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

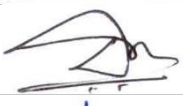
Product Details

Device Name	Variant Name
Gastroenterology Stents- With/without Hydrophilic coated	Biliary Stents (Flap, Straight flap, Amsterdam flap, Hockey stick, Double Pigtail, Single pigtail)

Product Classification

Class IIb, Rule 08 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
Prepared By	Mrs. Janaki	QA/RA-Documentation in-charge		20.05.2025
Reviewed By	Mr. Srinivas	QA/RA-Manager		20.05.2025
Approved By	Mr. Ashwin Khemani	Director		20.05.2025

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	Gastroenterology Stents- With/without Hydrophilic coated
Brand Name:	Devon
Variant Name:	Biliary Stents (Flap, Straight flap, Amsterdam flap, Hockey stick, Double Pigtail, Single pigtail)

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)

Single Registration Number (SRN) for Unit-I Manufacturing site:	IN-MF-000010584
Single Registration Number (SRN) for Unit-II Manufacturing site:	IN-MF-000045808

1.4 Basic UDI-DI

8903410GESFC

1.5 Medical Device Nomenclature

EMDN Code:	G03040301
MDN Code:	MDN 1104-2
MDS and MDT code:	MDS 1005 & MDT 2002, MDT 2008, MDT 2011

1.6 Class of device

Class IIb, Rule 08, 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

1.10 Conformity Assessment Procedure

Conformity assessment procedure followed is Annexure IX.

1.11 Link to SSCP in website

The link for the Summary of Safety and Clinical Performance (SSCP) is provided below:

2. Intended use of the device

2.1 Intended Purpose

Used to drain obstructed biliary ducts. In case of Hydrophilic coated, it is to improve the ease of insertion.

2.2 Indications & Target Populations

Indication:

- The most common indication for biliary stents is for treatment of obstructive jaundice from either benign or malignant causes. On occasion, stents are placed for management of bile leaks.

Target patient population: Adult

2.3 Contraindications

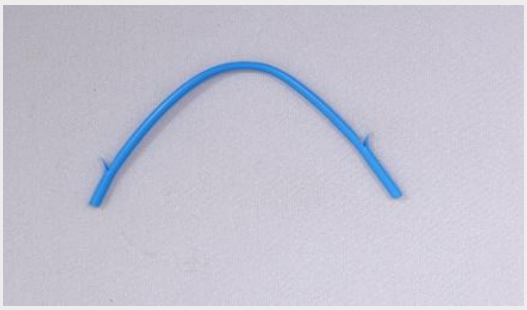
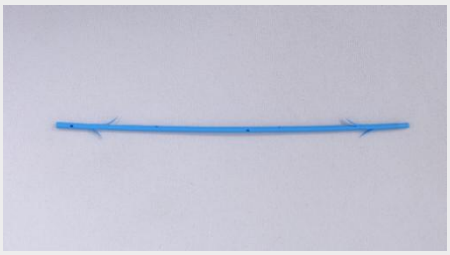
- Those specific to ERCP and any procedure to be performed in conjunction with stent placement
- Inability to pass guide wire or stent through obstructed area.

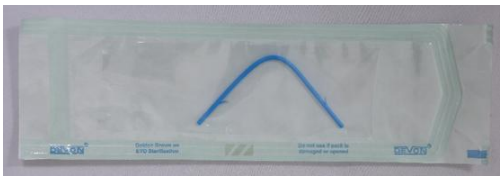
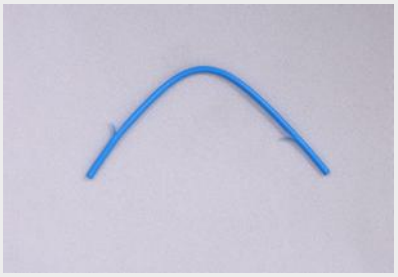
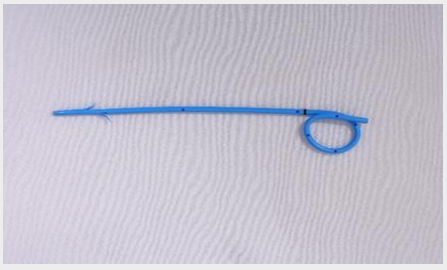
3. Device Description

