Statistical Analysis Plan

Version AA

A prospective, multi-center, single-arm study to evaluate the safety and efficacy of LithoVue ureteroscope system in Chinese patients with urinary disease

LithoVue Ureteroscope System

Study Reference Number U0628

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Revision History

Revision Number	Section	Change	Reason for Change

ABBREVIATIONS

CFDA	**China Food and Drug Administration**
SAP	**Statistical Analysis Plan**
qSOFA	**Quick Sepsis Related Organ Failure Assessment**
SIRS	**Systemic inflammatory response syndrome**
LCI	**Lower bound of the confidence interval**
SD	**Standard Deviation**
MedDRA	**Medical Dictionary for Regulatory Activities**
CRO	**Clinical research organization**
KUB X-ray	**Kidney Ureters Bladder X-ray**

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1. PROTOCOL SYNOPSIS

<table>
<tr><td colspan="2">A prospective, multi-center, single-arm study to evaluate the safety and efficacy of LithoVue ureteroscope system in Chinese patients with urinary disease LithoVue China Study</td></tr>
<tr><td>Study Objective</td><td>The aim of this study is to evaluate the safety and efficacy of LithoVue ureteroscope system in Chinese population, to support the regulatory approval by CFDA</td></tr>
<tr><td>Study Device</td><td>LithoVue Ureteroscope system (including Flexscope catheter and workstation)
<table><tr><td colspan="2">LithoVue Flexscope</td></tr><tr><td>• LithoVue Standard</td><td>M0067913500</td></tr><tr><td>• LithoVue Reverse</td><td>M0067913600</td></tr><tr><td colspan="2">LithoVue System Workstation</td></tr><tr><td>• LithoVue System Work station</td><td>M0067911200</td></tr></table></td></tr>
<tr><td>Planned Indication (s) for use</td><td>The LithoVue System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract</td></tr>
<tr><td>Device Specifications</td><td>The LithoVue System is a software-controlled digital flexible ureteroscope system that consists of the LithoVue System Workstation (Touch PC and Cart) and the LithoVue Single-Use Digital Flexible Ureteroscope (sterile, single-use disposable) catheter.
The LithoVue Single-Use Digital Flexible Ureteroscope catheter is a sterile, single-use device comprised of two main components: a handle with articulation controls and accessory access ports, and a flexible shaft portion.</td></tr>
<tr><td>Study Design</td><td>Prospective, multicenter, single-arm, pre-market study</td></tr>
<tr><td>Sample size</td><td>LithoVue China study will enroll 60 patients. The enrolling cap for each participates center is 40 patients.
All procedures in each participate center should be solely performed by experienced urologist who is skilled at therapeutic urology cases.</td></tr>
<tr><td>Sample size parameters</td><td>Considering from the specified formula and reference parameters the proportion considerations defined to P_1 :0.95, P_o :0.85, one-sided α :0.05, β :0.20 (power at 80%) achieved a sample size of 60</td></tr>
</table>

	subjects. Since the primary endpoint is captured in ureteroscope procedures, it's not necessary to consider attrition rate.
Total Sites	Three (3) investigational sites in China.
Primary Endpoint	Procedure success rate of LithoVue ureteroscope system Procedure success is defined as, scope condition is suitable to complete the procedure and not requiring immediate scope substitution; it is also considered as a procedure success if the clinical effect is the same as that from the LithoVue scope per investigator's judgement in the case of a scope change (non-LithoVue).
Secondary Endpoint	• Procedure routes: transurethral or percutaneous access • Target lesion's size and location • Procedure time: defined as the time between LithoVue catheter insertion and removal • Hospitalization time: defined as the time between patient admission and discharge • Stone clearance rate: clearance is defined as stone free or residual stone's diameter≤4mm on KUB and urinary CT at 4W post procedure. • Complication (Clavein-Dindo classification): a. Fever(>38.5o) b. Urinary tract infection requiring additional antibiotics (routine antibiotics is within 48 hours post procedure) c. Urinary sepsis, defined as infection and qSOFA score ≥2. (qSOFA score includes a. Change of consciousness (Glasgow score < 13) b. Systolic blood pressure ≤ 100 mmHg c. Respiratory frequency ≥22 times / min) d. Ureteral injury (moderate, medium and severer) e. Bleeding requiring transfusion f. Perirenal hematoma g. Steinstrasse h. Severe abdominal pain (requires additional hospitalization treatment or prolonged hospitalization time) • Image quality: Very good, good, fair, poor, bad • Maneuverability: Very good, good, fair, poor, bad Surgeon's overall satisfaction: Very good, good, acceptable, poor, bad
Study Enrollment	The enrollment cap for each participating center is 40 patients
Follow-up Plan	Follow up points are 48±24 hours post proced ure, 4W±7 days post

