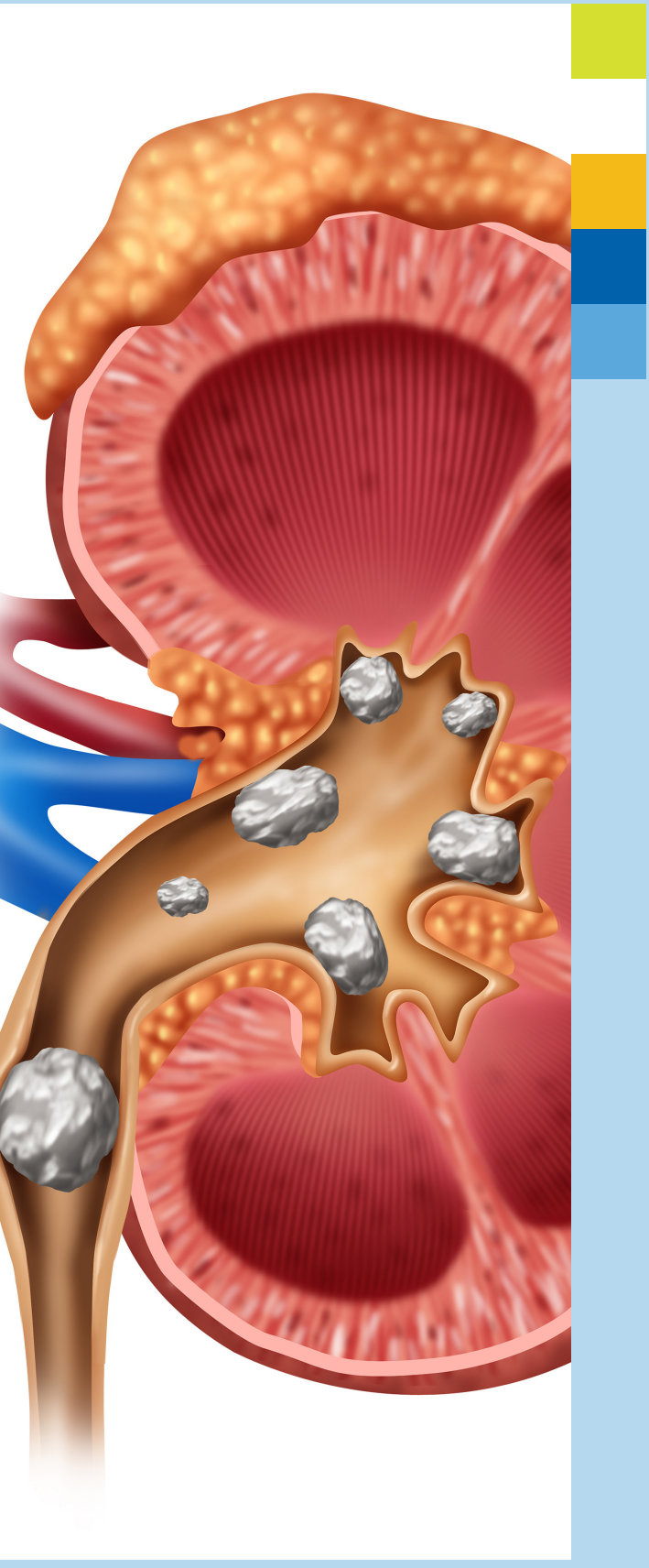
Rodrigo Silva,
Product Manager,
Zeus Industrial Products, Inc.

Reinforced Polyimide Tubing Applications

- ✔ Stone retrieval devices
- ✔ Urinary catheters
- ✔ Lumen for guidewires
- ✔ Introducer sheaths

Capabilities and Sizing

- Reinforced tubing is available in various lengths, thicknesses and densities depending on the device application.
- Internal diameters range from 0.010” to 0.070” (0.254 mm – 1.778 mm)
- Total wall thickness can be as low as 0.002” (0.051 mm)
- Tubing can be supplied in cut lengths to 78” (1.98 m)
- Full-load and half-load braid patterns can be specified
- Clockwise and counter-clockwise coiling are available
- Stainless steel and Nitinol wire are used for reinforcement
- Flat and round wire options are offered
- Customize wire density with 30 to 150 PPI/WPI
- Products are available in natural amber, green, red, and black



Improving nephrolithiasis procedures

Nephrolithiasis remains a common condition, with figures for this prevalent urological disorder increasing. The disease currently affects around 12%* of the world's population, primarily impacting those between 20 and 50 years old.

To date, manual extraction of renal calculi continues to be the most effective treatment.

Despite the efficacy of this routine procedure, however, ureteroscopy does have its limitations. Renal calculi located deep within the renal cavities can be difficult to reach and awkward to manipulate without harming the delicate tissues of the urinary system.

Furthermore, any damage to the urethra or ureter can result in urethral stricture, making subsequent ureteroscopy more difficult.

As a result, medical device engineers are constantly seeking to optimize the construction and capabilities of their equipment. Innovative materials such as braid and coil reinforced polyimide can significantly improve device designs and components.

By fine-tuning key material properties, engineers can optimize the performance of ureteroscope components including stone retrieval devices, paving the way for improved patient outcomes and increased procedural success.

* kidney.org/atoz/kidneystones

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