Summary Of Safety and Clinical Performance
Intended for Users

Reference

EU MDR 2017/745, Article 32 - Summary of safety and clinical performance & MDCG 2019-9 Rev.1 Summary of safety and clinical performance A guide for manufacturers and notified bodies

Product Details

Device Name	Variant Name
Ureteral Indwelling Pigtail Stent/Set-With/without Hydrophilic coated	Single Pigtail Stent,
	Double Pigtail Stent,
	Multi Length Stent

Product Classification

Class IIb, Rule 05 as per Annex VIII of MDR 2017/745

Manufacturer Details	Authorized Representative
1. Unit-I DEVON INNOVATIONS PRIVATE LIMITED No. 27A, Near State Bank of India, Electronic City Phase I, Hosur Main Road, Bangalore-560 100, India. Phone no: 080-28522354/28522367/28522368 2. Unit-II DEVON INNOVATIONS PRIVATE LIMITED Gupta complex, 1st floor, Khasra No: 519/370 Near EWS flats, sector-1, village Kamli Parwanoo 173220 Himachal Pradesh, India. Phone no: 01792232492 Email: srinivas@devoncath.com, nagendrakumar@devoncath.com Website: www.devoncath.com	Amstermed BV Saturnusstraat 46-62, Unit 032,2132 HB Hoofddorp The Netherlands. Ph: +31 23 56 56 337 Email: info@amstermed.nl Website: https://www.amstermed.nl

Approvals	Name	Function	Signature	Date
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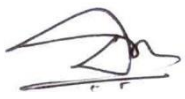
Reviewed By	Mr. Srinivas	QA/RA-Manager		07.03.2025
Approved By	Mr. Ashwin Khemani	Director		07.03.2025

Contents

Introduction

The Regulation (EU) 2017/745 on medical devices requires that the manufacturer shall draw up a summary of safety and clinical performance (SSCP) for implantable devices and class III devices, other than custom-made or investigational devices. The SSCP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices (Eudamed).

The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device. The SSCP will be an important source of information for intended users – both healthcare professionals and relevant for patients. It is one of several means intended to fulfill the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information.

The SSCP is not intended to:

- Give general advice on the diagnosis or treatment of particular medical conditions, nor
- Replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of a particular device, nor
- Replace the mandatory information on implant cards or in any other mandatory documents.

The main purpose of this document is to guide the presentation, content and validation of the SSCP. The word “shall” is used when there is a corresponding “shall” in the MDR, otherwise “should” or “recommended” etc. is used to indicate the interpretation of the MDR.

The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1 Device Trade Name(s)

Product Name	Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated
Brand Name:	Devon
Variant Name:	Single Pigtail Stent, Double Pigtail Stent, Multi Length Stent

1.2 Manufacturer’s Name & Address

Legal Manufacturer Name:	DEVON INNOVATIONS PRIVATE LIMITED
Registered Office & Manufacturing Unit-I Address:	No. 27A, Near State Bank of India, Electronic City Phase I, Hosur Main Road, Bangalore-560 100, India. Phone no: 080-28522354/28522367/28522368
Manufacturing Unit-II Address:	Gupta complex, 1st floor, Khasra No: 519/370, Near EWS flats, sector-1, village Kamli Parwanoo 173220 Himachal Pradesh, India. Phone no: 01792232492
Email:	srinivas@devoncath.com, nagendrakumar@devoncath.com
Website:	www.devoncath.com

1.3 Manufacturer's Single Registration Number (SRN)

IN-MF-000010584

1.4 Basic UDI-DI

8903410UIPS87

1.5 Medical Device Nomenclature

EMDN Code:	U020302
MDN Code:	MDN 1104-2
MDS and MDT code:	MDS 1005, MDT2001, MDT2002, MDT2008, MDT2011

1.6 Class of device

Class IIb, Rule 05, in accordance with Annex VIII of EU Medical Device Regulation 2017/745

1.7 Year of first certificate (CE) of the subject device

2012

1.8 Authorized Representative

Name:	Amstermed BV
Address:	Saturnusstraat 46-62, Unit 032,2132 HB Hoofddorp The Netherlands.
Phone:	+31 23 56 56 337
Email:	info@amstermed.nl
Website:	https://www.amstermed.nl
SRN:	NL-AR-000001971

1.9 NB Details

Name:	DNV Product Assurance AS
Address:	Veritasveien 1, 1363 Høvik, Norway
Website:	www.dnv.com
Notified Body No.:	2460

2. Intended use of the device

2.1 Intended Purpose

Used for temporary internal drainage from the Ureteropelvic junction to the bladder. In case of Hydrophilic coated, it is to improve the ease of insertion.