	procedure. Follow-up tests for 4W±7 days post procedure includes: Hospitalization time, Urinary CT and KUB, Stone clearance, Surgeons satisfaction score and Adverse events summary
Study Duration	The study is expected to last 9 months after first subject enrollment.
Inclusion Criteria	1. Willing and able to provide written informed consent to participate in the study. 2. Willing and able to comply with the study procedures. 3. Diagnosed as urinary disease and indicated for flexible ureteroscope procedures 4. For stone cases, the diameter of stones is less than or equal to 2cm in order to avoid staged procedures
Exclusion Criteria	1. Surgeries are contraindicated. 2. Flexible ureteroscope procedure is contraindicated 3. Based on doctor's evaluation, the patient's medical condition doesn't fit for this study 4. For stone case, the diameter of stones is greater than 2cm. 5. Women of childbearing potential who are or might be pregnant at the time of this study.
Statistical Methods	
Primary statistical hypothesis	The Procedure success rate of LithoVue ureteroscope system is the primary endpoint. Published literature result regarding this index is 95.6%. Based on previous clinical experience in China, the rate should be more than 85%. So, 85% is chosen as the objective performance value. The expected success rate is 95% based on investigator's decision. The primary objective is met if the lower bound of the confidence interval (LCI) is greater than the PG
Statistical Test method	The procedure success rate and other index for LithoVue ureteroscope system will be summarized descriptively. Categorical variables will be tabulated with frequencies, percentages and 95% confidence intervals. Continuous variables will be tabulated with mean, median, standard deviation, minimum, maximum, and 95% confidence interval of the mean.

2. INTRODUCTION

This Statistical Analysis Plan (SAP) has been designed and intend to document the planned analyses to be consistent with the objectives study protocol. This is a guiding document for conducting analysis for LithoVue China Study Protocol, 92178272Rev/Ver AA. The specified analyses may be provided in reports to competent authorities and/or for scientific presentations and/or manuscripts.

3. ENDPOINT ANALYSIS

3.1 Efficacy endpoint analysis

The primary and secondary endpoint analysis exhibited based on per protocol analysis and analyzed at LithoVue procedure and during both follow-ups. The two-follow-up period includes 48±24 hours post procedure and 4 weeks ±7 days post procedure.

3.2 Primary endpoint analysis

The primary endpoint analysis is to evaluate the procedure success rate endpoint analysis will be performed using 85% as the performance goal. For procedure success rate, the 90% exact one-sided Clopper-Pearson confidence interval of the proportion will be calculated. The primary objective is met if the Two-sided lower bound of the confidence interval (LCI) of clopper-Pearson at 90% CI is greater than the PG (85%). The endpoint analyzed only during LithoVue procedure timepoint

3.2.1 Primary endpoint considerations

Procedure Success Rate calculated based on efficacy analysis set presenting number of subjects and percentage, presenting 90% Clopper-Pearson confidence interval with one-sided exact binomial confidence bound at 95%.

