Boston Scientific Double-J PLUS Ureteral Stent Postmarket Patient Registry

DJUS-PLUS Registry
U0652
CLINICAL INVESTIGATION PLAN

Sponsored By

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Original Release: December 3, 2019

Current Version: September 15, 2021

Revision Version	Protocol Date	Template number and version	Protocol Section Modified	Summary of Changes	Justification for Modification
Revision A (initial)	December 3, 2019	**92120219_ Rev/Ver C**	**N/A**	**N/A**	**Initial Release**
Revision B	June 2, 2020	**92120219_ Rev/Ver C**	**Contact Information**	**Contact Information:** Removed Jennifer Saunders.	**Contact Information:** Updated section for accuracy (Clinical Contact only).
			Section 2. Protocol Synopsis; **Section 5.1 Commercial Device;** **Section 7.1 Scale and Duration**	**Device/System applied as standard of care: Removed** Double-J Ureteral Stents: Ascerta, Mardis Soft, and Stretch VL Flexima and modified/added Tria to Tria Soft and Tria firm.	The stents removed are no longer in production and therefore will not be studied in this registry. Tria stents were separated to Tria Soft and Tria Firm for clarity.
			Section 2. Protocol Synopsis; **Section 7.1 - Figure 7.1**	**Study Design Chart: Modified** planned indwell time flow chart	The flow chart was updated for clarity.
			Section 2. Protocol Synopsis; **Section 6 – Study Objectives and Endpoints; Section 11.3.1.2 Additional Endpoint 2 – Ureteral Stent Migration**	Stent Migration: Confirmed via imaging Changed to **Stent Migration: defined as any post procedure movement of the stent (either proximally towards the kidney or distally towards the bladder or complete distal migration) from its implant location; confirmed via imaging where necessary**	Stent migration definition was added to provide clarity.

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				"Note: External force or inadvertently pulled stents are not considered Stent migration."	
			Section 2. Protocol Synopsis; Section 10.6 – Post procedure follow-up	Post-Procedure (if Long term indwell of > 90 days): ≤ 90 days from Index Procedure Changed to **Post-Procedure** Follow-up Visit **(if Long term indwell of** greater than **90 days): ≤ 90 days from Index Procedure**	Post Procedure language modified to clarify the requirement.
			Section 2. Protocol Synopsis; Section 11.1.1.2 Sample size; 11.1.1.3 Statistical Methods	Statistical Test Method: Added "Only stents placed at least 12 hours will be included in the analysis". Sample Size Parameters Assuming that the Tria™ stent technical success rate is 94% for Stone Management, a sample size of 127 subjects with Tria™ placed for Stone Management is required to attain 90% power to demonstrate the primary hypothesis at the 2.5% significance level(one-sided). Approximately 142 Stone Management subjects with Tria™ stent procedures will be required to allow for 10% subject attrition Changed to Assuming that the Tria™ stent technical success rate is 94% for Stone Management, a sample size of 127 subjects with Tria™ placed **at least 12 hours** for Stone Management is required to attain	Criteria added to determine when to include stents in analysis. Language was added to define the criteria for stent indwell time.

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				90% power to demonstrate the primary hypothesis at the 2.5% significance level(one-sided). Approximately 142 Stone Management subjects with Tria™ stent procedures **where stents indwell at least 12 hours** will be required to allow for 10% subject attrition	
			Section 6 Study Objectives and Endpoints	Primary efficacy endpoint: Technical Success of the stents Changed to Primary efficacy endpoint: Technical Success of the stents **defined as Stented kidney drains (to bladder) during the planned indwell time with no re-intervention due to obstruction of the stented ureters**	Technical success of the stents defined to provide clarity.
			Table 10.1: Data Collection Schedule	Modified table to reflect changes presented in sections below.	The Screening/Enrollment and Baseline requirements have been modified to allow for data to be captured prior to the index procedure
			Section 10.4 Screening Assessments/Procedures	The Screening/Enrollment may occur prior to the Baseline Visit. At this visit, the assessments below must be completed Changed to The Screening/Enrollment and Baseline visit may occur on the same day or on different days. The following must be completed prior to collecting baseline data described in section 10.5	**The Screening/Enrollment and Baseline requirements have been modified to allow for data to be captured prior to the index procedure**

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			10.5 Baseline Visit	The assessments below must be completed prior to index procedure. **This visit may be combined with the Screening/Enrollment Visit** and may occur up to 45 calendar days prior to index procedure. Changed to **The assessments below must be completed prior to index procedure and may occur up to 45 calendar days prior to index procedure.**	**The Screening/Enrollment and Baseline requirements have been modified to allow for data to be captured prior to the index procedure.**
			10.5 Baseline Visit	Urinalysis/culture: UTI status, Pregnancy test for women of child bearing age **(if collected as SOC)** Changed to **Urinalysis/culture: UTI status, Pregnancy test for women of child bearing potential**	Pregnancy test is required to collect prior to the index procedure.
			10.5 Baseline Visit	**Added:** Physical examination: Height, Weight, BMI, Temperature QoL Questionnaires (PROMIS): • Adult Short Form v1.0 – Pain Intensity 3a Adult Short Form v1.0 – Pain Interference 6b	The Baseline visit requirements have been modified to allow for data to be captured prior to the index procedure
			10.6 Index Procedure (Double-J Ureteral Stent Placement)	**Added:** **Note: Baseline visit information may be collected on same day, prior to the index procedure"**	Providing further clarification on the data collection schedule; collecting time of the stent placement to determine the 12

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				After the index procedure, the following data will be collected: Stent Information – type, size, stent laterality (left or right), unilateral or bilateral Changed to After the index procedure, the following data will be collected: • **Stent Information – type, size, stent laterality (left or right), unilateral or bilateral,** time of stent placement	hour minimum stent placement time.
			10.7 Post-procedure Follow-up (if Long term indwell of > 90 days)	Section Header Post-procedure Follow-up (if Long term indwell of > 90 days) **– on or before 90 days from index procedure as indicated in individual stent DFU** Changed to **Post-procedure Follow-up (if Long term indwell of > 90 days)**	Providing further clarification on the post procedure follow-up schedule, visit window and when is visit not required.
			10.7 Post-procedure Follow-up (if Long term indwell of > 90 days)	Stent indwell time should be per individual DFU. The subjects should be followed in clinic on or before 90 days from index procedure if stent is not explanted and planned for a long term indwell. During this visit the following data will be collected. Changed to Stent indwell time should be per individual **IFU/DFU**. **If indwell of greater than 90 days is planned, a post-procedure follow-up should be completed between**	Providing further clarification on the post procedure follow-up schedule, visit window and when is visit not required.

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				45 - 90 days from index procedure as indicated in individual stent IFU/DFU. The subjects should be followed in clinic for the following data collection. Added: If indwell of less than 90 days is planned, a post-procedure follow-up is not required.	
			10.8 Stent Removal Visit (maximum indwell time as indicated in individual stent IFU/DFU)	At the stent removal visit, The following assessments must be performed, and data points collected: • Stent performance assessment enroll, was technically successful • Stent explant – explant successful Changed to At the stent removal visit, **the** following assessments must be performed, and data points collected: • Stent performance assessment – performed as indicated during the planned indwell time, **as assessed by study physician** Stent explant – explant successful; **time of explant**	Providing clarification that stent performance assessment should be completed only by physician participating in the study. Time of explant added to the 12 hour minimum stent placement time

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			10.8 Stent Removal Visit (maximum indwell time as indicated in individual stent IFU/DFU)	• **Added: If stents are removed inadvertently before intended indwell time, a device event assessment should be completed, and post-stent removal visit should be completed as indicated in section 10.9 and schedule of events table.**	Providing clarification on data collection
			11.1.1.3 Statistical Methods	For **each other** Double-J ureteral **stent** in the study, the technical success rates will be summarized by descriptive statistics including 95% confidence intervals by indication (i.e. stone management, benign obstruction, and malignant obstruction) respectively. Changed to For **non Tria™** Double-J ureteral **stents** in the study, the technical success rates will be summarized by descriptive statistics including 95% confidence intervals by indication (i.e. stone management, benign obstruction, and malignant obstruction) respectively **for each device type**.	Clarifying the description of non-Tria stents analysis
			Section 12 Health Economics Outcome	An economics analysis may be executed after the completion of this trial study **depending on the clinical findings**. Changed to **An economics analysis may be executed after the completion of this trial study.**	Deleted ambiguous language

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			Section 18.1 Reportable Events by investigational site to Boston Scientific	It is the responsibility of the investigator to assess and report to BSC any event which occurs in any of following categories: • All Serious Adverse Events • All Device Deficiencies • **All Device Related Adverse Events** (including Study Stent implant and explant related events) Changed to It is the responsibility of the investigator to assess and report to BSC any event which occurs in any of following categories: • All Serious Adverse Events • All Device Deficiencies • **All Adverse Device Effects** • **All Adverse Events related to the Index Procedure (inclusive of Study Stent Implant Procedure) and Study Stent Removal Procedure.** Adverse events to be reported include both anticipated and expected post procedural events, (such as pain, hematuria, urgency, frequency, etc.) in addition to any other unanticipated and unexpected events.	**Providing clarification for Adverse and Device events being collected for the study**

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			Section 18.3 Relationship to Device(s), Index Procedure (including Study Stent Implant Procedure), and Study Stent Removal Procedure	Section Header Relationship to Device(s) Changed to **Relationship to Device(s),** Index Procedure (including Study Stent Implant Procedure), and Study Stent Removal Procedure	**Providing clarification on assessment on AE relationship to device and procedures**
			Section 18.3 Relationship to Device(s), Index Procedure (including Study Stent Implant Procedure), and Study Stent Removal Procedure	The Investigator must assess the relationship of the reportable AE to the device, or procedure, including the study stent removal procedure. Changed to The Investigator must assess the relationship of the reportable AE to the device, **or Index procedure (including Study Stent Implant Procedure),** and the study stent removal procedure.	**Providing clarification on assessment on AE relationship to device and procedures**
			Table 18.3	Removed Unlikely Related Classification	
			Section 18.4 Investigator Reporting Requirements	**Removed: The investigator must report Adverse Device Effects, Serious Adverse Events (regardless of relationship to device and/or procedure), Device Deficiencies for each subject from the time of index procedure through the end of study participation, and any asymptomatic stent migration.**	Removed to make language consistent with the previous section
			Section 18.4 Investigator Reporting Requirements	The paper AE Notification Form or Device **Deficiency** Notification Form should be used to report AEs and/**or** device deficiencies **during this time.** Changed to	Providing clarification on how to notify sponsor of AE and device deficiency in case EDC is not available.

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				The paper AE Notification Form or Device Event **Notification Form should be used to report AEs and** device events, including **device deficiencies** as applicable **during** the time when EDC system is unavailable.	
			Section 18.7 Subject Death Reporting	Added **Autopsy report** (if applicable) to If the Subject expired outside of the hospital (e.g., home)	Added requirement for autopsy report in case of subject death
			Section 20.2 Independent Medical Reviewer	The IMR will review a safety event dossier, which may include copies of subject source documents provided by study sites, **for all reported cases of device deficiencies, procedure related AEs, ADEs, SADEs, and all SAEs for Tria™.** Changed to **IMR will also review and adjudicate all imaging and deaths reported by study investigators regardless of the stent type.** The IMR will review a safety event dossier, which may include copies of subject source documents provided by study sites.	Providing clarification on IMR responsibilities
			Section 23.1 Subject Reimbursement	Added **Subject Reimbursement** For the completion of post-stent removal follow-up visit, subjects will be compensated for participation in the study, in accordance with pertinent country laws and regulations and per the study site's regulations.	Subject reimbursement for that last follow-up visit (post stent removal visit) option is added. This visit is not SOC for all regions and subjects will be compensated for their time to come to clinic to complete the visit.

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			Throughout Document	Instructions for use (IFU) was added to all references of Directions for use (DFU).	Added Instructions for use to protocol in anticipation of the change in nomenclature being adapted for DFUs.
			Throughout Document	Minor typographical errors were corrected throughout the document	Typographical errors are corrected
Rev C	January 15, 2021	92120219_Rev/Ver F	**TITLE**	Added "**PLUS"** to title. Boston Scientific Double-J **PLUS** Ureteral Stent Postmarket Patient Registry – DJUS **PLUS** Registry	Registry now includes non-Double-J stents and the additional term PLUS allows for inclusion of non-Double J ureteral stents.
			Contact Information	Contact Information: Removed Sameera Dasari; **added Debra Jovanovich**. Contact Information: Updated **Northwestern University affiliation and contact information** for Dr. Krambeck.	Updated section for accuracy (Clinical Contact only).
			Section 2 Synopsis	Added**: Boston Scientific Urinary Diversion Stents are indicated for drainage following percutaneous, endoscopic, or operative procedures**	Added Indication for Use for new stent type.
			Section 2. Protocol Synopsis; **Section 5. Commerical Device Description**	Device/System applied as standard of care: Added: **Contour™ and Contour VL™ Injection Ureteral Stents; Percuflex™ Urinary Diversion Stent (UDS); Polaris™ Loop Ureteral Stent; Contour™, Contour VL™ and Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set, an associated accessory devices.** Added: **An Investigational Brochure is not required, as commercial product**	Additional stents/accessories added to registry. The stents removed are no longer in production and therefore will not be studied in this registry. Tria stents were separated to Tria Soft and Tria Firm for clarity.

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				information is available for BSC ureteral stents. Added: **Sec 5.3 Device Accountability**	Per ISO 14155, investigational brochure and device accountability may not be required if justification is provided.
			Section 2. Protocol Synopsis; **Section 7.1 - Figure 7.1**	**Study Design Chart: Modified** planned indwell time flow chart	The flow chart was updated for clarity.
			Section 2. Protocol Synopsis; **Section 6 – Study Objectives and Endpoints; Section 11.1.1 Primary Efficacy Endpoint**	Primary efficacy endpoint clarified and changed to: **For all stents except UDS:** Technical Success defined as stented kidney drains (to bladder) during the planned indwell time with no re-intervention due to obstruction of the stented ureters **For UDS: Technical success defined as drainage following stent placement during the planned indwell time with no re-intervention for obstruction**	Primary Endpoints clarified for different stent types.
			Section 2. Protocol Synopsis; **Section 6 – Study Objectives and Endpoints; Section 11.3.1.2 Additional Endpoint 2 – Ureteral Stent Migration**	Stent Migration exception note was further clarified. Note: **Movement of a stent by** external force or by inadvertent pulling is not considered a stent migration.	Stent migration definition was revised to provide clarity that stent movement caused by an external force does not meet the study definition of stent migration.

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			Section 2. Protocol Synopsis; Section 7.1 Scale and Duration	Number of Subjects: Increased to **1000**; **Number of sites: Increased to** 35 **sites (Up to** 15 **sites within the United States; Up to** 5 **sites within Canada; Up to** 10 **sites within Europe; Up to** 5 **sites within Japan)**	Increasing to accommodate as data for more stent types is being collected and additional sites may be required to complete enrollment.
			Section 2. Protocol Synopsis; Section 8.2 Inclusion Criteria	**Added: For all ureteral stent types except UDS:** Subject is undergoing placement of a Boston Scientific ~~Double J~~ Ureteral Stent(s) **included in the registry** **Added: Inclusion criteria for UDS:** • **Subject is undergoing placement of a Boston Scientific Urinary Diversion Stent(s)** • **The anatomical features of the involved renal collecting system are known by either prior or concurrent urography or axial CT imaging** • **Subject is willing and able to return for all follow-up visits.**	Subject population for UDS do not have the same requirements as subject population for ureteral obstruction. Hence inclusion criteria for UDS is specified separately.
			Section 2. Protocol Synopsis; Section 8.3 Exclusion Criteria	**Addition:** Subjects **undergoing placement of a BSC US or UDS** who meet any one of the following criteria (Table 8.3) cannot be included in this study or will be excluded from this clinical study. **For subjects receiving bilateral/multiple stenting, the final exclusion criterion is**	Clarifying that exclusion criteria are the same for all subject populations; Subjects who receive multiple stents that are not the same type have not met all eligibility criteria and should be exited from study.

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				confirmed during the stent placement procedure.	
			Section 4. Introduction	**Addition of background regarding urinary diversion**	Providing background literature for urinary diversion procedure.
			Section 5.2 Medical Equipment Description	**Addition of accessories used in the placement of UDS**	Clarifying what BSC accessories may be used with urinary diversion procedures.
			Section 7.2 Treatment Assignment; Section 9.4 Subject Status and Classification	Delete: and met all the eligibility criteria.	Clarify enrollment definition to align with ISO 14155.
			Section 10 Study Methods	Addition of COVID-19 Assessment at baseline and all follow-up visits, if available.	Based on current pandemic
			Table 10.1: Data Collection Schedule;	**Addition:**QoL Questionnaires (PROMIS®) (Except for UDS) Post-stent Removal visit: Laboratory Blood Test: **Collected only if SOC, not required per protocol.**	Pain questionnaires are not relevant to UDS subject. The lab tests at post-stent removal visit is not SOC for all centers. Visit may be completed remotely, assessment is optional.
			Section 10.5 Baseline Visit	Added: **Chemotherapy and radiation treatment history** **Note: QoL Questionnaires not required for subjects receiving UDS**	Treatments are relevant to UDS subjects; Pain questionnaires are not relevant to UDS subject.
			Section 10.6 Index Procedure	Added: Index procedure is defined as the **start time of sedation and/or anesthesia.** **Clarified data will be collected on Stent Positioner and UDS accessories**	Further clarification of definitions, what data will be collected and provided examples of inadvertent stent removal.