2.2 Indications & Target Population

Indication:

- Obstruction from urolithiasis
- Malignant obstruction (typically pelvis malignancies)
- Benign strictures
- Retroperitoneal fibrosis

Target patient population: Pediatrics and Adult

2.3 Contraindications

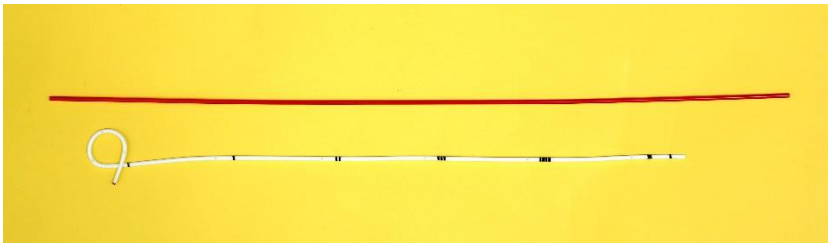
- Contraindicated surgical candidate
- Unexplained hematuria
- Unrepaired ureteral avulsion

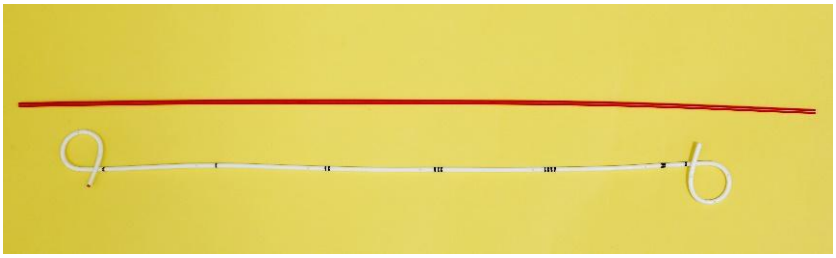
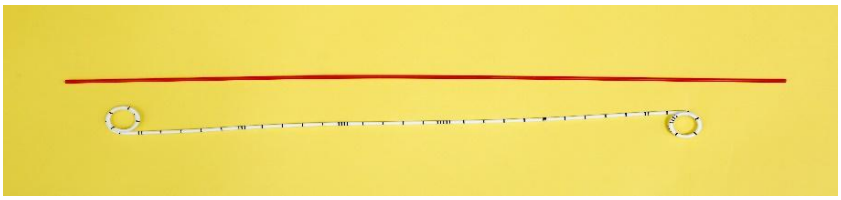
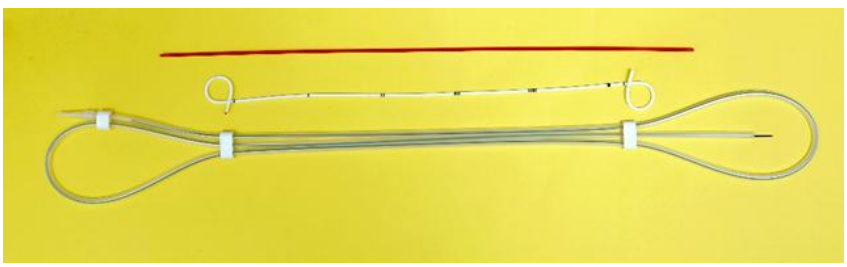
3. Device Description

3.1 Description of the Device

A stent is a hollow tube that maintains patency until healing can take place or an obstruction is relieved.

Product Image:

Product Name	Variant Name	Packing	Image
Ureteral Indwelling Pigtail Stent/Set-With/without Hydrophilic coated	Single pigtail stent	With Packing	
		Without Packing	

Product Name	Variant Name	Packing	Image
	Double Pigtail Stent	With Packing	
		Without Packing	
	Multi Length Stent	With Packing	
		Without Packing	
	Set	With Packing	
		Without Packing	

3.1.1 Device Models

#	Variant Name	Variant Description/Details
1.	Single pigtail stent	A stent is a hollow tube that maintains patency until healing can take place or an obstruction is relieved
2.	Double pigtail stent	
3.	Multi length stent	

3.1.2 Principle of Operation

A Ureteral Indwelling Pigtail Stent is a thin, flexible plastic tube that is inserted into the ureter to drain urine from the kidney into the bladder in the case of obstruction.

3.2 Reference to previous generation(s) or variants

Legacy Device Name:	Stents (Urology)- Ureteral Indwelling Double /single Pigtail Stent/set With /without Hydrophilic coated
Brand/Proprietary Name:	Devon
93/42/EEC (MDD) Cert. No.:	246182-2017-CE-IND-NA-PS, Rev.2.0
Notified Body Details:	DNV Product Assurance AS
Is any significant difference between Legacy Device & Device Under Evaluation?	There is no significant difference between legacy device and subject device with respect to raw materials used in production, device description, intended purpose, medical indications, target user, target patient population, side-effects, and contraindications.

3.3 Accessories Details

#	Accessory Name	Variant Name	Image	Classification	Material	Quantity	Intended Use	Usage
1.	Set Components Guide wire	Straight/J-tip		IIa	Stainless Steel	01	Guidewires facilitate the delivery of wide variety of Catheters and Stents to a Medical procedure site within the body. In case of Hydrophilic coated, it is to improve the ease of insertion.	Single use
		Zebra crossing Nitinol (Straight/J-tip)			Nitinol			

#	Accessory Name	Variant Name	Image	Classification	Material	Quantity	Intended Use	Usage
								

3.4 Combination with other Medical Devices

Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated is used in along with Guidewire and Cystoscope.

4. Risks and warnings

4.1 Residual risks and undesirable side effects

a. Residual Risks

- Urinary Tract Infection
- Stent Migration
- Contamination or Deterioration of product
- Stent fragmentation
- Haematuria
- Toxic to Environment
- Tissue Damage
- Delay in procedure, Inconvenience to the user

b. Adverse Events

- Migration
- Sepsis
- Encrustation

4.2 Warnings

All components of the Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated are for single use only.

