ID	Information Sheet	Revision Date	Rev. #
IS4507	SSCP	05/09/2023	03

An SSCP is part of the CER and will therefore be an attachment to a CER.
Consequently the SSCP approval will be approved via the CER approval.
This first page is for our own QMS documentation and should be removed for public release of the SSCP.

SSCP

Summary of Safety and Clinical Performance

Everest

Attachment 4 – TFC.1602.14

TITLE: Summary of Safety and Clinical Performance Everest PTCA dilatation catheters TFE. 1609.02.

CONCERNING PROJECT / CHANGE / KEYWORD:

PREPARED BY
NAME: Richa Rohilla **DATE: 08 August 2024**
FUNCTION: Deputy Manager, Regulatory Affairs **SIGNATURE:**

COMMENTS / REMARKS: This document is an attachment to the CER. Signature approvals of the latest CER TFC.1602.0x signifies approval of the SSCP TFC.1609.0x
……

APPROVAL / SUGGESTED DISTRIBUTION

FUNCTION	**: Clinical Research Manager**	**NAME : Dr. Brijesh Mishra**	**DATE:** 21-Mar-2025 **SIGN:** Dr Brijesh Mishra (Mar 21, 2025 19:43 GMT+5.5)
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TITLE: TFC.1609.06 SSCP_Everest semi-compliant_PTCA

SSCP

Summary of Safety and Clinical Performance

Everest PTCA balloon dilatation catheter

Basic UDI-DI: 872063420BMD-PTCAJ9

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Summary of safety and clinical performance

Intended for health care professionals

1 Device identification and general information

1.1 Device trade name

The scope of this SSCP are the following medical device:
Device trade name : Everest

1.2 Manufacturer's name and address

The manufacturer of the semi-compliant (SC) Everest balloon dilatation catheter is:

Name	: Blue Medical Devices B.V.
Person Responsible for Regulatory Compliance	: Alex Luijkx
Contact person	: Alex Luijkx
Visiting address	: Panovenweg 7
Postal code	: 5708 HR
City	: Helmond
Country	: The Netherlands
Phone	: +31(0)492 588 900
Website	: www.translumina.com

1.3 Manufacturer's SRN

The manufacturer's Single Registration Number is:
SRN : NL-MF-000002976

1.4 Basic UDI-DI

The Basic UDI-DI of the Everest PTCA catheter is

	Everest
Basic UDI-DI	872063420BMD-PTCAJ9 Everest: EVERxxxx01;

1.5 Medical Device Nomenclature description / text

The Everest PTCA catheter medical device nomenclature code used is:
Medical device Nomenclature code : UMDNS 17521
This code applies to Catheters, Angioplasty Balloon dilatation, Coronary Perfusing.

Device group CND: Cardiac angiography device
The CND/EMDN code of the device is C010401020101 describing: Angioplasty catheters, balloon dilatation, coronary/PTCA Balloon dilatation Catheter.

1.6 Class of device

By application of the classification rules in Annex VIII of the Medical Device Regulations MDR 2017/745 Blue Medical Devices B.V. Everest PTCA balloon dilatation catheter is a Class III medical device according

- rule 6 (described as surgically invasive device for transient/impermanent use), as the device is intended for use in direct contact with the heart or central circulatory system.

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1.7 Year when the first certificate (CE) was issued covering the device

The first approval for CE under the MDD 93/42/EEC was obtained for Everest PTCA balloon dilatation catheter in 2009.

1.8 Notified body name and single identification number

Name Notified body : British Standards Institute (BSI)
Single identification number : 2797

2 Intended use of the device

2.1 Intended purpose

The SC PTCA balloon catheter (Everest) is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial reperfusion in patients requiring a percutaneous coronary interventional (PCI) procedure in a blood vessel.
The SC PTCA balloon catheter (Everest) is intended for transient use (≤60 minutes).

2.2 Indications and target population

The SC PTCA balloon catheter (Everest) is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial reperfusion.

2.3 Contraindications and/or limitations

The Everest PTCA balloon dilatation catheter is contraindicated for

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of a significant stenosis

3 Device description

3.1 Description of the device

The Blue Medical Devices B.V. PTCA balloon dilatation catheter, Everest, is a rapid exchange (Rx) catheter with a semi-compliant (SC) balloon near the distal tip (Figure 1). The distal section of the outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 inch (0.36 mm) to facilitate advancement of the catheter through blood vessels, to and through the stenosis or stent to be dilated. The proximal section of the catheter is a single-lumen, stainless steel Hypotube with a single luer port hub for inflation/deflation of the balloon. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The PTCA balloon catheter is supplied with a balloon protector placed over the balloon to maintain a low profile and a eyed stylet is placed into the inner lumen to protect the patency of the catheter. The catheter tip is tapered to facilitate advancement of the catheter to and through a stenosis or stent. The shaft has a hydrophilic coating.

