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SailFish™ NC

Non-compliant Balloon Dilatation Catheter

INSTRUCTIONS FOR USE

CE 2797

JW Medical Systems Ltd.
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1. WARNINGS

- Before use, please confirm that the packaging is undamaged and unopened, and check the "expiration date" on the label. Do not use products that have exceeded their expiration date. Once the sterile bag is opened, the sterility and stability of the device cannot be guaranteed, so the device must be used immediately. Products that have exceeded their expiration date or, although within the expiration date, can no longer be used should be returned to JW MEDICAL SYSTEMS LTD. for handling.
- This product has been sterilized before leaving the factory and is intended for single use only. Do not re-sterilize or reuse it.
- Percutaneous Transluminal Coronary Angioplasty (PTCA) procedures should only be performed in hospitals that meet the following conditions: the facility must be capable of promptly performing emergency coronary artery bypass grafting (CABG) in the event of life-threatening or other serious complications.
- PTCA should be carefully considered before being performed on patients who cannot undergo coronary artery bypass grafting, including whether hemodynamic support should be provided during the procedure, as PTCA carries special risks for such patients.
- Use only the recommended balloon inflation medium. Do not use air or other gaseous media to inflate the balloon. If the patient has a severe adverse reaction to contrast agents that prevents their normal preoperative use, extreme caution should be exercised in deciding whether to perform the procedure on such patients.
- Inflation pressure must not exceed the rated burst pressure specified on the product label, as this may cause balloon rupture, leading to intimal damage or vascular dissection.
- The inflated balloon diameter should approximate the diameter of the vessel proximal and distal to the stenotic segment to minimize the risk of vascular damage.
- As long as the catheter is in contact with the vascular system, all manipulations should be performed under high-quality fluoroscopic visualization. Do not advance or retract the catheter unless the balloon has been fully deflated under vacuum and no resistance is felt. If resistance is encountered, identify and resolve the source of resistance before proceeding. Forcing the catheter forward or backward against resistance may cause vascular injury as well as catheter damage or separation.
- Do not apply excessive bending or twisting force to any part of the catheter, as this may cause shaft kinking, damage, or separation. If the shaft is already bent or twisted, do not use the catheter or attempt to straighten it, as this may cause the shaft to fracture. In such cases, use a new catheter instead. If significant resistance is present, do not force movement of the balloon catheter.
- If catheter damage or separation occurs, assess the patient's condition and remove the catheter appropriately before repair.

2. PRODUCT DESCRIPTION

1.Product Name: SailFish™ NC Non-compliant Balloon Dilatation Catheter

2.Product Model and Specification Naming Rules

The product model and specification consist of the product type, balloon nominal diameter, and balloon length.

NCB II-XXXYY
NCB II= Product Type (SailFish™ NC Non-compliant Balloon Dilatation Catheter)
XXX = Balloon Nominal Diameter
YY = Balloon Length

3.Product Models, Specifications, and Description

Table 1: Product Models and Specifications

Balloon Nominal Diameter (mm)	Balloon length (mm)					
	8	10	12	15	20	25
2.00	NCB II-20008	NCB II-20010	NCB II-20012	NCB II-20015	NCB II-20020	NCB II-20025
2.25	NCB II-22508	NCB II-22510	NCB II-22512	NCB II-22515	NCB II-22520	NCB II-22525
2.50	NCB II-25008	NCB II-25010	NCB II-25012	NCB II-25015	NCB II-25020	NCB II-25025
2.75	NCB II-27508	NCB II-27510	NCB II-27512	NCB II-27515	NCB II-27520	NCB II-27525
3.00	NCB II-30008	NCB II-30010	NCB II-30012	NCB II-30015	NCB II-30020	NCB II-30025
3.25	NCB II-32508	NCB II-32510	NCB II-32512	NCB II-32515	NCB II-32520	NCB II-32525
3.50	NCB II-35008	NCB II-35010	NCB II-35012	NCB II-35015	NCB II-35020	NCB II-35025
3.75	NCB II-37508	NCB II-37510	NCB II-37512	NCB II-37515	NCB II-37520	NCB II-37525
4.00	NCB II-40008	NCB II-40010	NCB II-40012	NCB II-40015	NCB II-40020	NCB II-40025
4.50	NCB II-45008	NCB II-45010	NCB II-45012	-	-	-

