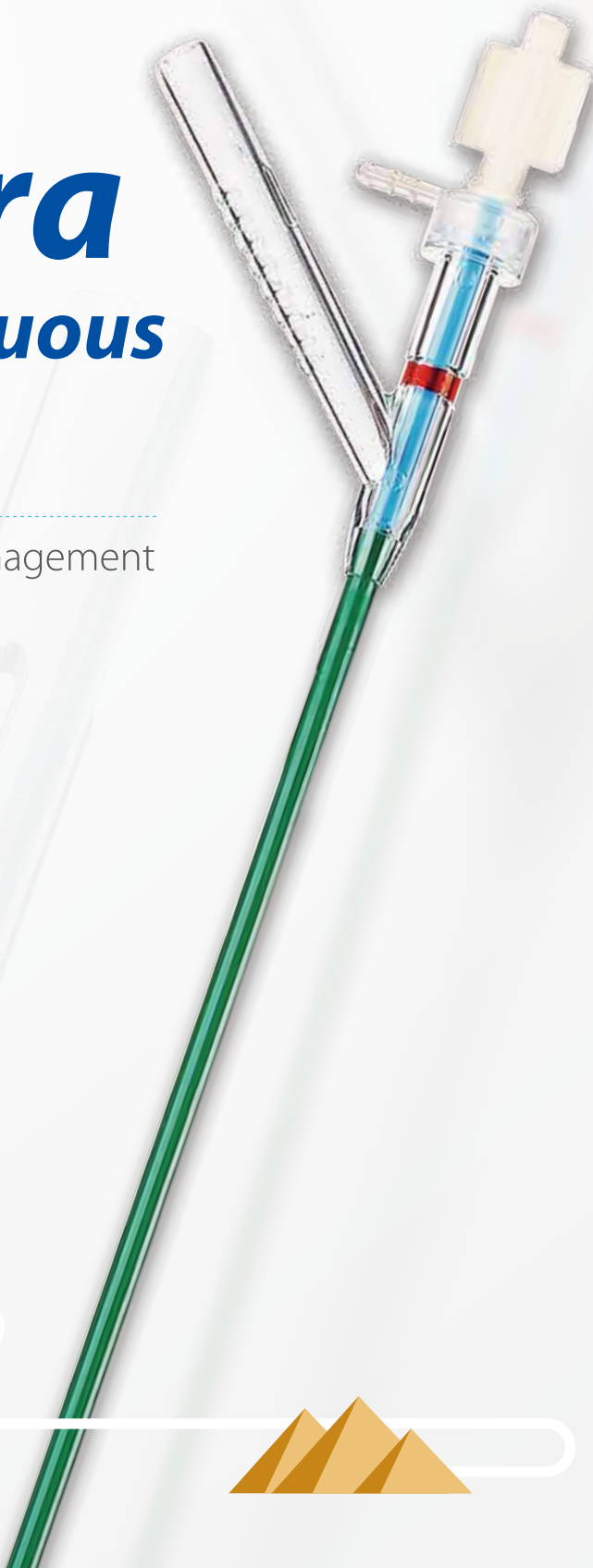


ClearPetra

System for Continuous Flow Lithotripsy

Revolutionary Technology in Stone Management

US Design Patent: US D715, 921 S
US Utility Patent: US 14/341, 905.



wellead

PROBLEMS DURING ENDOSCOPIC LITHOTRIPSY

Stone
retropulsion

Obscured
visual field

Difficulties
in extracting
residual stone
fragments

High
intra-luminal
pressure in
the urinary
tract

The ClearPetra System for Continuous Flow Lithotripsy of Well Lead Medical is designed for the effective and efficient treatment of urinary stones using **Negative Pressure Aspiration** through an oblique side port on the ClearPetra sheath. It has high stone clearance rate, reduces the intra-luminal pressure in the urinary tract, prevents stone retropulsion, improves visual field, obviates the need of stone baskets, forceps, or any anti-retropulsion devices, and saves operating time¹.

INDICATIONS

ClearPetra Ureteral Access Sheath

Use for renal stones, ureteral stones, ureteral steinstrasse

ClearPetra Nephrostomy Sheath

Use for renal stones and upper ureteral stones

ClearPetra Cystoscope Sheath

Use for bladder stones

Stone Collection Bottle

Use for collecting stones



BENEFITS

1 Reduces Intra-luminal Pressure

A vortex is created by the continuous irrigation and suction. It reduces the operational (intra-luminal) pressure and reduces the risk of surgery.