All variants of Everest PTCA balloon dilatation catheter with their Basic UDI-DI identified in section 1.4 are presented in Table 1 below, with model (product family) name and UDI-DI number.

Device trade name : Everest

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Table 1: Basic UDI-DI and UDI-DI for all variants (sizes) of the Everest

Product family	Balloon diameter (mm)	Balloon length (mm)	Rev #	Basic UDI-DI	UDI-DI
EVEREST	1.5	10	01	872063420BMD-PTCAJ9	EVER151001
EVEREST	1.5	15	01	872063420BMD-PTCAJ9	EVER151501
EVEREST	1.5	20	01	872063420BMD-PTCAJ9	EVER152001
EVEREST	1.5	30	01	872063420BMD-PTCAJ9	EVER153001
EVEREST	2.0	10	01	872063420BMD-PTCAJ9	EVER201001
EVEREST	2.0	15	01	872063420BMD-PTCAJ9	EVER201501
EVEREST	2.0	20	01	872063420BMD-PTCAJ9	EVER202001
EVEREST	2.0	30	01	872063420BMD-PTCAJ9	EVER203001
EVEREST	2.5	10	01	872063420BMD-PTCAJ9	EVER251001
EVEREST	2.5	15	01	872063420BMD-PTCAJ9	EVER251501
EVEREST	2.5	20	01	872063420BMD-PTCAJ9	EVER252001
EVEREST	2.5	30	01	872063420BMD-PTCAJ9	EVER253001
EVEREST	2.75	10	01	872063420BMD-PTCAJ9	EVER271001
EVEREST	2.75	15	01	872063420BMD-PTCAJ9	EVER271501
EVEREST	2.75	20	01	872063420BMD-PTCAJ9	EVER272001
EVEREST	2.75	30	01	872063420BMD-PTCAJ9	EVER273001
EVEREST	3.0	10	01	872063420BMD-PTCAJ9	EVER301001
EVEREST	3.0	15	01	872063420BMD-PTCAJ9	EVER301501
EVEREST	3.0	20	01	872063420BMD-PTCAJ9	EVER302001
EVEREST	3.0	30	01	872063420BMD-PTCAJ9	EVER303001
EVEREST	3.25	10	01	872063420BMD-PTCAJ9	EVER321001
EVEREST	3.25	15	01	872063420BMD-PTCAJ9	EVER321501
EVEREST	3.25	20	01	872063420BMD-PTCAJ9	EVER322001
EVEREST	3.25	30	01	872063420BMD-PTCAJ9	EVER323001
EVEREST	3.5	10	01	872063420BMD-PTCAJ9	EVER351001
EVEREST	3.5	15	01	872063420BMD-PTCAJ9	EVER351501
EVEREST	3.5	20	01	872063420BMD-PTCAJ9	EVER352001
EVEREST	3.5	30	01	872063420BMD-PTCAJ9	EVER353001
EVEREST	4.0	10	01	872063420BMD-PTCAJ9	EVER401001
EVEREST	4.0	15	01	872063420BMD-PTCAJ9	EVER401501
EVEREST	4.0	20	01	872063420BMD-PTCAJ9	EVER402001
EVEREST	4.0	30	01	872063420BMD-PTCAJ9	EVER403001

3.1.1 Principles of operation

The Everest PTCA balloon dilatation catheter is advanced through the vasculature over a routinely used 0.014" guidewire. Under high quality fluoroscopic guidance, the catheter is advanced until the PTCA balloon is positioned at the required location in the target lesion. The balloon is inflated (using standard

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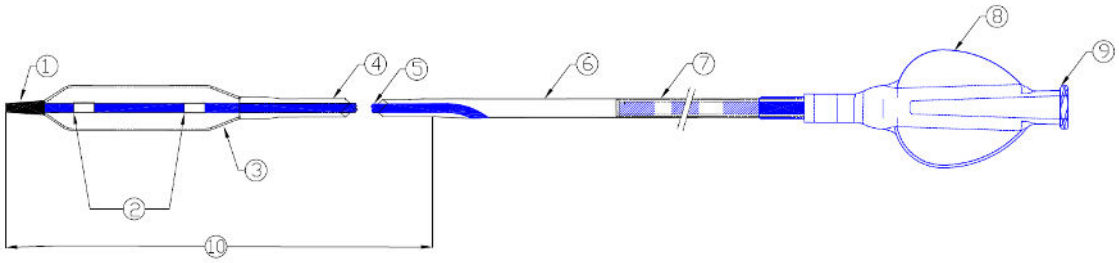
coronary interventional technique by means of an inflation device) and the lesion dilated. The deflated balloon catheter is withdrawn.