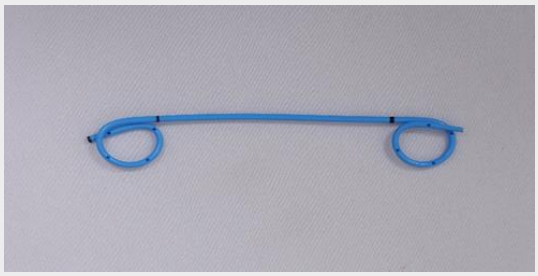
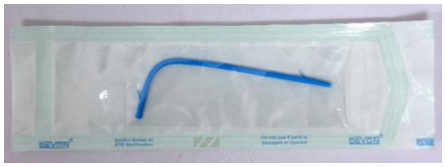
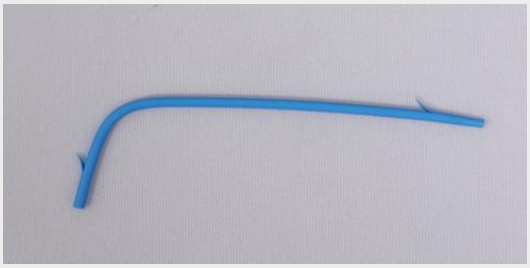
3.1 Description of the Device

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
Gastroenterology Stents- With/without Hydrophilic coated	Biliary Stents		
	Flap	With Packing	
		Without Packing	
	Straight flap	With Packing	
		Without Packing	

Product Name	Variant Name	Packing	Image
	Amsterdam flap	With Packing	
		Without Packing	
	Single pigtail	With Packing	
		Without Packing	
	Double Pigtail	With Packing	

Product Name	Variant Name	Packing	Image
		Without Packing	
	Hockey Stick	With Packing	
		Without Packing	

3.1.1 Device Models

#	Variant Name	Variant Description/Details
Biliary Stent		
1.	Flap	For improved antimigration effect
2.	Straight flap	For improved antimigration effect
3.	Amsterdam flap	For improved antimigration effect and to facilitate the flow of bile
4.	Single pigtail	Single Pigtail stents are useful when there is a risk of stent migration
5.	Double Pigtail	Double Pigtail stents are useful when there is a risk of stent migration
6.	Hockey Stick	For improved antimigration effect

3.1.2 Principle of Operation

A Gastroenterology Stents (biliary stent), also known as a bile duct stent, is a thin, hollow tube that is placed in the bile duct. The stent holds the duct open after the duct has been blocked or partly blocked. Fluids like bile need to flow through your bile duct into your intestine to help digestion.

3.2 Reference to previous generation(s) or variants

Legacy Device Name:	Stents (Gastroenterology)- Biliary Stents (Flap, Straight flap, Amsterdam flap, Double Pigtail, Single pigtail)-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

Not Applicable. The Gastroenterology Stents- With/without Hydrophilic coated does not have any accessories supplied by the manufacturer.

3.4 Combination with other Medical Devices

Gastroenterology Stents- With/without Hydrophilic coated is used in along with the Guidewire. The compatibility is evaluation as part of design verification.

4. Risks and warnings

4.1 Residual risks and undesirable side effects

a. Residual Risks

- Infection
- Stent migration/ Cholangitis
- Jaundice
- Perforation
- Occlusion/ Blockage/ Bleeding
- Toxic to environment

b. Adverse Events

- Bleeding
- Perforation
- Deviation
- Migration
- Occlusion

4.2 Warnings

All components of the Gastroenterology Stents- 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 infections 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 Gastroenterology Stents- With/without Hydrophilic coated. Hence FSCA or FSN is not applicable.

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 Gastroenterology Stents- With/without Hydrophilic coated belongs to the “Gastroenterology” 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 Gastroenterology Stents- 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 Gastroenterology Stents- 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 Gastroenterology Stents- 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.	Gastroenterology Stents- With/without Hydrophilic coated	Biliary Stent-Flap	Biliary Stent- Cotton-Huibregtse®	Cook® Medical
		Biliary Stent-Straight flap	Biliary Stent- Geenen® Sof-Flex®	Cook® Medical
		Biliary Stent-Amsterdam flap	Biliary Stent Cotton-Leung®	Cook® Medical
		Biliary Stent-Hockey stick	RX Duodenal Bend Biliary Stent	Boston Scientific
		Biliary Stent-Double Pigtail	Pancreatic Stent with No Ductal Flap- Zimmon Biliary Stent ZEBD	Cook® Medical
		Biliary Stent-Single pigtail	Biliary Stent- Zimmon SPSOS	Cook® Medical

The similar device's SSCP would be available in EUDAMED.