2 No More Stone Retropulsion

Effectively prevents retrograde stone migration with **Negative Pressure Aspiration** and at the same time removes the stone fragments.

3 Improved Visual Field

Under the continuous irrigation and suction, bleeding and dust storm from stone pulverization no longer obscure the visual field.

4 Improved Stone Clearance

Stone fragments will aggregate at the distal end of the ClearPetra sheath instead of scattering and are removed through the oblique side port on the ClearPetra Sheath by the continuous suction.

5 No Accessory Device Required

Stone baskets, forceps, and anti-retropulsion devices are no longer necessary. Under the Negative Pressure Aspiration, the stone fragments are evacuated spontaneously.



Instruction for Use

- 1 Advance the ClearPetra sheath over a guide wire until it is within 1 cm of the stone or steinstrasse. Remove the obturator and place the rubber cap onto the proximal straight end.
- 2 Connect the oblique tube of the ClearPetra sheath to a negative pressure aspirator or to the stone collection bottle with the clear tubing (packed separately) then onto the negative pressure aspirator. Activate the suction at continuous mode and maintain the pressure at 150 - 200 mm Hg.
- 3 Insert the endoscope through the center aperture of the rubber cap and turn on the continuous pressurized irrigation at a flow of 50 to 100 cc per minute. Advance the scope to the stone or the steinstrasse. Commence the lithotripsy using a Holmium-YAG Laser or pneumatic lithotripter. We recommend using a higher frequency and lower energy setting on the laser for finer stone fragmentation.
- 4 When using the ClearPetra sheath, the negative aspiration pressure can be adjusted using the pressure vent on the oblique side port of the sheath, or the pressure control knob located on the egress tube of the stone collection bottle.



During the process of lithotripsy, the stone fragments tend to aggregate at the distal opening of the ClearPetra sheath. The small stone fragments will exit in the space between the scope and the ClearPetra sheath. With larger fragments that are small enough to come into the ClearPetra sheath but too large to pass in the space between the scope and the ClearPetra sheath, withdraw the scope slowly to just proximal to the bifurcation (the red band) of the ClearPetra sheath. This will open up an unimpeded channel to the oblique tube to allow evacuation of the larger stone fragments.

- 5 After the surgery is completed, turn off the perfusion equipment and the negative pressure aspirator. Send the stone collection bottle with stone fragments to the laboratory for urinary stone analysis.

NOTICES

- Use endoscopes at least 3 Fr smaller and 7 cm longer than the ClearPetra sheath
- Make sure the tip of the ClearPetra sheath is within 5-10 mm distance of the stone
- Set the continuous negative aspiration at 150-200 mm Hg pressure
- Set the continuous pressurized irrigation at 50-100 cc per minute
- Turn on the suction before the pressurized irrigation

Example of Procedures with the ClearPetra Sheaths

Flexible ureteroscopy and Holmium Laser Lithotripsy with the ClearPetra Ureteral Access Sheath in a patient with renal stones of 20 x 25mm²



Advancing the ClearPetra sheath over a guide wire



Removing the obturator; commencing lithotripsy using a holmium laser. Stone dust exited the space between the scope and the ClearPetra sheath.



Placement of a Double-J stent after removal of the ClearPetra sheath

If any misunderstanding occurs due to print failure or misunderstanding of the content, Well Lead reserves the right of final explanation.