As per SAS documentation, "*The exact or Clopper-Pearson confidence limits for the binomial proportion are constructed by inverting the equal-tailed test based on the binomial distribution. The exact confidence limits P_L and P_U satisfy the following equations, for:*

$$\sum_{x=n_1}^{n} \binom{n}{x} p_L^x (1-p_L)^{n-x} \qquad \sum_{x=0}^{n_1} \binom{n}{x} p_U^x (1-p_U)^{n-x}$$

The lower confidence limit equals 0 when $n_1=0$, and the upper confidence limit equals 1 when $n_1=n$. PROC FREQ computes the exact (Clopper-Pearson) confidence limits by using distribution as

$$\boldsymbol{P_L} = \left(1+\frac{n-n_1}{(n_1+1)\,F(\,\alpha/2,\ 2(n_1+1),\ 2(n-n_1)\,)}\right)^{-1} \quad \boldsymbol{P_U} = \left(1+\frac{n-n_1+1}{n_1\,F(1-\alpha/2,\ 2n_1,\ 2(n-n_1+1)\,)}\right)^{-1}$$

3.2.2 Success Criteria for Primary Endpoint

LithoVue system will be concluded as meeting PG for device safety if the one-sided lower 95% confidence bound during procedure period is greater than 85%. A glimpse of SAS code in provided in below section 9.2 SAS code for Clopper-Pearson.

3.3 Secondary endpoint analysis

We have multiple secondary endpoint analysis analyzed at three timepoints as specified in protocol.

- Procedure routes based on transurethral or percutaneous access summarized at LithoVue procedure timepoint.
- Target lesion and location measured at LithoVue procedure timepoint.
- Procedure time as defined in protocol, as the time between LithoVue catheter insertion and removal measured during LithoVue procedure.
- The ordinal scoring expressions based on Image quality, Maneuverability and Irritation collected during LithoVue procedure.
- Hospital time information gathered during the second follow-up period after 4 weeks ±7 days post procedure
- Stone clearance rate: clearance is defined as stone free or residual stone's diameter≤4mm on KUB and urinary CT at 4W post procedure
- Surgeon satisfaction score summarized based on ordinal scoring expressions at 4W post procedure
- Complications based on Clavein-Dindo classification are summarized at 48 hrs. post procedure and at 4W post procedure for
    - Fever(>38.5^{o})
    - Urinary tract infection requiring additional antibiotics (routine antibiotics is within 48 hours post procedure)
    - Urinary sepsis (defined as infection and qSOFA score ≥2. (qSOFA score includes
        - Change of consciousness (Glasgow score < 13)
        - Systolic blood pressure ≤ 100 mmHg
        - Respiratory frequency ≥22 times / min)
    - Ureteral injury (moderate, medium and severer)
    - Bleeding requiring transfusion
    - Perirenal hematoma
    - Steinstrasse
    - Severe abdominal pain (requires additional hospitalization treatment or prolonged hospitalization time)

3.3.1 Secondary endpoint considerations

All secondary endpoints include, Procedure routes, Target lesion location, Image quality, Manoeuvrability, Surgeons satisfaction scores which are categorical are summarized using frequency and percentages. Continuous endpoints like target lesion size, procedure time are presented with mean ± SD, with minimum, maximum and counts.

All complication and treatment parameters summarized using counts and percentages as defined in protocol visit time points during procedure, at 2 days after procedure and at 4 weeks after procedure.

Urinary CT and KUB X- ray stone sizes are presented mean ± SD, with minimum, maximum and counts after 4-week post procedure.

Subject hospitalization information is also summarized using counts and percentages with total available subjects at visit.

3.4 Hypothesis

The primary effectiveness hypothesis is to be tested is that the procedure success rate of LithoVue ureteroscope system should be objectively performed more than 85% at a two-sided significance level of 10%.

The null hypothesis (Ho) fixed, as if the procedure success rate achieved after procedure done to the subjects the success rate is less than or equal to 85% and alternative hypothesis (H_a) fixed as procedure success rate is more than 85%. The hypothesis in-equalities defined below:

H_o: $p \leq 85\%$ (not met fixed hypothesis) vs. H_a: $p > 85\%$ (met Hypothesis), where p is the proportion of procedure success, during LithoVue procedure period.

Procedure success is defined as, Scope condition is suitable to complete the procedure and not requiring immediate scope substitution; it is also considered as a procedure success if the clinical effect is the same as that by the LithoVue scope per investigator's judgement in the case of a scope change (non-LithoVue).

For procedure success rate endpoint, the 90% exact Clopper-Pearson confidence interval of the proportion will be calculated and tested with a two-sided P-value at alpha= 10% level of significance.