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/29872885/	Endoscopic biliary drainage management for children with serious cholangitis caused by congenital biliary dilatation
2.	L3	https://pubmed.ncbi.nlm.nih.gov/21531412/	Is the addition of choleretic agents in multiple double-pigtail biliary stents

#	ID#	Source Link	Literature Title
			effective for difficult common bile duct stones in elderly patients? A prospective, multicentre study
3.	L5	https://pubmed.ncbi.nlm.nih.gov/31694012/	Comparison of Biliary Stent versus Biliary Sphincterotomy Alone in the Treatment of Bile Leak
4.	L7	https://www.researchgate.net/publication/287395153_History_of_Bile_Duct_Stenting_Rigid_Prostheses	History of Bile Duct Stenting: Rigid Prostheses
5.	L9	https://pubmed.ncbi.nlm.nih.gov/26862364/	Biliary and pancreatic stenting: Devices and insertion techniques in therapeutic endoscopic retrograde cholangiopancreatography and endoscopic ultrasonography
6.	L11	https://www.giejournal.org/article/S0016-5107(12)02753-8/fulltext	Pancreatic and biliary stents
7.	L12	https://pubmed.ncbi.nlm.nih.gov/12003425/	Biliary Stents in Malignant Obstructive Jaundice Due to Pancreatic Carcinoma: A Cost-Effectiveness Analysis
8.	L13	https://pubmed.ncbi.nlm.nih.gov/20822390/	Endoscopic stenting for palliation of malignant biliary obstruction
9.	L14	https://pubmed.ncbi.nlm.nih.gov/17960388/	Percutaneous drainage and stenting for palliation of malignant bile duct obstruction
10.	L15	https://pubmed.ncbi.nlm.nih.gov/16733103/	Biliary and pancreatic stents
11.	L16	https://pubmed.ncbi.nlm.nih.gov/20136988/	Gastrointestinal and biliary stents
12.	L17	https://www.giejournal.org/article/S0016-5107(23)00356-5/fulltext	Biliary and pancreatic stents
13.	L18	https://pubmed.ncbi.nlm.nih.gov/32522161/	A newly designed uncovered biliary stent for palliation of malignant obstruction: results of a prospective study
14.	L19	https://pubmed.ncbi.nlm.nih.gov/33909800/	Sphincterotomy alone versus sphincterotomy and biliary stent placement in the treatment of bile leaks: 10-year experience at a quaternary hospital
15.	L20	https://pubmed.ncbi.nlm.nih.gov/12783344/	A Prospective Randomized Study of Hydrophilic Polymer-Coated Polyurethane Versus Polyethylene Stents in Distal Malignant Biliary Obstruction

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.

We have not found any studies related to the product.

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. Infection 2. Stent migration/ Cholangitis 3. Jaundice 4. Perforation 5. Occlusion/ Blockage/ Bleeding 6. Toxic to environment	Subject Device 1. Restoration of duct function 2. Relief of obstruction Similar Device 1. Successful and safe in the treatment of postoperative leaks of the upper gastrointestinal tract 2. Cost-effective procedure 3. Long patency period 4. No mortality related to inserting stents 5. Improved Quality of life

Residual Risks	Medical Benefits
	6. Reduced sludge deposition 7. Reduced bacterial adherence 8. Lower morbidity 9. Earlier symptom relief 10. Technical ease and less time-consuming

All the residual risks were reviewed and analysed and also identified the medical benefits of the intended use outweigh the overall residual risk. Gastroenterology Stents- 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 EN ISO 14971:2019/A11:2021.

5.5 Ongoing or planned post-market clinical follow-up

Overall, 55 subjects have participated in this PMCF study of the product Gastroenterology Stents- With/without Hydrophilic coated. As per the PMCF study, the Gastroenterology Stents- 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 55 Subjects were enrolled for the PMCF study. As per the study, 48 (87%) subjects were male and 7 (13%) subjects were female.