- Duration of Use:
  - Periodic evaluation is advised. The Stent must not remain indwelling more than three months. These stents are not indented as permanent indwelling devices

  - Do not use device if there is any indication that the sterility of the device has been compromised.
- Adverse effects
  - Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.
- Reuse
  - Reusing single-use stents can lead to urinary tract infection in patients.

4.3 Precautions

Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use, and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

All Health care professionals is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.

4.4 Other relevant aspects of safety

There were no identified and/or received reportable events that led to death, a serious deterioration in the state of health of the patient, user, or other person for Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated. Hence FSCA or FSN is not performed.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to similar device, if applicable

The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated belongs to the "Urology" group. In the present market there are many similar devices and/or benchmark devices available with same intended purpose and are having the same generally acknowledged state-of-the-art.

These similar devices fall under "Well-Established Technology". Data from similar devices is considered for the conformation of conformity to the Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated relevant general safety and performance requirements. The similar device data is used to demonstrate ubiquity of design, lack of novelty, known safety and performance profile of a generic group of devices, etc.

The below mentioned similar devices data is used to evaluate the Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated relevant general safety and performance requirements as part of literature review. These similar devices contain the same Raw materials and same intended purpose, but due to insufficient information availability the full assessment of equivalence is not possible. Therefore, these similar devices are used for the same clinical intended purposes as the Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated and are considered to be similar but non-equivalent devices.

S.NO	Product Name	Variant Name	Similar Device	Manufacturer Name
1.	Ureteral Indwelling Pigtail Stent/Set- with/without Hydrophilic Coated	Single pigtail stent	Urinary diversion stent	Boston Scientific
		Double pigtail stent	Double pigtail ureteral stent	Cook Incorporated
		Multi length stent	Universa® Firm ureteral stent	Cook Incorporated

5.2 Summary Of Clinical Data from Conducted Investigations of the device before the CE-Marking

Not Applicable

5.3 Summary of clinical data from other sources

The below mentioned are literatures selected for detailed review for:

- Evaluation of state of the art
- Evaluation of clinical data from similar devices

#	ID#	Source Link	Literature Title
1.	L1	https://pubmed.ncbi.nlm.nih.gov/15851050/	Retrograde or antegrade double-pigtail stent placement for malignant ureteric obstruction?
2.	L3	https://pubmed.ncbi.nlm.nih.gov/12187045/	Early and Late Complications of Double Pigtail Ureteral Stent
3.	L5	https://pubmed.ncbi.nlm.nih.gov/18177241/	Clinical Evaluation of Double-Pigtail Stent in Patients with Upper Urinary Tract Diseases: Report of 2685 Cases
4.	L7	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5671964/#:~:text=Conclusions,than%20patients%20with%20pigtail%20stents.	Impact of loop-tail ureteral stents on ureteral stentrelated symptoms immediately after ureteroscopic lithotripsy: Comparison with pigail ureteral stents
5.	L9	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2362846/	Fluoroscopic Placement of Double-Pigtail Ureteral Stents
6.	L11	https://www.goldjournal.net/article/S0090-4295(04)00321-8/fulltext	Update On Ureteral Stents
7.	L13	https://www.researchsquare.com/article/rs-2492162/v1.pdf	Clinical effectiveness of modified single pigtail fishtail stent on preoperative stenting and postoperative stenting during flexible ureteroscopic lithotripsy
8.	L15	https://pubmed.ncbi.nlm.nih.gov/31696096/	Challenges To Attenuate Ureteric Stent-Related Symptoms: Reflections On The Need To Fashion A New Dynamic Stent Design Consequent Upon A Case Report
9.	L16	https://pubmed.ncbi.nlm.nih.gov/32293992/	Clinical Effectiveness of Single Pigtail Suture Stent on Patient Comfort: A Double-Blind Prospective Randomized Trial
10.	L17	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7717614/	Indwelling ureteric stents: Patterns of use and nomenclature
11.	L18	https://pubmed.ncbi.nlm.nih.gov/18294036/	Success of Ureteral Stents for Intrinsic Ureteral Obstruction
12.	L19	https://www.researchgate.net/publication/342661079_Histological_Inflammation_in_Human_Ureter_either_Healthy_or_Fitted_with_Double-Pigtail_Stent_or_a_Thin_03_F_Suture_Thread_A_Preliminary_Study	Histological Inflammation in Human Ureter either Healthy or Fitted with Double-Pigtail Stent or a Thin 0.3 F Suture Thread: A Preliminary Study
13.	L20	https://www.ncbi.nlm.nih.gov/pubmed/19419288	Ureteral stent: past, present and future
14.	L21	https://www.researchgate.net/publication/328297809_A_brief_review_of_the_literature_on_the_malignant_ureteral_obstruction	A brief review of the literature on the malignantUreteral obstruction