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				Added: **Note: External force or inadvertently pulled stents are not considered Stent migration. Inadvertent study stent removal should be reported as stent dislodgement if it occurs during the planned indwell time and was caused by an action other than the subject's decision to remove the study stent.**	
			Section 10.9 Post-Stent Removal visit	Added: **The visit may occur in the office or by telephone.** Laboratory Blood Test: **Collected only if SOC, not required per protocol**.	Aligned with SOC. The office visit and lab tests at post-stent remocal visit is not SOC for all centers. Visit may be completed remotely, Lab Assessment is optional.
			Section 13.1 Data Collection, Processing and Review	Addition of language on Database lock and archiving procedures at the end of the study	Protocol template change providing clarification on the database management at the end of the study.
			Section 13.2 Questionnaires	Addition of language to clarify questionnaires may be self-completed by subject or telephone administered by delegated research staff.	Remote follow-up visits have increased due to pandemic with allowance for telephone administration of questionnaires.
			Section 14 Deviations	Removed classification of Major and Minor deviations.	Aligning to revised BSC post-market protocol template.
			Section 15 Compliance	Removed Japan Medical Device GCP statement.	Regulation is required for pre-market studies only.

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			Section 15.2 Investigator Responsibilities	Addition of language that Curriculm Vitae and Financial Disclosure are required for all investigators	Clarification on the sponsor requirements.
			Section 16 Monitoring	The sponsor will put a plan in place to document the specific monitoring requirements. Addition of **remote** monitoring visit type	Clarification on the Monitoring plan and type of visits.
			Section 18.1 Reportable events by investigational sites to Boston Scientific	• All Serious Adverse Events • All Device Deficiencies • All Adverse Device Effects • All Adverse Events related to the Index Procedure (inclusive of Study Stent Implant Procedure) and Study Stent Removal Procedure. **Changed to** • **Serious Adverse Device Effects** • **Serious Adverse Events related to the Index Procedure (inclusive of Study Stent Implant Procedure) and Study Stent Removal Procedure** • **Serious Adverse Events resulting in death (regardless of relatedness to the study device and/or procedure, i.e., Index, Stent Implant, and/or Stent Removal)** • **Device Deficiencies** • **Adverse Device Effects**	Clarification on type of adverse events collected in the study.

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				• **Adverse Events related to the Index Procedure (inclusive of Study Stent Implant Procedure) and Study Stent Removal Procedure**.	
			Section 18.2 Safety Definitions	**Addition of Serious Health Threats, Hospitalizations and Prolonged Hospitalizations**	Modifications in compliance with ISO 14155:2020.
			Section 18.4 Safety Reporting; Section 18.5 Study Device Deficiencies	Changed Device Event to Device Deficiency throughout protocol and clarified definition for Stent Migration and Stent Dislodgement.	Removed the differentiation of Device Deficiency or Device Event. If reportable, it will be a possible Device Deficiency.
			Section 21.1.1 Criteria for premature termination of the study	Addition of • Suspicion of an unacceptable risk, including serious health threat. In this case, the sponsor shall suspend the clinical investigation while the risk is assessed. The sponsor shall terminate the clinical investigation if an unacceptable risk which cannot be controlled is confirmed. • Instructions by the IRB/EC/REB or regulatory authorities to suspend or terminate the clinical investigation.	Clarification on unacceptable risks that could lead to study termination.
			Section 22 Study Registration and Results	**Addition of Study registration information and clinical investigational report**	Providing further details on where the study will be registered and publication of the study results upon completion of the study.
			Section 23.1 Subject Reimbursement	Removed Subject Reimbursement for the completion of post-stent removal follow-up visit	This visit is not SOC and the protocol now allows visit to be completed in clinic or by

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					telephone which removes the need for subject stipend that was added for their travel time to complete the visit.
			Throughout Document	**Reference to Double-J where no long relevant**	Addition of non-Double-J stents such as Polaris Loop and Percuflex Urinary Diversion Stents.
			Throughout Document	**Minor typographical errors were corrected throughout the document**	Typographical errors are corrected.
Rev D	September 15, 2021	92120219_Rev/Ver G	**Synopsis – Follow-up schedule**	**Study procedures and follow-up visits ~~will~~ may occur as follows:** •Post-Stent Removal: **Typically,** 3 – 12 weeks from Stent Removal	Minor change to clarify that follow-up visit windows are recommendations based on current Standard of Care. Subject visits completed outside of the target dates will not require a "visit completed outside of window" protocol deviation.
			7.1 Scale and Duration	**Minor typographical error corrected:** Target enrollment ~~of 142 subjects enrolled for Polaris Ultra Ureteral stent and 25 subjects enrolled~~ for each additional stent type as outlined below:	Enrollment discrepancies noted between text and table. Enrollment targets outlined in Table are correct.
			Section 18 Safety Reporting	**Safety Definition Tables revised to align with revised European Regulations**	Required for Ethic Committee approval for investigational sites in Europe

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			Protocol Implementation Plan	**Protocol Rev D will only be implemented in Europe.** **Protocol Rev C will continue to be implemented in all regions except Europe.** **Note: Protocol Rev B was not implemented in any regions due to the required revisions included in Protocol Rev C.**	Protocol Rev D includes administrative changes and clarifications only. Section 18 Safety Reporting regulation updates are only required in Europe.

2. Protocol Synopsis

Boston Scientific Double-J PLUS Ureteral Stent Postmarket Patient Registry DJUS PLUS Registry	
Study Objective(s)	To obtain postmarket safety and efficacy data on Boston Scientific (BSC) Ureteral Stents
Indication(s) for Use	Boston Scientific Ureteral Stents are indicated for use to facilitate drainage from the kidney to the bladder, via endoscopic or fluoroscopic placement by a trained physician Boston Scientific Urinary Diversion Stents are indicated for drainage following percutaneous, endoscopic, or operative procedures
Device/System applied as Standard of Care	Boston Scientific Ureteral Stents, including (but not limited to): • Contour™ Ureteral Stent • Contour VL™ Ureteral Stent • Contour™ Injection Ureteral Stent • Contour VL™ Injection Ureteral Stent • Percuflex™ Ureteral Stent • Percuflex™ Plus Ureteral Stent • Percuflex™ Urinary Diversion Stent (UDS) • Polaris™ Ultra Ureteral Stent • Polaris™ Loop Ureteral Stent • Tria™ Soft Ureteral Stent • Tria™ Firm Ureteral Stent • Contour™ SureDrive™ Steerable Ureteral Stent Set • Contour VL™ SureDrive™ Steerable Ureteral Stent Set • Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set
Study Design	A prospective multi-center global registry

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	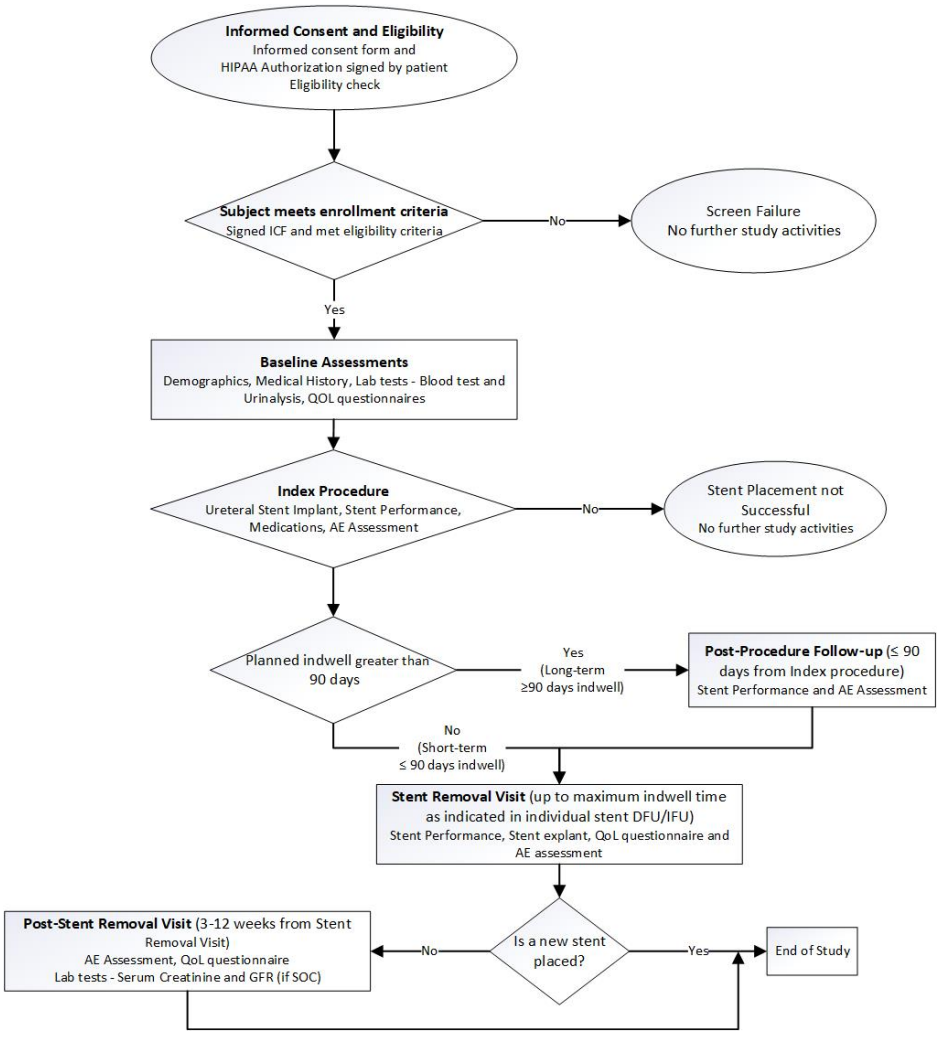
Planned Number of Subjects	Up to 1,000 subjects in the Registry. Target enrollment of 25 subjects per stent type, unless otherwise noted
Planned Number of Sites/ Countries	Up to 35 sites will enroll in the Registry: • Up to 15 sites within the United States • Up to 5 sites within Canada • Up to 10 sites within Europe

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	• Up to 5 sites within Japan

Primary Endpoints	The primary endpoints are:
	• Primary safety endpoint: Serious Adverse Device Effects (SADEs)
	• Primary efficacy endpoint:
	  o For all stents except UDS: Technical Success defined as stented kidney drains (to bladder) during the planned indwell time with no re-intervention due to obstruction of the stented ureters
	  o For UDS: Technical Success defined as drainage from the kidney following stent placement during the planned indwell time with no re-intervention for obstruction

Additional Endpoints	The additional endpoints are:
	• Quality of Life (QoL) – Patient-Reported Outcomes Measurement System (PROMIS®) for subjects ≥18 years
	  o PROMIS Adult Short Form v1.0 – Pain Intensity 3a
	  o PROMIS Adult Short Form v1.0 – Pain Interference 6b
	• Stent Migration: defined as any post procedure movement of the stent (either proximally towards the kidney or distally towards the bladder or complete distal migration) from its implant location; confirmed via imaging where necessary
	Note: External force or inadvertently pulled stents are not considered stent migration.

Method of Assigning Subjects to Treatment	This is an open-label postmarket registry
Follow-up Schedule	Each subject will be followed for a period up to 15 months after the Index Procedure depending on the intended stent indwell time. Study procedures and follow-up visits may occur as follows: • **Baseline Visit** • **Index Procedure**: Entirety of procedure including Stent Implant • **Post-Procedure Follow-up Visit** (only if Long term indwell of greater than 90 days): ≤ 90 days from Index Procedure

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	• **Stent Removal**: Typically, within 2 weeks to < 365 days from Index Procedure (see individual stent Instructions/Directions for use [IFU/DFU] for maximum indwell) • **Post-Stent Removal**: Typically, 3 – 12 weeks from Stent Removal
Study Duration	The study will take approximately 50 months from First Subject In until Last Subject Last Visit (dependent on stent indwell time) and study closeout. • Enrollment of up to 1,000 subjects will take approximately 30 months • The registry will be considered complete after all active subjects have completed their final follow-up visit and a final study report is generated
Participant Duration	The study duration for each subject is expected to be approximately between 8 weeks and 15 months (dependent on the study stent indwell time)
Inclusion Criteria	Enrollment is limited to the following inclusion criteria: For all ureteral stent types except UDS: • Subject is undergoing placement of a Boston Scientific Ureteral Stent(s) included in the registry • Subject anatomy is appropriate to accommodate a stent size available in the study • Subject is able to accurately detect and report bladder function and pain • Subject is willing and able to: o Complete patient QoL questionnaire at specified time points (for subjects aged ≥ 18 years) o Return for all follow-up visits For UDS only: • Subject is undergoing placement of a Boston Scientific Urinary Diversion Stent(s)

Boston Scientific Double-J PLUS Ureteral Stent Postmarket Patient Registry DJUS PLUS Registry	
	• The anatomical features of the involved renal collecting system are known by either prior or concurrent urography or axial CT imaging • Subject is willing and able to return for all follow-up visits
Exclusion Criteria	Subject undergoing placement of a BSC US or UDS is not permitted to enroll if they meet any of the following exclusion criteria: • Subject meets any of the contraindications as per individual stent IFU/DFU • Subject receiving different stent type in case of bilateral/multiple stenting • Subject with an indwelling ureteral stent(s) not planned to be removed prior to/or concurrently with the study stent implant
Primary Statistical Hypothesis	**The study is being statistically powered for only Tria™ implanted subjects for Stone Management.** Tria™ stents have technical success during planned indwell in more than 85% in stone management. The null and alternative hypotheses are: H0: $p \leq 0.85$ H1: $p > 0.85$ where p = the proportion of stented ureter(s)with technical success
Statistical Test Method	The hypotheses above will be evaluated based on the two-sided 95% exact Clopper-Pearson confidence interval for the proportion of stented ureters with technical success. Only stents placed at least 12 hours will be included in the analysis. If the lower bound of the confidence interval exceeds 85%, the alternative hypothesis will be demonstrated
Sample Size Parameters	Assuming that the Tria™ stent technical success rate is 94% for Stone Management, a sample size of 127 subjects with Tria™ placed at least 12 hours for Stone Management is required to attain 90% power to demonstrate the primary hypothesis at the 2.5% significance level(one-sided). Approximately 142 Stone Management subjects with Tria™ stent procedures where stents indwell at least 12 hours will be required to allow for 10% subject attrition

3. Table of Contents

3.1. *Table of Figures and Tables*

4. Introduction

4.1. *Background*

Ureteral stents have been available for several decades and are commonly used to restore flow of urine from the kidney to the bladder in obstructed ureters, or as a prophylactic placement following procedural interventions in the ureter to ensure that flow is not compromised during the acute post-procedural period. Stents may also be used for long-term drainage in patients with strictures or tumors, or to aid in ureteral healing after an accidental ureteral perforation or a therapeutic ureterotomy. With such a wide variety of uses, ureteral stents may remain indwelling for periods as short as 48 hours or up to as long as 365 days (see individual stent Instructions/Directions for Use (IFU/DFU) for maximum indwell time).

One such use of ureteral stents is temporary stenting following ureteroscopic treatment of upper urinary tract stones. These stones can range in size from a few millimeters to a few centimeters and are generally made up of mineral and acid salts, with 70-80% of kidney stones being made of calcium oxalate. The remaining make up of stones are split by those composed of struvite, uric acid and calcium phosphate. (Satyanand, Patel, Patel, Tarun, & Soniya, 2012) In a 2007-2010 survey showed kidney stone prevalence in the United States population estimated to be 10.6% for men and 7.1% for women with an overall unadjusted prevalence to be 8.8%. (Ziemba & Matlaga, 2017)

Treatment decisions for stones are determined at the individual case level and take into account stone size, stone location, and (if known) stone composition, as well as patient preference and physician expertise. Current treatment recommendations are generally endourologic procedures such as ureteroscopy (URS), shock wave lithotripsy (SWL), and percutaneous nephrolithotomy (PCNL). (Türk, et al., 2016) Ureteral stents are placed after ureteroscopy for stone removal to prevent pain (Torricelli, De, Hinck, Noble, & Monga, 2014) and to aid in future removal of residual stone fragments. (Chen, Tsai, Yu, Wu, & Lin, 2013) Thus, ureteral stents are a fundamental part of a urologic stone practice. Further, ureteral stents have been used for maintaining luminal patency in ureteral obstruction, including cases of malignant ureteral obstruction due to pelvic malignancy. If urine flow to the bladder is not possible, a ureteral stent is placed in the kidney to facilitate drainage following ureteral conduit construction and urinary diversion procedures; rerouting of urine flow to an opening in the wall of the abdomen (stoma). This stenting provides greater assurance of sustained internal urinary diversion, in addition to lessening concerns regarding anastomotic leaks from the pouch.