Subjects Group summary –55 (100%) subjects were adults.

Subject age summary:

<table>
<tr><th>Age Group</th><th>No: of subjects</th><th>Percentage (%)</th></tr>
<tr><td>31-40 Years</td><td>18</td><td>33%</td></tr>
<tr><td>41-50 Years</td><td>22</td><td>40%</td></tr>
<tr><td>51-60 Years</td><td>15</td><td>27%</td></tr>
</table>
</td></tr>
<tr><td>Target Users</td><td>Gastroenterologists</td></tr>
<tr><td>Study Site</td><td>Aster CMI hospital, Bangalore
SDM Hospital, Jaipur</td></tr>
<tr><td>Clinical Indication</td><td>Treatment of obstructive jaundice</td></tr>
<tr><td>Clinical Safety</td><td>All the subjects considered for this study benefitted out of using Gastroenterology Stents- With/without Hydrophilic coated. This clinically proves the safety of using our product on subjects with better efficacy.</td></tr>
</table>

Parameter	Study Results
Clinical Performance	The overall rating was 4 which is "Good" as per the definition, hence the product performance was clinically proven to be "Good".
Adverse events and Risks	No users reported any of the adverse events during the study No reports on the risks imposed by our Gastroenterology Stents- With/without Hydrophilic coated.
Follow Up Summary	The stent was removed during a follow up procedure. The subject had no issues with stent removal. The Gastroenterology Stents- With/without Hydrophilic coated effectively relieved the symptoms, and the patient experienced significant symptom improvement after the procedure. No complications were observed during follow-up.
Product Experience	The overall rating is 8, it is "Good" as per the definition. Hence this proves that our users were satisfied with the product and its purpose.

The Gastroenterology Stents- 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

- Endoscopic Retrograde Cholangiopancreatography

7. Suggested profile and training for users

Target Users: Gastroenterologist
A gastroenterologist is a medical specialist who focuses on the diagnosis, treatment, and management of diseases and disorders related to the digestive system, which includes the esophagus, stomach, small intestine, large intestine (colon), rectum, liver, pancreas, gallbladder, and bile ducts.

The target users are aware of basic operations of Gastroenterology Stents- 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	Title
Quality Management System Requirements			
1.	EN ISO 13485	2016/AC:2018/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management Requirements			
2.	EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14791:2019)
Biological Risk Evaluation Requirements			
3.	EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
4.	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
Labels & Symbols Requirements			
5.	EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
Packaging Requirements			
6.	EN ISO 11607-1	2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - (ISO 11607-1:2019)
7.	EN ISO 11607-2	2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
EO Sterilization Requirements			
8.	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 (ISO 11135:2014)
Sterility Test Requirements			
9.	EN ISO 11737-1	2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - (ISO 11737-1:2018)
10.	EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of

#	Standard ID	Current Issue	Title
			sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)

8.2 Other Applicable Standards

#	Standard ID	Current Issue	Title
Risk Management Requirements			
1.	ISO/TR 24971	2020	Medical devices – Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
Usability			
2.	EN 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
3.	IEC 62366-1	2015/A1:2020	Medical devices — Part 1: Application of usability engineering to medical devices Amendment 1
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 (ISO 10993-1:2018, including corrected version 2018-10)
5.	EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
6.	EN ISO 10993-5	2009/A11:2025	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 (ISO 10993-6:2016)
8.	EN ISO 10993-7	2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019)
9.	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
Instructions For Use Requirements			
10.	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Medical Device “Sterile” Requirements			
11.	EN 556-1	2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized

#	Standard ID	Current Issue	Title
			medical devices
Transport Requirements			
12.	ISTA 2A	2011	Partial Stimulation Performance Test Procedure Packaged Products weighing 150 lbs (68 kg) or less
Cleanroom Requirements			
13.	ISO 14644-1	2015	Clean Rooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness by Particle Concentration
14.	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			
15.	ISO/ TR 20416	2020	Medical devices – Post market surveillance for manufacturers
Stability Requirements			
16.	ASTM F 1980-21	2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
Labels & Symbols Requirements			
17.	ISO 15223-1	2021/Amd 1:2025	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific

