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 or own QMS documentation and should be removed for public release of the SSCP.

SSCP

Summary of Safety and Clinical Performance

Force NC[1]

Attachment 6 – TFL.1602.07

Date: 08 August 2024

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Asst. Manager Regulatory Affairs

[1] Force NC: Force NC and spin-off Across NC (identical catheter only with different trade name)

TITLE: TF7.1610.05 SSCP_Force NC Non-compliant_PTCA and Across NC Non-compliant_PTCA

SSCP

Summary of Safety and Clinical Performance

Force NC PTCA balloon dilatation catheter

Including spin-off with trade name Across NC

Basic UDI-DI: 872063420BMD-PTCAJ9

A Translumina Group company

To be completed upon final NB approval		Signature	Date
Prepared by	Richa Rohilla		
Reviewed by	Alex Luijkx		
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Table of contents

1 Device identification and general information 4
1.1 Device trade name 4
1.2 Manufacturer's name and address 4
1.3 Manufacturer's SRN 4
1.4 Basic UDI-DI 4
1.5 Medical Device Nomenclature description / text 4
1.6 Class of device 4
1.7 Year when the first certificate (CE) was issued covering the device 5
1.8 Notified body name and single identification number 5
2 Intended use of the device 5
2.1 Intended purpose 5
2.2 Indication(s) and target population(s) 5
2.3 Contraindications and/or limitations 5
3 Device description 5
3.1 Description of the device 5
3.1.1 Principles of operation 8
3.1.2 Key functional elements 8
3.1.3 Materials in direct contact 9
3.1.4 Special design attributes 9
3.2 Previous generation(s) or variants 9
3.3 Accessories intended to be used in combination with the device. 10
3.4 Other devices or products intended to be used in combination with the device 10
4 Risks and warnings 10
4.1 Residual risks and undesirable effects 10
4.2 Warnings and precautions 12
4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) 13
5 Summary of clinical evaluation 13
5.1 Summary of clinical data related to the equivalent device 13
5.2 Summary of clinical data from conducted investigations of the device before the CE-marking 13
5.3 Summary of PMS clinical data 13
5.3.1 PMCF procedure data 13
5.3.2 Blue Medical Devices B.V. Complaints database 15
5.3.3 Summary conclusion 17
5.4 An overall summary of the clinical performance and safety 17
5.5 Overall conclusion of the Benefit/Risk Acceptability Assessment 18
5.6 Summary of evaluation of undesirable side effects 18
5.7 Ongoing or planned post-market clinical follow-up 18
6 Possible diagnostic or therapeutic alternatives 19
7 Suggested profile and training for users 20
8 Reference to any harmonized standards and CS applied 20
9 Revision history 20

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 devices:
Device trade names : Force NC
Across NC (spin off: same catheter with different trade name)

1.2 Manufacturer's name and address

The manufacturer of Non-compliant (NC) Force NC and Across NC 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 Force NC PTCA catheter and Across NC PTCA catheter are

	Summit
Basic UDI-DI	872063420BMD-PTCAJ9 Force NC XFORxxxx01, Across NC ACROxxxx01

1.5 Medical Device Nomenclature description / text

The Force NC PTCA catheter and Across NC PTCA catheter medical devices 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 dilation 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. Force NC/Across NC 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.

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 Force NC PTCA balloon dilatation catheter in 2008.

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

In the below sections, Force NC PTCA balloon dilatation catheter signifies both the Force NC and Across NC PTCA balloon dilatation catheters as these are the same catheters but with only different trade names.

2.1 Intended purpose

Force NC PTCA (As per IFU)
The Force NC/ balloon dilatation catheter 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 Force NC PTCA balloon dilatation catheter is intended for transient use (≤60 minutes).

Across NC PTCA (As per IFU)
The PTCA balloon dilatation catheter 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 PTCA balloon dilatation catheter is intended for transient use (≤60 minutes).

2.2 Indication(s) and target population(s)

The NC PTCA balloon catheter (Force NC/Across NC) 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 Force NC 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. non-compliant (NC) PTCA balloon dilatation catheter, Force NC, is a rapid exchange (Rx) catheter with a non-compliant (NC) 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 Force NC/Across NC PTCA balloon dilatation catheters with Basic UDI-DI identified in Section 1.4 and presented in Table 1 (Force NC) and Table 2 (Across NC) below, with model (product family) name and UDI-DI number.