While usually used temporarily, occasionally patients may have long-term stent placement. Long-term indwell of a ureteral stent increases the risk of encrustation (accumulation of urine salts on the surface of the stent) and can lead to serious and difficult complications such as ureteral obstruction and renal impairment. The most common contributors to encrustation include urinary tract infection, extended indwell times (for chronic strictures or forgotten stents), urinary composition (hypercalciuria, hyperoxaluria, hypocitraturia, homocystinuria, and hyperuricosuria), and history of urolithiasis. Severely encrusted and retained stents are

serious and complex cases for the Endourologist to treat. Since encrustation most often occurs in the bladder and kidney, they often require a multimodal endoscopic approach to achieve stent-free status. (Mohan-Pillai, Keeley, Maussa, Smith, & Tolley, 1999)

Beyond encrustation, another area of interest in ureteral stents is patient discomfort. Ureteral stent pain is a known side-effect of indwelling stents. There have been various studies to determine the best way to measure and decrease the pain associated with ureteral stents with no apparent resolution for the issue. It is hypothesized that a stent composed of a soft flexible material may reduce stent related discomfort. A randomized controlled study of 155 subjects showed a significantly higher incidence of dysuria, renal, and suprapubic pain in those subjects who received a firm polyurethane stent versus a soft stent. (Koprowski, Kim, Modi, & Elsamra, 2016)

Other published studies have explored the duration of time the stent is left in place, (Ozgur, Ekici, Yuceturk, & Bayrak, 2013) use of image guidance in stent placement, (Grasso, et al., 2013) length and other physical features of the inserted stent, (Calvert, et al., 2013) and efficacy of pre-stenting prior to ureteroscopy. (Torricelli, De, Hinck, Noble, & Monga, 2014)

4.2. *Study Rationale*

Under normal conditions, urine is carried from the kidneys to the bladder via the ureters. A ureter may become obstructed as a result of a number of conditions including kidney stones, tumors, blood clots, postsurgical swelling, or infection. When the urine flow is blocked, it backs up into the kidney, which can lead to kidney swelling or hydronephrosis, as well as severe pain in the abdomen, flank, or side; nausea; vomiting; and hematuria. The goal of treatment for ureteral obstruction is to relieve or reduce the blockage and restore urinary drainage. Ureteral obstruction is commonly treated via placement of a ureteral stent; a thin, flexible tube that is threaded into the ureter and restores the flow of urine to the bladder. The most common reason for urinary diversion is bladder cancer that requires the bladder to be removed, a procedure called a cystectomy. Urinary diversion creates a new way for urine to exit body when urine flow is blocked or when there is a need to bypass the urinary tract.

The patient is usually placed under anesthesia for stent insertion, ensuring that the patient remains relaxed and immobile during the procedure. A cystoscope is inserted into the urethra to the bladder, and the opening to the ureter is identified. In some instances, a guidewire is inserted into the ureter under the aid of a fluoroscope. The stent is loaded onto the guidewire and subsequently advanced over the guidewire by a stent positioner (pusher). Once the stent is in place, the guidewire, positioner, and cystoscope are removed. If retrograde stenting is not possible, patients may have the stent placed percutaneously into the kidney, and subsequently into the ureter. Postoperative urine flow is monitored to ensure the stent has not been dislodged or obstructed. The stent may remain in place on a short-term (days to weeks) or long-term (weeks to months) basis and is removed most often cystoscopically. A

stent may also be removed with the attached retrieval line by a physician or nurse in an office setting or by the patient at home.

Although ureteral stents have been used safely in patients for over 30 years, there are limited clinical studies focusing specifically on the safety and efficacy of Boston Scientific's Ureteral Stents. Further, Boston Scientific (BSC) is launching the Tria™ Ureteral Stent (available in Soft and Firm durometers) with proprietary Percushield™ surface technology aimed at reducing calcium and magnesium urine salt accumulations. The goal of this registry is to collect real-world clinical data on BSCs Ureteral Stents to address changing European Regulatory requirements. In contrast to the limited published data for safety and efficacy of BSC Double-J Ureteral Stents, there are published clinical data sets on stent-related pain and Quality of Life (QoL), with many of studies showing increased side effects and reduced QoL associated with stent indwell (Scarneciu, Lupu, Pricop, & Scarneciu, 2015) (Lingeman, Preminger, Goldfischer, & Krambeck, 2009). This study will use a simplified patient QoL questionnaire to measure BSC stent-related pain at various times during the study; medications prescribed post-procedure will also be captured. These QoL data sets will be the first generated for the Tria™ stent family.

5. Commercial Device Description (part of Standard of Care)

5.1. *Commercial Device*

BSC offers a broad portfolio of Ureteral stents. A few Market-approved and commercially available stents are included in this registry.

The following market-approved devices will be evaluated:

- Contour™ Ureteral Stent
- Contour ™ SureDrive™ Steerable Ureteral Stent
- Contour VL™ Ureteral Stent
- Contour VL™ SureDrive™ Steerable Ureteral Stent
- Contour™ Injection Ureteral Stent
- Contour VL™ Injection Ureteral Stent
- Percuflex™ Ureteral Stent
- Percuflex™ Plus Ureteral Stent
- Percuflex™ Plus SureDrive™ Steerable Ureteral Stent
- Polaris™ Ultra Ureteral Stent
- Polaris™ Loop Ureteral Stent
- Tria™ Soft Ureteral Stent
- Tria™ Firm Ureteral Stent
- Percuflex™ Urinary Diversion Stent

The above list of devices could be expanded to include other BSC Ureteral Stent devices in this registry.

A copy of the device labeling and Instructions/Directions for Use (IFU/DFU) will be provided in local language(s) as required per national regulation. An Investigational Brochure has not been developed and per ISO 14155 is not required for this postmarket observational clinical investigation as commercial product information is available and study device(s) are used within the approved indication.

Appendix 1 provides a detailed list of all BSC Ureteral stents available to be used in the study along with their respective UPN/Product code.

5.2. *Medical Equipment Description*

Accessories that will be used in conjunction with the placement of a BSC Double-J Ureteral Stent during the procedure include the pigtail straightener and stent positioner. BSC ureteral access sheaths and BSC guidewires may also be used. Accessories that may be used in conjunction with the placement of a BSC UDS during a urinary diversion procedure include guidewire, catheter adaptors and drainage bag connector.

5.3. *Device Accountability*

Boston Scientific will not conduct investigational device accountability as required per ISO 14155 as all study devices are commercially available products and are being used within their approved indication. The study devices shall be maintained per each institutions standard practice.

6. Study Objectives and Endpoints

The objective of this study is to compile characteristics of real-world safety and efficacy outcomes for Boston Scientific Corporation's commercially approved Ureteral stents, when used according to the applicable IFU/DFU.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
The primary objective is to assess the clinical safety and efficacy of BSC Ureteral Stents	Primary safety endpoint: Serious Adverse Device Effects (SADE)	A ureteral stent is placed to open the ureter to allow passage of urine from the kidney, or from the kidney to the bladder. Any

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	Primary efficacy endpoint: For all stents except UDS: Technical Success of the stents defined as Stented kidney drains (to bladder) during the planned indwell time with no re-intervention due to obstruction of the stented ureters For UDS: Technical success defined as drainage following stent placement during the planned indwell time with no re-intervention due to obstruction	unplanned re-intervention due to an obstructed ureter would mean that there is not drainage from the kidney and the study stent failed to work as indicated, and there is an adverse event or serious adverse device event related to the stent such as urinary retention, dislodging or migration of the stent
Additional		
Quality of Life (QoL) (questionnaires)	Patient-Reported Outcomes Measurement System (PROMIS®) – • PROMIS Adult Short Form v1.0 – Pain Intensity 3a • PROMIS Adult Short Form v1.0 – Pain Interference 6b	Gain information specific to the patient's pain scale and quality of life for subjects treated with ureteral stents
Ureteral Stent Migration	Defined as any post procedure movement of the stent (i.e., either proximally towards the kidney or distally towards the bladder or complete distal migration) from its implant location; confirmed via imaging where necessary Note: Movement of a stent by external force or inadvertent pulling is not considered a stent migrations.	Capture real-world stent migration rates

7. Study Design

The Double-J PLUS Registry is a prospective, on-label, multi-center, global registry.

7.1. *Scale and Duration*

The registry will include:

- Up to 1,000 subjects will be enrolled at up to 35 sites
- At least 142 subjects will be enrolled for Tria™ Ureteral stent for stone management at sites within the United States, Europe, Canada and Japan. A hypothesis test will be performed for this patient group.
- Target enrollment for each additional stent type as outlined below.
- The enrollment period will be approximately 30 months.
- There will be up to 15 sites in the United States; 10 in EU, 5 in Canada and 5 in Japan.
- The study is expected to take 50 months from first subject enrollment until the study closeout.
- Each subject will be involved in the study for approximately 8 weeks to 15 months depending on the stent indwell time, from the index procedure.

Boston Scientific Ureteral Stents	Target Enrollment	Minimum Target Enrollment
• Tria Soft and Tria Firm	142	142
• Polaris Ultra	25	15
• Percuflex	25	15
• Contour Injection • Contour VL Injection	30	15 each
• Contour • Contour SureDrive Steerable	30	15 each
• Contour VL • Contour VL SureDrive Steerable	30	15 each
• Percuflex Plus • Percuflex Plus SureDrive Steerable	30	15 each
• Polaris Loop	25	15
• Percuflex UDS	25	15

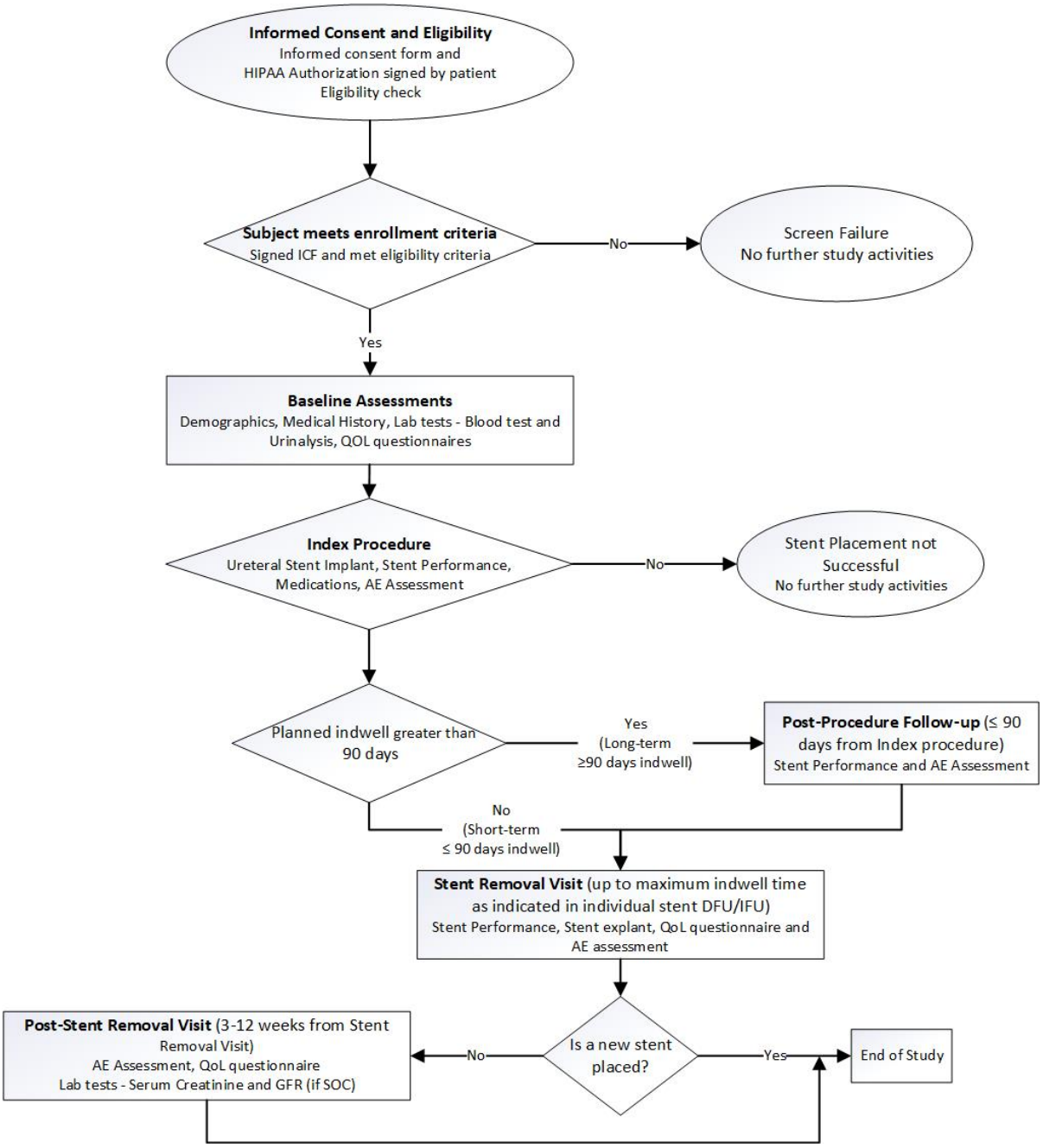

Figure 7.1: BSC Ureteral Stent Registry Study Design

7.2. *Treatment Assignment*

This is a post-market registry study and any subject who intends to receive BSC Ureteral Stent(s) or Urinary Diversion Stent(s) and is willing to provide a written informed consent will be approached and considered for enrollment in the study. Subject is considered enrolled in the study once the subject has signed the informed consent form. Each subject will be assigned a unique subject identifier in the Electronic Data Capture (EDC) system.

7.3. *Justification for the Study Design*

BSC Ureteral Stents are commercially available devices to relieve or reduce ureteral blockage and restore urinary drainage. With a cohort study design, enrolling subjects receiving the stent as standard of care procedure will provide real-world data.

8. Subject Selection

8.1. *Study Population and Eligibility*

Up to 1,000 implanted subjects may be included in the registry.

Subjects will generally be recruited from physician's practice and subject must meet the indications for a ureteral stent implant per the IFU/DFU. Patients who meet all of the following criteria (see Table 8.2) may be given consideration for inclusion in this clinical investigation, provided no exclusion criterion (see Section 8.3) is met.

8.2. *Inclusion Criteria*

Subjects who meet all of the following criteria (see Table 8.2) may be given consideration for inclusion in this clinical investigation, provided no exclusion criterion (see Section 8.3) is met.

Table 8.1: Inclusion Criteria

Inclusion Criteria	For all ureteral stent types except UDS: 1. Subject is undergoing placement of a Boston Scientific Ureteral Stent(s) included in the registry 2. Subject anatomy is appropriate to accommodate a stent size available in the study 3. Subject is able to accurately detect and report bladder function and pain 4. Subject is willing and able to: a. Complete patient QoL questionnaire at specified time points (for subjects aged ≥ 18 years) b. Return for all follow-up visits For UDS: 1. Subject is undergoing placement of a Boston Scientific Urinary Diversion Stent(s) 2. The anatomical features of the involved renal collecting system are known by either prior or concurrent urography or axial imaging 3. Subject is willing and able to Return for all follow-up visits

8.3. *Exclusion Criteria*

Subjects undergoing placement of a BSC US or UDS who meet any one of the following criteria (Table 8.3) cannot be included in this study or will be excluded from this clinical study. For subjects receiving bilateral/multiple stenting, the final exclusion criterion is confirmed during the stent placement procedure.

Table 8.2: Exclusion Criteria

Exclusion Criteria	1. Subject meets any of the contraindications as per individual stent IFU/DFU 2. Subject receiving different stent type in case of bilateral/multiple stenting 3. Subject with an indwelling ureteral stent(s) not planned to be removed prior to/or concurrently with the study stent implant

9. Subject Accountability

9.1. *Point of Enrollment*

Subjects will be considered enrolled in the study after he/she signs and dates the informed consent (ICF). No study specific (non-standard of care) procedure(s) or assessment(s) can take place until the informed consent is signed.

9.2. *Withdrawal*

All subjects enrolled in the clinical study (including those withdrawn from the clinical study) shall be accounted for and documented. If a subject withdraws from the study, the reason(s) shall be reported. If such withdrawal is due to problems related to device safety or performance, the investigator shall ask for the subject's permission to follow his/her status/condition outside of the clinical study.

Reasons for withdrawal include but are not limited to physician discretion and subject choice to withdraw consent. While study withdrawal is discouraged, subjects may withdraw from the study at any time, with or without reason, and without prejudice to further treatment. All applicable electronic Case Report Forms (eCRFs) up to the point of subject withdrawal and an End of Study eCRF must be completed. Additional data may no longer be collected after the point at which a subject has been withdrawn from the study or withdraws his/her consent. Data collected up to the point of subject withdrawal may be used for study analysis, unless local regulations apply.

9.2.1. Voluntary Withdrawal

Subjects may withdraw from the study at any time. At the time of withdrawal, the Investigator shall document the reason for the withdrawal. For subjects who withdraw from the study and decide to revoke their authorization to use and disclose their medical information, the information that has already been collected in the study record may continue to be used; however, no new information will be obtained or added.

9.2.2. Involuntary Withdrawal

Subjects may be involuntarily withdrawn from the study if the Investigator determines it is in the subject's best interest. If the subject is withdrawn at the investigator's discretion, the reason for withdrawal must be documented in the subject's medical records. Subjects who did not receive the study stent (implant failures) will be followed through hospital discharge and will be considered withdrawn.

9.3. *Lost to Follow-up*

If a subject fails to return to the clinic and/or is unable to be reached for a follow-up visit the site will attempt to contact the subject and reschedule the missed visit and counsel the subject on the importance of maintaining the assigned visit schedule and ascertain if the subject wishes to and/or should continue in the study.