Table 2: Product Description

Balloon Nominal Diameters (mm)	2.00; 2.25; 2.50; 2.75; 3.00; 3.25;3.50; 3.75; 4.00	4.50
Balloon Length (mm)	8; 10; 12; 15; 20; 25	8; 10; 12
Catheter Working Length (cm)	140	
Balloon Material	Nylon 12	
Balloon Compliance	Non-compliant	
Guiding Catheter Compatibility	5F	
Guidewire Inner Lumen Compatibility	0.014" PTCA guidewire	
Balloon Inflation:		
Nominal Pressure:	14 atm / 1419 kPa	14 atm / 1419 kPa
Rated Burst Pressure:	20 atm / 2027 kPa	18 atm / 1824 kPa

Table 3: Balloon Compliance Table (mm)

Pressure (atm/kPa)	14 /1419	15 /1520	16 /1621	17 /1723	18 /1824	19 /1925	20 /2027
Balloon Nominal Diameter (mm)	Balloon Diameter (mm, Tolerance±10%)						
2.00	2.00	2.02	2.03	2.05	2.07	2.08	2.10
2.25	2.25	2.27	2.28	2.30	2.32	2.33	2.35
2.50	2.50	2.52	2.53	2.55	2.57	2.58	2.60
2.75	2.75	2.77	2.78	2.80	2.82	2.83	2.85
3.00	3.00	3.02	3.03	3.05	3.07	3.08	3.10
3.25	3.25	3.28	3.30	3.33	3.35	3.38	3.40
3.50	3.50	3.53	3.55	3.58	3.60	3.63	3.65
3.75	3.75	3.78	3.80	3.83	3.85	3.88	3.90
4.00	4.00	4.03	4.05	4.08	4.10	4.13	4.15
4.50	4.50	4.54	4.58	4.61	4.65	-	-

3. PRODUCT PERFORMANCE, STRUCTURE AND INDICATIONS

1.Product Performance

The SailFish™ NC Non-compliant Balloon Dilatation Catheter is a rapid-exchange (RX) non-compliant (NC) balloon catheter intended for use in Percutaneous Transluminal Coronary Angioplasty (PTCA).

2.Product Structure

The SailFish™ NC Non-compliant Balloon Dilatation Catheter is a rapid-exchange non-compliant balloon catheter. Its structural diagram is shown below.

Figure 1 Schematic Diagram of SailFish™ NC Non-compliant Balloon Dilatation Catheter (Not drawn to scale)

1 - Tip	3 - Marker	5 - Distal Shaft	7 - Hypotube	9 - Bonding Point
2 - Balloon	4 - Inner Lumen	6 - Middle Shaft	8 - Strain Relief	10 - Hub

The Sailfish™ NC Non-compliant Balloon Dilatation Catheter consists of an integrated shaft system and a distal balloon. The shaft has two lumens, one for balloon inflation and deflation, and the other for advancing the catheter over a guidewire.

3.Indications

The indications for the SailFish™ NC Non-compliant Balloon Dilatation Catheter are as follows:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis to improve myocardial perfusion.
- Post-delivery expansion of balloon-expandable coronary stents.

4. INTENDED PURPOSE

The SailFish™ NC Non-compliant Balloon Dilatation Catheter is intended to be used on patients eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA) to treat Coronary Arterial Disease (CAD).

5. CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Patients suffering from coronary artery spasms, in the absence of a significant stenosis.
- Use outside the indications (use for purposes other than the approved indications).

6. INTENDED USERS

The SailFish™ NC Non-compliant Balloon Dilatation Catheter is a professional use medical device that is intended to be used by professionals who have received appropriate training and education in Percutaneous Coronary Intervention (PCI) procedures. SailFish™ NC Non-compliant Balloon Dilatation Catheter should only be used by interventional cardiologist. Standard PTCA techniques for procedures should be employed. There is no specific procedural or training requirements for this product to be provided by JW Medical to the healthcare professionals

7. PATIENT POPULATION

The SailFish™ NC Non-compliant Balloon Dilatation Catheter is intended to be used in patients eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA) procedures.