#	ID#	Source Link	Literature Title
15.	L22	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2955226/	Endoscopic placement of double-J ureteric stents in children as a treatment for primary obstructive megaureter
16.	L23	https://www.ncbi.nlm.nih.gov/pubmed/25428751	Comparison of efficacy and bladder irritation symptoms among three different ureteral stents: A double-blind, prospective, randomized controlled trial
17.	L24	https://www.ncbi.nlm.nih.gov/pubmed/19263375	Retrograde ureteral stent exchange underfluoroscopic guidance
18.	L25	https://www.ncbi.nlm.nih.gov/pubmed/11956422	A Randomized Outcomes Trial Of Ureteral Stents For Extracorporeal Shock Wave Lithotripsy Of Solitary Kidney Or Proximal Ureteral Stones
19.	L26	https://www.researchgate.net/publication/320658434_Ureteric_Stenting	Ureteric Stenting
20.	L27	https://www.ncbi.nlm.nih.gov/pubmed/31484100	Ureteral stent placement and percutaneous nephrostomy in the management of hydronephrosis secondary to cervical cancer
21.	L28	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6411265/	Percutaneous antegrade ureteral stent placement: single center experience
22.	L29	https://www.ncbi.nlm.nih.gov/pubmed/22882647	Multi-length or 24 cm ureteric stent? A multicentre randomised comparison of stent-related symptoms using a validated questionnaire
23.	L30	https://www.ncbi.nlm.nih.gov/pubmed/27658661	Preoperative Belladonna and Opium Suppository for Ureteral Stent Pain: a Randomized, Double-Blinded, Placebo Controlled Study
24.	L31	https://www.researchgate.net/publication/335995026_Ureteric_stents_Overview_of_current_clinical_applications_and_economic_implications	Ureteric stents: Overview of current clinical applications and economic implications
25.	L32	https://pubmed.ncbi.nlm.nih.gov/24751387/	Ureteroscope-assisted double-J stenting following laparoscopic ureterolithotomy
26.	L33	https://pubmed.ncbi.nlm.nih.gov/21927861/	How long should double J stent be kept in after ureteroscopic lithotripsy?
27.	L34	https://www.ncbi.nlm.nih.gov/pubmed/22899382	Changing to a loop-type ureteral stent decreases patients'stent-related symptoms
28.	L35	https://www.ncbi.nlm.nih.gov/pubmed/30577215	Externalized percutaneous stent vs. Internal double J stent: Short- and long-term Complications after kidney transplantation
29.	L36	https://www.ncbi.nlm.nih.gov/pubmed/22237375	Ureteral Stents Do Not Cause Bacterial Infections in Children After Ureteral Reimplantation
30.	L37	https://www.ncbi.nlm.nih.gov/pubmed/25733285	Ureteral Stent Failure in Pediatric Patients Under 10 Years: Occurrence and Risk Factors

Examples of clinical data registries are:

1. Clinicaltrials.gov: ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world. ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

2. Clinicaltrialsregister.eu: The European Union Clinical Trials Register allows you to search for protocol and results information on interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA); clinical trials conducted outside the EU / EEA that are linked to European pediatric-medicine development.

3. Ctri.gov: The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (http://icmr-nims.nic.in), is a free and online public record system for registration of clinical trials being conducted in India. Any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials are expected to register the trial in the CTRI before enrollment of the first participant. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrollment are captured.

Studies referred from device registries are given below:

Sl.no	Registry	Study No	Country	Study Title	Study Phase	Type of study	Number of subjects
1.	https://clinicaltrials.gov/study/NCT06455618?term=ureteral%20indwelling%20stent&rank=4	NCT06455618	China	The Feasibility, Safety, and Efficacy of Not Indwelling of Ureteral Stents in Percutaneous Nephrolithotomy	Not Applicable	Interventional	80
2.	https://clinicaltrials.gov/study/NCT02871609?term=ureteral%20indwelling%20stent&rank=2	NCT02871609	Switzerland	Assessment of Long-term Ureteral Stenting	Not Applicable	Observational	91
3.	https://clinicaltrials.gov/study/NCT06510790?term=ureteral%20double%20j%20stent&rank=1	NCT06510790	Nepal	Risk Factors for Bacterial Stent Colonization in Patients With a Double J Ureteral Stent	Not Applicable	Observational	48

The advantage of referring the data from a third-party registry is usually centered on patients or cases, which provides a sufficient level of traceability and detail for the study of our product. Using registries can be less expensive than initiating new and private device registries. The data in these registries might be relevant but may not contain the exact attributes needed to document/demonstrate clinical performance.

Hence, we cannot completely rely on the above registries to collect enough data for our devices. We have referred these registries only to gather information on similar devices and the study methodology.

5.4 An overall summary of the clinical performance and safety

Residual Risks	Medical Benefits
1. Urinary Tract Infection 2. Stent Migration 3. Contamination or Deterioration of product 4. Stent fragmentation 5. Haematuria 6. Toxic to Environment 7. Tissue Damage 8. Delay in procedure, Inconvenience to the user	Subject Device 1. Relief of urinary obstruction 2. Continuous urine drainage 3. Prevention of Ureteral Stricture Formation Similar Device 1. It promotes ureteral healing 2. Prevents complications of ureteral obstructions 3. Reduction of extravasations around ureter 4. Morbidity is minimal 5. Safe and useful to treat upper urinary tract diseases. 6. Maintain renal function, relieve pain. 7. Aid passage of upper urinary calculi after ureteroscopic lithotripsy 8. Better surgical outcomes 9. High success rate 10. Reduces SRSs (Stent related symptoms)

All the residual risks were reviewed and analysed and also identified the medical benefits of the intended use outweigh the overall residual risk. Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated complies with all the Safety and Performance requirements with respect to the intended use of the device from the Clinical Evaluation study. The clinical evaluation is complete and conforms to the general safety and performance requirements. The Clinical evidence is demonstrated with the relevant General Safety & Performance Requirements as per Annex I of MDR. Risk Mitigation has been established as per the guidelines of ISO 14971.