Before the subject may be considered lost to follow-up, the investigator must make the following attempts to contact the subject:

- Three documented telephone attempts
- One certified letter

If the subject can be reached and no longer wishes to participate in the study, the Investigator shall document the reason for the withdrawal and complete the End of Study eCRF.

If the subject is not able to be reached after the required attempts to contact the subject have been made and the subject has missed two consecutive follow-up visits, or the subject has missed the final post-stent removal visit, the subject may be considered lost to follow-up. The Investigator should document in the subject's medical record the attempts to contact the subject and the reason for withdrawal.

9.4. *Subject Status and Classification*

A subject will be considered enrolled after a signed informed consent is obtained. An implanted subject participation ends when he or she has completed all phases of the study including the last visit as shown in the Data Collection Schedule or if the study stent is replaced either for planned stent replacement or due to re-intervention. Subjects who are unable to have study stent implanted will be followed through discharge following index procedure and he or she will be considered withdrawn from the study.

9.5. *End-of-Study Definition*

A clinical study at each participating site is considered completed when participants are no longer being examined or the last participant's last study visit has occurred, and study closeout activities are completed

A subject is considered to have completed the study after he or she has completed all phases of the study including the last visit shown in the Data Collection Schedule (see section 10) or if the study stent is replaced either for planned stent replacement or due to re-intervention.

The end of the study is defined as completion of the final Clinical Study Report.

10. Study Methods

10.1. *Data Collection*

The data collection schedule is shown in Table 10.1. Assessments will be completed based on standard of care practices at the site and PROMIS® pain scale questionnaires will be collected. All study data will be recorded on source documentation and captured within electronic Case Report Forms (eCRFs) for the purposes of this study. Study data will be monitored by Boston Scientific or representatives and as applicable on a regular basis as outlined in the study Monitoring Plan.

Table 10.1: Data Collection Schedule

Procedure/Assessment	**Screening/ Enrollment Baseline Visit**	**Index Procedure** (≤ 45 days from Baseline visit)	**Post-Procedure Visit**	**Follow-up Visits**		
			Only if Long term indwell of greater than 90 days (45 – 90[2] days from Index procedure)	**Stent Removal Visit** (< 365[2] days from Index procedure)	**Post-Stent Removal visit** (3-12 weeks from Stent Removal)	**Unscheduled Visit**
Informed consent process, including informed consent signature date[1]	X					
Inclusion/Exclusion Criteria	X	X[2]				
Demographics	X					
Medical History	X					
Laboratory – Blood Test, Serum Creatinine and Glomerular Filtration Rate (GFR)	X				X[5]	X
Laboratory – Urinalysis/Culture UTI status and Pregnancy test[4]	X					X
Physical Assessment: Weight, Height, BMI, and Temperature	X					
QoL Questionnaires (PROMIS®) (Except for UDS):- Adult Short Form v1.0 – Pain Intensity 3a -Adult Short Form v1.0 – Pain Interference 6b	X - *Prior to Implant*			X - *Prior to Removal*	X	
Assessment of Adverse Events (including Clavien-Dindo Classification) and Device Deficiencies (including stent migrations and stent dislodgements)		X	X	X	X	X
Stent Performance Assessment		X	X	X		X
Boston Scientific Accessory Device Assessment		X				
Medication Assessment (Antibiotics, NSAIDs, anticholinergic, narcotic/opioid, Diuretic, Phenazopyridine, Alpha blockers)		X - *Prior to Discharge*				X - *Prior to Discharge*
Imaging[3]						X
COVID-19 Assessment (if available)	X[5]		X[5]	X[5]	X[5]	X[5]

1. Informed consent obtained before any study specific, non-standard of care screening tests or procedures are performed
2. See individual stent IFU/DFU for contraindications and maximum indwell time
3. Image to be collected if completed as Standard of care and when suspected of ureteral obstruction
4. Only at the baseline visit
5. Not-required; recommended if available or collected as standard of care

10.2. *Study Candidate Screening*

All interested subjects will undergo screening during which their eligibility for the study will be determined.

Subjects who do not meet the inclusion/exclusion criteria are considered screen failures. Information on screen failures will be captured in the screening logs and should include reasons for screen failure. These screen failures will not count towards the enrollment ceiling.

If the subject has completed the informed consent process and met all inclusion/exclusion criteria, the subject will progress to the index procedure and follow-up phases of the study, if stent(s) is implanted.

10.2.1. Strategies for Recruitment and Retention

Subjects will be recruited from clinician practice who are receiving device as standard of care. For the completion of post-stent removal follow-up visit, subjects will be compensated for participation in the study, in accordance with pertinent country laws and regulations and per the study site's regulations.

10.3. *Informed Consent*

Written informed consent must be obtained from all potential study candidates before any study specific, non-standard of care screening tests or procedures are performed. Only current Institutional Review Board (IRB), Ethics Committee (EC) or Research Ethics Board (REB) approved study specific ICF must be used. Study personnel should explain that even if a subject agrees to participate in the study and signs an ICF, certain screening procedures might demonstrate that the subject is not eligible to continue participation. Written informed consent must be recorded appropriately by means of the subject's dated signature.

10.4. *Screening Assessments/Procedures*

The Screening/Enrollment and Baseline visit may occur on the same day or on different days. The following must be completed prior to collecting baseline data described in section 10.5:

- Informed Consent Process, including informed consent signature
- Review of Inclusion/Exclusion Criteria

10.5. *Baseline Visit [up to 45 days prior to Index procedure]*

The Baseline Visit will occur prior to the subject having index procedure/stent placement. The assessments below must be completed prior to index procedure and may occur up to 45 calendar days prior to index procedure.

The baseline assessments below can be completed on the same day as Index procedure, prior to the stent implant.

- Demographics: Age, Gender, Race and Ethnicity
- Diagnosis/Medical History (only active medical problems at the time of baseline assessment, including Neoadjuvant chemotherapy (within 6 months prior to stent placement for bladder cancer); Radiation status (pelvis and abdomen))
- Labs: Serum Creatinine, GFR
- Urinalysis/culture: UTI status, Pregnancy test for women of child-bearing potential
- Physical examination: Height, Weight, BMI, Temperature
- COVID-19 assessment: prior diagnosis, test result, vaccination status (if available)
- QoL Questionnaires (PROMIS):
    - Adult Short Form v1.0 – Pain Intensity 3a
    - Adult Short Form v1.0 – Pain Interference 6b

Note: QoL Questionnaires not required for subjects receiving UDS

10.6. *Index Procedure –BSC Ureteral Stent Placement*

Index procedure is defined as the start time of sedation and/or anesthesia and includes the entirety of the procedure in which the study stent is implanted, however also includes ureteral access sheath insertion, scoping, irrigation, laser lithotripsy, basketing, etc. The stent placement will be performed by a trained physician and per the individual stent IFU/DFU.

Note: Baseline visit information may be collected on same day, prior to the index procedure.

After the index procedure, the following data will be collected:

- Stent Information – type, size,stent laterally (left or right), unilateral or bilateral, time of stent placement
- Stent Performance Assessment – implanted and performed as indicated within IFU/DFU
- Accessory Device Performance and Safety Assessment (BSC Guidewire, BSC Ureteral Access Sheaths {UAS}, BSC Stent Positioner, BSC UDS Accessories) - used during the index procedure
- Medication Assessment (post-procedure) - antibiotics, NSAIDs, anticholinergic, narcotic/opioid, Diuretic, Phenazopyridine, Alpha blockers
- Assessment of Adverse Events (including Clavien-Dindo Classification) and Device Deficiencies (including stent migrations and stent dislodgements)

10.7. *Post-procedure Follow-up (only for planned indwell greater than 90 days)*

Stent indwell time should be per individual IFU/DFU. If indwell of greater than 90 days is planned, a post-procedure follow-up should be completed between 45 - 90 days from the index procedure as indicated in individual stent IFU/DFU.

The subjects should be followed in clinic for the following data collection:

- Stent Performance Assessment – stent performed as indicated
- Assessment of Adverse Events (including Clavien-Dindo Classification) and Device Deficiencies (including stent migrations and stent dislodgements)
- COVID-19 Assessment: New diagnosis, test result, vaccination status, if available

If indwell of less than 90 days is planned, a post-procedure follow-up is not required.

10.8. *Stent Removal Visit (maximum indwell time as indicated in individual stent IFU/DFU)*

The stent removal should be per the individual stent IFU/DFU. The indwell time should not exceed indwell period indicated in the individual IFU/DFU. The stent removal shall occur per standard practice.

At the stent removal visit, the following assessments must be performed and data points collected:

- Stent Performance Assessment – performed as indicated during the planned indwell time, as assessed by study physician
- Stent Explant – explant successful; time of explant
- QoL Questionnaires (PROMIS): to be completed before stent removal
    - Adult Short Form v1.0 – Pain Intensity 3a
    - Adult Short Form v1.0 – Pain Interference 6b

Note: QoL Questionnaires not required for subjects receiving Urinary Diversion Stent

- Assessment of Adverse Events (including Clavien-Dindo Classification) and Device Deficiencies (including stent migrations and stent dislodgements)
- COVID-19 Assessment: New diagnosis, test result, vaccination status, if available

If stent is explanted in a non-study clinic facility (e.g., at home, another clinic), the required assessments will be completed via telephone.

If stents are removed inadvertently before intended indwell time, the post-stent removal visit should be completed as indicated in section 10.9 and schedule of events table.

10.9. *Post-Stent Removal Visit (Typically, 3 to 12 weeks) from stent removal visit*

The post-stent removal visit should occur between 3 – 12 weeks from the Stent Removal Visit. The visit may occur in the office or by telephone. At this visit the following assessments will be performed and data points collected:

- Labs – Serum Creatinine and GFR (not required, collected if office visit and SOC)
- QoL Questionnaires (PROMIS):
  - Adult Short Form v1.0 – Pain Intensity 3a
  - Adult Short Form v1.0 – Pain Interference 6b

  Note: QoL Questionnaires not required for subjects receiving Urinary Diversion Stent
- Assessment of Adverse events (including Clavien-Dindo Classification)
- COVID-19 Assessment: New diagnosis, test result, vaccination status, if available

10.10. *Unscheduled Visit*

Subjects may have additional visits (other than the study visits specified above), that are unplanned visits and are considered as unscheduled visits. Some examples of these visits may include a visit for a change in symptoms or to check on a medical event that could not be resolved during one of the scheduled study visits.

If an unscheduled visit is for a suspected ureteral obstruction, the following will be attempted to be collected:

- Laboratory Blood test – Serum Creatinine and GFR
- Laboratory Urinalysis – UTI status
- Adverse Event (including Clavien-Dindo Classification) and Device Deficiency (including stent migrations and stent dislodgements) Assessment
- Stent Performance Assessment
- Imaging
- Medication
- COVID-19 Assessment: New diagnosis, test result, vaccination status, if available

10.11. *Study Completion*

Each subject will be followed to the post-stent removal follow-up visit. All subjects completing the post-stent removal follow-up visit will be considered to have completed the study. Subjects with any ongoing Adverse Events at the end of the study should be followed per institutions SOC.

Upon completion of the study, all adverse events indicated as “ongoing” should be changed to one of the following outcomes:

- Not Recovered/Not Resolved
- Resolved
- Resolved with sequelae
- Unknown

The outcome of "unknown" should only be used for subjects who are lost to follow-up. Whenever possible, sites should enter a reason for each ongoing/unresolved adverse event at time of study exit.

10.12. *Local Laboratory documentation*

The laboratory (blood and urine) analysis, collected in the study will be completed at the local centers per standard of care. Appropriate laboratory certifications and documentation records are required to be maintained at the site.

10.13. *Source Documents*

It is preferable that original source documents are maintained, when available. In lieu of original source documents, certified copies are required to be maintained. A certified copy is a copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

11. Statistical Considerations

11.1. *Endpoints*

11.1.1. Primary Efficacy Endpoint – Technical Success

The primary efficacy endpoint is the technical success of Tria™ in stone management. For all stents except UDS, technical success is defined as stented kidney drains (to bladder) during the planned indwell time with no re-intervention due to obstruction of the stented ureter(s). For UDS, technical success is defined as drainage following stent placement during the planned indwell time with no re-intervention for obstruction. Restenting with a new study stent may only occur during the initial stent placement procedure for such situations as stent misplacement, improper stent size choice, or other conditions, as necessary and will not be considered as a primary effectiveness endpoint failure or a secondary endpoint failure for stricture resolution.

11.1.1.1. Hypotheses

The study will evaluate whether Tria™ stents have technical success during planned indwell in more than 85% in stone management. The null and alternative hypotheses for this evaluation are

H_0: $p \leq 85\%$

H_1: $p > 85\%$

where p is the proportion of stented ureter(s) with technical success.

11.1.1.2. Sample Size

There are two published studies on the patency in the stone management for Double J stents. The success rates were 98% with a 95% CI [94%, 99%] (Calvert, et al., 2013) and 96% with a 95% CI [92%, 99%] (El-Faqih SR, 1991). As a result, an 94% patency rate is estimated as the performance for the Double J stents. The performance goal of 85% is chosen for the patency for TRIA in the stone management, with a non-inferiority margin of 9%.

With a one-sided type I error of 0.025 and a type II error of 0.10 (90% power), a sample size of 127 subjects with Tria™ placed at least 12 hours for stone management are needed to demonstrate the proportion of stented ureters with technical success exceeds 85%. Assuming a 10% attrition rate, at least 142 stone management subjects with Tria™ stent procedures where stents indwell at least 12 hours are required.

11.1.1.3. Statistical Methods

The hypotheses above will be evaluated based on the two-sided 95% exact Clopper-Pearson confidence interval for the proportion of stented ureters with technical success. Only stents placed at least 12 hours will be included in the analysis. If the lower bound of the confidence interval exceeds 85%, the alternative hypothesis will be demonstrated. Sensitivity analysis to missing data will be performed using tipping-point analysis.

In addition, a Generalized Estimating Equation (GEE) model will be used to estimate the technical success rate to account for within-subject correlation due to bilateral stent placement if applicable.

Descriptive statistics including 95% confidence intervals will be utilized to summarize the technical success rates for the non-stone management subjects treated with Tria™ stents respectively.

For non Tria™ ureteral stents in the study, the technical success rates will be summarized by descriptive statistics including 95% confidence intervals by indication (i.e. stone management, benign obstruction, malignant obstruction, ureteral dysfunction, bladder cancer, and other as applicable) respectively for each device type. Only stents placed at least 12 hours will be included in the analysis.

11.1.2. Primary Safety Endpoint - SADE

The primary safety endpoint is serious adverse device effect related to the study stent(s) implanted.

11.1.2.1. Hypotheses

There is not a pre-specified pass/fail hypothesis for this endpoint.

11.1.2.2. Statistical Methods

Rates of serious adverse device effects will be summarized using descriptive statistics (event counts, proportion of subjects with a SADE) for each study stent type implanted respectively.

In addition, all AEs will be summarized by relatedness to procedure and/or device for each study stent type implanted respectively.

11.2. *General Statistical Methods*

11.2.1. Analysis Sets

The Intent-to-Treat (ITT) subject population includes all subjects who provide written informed consent to be enrolled into the study, and have the stent placement procedure initiated.

The As Treated (AT) Population includes all subjects for whom the stent placement is completed.

The Per Protocol (PP) population includes all subjects in the AT Population who meet all eligibility criteria.

The endpoint analyses will be performed for the ITT population. The AT and PP populations will be evaluated as sensitivity analyses for the primary efficacy endpoint and the safety outcomes will also be assessed using the AT population.

11.2.2. Control of Systematic Error/Bias

All subjects will be treated according to the directions in the Operating Manual and IFU/DFU.

The primary efficacy endpoint analysis based on the exact Clopper-Pearson confidence interval is specified to be conservative in order to avoid bias towards demonstrating the primary hypothesis (i.e., achieving the performance goal) of the study. Furthermore, the potential of bias from missing data for the primary efficacy endpoint will be assessed through tipping point analysis.

11.2.3. Number of Subjects per Investigative Site

The study will be conducted at up to 35 sites. Sites will be encouraged to enroll a minimum of 10 subjects.

11.3. *Data Analyses*

The analyses will include the available cases unless specified otherwise. Presentation of summary statistics for continuous variables will include N, mean, median, standard deviation, minimum, and maximum values. For categorical variables, the number and percentage under each category will be presented.

11.3.1. Other Endpoints/Measurements

11.3.1.1. Additional Endpoint 1 - QoL

To evaluate the change in quality of life as measured by Patient-Reported Outcomes Measurement System (PROMIS®) at Stent Removal Visit compared to Index Procedure.

The endpoints are Pain Interference assessed by the PROMIS Short Form v1.0 - Pain Interference 6b instrument, and Pain Intensity assessed by the PROMIS Scale v1.0 – Pain Intensity 3a scale.

11.3.1.1.1 Statistical Methods

Descriptive statistics including 95% confidence intervals will be used to summarize the pain interference and pain intensity at Index Procedure, and Stent Removal Visit along with change from Index Procedure for each ureteral study stent type implanted respectively (excluding urinary diversion stents).

11.3.1.2. Additional Endpoint 2 - Ureteral Stent Migration

The endpoint is ureteral stent migration defined as any post procedure movement of the stent (i.e., either proximally towards the kidney or distally towards the bladder or complete distal migration) from its implant location; confirmed via imaging where necessary. Note: Movement of a stent by external force or by inadvertent pulling is not considered a stent migration.

