

PCNL Kits

The Percutaneous Nephrolithotomy (PCNL) with ZIPwire Kits are convenience kits which contain multiple devices used to perform percutaneous removal of calculi in the kidney.

The Lingeman Percutaneous Tract Kit with ZIPwire™ Guidewire contains the following components:

- ZIPwire Stiff Hydrophilic Guidewire
- PTFE Coated Moveable Core Guidewire – “J” Tip
- PTFE Coated Moveable Core Guidewire – Straight Tip
- Amplatz Super Stiff™ PTFE Coated Guidewire
- Occluder™ Occlusion Balloon Catheter
- Percutaneous Access Needle
- 8/10 Dilator/Sheath Set
- Amplatz Type Renal Dilator
- NephroMax™ High Pressure Nephrostomy Balloon Catheter
- Encore™ 26 Inflation Device
- Urolok™ II Scope Adaptor
- Re-Entry™ Malecot Nephrostomy Catheter Set

The Percutaneous Tract Kit with ZIPwire Guidewire contains the following components:

- Zipwire Stiff Hydrophilic Guidewire
- PTFE Coated Moveable Core Guidewire
- Zebra™ Guidewire
- Amplatz Super Stiff PTFE Coated Guidewire
- Occluder Occlusion Balloon Catheter
- Percutaneous Access Needle
- 8/10 Dilator/Sheath Set
- Amplatz Type Renal Dilator
- NephroMax High Pressure Nephrostomy Balloon Catheter
- Encore 26 Inflation Device
- Re-Entry Malecot Nephrostomy Catheter Set

Refer to the Instructions for Use provided with the devices in the kit for applicable indications for use, contraindications, warnings and precautions.

Intended Use/Indications for Use for selected devices provided in the kit:

Occluder™ Occlusion Balloon Catheter

The Occlusion Balloon Catheters are indicated for use for temporary ureteral occlusion and applications including, renal opacification, dislodgment of calculi and preventative calculi migration.

Any use for procedures other than those indicated in instructions is not recommended.

Percutaneous Access Needle

The Percutaneous Access Needle is intended to facilitate access into the renal pelvis, and to advance guidewires into the collecting system in an antegrade manner.

NephroMax™ High Pressure Nephrostomy Balloon Catheter:

The NephroMax Balloon Catheters are recommended for dilatation of the nephrostomy tract.

Re-Entry™ Malecot Nephrostomy Catheter:

The Malecot Nephrostomy Catheter Set is intended to establish percutaneous nephrostomy drainage and is indicated for the following:

- Diagnostic Indications:
 - Antegrade pyelography
 - Pressure/perfusion study (Whitaker test)
- Therapeutic Indications:
 - Nephrostomy catheter drainage
 - Perfusion chemolysis of renal stones
 - Percutaneous nephrolithotomy
 - Percutaneous resection and coagulation of urothelial tumors

Contraindications

Contraindications can be found in the product labeling supplied with the devices in the kit.

Warnings

- For single use only. Do not reuse, reprocess or resterilize.

Warnings can be found in the product labeling supplied with the devices in the kit.

Potential Adverse Events

Potential Adverse Events can be found in the product labeling supplied with the devices in the kit.

Precautions

Precautions can be found in the product labeling supplied with each device.

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

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