8.3 List of Guidelines

#	Guideline	Current Issue	Title
1.	MEDDEV 2.7.1 Rev. 4	June 2016	Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
2.	MEDDEV 2.5/5 Rev. 3	February 1998	Translation Procedure - Guidelines relating to the application of: The council directive 90/385/EEC on active implantable medical devices The council directive 93/42/EEC on medical devices
3.	MEDDEV 2.12-1 Rev. 8	January 2013	Guidance document - Market surveillance - Guidelines on a Medical Devices Vigilance System
4.	NB-MED 2.12/Rec. 1	February 2020	Post-Marketing Surveillance (PMS) post market/production

#	Guideline	Current Issue	Title
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
12.	MDCG 2020-3 Rev.1 6	September 2023	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR - May 2023
13.	MDCG 2024-2	Feb 2024	MDCG 2024-2 Procedures for the updates of the European Medical Device Nomenclature

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	Gastroenterology Stents- With/without Hydrophilic coated
Brand Name:	Devon
Models:	Biliary Stents (Flap, Straight flap, Amsterdam flap, Hockey stick, Double

	Pigtail, Single pigtail)
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	8903410GESFC
Year when the device was first CE-marked	2012

2. Intended use of the device

2.1 Intended Purpose

Used to drain obstructed biliary ducts. In case of Hydrophilic coated, it is to improve the ease of insertion.

2.2 Indications & Target Populations

Indication:

The most common indication for biliary stents is for treatment of obstructive jaundice from either benign or malignant causes. On occasion, stents are placed for management of bile leaks

Target patient population: Adult

2.3 Contraindications

- Those specific to ERCP and any procedure to be performed in conjunction with stent placement
- Inability to pass guide wire or stent through obstructed area.

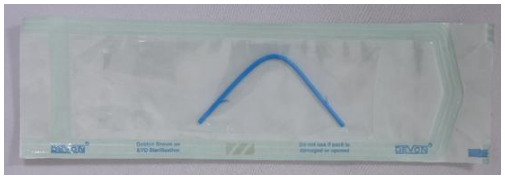
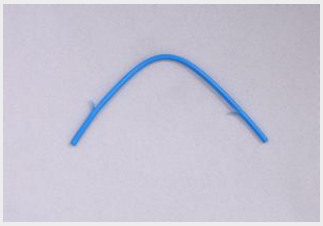
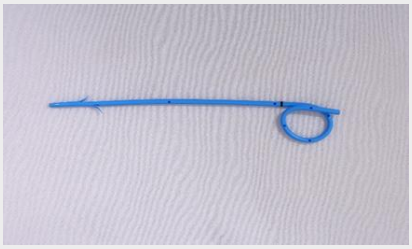
3. Device Description

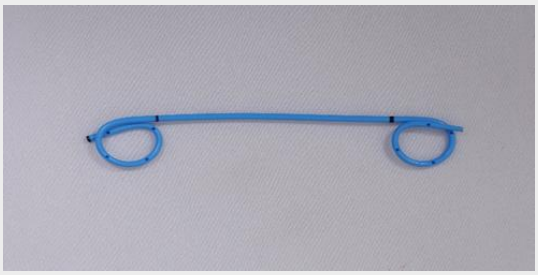
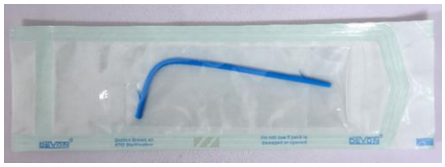
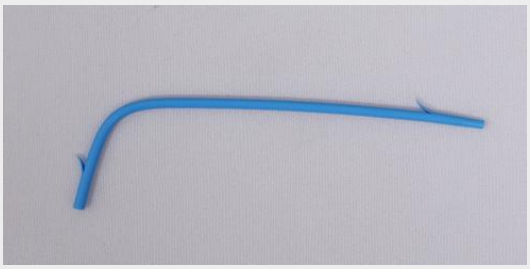
3.1 Device description

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
Gastroenterology Stents- With/without Hydrophilic coated	Biliary Stents		
	Flap	With Packing	
		Without Packing	
	Straight flap	With Packing	

Product Name	Variant Name	Packing	Image
		Without Packing	
	Amsterdam flap	With Packing	
		Without Packing	
	Single pigtail	With Packing	
		Without Packing	

Product Name	Variant Name	Packing	Image
	Double Pigtail	With Packing	
		Without Packing	
	Hockey Stick	With Packing	
		Without Packing	

3.2 Materials that come in contact with patient

Material that comes in contact with patient is stent, guide wire.