11.3.1.2.1 Statistical Methods

Descriptive statistics including 95% confidence intervals will be used to summarize the ureteral stent migration rate for each study stent type implanted respectively.

11.3.2. Interim Analyses

No formal interim analyses are planned for the purpose of stopping the study early for declaring effectiveness or for futility.

11.3.3. Subgroup Analyses

The study efficacy and safety endpoints will be summarized by indication (i.e. stone management, benign obstruction, malignant obstruction, ureteral dysfunction, bladder cancer, and other as applicable) for each study stent type respectively.

11.3.4. Justification of Pooling

Fisher's Exact test or Chi-squared test will be applied to evaluate the homogeneity of the technical success rates by indication (i.e. stone management, benign obstruction, malignant obstruction, ureteral dysfunction, bladder cancer, and other as applicable) across the study sites for each study stent type implanted respectively.

11.3.5. Multivariable Analyses

There are no planned multivariable analyses.

11.3.6. Changes to Planned Analyses

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

12. Health Economics Outcomes

No formal health economics analysis is currently planned to be completed as part of this trial study. An economics analysis may be executed after the completion of this trial study. The primary safety endpoints may be used to calculate the costs associated with treating reported adverse events.

13. Data Management

13.1. *Data Collection, Processing, and Review*

Subject data will be recorded in a limited access secure electronic data capture (EDC) system.

The clinical database will reside on a production server hosted by Medidata EDC System. All changes made to the clinical data will be captured in an electronic audit trail and available for review by the sponsor or its representative. The associated Rave software and database have been designed to meet regulatory compliance for deployment as part of a validated system compliant with laws and regulations applicable to the conduct of clinical studies pertaining to the use of electronic records and signatures. Database backups are performed regularly.

The Investigator provides his/her electronic signature on the appropriate electronic case report forms (eCRFs) in compliance with local regulations. A written signature on printouts of the eCRFs must also be provided if required by local regulation. Changes to data previously submitted to the sponsor require a new electronic signature by the Investigator acknowledging and approving the changes.

Visual and/or electronic data review will be performed to identify possible data discrepancies. Manual and/or automatic queries will be created in the Medidata EDC system and will be issued to the site for appropriate response. Site staff will be responsible for resolving all queries in the database.

All access to the clinical database will be changed to "Read only" after all data is either "Hard Locked" or "Entry Locked". Once acceptance of the final report or finalization of publications (as applicable) is received, final database storage and archiving activities can begin. Once all of the closeout activities are completed a request to IT is submitted to have the "Database Locked" or Decommissioned and all database access revoked.

13.2. *Questionnaires*

Paper questionnaires that are completed by the subject are transcribed into the EDC database by the site staff. For follow-up visits completed remotely, the paper questionnaires will be answered by the subject and responses documented on the paper questionnaire by the delegated research team member.

13.3. *Data Retention*

The Principal Investigator or his/her designee or Investigational site will maintain all essential study documents and source documentation that support the data collected on the study subjects in compliance with applicable regulatory requirements.

The Principal Investigator or his/her designee will take measures to prevent accidental or premature destruction of these documents. If for any reason the Principal Investigator or his/her designee withdraws responsibility for maintaining these essential documents, custody must be transferred to an individual who will assume responsibility and BSC must receive written notification of this custodial change. Sites are required to inform Boston Scientific in writing where paper or electronic files are maintained in case files are stored off site and are not readily available.

14. Deviations

An Investigator must not make any changes or deviate from this protocol, except to protect the life and physical well-being of a subject in an emergency. An investigator shall notify the sponsor and the reviewing IRB/EC/REB, and the regulatory authority if applicable, of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency, and those deviations which affect the scientific integrity of the clinical investigation. Such notice shall be given as soon as possible, but no later than 5 working days

after the emergency occurred, or per prevailing local requirements, if sooner than 5 working days.

All deviations from the investigational plan, with the reason for the deviation and the date of occurrence, must be documented and reported to the sponsor using EDC (Electronic Data Capturing) system. Sites may also be required to report deviations to the IRB/EC/REB, and the regulatory authority, per local guidelines and national/government regulations.

Deviations will be reviewed and evaluated on an ongoing basis and, as necessary, appropriate corrective and preventive actions (including IRB/EC/REB notification, site re-training, or site discontinuation/termination) will be put into place by the sponsor.

15. Compliance

15.1. *Statement of Compliance*

This clinical investigation is financed by the study sponsor. Before the investigational site can be "Authorized to Enroll," the investigational site must enter into a Clinical Study Agreement with the sponsor that details the financing of the study as well as the rights and obligations of the investigational site and the investigator. This study will be conducted in accordance with applicable FDA regulations (21 CFR 50, 54, 56), ISO 14155: Clinical Investigation of Medical Devices for Human Subjects, ICH Good Clinical Practice, ethical principles that have their origins in the Declaration of Helsinki, and applicable individual country laws and regulations. Applicability of the above principles have been reviewed for this post-market observational clinical investigation and justifications for ISO 14155 exemptions noted in the appropriate sections.

The study shall not begin until the required approval/favorable opinion from the IRB/EC/REB and/or regulatory authority has been obtained, if appropriate. Also, the study shall not begin prior to issuance of the site Authorization to Enroll, as provided by the sponsor. Any additional requirements imposed by the IRB/EC/REB or regulatory authority shall be followed, if appropriate.

Japan only: Clinical Trial Organization will be documented and available on a separate document.

15.2. *Investigator Responsibilities*

The Principal Investigator of an investigational site is responsible for ensuring that the study is conducted in accordance with the Clinical Study Agreement, the clinical investigation plan, the spirit of ISO 14155, ethical principles that have their origins in the Declaration of Helsinki, any conditions of approval imposed by the reviewing IRB/EC/REB, and prevailing local and/or country laws and/or regulations, whichever affords the greater protection to the subject.

The Principal Investigator's responsibilities include, but are not limited to, the following.

- Prior to beginning the study, sign the Clinical Study Agreement and comply with the Investigator responsibilities as described in such Agreement.
- Provide his/her qualifications (all investigators including sub-investigators) and experience to assume responsibility for the proper conduct of the study and that of key members of the site team through up-to-date curriculum vitae or other relevant documentation and disclose potential conflicts of interest, including financial, that may interfere with the conduct of the clinical study or interpretation of results.
- Make no changes in or deviate from this protocol, except to protect the life and physical well-being of a subject in an emergency; document and explain any deviation from the approved protocol that occurred during the clinical investigation.
- Create and maintain source documents throughout the clinical study and ensure their availability with direct access during monitoring visits or audits; ensure that all clinical-investigation-related records are retained per requirements.
- Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.
- Record, report, and assess (seriousness and relationship to the device/procedure) every adverse event as applicable per the protocol and observed device deficiency.
- Report to sponsor, per the protocol requirements, all reportable events.
- Report to the IRB/EC/REB and regulatory authorities any SAEs and device deficiencies that could have led to a SADE and potential/USADE or UADE, if required by applicable laws or regulations or this protocol or by the IRB/EC/REB, and supply BSC with any additional requested information related to the safety reporting of an event.
- Allow the sponsor to perform monitoring and auditing activities and be accessible to the clinical research monitor or auditor and respond to questions during monitoring visits or audit(s).
- Allow and support regulatory authorities and the IRB/EC/REB when performing auditing activities.
- Ensure that informed consent is obtained in accordance with applicable laws, this protocol and local IRB/EC/REB requirements.
- Provide adequate medical care to a subject during and after a subject's participation in a clinical study in the case of adverse events, as described in the Informed Consent Form (ICF).
- Inform the subject of the nature and possible cause of any adverse events experienced.
- As applicable, provide the subject with necessary instructions on proper use, handling, storage, and return of the device when it is used/operated by the subject.
- Inform the subject of any new significant findings occurring during the clinical investigation, including the need for additional medical care that may be required.

- Provide the subject with well-defined procedures for possible emergency situations related to the clinical study, and make the necessary arrangements for emergency treatment, including decoding procedures for blinded/masked clinical investigations, as needed.
- Ensure that clinical medical records are clearly marked to indicate that the subject is enrolled in this clinical study.
- Ensure that, if appropriate, subjects enrolled in the clinical investigation are provided with some means of showing their participation in the clinical investigation, together with identification and compliance information for concomitant treatment measures (contact address and telephone numbers shall be provided).
- Inform, with the subject's approval or when required by national regulations, the subject's personal physician about the subject's participation in the clinical investigation.
- Make all reasonable efforts to ascertain the reason(s) for a subject's premature withdrawal from clinical investigation while fully respecting the subject's rights.
- Ensure that an adequate investigation site team and facilities exist and are maintained and documented during the clinical investigation.
- Discuss or review questionnaire responses from subjects and subsequently report adverse event(s) if warranted.

15.2.1. Delegation of Responsibility

When specific tasks are delegated by an investigator, including but not limited to conducting the informed consent process, the Principal Investigator is responsible for providing appropriate training, are competent to perform the tasks they have been delegated and adequate supervision of those to whom tasks are delegated. Where there is a sub investigator at a site, the sub investigator should not be delegated the primary supervisory responsibility for the site. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study.

15.3. *Institutional Review Board/ Ethics Committee*

The investigational site will obtain the written and dated approval/favorable opinion of the IRB/EC/REB for the clinical investigation before recruiting subjects and implementing all subsequent amendments, if required.

A copy of the written IRB/EC/REB and/or competent authority (CA) approval of the protocol (or permission to conduct the study) and ICF, must be received by the sponsor before recruitment of subjects into the study. Prior approval must also be obtained for other materials related to subject recruitment or which will be provided to the subject.

Any amendment to the protocol will require review and approval by the IRB/EC/REB before the changes are implemented to the study. All changes to the ICF will be IRB/EC/REB approved; a determination will be made regarding whether a new ICF needs to be obtained from participants who provided consent, using a previously approved ICF.

Annual IRB/EC/REB approval and renewals will be obtained throughout the duration of the study as required by applicable local/country laws or regulations or IRB/EC/REB requirements. Copies of the study reports and the IRB/EC/REB continuance of approval must be provided to the sponsor.

15.4. *Sponsor Responsibilities*

All information and data sent to BSC concerning subjects or their participation in this study will be considered confidential by BSC and will be kept confidential in accordance with all applicable laws and regulations. Only authorized BSC personnel and/or a BSC representative including, but not limited to Contract Research Organization (CRO), will have access to this information. Authorized regulatory personnel have the right to inspect and copy all records pertinent to this study. Study data collected during this study may be used by BSC for the purposes of this study, publication, and to support future research and/or other business purposes, such as overseeing and improving the performance of its device, new medical research and proposals for developing new medical products and procedures. All data used in the analysis and reporting of this study or shared with a third-party researcher will be without identifiable reference to specific subjects.

Information received during the study will not be used to market to subjects; subject names will not be placed on any mailing lists or sold to anyone for marketing purposes.

15.5. *General Data Protection Regulations (GDPR)*

Data collected from clinical trial data subjects are considered “personal data” (including sensitive personal data in some cases). The protection of clinical trial subject personal data and compliance with privacy, data protection laws and regulations are of critical importance to BSC. Data collection has been carefully considered for this study and has been restricted to the strict essentials with a clear, specific and detailed purpose to mitigate the risk and the impact of data breach and to comply with data privacy laws (including but not limited to HIPAA and GDPR). Section 10 of the protocol defines the data that need to be collected to fulfill the objectives of the clinical study.

Personal data collected by Boston Scientific includes, but is not limited to:

- Geographic data (site name)
- Important Dates
    - Informed consent date
    - Age at the time of study enrollment
    - Procedure date
    - Adverse event start/end date
    - Hospitalization admission/discharge date

- Subject visit dates

The purposes of the personal data processing will be carefully defined within the informed consent form. Personal data will not be used for a purpose other than the one stated in the informed consent provided to the subjects. Personal data shall not be disclosed, made available, or otherwise used, processed, transferred, or stored for purposes other than those specified in the informed consent form, except:

- with the consent of the data subject; or
- processing is necessary for compliance with a legal obligation.

15.5.1. Transparency

BSC must only collect personal data by fair and lawful means. BSC must be transparent and open with individuals about how BSC collects and uses personal data, with whom BSC shares it, and where it may be processed.

For this transparency principle, BSC must provide information to our health care providers and their study subjects about the purpose for collecting their personal data; who will have access to the data and to whom it may be shared, if it will be accessed or transferred to another country; and who to contact with questions or requests.

15.5.2. Rights to Data Subjects

In GDPR, a data subject is any living individual to whom the personal data relates. A data subject includes study subjects. Data subjects shall have the right to:

- obtain from BSC confirmation of whether BSC has data relating to the individual;
- have data relating to them communicated:
  - within a reasonable time (within 30 days from receipt of request, extendable if complicated or unclear request);
  - at a charge, if any, that is not excessive;
  - in a reasonable manner; and
  - in a form that is readily intelligible to the individual;
- be given reasons if a request made under subparagraphs (a) and (b) is denied, and to be able to challenge such denial;
- challenge data relating to the individual and, if the challenge is successful, to have the data erased, rectified, completed, or amended. During the period of such challenge, the individual can require that access to the data be restricted;
- "opt out"/oppose that their personal data are used for marketing purposes; and,
- when requested, BSC must also communicate any rectification or erasure of personal data or restriction of processing to each recipient to whom the personal data have been disclosed, unless this proves impossible or involves disproportionate effort.

These rights will also be listed in the subject informed consent form.

15.6. *Insurance*

Where required by local/country regulation, proof and type of insurance coverage, by BSC for subjects in the study will be obtained.

16. Monitoring

Monitoring will be performed during the study to assess continued compliance with the protocol and applicable regulations. The sponsor will put a plan in place to document the specific monitoring requirements. In addition, the clinical research monitor verifies that study records are adequately maintained, that data are reported in a satisfactory manner with respect to timeliness, adequacy, and accuracy, and that the Principal Investigator continues to have sufficient staff and facilities to conduct the study safely and effectively. The Principal Investigator/institution guarantees direct access to original source documents by BSC personnel, their designees, and appropriate regulatory authorities.

The study may also be subject to a quality assurance audit by BSC or its designees, as well as inspection by appropriate regulatory authorities. It is important that the Principal Investigator and relevant study personnel are available during on-site or remote monitoring visits or audits and that sufficient time is devoted to the process.

17. Potential Risks and Benefits

17.1. *Instructions/Directions for Use*

Please refer to the Instructions/Directions for Use (IFU/DFU) for an overview of anticipated adverse (device) effects and risks associated to the commercial device(s).

17.2. *Risks associated with Participation in the Clinical Study*

The BSC ureteral stents and urinary diversion stents are commercially available devices. None of the procedures associated with this study fall outside of standard of care procedure. Therefore, there are no foreseen additional risks associated with the device implant procedure, testing, or withdrawal from the study.

17.3. *Possible Interactions with Concomitant Medical Treatments, if applicable*

Please refer to the individual ureteral stent IFU/DFU for the interactions with medications recommended per the post procedural medication regime.

17.4. *Risk Minimization Actions*

Additional risks may exist. Risks can be minimized through compliance with this protocol, IFU/DFU, performing procedures in the appropriate hospital environment, adherence to subject selection criteria, close monitoring of the subject's physiologic status during research

procedures and/or follow-ups and by promptly supplying BSC with all pertinent information required by this protocol.

17.5. *Anticipated Benefits*

The benefits of having any ureteral stent include the facilitation of drainage from the kidney, or kidney to the bladder. Ureteral stents may also aid the ureter as it heals after procedural intervention. The information gathered from this study may help physicians worldwide develop a better understanding of the safety and efficacy of ureteral stents, literature reported stent related pain and QoL associated with stent indwell time.

18. Safety Reporting

18.1. *Reportable Events by investigational site to Boston Scientific*

It is the responsibility of the investigator to assess and report to BSC any event which occurs in any of following categories from the time of index procedure to end of the study:

- Serious Adverse Device Effects
- Serious Adverse Events related to the Index Procedure (inclusive of Study Stent Implant Procedure) and/or Study Stent Removal Procedure
- Serious Adverse Events resulting in death (regardless of relatedness to the study device and/or procedure, i.e., Index, Stent Implant, and/or Stent Removal)
- Device Deficiencies
- Adverse Device Effects
- Adverse Events related to the Index Procedure (inclusive of Study Stent Implant Procedure) and/or Study Stent Removal Procedure.

Adverse events to be reported include both anticipated and expected post procedural events (such as pain, hematuria, urgency, frequency, urinary leakage and ureteral strictures, etc.) in addition to any other unanticipated or unexpected events.

When possible, the medical diagnosis should be reported as the Event Term instead of individual symptoms.

If it is unclear whether an event fits one of the above categories, or if the event cannot be isolated from the device or procedure, it should be submitted as an adverse event and/or device deficiency.

Any reportable events, experienced by the study subject from the time of index procedure to end of the study, must be recorded on an eCRF.

It is the responsibility of investigator or designee to update eCRFs with new findings/updates in relation to already reported events as soon as they become aware.

Underlying diseases and chronic conditions are not reported as AEs unless there is an increase in severity or frequency during the investigation. Death should not be recorded as an AE but should only be reflected as an outcome of one (1) specific SAE (see Table 18.2 for safety definitions).

Refer to IFU/DFU for the known risks associated with the commercial device(s).

