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**SailFish™**

PTCA Balloon Dilatation Catheter

INSTRUCTIONS FOR USE

JW Medical Systems Ltd.  
a company of the Biosensors International Group

## 1. WARNINGS

- Only physicians who have received appropriate training and education should perform Percutaneous Transluminal Coronary Angioplasty (PTCA) procedure.
- PTCA procedure should only be performed in hospitals that allow emergency coronary artery bypass grafting (CABG) to be performed in the event of potential life-threatening or other serious complications.
- PTCA procedure in patients who are not acceptable candidates for coronary artery bypass surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries additional risk.

- This device is intended for single use only.

- Do not resterilize and/or reuse this device, as this may degrade its performance, lead to device failure and procedural complications with severe injury or patient death. Reuse and resterilization bear the risks of cross contamination, patient infection, and patient to patient infection.

- Use this product under pressure monitoring.

- Do not exceed the rated burst pressure as indicated in Table 1. Use of pressures higher than the rated burst pressure may result in a rupture of balloon with possible intimal damage and vascular dissection.

- To reduce the potential for vessel damage, the inflated diameter of the balloon should not exceed the diameter of the vessel just proximal and distal to the stenosis.

- The device should be manipulated under high-quality fluoroscopic observation when the balloon catheter is exposed to the vascular system. Do not advance or retract the balloon catheter unless the balloon is fully deflated under vacuum and no resistance is felt. If resistance is felt, determine and address its cause before proceeding. Continuing to advance or retract the balloon catheter against resistance may result in damage to the vessels, and in damage or separation of the balloon.

- Exercise caution when handling and manipulating this product; manipulation, advancement, or removal may cause damage or detachment of the external coating, leading to clinical adverse events.

- In order to prevent kinking, damage, or separation of the shaft, never apply extreme bending or twisting forces to any section of the balloon catheter.

- The balloon dilatation catheter is not intended for stent deployment.

- The safety and effectiveness of the balloon dilatation catheter have not been established in the following patient populations:

- Pregnancy: No data are available to support use in pregnant women.

- Pediatric use: The safety and efficacy in pediatric patients has not been established.

Carefully consider whether it is appropriate to use the balloon dilatation catheter in the above patient populations.

## 2. DEVICE DESCRIPTION

**1.Product Name :** SailFish™ PTCA Balloon Dilatation Catheter

**2.Catalog numbers Format :**

The product model and specification consist of the series number, balloon outer diameter, and balloon length.

SCB II-XXXX

SCB II= Product Type (SailFish™ PTCA Balloon Dilatation Catheter)

XXX = Balloon Nominal Diameter

YY = Balloon Length

The product is divided into several models and specification based on the balloon dimension.

**3.Product Model :**

Refer to Table 1.

Table 1 : Model for product

S/N	Models	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Nominal Pressure (NP) (atm/kPa)	RBP (atm/kPa)
1	SCB II-10008	1.00	8	8/811	14/1419
2	SCB II-10010	1.00	10	8/811	14/1419
3	SCB II-10015	1.00	15	8/811	14/1419
4	SCB II-10020	1.00	20	8/811	14/1419
5	SCB II-12508	1.25	8	8/811	14/1419
6	SCB II-12510	1.25	10	8/811	14/1419
7	SCB II-12515	1.25	15	8/811	14/1419
8	SCB II-12520	1.25	20	8/811	14/1419
9	SCB II-15008	1.50	8	8/811	14/1419
10	SCB II-15010	1.50	10	8/811	14/1419
11	SCB II-15015	1.50	15	8/811	14/1419
12	SCB II-15020	1.50	20	8/811	14/1419
13	SCB II-20008	2.00	8	8/811	14/1419
14	SCB II-20010	2.00	10	8/811	14/1419
15	SCB II-20015	2.00	15	8/811	14/1419
16	SCB II-20020	2.00	20	8/811	14/1419
17	SCB II-20025	2.00	25	8/811	14/1419
18	SCB II-20030	2.00	30	8/811	14/1419
19	SCB II-20040	2.00	40	8/811	14/1419
20	SCB II-22508	2.25	8	8/811	14/1419
21	SCB II-22510	2.25	10	8/811	14/1419
22	SCB II-22515	2.25	15	8/811	14/1419
23	SCB II-22520	2.25	20	8/811	14/1419
24	SCB II-25008	2.50	8	8/811	14/1419
25	SCB II-25010	2.50	10	8/811	14/1419
26	SCB II-25015	2.50	15	8/811	14/1419
27	SCB II-25020	2.50	20	8/811	14/1419
28	SCB II-25025	2.50	25	8/811	14/1419
29	SCB II-25030	2.50	30	8/811	14/1419
30	SCB II-25040	2.50	40	8/811	14/1419
31	SCB II-27508	2.75	8	8/811	14/1419
32	SCB II-27510	2.75	10	8/811	14/1419
33	SCB II-27515	2.75	15	8/811	14/1419
34	SCB II-27520	2.75	20	8/811	14/1419
35	SCB II-30008	3.00	8	8/811	14/1419
36	SCB II-30010	3.00	10	8/811	14/1419