3.1.2 Key functional elements

A schematic representation of the rapid exchange Everest PTCA balloon dilatation catheter with indicated key functional elements is shown *Figure 1*.

Figure 1: *Schematic representation of the rapid exchange Everest PTCA balloon dilatation catheter, with key functional elements indicated*



No.	Functional element	No.	Functional element
1	Soft tip	6	Intermediate shaft
2	Radiopaque Marker Bands	7	Hypotube
3	Balloon	8	Hub with Strain Relief
4	Outer Body / Distal shaft	9	Luer Hub Lock
5	Inner Body	10	Hydrophilic Coating

3.1.3 Materials in direct contact

Materials that come in direct contact with the patient (blood, heart vasculature, central circulating system) are:

- PTFE *Hypotube*
- Pebax *Outerbody, Intermediate Shaft, Soft-tip (tip tubing)*
- Pebax and HDPE *Innerbody*
- Polyamide composite material *Balloon material*
- Hydrophilic coating

Materials that come in indirect contact with the patient are:

- PI/IR marker
- Luer Hub Lock

The contact duration of the materials is ≤60 minutes.
Sterilization of the device is with EtO.

3.1.4 Special design attributes

3.1.4.1 Medicinal substances

Blue Medical Devices B.V. states that Everest PTCA balloon dilatation catheter does not incorporate a medicinal substance.

3.1.4.2 Components of biological origin

Blue Medical Devices B.V. states that Everest PTCA balloon dilatation catheter does not incorporate viable materials of animal origin.

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3.1.4.3 Components of human origin
Blue Medical Devices B.V. states that Everest PTCA balloon dilatation catheter does not incorporate tissues and/or blood derivatives of human origin.

3.1.4.4 Absorption/dispersion in the body
Blue Medical Devices B.V. states that Everest PTCA balloon dilatation catheter does not contain substances that are absorbed or dispersed into the body during use.

3.1.4.5 CMR substances
Not applicable. Based on the biological safety evaluation (TF0.0812.0x) and the characteristics of the body contacting materials Blue Medical Devices B.V. states that Everest PTCA balloon dilatation catheter does not contain substances that are carcinogenic, mutagenic or toxic to reproduction.

3.2 Previous generation(s) or variants

The Everest PTCA balloon dilatation catheter is a Blue Medical Devices B.V. 4th Generation semi-compliant PTCA balloon dilatation catheter. The Everest PTCA balloon dilatation catheter is based on the Blue Medical Devices previous generations semi-compliant PTCA balloon dilatation catheters. The successive improvements of these devices in pushability and trackability, crossability dimensions of distal catheter section and deflated balloon, and lower guidewire friction ultimately led to the 3rd generation XW3 PTCA balloon dilatation catheter, and the currently marketed 4th generation Everest PTCA balloon dilatation catheter. The previous generations, including XW3, are not currently marketed products.

3.3 Accessories intended to be used in combination with the device.

Blue Medical Devices B.V. states that Everest PTCA balloon dilatation catheter is intended to be used in accordance with established minimally invasive / coronary catheterization procedures, which includes the accompanying devices that are required to be used in combination with the Everest PTCA balloon dilatation catheter in these procedures.

3.4 Other devices or products intended to be used in combination with the device

Not applicable. Blue Medical Devices B.V. states that Everest PTCA balloon dilatation catheter is not intended to be used in combination with specific accessories other than generic devices routinely required for the interventional PTCA procedure as described in the directions of use.

4 Risks and warnings

4.1 Residual risks and undesirable effects

The Risk Management process has assured that the hazards (failure modes) which could lead to potential harms to the patient were identified, and all reasonable practicable activities (risks mitigation measures) have been implemented to achieve risk acceptability through safety by design and/or in-line process controls, and usability risk control measures to prevent the hazards from occurring.

Improper use and/or handling by the user/customer cannot be eliminated through safety by design and/or in-line process controls. Usability risk control measures, to prevent hazards from occurring, have been implemented by appropriate labelling and/or IFU (procedure) text.

The implemented control measures are outlined in the below Table 2, which are covered in “warnings and precautions” as listed in section 4.2.