Device trade names : Force NC and Across NC

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

Product family	Balloon diameter (mm)	Balloon length (mm)	Rev #	Basic UDI-DI	UDI-DI
FORCE NC	2.0	05	01	872063420BMD-PTCAJ9	XFOR200501
FORCE NC	2.0	10	01	872063420BMD-PTCAJ9	XFOR201001
FORCE NC	2.0	15	01	872063420BMD-PTCAJ9	XFOR201501
FORCE NC	2.0	20	01	872063420BMD-PTCAJ9	XFOR202001
FORCE NC	2.25	05	01	872063420BMD-PTCAJ9	XFOR220501
FORCE NC	2.25	10	01	872063420BMD-PTCAJ9	XFOR221001
FORCE NC	2.25	15	01	872063420BMD-PTCAJ9	XFOR221501
FORCE NC	2.25	20	01	872063420BMD-PTCAJ9	XFOR222001
FORCE NC	2.5	05	01	872063420BMD-PTCAJ9	XFOR250501
FORCE NC	2.5	10	01	872063420BMD-PTCAJ9	XFOR251001
FORCE NC	2.5	15	01	872063420BMD-PTCAJ9	XFOR251501
FORCE NC	2.5	20	01	872063420BMD-PTCAJ9	XFOR252001
FORCE NC	2.75	05	01	872063420BMD-PTCAJ9	XFOR270501
FORCE NC	2.75	10	01	872063420BMD-PTCAJ9	XFOR271001
FORCE NC	2.75	15	01	872063420BMD-PTCAJ9	XFOR271501
FORCE NC	2.75	20	01	872063420BMD-PTCAJ9	XFOR272001
FORCE NC	3.0	05	01	872063420BMD-PTCAJ9	XFOR300501
FORCE NC	3.0	10	01	872063420BMD-PTCAJ9	XFOR301001
FORCE NC	3.0	15	01	872063420BMD-PTCAJ9	XFOR301501
FORCE NC	3.0	20	01	872063420BMD-PTCAJ9	XFOR302001
FORCE NC	3.25	05	01	872063420BMD-PTCAJ9	XFOR320501
FORCE NC	3.25	10	01	872063420BMD-PTCAJ9	XFOR321001
FORCE NC	3.25	15	01	872063420BMD-PTCAJ9	XFOR321501
FORCE NC	3.25	20	01	872063420BMD-PTCAJ9	XFOR322001
FORCE NC	3.5	05	01	872063420BMD-PTCAJ9	XFOR350501
FORCE NC	3.5	10	01	872063420BMD-PTCAJ9	XFOR351001
FORCE NC	3.5	15	01	872063420BMD-PTCAJ9	XFOR351501
FORCE NC	3.5	20	01	872063420BMD-PTCAJ9	XFOR352001
FORCE NC	3.75	05	01	872063420BMD-PTCAJ9	XFOR370501
FORCE NC	3.75	10	01	872063420BMD-PTCAJ9	XFOR371001
FORCE NC	3.75	15	01	872063420BMD-PTCAJ9	XFOR371501

Product family	Balloon diameter (mm)	Balloon length (mm)	Rev #	Basic UDI-DI	UDI-DI
FORCE NC	3.75	30	01	872063420BMD-PTCAJ9	XFOR373001
FORCE NC	4.0	05	01	872063420BMD-PTCAJ9	XFOR400501
FORCE NC	4.0	10	01	872063420BMD-PTCAJ9	XFOR401001
FORCE NC	4.0	15	01	872063420BMD-PTCAJ9	XFOR401501
FORCE NC	4.0	20	01	872063420BMD-PTCAJ9	XFOR402001
FORCE NC	4.5	05	01	872063420BMD-PTCAJ9	XFOR450501
FORCE NC	4.5	10	01	872063420BMD-PTCAJ9	XFOR451001
FORCE NC	4.5	15	01	872063420BMD-PTCAJ9	XFOR451501
FORCE NC	4.5	20	01	872063420BMD-PTCAJ9	XFOR452001

