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LithoVue Empower™
Retrieval Deployment Device

Product Review for the Purchasing Committee

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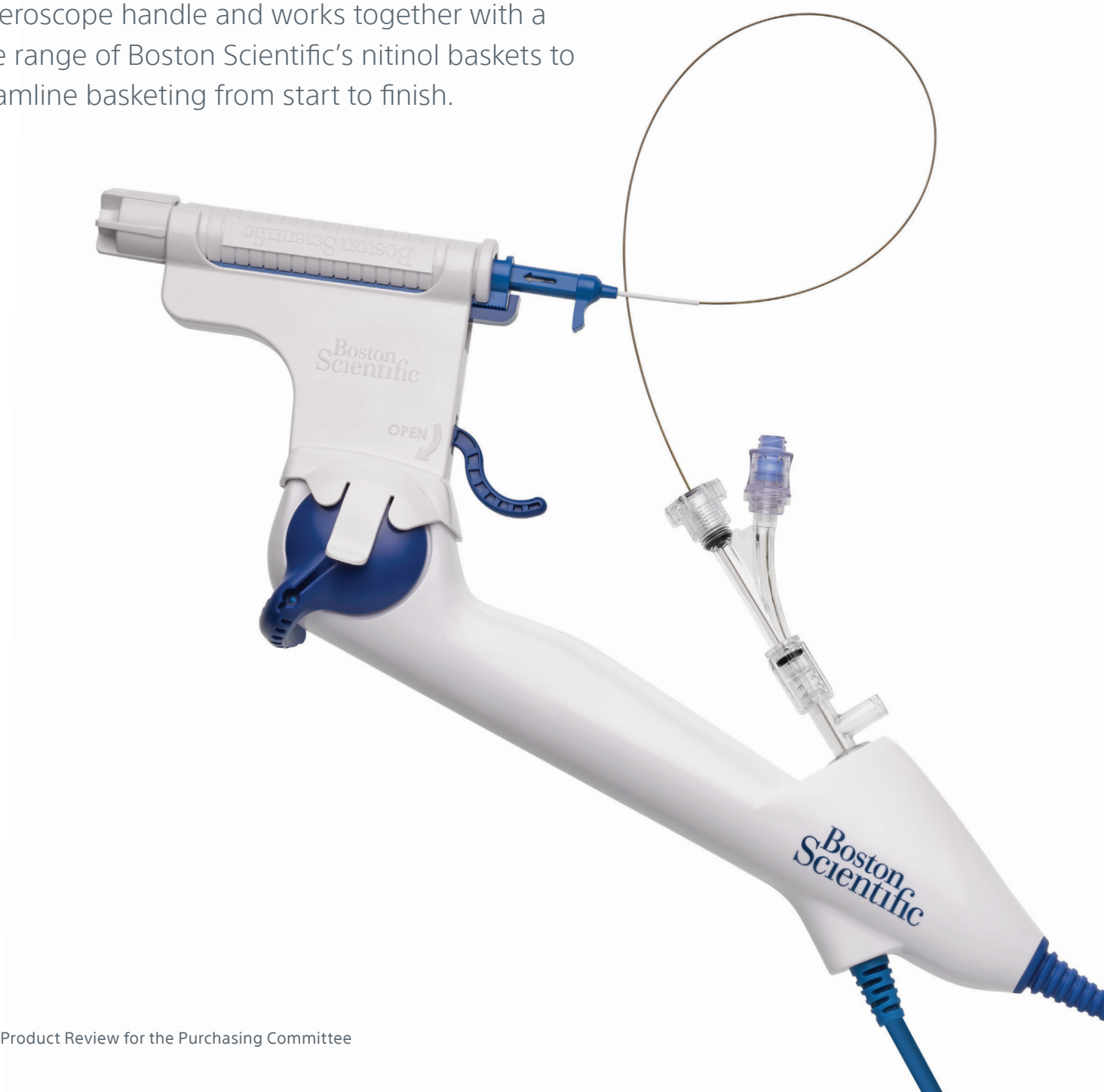
Product Overview

The new LithoVue Empower™ Retrieval Deployment Device turns stone removal into a single-handed task. The intuitive single-use device snaps securely onto the LithoVue™ Single-Use Digital Flexible Ureteroscope handle and works together with a wide range of Boston Scientific's nitinol baskets to streamline basketing from start to finish.



Procedural Improvements

What procedural improvement does the requested product provide?

Together with the LithoVue™ Single-Use Digital Flexible Ureteroscope, the LithoVue Empower™ Retrieval Deployment Device turns stone basketing from a two-person task into a one-handed task. In one bench study the LithoVue Empower Device reduced the staff required to basket from two people to one, putting complete control into the surgeon's hands.[1]

Conventional stone basketing requires two OR staff members — the surgeon holds the ureteroscope and advances the basket while giving directions to the assistant who operates the handle. Both the assistant's experience with stone removal and ability to effectively communicate with the surgeon can impact the operative outcomes.[2] A 2015 publication in the AORN Journal found a third of surgical errors can be attributed to a staff member's level of experience or their difficulty performing a specific technique or procedure.[3] The LithoVue Empower Device allows for single-surgeon basketing, which eliminates assistant skill level and coordination from the equation.[1,2,4-6]

How might this product improve the level of staff satisfaction?