37	SCB II-30015	3.00	15	8/811	14/1419
38	SCB II-30020	3.00	20	8/811	14/1419
39	SCB II-30025	3.00	25	8/811	14/1419
40	SCB II-30030	3.00	30	8/811	14/1419
41	SCB II-30040	3.00	40	8/811	14/1419
42	SCB II-32508	3.25	8	8/811	14/1419
43	SCB II-32510	3.25	10	8/811	14/1419
44	SCB II-32515	3.25	15	8/811	14/1419
45	SCB II-32520	3.25	20	8/811	14/1419
46	SCB II-35008	3.50	8	8/811	14/1419
47	SCB II-35010	3.50	10	8/811	14/1419
48	SCB II-35015	3.50	15	8/811	14/1419
49	SCB II-35020	3.50	20	8/811	14/1419
50	SCB II-35025	3.50	25	8/811	14/1419
51	SCB II-35030	3.50	30	8/811	14/1419
52	SCB II-35040	3.50	40	8/811	14/1419
53	SCB II-37508	3.75	8	8/811	14/1419
54	SCB II-37510	3.75	10	8/811	14/1419
55	SCB II-37515	3.75	15	8/811	14/1419
56	SCB II-37520	3.75	20	8/811	14/1419
57	SCB II-40008	4.00	8	8/811	14/1419
58	SCB II-40010	4.00	10	8/811	14/1419
59	SCB II-40015	4.00	15	8/811	14/1419
60	SCB II-40020	4.00	20	8/811	14/1419
61	SCB II-40025	4.00	25	8/811	14/1419
62	SCB II-40030	4.00	30	8/811	14/1419
63	SCB II-40040	4.00	40	8/811	14/1419
64	SCB II-45008	4.50	8	8/811	14/1419
65	SCB II-45010	4.50	10	8/811	14/1419
66	SCB II-45015	4.50	15	8/811	14/1419
67	SCB II-45020	4.50	20	8/811	14/1419
68	SCB II-50008	5.00	8	8/811	14/1419
69	SCB II-50010	5.00	10	8/811	14/1419
70	SCB II-50015	5.00	15	8/811	14/1419
71	SCB II-50020	5.00	20	8/811	14/1419

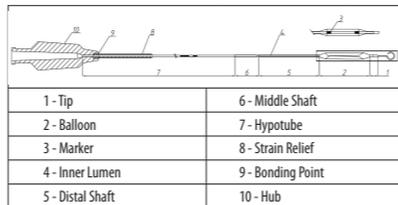
## 3. PERFORMANCE, STRUCTURE AND INTENDED PURPOSE

**1.Performance :**

SailFish™ PTCA Balloon Dilatation Catheter is a rapid exchange balloon catheter intended for use in PTCA on coronary artery lesions.

**2.Structure :**

The SailFish™ PTCA Balloon Dilatation Catheter is a rapid exchange balloon catheter, whose structural diagram is shown in the figure.



The SailFish™ PTCA Balloon Dilatation Catheter is a rapid-exchange, consisting of an integrated shaft and a balloon near the distal end. The shaft contains two lumens: one for balloon inflation and deflation, and the other for advancing the catheter along the guidewire.

There are two markers on the hypotube to determine the position of the dilatation catheter relative to the tip of the guiding catheter in different puncture situations of the femoral artery and brachial artery. The distal inner lumen is equipped with markers (3), which can help identify the accurate position of the balloon under X-ray monitoring.

The Nominal Inflation Pressure of the balloon is 8atm, and the Rated Burst Pressure is 14atm.