Table 2: Basic UDI-DI and UDI-DI for all variants (sizes) of the Across NC

Product family	Balloon diameter (mm)	Balloon length (mm)	Rev #	Basic UDI-DI	UDI-DI
ACROSS NC	2.0	05	01	872063420BMD-PTCAJ9	ACRO200501
ACROSS NC	2.0	10	01	872063420BMD-PTCAJ9	ACRO201001
ACROSS NC	2.0	15	01	872063420BMD-PTCAJ9	ACRO201501
ACROSS NC	2.0	20	01	872063420BMD-PTCAJ9	ACRO202001
ACROSS NC	2.25	05	01	872063420BMD-PTCAJ9	ACRO220501
ACROSS NC	2.25	10	01	872063420BMD-PTCAJ9	ACRO221001
ACROSS NC	2.25	15	01	872063420BMD-PTCAJ9	ACRO221501
ACROSS NC	2.25	20	01	872063420BMD-PTCAJ9	ACRO222001
ACROSS NC	2.5	05	01	872063420BMD-PTCAJ9	ACRO250501
ACROSS NC	2.5	10	01	872063420BMD-PTCAJ9	ACRO251001
ACROSS NC	2.5	15	01	872063420BMD-PTCAJ9	ACRO251501
ACROSS NC	2.5	20	01	872063420BMD-PTCAJ9	ACRO252001
ACROSS NC	2.75	05	01	872063420BMD-PTCAJ9	ACRO270501
ACROSS NC	2.75	10	01	872063420BMD-PTCAJ9	ACRO271001
ACROSS NC	2.75	15	01	872063420BMD-PTCAJ9	ACRO271501
ACROSS NC	2.75	20	01	872063420BMD-PTCAJ9	ACRO272001
ACROSS NC	3.0	05	01	872063420BMD-PTCAJ9	ACRO300501
ACROSS NC	3.0	10	01	872063420BMD-PTCAJ9	ACRO301001
ACROSS NC	3.0	15	01	872063420BMD-PTCAJ9	ACRO301501
ACROSS NC	3.0	20	01	872063420BMD-PTCAJ9	ACRO302001
ACROSS NC	3.25	05	01	872063420BMD-PTCAJ9	ACRO320501
ACROSS NC	3.25	10	01	872063420BMD-PTCAJ9	ACRO321001
ACROSS NC	3.25	15	01	872063420BMD-PTCAJ9	ACRO321501
ACROSS NC	3.25	20	01	872063420BMD-PTCAJ9	ACRO322001
ACROSS NC	3.5	05	01	872063420BMD-PTCAJ9	ACRO350501
ACROSS NC	3.5	10	01	872063420BMD-PTCAJ9	ACRO351001

Product family	Balloon diameter (mm)	Balloon length (mm)	Rev #	Basic UDI-DI	UDI-DI
ACROSS NC	3.5	15	01	872063420BMD-PTCAJ9	ACRO351501
ACROSS NC	3.5	20	01	872063420BMD-PTCAJ9	ACRO352001
ACROSS NC	3.75	05	01	872063420BMD-PTCAJ9	ACRO370501
ACROSS NC	3.75	10	01	872063420BMD-PTCAJ9	ACRO371001
ACROSS NC	3.75	15	01	872063420BMD-PTCAJ9	ACRO371501
ACROSS NC	3.75	30	01	872063420BMD-PTCAJ9	ACRO373001
ACROSS NC	4.0	05	01	872063420BMD-PTCAJ9	ACRO400501
ACROSS NC	4.0	10	01	872063420BMD-PTCAJ9	ACRO401001
ACROSS NC	4.0	15	01	872063420BMD-PTCAJ9	ACRO401501
ACROSS NC	4.0	20	01	872063420BMD-PTCAJ9	ACRO402001
ACROSS NC	4.5	05	01	872063420BMD-PTCAJ9	ACRO450501
ACROSS NC	4.5	10	01	872063420BMD-PTCAJ9	ACRO451001
ACROSS NC	4.5	15	01	872063420BMD-PTCAJ9	ACRO451501
ACROSS NC	4.5	20	01	872063420BMD-PTCAJ9	ACRO452001

