SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

for

INVADER™ PTCA BALLOON DILATATION CATHETER

Updated by: Ayça Pamukoğlu Kayhan

Reviewed and Approved by: Didem Kantar

ALVIMEDICA TIBBİ ÜRÜNLER SAN. VE DIŞ TİC. A.Ş.
İstanbul Trakya Serbest Bölgesi Ferhatpaşa Şb.
Atatürk Bulv. No: 15 Çatalca / İstanbul
Tel: 0212 786 60 80 Fax: 0212 786 60 90
Büyükçekmece V.D. 631 054 67 48
Mersis No: 0631054674800015

Date of the Report: 31.07.2025

Index

1 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 patient section is not provided as INVADER™ PTCA Balloon Dilatation Catheter is not an implantable medical device and therefore not required according to MDCG 2019-9.

WARNING: The SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for healthcare professionals.

2 DEVICE IDENTIFICATION AND GENERAL INFORMATION

Trade Name: INVADER™ PTCA Balloon Dilatation Catheter

Manufacturer Name and Address: Alvimedica Tıbbi Ürünler Sanayi ve Dış Ticaret A.Ş -İstanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi, Atatürk Bulvarı No:16 34540 - Çatalca, İstanbul, Turkey

Authorised representive: NA

Manufacturer's Single Registration Number (SRN): TR-MF-000029915

Basic UDI-DI: 086991955InvaderPTCAVA

MEDICAL DEVICE NOMENCLATURE

PTCA Balloon Dilatation Catheter; EMDN Code C010401020101

Class Of Device: Class III per MDR (EU) 2017/745 Annex VIII, Rule 6.

First Certificate (CE): Invader™ PTCA Balloon Dilatation Catheter is CE marking approved under MDD 93/42/EEC on 11th August 2008 by DEKRA NB number 0344.

Notified Body: ICIM S.P.A. - Piazza Don Enrico Mapelli, 7520099 - Sesto San Giovanni (MI) - Italy - Notified Body number : 0425.

MDD CE 2161507CE02 and related Addendum: issued 14th June 2018 expiration date 1st June 2023

MDD CE 2161507DE01 and related Addendum: issued 14th June 2018 expiration date 1st June 2023

0425-MDR-006772-00 EU Quality Management System Certificate issued 4th July 2023 expiration date 3rd July 2028.

0425-MDR-006773-00 EU Technical Documentation Assessment Certificate issued 4th July 2023 expiration date 3rd July 2028.

3 INTENDED USE OF THE DEVICE

3.1 INTENDED PURPOSE

The INVADER™ PTCA Balloon Dilatation Catheter is intended to be used for dilating stenoses in the coronary artery or bypass graft so as to increase myocardial perfusion.

- Patients should be eligible for coronary bypass surgery.
- It is indicated for patients with single-artery non-calcified atherosclerotic lesions that can be dilated using a PTCA catheter.
- This procedure can also be indicated in certain patients who have multi-artery disease, and in patients who have undergone aorta-coronary bypass surgery but still have:

  > recurrent symptoms;

  > progressive coronary artery disease;

  > stenosis or obstruction in bypass grafts

3.2 INDICATIONS AND TARGET POPULATION

Patients who are eligible for percutaneous coronary intervention (PCI).
Product should not be used in the pregnant or nursing women and pediatric patients.

3.3 CONTRAINDICATIONS AND/OR LIMITATIONS

The INVADER™ PTCA Balloon Dilatation Catheter is contraindicated in patients:

- who are not eligible for coronary bypass surgery
- who have fully obstructed coronary arteries
- who have diffuse lesions
- who have severe stenosis of the left main coronary artery

4 DEVICE DESCRIPTION

4.1 DESCRIPTION OF THE DEVICE

INVADER™ PTCA Balloon Dilatation Catheter is a single use, Ethylene Oxide (EO) sterilized, monorail rapid exchange (RX) coronary angioplasty balloon dilatation catheter. The ALVIMEDICA INVADER™ PTCA has been designed to dilate the stenotic atherosclerotic lesions in coronary arteries or bypass grafts.

The dilation part of the catheter is the balloon near the distal tip. The catheter is hydrophilic coated on the distal shaft excluding the balloon. Radiopaque marker bands are located on both the proximal and distal shoulders of the balloon. Two depth markers, on the proximal shaft aid in determining when the balloon is exiting the guiding catheter, in the cases of brachial or femoral approach, respectively. A separate lumen on the catheter shaft is intended for use as a guidewire

lumen beginning at approximately 27 cm from the distal tip. The PTFE coated proximal end of the catheter is used as the balloon inflating port. The balloon is inflated by injecting a contrast liquid from this end. The balloon material can be inflated to a given size at a given pressure.

The catheters are for single-use only.