**3.Intended purpose**

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

## 4. INDICATIONS

The SailFish™ PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion in patient eligible for a PTCA procedure.

## 5. CONTRAINDICATIONS

- Unprotected left main coronary artery.

- Patients suffering from coronary artery spasm, in the absence of a significant stenosis.

## 6. INTENDED USERS

The SailFish™ PTCA 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. The SailFish™ PTCA 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 Systems to the healthcare professionals.

## 7. PATIENT POPULATION

The SailFish™ PTCA 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.

- Myocardial revascularization by PTCA/PCI is a minimally invasive procedure that improves blood flow to the heart, decreasing heart-related chest pain (angina) and improving exercise capacity. In Acute Coronary Syndromes, PTCA/PCI reduces the risk of death and recurrent Myocardial Infarction.

- Lesion preparation with a PTCA Balloon Catheter prior to stenting facilitates stent delivery, reduces plaque shift and allows optimal stent expansion.

## 9. OPERATOR'S MANUAL

**1.Inspection Prior to Use :**

Prior to use, please check carefully: the expiration date of the product and inspect the sterile package integrity, whether the packaging of the product is damaged;

Refer to Table 2 for accessories that are required for PTCA procedure but not supplied with this product.

Table 2 : List of accessories

Quantity	Item
1	Percutaneous needle
2-3	5F-8F arterial sheath and dilator
2-3	Guiding catheter (5F=1.7mm, 6F=2.0mm, 7F=2.3mm, 8F=2.7mm)
1	Guidewire, 0.014" maximum diameter x 175 cm length
1	3-4 port manifold
1	Y connector
1	Inflation device with pressure gauge and 3-way stopcock
2-3	10-20 mL syringe
1000U/500 cc	Heparinized sterile saline (HepNS)
1	Rotating hemostatic valve

**2.Pre-procedure Inspection :**

After unpacking the product, inspect the catheter for bends, kinks, and other damage.

Do not use the product if any defects are noted or if there is any doubts about the product.

**PRECAUTION :**

This product is a single-use medical device and cannot be resterilized or reused. Pay attention to the "expiration date" of the product, it must be used before the labeled expiration date.

**3.Product Operational Procedure :**

1) Preparation of Balloon Catheter :

i. Open the package, take out the balloon catheter, Carefully remove the protective sleeve from the balloon ;

ii. Prepare a pressure inflation device with balloon inflation solution, usually a mixture of contrast medium/sterile saline (1:1);

iii. Remove air from the balloon :  
a. Prepare a 20mL syringe (or pressure inflation device) and draw about 4mL of balloon inflation solution ;

b. Connect the syringe (or pressure inflation device) to the balloon catheter with the syringe and distal end of the catheter facing down ;

c. Apply negative pressure, hold for 15 seconds, and then slowly restore the pressure to normal pressure, so that the balloon inflation solution is filled into the catheter and balloon ;

d. Detach the syringe (or pressure inflation device) from the catheter, expel the air from the syringe (or pressure inflation device), and then reconnect, repeat step c until no air bubbles are seen, and then restore the syringe (or pressure inflation device) to normal pressure ;

e. Detach the syringe (or pressure inflation device) from the catheter and connect the catheter to the pressure inflation device prepared in step ii.

2) Delivery Procedure:

i. Prepare the vascular access device according to standard PTCA procedures;

ii. Insert a guiding catheter with a hemostatic valve;

iii. Insert a 0.014" (0.36 mm) guide wire into the guiding catheter, the length of the guide wire should be sufficient to reach the distal end of the stenotic lesion;

iv. Insert the proximal end of the guide wire through the tip of the catheter into the inner lumen of the catheter;

v. Open the hemostatic valve, insert the balloon catheter into the guiding catheter, and close the hemostatic valve;

vi. Under X-ray monitoring, push the balloon catheter to the lesion site through the guide wire. Position the balloon with the guidance of angiography and balloon radiopaque markers.

3) Balloon Dilatation

i. Refer to the balloon compliance table on the outer label of the box or the compliance card, and select the balloon inflation pressure that is suitable for the diameter of the diseased blood vessel;

ii. Before inflation, reconfirm the correct balloon position with the markers inside the balloon;

iii. Rotate the three-way valve to ensure that the passage between the balloon catheter and the pressure inflator is open;

iv. Under X-ray monitoring, inflate the balloon to the appropriate pressure, but not exceeding the RBP;

v. After the lesion has been dilated, deflate the balloon completely. After complete deflation, withdraw the balloon catheter back into the guiding catheter until complete removal.