3.3 Information about medicinal substances in the device, if any

Gastroenterology Stents- 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 biliary tract to bypasses the obstruction to the flow of bile which is drained through the gastroenterology stent bypassing the obstruction. The device thus improves the lumen patency of the biliary 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.

3.5 Description of accessories, if any

Not Applicable. The Gastroenterology Stents- With/without Hydrophilic coated does not have any accessories supplied by the manufacturer.

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 the risk control measures for each hazard for reducing the risks to an acceptable level.

The Gastroenterology Stents- 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 Gastroenterology Stents- With/without Hydrophilic coated is reached all the safety and performance claims when used as per the defined indented purpose.

The Gastroenterology Stents- 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

- Infection
- Stent migration/ Cholangitis
- Jaundice
- Perforation
- Occlusion/ Blockage/ Bleeding
- Toxic to environment

4.3 Adverse events

- Bleeding
- Perforation
- Deviation
- Migration
- Occlusion

4.4 Warnings

All components of the Gastroenterology Stents- 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 infections 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 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.

4.6 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 Gastroenterology Stents- With/without Hydrophilic coated. Hence FSCA or FSN is not applicable.

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

5.1 Clinical background of the device

The Gastroenterology Stents- With/without Hydrophilic coated is a designed and developed as per the latest and/or current technical, international and regulatory. The Gastroenterology Stents- With/without Hydrophilic coated performance complies all necessary requirements required for its intended purpose. The Gastroenterology Stents- 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 Gastroenterology Stents- 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

Gastroenterology Stents- With/without Hydrophilic coated is having a CE certified medical device under EU MDD 93/42/EEC. Hence, the Gastroenterology Stents- 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 (Gastroenterology)- Biliary Stents (Flap, Straight flap, Amsterdam flap, Double Pigtail, Single pigtail)-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 Gastroenterology Stents- With/without Hydrophilic coated belongs to the "Gastroenterology" 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.	Gastroenterology Stents- With/without Hydrophilic coated	Biliary Stent-Flap	Biliary Stent- Cotton-Huibregtse®	Cook® Medical
		Biliary Stent-Straight flap	Biliary Stent- Geenen® Sof-Flex®	Cook® Medical
		Biliary Stent-Amsterdam flap	Biliary Stent Cotton-Leung®	Cook® Medical
		Biliary Stent-Hockey stick	RX Duodenal Bend Biliary Stent	Boston Scientific
		Biliary Stent-Double Pigtail	Pancreatic Stent with No Ductal Flap- Zimmon Biliary Stent ZEBD	Cook® Medical
		Biliary Stent-Single pigtail	Biliary Stent- Zimmon SPSOS	Cook® Medical

5.3 Safety

We have reviewed and analysed all the residual risks and also 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. Infection 2. Stent migration/ Cholangitis 3. Jaundice 4. Perforation 5. Occlusion/ Blockage/ Bleeding 6. Toxic to environment	Subject Device 1. Restoration of duct function 2. Relief of obstruction Similar Device 1. Successful and safe in the treatment of postoperative leaks of the upper gastrointestinal tract 2. Cost-effective procedure 3. Long patency period

Residual Risks	Medical Benefits
	4. No mortality related to inserting stents 5. Improved Quality of life 6. Reduced sludge deposition 7. Reduced bacterial adherence 8. Lower morbidity 9. Earlier symptom relief 10. Technical ease and less time-consuming

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: Gastroenterologist

A gastroenterologist is a medical specialist who focuses on the diagnosis, treatment, and management of diseases and disorders related to the digestive system, which includes the esophagus, stomach, small intestine, large intestine (colon), rectum, liver, pancreas, gallbladder, and bile ducts.

The target users are aware of basic operations of Gastroenterology Stents- 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	20.05.2025	Initial Release	o Yes Validation language: English o **No**