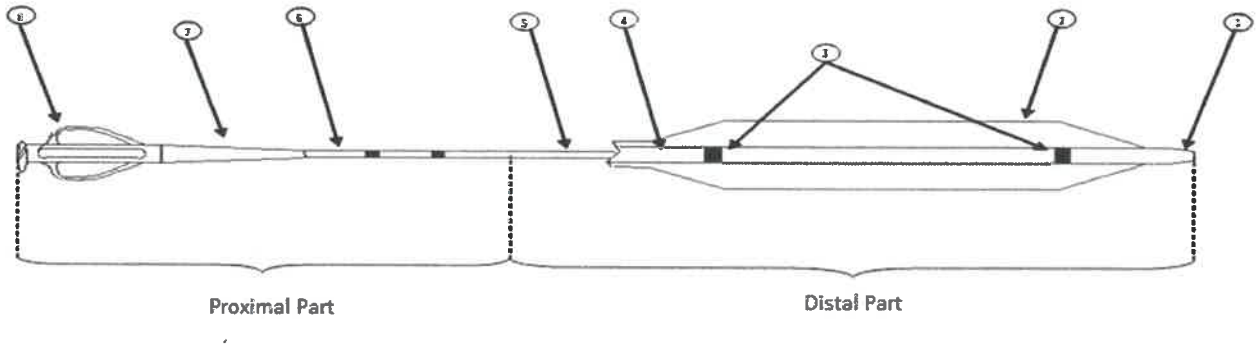

Figure 1. Representative image of the Balloon catheter

Model & Type

Figure 2. Available models

L [mm] / Ø [mm]	6	10	12	15	20	25	30	34
1.25	512110021610	512110021611	512110021612	512110021613	512110021614	-	-	-
1.50	512110021615	512110021616	512110021501	512110021617	512110021502	-	-	-
2.00	512110021618	512110021619	512110021503	512110021504	512110021506	512110021508	-	-
2.25	512110021620	512110021621	512110021622	512110021623	512110021624	512110021625	-	-
2.50	512110021626	512110021627	512110021509	512110021510	512110021512	512110021514	512110021516	512110021517
2.75	512110021628	512110021629	512110021551	512110021552	512110021554	512110021556	512110021558	512110021559
3.00	512110021630	512110021631	512110021518	512110021519	512110021521	512110021523	512110021525	512110021526
3.25	-	512110021632	512110021633	512110021634	512110021635	512110021636	512110021637	512110021638
3.50	-	512110021639	512110021527	512110021528	512110021530	512110021532	512110021534	512110021535
3.75	-	512110021640	512110021641	512110021642	512110021643	512110021644	512110021645	512110021646
4.00	-	512110021647	512110021536	512110021537	512110021539	512110021541	512110021543	512110021544
4.50	-	512110021648	512110021546	512110021547	512110021549	512110021649	512110021650	512110021651
5.00	-	512110021652	512110021653	512110021654	512110021655	-	-	-

Ø / Pressure [atm]	1.25 mm	1.50 mm	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm	4.50 mm	5.00 mm
8	1.24	1.48	2.01	2.21	2.56	2.76	3.02	3.22	3.51	3.74	4.01	4.51	5.02
9	1.27	1.52	2.04	2.26	2.60	2.80	3.06	3.26	3.55	3.80	4.05	4.55	5.11
10	1.30	1.55	2.07	2.30	2.63	2.83	3.09	3.30	3.58	3.85	4.08	4.59	5.18
11	1.33	1.58	2.10	2.33	2.66	2.85	3.12	3.33	3.60	3.90	4.11	4.62	5.24
12	1.36	1.61	2.12	2.37	2.68	2.87	3.14	3.36	3.63	3.93	4.14	4.65	5.30
13	1.40	1.64	2.15	2.40	2.71	2.90	3.16	3.40	3.65	3.96	4.17	4.68	5.34
14	1.43	1.67	2.18	2.43	2.74	2.92	3.19	3.42	3.68	3.99	4.19	4.70	5.39
15	1.47	1.71	2.21	2.47	2.77	2.94	3.22	3.46	3.70	4.02	4.22	4.74	5.42
16	1.51	1.75	2.24	2.50	2.80	2.97	3.24	3.49	3.73	4.05	4.24	4.77	5.47

Nominal Pressure

Rated Burst Pressure

4.2 PREVIOUS GENERATION

NOT APPLICABLE

4.3 ACCESSORIES TO BE USED IN COMBINATION WITH THE DEVICE

INVADER™ PTCA Balloon Dilatation Catheter does not contain separate components/ accessories, is not sold as part of a kit.

4.4 OTHER DEVICES AND PRODUCTS TO BE USED IN COMBINATION WITH THE DEVICE

Compatible guiding catheter with a 5F (1.422 mm) or larger and guidewire (max. 0.014", 0.356 mm) diameter or less, inflation device, introducer sheath and syringes.

5 RISK AND WARNINGS

5.1 RESIDUAL RISKS AND UNDESIRABLE EFFECTS

Potential adverse effects are those related to the PCI procedure:

- Dissection of the coronary artery
- Tearing, perforation of, or damage to the coronary artery
- Complete obstruction of the coronary artery or bypass graft
- Thrombosis of the coronary artery
- Unstable angina
- Acute myocardial infarction
- Restenosis of the dilated artery
- Spasm of the coronary artery
- Arrhythmias, including ventricular fibrillation

- Hemorrhage and hematoma
- Drug reactions, allergic reaction to contrast material
- Hypertension – hypotension
- Infection
- Arteriovenous fistula
- Embolism
- Death
- Urgent coronary artery bypass graft surgery
- Renal failure

5.2 WARNINGS AND PRECAUTIONS

- The INVADER™ PTCA Balloon Dilatation Catheter has been designed for single use only, reuse is not recommended. Do not resterilize it.
- Keep the catheter in a cool, dry and dark place.
- Do not use the catheter after the expiry date printed on the packaging.
- Use diluted contrast material only.
- Do not use air or any other gas to inflate the balloon.
- Check the packaging for any damage.
- Do not exceed the rated burst pressure as indicated in the Instructions For Use when inflating the balloon.
- Use of an inflation device with an incorporated pressure gauge is recommended.
- The diameter of the inflated balloon should not be exceeded at the points just proximal and distal to the stenosis.
- The INVADER™PTCA Balloon Dilatation Catheter should only be used by experienced physicians who have been trained in PTCA operations.
- Give appropriate anticoagulation and vasodilatation therapy prior to catheterization.
- The PTCA operation should only be performed in medical centers capable of carrying out emergency coronary bypass surgery in case of severe complications.
- Do not tighten the hemostatic adapter in the Y-connector, as this can compress the shaft, thus impeding the inflation and deflation of the balloon.
- All procedures performed once the catheter has been introduced into the body should be carried out under quality fluoroscopy. Never pull or push the catheter unless the balloon has been fully deflated under vacuum. If any resistance is encountered during the procedure, simply stop and try to identify the cause and then gradually advance the

balloon catheter to prevent the occurrence of kinking on the proximal shaft. If you fail to identify the cause, remove the entire system.