Stone retrieval accounts for approximately 20% of total flexible ureteroscopy procedure time.[7] During endourological procedures, surgeons may experience physical fatigue due to repetitive tasks and awkward postures.[8] In one bench top test, LithoVue Empower showed similar cumulative muscular workload when compared to two-surgeon stone basketing and decreased muscular workload when compared to single-surgeon basketing.[1]

LithoVue Empower may improve staff satisfaction by eliminating miscommunications between surgeons and nurse assistants while basketing. Tensions in the operating room impact staff satisfaction, leading to burnout and ultimately, financial burden on healthcare systems.[6] These events between surgeons and nurses can cause poor communication, potentially leading to negative surgical outcomes.[3,9] With LithoVue Empower, scrub assistants can focus on other aspects of the surgery, while the surgeon alone can control stone manipulation.

Journal Evidence

PRESENTED AT

33rd EUS Annual Meeting

ANNUAL CONGRESS

May 18, 2018 ▪ San Francisco, CA

Presentation Title: ERGONOMICS AND PROCEDURE TIME OF NOVEL RETRIEVAL DEPLOYMENT DEVICE FOR SINGLE SURGEON URETEROSCOPY

Author Block: Gregory A. Joice[1], Wesley W. Ludwig[1], Zeyad R. Schwen[1], Brian R. Matlaga[1]

[1]The James Buchanan Brady Department of Urology, Johns Hopkins Hospital

Introduction

Ureteroscopic stone manipulation and retrieval typically requires two experienced individuals: one to drive the ureteroscope and a second to manipulate the stone basket or grasper. Recently, a retrieval deployment device (RDD) has been developed that allows the primary surgeon to activate the stone basket while simultaneously controlling the ureteroscope. We performed a study to characterize the procedure time and ergonomics of this approach.

Methods

We performed a three-arm evaluation of the ergonomics of flexible ureteroscopy utilizing a simulation model of stone retrieval. In Arm 1, two experienced operators performed stone manipulation and retrieval, one managed the ureteroscope and the other managed the retrieval tool. In Arm 2, a single operator managed both the ureteroscope and retrieval tool. In Arm 3, a single operator managed the ureteroscope conventionally, but utilized the novel RDD (LithoVue™ Empower, Boston Scientific, Marlborough, MA) to control the retrieval tool. Fifteen tasks were performed for each arm and median procedure time was calculated. Electromyography was used to compare and quantify cumulative muscular workload (CMW) and average muscular work per second (AWS) of the right and left thenar, flexor carpi ulnaris (FCU), extensor carpi ulnaris (ECU), biceps, triceps and deltoid muscles.

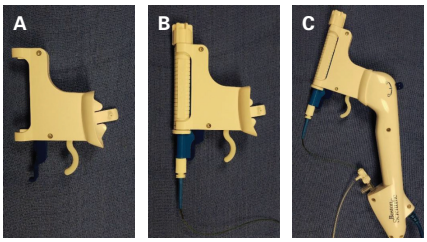


Figure 1: Images of the LithoVue Empower retrieval deployment device.

A – Device alone prior to basket or ureteroscope loading.

B – After loading of nitinol ureteroscopic retrieval device.

C – Complete configuration of device loaded with ureteroscopic basket and attached to the LithoVue Single-Use Digital Flexible Ureteroscope. Steady state exists in the closed state and upon pulling the trigger opens the basket that will close again upon release.

Results

Median procedure time was significantly improved with the RDD when compared to single-surgeon URS (29.4 vs. 51.3 seconds, $p < 0.001$) but unchanged compared to two-surgeon URS (29.4 vs. 27.9 seconds, $p = 0.64$). Two surgeon URS also was significantly faster than single-surgeon URS (27.9 vs. 51.3 seconds, $p < 0.001$). CMW was similar between RDD and two-surgeon URS but both had decreased CMW across all muscle groups compared to single-surgeon URS ($p < 0.01$). AWS was overall similar between RDD and two-surgeon URS across all muscle groups. RDD had significantly improved AWS compared to single-surgeon URS specifically in the thenar, FCU and ECU muscles (<0.05) of the dominant arm.

Conclusion

The novel RDD, as tested, permitted a single-surgeon to perform flexible ureteroscopy with stone manipulation and retrieval using less muscular workload than single-surgeon URS and similar workload to two-surgeon URS. Task completion time was also improved with RDD over the single-surgeon model and similar to the two-surgeon model.

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URO-554004-AA JUN 2018

PRESENTED AT

36th World Congress of Endourology

ANNUAL CONGRESS

20-23 September 2018 ▪ Paris, France

Presentation Title: MOVING FROM FOUR HANDS TO TWO DURING FLEXIBLE URETEROSCOPY WITH STONE MANIPULATION

Author Block: Brian Matlaga, MD; Kelly Healy, MD; Adam Kaplan, MD; David Leavitt, MD

Introduction

Ureteroscopy typically requires two individuals: a surgeon who manipulates the endoscope and an assistant who operates the basket or grasper. The skill level of the assistant can vary from inexperienced to experienced. A novel device designed for the LithoVue™ Ureteroscope (Boston Scientific, Marlborough, MA) enables a single-surgeon approach to ureteroscopy (URS), as the surgeon simultaneously manipulates the ureteroscope and operates a stone retrieval device. We sought to assess the workloads of these ureteroscopy paradigms.