3.5 Effectiveness sample size

The overall sample size calculated based on primary effectiveness endpoint. Approximately 60 subjects are planned to be enrolled in the single-arm study. Using the below suggested formula for calculating sample size

$$n = \left[\frac{z_\alpha \sqrt{p_0(1-p_0)} + z_\beta \sqrt{p_1(1-p_1)}}{p_1 - p_0} \right]^2$$

The sample size justification is based on the proportions P_1 as 0.95, P_0 as 0.85, fixing Type1 error at 5% and Type2 error at 20% attaining power of 80%.

3.6 Effectiveness Statistical analysis

Procedure success rate endpoint, the 90% exact Clopper-Pearson confidence interval of the proportion will be calculated.

3.7 Safety endpoint analysis

There is no specific safety assessment analysis specified other than Adverse events. However, the safety endpoints are pre-specified in the Safety Plan and will be monitored against the reference rates on a regular basis.

Severe infectious complication includes any of the systemic inflammatory response syndrome (SIRS), urinary sepsis, and septic shock events. Adverse events summarized for all time points including LithoVue procedure period and two-follow-up periods, 48± 24 hours post procedure and 4 weeks ±7 days post procedure .

4. GENERAL STATISTICAL METHODS

4.1 Analysis datasets

Efficacy analysis set will be comprised of all subjects that sheath is accessed into the urinary tract or percutaneous route is established. Safety analysis set will be comprised of all subjects that sheath is accessed into the urinary tract or percutaneous route is established. All analysis is based and presented as mentioned in protocol and check with any outliers exist in the data. All enrolled subjects are included in per-protocol analysis.

We don't have per-protocol population defined as per protocol, so for maintaining consistency we are presenting reports on per-protocol.

4.2 Control of Systematic Error/Bias

Selection of subjects will be made from the Investigators' general or professional referral population. All subjects meeting the inclusion/exclusion criteria and that have signed the protocol-specific ICF will be eligible for enrollment in the trial. Consecutively eligible subjects should be enrolled into the trial to minimize selection bias. In determining subject eligibility for the trial, the investigator's assessment of imaging will be used. However, the MRI core laboratory will independently analyze the images and the data obtained from the core laboratory will be utilized for analyses.

4.3 Enrollment for each Investigative Site

The enrollment cap for each participating center is 40 patients.

4.4 General considerations

All continuous measurements will be summarized descriptively at each visit by treatment using observed data. Endpoints that are analysed untransformed and endpoints that are not formally analysed are summarized by the arithmetic mean, standard deviation (SD), minimum and maximum value with counts (N). Mean and SDs rounded to one decimal, minimum, maximum is presented exact as per the data values.

All categorical variables will be tabulated with frequencies, percentages and presenting 95% confidence intervals as required. The summaries exhibited with frequencies in numerator and total subjects considered in denominator with percentages. All frequency counts presented with exact number and percentages rounded to one decimal.

4.5 Subject disposition

4.5.1 Subject disposition summaries and listings

A subject disposition exhibit will be provided for each site with investigator and institution name with subjects enrolled per site. Only counts are provided in this table.

Subject disposition status for all subjects summarized based on 'Time since index procedure' for pre-defined categories of follow-up period.

Subjects with less than 2 days follow up and at least 2 days follow-up and with at least 7 days, 14 days, 21 days and 35 days follow up durations. Proportion of subject's information presented for this summary based on Number of subjects at a duration point (2, 7, 14, 21, 35 days) with total enrolled subjects with percentages. Duration is calculated based on snapshot date and procedure date.

A table based on Subject Disposition of Clinical Follow-up Compliance will be provided for 2 days after procedure and for 4 weeks after procedure.

A listing for site reported deaths will be presented with subject ID and its relationship with device or procedure, date of death and days from index procedure will be presented.

A standard exhibit based on subject disposition and clinical follow-up compliance is presented for both 48 hr clinical follow-up and 4 week clinical follow-up periods including eligibility, withdrawal reasons, missing information and deaths information.