8. INTENDED CLINICAL BENEFIT

The clinical benefits are expected to be the same as for the other PTCA balloon catheters.

- Lesion preparation with a PTCA Balloon Catheter prior to stenting facilitates stent delivery, for the purpose to reduce plaque shift and allows optimal stent expansion.
- Post-delivery expansion of balloon expandable coronary stents.ng

9. Instructions for Use and Precautions

1.Inspection Prior to Use:

Prior to use, inspect the sterile package integrity, do not use if it is damaged. Carefully examine the balloon catheter prior to use and particularly look at the balloon catheter to detect any bends, kinks, or other damage. Verify all equipment as well to be used during the procedure. Do not use any damaged equipment, a product from a damaged package or breached sterile pouch, or an expired product. Verify that the balloon catheter size is suitable for the specific procedure for which it is intended.

2.Materials required

One or more of each of the following material are required for PTCA but not supplied with the SailFish™ NC Non-compliant Balloon Dilatation Catheter:

- Arterial sheath and dilator set
- Guiding catheter (femoral or brachial) in the appropriate configuration to selectively cannulate the coronary artery and with minimum inner diameter of 0.056 inch/1.42mm (5F compatible)
- Guidewire, 0.014 inch/0.36 mm maximum diameter x 190 cm minimum length
- Guidewire torque device
- Inflation device with manometer
- Hemostatic valve(s)
- Three-way stopcock
- Luer-lock syringes 10 ml, 20 ml
- Sterile saline or heparinized sterile saline
- Contrast medium diluted 1:1 with normal saline

3.Balloon catheter and inflation device preparation

Prepare each equipment to be used following instructions of its manufacturer.

Complete the following steps to prepare The SailFish™ NC Non-compliant Balloon Dilatation Catheter for use:

1.Remove the balloon catheter from the package.

2.Carefully remove the protective sheath covering the balloon from the distal end of the balloon catheter. The pre-attached stylet is automatically removed.

3. Prepare the inflation device with an appropriate inflation medium (a 1:1 mixture of contrast medium and sterile saline).

4.Prepare the balloon catheter for purging using the following procedure:

a.Fill a 20 ml Luer-lock syringe or the inflation device with the recommended inflation medium (typically 4 ml of a 1:1 mixture of contrast medium and sterile saline). Do not use air or any gaseous medium to inflate the balloon catheter.

b.Attach the syringe or inflation device to the inflation port of the balloon catheter, orient the balloon catheter with the distal tip and the balloon pointing in a downward vertical position.

c.Apply negative pressure. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the balloon catheter.

d.Disconnect the syringe or inflation device from the inflation port of the balloon catheter.

e.Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the balloon catheter.

f.Maintain negative pressure on the balloon until air no longer returns to the device. If air is continuously aspirated (can be revealed by bubbles), verify that the balloon has no leaks by inflating the balloon with the inflation medium. Do not use the balloon catheter if there are any leaks.

g.Slowly release the device pressure to neutral.

h.Disconnect the 20ml luer-lock syringe (if used) and connect the inflation device to the inflation port of the balloon catheter without introducing air into the system.

CAUTION: All air must be completely removed from the balloon and displaced with contrast prior to insertion into the patient's body (repeat steps 4c through 4g, if necessary), as failure to do so may lead to complications.

4.Insertion and use

1.Prepare the vascular access site according to standard practice.

2.Flush and fill the guidewire lumen of the balloon catheter with heparinized normal saline.

3.Prior to using The SailFish™ NC Non-compliant Balloon Dilatation Catheter device, ensure that a guiding catheter is in place and offers support for advancing the balloon catheter into the vessel, and that the guidewire is adequately positioned through the lesion.

4.Insert the guidewire through the hemostatic valve connected to the guiding catheter, following the manufacturer's guidelines or standard practice. Under fluoroscopic guidance, carefully advance the guidewire through the guiding catheter to the desired vessel and across the target stenosis. Attach a torque device to the guidewire, if desired.