References

- 1 Guohua Zeng, Dong Wang, Tao Zhang, Shaw P Wan. Modified Access Sheath for Continuous Flow Ureteroscopic Lithotripsy: A Preliminary Report of a Novel Concept and Technique. *Journal of Endourology* 2016 09 24; 30(9):992-6.
- 2 Ghani KR, Sammon JD, Bhojani N et al. Trends in percutaneous nephrolithotomy use and outcomes in the United States. *J Urol* 2013; 190:558-64
- 3 Zeng G, Mai Z, Zhao Z et al. Treatment of upper urinary calculi with Chinese minimally invasive percutaneous nephrolithotomy: a single-center experience with 12,482 consecutive patients over 20 years. *Urolithiasis* 2013; 41: 225-9
- 4 Desai J, Zeng G, Zhao Z, Zhong W, Chen W, Wu W. A novel technique of ultra-mini-percutaneous nephrolithotomy: introduction and an initial experience for treatment of upper urinary calculi less than 2 cm. *Biomed Res Int* 2013; 2013: 490793
- 5 Zeng, G., Wan, S., Zhao, Z., Zhu, J., Tuerxun, A., Song, C., Zhong, L., Liu, M., Xu, K., Li, H., Jiang, Z., Khadgi, S., Pal, S. K., Liu, J., Zhang, G., Liu, Y., Wu, W., Chen, W. and Sarica, K. (2016), Super-mini percutaneous nephrolithotomy (SMP): a new concept in technique and instrumentation. *BJU International*, 117: 655-661. doi: 10.1111/bju.13242
- 6 Zanetti, S. et al. Innovations in endourology: A closed-circuit vacuum-assisted mini-PCNL system. *European Urology Supplements*. 17 (2018) Volume 17, Issue 8. 263
- 7 Fontana, Matteo & Zanetti, Stefano & De Lorenzis, Elisa & Lorusso, V & Morelli, M & Sampogna, Gianluca & Luzzago, Stefano & Sabatini, I & Gallioli, Andrea & Boeri, Luca & Palmisano, F & Piccoli, M & Albo, Giancarlo & Longo, F & Montanari, Emanuele. (2019). First experience with vacuum-assisted mini percutaneous nephrolithotomy (vmPCNL): Preliminary results. *European Urology Supplements*. 18. e22-e23. 10.1016/S1569-9056(19)30017-X.
- 8 Zanetti, Stefano & Sampogna, Gianluca & Fontana, Matteo & De Lorenzis, Elisa & Gallioli, Andrea & Lorusso, V & Morelli, M & Boeri, Luca & Longo, F & Albo, Giancarlo & Montanari, Emanuele. (2019). Semi-closed circuit vacuum-assisted mini-percutaneous nephrolithotomy with holmium laser lithotripsy. *European Urology Supplements*. 18. e2247. 10.1016/S1569-9056(19)31629-X.
- 9 Sampogna, Gianluca & Zanetti, Stefano & Berrettini, Alfredo & Gnech, M & Gianantonio, Manzoni & Montanari, Emanuele. (2019). Closed-circuit vacuum-assisted miniperc system for kidney stones in children: Our initial experience. *European Urology Supplements*. 18. e575-e576.
- 10 Giusti G, Piccinelli A, Taverna G, Benetti A, Pasini L, Corinti M, et al. Miniperc? No, thank you! *Eur Urol*.2007;51:810-4.
- 11 Available at: <http://www.shippertmedical.com/UserFiles/File/Timesaving.pdf>. Accessed January 14, 2010.

The ClearPetra Nephrostomy Sheath improves the stone clearance in percutaneous nephrolithotomy (PCNL), shortens treatment time, and lowers the incidence of complications.

Table 1 Comparison of different procedures of PCNL

OR Time (min)	Tract size	Visualization	Intra-luminal Pressure	Egress of stone fragments	Advantage	Short coming
PCNL ^[2]	30Fr	good	negative	Active	Easiest in stone fragments retrieval	More invasive and higher risk of bleeding
MPCNL ^[3]	<18Fr	+/-	+/-	Passive	Less invasive, less risk of bleeding	Stones are retrieved using pressurized irrigation or stone forceps
UMP ^[4]	12-14Fr	+/-	+/-	Passive	Least invasive and minimum risk of bleeding	Longer operating time. Stone are removed using pressurized irrigation
SMP ^[5-9] with modified Sheaths with Suction-Evacuation Function	12-14Fr	good	negative	Active	Least invasive, minimum bleeding, shorter operating time, stones are removed using suction	

ClearPetra can save cost by reducing the operating time.

Table 2 Comparison of operating time of PCNL

OR Time (min)	Mean stone Size & Procedure
155.5 +/- 32.9	<2cm, MiniPerc ^[10]
45.6 (25 – 115)	2.2cm, SMP with ClearPetra ^[11]
109.9	Average OR Time Saving
@ US\$62	Cost of OR per minute ^[11]
US\$6,813.80	Approximate Average Cost Saving

The ClearPetra Ureteral Access Sheath makes ureteroscopic lithotripsy (URS) simpler, safer, faster and cost effective.