5.5 Ongoing or planned post-market clinical follow-up

Overall, 35 subjects have participated in this PMCF study of the product Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated. As per the PMCF study, the Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated have met the primary and secondary objectives.

Overall study results:

<table>
<tr><th>Parameter</th><th>Study Results</th></tr>
<tr><td>Subjects</td><td>A total of 60 Subjects were enrolled for the PMCF study. As per the study, all 46 (77%) subjects were male and 14 (23%) subjects were female.

Subjects Group summary – 21 (35%) subjects were paediatric and 39 (65%) subjects were adults. .

Subject age summary:
<table>
<tr><th>Age Group</th><th>No: of subjects</th><th>Percentage (%)</th></tr>
<tr><td>less than 10</td><td>6</td><td>10</td></tr>
<tr><td>10-20 Years</td><td>17</td><td>28</td></tr>
<tr><td>21-30 Years</td><td>1</td><td>2</td></tr>
<tr><td>31-40 Years</td><td>3</td><td>5</td></tr>
<tr><td>41-50 Years</td><td>25</td><td>42</td></tr>
<tr><td>51-60 Years</td><td>6</td><td>10</td></tr>
<tr><td>61-70 Years</td><td>2</td><td>3</td></tr>
</table></td></tr>
<tr><td>Target Users</td><td>Urologist</td></tr>
<tr><td>Study Site</td><td>- Lokamanya Hospital
- Paedia Pal Clinic, Pune
- National Kidney Hospital, Jalandhar</td></tr>
<tr><td>Clinical Indication</td><td>- Obstruction from urolithiasis
- Benign Strictures
- Malignant obstruction (typically Pelvis Malignancies)
- Retroperitoneal fibrosis</td></tr>
<tr><td>Clinical Safety</td><td>All the subjects considered for this study benefitted out of using Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated. This clinically proves the safety of using our product on subjects with better efficacy.</td></tr>
<tr><td>Clinical Performance</td><td>The overall rating is 4 which is “Good” as per the definition, hence the product performance is clinically proven to be “Good”.</td></tr>
<tr><td>Follow up summary</td><td>The stent was successfully removed during the follow-up procedure, and the subjects experienced no issues with the removal.

The Ureteral Indwelling Pigtail Stent/Set - With/without Hydrophilic Coated effectively relieved the obstructive symptoms, and the patient experienced significant symptom improvement after the procedure. No complications were observed during the follow-up period.</td></tr>
<tr><td>Adverse events and Risks</td><td>No adverse events were reported by any users during the study. Additionally, no risks associated with the Ureteral Indwelling Pigtail Stent/Set—with or without a hydrophilic coating—were reported.</td></tr>
<tr><td>Product Experience</td><td>The overall rating is 8, it is “Good” as per the definition. Hence this proves that our users are satisfied with the product and its purpose.</td></tr>
</table>

The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated from Devon Innovations Private Limited has reached all the safety and performance requirements with respect to the intended use of the device from the Post Market Follow up Clinical study. The Performance and Safety of the device as we claimed have been established in the Technical File and Instruction for Use (IFU). There were no new risks identified from the PMCF study for the product hence there is no addition to the residual risks which we have already identified in the Risk Management Report and that is been mitigated and are acceptable when weighed against the benefits to the patient.

6. Possible diagnostic or therapeutic alternative

- Percutaneous nephrostomy Placement

7. Suggested profile and training for users

Target Users: Urologist

Urologists diagnose and treat diseases of the urinary tract in both men and women. They also diagnose and treat anything involving the reproductive tract in men.

The target users are aware of basic operations of Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated. There is no special user training is required. However, the device related directions for use information are provided in the Instruction for Use.

8. Reference to any harmonized standards and CS applied

8.1 Applicable Harmonized Standards

#	Standard ID	Current Issue	Tittle
Quality Management System Requirements			
1.	EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
Risk Management Requirements			
2.	EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices
Usability			
3.	EN 62366-1	2015+AC:2015+ AC:2016+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
Biological Risk Evaluation Requirements			
4.	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5.	EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

#	Standard ID	Current Issue	Tittle
6.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
7.	EN ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
8.	EN ISO 10993-7	2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
9.	EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
10.	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
11.	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation
Labels & Symbols Requirements			
12.	EN ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
Instructions For Use Requirements			
13.	EN ISO 20417	2021	Medical devices — Information to be supplied by the manufacturer
Packaging Requirements			
14.	EN ISO 11607-1	2020/A1:2023	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
15.	EN ISO 11607-2	2020/A1:2023	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EO Sterilization Requirements			
16.	EN ISO 11135	2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
Sterility Test Requirements			
17.	EN ISO 11737-1	2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
18.	EN ISO 11737-2	2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
Post Market Surveillance Requirements			
19.	ISO/ TR 20416	2020	Medical devices – Post market surveillance for manufacturers
Medical Device “STERILE” Requirements			
20.	EN 556-1	2001+AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"