5.Ensure The SailFish™ NC Non-compliant Balloon Dilatation Catheter is advanced over the guidewire, with the guidewire positioned beyond the target stenosis and into the distal segment of the coronary artery.

6.Re-advance the guidewire into the distal port/lumen of the balloon catheter and retrieve it from the guiding catheter hub/exit.

7.Thoroughly aspirate and flush the hemostatic valve and the guiding catheter in preparation for introduction of the balloon catheter.

8.Advance the balloon catheter over the guidewire until it reaches the hemostatic valve of the guiding catheter. Loosen the hemostatic valve and insert the balloon catheter while maintaining the guidewire position and ensuring the balloon is completely deflated. Advance the balloon catheter into the guiding catheter, and tighten the hemostatic valve to create a seal around the catheter. It should be noted that the hemostatic valve around the balloon catheter shaft should not be overtightened, as this could cause lumen constriction, which would affect the inflation/deflation of the balloon. The movement of the balloon catheter within the guiding catheter should not be restricted. If unusual resistance is felt, do not advance the catheter within the adaptor.

9.Advance the balloon catheter until the appropriate proximal marker approaches the hub of the guiding catheter. Under fluoroscopy, continue to advance the balloon catheter over the guidewire and into the stenosis.

10.Verify the positioning of the balloon across the lesion prior to inflation, using the radiopaque markers of the balloon for reference and inflate the balloon slowly to the appropriate pressure(Do not to exceed 10 total inflations). Do not exceed the rated balloon burst pressure (refer to compliance card provided with the device and RBP mentioned in Table 1: Device Description).

11.Following expansion of the lesion area and confirmation of the treatment effect by standard angiography, pull the plunger of the inflation device to create a vacuum, while controlling the balloon's deflation process under fluoroscopy.

12.After complete deflation, withdraw the balloon catheter back into the guiding catheter until complete removal.

13.If procedure is completed, remove the guiding catheter from the vessel and follow standard practice for management of the insertion site.

5.Exchange Procedure Technique

The SailFish™ NC Non-compliant Balloon Dilatation Catheter is a rapid exchange balloon catheter. To perform an exchange procedure, refer to following guidance:

1.Loosen the hemostatic valve.

2.Hold the guidewire and hemostatic valve in one hand, while grasping the balloon shaft in the other hand.

3.Maintain guidewire position in the coronary artery by holding the wire stationary and begin pulling the balloon catheter out of the guiding catheter, while monitoring the wire position under fluoroscopy.

4.Withdraw the deflated balloon catheter until the notch in the guidewire lumen is reached (marker indicates notch). Carefully pull the flexible, distal portion of the balloon catheter out of the hemostatic valve, while maintaining the guidewire's position across the lesion.

5.Slide the distal tip of the balloon catheter out of the hemostatic valve and tighten onto the guidewire to hold it securely in place. Completely remove the balloon catheter from the guidewire.

6.Prepare the next balloon catheter to be used, as previously described in section 3 'Balloon catheter and inflation device preparation'.

7.Backload another balloon catheter onto the guidewire, as previously described under section 4, 'Insertion and use', and continue the procedure accordingly.

6.Precautions

- Prior to angioplasty, the balloon catheter should be examined to verify its integrity and ensure that its size is suitable for the specific procedure for which it is to be used. If the device is kinked it should not be used.
- During the procedure, provide as needed appropriate anti-coagulant and coronary vasodilator therapy to the patient. Continue this therapy for an appropriate period of time after the procedure.
- When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.
- Dispose of the device and its packaging in accordance with local regulations.
- Do not expose the balloon catheter to organic solvents, e.g. isopropyl alcohol. Such an exposure can degrade balloon catheter performance.