Methods

We performed an in vitro evaluation of ureteroscopic stone manipulation with an experienced assistant (EA), an inexperienced assistant (IA) and a device designed for single-surgeon ureteroscopic stone manipulation (LithoVue Empower™, Boston Scientific). Four fellowship-trained endourologists were the primary surgeons and also served as the EA for one another. The IA was a nurse naïve to URS. Stone manipulation was performed with Dakota™, Zero Tip™ and Escape™ (Boston Scientific, Marlborough, MA). Time to stone capture and communication between surgeon and assistant were recorded. Workload was characterized by the NASA Task Load Index (TLX) instrument, which quantifies mental, physical and temporal demand as well as performance, effort and frustration of a task. Statistical analysis was performed for each item on the TLX, time to stone retrieval and number of communications during stone capture, using Kruskal-Wallis or Tukey-Kramer tests as appropriate.

Results

Four surgeons performed nine trials, each of which removed 10 stones (360 total stone retrievals). There were 3 arms of the trial: (1) EA, (2) IA and (3) LithoVue Empower. Time to basket was similar among the three arms (median: 12, 16 and 15 seconds, respectively). LithoVue Empower required no communications during stone capture; the IA required significantly more communications than did the EA ($p<0.05$) (Figure 1). Compared to the IA, LithoVue Empower demonstrated significantly lower temporal demands and frustration scores on the TLX ($p<0.05$). No differences were found between LithoVue Empower and EA (Figures 2 and 3).

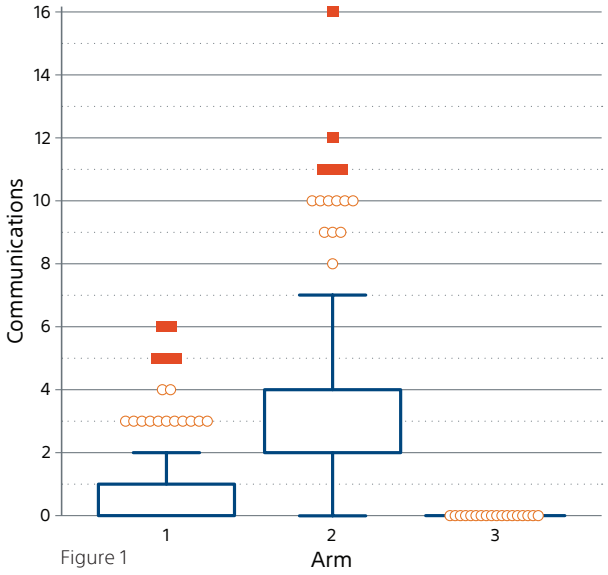

Figure 1

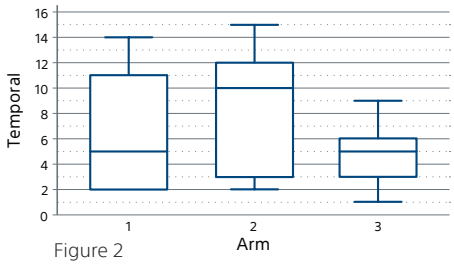

Figure 2

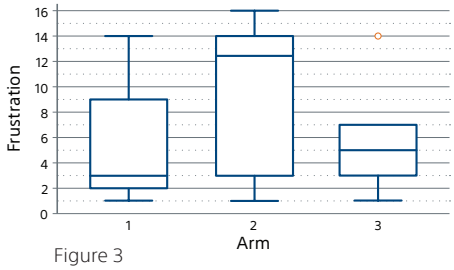

Figure 3

Conclusions

Clearance Testing

The novel device permitted single-surgeon URS and stone capture without sacrificing efficiency. The device eliminated the need for surgeon-assistant communication during stone capture and improved certain TLX metrics. The findings of this pilot study are encouraging and further evaluation with the LithoVue Empower Retrieval Deployment Device is warranted.

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URO-562410-AA AUG 2018

Utilization Information

Is there a requirement for staff training?	A brief in-service by a Boston Scientific sales representative is recommended for the OR staff prior to use.
Does this product/procedure require a company representative to be present to operate equipment or to provide assistance to the physician?	No
Is there any other equipment involved with the use of this product that will need to be leased, purchase consigned or rented?	The LithoVue Empower™ Retrieval Deployment Device must be used with Boston Scientific nitinol baskets and the LithoVue™ Single-Use Digital Flexible Ureteroscope.
Will this product interface with any other equipment/ supplies currently utilized at this facility?	Yes, this product must be used with the LithoVue Single-Use Digital Flexible Ureteroscope and the following Boston Scientific baskets: Zero Tip™, Dakota™, Escape™ and Graspit™ Nitinol Stone Retrieval Baskets. See Compatible Devices section for further details.
What is the average length of procedure time to use this product/perform this procedure (surgery minutes)?	45 minutes for ureteroscopy
Will this product replace or supplement a current, in-house product?	The LithoVue Empower Device will not replace a current product, but it may reduce the number of individuals required during stone basketing.
What department(s) will use and/or be affected by this product?	Operating Room, Cysto Suite, Urology Suite and Purchasing
Will this product require evaluation by any of the following departments? • Epidemiology/Infection Control • Safety and Security • Bio Engineering Maintenance • Pathology/Labs	No

Material/Environment

Does this product contain metal substances that may affect tests and/or procedures performed on patients?	No
If yes, is this product MRI safe?	Not applicable
Is this considered an implantable device?	No
Does this item and its packaging contain no detectable latex?	Yes. Material certifications confirm no detectable latex is used in the device or its packaging.
Is this a pharmaceutical or contain any pharmaceutical product?	No
Does the product require a Material Safety Data Sheet?	No
Is this product reusable?	No, it is single use.
Does this product require additional waste or any anticipated recycling costs?	No
Does this product qualify as hazardous waste?	No
Does this product contain any of the following? • Mercury • PVC • Halogenated flame retardants/halogenated organic chemicals (HOCs) • Persistent bio-accumulative toxic compounds (PBTs)	No
Storage considerations	Per the DFU, store in a cool, dry, dark place.
Shelf life	Currently, the approved shelf life of this product is one year.