18.2. *Definitions and Classification*

Safety definitions are provided in Table 18.2. Administrative edits were made on the safety definitions from applicable regulations and guidance including (but not limited to) 21 CFR Part 812, ISO 14155 and EU MDR 2017/745/MDCG 2020-10/1 Guidance on Safety Reporting in Clinical Investigations for clarification purposes.

Table 18.2: Safety Definitions

Term	Definition
Adverse Event (AE) *Ref: ISO 14155* *Ref: MDCG 2020-10/1*	Any untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, in the context of a clinical investigation, whether related to the study medical device and whether anticipated or unanticipated. **NOTE 1**: This includes events related to the study medical device or comparator. **NOTE 2**: This definition includes events related to the procedures involved. **NOTE 3**: For users or other persons, this definition is restricted to events related to the study medical device.
Adverse Device Effect (ADE) *Ref: ISO 14155* *Ref: MDCG 2020-10/1*	Adverse event related to the use of the study medical device. **NOTE 1**: This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the study medical device. **NOTE 2**: This definition includes any event resulting from use error or from intentional misuse of the study medical device. **NOTE 3**: This includes 'comparator' if the comparator is a medical device.
Serious Adverse Event (SAE) *Ref: ISO 14155* *Ref: MDCG 2020-10/1*	Adverse event that led to any of the following: a) death, b) serious deterioration in the health of the subject, users or other persons as defined by either: 1) a life-threatening illness or injury, or 2) a permanent impairment of a body structure or a body function, including chronic diseases, or

Table 18.2: Safety Definitions

Term	Definition
	3) in-patient hospitalization or prolongation of existing hospitalization, or 4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function c) foetal distress, fetal death, or a congenital abnormality or birth defect including physical or mental impairment. **NOTE 1:** Planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigational plan, without a serious deterioration in health, is not considered a serious adverse event.
Serious Adverse Device Effect (SADE) *Ref: ISO 14155* *Ref: MDCG 2020-10/1*	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Unanticipated Adverse Device Effect (UADE) *Ref: 21 CFR Part 812*	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
Unanticipated Serious Adverse Device Effect (USADE) *Ref: ISO 14155* *Ref: MDCG 2020-10/1*	Serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current risk assessment. **NOTE 1**: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.
Device Deficiency *Ref: ISO 14155* *Ref: MDCG 2020-10/1*	An inadequacy of a medical device related to its identity, quality, durability, reliability, usability, safety or performance. **NOTE 1**: Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling. **NOTE 2**: This definition includes device deficiencies related to the device under study.
Serious Health Threat *Ref: ISO 14155*	Signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in subjects, users or other persons, and that requires prompt remedial action for other subjects, users or other persons. **Note 1**: This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.

Table 18.2: Safety Definitions

Term	Definition
The following definitions will be used for defining hospitalization or prolongation of hospitalization for SAE classification purposes:	
Hospitalizations	Pre-planned, protocol-specified admission related to the clinical study (e.g. procedure required by protocol)Note: Hospitalization include: • New, unplanned admission for evaluation or treatment of an event occurring following stent placement, • Admitted to hospital for greater than or equal to 24 hrs Hospitalization does not include: • emergency room visit that does not result in in-patient admission Note: although an emergency room visit does not itself meet the definition for hospitalization, it may meet other serious criteria (e.g. medical or surgical intervention to prevent permanent impairment or damage) • elective and pre-planned treatment/surgery for a pre-existing condition that is documented in the subject's record at the time of consent/enrollment • admission for social reasons and/or respite care in the absence of any deterioration in the subject's general condition (e.g. subject is homeless, caregiver relief)
Prolongation of hospitalization	In-patient admission to the hospital that is prolonged beyond the expected standard duration for the condition under treatment. Note: new adverse events occurring during the hospitalization are evaluated to determine if they prolonged hospitalization or meet another SAE criteria.

18.3. *Relationship to Device(s), Index Procedure (including Study Stent Implant Procedure), and/or Study Stent Removal Procedure*

The Investigator must assess the relationship of the reportable AE to the device, and/or Index procedure (including Study Stent Implant Procedure), and/or the study stent removal procedure. See criteria in Table 18.3 .

Table 18.3: Criteria for Assessing Relationship of Study Device, Index Procedure (including Study Stent Implant Procedure), and Study Stent Removal Procedure to Adverse Event

Classification	Description
Not Related *Ref: MDCG 2020-10/1*	Relationship to the device, comparatoror procedures can be excluded when: - the event has no temporal relationship with the use of the study device or the procedures related to the use of the study device; - the serious event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible; - the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible – and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious event; - the event involves a body-site, or an organ that cannot be affected by the device or procedure; - the serious event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors); - the event does not depend on a false result given by the study device used for diagnosis, when applicable; - In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.
Possibly Related *Ref: MDCG 2020-10/1*	The relationship with the use of the study device or comparator, or the relationship with procedures is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed or no information has been obtained should also be classified as possible.
Probably Related *Ref: MDCG 2020-10/1*	The relationship with the use of the study device, or comparator, or the relationship with procedures seems relevant and/or the event cannot be reasonably explained by another cause.

Table 18.3: Criteria for Assessing Relationship of Study Device, Index Procedure (including Study Stent Implant Procedure), and Study Stent Removal Procedure to Adverse Event

Classification	Description
Causal Relationship *Ref: MDCG 2020-10/1*	The serious event is associated with the study device, comparator or with procedures beyond reasonable doubt when: - the event is a known side effect of the product category the device belongs to or of similar devices and procedures; - the event has a temporal relationship with the study device use/application or procedures; - the event involves a body-site or organ that -the study device or procedures are applied to; -the study device or procedures influence; - the serious event follows a known response pattern to the medical device (if the response pattern is previously known); - the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious event (when clinically feasible); - other possible causes (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out; - harm to the subject is due to error in use; - the event depends on a false result given by the study device used for diagnosis, when applicable; - In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

18.4. *Investigator Reporting Requirements*

The communication requirements for reporting to BSC are as shown in Table 18.4. These events should be reported via electronic data capture (EDC) system and may be reported via phone, or email if the EDC system is unavailable. The paper AE Notification Form or Device Deficiency Notification Form should be used to report AEs and Device Deficiencies as applicable during this time when the EDC system is unavailable.

Table 18.4: Investigator Reporting Timelines

Event Classification	**Communication Method**	**Communication Timeline post-market studies*** (EU MDR 2017/745, *MDCG 2020-10/1* MEDDEV 2.12/1: GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM)
Unanticipated Adverse Device Effect / Unanticipated Serious Adverse Device Effect NOT APPLICABLE; post market non-interventional study; standard of care	Complete AE eCRF page with all available new and updated information.	• Within 1 business day of first becoming aware of the event. • Terminating at the end of the study.
	Provide all relevant source documentation (deidentified/ pseudonymized) for reported event.	• Upon request of sponsor.
Serious Adverse Event	Complete AE eCRF page with all available new and updated information.	• Within 10 calendar days after becoming aware of the event or as per local/regional regulations. • Reporting required through the end of the study.
	Provide all relevant source documentation (de-identified/ pseudonymized) for reported event as requested.	• When documentation is available • Upon request of Sponsor
Serious Adverse Device Effects	Complete AE eCRF page with all available new and updated information.	• Within 3 calendar days of first becoming aware of the event or as per local/regional regulations. • Reporting required through the end of the study.
	Provide all relevant source documentation (de-identified/ pseudonymized) for reported event.	• When documentation is available • Upon request of sponsor
Device Deficiencies (including but not limited to malfunctions, use errors, andinadequacies in information supplied by the manufacturer, including labeling) Note: Any Device Deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, circumstances had been less fortunate is considered a reportable event.	Complete DeviceDeficiency CRF with all available new and updated information.	• Within 3 calendar days of first becoming aware of the event. • Reporting required through the end of the study.
	Provide all relevant source documentation (de-identified/ pseudonymized) for reported event.	• Upon request of sponsor

Event Classification	Communication Method	Communication Timeline post-market studies* (EU MDR 2017/745, *MDCG 2020-10/1* MEDDEV 2.12/1: GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM)
Index Procedure (including Study Stent Implant Procedure) **Related Adverse Events, Study Stent Removal Procedure Related Adverse Events** and **Adverse Device Effects**	Complete AE eCRF page, which contains such information as date of AE, treatment of AE resolution, assessment of seriousness and relationship to the device.	• In a timely manner (e.g. recommend within 30 business days) after becoming aware of the information. • Reporting required through end of study.
	Provide all relevant source documentation (de-identified/ pseudonymized) for reported event as requested.	• Upon request of sponsor

18.5. *Study Device Deficiencies*

Device deficiencies, for BSC Ureteral Stents and BSC Urinary Diversion Stents will be documented and reported to BSC. Device deficiencies should also be documented in the subject's source records.

Stent migrations and stent dislodgements should be reported as potential device deficiencies.

Stent migration is defined as any post procedure movement of the stent (either proximally towards the kidney or distally towards the bladder or complete distal migration) from its implant location; confirmed via imaging where necessary.

Stent dislodgement is defined as removal of the stent during the planned indwell time by external force or inadvertent pulling.

Device deficiencies are not adverse events. However, an adverse event that results from a device deficiency, should be recorded as an adverse event on the appropriate eCRF.

18.6. *Reporting to Regulatory Authorities / IRBs / ECs / REBs/ Investigators*

BSC is responsible for reporting adverse event information to all participating Principal Investigators, IRBs/ECs/REBs and regulatory authorities, as applicable.

The Principal Investigator is responsible for informing the IRB/EC/REB, and regulatory authorities of SAEs as required by local/regional regulations.

18.7. *Subject Death Reporting*

A subject death that occurs during the study should be reported to Boston Scientific as soon as possible and, in any event, within three (3) calendar days of site notification. The site's

IRB/EC/REB must be notified of any deaths in accordance with that site's IRB/EC/REB policies and procedures.

Notification of death should include a narrative that provides detailed information describing the circumstances surrounding the death. The details listed below should be addressed in the death narrative, for BSC to understand the circumstance surrounding the death:

- Date of death
- Immediate cause of death
- Whether the death was related to the study device or procedure
- Any other circumstances surrounding the death
- Investigator or sub-investigator signature and date

Also submit the following documentation:

- If the Subject expired in the hospital:
    - A copy of the medical records for that admission (e.g., H & P, consults, test results, operative reports, and/or progress notes from the hospital chart)
    - Death certificate (if available)
    - Autopsy report (if applicable)
- If the Subject expired outside of the hospital (e.g., home):
    - A copy of the most recent clinic visit (if not already submitted to Boston Scientific)
    - Death certificate (if available)
    - Autopsy report (if applicable)

The Independent Medical Reviewer will review information regarding subject deaths.

19. Informed Consent

Subject participation in this clinical study is voluntary. Informed Consent is required from each subject or his/her legally authorized representative. The Investigator is responsible for ensuring that Informed Consent is obtained prior to the use of any study devices, study-required procedures and/or testing, or data collection.

The obtaining and documentation of Informed Consent must be in accordance with the principles of the Declaration of Helsinki, ISO 14155, any applicable national regulations, and local Ethics Committee and/or Regulatory authority, as applicable. The ICF must be accepted by BSC or its delegate (e.g. CRO) and approved by the site's IRB/EC/REB, or central IRB, if applicable.

Boston Scientific will provide a study-specific template of the ICF to investigators participating in this study. The ICF template may be modified to meet the requirements of the investigative site's IRB/EC/REB. Any modification requires acceptance from BSC prior to use of the form. The ICF must be in a language understandable to the subject and if needed, BSC will assist the site in obtaining a written consent translation. Translated consent forms must also have IRB/EC/REB approval prior to their use. Privacy language shall be included in the body of the form or as a separate form as applicable.

The process of obtaining Informed Consent shall at a minimum include the following steps, as well as any other steps required by applicable laws, rules, regulations and guidelines:

- be conducted by the Principal Investigator or designee authorized to conduct the process,
- include a description of all aspects of the clinical study that are relevant to the subject's decision to participate throughout the clinical study,
- avoid any coercion of or undue influence of subjects to participate,
- not waive or appear to waive subject's legal rights,
- use native language that is non-technical and understandable to the subject or his/her legal representative,
- provide ample time for the subject to consider participation and ask questions if necessary,
- ensure important new information is provided to new and existing subjects throughout the clinical study.

The ICF shall always be signed and personally dated by the subject or legal representative competent to sign the ICF under the applicable laws, rules, regulations and guidelines and by the investigator and/or an authorized designee responsible for conducting the informed consent process. If a legal representative signs, the subject shall be asked to provide informed consent for continued participation as soon as his/her medical condition allows. The original signed ICF will be retained by the site and a copy of the signed and dated document and any other written information must be given to the person signing the form.

Failure to obtain subject consent will be reported by BSC to the applicable regulatory authority according to their requirements (e.g., FDA requirement is within 5 working days of learning of such an event). Any violations of the informed consent process must be reported as deviations to the sponsor and local regulatory authorities (e.g. IRB/EC/REB), as appropriate.

If new information becomes available that can significantly affect a subject's future health and medical care, that information shall be provided to the affected subject(s) in written form via a revised ICF or, in some situations, enrolled subjects may be requested to sign and date an addendum to the ICF. In addition to new significant information during the course of a study, other situations may necessitate revision of the ICF, such as if there are amendments to the applicable laws, protocol, a change in Principal Investigator, administrative changes, or

following annual review by the IRB/EC/REB. The new version of the ICF must be approved by the IRB/EC/REB. Acceptance by Boston Scientific is required if changes to the revised ICF are requested by the site's IRB/EC/REB. The IRB/EC/REB will determine the subject population to be re-consented.

A Screening/Enrolment Log will be maintained to document select information about candidates who fail to meet the general or "other specific" entry criteria.

20. Committees

20.1. *Safety Monitoring Process*

Personnel from the BSC Medical Safety and Safety Trial Operations group review safety data as it is reported by the sites throughout the duration of the study. During scheduled monitoring activities, clinical research monitors further support this review through their review of source documents and other data information. The BSC Medical Safety and Safety Trial Operations team include a physician Medical Director and individuals with subject matter expertise to evaluate and classify the events into the categories outlined above.

20.2. *Independent Medical Reviewer*

A single Independent Medical Reviewer (IMR) with pertinent expertise, will review and adjudicate relevant events reported by study investigators only for subjects who have received Tria™ Firm or Tria™ Soft stents. The IMR will also review and adjudicate all imaging and deaths reported by study investigators, regardless of stent type. The IMR will review a safety event dossier, which may include copies of subject source documents provided by study sites.

IMR responsibilities, qualifications, membership, and procedures are outlined in the IMR Charter.

20.3. *Steering Committee*

A Steering committee composed of recognized key opinion leaders/physicians in the field of Urology will be convened. The Steering Committee for the study will provide the following:

- Oversight of protocol development, data integrity, and timely dissemination and publication of the study results, and
- Prepare for, participate in, and/or facilitate investigator meetings, study Steering committee meetings or any other meetings at BSC's request, providing, among other things, leadership, protocol insight, and
- Serve as a general spokesperson for the study through word of mouth and podium presence at major clinical conferences, symposia, and various educational meetings, and

- Prepare for, participate in, and/or facilitate scheduled teleconferences, webcasts, and one-on-one contact with site investigators to discuss enrolment issues, study progress, and/or any new or pertinent study information, and
- Advise and assist BSC with the data preparation and analysis process.

21. Suspension or Termination

21.1 Premature Termination of the Study

Boston Scientific reserves the right to terminate the study at any stage but intends to exercise this right only for valid scientific or business reasons and reasons related to protection of subjects. Investigators, associated IRBs/ECs/REBs, and regulatory authorities, as applicable, will be notified in writing in the event of study termination.

21.1.1 Criteria for Premature Termination of the Study

Possible reasons for premature study termination include, but are not limited to, the following:

- Suspicion of an unacceptable risk, including serious health threat. In this case, the sponsor shall suspend the clinical investigation while the risk is assessed. The sponsor shall terminate the clinical investigation if an unacceptable risk which cannot be controlled is confirmed.
- Instructions by the IRB/EC/REB or regulatory authorities to suspend or terminate the clinical investigation.
- An enrollment rate far below expectation that prejudices the conclusion of the study.
- A decision on the part of Boston Scientific to suspend or discontinue development/marketing of the device.

21.2 Termination of Study Participation by the Investigator or Withdrawal of IRB/ EC/REB Approval

Any investigator, or associated IRB/EC/REB or regulatory authority may discontinue participation in the study or withdraw approval of the study, respectively, with suitable written notice to Boston Scientific. Investigators, associated IRBs/ECs/REBs, and regulatory authorities, as applicable, will be notified in writing in the event of these occurrences.

21.3 Requirements for Documentation and Subject Follow-up

In the event of premature study termination, a written statement as to why the premature termination has occurred will be provided to all participating sites by Boston Scientific. The IRB/EC/REB and regulatory authorities, as applicable, will be notified. Detailed information on how enrolled subjects will be managed thereafter will be provided.

In the event an IRB/EC/REB terminates participation in the study, participating investigators, associated IRBs/ECs/REBs, and regulatory authorities, as applicable, will be notified in writing. Detailed information on how enrolled subjects will be managed thereafter will be provided by Boston Scientific.

In the event a Principal Investigator terminates participation in the study, study responsibility will be transferred to another investigator, if possible. In the event there are no opportunities to transfer Principal Investigator responsibility; detailed information on how enrolled subjects will be managed thereafter will be provided by Boston Scientific.