4.6 Baseline characteristics and Medical History

4.6.1 Baseline and Medical history summaries

All procedure characteristics which are categorical, summarized using counts and percentages with total screening subjects as defined in protocol visit time points during LithoVue procedure time. The continuous endpoints are presented with mean ±SD, with minimum, max imum and counts.

Baseline characteristics like Gender and Race and Urinary System Medical History and Diagnosis are summarized using counts and percentages at screening visit. Continuous endpoints like Age, diameter of stone (mm) and diameter of tumor (mm) are presented with mean ± SD, with minimum, maximum and counts with total screening subjects.

4.7 Analysis of Lab Tests

4.7.1 Lab test summaries

No lab measurements evaluated for this study

4.8 Analysis of Adverse and Serious adverse events

4.8.1 Adverse and serious adverse events summaries and listings

Subject-level event rates will be calculated at various time points (e.g. exact days) based on all events reported by the site regardless of whether they are ultimately adjudicated. Frequency of site reported Serious adverse events and non-serious adverse events are exhibited using counts and percent with total available subjects based on safety population. The events are summarized by MedDRA system organ class and MedDRA system preferred terms with events and rates. These tables are presented by “Related to device”, “Related to procedure” and for Total Serious and Non-Serious adverse events.

A listing provided based on site reported AE in connecting to study device and study procedure and duration of events from onset date to procedure date. with the other AE exhibits with AE term, AE date and duration days will be provided. Another listing based on unanticipated device effects also presented in connecting to study device and study procedure and duration of events from onset date to procedure date. with the other AE exhibits with AE term, AE date and duration days for both onset and resolution will be provided with outcome and seriousness consideration.

For calculating events and rates, need to consider ‘Events numbers’ are total episodes of each type of event among all subjects. ‘Rate of Subjects with Event’ numbers are percent of subjects who experienced one or more episodes of the event. ‘Events’ numbers for “TOTAL” are the sum of the individual event category totals. ‘Rate of Subjects with Event’ numbers for “TOTAL” is the percent of subjects who experienced an adverse event.

5. ADDITIONAL STATISTICAL ANALYSIS

5.1 Other additional analysis

5.1.1 *Device Deficiencies*

A table exhibited based on device deficiencies with count and percent for the available parameters and a supported listing also provided by subject, deficiency type, and if its leading to any event and preventive action taken for that.

5.1.2 *Protocol deviations*

A summary table for Deviations from Investigational Protocol collated during procedure and post procedure for all the planned events as specified in protocol.

- Adverse Event
- Device Deficiency
- End of Treatment
- End of Study
- Informed Consent
- Procedure
- Screening/Baseline
- 48(±24) hours Visit
- 4 weeks (±7 Days) Visit

A summary table by protocol deviation are summarized with counts and percent with total available subjects and each subject is counted only once under a deviation category irrespective of their visits/required procedures/assessments.

A connected listing will be provided by subject with deviation, reason, visit and assessment/procedure requirement during the study.

5.2 Interim Analysis

No interim analysis planned for this study

5.3 Subgroup Analysis

No sub-group analysis planned for this study as per the current considerations. Will update in SAP Amendment if required.

5.4 Justification for pooling

No pooling of categories planned for the study.

6. ANALYSES SOFTWARE

All statistical analyses will be performed and validated by the independent CRO (e.g. IQVIA in Bangalore) using the Statistical Analysis Software (SAS), version 9.2 or later (Copyright © 2002-2010 by SAS Institute Inc., Cary, North Carolina 27513, USA. All rights reserved). BSC will review statistical reports.

7. CHANGES TO PLANNED ANALYSES

Any changes to the planned statistical analyses made prior to performing the primary endpoint analysis will be documented in an amended Statistical Analysis Plan approved prior to performing the analysis. Changes from the planned statistical methods after performing the analysis will be documented in the clinical study report along with a reason for the deviation.

8. VALIDATION

All clinical data reports generated per this plan will be validated per 90702587, Global WI: Clinical Data Reporting Validation. Statistical analyses and validation will be done by IQVIA ™.

9. PROGRAMMING CONSIDERATIONS

All statistical programming tasks will be performed by IQVIA™ independently.