Ordering Information

Manufacturer	Boston Scientific
Manufacturer Federal Tax ID	04 269 5240
Ordering code	M0067919900
GTIN code	08714729977612
Package unit	One unit
Minimum order quantity	One
Lead time in working days	1-2 days
Packaging dimensions	4.75" X 1.75" X 7.63"
List price	Please speak with your Boston Scientific sales representative for the price per each unit.
Is this item/technology on contract with GPO and/or IDNs?	Please speak with your Boston Scientific sales representative for the contract status of specific GPOs and IDNs.
Method of purchase	The purchase would be an outright purchase.
Mode of transportation	FedEx® delivery
Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space?	No, this product is used in conjunction with the LithoVue Single-Use Digital Flexible Ureteroscope and a variety of Boston Scientific nitinol baskets.

Compatible Devices

	Description	Configuration	UPN Product Number
	LithoVue™ Single-Use Digital Flexible Ureteroscope	Standard Reflection Reverse Reflection	M006**7913500** M006**7913600**
	Zero Tip™ Nitinol Stone Retrieval Basket	1.9F x 120cm 2.4F x 120cm 3.0F x 120cm	M006**3901050** M006**3901010** M006**3901030**
	Dakota™ Nitinol Stone Retrieval Basket	1.9F x 120cm x 8mm 1.9F x 120cm x 11mm	M006**3905000** M006**3905010**
	Escape™ Nitinol Stone Retrieval Basket	1.9F x 120cm	M006**3902010**
	Graspit™ Nitinol Stone Retrieval Forceps	2.6F x 120cm 3.3F x 120cm	M006**3204010** M006**3204030**
	UroLok™ II Scope Adaptor		M006**7301401**
	Gateway™ Advantage Y-Adapter		M006**7301501**

Directions for Use

Boston Scientific

LithoVue Empower™

Retrieval Deployment Device

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50572380-01 Rev. A

2018-04

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LithoVue Empower™

Retrieval Deployment Device

℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

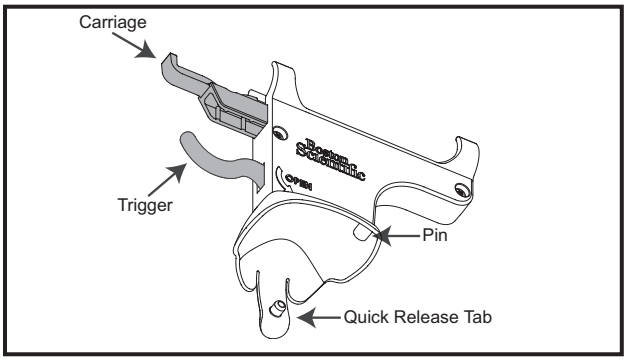
The device is designed to allow simultaneous, single-handed operation of the LithoVue™ Single-Use Digital Flexible Ureteroscope and Boston Scientific nitinol retrieval devices defined in Table 1. The device was tested and is compatible with Gateway™ Advantage Y-Adaptor and UroLok™ II Adaptor. The LithoVue Single-Use Digital Flexible Ureteroscope is also referred to as the LithoVue Ureteroscope in these instructions.

Table 1

Product Name	Device Size	REF
Zero Tip™ Nitinol Stone Retrieval Basket	1.9F X 120 cm	M006**3901050**
	2.4F X 120 cm	M006**3901010**
	3.0F X 120 cm	M006**3901030**
Dakota™ Nitinol Stone Retrieval Device	1.9F X 120 cm X 8 mm	M006**3905000**
	1.9F X 120 cm X 11 mm	M006**3905010**
Escape™ Nitinol Stone Retrieval Basket	1.9F X 120 cm	M006**3902010**
Graspit™ Nitinol Stone Retrieval Forceps	2.6F X 120 cm	M006**3204010**
	3.3F X 120 cm	M006**3204030**

The LithoVue Empower Retrieval Deployment Device has four main features; the carriage, pin, quick release tab, and trigger. The carriage holds the retrieval device. The pin and tab secure the LithoVue Empower Retrieval Deployment Device to the LithoVue Ureteroscope. The trigger actuates the retrieval device. Refer to Figure 1.

Figure 1



USER INFORMATION

Read this DFU before using LithoVue Empower. Study labeling thoroughly for safe handling and storage. Use the device as intended. Only physicians who have training in urological endoscopic procedures and associated disease states requiring endoscopic intervention should use the LithoVue Empower.

CONTENTS

(1) LithoVue Empower

INTENDED USE/ INDICATIONS FOR USE

LithoVue Empower Retrieval Deployment Device is used in the treatment of Urological stone disease. The LithoVue Empower Retrieval Deployment Device is an accessory that allows LithoVue Ureteroscope and compatible retrieval devices (see Table 1) to be used simultaneously with a single hand.

CONTRAINDICATIONS

Contraindications for this device are fully consistent with the stone retrieval devices in Table 1 and LithoVue Ureteroscope contraindications, respectively.

PRECAUTIONS

Before using, inspect the pouch for any breach of the package to ensure a sterile product and inspect product for any damage. If seal has been broken or product is damaged DO NOT USE. Immediately return package and product to your Boston Scientific representative.