#	Standard ID	Current Issue	Tittle
			- Part 1: Requirements for terminally sterilized medical devices

8.2 Other Applicable Standards

#	Standard ID	Current Issue	Tittle
Quality Management System Requirements			
1.	ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
Risk Management Requirements			
2.	ISO 14971	2019	Medical devices - Application of risk management to medical devices
3.	ISO/TR 24971	2020	Medical devices – Guidance on the application of ISO 14971
Usability			
4.	IEC 62366-1	2015/Amd 1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
Biological Risk Evaluation Requirements			
5.	ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6.	ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
7.	ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
8.	ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
9.	ISO 10993-7	2008/Amd 1:2019	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
10.	ISO 10993-10	2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
11.	ISO 10993-11	2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
12.	ISO 10993-23	2021	Biological evaluation of medical devices — Part 23: Tests for irritation
Labels & Symbols Requirements			
13.	ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
Instructions For Use Requirements			
14.	ISO 20417	2021	Medical devices — Information to be supplied by the manufacturer
Packaging Requirements			

#	Standard ID	Current Issue	Tittle
15.	ISO 11607-1	2019/Amd 1:2023	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
16.	ISO 11607-2	2019/Amd 1:2023	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
Transport Requirements			
17.	ISTA 2A	2011	Partial Simulation Performance Test Procedure Packaged Products weighing 150 lbs (68 kg) or less
EO Sterilization Requirements			
18.	ISO 11135	2014/AMD 1:2018	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
Sterility Test Requirements			
19.	ISO 11737-1	2018/AMD 1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
20.	ISO 11737-2	2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
Cleanroom Requirements			
21.	ISO 14644-1	2015	Clean Rooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness by Particle Concentration
22.	ISO 14644-2	2015	Clean Rooms and Associated Controlled Environments – Part 2: Monitoring to Provide Evidence of Clean Room Performance Related to Air Cleanliness by Particle Concentration
Post Market Surveillance Requirements			
23.	ISO/ TR 20416	2020	Medical devices – Post market surveillance for manufacturers
Stability Requirements			
24.	ASTM F 1980-21	---	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices

8.3 List of Guidelines

#	Guideline	Current Issue	Tittle
1.	MEDDEV 2.7.1 Rev. 4	June 2016	Clinical Evaluation
2.	MEDDEV 2.5/5 Rev. 3	February 1998	Translation Procedure
3.	MEDDEV 2.12-1 Rev. 8	January 2013	Vigilance Control
4.	NB-MED 2.12/Rec. 1	July 2019	Post Market surveillance
5.	MDCG 2021-24	Oct 2021	Guidance on classification of medical devices
6.	MDCG 2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC.
7.	MDCG 2018-1 Rev.4	April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
8.	MDCG 2020-7	April 2020	Post-market clinical follow-up (PMCF) Plan Template - A guide for manufacturers and notified bodies
9.	MDCG 2020-8	April 2020	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies
10.	MDCG 2022-21	December 2022	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 (MDR)
11.	MDCG 2019-9 Rev.1	March 2022	Summary of safety and clinical performance A guide for manufacturers and notified bodies

Summary Of Safety and Clinical Performance

Intended for Patients

Introduction

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance is prepared for users/healthcare professionals.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions for Use to provide information on the safe use of the device.

The following information is intended for patient.

READABILITY

The SSCP has one part for intended users/healthcare professionals, and a second part for patients. It provides clear information at an appropriate depth to reflect the healthcare professionals' and the patients' different levels of knowledge. The readability of the part of the SSCP intended for patients is assessed by a test given to lay persons.

The readability was assessed by providing the document to laypersons with different literacy background to read. All the laypersons who have read the document were able to understand the terms and details of the device properly. Also, they agreed that the document language was legible and understandable. The manufacturer used this method to confirm that the SSCP was written in a way that is clear to the patient.

1. Device identification and general information

Product Name	Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated
Brand Name:	Devon

Models:	Single Pigtail Stent, Double Pigtail Stent, Multi Length Stent
Manufacturer's Name & Address	DEVON INNOVATIONS PRIVATE LIMITED Registered Office & Manufacturing Unit-I Address: No. 27A, Near State Bank of India, Electronic City Phase I, Hosur Main Road, Bangalore-560 100, India. Phone no: 080-28522354/28522367/28522368 Manufacturing Unit-II Address: Gupta complex, 1st floor, Khasra No: 519/370,Near EWS flats, sector-1, illage Kamli Parwanoo 173220 Himachal Pradesh, India. Phone no: 01792232492 Email: srinivas@devoncath.com nagendrakumar@devoncath.com Website: www.devoncath.com
Basic UDI-DI	8903410UIPS87
Year when the device was first CE-marked	2012

2. Intended use of the device

2.1 Intended Purpose

Used for temporary internal drainage from the Ureteropelvic junction to the bladder. In case of Hydrophilic coated, it is to improve the ease of insertion.