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Table 2: Potential harms and implemented usability risk control measures

Potential harm	Implemented usability risk control measures in IFU and/or labelling	Occurrence rates (per unit sales)
		Official Complaints Everest + PMCF
Air-embolism	Instructions on preparation and that the use of the device is to be performed by qualified physicians.	0%
Embolism	Instruction and/or warning and/or labelling on single use device, hub product identification, fluoroscopic control, catheter handling.	0%
Major vessel dissection	Instructions and/or warnings on Rated Burst Pressure, compliance chart, fluoroscopic control, catheter handling.	0%
Vessel perforation and/or rupture	Instructions and/or warnings on Rated Burst Pressure, compliance chart, fluoroscopic control, hub product identification, catheter handling.	0%
Acute Myocardial Infarction	Instructions and/or warnings on Rated Burst Pressure, compliance chart, catheter handling.	0%
Infection	Easy opening box, and Instructions and/labelling indicating single use, “use before date”, rough handling, following hospital procedure.	0%
Death	Instructions on procedure regarding in deflation, preparation device, catheter handling.	0%
Occlusion of coronary artery/bypass graft	Instruction warning and labelling on single use device .	0%
Additional percutaneous/surgical intervention	Instructions and/or labelling and/or warnings on device preparation, inflation & deflation procedure, hub product identification, Rated Burst Pressure, compliance chart, fluoroscopic control, catheter handling, “use before date”.	0%

Percutaneous devices used for dilatation of target lesions are an integral part of coronary catheterization. There are potential complications that could be encountered during all coronary catheterization procedures which cannot be further reduced by taking design and/or inline process controls risk mitigation measures and/or through protective measures or information for safety.
Therefore, potential complications (harms) that can be encountered during all coronary catheterization procedures (either with or without the application of angioplasty devices under normal conditions of use) are listed in the IFUs of the Blue Medical Devices PTCA balloon dilatation catheters. These potential harms can include, but are not limited to:

- Death.
- Acute myocardial infarction.
- Total occlusion of the coronary artery or bypass graft.
- Coronary vessel dissection, perforation, rupture or injury.
- Restenosis of the dilated vessel.

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- Haemorrhage or haematoma.
- Unstable angina.
- Arrhythmias, including ventricular fibrillation.
- Drug reactions, allergic reaction to contrast medium.
- Hypo/hypertension.
- Infection.
- Coronary artery spasm.
- Arteriovenous fistula.
- Embolism.

4.2 Warnings and precautions

Warnings and precautions related to the preparation of a device or relating to procedural steps are contained in the IFU.
The IFU can be assessed on the manufacturer's website: ***www.translumina.com***

Warnings

- For single patient, single procedure use only. Do NOT resterilize and/or reuse as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are acceptable candidates for coronary artery bypass graft surgery requires careful consideration. This includes possible hemodynamic support during PTCA as treatment of this patient population carries special risk.
- When the balloon dilatation catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic guidance. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon Pressure: do not exceed the rated burst pressure (RBP) indicated on the packaging. The rated burst pressure (RBP) is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure (RBP).
- Use of a pressure-monitoring device is recommended to prevent over pressurization.
- PTCA should only be performed at hospitals where emergency coronary bypass surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to "Use Before"("expiry") date specified on the package.
- Treatment of vessels with moderate or heavy lesion calcification is associated with decreased success rates up to 60-85% and increases the risk of acute closure vessel, trauma, balloon burst, balloon entrapment and associated complications.
- An incorrectly prepared balloon dilatation catheter may prolong the deflation time.
- Loss of vacuum or a continuous stream of air entering the syringe upon aspiration indicates the presence of a leak in the system (inspect the system for integrity).
- Do not torque the balloon dilatation catheter shaft.
- After use, the equipment used in angioplasty, may be a potential biohazard.
- Handle carefully and dispose of in accordance with hospital policy and appropriate applicable federal regulations.

Precautions

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- Prior to angioplasty procedure, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it will be used.
- Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the catheter.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN)

Not applicable. There have been no FSCA.

5 Summary of clinical evaluation

The conformity to the GSPR of the Everest PTCA balloon dilatation catheters was assessed and endorsed by the Notified Body based on the clinical data forming the clinical evidence, the evaluation of undesirable side-effects and the acceptability of the benefit-risk ratio.

5.1 Summary of clinical data related to the equivalent device

Not applicable.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking

No clinical investigations were conducted with the Everest PTCA balloon dilatation catheter prior to CE-certification (MDD 93/92/EEC) in 2009.