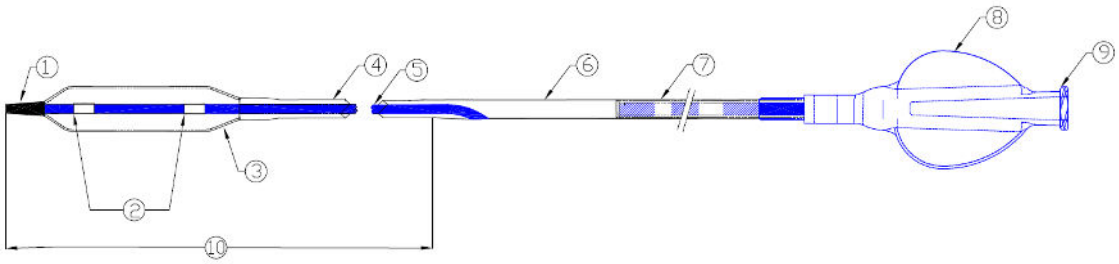
3.1.1 Principles of operation

The Force NC/Across NC 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 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 Force NC PTCA balloon dilatation catheter with indicated key functional elements is shown *Figure 1*.

Figure 1: *Schematic representation of the rapid exchange Force NC 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 Force NC 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 Force NC PTCA balloon dilatation catheter does not incorporate viable materials of animal origin.

3.1.4.3 Components of human origin

Blue Medical Devices B.V. states that Force NC 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 Force NC 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 Force NC PTCA balloon dilatation catheter does not contain substances that are carcinogenic, mutagenic or toxic to reproduction.

3.2 Previous generation(s) or variants

The Force NC PTCA balloon dilatation catheter is a Blue Medical Devices B.V. 4th Generation PTCA balloon dilatation catheter and is the first Blue Medical Devices PTCA balloon dilatation catheter with a non-compliant (NC) balloon. The Force NC PTCA balloon dilatation catheter is based on the Blue Medical Devices 4th Generation semi-compliant PTCA balloon dilatation catheter, Everest.
The Force NC and Everest PTCA balloon dilatation catheters have the same Basic UDI-DI: 872063420BMD-PTCAJ9. The UDI-DI for Force NC is XFORxxxx01 and that of the Everest is EVERxxxx01.
The main difference between the Force NC PTCA balloon dilatation catheter and the Everest PTCA balloon dilatation catheter is balloon compliance. The non-compliant balloon of the Force NC PTCA catheter withstands higher nominal (NP) and rated burst pressures (RBP) than the semi-compliant balloon of the Everest PTCA catheter. Both types of balloons are polyamide composite material.
The range of balloon diameters and lengths differs between the Force NC and Everest PTCA balloon dilatation catheters. Besides the differences given in *Table 3*, all other technical specifications (dimensional and materials) are the same. Both Force NC and Everest PTCA balloon dilatation catheters have the same rapid exchange design, with the same key functional elements (Figure 1).

Table 3: Differences between the Everest and Force NC PTCA balloon dilatation catheters.

Characteristic	EVEREST (semi-compliant)	FORCE NC (non-compliant)
Nominal P (NP)	6 bar	12 bar
Rated Burst Pressure (RBP)	Ø 1.5 - 3.5 mm =16 bar Ø 4.0 mm =14 bar	Ø 2.50 - 3.00 mm =21 bar Ø 3.25 - 4.50 mm =19 bar
Balloon material	Semi-compliant polyamide	Non-compliant polyamide
Balloon sizes Ø (mm)	1.50, 2.00, 2,50, 3.00, 3.50, 4.00	2.00, 2.50, 2.75, 3.00, 3.25, 3,50,4.00, 4,50
Balloon lengths (mm)	10, 15, 20, 30	5, 10, 15, 20
Sterilization method	Gamma	EtO

A semi-compliant balloon is a flexible balloon. A non-compliant (NC) balloon is a balloon which is stiffer than a standard semi-compliant balloon and can be used for post-dilatation in tough, calcified lesions and for stent post-dilatation ensuring optimal stent expansion and apposition. The Force NC PTCA balloon dilatation catheter tolerates higher inflation pressures with a constant relationship between changes in applied pressure and the changes in observed volume. This is different to the semi-compliant Everest PTCA balloon dilatation catheter which increases in diameter with increasing inflation pressure as so all semi-compliant balloons. Non-compliance allows use of greater force without the risk of overstretching other parts of the treated segment particularly the distal segment. An non-compliant balloon can reach and maintain the required diameter despite very high pressure inflation. The diameter is predictable and constant over its entire length. This is particularly relevant in long or calcified lesions.

