Safety and Device Performance of the Uriprene® Degradable Temporary Ureteral Stent Following Uncomplicated Ureteroscopy

NCT04565795

Status	RECRUITING
Phase	Not Applicable
Sponsor	Adva-Tec
Enrollment	87 participants

Key Eligibility Criteria

Inclusion (5)

- Subjects who are \>21, \<80 years of age; inclusive of males and females.
- Subjects with unilateral ureteral or renal stones who have undergone a successful, uncomplicated ureteroscopy (UURS).
- Subjects with asymptomatic, contralateral renal stones in sizes \<4mm WHICH ARE NOT IN THE RENAL PELVIS OR URETER and who have had uncomplicated ureteroscopy (UURS) can be included. If, during the course of treatment of the target ureter with the Uriprene stent the patient's asymptomatic stone becomes symptomatic and requires treatment, the patient can only be managed with standard of care treatment including the use of an approved ureteral stent, if necessary.
- Subjects with a height and body size able to accommodate a 20, 22, 24, 26, 28, or 30 mm long ureteral stent, as judged by the Investigator.
- Subjects with the ability to understand the requirements of the study, who have provided written informed consent, and are willing to undergo all follow-up assessments according to the specified schedule.

Exclusion (21)

- Subjects with a history of an anatomical abnormality of the urinary tract.
- Presence of ureteral fistula.
- Presence of urothelial cancer, ureteral tumor, or renal tumor.
- Presence of extrinsic compression of the ureter.
- Presence of ureteral blockage or stricture.

... and 16 more (see full listing online)

Locations (4 total)

Mayo Clinic Arizona, Phoenix, Arizona, United States
University of California Los Angeles, Los Angeles, California, United States
University of Florida, Gainesville, Florida, United States
... and 1 more locations