5.3 Summary of PMS clinical data

5.3.1 PMCF procedure data

Post Market Clinical Feedback (PMCF) was collected on clinical procedure data from multiple physicians (end-users) in various countries in- and outside of Europe.

Pivotal Everest PTCA catheter data:
The clinical application of 141 Everest PTCA balloon dilatation catheter was evaluated (pivotal data). Physicians rated catheter characteristics relevant to the performance and safety of the Everest PTCA balloon dilatation catheter, and indicated if any safety issues had occurred. A summary of the PMCF data is given in Table 3.

Table 3: Summary of pivotal PMCF procedure data 2010 – 2021

Year	Evaluators	Summary EVEREST PTCA balloon dilatation catheter data
2010	24 Physicians (end-users) in 4 hospitals in the Netherlands	**N=125** Everest catheters were evaluated during PCI procedures (procedure data). There was no correlation between lesion characteristics and procedure data outcomes. This was due to that he catheter scored at all ratings mostly *Good*, which consequently means that there was few data with ratings score *Acceptable* and/or *Poor*. Therefore, a statistic comparison was difficult to conduct. A significant difference was found in the case of rewrap of the balloon between a calcification present or not. A significant better rewrap is seen when no calcification is present.

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		For all other attributes analyzed: thrombus, balloon positioning, lesion type, artery, and tortuosity no significant differences were found. In conclusion, the Everest performs excellent according to interventional cardiologists who used the catheter. All ratings scored 95% and higher, except for the rating *Rewrap*, which scores 89.3%. In addition, 99.1% of the procedures were successful and positioning of the balloon was in 94.2% of the cases Easy, while the type of lesions were reasonably evenly distributed. There were no adverse events
2016	Physicians (end-users) (n=2) in one hospital in Vietnam	**N=3** Everest PTCA catheters. The procedures were performed in the left circumflex artery (LCX) (n=2) and LAD (n=1). The lesion in the LAD was a Type B1 lesion with no tortuosity, no calcification and no thrombus. The two LCX lesions were Type B2 lesions with moderate tortuosity, calcification and no thrombus. Overall performance was rated as good (n=1) and acceptable (n=2). There were neither device anomalies nor patient safety issues reported.
2021	Physicians (n=8) in different countries: Vietnam, Ukraine & Latvia	**N=13** Everest PTCA catheters were evaluated. PMCF is still ongoing in 2021. N=14 lesions were treated with n=13 Everest PTCA catheters. Lesion locations were in the LAD (4x), RCA (8x), D2 (1x) and RPL (1x). Lesions were Type A (5x), Type B1 (4x), Type B2 (3x) and Type C (1x). Calcification in 8 of 13 lesions. Max. inflation pressure was 16 bar. N=8 balloons were inflated multiple times (2-4 inflations). The n=13 Everest PTCA catheters showed Overall excellent/good performance. All performance characteristics received ratings Excellent/Good/Average. There were neither device anomalies nor patient safety issues reported.
2023	Physicians (end-users) (N=4) in France and Pakistan	The Clinical Feedbacks analysis contains detailed information on nine cases involving the use of PTCA balloons in France and Pakistan. The data includes feedback receiving dates ranging from February to November 2023, and hospitals involved such as Albert Schweitzer and Cl. Pasteur Essey LES Nancy in France and NICVD in Pakistan. Lesion locations vary. Lesion types include A, B1, B2, and C, with vessel tortuosity categorized as none, moderate, or severe. All cases involve calcification and the use of Everest semi compliant balloons, with balloon diameters typically 2.00 mm or 2.50 mm. The length of the Everest semi compliant balloons varies between 10 mm and 15 mm, with maximum inflation pressures ranging from 10 to 18 bars. The number of inflations per balloon ranges from 1 to 2, 3 Everest PTCA balloon catheters were inflated multiple times (n=2). No cases required a second balloon, suggesting effective initial treatment. The overall performance of the Everest PTCA balloon dilatation catheter was rated excellent (n=3), acceptable (n=1), and Similar (n=5) in 2023. There were very limited no. of feedback forms collected for PTCA catheters. Therefore, PMCF data collection will be continued throughout 2024. The data does show only excellent ratings, indicating acceptable clinical performance of the Everest. The current rates show that the Everest has acceptable clinical performance. No adverse events were recorded via PMCF and no new risks or side-effects were identified. Overall performance was good and acceptable. There were no device anomalies and no safety issues.