Table 3 Comparison of cost of URS

Conventional URS		URS with ClearPetra Sheath	
Instruments needed	Cost	Instruments needed	Cost
Access Sheath		ClearPetra Sheath ONLY	
Stone Basket			
Anti-retropulsion device			

Please fill in the cost and see how much the ClearPetra sheath can save!

ClearPetra Ureteral Access Sheath

Cat. No.	ID/OD×Length	Cat. No.	ID/OD×Length	Cat. No.	ID/OD×Length
90111013	10/12Fr × 13cm	90111146	11/13Fr × 46cm	90111336	13/15Fr × 36cm
90111026	10/12Fr × 26cm	90111155	11/13Fr × 55cm	90111340	13/15Fr × 40cm
90111036	10/12Fr × 36cm	90111213	12/14Fr × 13cm	90111346	13/15Fr × 46cm
90111040	10/12Fr × 40cm	90111226	12/14Fr × 26cm	90111355	13/15Fr × 55cm
90111046	10/12Fr × 46cm	90111236	12/14Fr × 36cm	90111413	14/16Fr × 13cm
90111055	10/12Fr × 55cm	90111240	12/14Fr × 40cm	90111426	14/16Fr × 26cm
90111113	11/13Fr × 13cm	90111246	12/14Fr × 46cm	90111436	14/16Fr × 36cm
90111126	11/13Fr × 26cm	90111255	12/14Fr × 55cm	90111440	14/16Fr × 40cm
90111136	11/13Fr × 36cm	90111313	13/15Fr × 13cm	90111446	14/16Fr × 46cm
90111140	11/13Fr × 40cm	90111326	13/15Fr × 26cm	90111455	14/16Fr × 55cm

ClearPetra Nephrostomy Sheath

Cat. No.	ID/OD×Length	Cat. No.	ID/OD×Length	Cat. No.	ID/OD×Length
90121013	10/12Fr×13cm	90121613	16/18Fr×13cm	90122213	22/24Fr×13cm
90121015	10/12Fr×15cm	90121615	16/18Fr×15cm	90122215	22/24Fr×15cm
90121017	10/12Fr×17cm	90121617	16/18Fr×17cm	90122217	22/24Fr×17cm
90121021	10/12Fr×21cm	90121621	16/18Fr×21cm	90122221	22/24Fr×21cm
90121213	12/14Fr×13cm	90121813	18/20Fr×13cm	90122413	24/26Fr×13cm
90121215	12/14Fr×15cm	90121815	18/20Fr×15cm	90122415	24/26Fr×15cm
90121217	12/14Fr×17cm	90121817	18/20Fr×17cm	90122417	24/26Fr×17cm
90121221	12/14Fr×21cm	90121821	18/20Fr×21cm	90122421	24/26Fr×21cm
90121413	14/16Fr×13cm	90122013	20/22Fr×13cm	90122613	26/28Fr×13cm
90121415	14/16Fr×15cm	90122015	20/22Fr×15cm	90122615	26/28Fr×15cm
90121417	14/16Fr×17cm	90122017	20/22Fr×17cm	90122617	26/28Fr×17cm
90121421	14/16Fr×21cm	90122021	20/22Fr×21cm	90122621	26/28Fr×21cm

ClearPetra Cystoscope Sheath

Cat. No.	ID/OD×Length	Cat. No.	ID/OD×Length	Cat. No.	ID/OD×Length
90131821	18/20Fr × 21cm	90132021	20/22Fr × 21cm	90132221	22/24Fr × 21cm
90131824	18/20Fr × 24cm	90132024	20/22Fr × 24cm	90132224	22/24Fr × 24cm

Stone Collection Bottle

Cat. No.	Size (ml)
79880200	200ml for 10Fr-22Fr sheath
79880140	140ml for 10Fr-22Fr sheath
79880141	140ml for 24Fr and 26Fr Sheath

WELL LEAD MEDICAL CO., LTD.

Address: 47 Guomao Avenue South, Panyu, Guangzhou, China

Tel: +86-20-84758878 Fax: +86-20-84758224 Post Code: 511434

www.welllead.com.cn www.clearpetra.com e-mail: clearpetra@welllead.com.cn



wl.clearpetra.v1.190413