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

Blue Medical Devices B.V. states that Force NC PTCA 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 Force NC PTCA 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 Force NC PTCA 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 4, which are covered in “warnings and precautions” as listed in section 4.2.

Table 4: 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 Force
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.	0.001%
Occlusion of coronary artery/bypass graft	Instruction warning and labelling on single use device .	
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 NC 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.
- 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.
- Do not use if packaging is damaged or unintentionally opened prior to use.
- 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

- 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 Force NC PTCA balloon dilatation balloon catheter 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 Force NC PTCA balloon dilatation catheter prior to CE-certification (MDD 93/92/EEC) in 2008.

5.3 Summary of PMS clinical data

5.3.1 PMCF procedure data

Besides regular Post Market Surveillance (PMS), 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 Force NC PTCA catheter data:

The clinical application of 211 Force NC PTCA balloon dilatation catheter was evaluated (pivotal data). Physicians rated catheter characteristics relevant to the performance and safety of the Force NC PTCA balloon dilatation catheter, and indicated if any safety issues had occurred. A summary of the PMCF data is given in Table 5.

Table 5: Summary of pivotal PMCF data 2008 - 2023

Year	Evaluators	Summary
2008	Physicians N=21; Hospitals, N=6 (the Netherlands)	N=78 catheters were used in 60 procedures. All performance characteristics scored were mostly judged to be “Good”. In only 4 cases it was difficult to position the balloon. Overall it can be concluded that the Force NC PTCA balloon shows good performance. There were no safety issues. No (adverse) events were recorded, no new risks and no side-effects were identified.
2012	Physicians N=5; Hospitals, N=2 (the Netherlands)	N=24 catheters were used in 20 procedures. All performance were mostly judged to be “Good” or “Average”. No poor ratings were given. Overall it can be concluded that the Force Non-Compliant PTCA balloon shows good performance. There were no safety issues. No (adverse) events were recorded. No new risks and no side-effects were identified.
2019	Physicians (end-users), N=4 -<8;	N=14 catheters. Of the 14 procedures, 13 were successful. The ability to position the FORCE NC balloon at the target lesion was rated as easy in 11 cases and moderate in n=1. There was one failure as the physician was unable to cross/position the catheter tip in a stent. The majority of characteristics received “good” ratings, rewrap scored the lowest, receiving an average rating in 54% of cases. There were no poor ratings.

	Hospitals, N=5 (Taiwan, Mexico)	No adverse events were reported and no new risks were identified.
2019	Physicians N= ≥28; Hospitals, N≥15 (Iran, Pakistan, Egypt, China & Korea)	N=68 forms: 69% of the Force NC were used for Post-dilatation of stents. 57.7% of lesions were types B2 or C (33.4%). Most performance characteristics were judged to be "Good" and "Acceptable", with a low percentage of "Poor" ratings mainly pertaining to aspects of balloon profile and rewrap. The study outcomes indicate the Force Non-Compliant PTCA balloon to be safe, with overall acceptable to good performance. There were no (adverse) events/complications recorded and no new risks were identified.
2020 / 2021	Physicians (n=17); N=10 hospitals (Iran, Vietnam, Korea, Taiwan, Latvia)	N=17 catheters were evaluated during a procedure with the Force NC by 10 physicians in 10 hospitals. The ratings for the performance characteristics were excellent – average; there were no poor ratings given. Overall performance was excellent n=4, good n=8, and average n=5. There were no safety issues reported, and no new risks and no side-effects identified.
2022	Physicians (n=7); N=5 hospitals (Switzerland, Italy, Spain, Slovakia)	N=10 catheters were evaluated following a procedure by 7 physicians in 5 hospitals. The physicians compared the Force NC with brand name "Across NC" (spin-off) performance characteristics with competitor catheters (Maverick NC, Emerge NC, Euphora NC). The target lesions were in the RCA/RV (n=5), LAD (n=2), LCX (n=2) and Dx (n=1). Calcification was severe in n=5, moderate in n=2. The lesion length was mean 41.9mm (range, 15-80mm) and stenosis length was mean 19.6mm (range, 10-30mm). The percentage stenosis of the lesions were <90%, n=3; 90-99%, n=4; and 100% (CTO), n=1. Individual and performance ratings showed the Across NC to be similar or better/much better when compared to competitor catheters. Technical success was achieved in all cases. There were no safety issues and no new risks and no side-effects identified.
2023	Physicians (n=5); N=4 hospitals (France and Pakistan)	N=09 catheters procedure Clinical Feedbacks analysis provides comprehensive details of Force NC PTCA balloon feedbacks from France and Pakistan, covering feedback from March to December 2023. The hospitals involved include Schweitzer, Cl. Pasteur Essey LES Nancy, and HAS in France, as well as NICVD in Pakistan. The lesions treated vary in type, with classifications including A (n=1), B1 (n=3), B2 (n=3), and C (n=2). Vessel tortuosity ranges from none (n=3) to moderate (n=5) and severe (n=1). Calcification was present in n=5 cases, while n=3 cases involve non-calcified lesions. All cases used Force NC balloons, with diameters ranging from 1.00 mm (n=1) to 3.50 mm (n=4). Balloon lengths used are between 10 mm and 15 mm, with a median inflation pressure of 17 bar and maximum pressures from 8 to 24 bars. The number of inflations per balloon ranges from 1 to 7.The particular balloon size of 3.00mm diameter was inflated 7 times and used for multiple lesions (mid, proximal and distal LAD). specifically in the LAD. Notably, no cases required a second balloon. Technical success was achieved in all cases. There were no safety issues and no new risks and no side-effects identified.