Supplementary to the pivotal Everest PTCA balloon dilatation catheter data:

Data is presented concerning the Blue Medical Devices B.V. semi-compliant Protégé DEB PTCA (Basic UDI-DI 872063420BMD-DEB6S, UDI-DI PROxxxx01), which is the Blue Medical Devices semi-compliant Everest PTCA balloon dilatation catheter with a drug coating (3µg/mm^2 Paclitaxel) on the

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surface of the balloon. The Everest and Protégé DEB PTCA catheters have the same purpose of use, the same mode of operation, the same fundamental design, and the same handling and performance characteristics for the dilatation of a lesion in PCI to give the same procedure (immediate) outcomes. The application of any PTCA catheter – with or without a drug coating - in PCI gives immediate revascularization outcomes: (a) performance outcome in terms of the dilatation of a target lesion to minimize residual stenosis to as low as possible, and device integrity and/or device failures; and (b) procedure safety outcome in terms of device-related complications and/or device integrity.

The procedure data of 307 patients treated with Protégé DEB balloons as part of the PEARL registry (2014-2019) which was performed in 4 hospitals in the Netherlands. N=346 Protégé DEB were applied in 307 patients to treat N=388 lesions. 62.6% lesions were Type B2 and Type C. Overall, 31.6% of lesions had moderate to heavy calcification. Mean pre-procedure % stenosis was 86.3%. Pre-dilatation was performed in 66.2%. Post-procedure semi-compliant DEB outcome was 84% lesions with ≤30% residual stenosis, and TIMI flow III post-DEB in 97.8%. Multiple inflations (2-3 inflations; average pressure 13.5 bar) were performed with 33.1% of the semi-compliant balloons, with successful retraction out of the lesion/stent and into the guiding catheter. All balloons were successfully retracted from the vessel and into the guiding catheter. These data indicate good semi-compliant DEB PTCA catheter procedure performance; a balloon catheter with the same procedure performance characteristics as the Everest PTCA balloon dilatation catheter. Complications occurring due to the PTCA dilatation procedure were low and there were no reported procedure myocardial repercussions for the involved patients. All dissections following balloon dilatation were successfully stented when required. Of the 346 balloon catheters, n=4 devices failures (1.2%), namely two suboptimal results with cross-over to stenting and two balloon burst (one on 3rd inflation of CTO lesion; second on 1st inflation of a non-predilated ISR Type C lesion) without further complications. Per patient basis, n=12 procedure DEB-related complications (3.9%), of which n=1 occlusion in a small side-branch caused by lesion dilatation in mid-LAD, and n=11 dissections which were successfully stented. The procedures successfully completed without further complications. All recorded complications are known events that can occur when undertaking a PCI procedure and are applicable for all PTCA balloon dilatation catheters.

The semi-compliant PTCA balloon dilatation catheter showed overall good performance and safety. The devices failures and complications are known issues which can occur in PTCA procedures. There were no unknown or unforeseeable events and/or safety issues.

5.3.2 Blue Medical Devices B.V. Complaints database

The total n=22 customer complaints were received by Blue Medical Devices from 2013-2023 involving the Everest PTCA catheter and/or packaging. Sales data was available from 2013-2023. For this latter period, based on the total units sold the overall complaint occurrence rate is 0.012%. Of the total 20 complaints, 13 were pre-procedure, one unknown, and 7 intra-procedures and n=2 complaints regarding the balloon rupture was reported in PMCF survey. There were no patient injuries/harm reported.

The below Table 4 gives an overview of the Everest PTCA procedure failures (Blue Medical Devices complaints database + PMCF) and correspondence with those failures registered for competitor PTCA balloon dilatation catheters in the FDA Maude database.

During the life-time of the Everest PTCA balloon dilatation catheter, the reported complaints and events show no new risks or hazards.

Table 4: Overview of device-related identified procedure failures (hazards) comparison literature and Everest PTCA balloon dilatation catheters

Device-related identified procedure failures (Hazards)		
Literature	**Everest PTCA balloon dilatation catheter: Complaints Database Manufacturer + PMCF**	
Failures for competitor PTCA balloon dilatation	**Reported Failure**	**Number (n) &**

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devices reported in FDA Maude database		Occurrence [n/total units sold]
Balloon Rupture	Balloon burst	**Everest** PTCA: n=2 [0.0012] [PMCF]
Material Split/cut or torn	Damaged balloon	**Everest** PTCA: n=1 [0.00061]
Material Rupture (Shaft/balloon)		
Detachment of Device or device Component		
Deflation Problem	Deflation problem	**Everest** PTCA: n=1 [0.00061]
Difficult to Remove		
Material Puncture / Hole		
Entrapment of Device		
Difficult to Advance		
Failure to Advance		
Material Integrity Problem		
Material Deformation		
Failure to Fold		
Inflation Problem	No inflation (leak in balloon/unknown)	**Everest** PTCA; n=5 [0.003]
Device Damaged by Another Device		
Incorrect compliance chart		
Fracture Shaft		
Fracture Luer		
Improper or Incorrect procedure (not following IFU/labelling)		
Pre-procedure fracture (catheter damage)	Unpacking product difficulties/ pre-procedure catheter damage/break, tip damage, kink-bending	**Everest** PTCA: n=13 [0.0085]