The Principal Investigator or his/her designee must return all study-related documents and devices, if supplied by Boston Scientific, unless this action would jeopardize the rights, safety, or welfare of the subjects.

21.4 Criteria for Suspending/Terminating a Study Site

Boston Scientific reserves the right to stop the inclusion of subjects at a study site at any time after the study initiation visit if no subjects have been enrolled for a period beyond 3 months after site initiation, or if the site has multiple or severe protocol violations/noncompliance without justification and/or fails to follow remedial actions.

In the event of termination of site participation, all devices and testing equipment, as applicable, will be returned to BSC unless this action would jeopardize the rights, safety or well-being of the subjects. The IRB/EC/REB and regulatory authorities, as applicable, will be notified. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

22. Study Registration and Results

22.1. *Study Registration*

To comply with applicable laws and regulations, the study will be registered on a publicly accessible database.

22.2. *Clinical Investigation Report*

Study results will be made available in accordance with the legal requirements and the recognized ethical principles, in accordance with the Boston Scientific Policy. A Clinical Investigation Report will be made available to all investigators, IRB/EC/REB and regulatory authorities, as applicable in accordance with the Boston Scientific Policy and local requirements. As applicable an abbreviated Clinical Investigation Report will be made available on a publicly accessible database.

23. Publication Policy

BSC requires disclosure of its involvement as a sponsor or financial supporter in any publication or presentation relating to a BSC study or its results. BSC will submit study results for publication (regardless of study outcome) following the conclusion or termination of the study. Boston Scientific adheres to the Contributorship Criteria set forth in the Uniform Requirements of the International Committee of Medical Journal Editors (ICMJE; http://www.icmje.org). In order to ensure the public disclosure of study results in a timely manner, while maintaining an unbiased presentation of study outcomes, BSC personnel may assist authors and investigators in publication preparation provided the following guidelines are followed:

- All authorship and contributorship requirements as described above must be followed.
- BSC involvement in the publication preparation and the BSC Publication Policy should be discussed with the Coordinating Principal Investigator(s) and/or Executive/Steering Committee at the onset of the project.
- The First and Senior authors are the primary drivers of decisions regarding publication content, review, approval, and submission.

The data, analytic methods, and study materials for this clinical trial may be made available to other researchers in accordance with the Boston Scientific Data Sharing Policy (https://www.bostonscientific.com/).

24. Reimbursement and Compensation for Subjects

24.1. *Subject Reimbursement*

Subjects may be compensated for participation in the study, in accordance with pertinent country laws and regulations and per the study site's regulations.

24.2. *Compensation for Subject's Health Injury*

Boston Scientific will purchase an insurance policy to cover the cost of potential health injury for study subjects, if required by applicable law.

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26. Abbreviations and Definitions

26.1. *Abbreviations*

Abbreviations are shown in Table 26.1.

Table 26.1: Abbreviations

Abbreviation/Acronym	Term
AE	Adverse Event
AT	As Treated
BSC	Boston Scientific Corporation
CA	Competent Authority
CCGs	Case Report Form Completion Guidelines
DFU	Directions for Use
EC	Ethics Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
GDPR	Global Data Protection
HIPAA	Health Information Portability and Accountability Act
ICF	Informed Consent Form
IFU	Instructions For Use
IRB	Institutional Review Board
ITT	Intent to Treat
PP	Per Protocol
QoL	Quality of Life
REB	Research Ethics Board
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
SOC	Standard of Care
UAS	Ureteral Access Sheaths
UDS	Urinary Diversion Stent
US	Ureteral Stent

26.2. *Definitions*

Terms are defined in Table 26.2.

Table 26.2: Definitions

Term	Definition
Adverse Device Effect	See Table 18.2-1, Safety Definitions
Adverse Event	See Table 18.2-1, Safety Definitions
As Treated	All subjects for whom placement of the device is completed.
Consent Ineligible	A subject who has signed the ICF but is found to not meet eligibility criteria. These subjects can still receive the BSC Ureteral Stent per standard of care treatment, but do not count toward enrollment. The subjects will be exited and will not undergo any study related procedures once their ineligibility has been determined. These subjects do not count toward enrollment.
Data Controller	In GDPR: The entity which determines the purposes (why the entity needs to process data) and means (database managed through a software, hard copy files, centralized database) of personal information processing.
Data Processor	In GDPR: The person or entity processing the data on behalf and according to the instructions of the data controller. An entity which uses an external data processor must ensure that, in the contract, its data processor offers adequate guarantees to ensure the security and confidentiality of the data communicated.
Data Subject	In GDPR: Any living individual to whom the personal data relates. Examples of data subjects in this study are physicians and subjects.
Deviation (Clinical Protocol)	A departure from the requirements established in the clinical trial protocol (e.g., inclusion/exclusion criteria; visit windows, required procedures, and any specified consenting process requirements).
Exited Prior to Procedure	A subject who signs the informed consent, meets eligibility criteria but then does not undergo have the index study procedure initiated (first incision) or receive the study device. The original ICF and screening documentation for these patients should be maintained in the site's files. There are no follow-up requirements and these subjects do not count toward enrollment. Any data collected prior to procedure is not included in statistical analyses. These subjects do not count toward enrollment.
General Data Protection Regulation (GDPR)	The General Data Protection Regulation (GDPR) is a European law that will govern how companies (whether EU-based or not) use personal data.
Identifiers	"Identifiers" are personal data that can be used alone or in combination with other identifiers to identify an individual.
Index Procedure	Describes the entirety of the procedure in which the stent is implanted; includes ureteral access sheath insertion, scoping, irrigation, laser lithotripsy, basketing, stent implant, etc.
Independent Medical Reviewer	An independent practitioner with trial relevant therapeutic expertise that reviews and adjudicates important endpoints and relevant adverse events reported by study investigators.
Intent-To-Treat	A subject who signs the informed consent, meets eligibility criteria, and for whom the index procedure is initiated.
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Table 26.2: Definitions	
Term	**Definition**
Monitoring	EN ISO 14155Act of overseeing the progress of a clinical investigation and to ensure that it is conducted, recorded, and reported in accordance with the CIP, written procedures, this International Standard, and the applicable regulatory requirements ICH E6 1.38 - The act of overseeing the progress of a clinical study and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), GCP, and the applicable regulatory requirement(s). FDA Guidance - Generally refers to the methods used by sponsors of investigational studies, or CROs delegated responsibilities for the conduct of such studies, to oversee the conduct of and reporting of data from clinical investigations, including appropriate investigator supervision of study site staff and third-party contractors.
Multi-center study	A clinical trial conducted according to a single protocol but at more than one site, and therefore carried out by more than one investigator.
Patient-Reported Outcome (PRO)	A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured by self-report or by interview provided that the interviewer records only the patient's response.
Per Protocol	All subjects in the As Treated Population who have no major protocol deviations.
Personal Data	GDPR defines "Personal data" to be any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
Point of Enrollment	Time at which subject has signs and dates the informed consent (ICF) and meets the eligibility criteria.
Processing	Any use of personal data by BSC (or a third party on behalf of BSC), including data collection, data sharing, anonymization, and data storage (note the mere storage of data is considered as processing).
RAVE	Proprietary electronic data capture system for capturing, managing and reporting clinical study data.
Recruitment	Active efforts to identify subjects who may be suitable for enrollment in the clinical investigation.
Sensitive Personal Data	GDPR defines "Sensitive personal" data as a subset of Personal Data, which, due to their nature have been classified as deserving additional privacy and security protections because their processing may create a risk for an individual's fundamental right and freedom.
Serious Adverse Device Effect (SADE)	See Table 18.2-1, Safety Definitions

Table 26.2: Definitions	
Term	**Definition**
Serious Adverse Event (SAE)	See Table 18.2-1, Safety Definitions
Site Noncompliance	A departure from the regulations established by the relevant regulatory authorities. Includes all clinical site noncompliance that does not represent a direct deviation from the clinical trial protocol, e.g. IRB/IEC and sponsor reporting, device storage and accountability, staff qualifications and training, facilities, and equipment required to conduct the clinical trial, collection and documentation of data in source documents and CRFs, investigator oversight, etc.
Source Data	All information in original records of clinical findings, observations, or other activities in a clinical investigation, necessary for the reconstruction and evaluation of the clinical investigation. *(Ref. ISO 14155-2011)*
Source Document	Printed, optical or electronic document containing source data. Examples: Hospital records, laboratory notes, device accountability records, photographic negatives, radiographs, records kept at the investigation site, at the laboratories and at the medico-technical departments involved in the clinical investigation. *(Ref. ISO 14155-2011)*
Study Stent Implant Procedure	Describes the portion of the index procedure only inclusive of placing the stent
Technical Success	For Ureteral Stents: Stented kidney drains (to bladder) during the planned indwell time with no re-intervention due to obstruction of the stented ureters For Urinary Diversion Stents: Drainage followingstent placement during the planned indwell time with no re-intervention due to obstruction

27. Appendices

27.1. *Appendix 1 Ureteral Stent Product Codes*

Product Description	UPN/Product Code
Contour Ureteral Stent	
Contour™ Ureteral Stent 6F x 20cm	M0061802200
Contour™ Ureteral Stent 6F x 22cm	M0061802210
Contour™ Ureteral Stent 6F x 24cm	M0061802220
Contour™ Ureteral Stent 6F x 26cm	M0061802230
Contour™ Ureteral Stent 6F x 28cm	M0061802240
Contour™ Ureteral Stent 6F x 30cm	M0061802250
Contour™ Ureteral Stent 7F x 20cm	M0061802300
Contour™ Ureteral Stent 7F x 22cm	M0061802310
Contour™ Ureteral Stent 7F x 24cm	M0061802320
Contour™ Ureteral Stent 7F x 26cm	M0061802330
Contour™ Ureteral Stent 7F x 28cm	M0061802340
Contour™ Ureteral Stent 7F x 30cm	M0061802350
Contour™ Ureteral Stent 8F x 20cm	M0061802400
Contour™ Ureteral Stent 8F x 22cm	M0061802410
Contour™ Ureteral Stent 8F x 24cm	M0061802420
Contour™ Ureteral Stent 8F x 26cm	M0061802430
Contour™ Ureteral Stent 8F x 28cm	M0061802440
Contour™ Ureteral Stent 8F x 30cm	M0061802450
Contour™ Ureteral Stent 6F x 20cm	M0061805200
Contour™ Ureteral Stent 6F x 22cm	M0061805210
Contour™ Ureteral Stent 6F x 24cm	M0061805220
Contour™ Ureteral Stent 6F x 26cm	M0061805230
Contour™ Ureteral Stent 6F x 28cm	M0061805240
Contour™ Ureteral Stent 6F x 30cm	M0061805250
Contour™ Ureteral Stent 7F x 22cm	M0061805310

Product Description	UPN/Product Code
Contour™ Ureteral Stent 7F x 24cm	M0061805320
Contour™ Ureteral Stent 7F x 26cm	M0061805330
Contour™ Ureteral Stent 7F x 28cm	M0061805340
Contour™ Ureteral Stent 8F x 24cm	M0061805420
Contour™ Ureteral Stent 8F x 26cm	M0061805430
Contour VL Ureteral Stent	
Contour VL™ Variable Length Ureteral Stent 4.8F x 22cm-30cm	M0061801550
Contour VL™ Variable Length Ureteral Stent 6F x 22cm-30cm	M0061801560
Contour VL™ Variable Length Ureteral Stent 7F x 22cm-30cm	M0061801570
Percuflex Ureteral Stent	
Percuflex™ Ureteral Stent 6F x 28cm	M0061453630
Percuflex™ Ureteral Stent 6F x 30cm	M0061453640
Percuflex™ Ureteral Stent 7F x 20cm	M0061453690
Percuflex™ Ureteral Stent 7F x 22cm	M0061453700
Percuflex™ Ureteral Stent 7F x 24cm	M0061453710
Percuflex™ Ureteral Stent 7F x 26cm	M0061453720
Percuflex™ Ureteral Stent 7F x 28cm	M0061453730
Percuflex™ Ureteral Stent 7F x 30cm	M0061453740
Percuflex™ Ureteral Stent 8F x 20cm	M0061453790
Percuflex™ Ureteral Stent 8F x 22cm	M0061453800
Percuflex™ Ureteral Stent 8F x 24cm	M0061453810
Percuflex™ Ureteral Stent 8F x 26cm	M0061453820
Percuflex™ Ureteral Stent 8F x 28cm	M0061453830
Percuflex™ Ureteral Stent 8F x 30cm	M0061453840
Percuflex Plus Ureteral Stent	
Percuflex™ Plus Ureteral Stent 4.8F x 10cm	M0061751950
Percuflex™ Plus Ureteral Stent 4.8F x 12cm	M0061751960
Percuflex™ Plus Ureteral Stent 4.8F x 14cm	M0061751970

Product Description	UPN/Product Code
Percuflex™ Plus Ureteral Stent 4.8F x 16cm	M0061751980
Percuflex™ Plus Ureteral Stent 4.8F x 18cm	M0061751990
Percuflex™ Plus Ureteral Stent 4.8F x 20cm	M0061752500
Percuflex™ Plus Ureteral Stent 4.8F x 22cm	M0061752510
Percuflex™ Plus Ureteral Stent 4.8F x 24cm	M0061752520
Percuflex™ Plus Ureteral Stent 4.8F x 26cm	M0061752530
Percuflex™ Plus Ureteral Stent 4.8F x 28cm	M0061752540
Percuflex™ Plus Ureteral Stent 4.8F x 30cm	M0061752550
Percuflex™ Plus Ureteral Stent 6F x 20cm	M0061752600
Percuflex™ Plus Ureteral Stent 6F x 22cm	M0061752610
Percuflex™ Plus Ureteral Stent 6F x 24cm	M0061752620
Percuflex™ Plus Ureteral Stent 6F x 26cm	M0061752630
Percuflex™ Plus Ureteral Stent 6F x 28cm	M0061752640
Percuflex™ Plus Ureteral Stent 6F x 30cm	M0061752650
Percuflex™ Plus Ureteral Stent 7F x 20cm	M0061752700
Percuflex™ Plus Ureteral Stent 7F x 22cm	M0061752710
Percuflex™ Plus Ureteral Stent 7F x 24cm	M0061752720
Percuflex™ Plus Ureteral Stent 7F x 26cm	M0061752730
Percuflex™ Plus Ureteral Stent 7F x 28cm	M0061752740
Percuflex™ Plus Ureteral Stent 7F x 30cm	M0061752750
Percuflex™ Plus Ureteral Stent 8F x 20cm	M0061752800
Percuflex™ Plus Ureteral Stent 8F x 22cm	M0061752810
Percuflex™ Plus Ureteral Stent 8F x 24cm	M0061752820
Percuflex™ Plus Ureteral Stent 8F x 26cm	M0061752830
Percuflex™ Plus Ureteral Stent 8F x 28cm	M0061752840
Percuflex™ Plus Ureteral Stent 8F x 30cm	M0061752850
Percuflex™ Plus Ureteral Stent 4.8F x 22cm braided retrieval line	M0061755510
Percuflex™ Plus Ureteral Stent 4.8F x 24cm braided retrieval line	M0061755520

Product Description	UPN/Product Code
Percuflex™ Plus Ureteral Stent 4.8F x 26cm braided retrieval line	M0061755530
Percuflex™ Plus Ureteral Stent 4.8F x 28cm braided retrieval line	M0061755540
Percuflex™ Plus Ureteral Stent 6F x 20cm braided retrieval line	M0061755600
Percuflex™ Plus Ureteral Stent 6F x 22cm braided retrieval line	M0061755610
Percuflex™ Plus Ureteral Stent 6F x 24cm braided retrieval line	M0061755620
Percuflex™ Plus Ureteral Stent 6F x 26cm braided retrieval line	M0061755630
Percuflex™ Plus Ureteral Stent 6F x 28cm braided retrieval line	M0061755640
Percuflex™ Plus Ureteral Stent 6F x 30cm braided retrieval line	M0061755650
Percuflex™ Plus Ureteral Stent 7F x 22cm braided retrieval line	M0061755710
Percuflex™ Plus Ureteral Stent 7F x 24cm braided retrieval line	M0061755720
Percuflex™ Plus Ureteral Stent 7F x 26cm braided retrieval line	M0061755730
Percuflex™ Plus Ureteral Stent 7F x 28cm braided retrieval line	M0061755740
Percuflex™ Plus Ureteral Stent 8F x 22cm braided retrieval line	M0061755810
Percuflex™ Plus Ureteral Stent 8F x 24cm braided retrieval line	M0061755820
Percuflex™ Plus Ureteral Stent 8F x 26cm braided retrieval line	M0061755830
Percuflex™ Plus Ureteral Stent 8F x 28cm braided retrieval line	M0061755840
Polaris Ureteral Stent	
Polaris™ Ultra Ureteral Stent 5F x 10cm	M0061921110
Polaris™ Ultra Ureteral Stent 5F x 12cm	M0061921120
Polaris™ Ultra Ureteral Stent 5F x 14cm	M0061921130
Polaris™ Ultra Ureteral Stent 5F x 16cm	M0061921140
Polaris™ Ultra Ureteral Stent 5F x 18cm	M0061921150
Polaris™ Ultra Ureteral Stent 5F x 20cm	M0061921200
Polaris™ Ultra Ureteral Stent 5F x 22cm	M0061921210
Polaris™ Ultra Ureteral Stent 5F x 24cm	M0061921220
Polaris™ Ultra Ureteral Stent 5F x 26cm	M0061921230
Polaris™ Ultra Ureteral Stent 5F x 28cm	M0061921240
Polaris™ Ultra Ureteral Stent 5F x 30cm	M0061921250