- Do not use the contrast materials Ethiodol or Lipiodol.
- Do not expose the insertion system to organic solvents (i.e. alcohol, etc.)

The product might be a potential biohazard, after use. The product must be handled and disposed of in accordance with accepted medical practice, applicable local laws and regulations. Alvimedica is not responsible for the handling and disposal of the product after use.

- The Summary of Safety and Clinical Performance (SSCP) for this device can be found at Alvimedica web site www.alvimedica.com and in EUDAMED database when available.

5.3 SUMMARY OF FIELD SAFETY CORRECTIVE ACTIONS

No field safety corrective actions have been taken. In particular, we haven't received any field safety notices nor general safety information.

6 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

6.1 SUMMARY OF CLINICAL DATA RELATED TO EQUIVALENT DEVICE

The concept of equivalence has not been applied to any other medical devices available on the market.

6.2 SUMMARY OF CLINICAL DATA FROM CONDUCTED INVESTIGATIONS OF THE DEVICE BEFORE THE CE-MARKING

6.2.1. Pre-market clinical investigation

There is no pre-market clinical investigation was conducted on the Invader™ PTCA Balloon Dilatation Catheters but from the time since 11.08.2008 Invader™ PTCA Balloon Dilatation Catheters has been available on the market the overall assessment from the users is always shows good performing with a high market satisfaction/low customer complaint ratio.

6.2.2. Relevant pre-clinical studies

Pre-clinical tests

A preclinical evaluation of the device with the proposed modifications was performed in order to assess the safety and the efficacy.

Bench tests

In vitro performance of Invader PTCA catheters are evaluated by performing visual control, tensile test, corrosion test, leakage test, effective length and diameter of balloon, rated burst pressure, balloon fatigue, balloon inflation/deflation time, compliance, effective length of catheter (UCL), friction, trackability, torquability and kissing balloon tests according to the relevant Design Verification protocol. All the results are found within tolerances and acceptable as stated in each Design Verification Report. Also all the list of the bench tests are stated in the Technical File of Invader PTCA with the code STED-MDR-00002.

6.3 SUMMARY OF CLINICAL DATA FROM OTHER SOURCES

As specified in the Clinical Evaluation Procedure and the Clinical Evaluation Plan, the literatures obtained are evaluated and eliminated within the scope of the inclusion/exclusion criteria (MEDDEV 2.7/1 Rev.4, 2016). So within this scope The Clinical Researcher conducted the literature search and analyzed the literature data in the document with the code DVA-00544 Clinical Evaluation Report of INVADER™ PTCA Balloon Dilatation Catheter. According to this report the final result is shown as in the below Table 2.

Table 2. Literature Database Results

Total Literature	Database			Exclusion Criteria	Inclusion Criteria
	PubMed	Cochrane Library	ScienceDirect		
733	540	193	0	680	53

After the literature search in the last 3 years the detailed evaluation is performed according to MDCG 2020-6. Almost all literature is at Level 1, this situation shows that the relevant literatures are selected and eliminated with the right strategy. So this result shows our clinical evidence is strong with the selection of keywords related to the product, the number of literatures obtained, and the number of literatures eliminated. No adverse events, feedback or risks were encountered in the literature regarding our product and equivalent products stated during literature search. As a result of these comprehensive studies have provided valuable information about the

performance and safety features of the device. Importantly, no article has shown significant differences in clinical outcome.

6.4 AN OVERALL SUMMARY OF CLINICAL PERFORMANCE AND SAFETY

5.4.1. Evaluation of Surveys Through Product Evaluation Forms

The PEFs are collected customers' satisfaction grade, classified from poor to excellent in five steps, for the device features, including the overall performance and usability. A score ranging from 1 to 5 has been assigned to each evaluation, and the average score has been calculated. Furthermore, per each feature, the Customer Satisfaction Score (CSS) has also been calculated, which is the percentage of customers assigning an Above average or Average grade.

The surveys'results in the last 3 years are represented from the below tables & graphs:

Table 3. Table of PEFs scores for 2024

-	Crossability (n=15)		Entry profile (n=15)		Visibility (n=15)		Inf./defl. Time (n=15)		Stability (n=15)		Behaviour (n=15)		Refold profile (n=15)		Overall performance (n=15)		Usability (n=15)	
-	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Excellent	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%
Above average	6	40%	6	40%	9	60%	3	20%	8	53,3%	7	46,6%	8	53,3%	7	46,6%	8	53,3%
Average	7	46,6%	7	46,6%	5	33,3%	12	80%	6	40%	6	40%	4	26,6%	4	26,6%	6	40%
Below Av	2	13,3%	2	13,3%	1	6,66%	0	0,0%	1	6,66%	2	13,3%	2	13,3%	4	26,6%	1	6,66%
Poor	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	1	6,66%	0	0,0%	0	0,0%
Customer Satisfaction Score	**86,6%**		**86,6%**		**93,3%**		**100%**		**93,3%**		**86,6%**		**80%**		**73,3%**		**93,3%**	