There were one Field Safety Corrective Actions (FSCA) reported in 2022. All identified hazards and possible complications (risks) have been taken into account in the Risk Management Process of the Everest PTCA balloon dilatation catheter.

5.3.3 Summary conclusion

The clinical data generated for the marketed Everest PTCA balloon dilatation catheter covers all safety aspects for the clinical application of the device, and gives confirmation on the clinical safety, performance and usability of the device for its intended purpose (use).

5.4 An overall summary of the clinical performance and safety

The clinical performance and safety data generated for the marketed Everest PTCA balloon dilatation catheter covers all performance aspects for the clinical application of the device and gives confirmation on the performance of the device for its intended purpose (use). The performance and safety results

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presented in the Everest PTCA balloon dilatation catheter clinical data sets and in one Protégé DEB (Everest with drug) data set, as well as other PMS feedback, shows acceptability of all performance characteristics of the Everest PTCA balloon dilatation catheter. The number of device failures reported in the Blue Medical Devices B.V. complaints database over the lifetime of the Everest PTCA balloon dilatation catheter is low.

The claimed clinical benefit is supported by the documented data:

- For patients suffering from stenotic lesions in the coronary artery system that require PCI, PTCA balloon dilatation catheter characteristics shows clinical benefits in that following successful guidewire crossing of the target lesion, procedure technical success was achieved for the Everest PTCA balloon dilatation catheter, with the benefit of optimizing lesion preparation and/or post-dilatation for an overall successful PCI procedure for improving myocardial reperfusion.

The claimed clinical performance objectives are supported by the documented data:

- Following successful guidewire crossing of the lesion, procedure device technical success of Everest PTCA balloon dilatation catheter is >98% (acceptance criteria ≥95%), i.e. technically successful PTCA catheter procedure. This encompasses catheter characteristics for delivery, lesion crossing, inflation/deflation, rewrap, removal / retraction from the target lesion, through vessels and back into the guiding catheter.

The claimed clinical safety objective is supported by the documented data:

- The safety criteria (completion of procedure without PTCA balloon catheter-related procedure serious adverse events (<1%)) was met. There were no (0%) device-related serious adverse events reported.

5.5 Overall conclusion of the Benefit/Risk Acceptability Assessment

Based on the data available in the current literature, and the assessment of the accumulated Blue Medical Devices Everest PTCA balloon dilatation catheter clinical data, the risks associated with the Blue Medical Devices Everest PTCA balloon dilatation catheter is anticipated to be no greater than those associated with other intravascular devices intended for the balloon dilatation in the coronary artery for the purpose of improving myocardial reperfusion during a PCI procedure.

The Blue Medical Devices PTCA balloon dilatation catheter Everest PTCA catheter features design characteristics that will be beneficial in terms of deliverability (pushability, trackability), lesion crossability, balloon crossing profile, balloon compliance, inflation (vessel narrowing dilatation) / deflation.

Conclusion of the Benefit/Risk assessment: The overall residual risk is acceptable when weighed against the benefit.

5.6 Summary of evaluation of undesirable side effects

The hazards (failure modes) which could lead to potential harms to the patient were identified, as given in Table 2 in section 4.1, and all reasonable practicable activities (risks mitigation measures) were implemented to achieve risk acceptability by safety by design and/or in-line process controls and usability risk control measures to prevent the hazards from occurring. The accumulated clinical data for the Everest PTCA balloon dilatation catheter indicates that there were no reported occurrences of the potential harms.
All percutaneous devices used in coronary catheterization procedures are for single use / single procedure only and must not be resterilized and/or reused as this could potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination. A warning is included in the labeling/IFU.

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The individual and overall residual risks are determined not to be different compared to the state of the art.

5.7 Ongoing or planned post-market clinical follow-up

As part of the Post Market Surveillance program, Blue Medical Devices B.V. will continue performing annual Post Market Clinical Follow-Up (PMCF) in the form of a user-survey(s) on Everest PTCA balloon dilatation catheters to obtain continuous extensive customer feedback on procedure safety and performance, and usability. The need for a PMCF study will be continually assessed according to the risk management process.
Based on the outcome of the risk management process, there are no residual risks or uncertainties or unanswered questions that would require specific evaluation during PMS.