9.1 Derivation of Variables

The number of subjects included in the event rates (overall and individual components) will be based on subjects who have adequate follow-up and/or have experienced any component of events within the analysis interval.

The last follow-up date will be the latest of the following dates for each subject: onset date of an event, treatment evaluation follow-up dates, end of study date, end of treatment date, and follow-up visit dates.

9.2 Methods for Handling Missing Data

All subjects who are enrolled will be eligible for evaluation. Adjustments for missing outcomes data will be performed if deemed necessary to eliminate or minimize bias and will be described completely. All data will be included in the analysis unless judged to be invalid.

When calculating rates of adverse events, missing and partial dates will be handled as shown in the table below.

Partial Date	Action taken
Entire adverse event onset date is missing	The procedure date will be used for the onset date.
The month and the day of the month are missing but the year is available	January 1st will be used for the month and day of the onset date. However, if the imputed date falls before the procedure date, then the procedure date will be used for the onset date.
Day is missing, but the month and year are available	The 1st will be used as the day of the onset date. However, if the imputed date falls before the procedure date, then the procedure date will be used for the onset date.

9.3 Rules and Definitions

For baseline categorical variables, missing values will not be counted in rate denominators.

9.4 SAS code for Clopper-Pearson

The confidence intervals for Clopper-Pearson and binomial proportion of CI are produced using PROC FREQ procedure. Below is a glimpse of sample code to extract the required values.

For example, the worst-case scenario in the PG testing of the primary endpoint hypotheses is used for the exercise. A dummy frequency table is coded as below:

```
data main;
        input code $4. count;
        datelines;
yes 56
no  4
;
run;

proc freq data=main order=freq;
        tables code / binomial (exact p=0.85) alpha=.1;
        tables code / binomial (cl=Wald p=0.85) alpha=.05;
        title "Procedure success rate of enrolled subjects";
        weight Count;
run;
```

The SAS code is presented for the binomial proportion for PG>85% with 90% Clopper-Pearson confidence intervals is specified. The use of ORDER=FREQ, in the SAS program, keep the

highest frequency of success/failure as base and option binomial (EXACT) with alpha=0.1 will generate 90% Clopper-Pearson Confidence limits. We also get Wald's (Asymptotic) 95 % Confidence limits for 0.85 proportion that need to present in the exhibit.

Procedure success rate of enrolled subjects

The FREQ Procedure

code	Frequency	Percent	Cumulative Frequency	Cumulative Percent
yes	56	93.33	56	93.33
no	4	6.67	60	100.00

Binomial Proportion	
code = yes	
Proportion	0.9333
ASE	0.0322

Confidence Limits for the Binomial Proportion		
Proportion = 0.9333		
Type	90% Confidence Limits	
Clopper-Pearson (Exact)	0.8539	0.9769

Test of H0: Proportion = 0.85	
ASE under H0	0.0461
Z	1.8078
One-sided Pr > Z	0.0353
Two-sided Pr > |Z|	0.0706

Sample Size = 60

code	Frequency	Percent	Cumulative Frequency	Cumulative Percent
yes	56	93.33	56	93.33
no	4	6.67	60	100.00

Binomial Proportion	
code = yes	
Proportion	0.9333
ASE	0.0322

Confidence Limits for the Binomial Proportion		
Proportion = 0.9333		
Type	95% Confidence Limits	
Wald	0.8702	0.9965

Test of H0: Proportion = 0.85	
ASE under H0	0.0461
Z	1.8078
One-sided Pr > Z	0.0353
Two-sided Pr > |Z|	0.0706

Sample Size = 60

By using formula also, we can test but it can minor difference in slope nearby values due to rounding issues from SAS automations.

```
 data test;
  input n n1 alpha;
  phat = n1/n;
  fvalue1 = finv((alpha/2), 2*n1, 2*(n-n1));
  fvalue2 = finv( (1-alpha/2), 2*(n1+1), 2*(n-n1));
  pL = (1+   ((n-n1+1)/(n1*fvalue1) ))**(-1);
  pU = (1+  ((n-n1)/((n1+1)*fvalue2) ))**(-1);
datelines;
60 56 0.10
;

proc print;
run;
```