WARNING

The use of this device must be restricted to use by or under the supervision of physicians trained in urological endoscopic procedures.

Caution: Visually inspect the device for loose, bent or broken parts, cracks, or other abnormalities. If an abnormality is detected, DO NOT USE. Broken parts, or cracks will hinder the mechanical operation of the LithoVue Empower™ Retrieval Deployment Device. If the device fails to operate properly in any way or shows any signs of damage, DO NOT USE IT. Call Boston Scientific Customer Service and return the product. If there is breach to the package seal or if the device is damaged, DO NOT USE.

WARNING

Failure to perform inspection and operational checks may result in patient injury and/or damage to the device.

ADVERSE EVENTS

- Edema
- Pain/Discomfort
- Stenosis/Stricture
- Inflammation
- Laceration
- Infection
- Hematuria

HOW SUPPLIED

The device is supplied in a sealed pouch and for single use only.

Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place. Rotate inventory so that products are used prior to the expiration date on package label.

OPERATIONAL INSTRUCTIONS

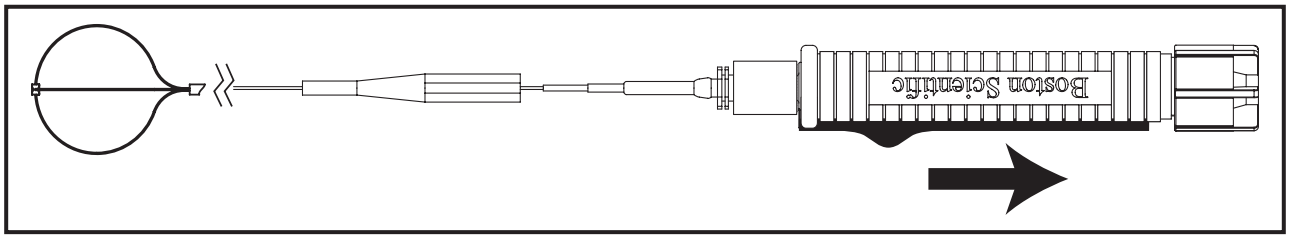
Read, understand and follow all directions for use supplied with retrieval devices, compatible adaptors, (e.g. Gateway™ Advantage Y-Adaptor, and UroLok™ II Adaptor), and LithoVue Ureteroscope.

Prior to Use

Remove the device from the carton. Pull apart the top two edges of the pouch located above the product label to break the seal and present the product to the sterile field. Inspect the LithoVue Empower Retrieval Deployment Device for any visible damage.