10. POTENTIAL ADVERSE EVENTS

(Including but not limited to the following)

Adverse events that may be associated with the use of a PTCA balloon catheter in native coronary arteries, include but not limited to:

- abrupt vessel closure or spasm
- acute myocardial infarction
- angina or unstable angina
- aneurysm or pseudoaneurysm , arteriovenous fistula
- arrhythmias, including ventricular fibrillation
- Allergic reaction to anti-coagulation and/or anti-thrombotic therapy, contrast medium, or delivery system materials
- hemorrhage or hematoma (in particular at puncture site)
- cardiac tamponade/pericardial effusion
- cardiogenic shock
- dissection, perforation, rupture, or injury of the treated coronary artery
- coronary thrombosis
- emergency Coronary Artery Bypass Grafting (CABG)
- Death
- embolism
- Hypotension, hypertension
- infection and/or pain at insertion site
- restenosis of dilated vessel
- Renal failure
- stroke, transient ischemic attack (TIA)
- total occlusion of the coronary artery, bypass graft or side branches
- Thrombosis

11. REFERENCE

The physician should consult recent literature on current medical practice of coronary balloon dilatation, such as that published by the American College of Cardiology and the American Heart Association (ACC/AHA) or European Society of Cardiology (ESC).

12. HOW SUPPLIED AND DISPOSAL

This product has been sterilized with ethylene oxide, sterile, non-pyrogenic.

This product does not contain latex.

CONTENTS: One SailFish™ NC Non-compliant Balloon Dilatation Catheter; one Instructions for Use and one certificate of conformity, one compliance card.

DISPOSAL: Disposal of the device and its packaging should be handled in an environmentally sustainable manner according to local regulations. Hazardous waste from contaminated devices and packaging may present a biohazard and must be disposed of in appropriate containers which meet specific technical requirements.

13. SUMMARY REPORT ON SAFETY AND CLINICAL PERFORMANCE

The summary of safety and clinical performance (SSCP) for this product can be found in the European database on medical devices (Eudamed): https://ec.europa.eu/tools/eudamed, by entering the Basic UDI-DI of NCB II (69348914NCB2VS).

14. ADVERSE EVENT REPORTING

Any serious incident in relation to the device should be reported to JW Medical Systems Ltd. and the relevant competent authority as required by local regulations.

15. WARRANTY

JW Medical Systems Ltd. and their respective affiliates warrants that its products are manufactured to the specifications set forth on its packaging, instructions for use and related literature. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.

JW Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

16. SHELF LIFE

This product has a shelf life of 3 years from the date of manufacture when stored under recommended conditions. Do not use the device after the expiration date indicated on the label or packaging.

17. STORAGE CONDITIONS AND STORAGE METHODS

1.This product is sterilized with ethylene oxide (EO). Do not use if the product packaging is open or damaged; the product must be used immediately once the package is opened. This product is a single use product and cannot be re-sterilized or reused.

2.Storage requirements: Store in a cool, dark and dry place. Do not store above 30℃

3.The product should be stored under the above storage requirements. Please use it before the labelled expiration date; do not use product that have expired. If the product has exceeded the shelf life or cannot be used even though it is within its shelf life, please send the product to JW Medical Systems.

18. EXPLANATION OF PRODUCT GRAPHICS, SYMBOLS, AND ABBREVIATIONS

1.Product illustration, the catheter working length is 140 cm. The proximal catheter stainless steel shaft outer diameter is 1.9F, the distal catheter outer diameter is 2.6F.

0.014" GW indicates the guidewire diameter is 0.014 inches.

2.NCBII-XXXYY, is the Model for this product.

3.Symbols

	Manufacturer		Do not re-use
	Date of manufacture		Consult instructions for use
REF	Catalog number	STERILE EO	Sterilized using ethylene oxide
LOT	Batch code		Use-by date
	Caution	EU REP	Authorized representative in the European Community/European Union
MD	Medical Device		Do not use if package is damaged and consult instructions for use
	Single sterile barrier system with protective packaging inside	UDI	Unique Device Identifier
CE 2797	CE marking and Notified Body Code		Do not store above 30°C
	Keep dry		

4.English abbreviation in the compliance table: NP indicates Nominal Pressure which is the pressure used to expand the balloon to the reference outer diameter.

5.P/N indicates the part number. 03.04.019.050

[Date of manufacture]: Refer to label

[Expiration date]: Refer to label

[Shelf life]: 3 years

[Manufacturer]: JW Medical Systems Ltd.

[IFU Document No.]: DP-0304019050

[IFU Revision]: X01

[Basic UDI-DI]: 69348914NCB2VS

[IFU Revision Date]: 2026.01.05

After-sale service: JW Medical Systems LTD.

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