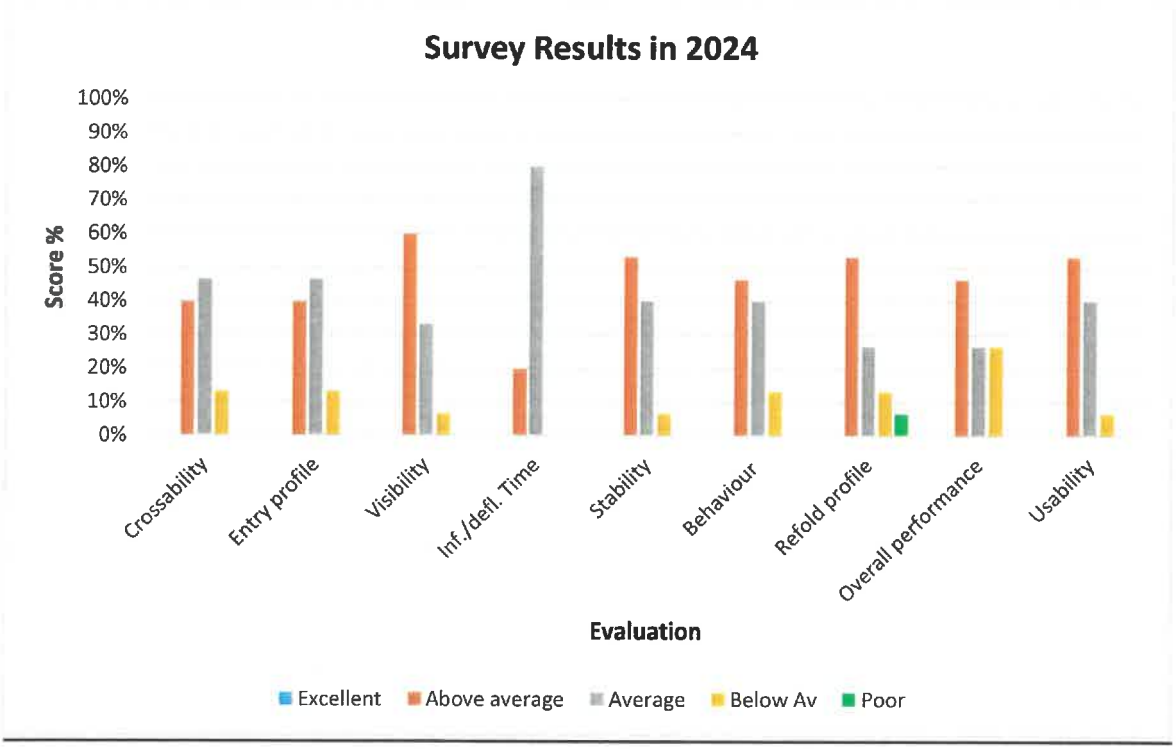

Figure 3. Graphs of PEFs scores for 2024

Table 4. Table of PEFs scores for 2023

-	Crossability (n=11)		Entry profile (n=11)		Visibility (n=11)		Inf./defl. Time (n=11)		Stability (n=11)		Behaviour (n=11)		Refold profile (n=11)		Overall performance (n=11)		Usability (n=11)	
-	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Excellent	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%
Above average	4	36,6%	2	18,18%	0	0,0%	3	27,27%	2	18,18%	2	18,18%	5	45,45%	3	27,27%	3	27,2%
Average	4	36,6%	6	54,54%	7	63,63%	6	54,54%	6	54,54%	5	45,45%	3	27,27%	4	36,6%	3	27,2%
Below Av	3	27,27%	3	27,27%	4	36,36%	2	18,18%	3	27,27%	4	36,36%	3	27,27%	4	36,36%	5	45,4%
Poor	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%
Customer Satisfaction Score	72,72%		72,72%		63,63%		81,81%		72,72%		63,63%		72,72%		63,63%		54,54%	