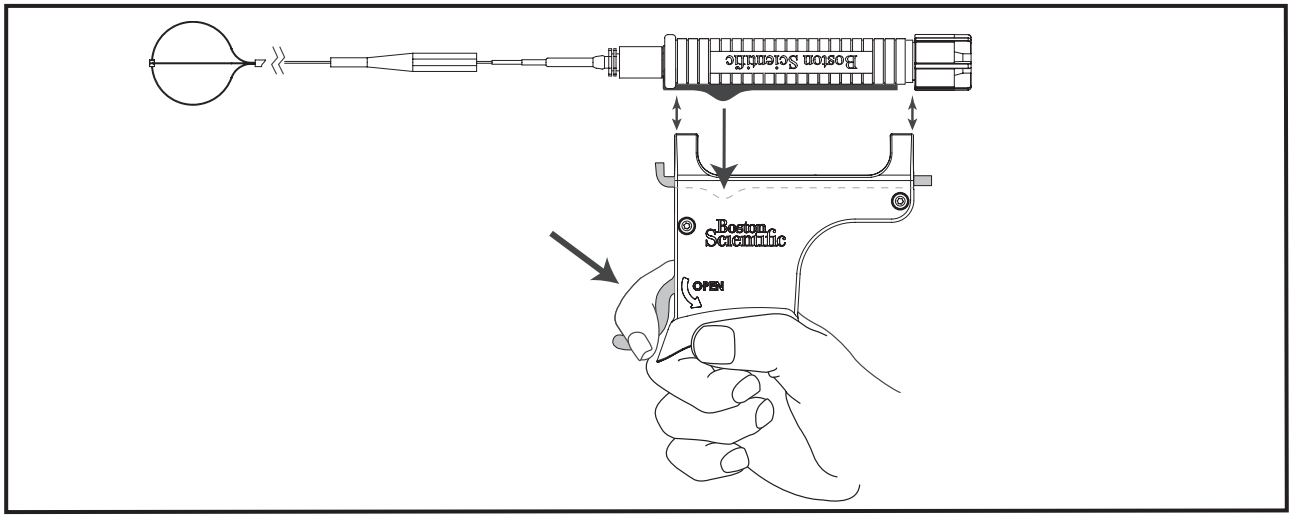
ASSEMBLY

Step 1



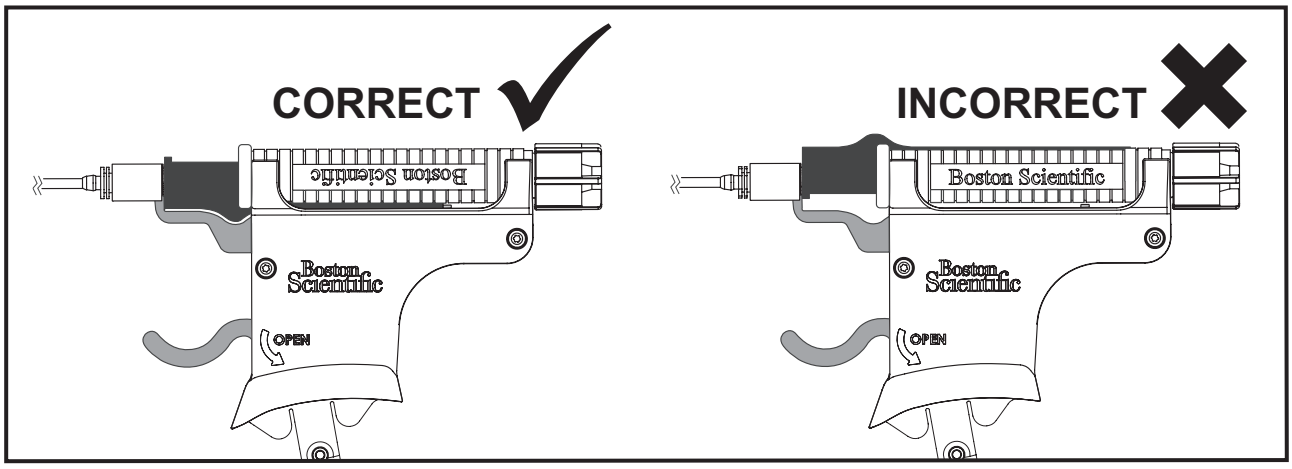
Verify the retrieval device is in the open position. The slide will be at the proximal end of the retrieval handle.

Step 2



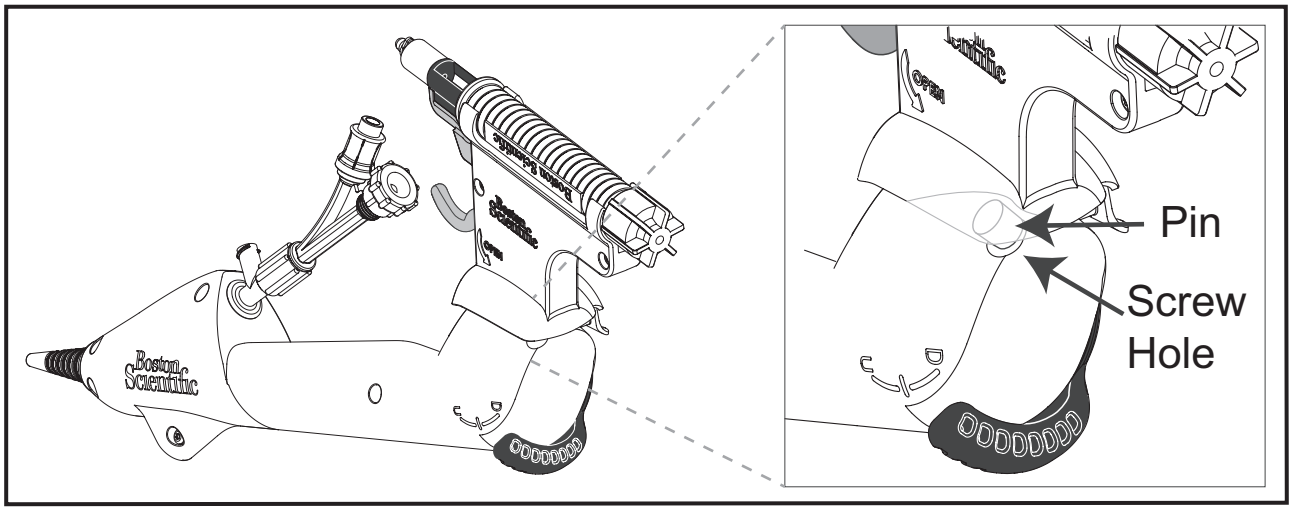
Hold down the trigger and place the retrieval device, with the "Boston Scientific" logo facing upside down, into the LithoVue Empower™ Retrieval Deployment Device. The retrieval device will snap in place when it's secured properly. Once attached securely, you may release the trigger.

Step 3



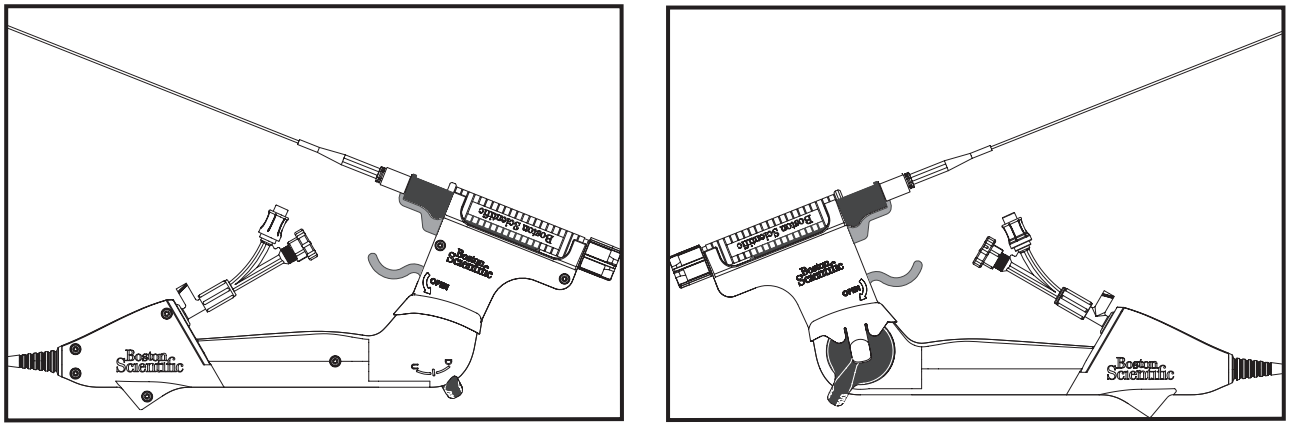
Verify the retrieval device is correctly attached to the LithoVue Empower Retrieval Deployment Device.