The balloon compliance table is shown in Table 3 :

Table 3 : Balloon compliance table(mm)

Pressure (atm/kPa)	Balloon Outer Diameter (The tolerance of the outer diameter of the balloon is ±15% for 1.00-1.50 and is ±10% for other model balloon)															
	1.00	1.25	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00		
8/811	1.00	1.25	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00		
9/912	1.02	1.27	1.53	2.03	2.28	2.54	2.79	3.05	3.30	3.58	3.81	4.07	4.57	5.08		
10/1013	1.04	1.29	1.55	2.06	2.31	2.58	2.83	3.10	3.36	3.64	3.88	4.14	4.65	5.17		
11/1115	1.05	1.31	1.58	2.09	2.34	2.62	2.87	3.15	3.41	3.70	3.94	4.21	4.73	5.25		
12/1216	1.07	1.33	1.60	2.12	2.37	2.66	2.91	3.20	3.47	3.75	4.01	4.28	4.80	5.34		
13/1317	1.09	1.35	1.63	2.15	2.40	2.70	2.95	3.25	3.52	3.81	4.07	4.35	4.88	5.42		
14/1419	1.11	1.37	1.65	2.18	2.43	2.74	2.99	3.30	3.58	3.86	4.13	4.42	4.95	5.50		

The most ideal dilatation is when the balloon is completely apposed to the arterial wall, so the balloon diameter selected is required to match the diameter of the reference vessel.

**PRECAUTION :**

Before performing balloon dilatation, it is necessary to confirm the selection of the appropriate product model.

Extreme care must be taken when removing the balloon catheter from the packaging and passing it through the hemostatic valve to ensure that the balloon system remains intact or remains sterile at all times.

Do not inflate the balloon prematurely.

Do not exceed the RBP for the balloon.

If resistance is felt during the procedure, do not force passage. The resistance can damage the balloon catheter. Should unusual resistance be felt during the advancement of the balloon catheter through the guide catheter, remove the entire system as a single unit.

If necessary, the same balloon can be inflated no more than 10 inflation.

## 4) Balloon Withdrawal:

- i. Deflate the balloon catheter according to the PTCA standard operating procedures to ensure that the balloon is fully deflated;
- ii. Fully open the hemostatic valve;
- iii. Withdraw the catheter while maintaining the position of the guide wire and the inflation device at negative pressure;
- iv. Tighten the hemostatic valve;
- v. Repeat angiography to confirm treatment outcome.

**PRECAUTION :**

- Failure to follow the steps above and/or pushing or retracting the catheter with excessive force may result in dislodgement of catheter accessories or catheter damage.
- If it is necessary to retain the current position of the guide wire for the next vessel or lesion, leave the guide wire in place and move only all other accessories of the catheter.

## 10. POTENTIAL ADVERSE EVENTS (Including but not limited to the following)

- Acute myocardial infarction
- Sudden vascular occlusion or spasm
- Arrhythmias, including ventricular fibrillation or other conduction abnormalities
- Arteriovenous fistula
- Allergic reactions to anticoagulant and/or antithrombotic therapy, contrast agents, or delivery systems
- Bleeding (especially at the puncture site)
- Coronary artery dissection, perforation, rupture, or damage
- Pericardial tamponade
- Coronary artery thrombosis
- Coronary artery spasm
- Death
- Embolism
- Hypotension/hypertension
- Bleeding or edema
- Infection and/or pain at the insertion site
- Coronary artery stenosis
- Renal failure
- Stroke
- Complete occlusion of coronary artery or its branches
- Thrombosis
- Unstable angina

## 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

Sterile, Non-Pyrogenic. This device is sterilized with ethylene oxide sterilization.

CONTENTS: One (1) SailFish™ PTCA Balloon Dilatation Catheter, one (1) Instructions for Use and one (1) 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 (693489145CB2WV).

## 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°C

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. EN SYMBOLS USED IN LABELING

1.SCB II-XXXXY is the model of this product.

2.Symbols description :

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

After-sale service: JW Medical Systems LTD.

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