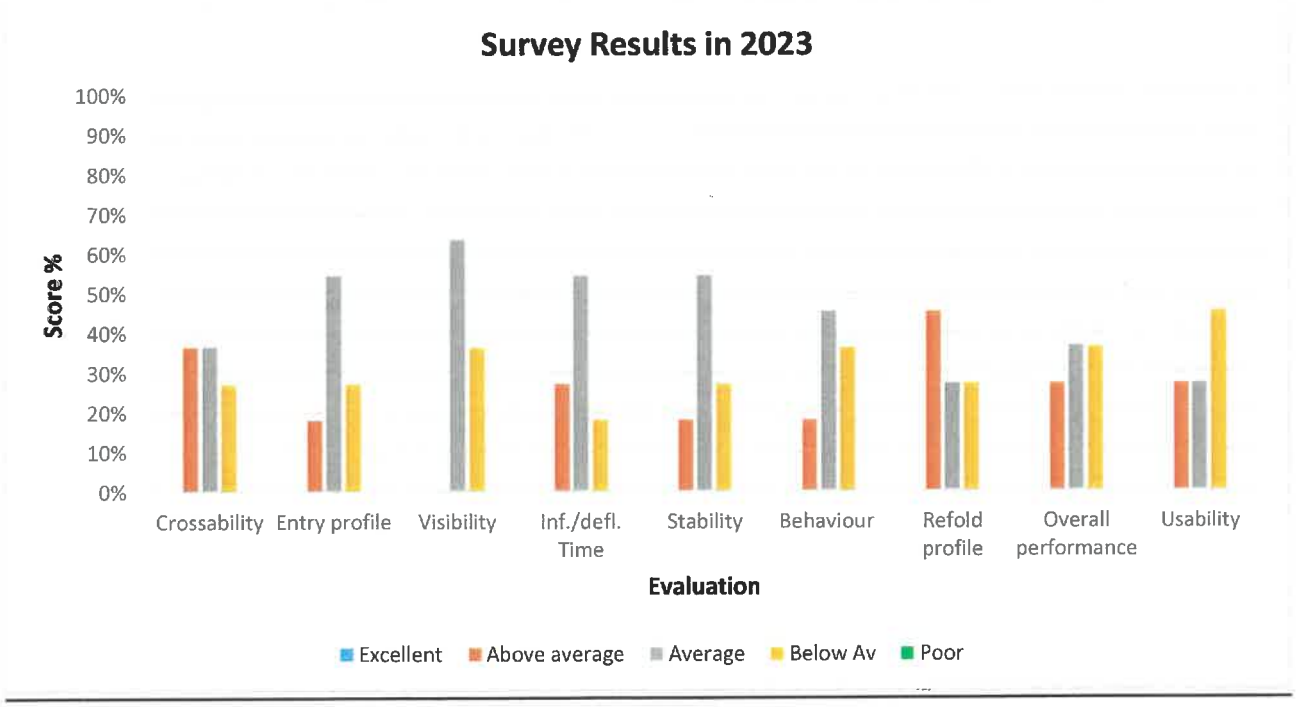

Figure 4. Graphs of PEFs scores for 2023

Table 5. Table of PEFs scores for 2022

	Crossability (n=43)		Entry profile (n=43)		Visibility (n=43)		Inf./defl. Time (n=43)		Stability (n=43)		Behaviour (n=43)		Refold profile (n=43)		Overall performance (n=43)		Usability (n=43)	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Excellent	5	11,6%	12	27,9%	14	32,6%	15	34,9%	13	30,2%	14	32,6%	8	18,6%	10	23,3%	7	16,3%
Above average	21	48,8%	18	41,9%	17	39,5%	15	34,9%	16	37,2%	13	30,2%	19	44,2%	17	39,5%	13	30,2%
Average	17	39,5%	13	30,2%	12	27,9%	13	30,2%	14	32,6%	14	32,6%	15	29,4%	16	37,2%	23	53,5%
Below Av	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	3	5,9%	0	0,0%	0	0,0%
Poor	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%
Customer Satisfaction Score	**60,5**		**69,8**		**72,1**		**69,8**		**67,4**		**62,6**		**62,8**		**62,88**		**46,5**	

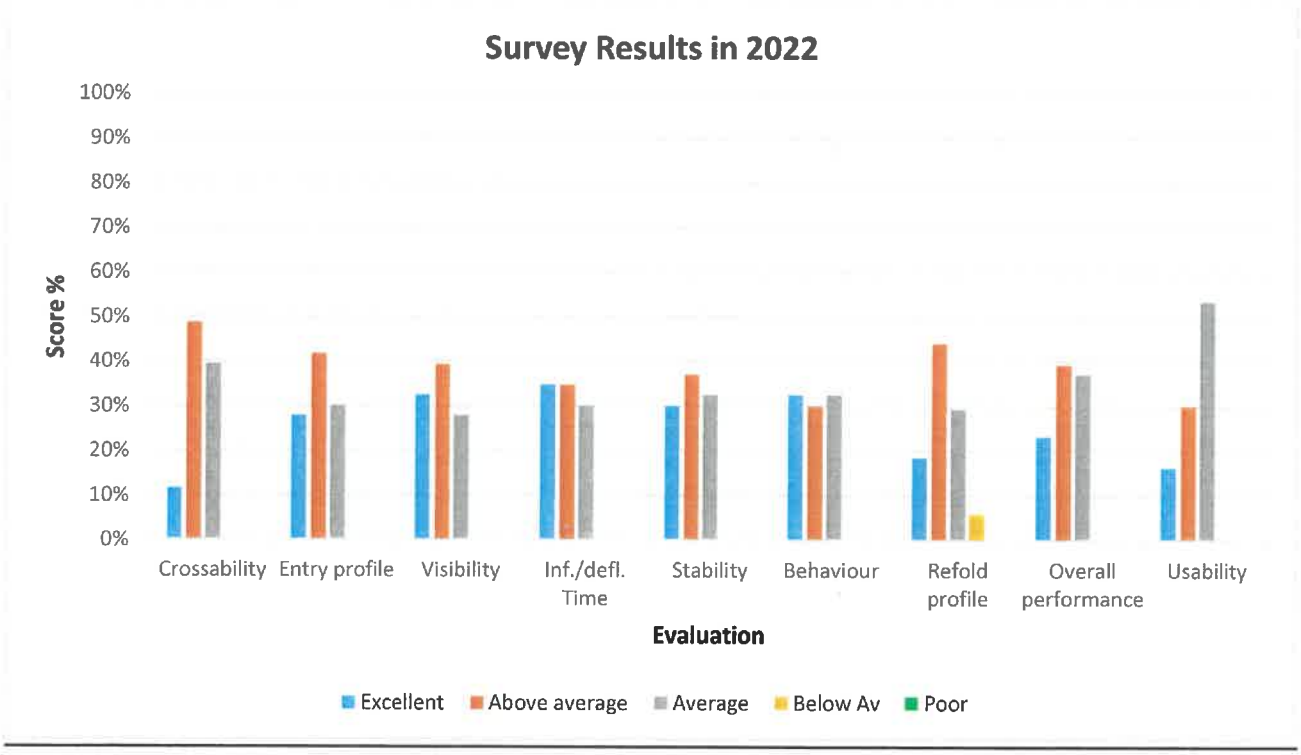

Figure 5. Graphs of PEFs scores for 2022

Conclusion: According to the overall evaluation for the latest 3 years results between 2022-2024 indicates that Invader™ PTCA is a safe and effective product with a good satisfactory rate given by the customers.