Step 4



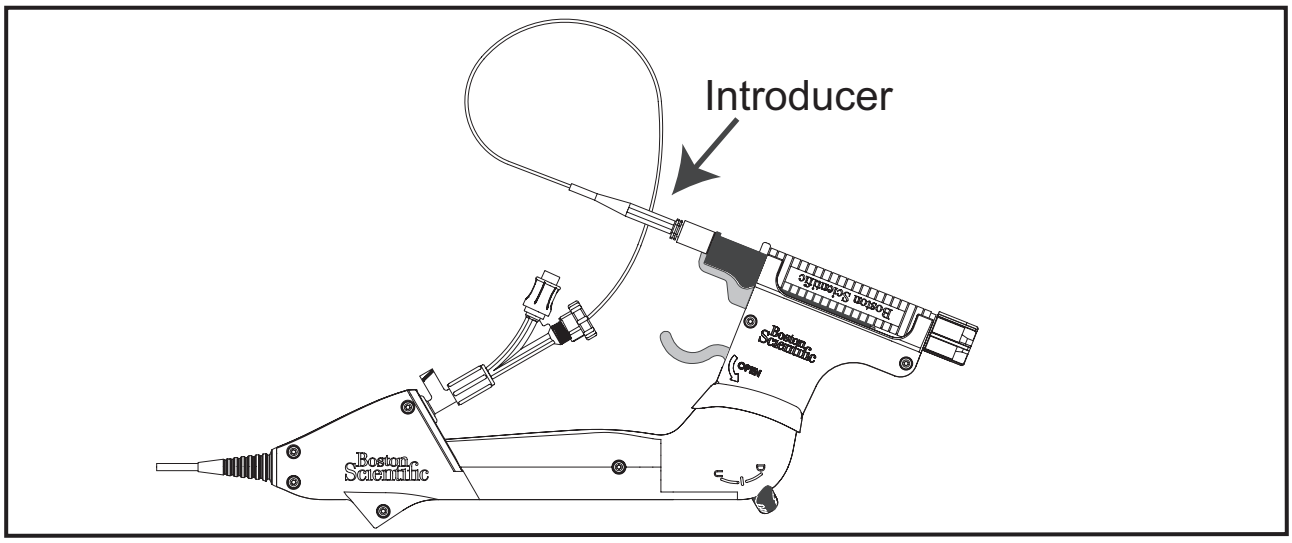
To secure the LithoVue Empower™ Retrieval Deployment Device onto LithoVue Ureteroscope, line up LithoVue Empower Retrieval Deployment Device pin with the screw hole above the D/U markers on LithoVue Ureteroscope. This side must be attached first. Pressing down will snap the device into place when both sides are aligned correctly.

Step 5



Verify the final assembly matches the above images.