6 Possible diagnostic or therapeutic alternatives

Stand-alone balloon angioplasty intervention (or plain old balloon angioplasty [POBA]) is no longer the common treatment approach. Therefore, in current practice balloon angioplasty is most often applied in procedures in which devices such as drug-eluting balloons and/or coronary drug eluting stents are the "main" procedure treatment component.
State of the Art literature indicates a number of alternative treatments and/or devices:

- Drug-eluting balloons (DEB): DEB catheters are conventional (standard) semi-compliant or non-compliant angioplasty balloons covered with an anti-restenotic drug, which is released into the vessel wall during inflation of the balloon, for better long term outcomes with respect to lesion restenosis. The complications that can occur with a DEB PTCA catheter are no different to those of standard balloon angioplasty catheter in terms of the peri-procedure complications. Standard semi-compliant and non-compliant PTCA balloon catheters are often used to pre-dilate the lesion prior to DEB application.
- Coronary drug-eluting stents (DES) are the most widely used intracoronary devices in PCI due to improved *longer term* clinical outcomes. Standard semi-compliant and non-compliant PTCA balloons are often used for pre- and/or post-dilatation.
- Coronary Artery Bypass Grafting (CABG) has been considered the standard of care for patients with unprotected left main (LM) CAD (i.e. patients without prior CABG or a patent graft to the left anterior descending (LAD) or left circumflex artery), a reasonable alternative to CABG is PCI to improve survival in selected stable patients who have ≥50% diameter stenosis and either of the following:
    - Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g. stenosis of the ostium or trunk vs distal bifurcation or trifurcation stenoses)
    - Clinical characteristics that predict a significantly higher risk of adverse surgical outcomes

  A consideration in the choice of CABG rather than PCI is if the patient does not tolerate or comply with dual antiplatelet therapy (DAPT).
- Rotational and Orbital Atherectomy. Atherectomy can be used for specific lesions unsuitable for balloon angioplasty and/or stent.
- A cutting and scoring PTCA catheters are balloon lesion-tipped catheters with respectively cutting (micro-blades) and scoring elements attached, which are used in those circumstances where a lesion is resistant to high pressure balloon dilatation.
- Medical therapy is recommended as first-line therapy in patients with stable angina unless one or more of the following indications for cardiac catheterization and PCI or CABG are present:
    - Severe symptoms
    - A change in symptom severity
    - Failed medical therapy
    - High-risk coronary anatomy or noninvasive findings

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- Worsening left ventricular dysfunction

Medical Society Guideline: F.-J. Neumann *et al.*, "2018 ESC/EACTS Guidelines on myocardial revascularization The Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) Developed with the special contribution of the," *Eur. Heart J.*, vol. 40, no. 2, pp. 87–165, 2019, doi: 10.1093/eurheartj/ehy394.

7 Suggested profile and training for users

The target users are medical professionals who perform and assist in catheterization procedures in a clinical laboratory setting, during percutaneous intervention (e.g. PTCA, coronary stent placement).
Use of the product is restricted to healthcare professionals in an interventional suite with angiography equipment, with personnel with relevant and adequate training and who familiar with the possible/conceivable complications. The Blue Medical Devices PTCA catheter can only be purchased on prescription of a physician.

8 Reference to any harmonized standards and CS applied

Key applicable (harmonised) standards and guidance documents specifically for PTCA:

- ISO 10555-1:2023 Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
- ISO 10555-4:2023 Intravascular catheters – Sterile and single-use catheters – Part 4: Balloon Dilatation Catheters
- ISO 10993-1:2021 - Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- ISO 10993-4:2017-10 - Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 - Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-7:2008/A1:2022 - Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
- 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 11607-1:2020/A1:2023 - Packaging for terminally sterilized medical devices. Part-1 Requirements for materials, sterile barrier systems and packages systems
- ISO 11607-2:2020/A1:2023 - Packaging for terminally sterilized medical devices. Part-2: Validation requirements for forming, sealing and assembly processes
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

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9 Revision history

SSCP Revision number	Date issued	Change description	Revision validated by the notified body	
01	13-06-2022	First issue	X	Yes Validation language: English
			☐	No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
02	08-08-2024	Review and update for the fiscal year 2023.	☐	Yes Validation language: English
			X	No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

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TFC.1609.02 SSCP_Everest semi-compliant_PTCA catheter_Final_19Mar2025

Final Audit Report 2025-03-21

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