5.4.2. Evaluation of The Post Market Clinical Follow-Up

Study title

Balloon dilatation catheter for the dilation of stenotic atherosclerotic lesions in coronary artery or bypass grafts: evaluation of safety and performance in everyday clinical practice. The Invader ™ Percutaneous Transluminal Coronary Angioplasty (PTCA) Post Market Clinical Follow-up (PMCF) Study.

Objective

The objective of the prospective observational clinical study is to collect clinical data on the non-implantable medical device Invader™ PTCA in an unselected population in the current clinical practice.

Study Design

The study is a prospective observational study to collect real-world data on the non-implantable medical device Invader™ PTCA in an unselected population in the current clinical practice.

Sample Size

Due to the observational nature of the study, no statistical hypothesis is applicable and, therefore, no sample size calculation was performed. A number of 100 enrolled subjects was estimated to provide enough information to evaluate the objective of the study.

Safety of device

Three patients (3%) had complications during or after the procedure: two dissections of the coronary artery, one damage to the coronary artery, and one had hemorrhage/hematoma after the procedure. None of the complications was related to the device. All the patients with complications had full recovery.

Ninety-six patients were discharged within 48 hours, while four of them remained hospitalized due to non-device related reasons. Only one patient had stable angina at discharge, while the remaining 99 were asymptomatic. Complications/adverse events and discharge status of the patients are given in the following table.

		N=100	n (%)
Has there been any complications before, during or after the procedure, n (%)	Yes	100	4 (4.0)
	No		96 (96.0)
Complications, n (%)	Dissection of the coronary artery	100	2 (2.0)
	Tearing-perforation of or damage to the coronary artery		1 (1.0)

	Hemorrhage and hematoma		1 (1.0)
Occurrence time for complications, n (%)	During Procedure (after insertion of the device and before its removal) During hospitalization or maximum 48 hours after procedure	4	3 (75.0) 1 (25.0)
Relation with the device, n (%)	Not Related	4	4 (100.0)
Level of recovery, n (%)	Full recovery	4	4 (100.0)
Discharge Status, n (%)	Discharged within 48 hours Hospitalization (After 48-hour follow-up)	100	96 (96.0) 4 (4.0)
Cardiac status at discharge, n (%)	Asymptomatic Stable angina	100	99 (99.0) 1 (1.0)

Conclusion
The present observational study aimed to collect clinical data in the "real world" use of the non-implantable device INVADER™ PTCA, in 100 consecutive patients showed that INVADER™ PTCA is an effective and safe device to be used in percutaneous coronary interventions.

6.5 ONGOING OR PLANNED POST-MARKET CLINICAL FOLLOW-UP

Given the extensive experience with the device since its launch and the findings from INVADER™ PTCA Balloon Dilatation Catheter PMCF study, which shows that the device is performing well with no cause for concern, we believe that no further post-market clinical study is needed.

The proactive collection of Customer Feedback via Performance Evaluations Forms (PEFs) specifically designed continues throughout the product life.

7 POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

The use of PTCA Balloon Dilatation Catheters is a well-established practice since the introduction of the percutaneous treatment of coronary artery disease, and no valid alternative is available.

8 SUGGESTED PROFILE AND TRAINING FOR USERS

The INVADER™PTCA Balloon Dilatation Catheter should only be used by experienced physicians who have been trained in PTCA operations.

9 REFERENCE TO ANY HARMONISED STANDARDS AND CS (COMMON SPECIFICATION) APPLIED

STANDARD CODE	STANDARD NAME
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)
EN ISO 10993-4 V2:2017	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 4: SELECTION OF TESTS FOR INTERACTIONS WITH BLOOD (ISO 10993-4:2017)
EN ISO 10993-5:2009	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 5: TESTS FOR IN VITRO CYTOTOXICITY (ISO 10993-5:2009)
EN ISO 10993-6:2016	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 6: TESTS FOR LOCAL EFFECTS AFTER IMPLANTATION (ISO 10993-6:2016)
EN ISO 10993-7:2008/ AMD1:2019	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)
EN ISO 10993-10:2021	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 10: TESTS FOR SKIN SENSITIZATION (ISO 10993-10:2021)
EN ISO 10993-11:2018	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 11: TESTS FOR SYSTEMIC TOXICITY (ISO 10993-11:2017)
EN ISO 10993-12:2021	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 12: SAMPLE PREPARATION AND REFERENCE MATERIALS (ISO 10993-12:2021)

STANDARD CODE	STANDARD NAME
ISO 10993-18:2020	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 18: CHEMICAL CHARACTERIZATION OF MEDICAL DEVICE MATERIALS WITHIN A RISK MANAGEMENT PROCESS
ISO 10993-15:2019	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 15: IDENTIFICATION AND QUANTIFICATION OF DEGRADATION PRODUCTS FROM METALS AND ALLOYS
ISO 10993-23:2021	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 23: TESTS FOR IRRITATION
EN ISO 11135:2014/ A1:2019	STERILIZATION OF HEALTH CARE PRODUCTS - ETHYLENE OXIDE REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES AMENDMENT 1: REVISION OF ANNEX E, SINGLE BATCH RELEASE (ISO 11135:2014/AMD 1:2018)
EN ISO 11737-1:2018	STERILIZATION OF HEALTH CARE PRODUCTS - MICROBIOLOGICAL METHODS - PART 1: DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS (ISO 11737-1:2018)
EN ISO 11737-2:2020	STERILIZATION OF HEALTH CARE PRODUCTS - MICROBIOLOGICAL METHODS - PART 2: TESTS OF STERILITY PERFORMED IN THE DEFINITION, VALIDATION AND MAINTENANCE OF A STERILIZATION PROCESS (ISO 11737-2:2019) / 2020
EN ISO 11607-1:2020	PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES - PART 1: REQUIREMENTS FOR MATERIALS, STERILE BARRIER SYSTEMS AND PACKAGING SYSTEMS (ISO 11607-1:2006, INCLUDING AMD 1:2014)
EN ISO 11607-2 :2020	PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES - PART 2: VALIDATION REQUIREMENTS FOR FORMING, SEALING AND ASSEMBLY PROCESSES (ISO 11607-2:2006, INCLUDING AMD 1:2014)
EN 868-2:2017	PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES - PART 2: STERILIZATION WRAP - REQUIREMENTS AND TEST METHODS