Supplementary to the pivotal Force NC PTCA balloon dilatation catheter data:

Data is presented concerning the Blue Medical Devices B.V. Protégé NC DEB PTCA (Basic UDI-DI 872063420BMD-DEB6S, UDI-DI PNCxxxx01), which is the Blue Medical Devices Force NC PTCA balloon dilatation catheter with a drug coating (3µg/mm^2 Paclitaxel) on the balloon. The Force NC and Protégé NC 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 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 data of patients of 206 patients treated with n=225 Protégé NC DEB balloons in the PEARL registry (2014-2019) and performed in 4 hospitals in the Netherlands, indicates lesions with a high complexity (81% Type B2/C). 51% of the 230 lesions were not predilated prior to Protégé NC DEB dilatation. In 99.5% of all lesions, balloon crossing was achieved. The Protégé NC DEB dilatation success rate was high (95%), with only n=2 of non-predilated lesions showing a residual stenosis >30%. Overall, of the 230 treated lesions with/ without predilatation, there were only 12 with residual stenosis >30%. Multiple inflations (2-3) were performed with more than half of the NC balloons, with successful retraction out of the lesion/stent and into the guiding catheter. Balloon inflation and deflation, even in those cases inflated above RBP, was without device-related anomalies (such as balloon burst) and no patient complications. All balloons were successfully retracted from the vessel and into the guiding catheter. These data indicate good Protégé NC DEB catheter procedure performance; a balloon catheter with the same procedure performance characteristics as the Force NC 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. The overall procedural complication rate was low (3.3%), with 3 of the 7 complications at the access site, and one a pre-PCI procedure VF which was alleviated by procedure defibrillation. The procedures were successfully completed. All recorded complications are known events that can occur when undertaking a PCI procedure and are applicable for all PTCA balloon catheters.

5.3.2 Blue Medical Devices B.V. Complaints database

Total n=85 customer complaints were received by Blue Medical Devices from 2013-2023 involving the Force NC PTCA catheter and/or packaging. Sales data was available from 2013-2023. For this period, based on the total units sold the overall complaint occurrence rate is 0.034%. Of the total 85 complaints,

N=12 reports in the pre-procedure (unpacking the device), n=4 Other product problems, n=4 Unknown, n=9 Crossability problems, n=13 Deflation problems, n=2 User not following IFU, n=11 tip defect, n=5 Damaged balloon, n=12 Catheter break, n=4 Guidewire problems, n=4 inflation problem, n=3 Hub printing missing/not clear, n=1 Kink/ bending in catheter etc. and none in the category patient injury. There was n=2 deaths reported related to a possible deflation problem and n=2 reported related to patient discomfort.