Product Description	UPN/Product Code
Polaris™ Ultra Ureteral Stent 6F x 20cm	M0061921300
Polaris™ Ultra Ureteral Stent 6F x 22cm	M0061921310
Polaris™ Ultra Ureteral Stent 6F x 24cm	M0061921320
Polaris™ Ultra Ureteral Stent 6F x 26cm	M0061921330
Polaris™ Ultra Ureteral Stent 6F x 28cm	M0061921340
Polaris™ Ultra Ureteral Stent 6F x 30cm	M0061921350
Polaris™ Ultra Ureteral Stent 7F x 20cm	M0061921400
Polaris™ Ultra Ureteral Stent 7F x 22cm	M0061921410
Polaris™ Ultra Ureteral Stent 7F x 24cm	M0061921420
Polaris™ Ultra Ureteral Stent 7F x 26cm	M0061921430
Polaris™ Ultra Ureteral Stent 7F x 28cm	M0061921440
Polaris™ Ultra Ureteral Stent 7F x 30cm	M0061921450
Polaris™ Ultra Ureteral Stent 8F x 20cm	M0061921500
Polaris™ Ultra Ureteral Stent 8F x 22cm	M0061921510
Polaris™ Ultra Ureteral Stent 8F x 24cm	M0061921520
Polaris™ Ultra Ureteral Stent 8F x 26cm	M0061921530
Polaris™ Ultra Ureteral Stent 8F x 28cm	M0061921540
Polaris™ Ultra Ureteral Stent 8F x 30cm	M0061921550
Tria Firm Ureteral Stent	
Tria™ Firm Ureteral Stent 4.8F x 10cm	M0061902050
Tria™ Firm Ureteral Stent 4.8F x 12cm	M0061902060
Tria™ Firm Ureteral Stent 4.8F x 14cm	M0061902070
Tria™ Firm Ureteral Stent 4.8F x 16cm	M0061902080
Tria™ Firm Ureteral Stent 4.8F x 18cm	M0061902090
Tria™ Firm Ureteral Stent 4.8F x 20cm	M0061902100
Tria™ Firm Ureteral Stent 4.8F x 22cm	M0061902110
Tria™ Firm Ureteral Stent 4.8F x 24cm	M0061902120
Tria™ Firm Ureteral Stent 4.8F x 26cm	M0061902130

Product Description	UPN/Product Code
Tria™ Firm Ureteral Stent 4.8F x 28cm	M0061902140
Tria™ Firm Ureteral Stent 4.8F x 30cm	M0061902150
Tria™ Firm Ureteral Stent 6F x 20cm	M0061902200
Tria™ Firm Ureteral Stent 6F x 22cm	M0061902210
Tria™ Firm Ureteral Stent 6F x 24cm	M0061902220
Tria™ Firm Ureteral Stent 6F x 26cm	M0061902230
Tria™ Firm Ureteral Stent 6F x 28cm	M0061902240
Tria™ Firm Ureteral Stent 6F x 30cm	M0061902250
Tria™ Firm Ureteral Stent 7F x 20cm	M0061902300
Tria™ Firm Ureteral Stent 7F x 22cm	M0061902310
Tria™ Firm Ureteral Stent 7F x 24cm	M0061902320
Tria™ Firm Ureteral Stent 7F x 26cm	M0061902330
Tria™ Firm Ureteral Stent 7F x 28cm	M0061902340
Tria™ Firm Ureteral Stent 7F x 30cm	M0061902350
Tria™ Firm Ureteral Stent 8F x 20cm	M0061902400
Tria™ Firm Ureteral Stent 8F x 22cm	M0061902410
Tria™ Firm Ureteral Stent 8F x 24cm	M0061902420
Tria™ Firm Ureteral Stent 8F x 26cm	M0061902430
Tria™ Firm Ureteral Stent 8F x 28cm	M0061902440
Tria™ Firm Ureteral Stent 8F x 30cm	M0061902450
Tria™ Firm Ureteral Stent 4.8F x 10cm w/o Sideholes	M0061902550
Tria™ Firm Ureteral Stent 4.8F x 12cm w/o Sideholes	M0061902560
Tria™ Firm Ureteral Stent 4.8F x 14cm w/o Sideholes	M0061902570
Tria™ Firm Ureteral Stent 4.8F x 16cm w/o Sideholes	M0061902580
Tria™ Firm Ureteral Stent 4.8F x 18cm w/o Sideholes	M0061902590
Tria™ Firm Ureteral Stent 4.8F x 20cm w/o Sideholes	M0061902600
Tria™ Firm Ureteral Stent 4.8F x 22cm w/o Sideholes	M0061902610
Tria™ Firm Ureteral Stent 4.8F x 24cm w/o Sideholes	M0061902620

Product Description	UPN/Product Code
Tria™ Firm Ureteral Stent 4.8F x 26cm w/o Sideholes	M0061902630
Tria™ Firm Ureteral Stent 4.8F x 28cm w/o Sideholes	M0061902640
Tria™ Firm Ureteral Stent 4.8F x 30cm w/o Sideholes	M0061902650
Tria™ Firm Ureteral Stent 6F x 20cm w/o Sideholes	M0061902700
Tria™ Firm Ureteral Stent 6F x 22cm w/o Sideholes	M0061902710
Tria™ Firm Ureteral Stent 6F x 24cm w/o Sideholes	M0061902720
Tria™ Firm Ureteral Stent 6F x 26cm w/o Sideholes	M0061902730
Tria™ Firm Ureteral Stent 6F x 28cm w/o Sideholes	M0061902740
Tria™ Firm Ureteral Stent 6F x 30cm w/o Sideholes	M0061902750
Tria™ Firm Ureteral Stent 7F x 20cm w/o Sideholes	M0061902800
Tria™ Firm Ureteral Stent 7F x 22cm w/o Sideholes	M0061902810
Tria™ Firm Ureteral Stent 7F x 24cm w/o Sideholes	M0061902820
Tria™ Firm Ureteral Stent 7F x 26cm w/o Sideholes	M0061902830
Tria™ Firm Ureteral Stent 7F x 28cm w/o Sideholes	M0061902840
Tria™ Firm Ureteral Stent 7F x 30cm w/o Sideholes	M0061902850
Tria™ Firm Ureteral Stent 8F x 20cm w/o Sideholes	M0061902900
Tria™ Firm Ureteral Stent 8F x 22cm w/o Sideholes	M0061902910
Tria™ Firm Ureteral Stent 8F x 24cm w/o Sideholes	M0061902920
Tria™ Firm Ureteral Stent 8F x 26cm w/o Sideholes	M0061902930
Tria™ Firm Ureteral Stent 8F x 28cm w/o Sideholes	M0061902940
Tria™ Firm Ureteral Stent 8F x 30cm w/o Sideholes	M0061902950
Tria Soft Ureteral Stent	
Tria™ Soft Ureteral Stent 6F x 20cm	M0061903200
Tria™ Soft Ureteral Stent 6F x 22cm	M0061903210
Tria™ Soft Ureteral Stent 6F x 24cm	M0061903220
Tria™ Soft Ureteral Stent 6F x 26cm	M0061903230
Tria™ Soft Ureteral Stent 6F x 28cm	M0061903240
Tria™ Soft Ureteral Stent 6F x 30cm	M0061903250

Product Description	UPN/Product Code
Tria™ Soft Ureteral Stent 7F x 20cm	M0061903300
Tria™ Soft Ureteral Stent 7F x 22cm	M0061903310
Tria™ Soft Ureteral Stent 7F x 24cm	M0061903320
Tria™ Soft Ureteral Stent 7F x 26cm	M0061903330
Tria™ Soft Ureteral Stent 7F x 28cm	M0061903340
Tria™ Soft Ureteral Stent 7F x 30cm	M0061903350
Tria™ Soft Ureteral Stent 8F x 20cm	M0061903400
Tria™ Soft Ureteral Stent 8F x 22cm	M0061903410
Tria™ Soft Ureteral Stent 8F x 24cm	M0061903420
Tria™ Soft Ureteral Stent 8F x 26cm	M0061903430
Tria™ Soft Ureteral Stent 8F x 28cm	M0061903440
Tria™ Soft Ureteral Stent 8F x 30cm	M0061903450
Tria™ Soft Ureteral Stent 6F x 20cm w/o Sideholes	M0061903700
Tria™ Soft Ureteral Stent 6F x 22cm w/o Sideholes	M0061903710
Tria™ Soft Ureteral Stent 6F x 24cm w/o Sideholes	M0061903720
Tria™ Soft Ureteral Stent 6F x 26cm w/o Sideholes	M0061903730
Tria™ Soft Ureteral Stent 6F x 28cm w/o Sideholes	M0061903740
Tria™ Soft Ureteral Stent 6F x 30cm w/o Sideholes	M0061903750
Tria™ Soft Ureteral Stent 7F x 20cm w/o Sideholes	M0061903800
Tria™ Soft Ureteral Stent 7F x 22cm w/o Sideholes	M0061903810
Tria™ Soft Ureteral Stent 7F x 24cm w/o Sideholes	M0061903820
Tria™ Soft Ureteral Stent 7F x 26cm w/o Sideholes	M0061903830
Tria™ Soft Ureteral Stent 7F x 28cm w/o Sideholes	M0061903840
Tria™ Soft Ureteral Stent 7F x 30cm w/o Sideholes	M0061903850
Percuflex Urinary Diversion Stent	
Percuflex Urinary Diversion Stent Set, Open Tip 6Fr (2.0mm) x 80cm	M0061602050
Percuflex Urinary Diversion Stent Set, Open Tip 7Fr (2.3mm) x 80cm	M0061602100
Percuflex Urinary Diversion Stent Set, Open Tip 8Fr (2.7mm) x 80cm	M0061602150
Percuflex Urinary Diversion Stent Set, Closed Tip 6Fr (2.0mm) x 80cm	M0061602250
Percuflex Urinary Diversion Stent Set, Closed Tip 7Fr (2.3mm) x 80cm	M0061602300

Product Description	UPN/Product Code
Percuflex Urinary Diversion Stent Set, Closed Tip 8Fr (2.7mm) x 80cm	M0061602350
Polaris Loop Ureteral Stent	
Polaris Loop Ureteral Stent, 5 Fr x 10cm	M0061552110
Polaris Loop Ureteral Stent, 5 Fr x 12cm	M0061552120
Polaris Loop Ureteral Stent, 5 Fr x 14cm	M0061552130
Polaris Loop Ureteral Stent, 5 Fr x 16cm	M0061552140
Polaris Loop Ureteral Stent, 5 Fr x 18cm	M0061552150
Polaris Loop Ureteral Stent, 5 Fr x 20cm	M0061552200
Polaris Loop Ureteral Stent, 5 Fr x 22cm	M0061552210
Polaris Loop Ureteral Stent, 5 Fr x 24cm	M0061552220
Polaris Loop Ureteral Stent, 5 Fr x 26cm	M0061552230
Polaris Loop Ureteral Stent, 5 Fr x 28cm	M0061552240
Polaris Loop Ureteral Stent, 5 Fr x 30cm	M0061552250
Polaris Loop Ureteral Stent, 6 Fr x 20cm	M0061552300
Polaris Loop Ureteral Stent, 6 Fr x 22cm	M0061552310
Polaris Loop Ureteral Stent, 6 Fr x 24cm	M0061552320
Polaris Loop Ureteral Stent, 6 Fr x 26cm	M0061552330
Polaris Loop Ureteral Stent, 6 Fr x 28cm	M0061552340
Polaris Loop Ureteral Stent, 6 Fr x 30cm	M0061552350
Polaris Loop Ureteral Stent, 7 Fr x 20cm	M0061552400
Polaris Loop Ureteral Stent, 7 Fr x 22cm	M0061552410
Polaris Loop Ureteral Stent, 7 Fr x 24cm	M0061552420
Polaris Loop Ureteral Stent, 7 Fr x 26cm	M0061552430
Polaris Loop Ureteral Stent, 7 Fr x 28cm	M0061552440
Polaris Loop Ureteral Stent, 7 Fr x 30cm	M0061552450
Polaris Loop Ureteral Stent, 8 Fr x 20cm	M0061552500
Polaris Loop Ureteral Stent, 8 Fr x 22cm	M0061552510
Polaris Loop Ureteral Stent, 8 Fr x 24cm	M0061552520
Polaris Loop Ureteral Stent, 8 Fr x 26cm	M0061552530
Polaris Loop Ureteral Stent, 8 Fr x 28cm	M0061552540
Polaris Loop Ureteral Stent, 8 Fr x 30cm	M0061552550
Contour™ SureDrive™ Steerable Ureteral Stent (with steerable positioner)	
Contour™ SureDrive™ Steerable Ureteral Stent Set 6Fx20cm	M0061458590
Contour™ SureDrive™ Steerable Ureteral Stent Set 6Fx22cm	M0061458600
Contour™ SureDrive™ Steerable Ureteral Stent Set 6Fx24cm	M0061458610
Contour™ SureDrive™ Steerable Ureteral Stent Set 6Fx26cm	M0061458620
Contour™ SureDrive™ Steerable Ureteral Stent Set 6Fx28cm	M0061458630
Contour™ SureDrive™ Steerable Ureteral Stent Set 7Fx20cm	M0061458640

Product Description	UPN/Product Code
Contour™ SureDrive™ Steerable Stent Set 7Fx22cm	M0061458650
Contour™ SureDrive™ Steerable Stent Set 7Fx24cm	M0061458660
Contour™ SureDrive™ Steerable Stent Set 7Fx26cm	M0061458670
Contour™ SureDrive™ Steerable Stent Set 7Fx28cm	M0061458680
Contour™ SureDrive™ Steerable Stent Set 8Fx22cm	M0061458690
Contour™ SureDrive™ Steerable Stent Set 8Fx24cm	M0061458700
Contour™ SureDrive™ Steerable Stent Set 8Fx26cm	M0061458710
Contour™ SureDrive™ Steerable Stent Set 8Fx28cm	M0061458720
Contour™ VL SureDrive™ Steerable Ureteral Stent (with steerable positioner)	
Contour VL™ SureDrive™ Steerable Ureteral Stent Set 4.8Fx22cm-30cm	M0061458730
Contour VL™ SureDrive™ Steerable Ureteral Stent Set 6Fx22cm-30cm	M0061458740
Contour VL™ SureDrive™ Steerable Ureteral Stent Set 7Fx22cm-30cm	M0061458750
Contour™ Injection Stent Sets and Contour VL™ Injection Stent Sets	
Contour™ Injection Stent Set 4.8Fx24cm	M0061856070
Contour™ Injection Stent Set 4.8Fx26cm	M0061856080
Contour™ Injection Stent Set 4.8Fx28cm	M0061856090
Contour™ Injection Stent Set 6Fx22cm	M0061856120
Contour™ Injection Stent Set 6Fx24cm	M0061856130
Contour™ Injection Stent Set 6Fx26cm	M0061856140
Contour™ Injection Stent Set 6Fx28cm	M0061856150
Contour™ Injection Stent Set 6Fx30cm	M0061856160
Contour™ Injection Stent Set 7Fx20cm	M0061856170
Contour™ Injection Stent Set 7Fx22cm	M0061856180
Contour™ Injection Stent Set 7Fx24cm	M0061856190
Contour™ Injection Stent Set 7Fx26cm	M0061856200
Contour™ Injection Stent Set 7Fx28cm	M0061856210
Contour™ Injection Stent Set 7Fx30cm	M0061856220
Contour VL™ Injection Stent Set - Variable Length Injection Stent Set 4.8Fx22cm-30cm	*M0061856290
Contour VL™ Injection Stent Set - Variable Length Injection Stent Set 6Fx22cm-30cm	*M0061856300
Contour VL™ Injection Stent Set - Variable Length Injection Stent Set 7Fx22-30cm	*M0061856310
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent (with steerable positioner)	
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 4.8Fx20cm	M0061457410
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 4.8Fx22cm	M0061457420
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 4.8Fx24cm	M0061457430
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 4.8Fx26cm	M0061457440
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 4.8Fx28cm	M0061457450

Product Description	UPN/Product Code
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 6Fx20cm	M0061457460
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 6Fx22cm	M0061457470
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 6Fx24cm	M0061457480
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 6Fx26cm	M0061457490
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 6Fx28cm	M0061457500
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 7Fx20cm	M0061458500
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 7Fx22cm	M0061458510
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 7Fx24cm	M0061458520
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 7Fx26cm	M0061458530
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 7Fx28cm	M0061458540
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 8Fx22cm	M0061458550
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 8Fx24cm	M0061458560
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 8Fx26cm	M0061458570
Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set 8Fx28cm	M0061458580

27.2. *Appendix 2 Clavien-Dindo Classification*

Grades	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III	Requiring surgical, endoscopic or radiological intervention
- IIIa	Intervention not under general anesthesia
- IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU-management
- IVa	single organ dysfunction (including dialysis)
- IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix “d”	d for disability

**brain hemorrhage, ischemic stroke, subarrachnoidalbleeding,but excluding transient ischemic attacks (TIA);IC: Intermediate care; ICU: Intensive care unit.*