STANDARD CODE	STANDARD NAME
EN 868-4:2017	PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES - PART 4: PAPER BAGS - REQUIREMENTS AND TEST METHODS
EN 868-5:2018	PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES - PART 5: SEALABLE POUCHES AND REELS OF POROUS MATERIALS AND PLASTIC FILM CONSTRUCTION - REQUIREMENTS AND TEST METHODS
EN 868-6:2017	PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES - PART 6: PAPER FOR LOW TEMPERATURE STERILIZATION PROCESSES - REQUIREMENTS AND TEST METHODS
EN ISO 15223-1:2021	MEDICAL DEVICES - SYMBOLS TO BE USED WITH INFORMATION TO BE SUPPLIED BY THE MANUFACTURER - PART 1: GENERAL REQUIREMENTS (ISO 15223-1:2021)
EN ISO 14644-1:2015	CLEANROOMS AND ASSOCIATED CONTROLLED ENVIRONMENTS - PART 1: CLASSIFICATION OF AIR CLEANLINESS BY PARTICLE CONCENTRATION (ISO 14644-1:2015)
EN 1041:2008+A1:2013	INFORMATION SUPPLIED BY THE MANUFACTURER OF MEDICAL DEVICES
EN ISO 11070:2014	STERILE SINGLE-USE INTRAVASCULAR INTRODUCERS, DILATORS AND GUIDEWIRES (ISO 11070:2014)
EN ISO 14644-2: 2015	CLEANROOMS AND ASSOCIATED CONTROLLED ENVIRONMENTS - PART 2: MONITORING TO PROVIDE EVIDENCE OF CLEANROOM PERFORMANCE RELATED TO AIR CLEANLINESS BY PARTICLE CONCENTRATION (ISO 14644-2:2015)
EN ISO 14644-3: 2019	CLEANROOMS AND ASSOCIATED CONTROLLED ENVIRONMENTS - PART 3: TEST METHODS (ISO 14644-3:2019)
EN ISO 13485:2016 A11:2021	MEDICAL DEVICES. QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS FOR REGULATORY PURPOSES (ISO 13485:2016)
EN ISO 14971:2019-A11 2021	MEDICAL DEVICES — APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES

STANDARD CODE	STANDARD NAME
ISO 24971:2020	MEDICAL DEVICES — GUIDANCE ON THE APPLICATION OF ISO 14971
EN 556-1:2001/AC:2006	STERILIZATION OF MEDICAL DEVICES - REQUIREMENTS FOR MEDICAL DEVICES TO BE DESIGNATED "STERILE" – PART 1: REQUIREMENTS FOR TERMINALLY STERILIZED MEDICAL DEVICES
EN ISO 10555 -1:2013/ A1:2017	INTRAVASCULAR CATHETERS – STERILE AND SINGLE-USE CATHETERS - PART 1: GENERAL REQUIREMENTS – AMENDMENT 1 (ISO 10555-1:2013/ AMD 1:2017)
EN ISO 14155:2020	CLINICAL INVESTIGATION OF MEDICAL DEVICES FOR HUMAN SUBJECTS – GOOD CLINICAL PRACTICE
EN ISO 80369-7:2021	SMALL-BORE CONNECTORS FOR LIQUIDS AND GASES IN HEALTHCARE APPLICATIONS - PART 7: CONNECTORS FOR INTRAVASCULAR OR HYPODERMIC APPLICATIONS
EN ISO/IEC 17050-1 :2010	CONFORMITY ASSESSMENT - SUPPLIER'S DECLARATION OF CONFORMITY - PART 1: GENERAL REQUIREMENTS (EN ISO/IEC 17050-1:2004, CORRECTED VERSION 2007-06-15)
EN ISO/IEC 17050-2:2004	CONFORMITY ASSESSMENT - SUPPLIER'S DECLARATION OF CONFORMITY - PART 2: SUPPORTING DOCUMENTATION (ISO/IEC 17050-2:2004)
EN ISO 11138-1:2017	STERILIZATION OF HEALTH CARE PRODUCTS - BIOLOGICAL INDICATORS - PART 1: GENERAL REQUIREMENTS (ISO 11138-1:2017)
EN ISO 11138-2:2017	STERILIZATION OF HEALTH CARE PRODUCTS - BIOLOGICAL INDICATORS - PART 2: BIOLOGICAL INDICATORS FOR ETHYLENE OXIDE STERILIZATION PROCESSES (ISO 11138-2:2017)
EN ISO 11138-7:2019	STERILIZATION OF HEALTH CARE PRODUCTS - BIOLOGICAL INDICATORS - PART 7: GUIDANCE FOR THE SELECTION, USE AND INTERPRETATION OF RESULTS (ISO 11138-7:2019)
EN ISO 14937:2009	STERILIZATION OF HEALTH CARE PRODUCTS - GENERAL REQUIREMENTS FOR CHARACTERIZATION OF A STERILIZING AGENT AND THE DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES (ISO 14937:2009)
EN ISO 11139:2018	STERILIZATION OF HEALTH CARE PRODUCTS - VOCABULARY - TERMS USED IN STERILIZATION AND RELATED EQUIPMENT AND PROCESS STANDARDS (ISO 11139:2018) / 2018