The reported complaints and events over the life-time of the Force NC PTCA balloon dilatation catheters show no new risks or hazards.

Device-related identified procedure failures (Hazards)		
Literature	**Force NC PTCA balloon dilatation catheter: Complaints Database Manufacturer + PMCF**	
Failures for competitor PTCA balloon dilatation devices reported in FDA Maude database	**Reported Failure**	**Number (n) & Occurrence [n/total units sold]**
Balloon Rupture	Balloon burst	Force NC PTCA: n=5 (5.882%)
Material Split/cut or torn	Damaged balloon	
Difficult to cross	Crossability problems	Force NC PTCA: n=9 (10.588%)
Material Rupture (Shaft/balloon)		
Detachment of Device or device Component		
Deflation Problem	Deflation problem	Force NC PTCA: n=13 (15.294%)
Guidewire problems/Guiding problems	Patient discomfort	Force NC PTCA: n=4 (4.706%)
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)	Force NC PTCA; n=5 (5.882%)
Device Damaged by Another Device		
Incorrect compliance chart		
Fracture Shaft		
Fracture Luer		
Improper or Incorrect procedure (not following IFU/labelling)	User not following IFU	Force NC PTCA: n=2 (2.353%)
Pre-procedure fracture (catheter damage)	Unpacking product difficulties/ pre-procedure catheter damage/break, tip damage, kink-bending	Force NC PTCA: n=39 (45.882%)
Other product problems/Unknown		Force NC PTCA: n=8 (9.412%)

Failure code	2013	2014	2015	2016	2017	2018	2019	2020	2022	2023	Total	Occurrence rate (Complaints / Units)
Catheter break			5	2	1	3		1			12	0.0000576
Crossability problems				3	1	1	4				9	0.0000432
Damaged balloon	3		1		1						5	0.0000240
Deflation problems				4	4	2	1	2			13	0.0000624
Guidewire problems					1						1	0.00000480
Guiding problems	2					1					3	0.0000144
No inflation				2			3				5	0.000024
Other product problems	1				1	2					4	0.0000192
Unpacking product difficult						5	7				12	0.0000576
Hub printing missing/not clear		2	1								3	0.0000144
Kink/ bending in catheter	1										1	0.0000480
Tip defect	1		10								11	0.0000528
Unknown	3				1						4	0.0000192
User not following IFU									1	1	2	0.000004
Total # of complaints	**11**	**2**	**17**	**11**	**10**	**14**	**15**	**3**	**1**	**1**	**85**	

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There were no Field Safety Corrective Actions (FSCA) during the life-time of the device as a result of complaints with clinical risks. All identified hazards and possible complications (risks) have been taken into account in the Risk Management Process of the Force NC PTCA balloon dilatation catheter.

5.3.3 Summary conclusion

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

The claimed clinical benefits are supported by the documented data:

- For patients suffering from stenotic lesions in the coronary artery system that require PCI, PTCA balloon catheter characteristics shows clinical benefits in that following successful guidewire crossing of the target lesion, procedure technical success of ≥95% was achieved for the Force NC 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 success (technical) of Force NC PTCA catheter is >99.7% (acceptance criteria ≥95%), i.e. technically successful PTCA catheter procedure. This encompasses device 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 objectives are supported by the documented data:

- The safety criteria (completion of procedure without PTCA balloon catheter-related procedure serious adverse events (<1%)) was met. The PMCF pivotal data indicates that there were no device-related serious adverse events during balloon angioplasty procedure (0%); the Blue Medical Devices complaint database recorded two deaths reported to be related to the Force NC since the device has been on the market (0.001%).

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 Force NC PTCA catheters clinical data, the risks associated with the Blue Medical Devices PTCA catheters Force NC are 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 Force NC PTCA balloon dilatation 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, and compatibility with commercially available 0.014” guidewires.

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 Force NC 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.
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 Force NC 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 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 procedure 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
    - 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 11607-1:2019/A1:2023 - Packaging for terminally sterilized medical devices. Part-1 Requirements for materials, sterile barrier systems and packages systems
- ISO 11607-2:2019/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

9 Revision history

SSCP Revision number	Date issued	Change description	Revision validated by the notified body	
01	17-03-2022	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
			☐	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)