Step 6

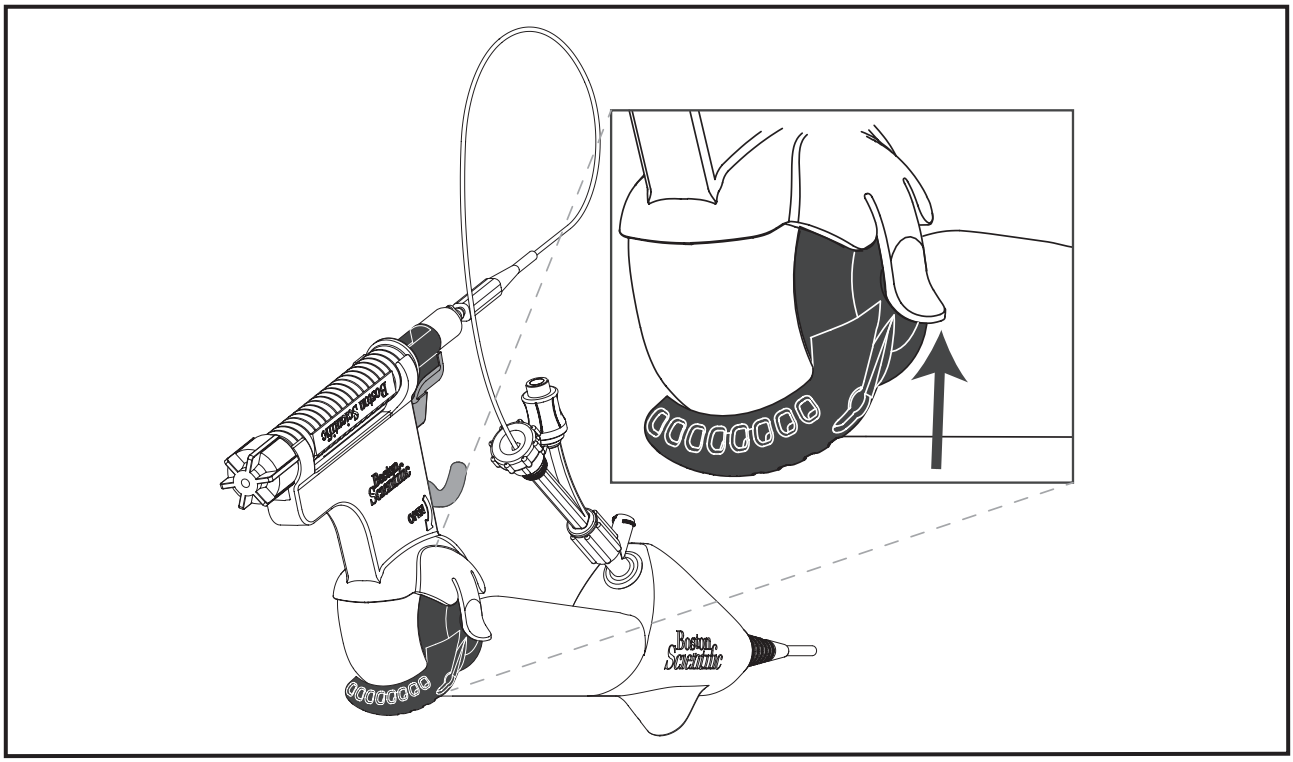


Loop the retrieval device wire around, and insert the distal end through the scope adaptor. If using an introducer, it may be returned to the base of the device as shown in Step 6.

OPERATION OF DEVICE

Test the retrieval device by actuating the LithoVue Empower™ Retrieval Deployment Device trigger to verify that the retrieval device opens and closes when assembled fully. The trigger is used to open and close the retrieval device during the case. Please refer to the respective DFUs for the retrieval device and LithoVue Ureteroscope for product use.

REMOVAL



To remove the device at any point during the case, lift the quick release tab as shown above. The device can be snapped back onto the scope by following the directions for Steps 4 to 6.

DISPOSAL OF THE LITHOVUE EMPOWER™ RETRIEVAL DEPLOYMENT DEVICE AND PACKING MATERIALS

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização

Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
Conteúdo

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Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

Lot
Lote
Lot
Charge
Lotto
Partij
Lote

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

Argentina Local Contact
Contacto local en Argentina
Contact local en Argentine
Lokaler Kontakt Argentinien
Contatto locale per l'Argentina
Contactpersoon Argentinië
Contacto local na Argentina

For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.

Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

EC REP

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AUS

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ARG

Argentina Local Contact

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Legal Manufacturer

Manufactured for:
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Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

CE 0086

Regulatory Information

The LithoVue Empower™ Retrieval Deployment Device (product number: M0067919900) is marketed in the US, in accordance with FDA regulations per 21 CFR 876.1500. and is exempt from 510(k) clearance. This means that the FDA does not require 510(k) clearance in order to market this product in the US.

Regulation medical specialty	Gastroenterology/Urology
Regulation description	Endoscope and accessories
Device classification name	Ureteroscope and accessories, flexible/rigid
Trade/device name	LithoVue Empower™ Retrieval Deployment Device
Intended use	The LithoVue Empower Retrieval Deployment Device is used in the treatment of urological stone disease. The LithoVue Empower Retrieval Deployment Device is an accessory that allows LithoVue Ureteroscope and compatible retrieval devices (see **Compatible Devices section**) to be used simultaneously with a single hand.
510(k) number	Not applicable. This product is 510(k) exempt by the FDA.
Regulation Number	21 CFR 876.1500
FDA classification	LithoVue Empower™ Retrieval Deployment Device is a Class II Exempt device in the US and, as such, 510(k) clearance is not required by the FDA.

Reimbursement Information

Is this product reimbursable by insurance?	The procedures for which it is used are reimbursable. Billing guides with respective coding and Medicare reimbursement for Ureteroscopy with and without Lithotripsy and PCNL are 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)?	The LithoVue Empower™ Retrieval Deployment Device does not have a Medicare Pass-Through Code.
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.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Procedure Name	Ureteroscopic Stone Removal with or without Lithotripsy
APC Code	**5375**
CPT® Code	**52352 –** Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included) **52353 –** Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included) **52356 –** Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)
ICD-10-PCS Procedure Code	**0TC38ZZ –** Extirpation of Matter from Right Kidney Pelvis, Via Natural or Artificial Opening Endoscopic **0TC48ZZ –** Extirpation of Matter from Left Kidney Pelvis, Via Natural or Artificial Opening Endoscopic **0TC68ZZ –** Extirpation of Matter from Right Ureter, Via Natural or Artificial Opening Endoscopic **0TC78ZZ –** Extirpation of Matter from Left Ureter, Via Natural or Artificial Opening Endoscopic **0TF38ZZ –** Fragmentation in Right Kidney Pelvis, Via Natural or Artificial Opening Endoscopic **0TF48ZZ –** Fragmentation in Left Kidney Pelvis, Via Natural or Artificial Opening Endoscopic **0TF68ZZ –** Fragmentation in Right Ureter, Via Natural or Artificial Opening Endoscopic **0TF78ZZ –** Fragmentation in Left Ureter, Via Natural or Artificial Opening Endoscopic
ICD-10-CM Diagnosis Code	**N13.2 –** Hydronephrosis with renal and ureteral calculous obstruction **N20.0 –** Calculus of kidney **N20.1 –** Calculus of ureter **N20.2 –** Calculus of kidney with calculus of ureter **N20.9 –** Urinary calculus, unspecified
Possible MS-DRG Assignment	**668 –** Transurethral procedures with major complication or comorbidity (MCC)* **669 –** Transurethral procedures with complication or comorbidity (CC)* **670 –** Transurethral procedures without CC/MCC

* The patient's medical record must support the existence and treatment of the complication or comorbidity.

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