

# LithoVue Empower™ Retrieval Deployment Device

## Prescriptive Information

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.  
**Caution:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

### 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.

### 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.

Table 1

Product Name	Device Size	REF
Zero Tip™ Nitinol Stone Retrieval Basket	1.9F X 120 cm	M0063901050
	2.4F X 120 cm	M0063901010
	3.0F X 120 cm	M0063901030
Dakota™ Nitinol Stone Retrieval Device	1.9F X 120 cm X 8 mm	M0063905000
	1.9F X 120 cm X 11 mm	M0063905010
Escape™ Nitinol Stone Retrieval Basket	1.9F X 120 cm	M0063902010

### 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.

**Warnings**

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.

**Warnings**

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

**Adverse Events**

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

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