2.2 Indications & Target Population

Indication:

- Obstruction from urolithiasis
- Malignant obstruction (typically pelvis malignancies)
- Benign strictures
- Retroperitoneal fibrosis

Target patient population: Pediatrics and Adult

2.3 Contraindications

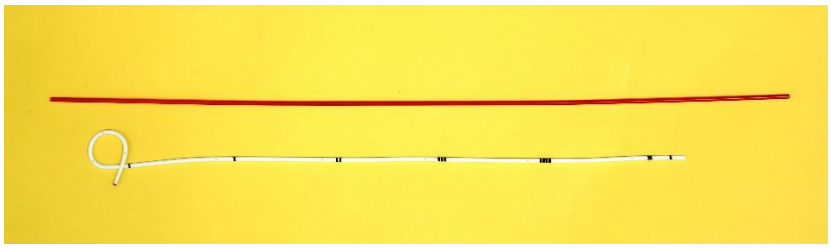
- Contraindicated surgical candidate
- Unexplained hematuria
- Unrepaired ureteral avulsion

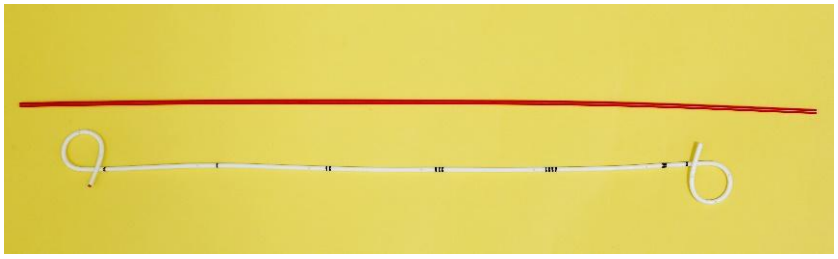
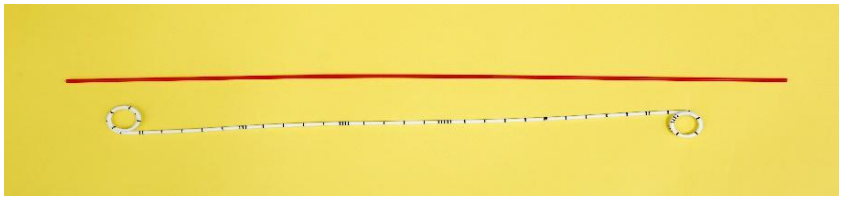
3. Device Description

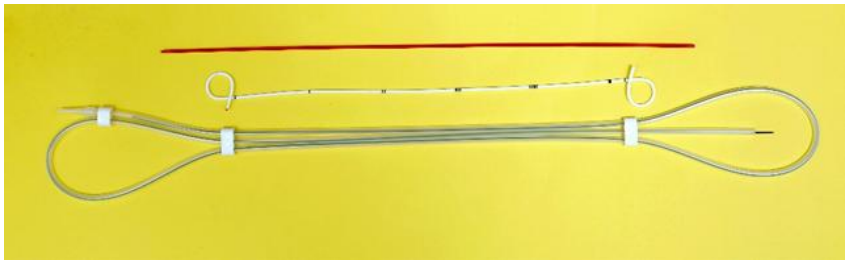
3.1 Device description

A stent is a hollow tube that maintains patency until healing can take place or an obstruction is relieved.

Product Image:

Product Name	Variant Name	Packing	Image
Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated	Single pigtail stent	With Packing	
		Without Packing	

Product Name	Variant Name	Packing	Image
	Double Pigtail Stent	With Packing	
		Without Packing	
	Multi Length Stent	With Packing	
		Without Packing	
	Set	With Packing	

Product Name	Variant Name	Packing	Image
		Without Packing	

3.2 Materials that come in contact with patient

Material that comes in contact with patient polyurethane and carbothane.

3.3 Information about medicinal substances in the device, if any

Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated does not incorporate medicinal substances. Hence this declaration is not applicable

3.4 Description of how the device is achieving its intended mode of action

The device is a hallow tube which once implanted at the intended location in the urinary tract bypasses the obstruction to the flow of urine and the urine is drained through the urology stent bypassing the obstruction. The device thus improves the lumen patency of the urinary tract until the lesion causing the obstruction is healed or the obstruction is removed. The device is a temporary implant and can be removed once the intended purpose is achieved. They can be placed to help reduce sharp pain from a stone or to allow drainage when infection is present or when a stone prevents a kidney from working adequately.

3.5 Description of accessories, if any

#	Accessory Name	Variant Name	Image	Classification	Material	Quantity	Intended Use	Usage
	Set Components Guide wire	Straight/J-tip	 	IIa	Stainless Steel	01	Guidewires facilitate the delivery of wide variety of Catheters and Stents to a Medical procedure site within the body. In case of Hydrophilic coated, it is to improve the ease of insertion.	Single use
		Zebra crossing Nitinol (Straight/J-tip)	 		Nitinol			

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1 How potential risks have been controlled or managed

We have established and maintaining a strong quality management system and continuous process monitoring controls as per EN ISO 13485:2016/A11:2021 requirements. As per the risk management plan, all the necessary and possible risk control measures are implemented to reduce the risk to practicable acceptable level. We have implemented all necessary risk control measures for each hazard to reduce the risks to an acceptable level.