STANDARD CODE	STANDARD NAME
EN 17141:2020	CLEANROOMS AND ASSOCIATED CONTROLLED ENVIRONMENTS - BIOCONTAMINATION CONTROL
EN 62366-1:2015	MEDICAL DEVICES - PART 1: APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES
MEDDEV 2.7/1 REV.4	CLINICAL EVALUATION A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES
MEDDEV 2.12/1 REV.8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV 2.12-2 REV2	-UP STUDIES
MEDDEV 2.5/5 REV.3	TRANSLATION PROCEDURE
GHTF-SG2-N54R8 2006	MEDICAL DEVICES POST MARKET SURVEILLANCE: GLOBAL GUIDANCE FOR ADVERSE EVENT REPORTING FOR MEDICAL DEVICES
GHTF-SG3-N15R8 2005	IMPLEMENTATION OF RISK MANAGEMENT PRINCIPLES AND ACTIVITIES WITHIN A QUALITY MANAGEMENT SYSTEM
GMP-ANNEX I	GMP-ANNEX I -MANUFACTURE OF STERILE MEDICINAL PRODUCTS (CORRECTED VERSION)
ASTM D5276-19	STANDARD TEST METHOD FOR DROP TEST OF LOADED CONTAINERS BY FREE FALL / 2019
ASTM E122 - 17	STANDARD PRACTICE FOR CALCULATING SAMPLE SIZE TO ESTIMATE, WITH SPECIFIED PRECISION, THE AVERAGE FOR A CHARACTERISTIC OF A LOT OR PROCESS / 2017
ASTM E29-19	STANDARD PRACTICE FOR USING SIGNIFICANT DIGITS IN TEST DATA TO DETERMINE CONFORMANCE WITH SPECIFICATIONS / 2019
ASTM F 756-00	STANDARD PRACTICE FOR ASSESSMENT OF HEMOLYTIC PROPERTIES OF MATERIALS / 2000
ASTM F1886 F1886M - 16	STANDARD TEST METHOD FOR DETERMINING INTEGRITY OF SEALS FOR FLEXIBLE PACKAGING BY VISUAL INSPECTION / 2016
ASTM F1929 - 15	STANDARD TEST METHOD FOR DETECTING SEAL LEAKS IN POROUS MEDICAL PACKAGING BY DYE PENETRATION/2015
ASTM F1980 - 16	STANDARD GUIDE FOR ACCELERATED AGING OF STERILE BARRIER SYSTEMS FOR MEDICAL DEVICES / 2016
ASTM F2096 - 11	STANDARD TEST METHOD FOR DETECTING GROSS LEAKS IN PACKAGING BY INTERNAL PRESSURIZATION (BUBBLE TEST) / 2011
ASTM F2475-20	STANDARD GUIDE FOR BIOCOMPATIBILITY EVALUATION OF MEDICAL DEVICE PACKAGING MATERIALS / 2020

STANDARD CODE	STANDARD NAME
ASTM F640 - 12	STANDARD TEST METHODS FOR DETERMINING RADIOPACITY FOR MEDICAL USE / 2012
ASTM F88 F88M - 15	STANDARD TEST METHOD FOR SEAL STRENGTH OF FLEXIBLE BARRIER MATERIALS / 2015
ASTM F640 – 20	STANDARD TEST METHODS FOR DETERMINING RADIOPACITY FOR MEDICAL USE
ISO 11138-8 / 2021	STERILIZATION OF HEALTH CARE PRODUCTS — BIOLOGICAL INDICATORS PART 8: METHOD FOR VALIDATION OF A REDUCED INCUBATION TIME FOR A BIOLOGICAL INDICATOR
Medical Device Directive	Medical Device Directive 93/42/EEC as amended by 2007/47/EC
Medical Device Regulation Regulation	(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
EN ISO 14155:2020	Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practices
MDCG-2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies - March 2022
MDCG-2020-7	Guidance on PMCF plan template
MDCG-2020-8	Guidance on PMCF evaluation report template
MDCG-2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
IMDRF/NCAR WG/N14 FINAL:2017 (EDITION 2)	MEDICAL DEVICES: POST MARKET SURVEILLANCE: NATIONAL COMPETENT AUTHORITY REPORT EXCHANGE CRITERIA AND REPORT FORM
IMDRF/MDCE WG/N65	POST-MARKET CLINICAL FOLLOW-UP STUDIES

10 REVISION HISTORY

SSCP Revision Numbe	Data Issued	Change Description	Revision Validated by the Notified Body
0	30.09.2022	New Document	N.A
1	27.06.2023	Par. 2 Par. 2 inserted previous reference to MDD CE	NA
2	02.05.2024	- TR-MF-000029915 - 086991955InvaderPTCAVA -0425-MDR-006772-00 EU Quality Management System Certificate issued 4th July 2023 expiration date 3rd July 2028. -0425-MDR-006773-00 EU Technical Documentation Assessment Certificate issued 4th July 2023 expiration date 3rd July 2028.	NA
3	31.07.2025	PSUR, PMCF ve CER kapsamıyla uyumlu olacak şekilde tüm bölümleri gözden geçirilerek revize edilmiştir. Bu nedenle, revizyonlar ayrıca altı çizilerek belirtilmemiştir. / All sections have been reviewed and revised to ensure compliance with PSUR, PMCF and CER. Therefore, the revisions have not been highlighted.	NA