The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated risk management is completed by risk estimation, risk analysis, risk evaluation, risk control, overall residual risk evaluation, production, and postproduction information. The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated have reached all the safety and performance claims when used as per the defined intended purpose.

The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated medical benefits and residual risks are compared based on medical condition, literature data certainty, similar device data (benefits & residual risks) from the market, acknowledged state of the art.

4.2 Residual Risks

- Urinary Tract Infection
- Stent Migration
- Contamination or Deterioration of product
- Stent fragmentation
- Haematuria
- Toxic to Environment
- Tissue Damage
- Delay in procedure, Inconvenience to the user

4.3 Adverse events

- Migration
- Sepsis
- Encrustation

4.4 Warnings

All components of the Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated are for single use only.

- Duration of Use:
  - Periodic evaluation is advised. The Stent must not remain indwelling more than three months. These stents are not intended as permanent indwelling devices
  - Do not use device if there is any indication that the sterility of the device has been compromised.
- Adverse effects: Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.
- Reuse: Reusing single-use stents can lead to urinary tract infection in patients.

4.5 Precautions

Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use, and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

All Health care professionals are responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.

4.6 Summary of any field safety corrective action, (FSCA including FSN) if applicable

There were no identified and/or received reportable events that led to death, a serious deterioration in the state of health of the patient or user, for Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated. Hence FSCA or FSN is not performed.

5. Summary of clinical evaluation and post-market clinical follow-up

5.1 Clinical background of the device

The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated is designed and developed as per the latest and/or current technical, international and regulatory. The Ureteral Indwelling Pigtail Stent/Set-

With/without Hydrophilic coated performance complies all necessary requirements required for its intended purpose. The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated related all known foreseeable hazards are identified and associated risk are reduced as far as possible by implementing all necessary risk control measures as per the requirements of EN ISO 14971:2019/A11:2021. The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated is manufactured as per the defined standard operating procedures in controlled environments by training personnel and complies all necessary requirements of EN ISO 13485:2016/A11:2021.

5.2 The clinical evidence for the CE-marking

Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated is a CE certified medical device under EU MDD 93/42/EEC. Hence, the Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated comply the definition as a legacy device as per the MDCG 2020-6:2020 – Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC.

Device Name:	Stents (Urology)- Ureteral Indwelling Double /single Pigtail Stent/set With/without Hydrophilic coated
Brand/Proprietary Name:	Devon
93/42/EEC (MDD) Cert. No.:	246182-2017-CE-IND-NA-PS, Rev.2.0
Notified Body Details:	DNV Product Assurance AS

The Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated belongs to the “Urology” group. In the present market there are many similar devices and/or benchmark devices available with same intended purpose and are having the same generally acknowledged state-of-the-art.

S.NO	Product Name	Variant Name	Similar Device	Manufacturer Name
1.	Ureteral Indwelling Pigtail Stent/Set- with/without Hydrophilic Coated	Single pigtail stent	Urinary diversion stent	Boston Scientific
		Double pigtail stent	Double pigtail ureteral stent	Cook Incorporated
		Multi length stent	Universa® Firm ureteral stent	Cook Incorporated

5.3 Safety

We have reviewed and analyzed all the residual risks and identified the medical benefits of the intended use outweigh the overall residual risk. All the residual risks are acceptable by providing appropriate information to the end user's awareness in the form of "Label' and 'Instructions for Use".

Residual Risks	Medical Benefits
1. Urinary Tract Infection 2. Stent Migration 3. Contamination or Deterioration of product 4. Stent fragmentation 5. Haematuria 6. Toxic to Environment 7. Tissue Damage 8. Delay in procedure, Inconvenience to the user	1. Subject Device 2. Relief of urinary obstruction 3. Continuous urine drainage 4. Prevention of Ureteral Stricture Formation Similar Device 1. It promotes ureteral healing 2. Prevents complications of ureteral obstructions 3. Reduction of extravasations around ureter 4. Morbidity is minimal 5. Safe and useful to treat upper urinary tract diseases. 6. Maintain renal function, relieve pain. 7. Aid passage of upper urinary calculi after ureteroscopic lithotripsy 8. Better surgical outcomes 9. High success rate 10. Reduces SRSs (Stent related symptoms)

6. Possible diagnostic or therapeutic alternative

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

7. Suggested profile and training for users

Target Users: Urologist

Urologists diagnose and treat diseases of the urinary tract in both men and women. They also diagnose and treat anything involving the reproductive tract in men.

The target users are aware of basic operations of Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated. There is no special user training is required. However, the device related directions for use information are provided in the Instruction for Use.

8. Revision history

SSCP Rev. No.	Date Issued	Change description	Rev. Validated by the NB
00	26.12.2024	Initial Release	**o Yes** Validation language: **English** o No
01	07.03.2025	1. Alternative treatment is updated in section 6 of the part intended for users 2. Year of first certificate (CE) is updated as 2012 in section 1.7 of the part intended for users	o Yes Validation language: English **o No**