



Coronary Stent System
INSTRUCTIONS FOR USE



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Device Description:

The *Symbiorph Biomedical Corp. SYMFLEX CC Rapid Exchange Coronary Stent System* is made up of a balloon-expandable intracoronary stent premounted on a balloon delivery system. Two radiopaque markers provide help in accurate positioning of the stent during fluoroscopy. The delivery system has a length of 135 cm and is compatible with 0.014" guidewires. The *SYMFLEX CC Coronary Stent* is manufactured from a Cobalt Chromium alloy. The stents come in multiple lengths and diameters and are laser cut seamless tubes.

Contents:

The *Symbiorph Biomedical Corp. SYMFLEX CC Rapid Exchange Coronary Stent System* contains one coronary stent premounted on a stent delivery system. The *SYMFLEX CC Stent System* is **STERILE** (ETO) in an unopened and undamaged package. **IT IS MEANT FOR SINGLE USE. DO NOT RESTERILIZE.** It should be stored in a cool dry place and should be kept away from sunlight. It must be used before the "Use By" date noted on the package.

Caution: Should there be damage to the sterile barrier, DO NOT USE.

Intended Use:

Symbiorph Biomedical Corp. SYMFLEX CC Coronary Stents are intended for use in patients eligible for Percutaneous Coronary Intervention (PCI) with reference vessel diameter of 2.0 – 4.0 mm. Stents may be deployed to maintain vessel patency.

Indications For Use:

SYMFLEX CC Coronary Medium Vessel Stents (3.0 – 4.0mm) are indicated for

- Patients with symptomatic ischemic heart disease due to discrete *de novo* or restenotic native coronary artery lesions
- Patients with symptomatic ischemic heart disease due to lesions in saphenous vein bypass grafts
- Restoring coronary flow in patients experiencing acute myocardial infarction, as confirmed by ST segment elevation or angiographic findings, who present within 12 hours of symptom onset.

SYMFLEX CC Coronary Small Vessel Stents (2.0 – 2.75mm)

are indicated for

- Improving coronary luminal diameter in patients with abrupt or threatened closure with failed interventional therapy of *de novo* and restenotic native coronary artery lesions.

Contraindications For Use:

- Coronary artery spasm
- Patients with metal allergies
- Patients who are non candidates for CABG
- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

Potential Adverse Events:

The following complications may be associated with the use of coronary stenting devices or PTCA:

- Acute myocardial infarction
- Allergic reaction to contrast medium
- Arrhythmias
- Arteriovenous fistula
- Bleeding complications
- Cerebrovascular accident
- Coronary pseudoaneurysm
- Death
- Dissection of coronary artery
- Drug reactions
- Endocarditis
- Hematoma
- Hemorrhage
- Hypotension
- Injury of the coronary artery
- Pain and tenderness
- Pyrogenic reaction
- Restenosis of the dilated artery
- Sepsis/infection
- Short-term hemodynamic deterioration
- Total occlusion of coronary artery
- Unstable angina
- Vascular thrombosis
- Ventricular fibrillation
- Vessel dissection
- Vessel perforation

- Vessel spasm

The following additional complications may be associated with the use of coronary stenting devices:

- Allergic reaction to metal
- Systemic stent embolism

Warnings / Precautions:

Only doctors with adequate experience of angiography and PCI are in best position to use this product. The long-term effects of stents in general and *SYMFLEX CC* in particular and the risks associated with lifelong carrying of these implants are not known.

1. *SYMFLEX CC Coronary Stents* are provided in ready to use sterile package, for single use only. It should be used before the "Use By" date noted on the package.
2. Use of the *SYMFLEX CC Coronary Stents* requires advance technical skills in the field of PCI. This set of instructions will not be replacement to the expertise achieved through formal training and experience in critical patient's management.
3. Do not remove the stent from the stent delivery system; the stent cannot be removed and placed on another balloon catheter for deployment.
4. Significant amounts of air in the balloon may cause uneven expansion of the stent and difficulty in deployment of the stent. Do not pre-inflate balloon prior to stent deployment. Use balloon preparation technique described within this instructional material.
5. The *SYMFLEX CC Coronary Stents* do not provide for distal dye injections or pressure measurements through the guidewire lumen.
6. Expansion of the stent should not be undertaken if the stent is not appropriately positioned in the vessel. If the position of the stent is not optimal, it should not be expanded. (See Removal of an Unexpanded Stent).
7. Incomplete deployment of the stent (i.e., stent not fully expanded) may cause procedural complications resulting in patient injury.
8. Advancement of a *SYMFLEX CC Coronary Stent* through a previously stented segment may cause procedural complications resulting in patient injury.
9. Administration of appropriate antiplatelet and antithrombotic adjunctive therapy is critical to

successful stent implantation and follow-up. The final decision regarding medications is left to the physician's discretion.

10. Caution must be taken when using ancillary equipment, such as intravascular ultrasound catheters, to avoid dislodgement of the stent.
11. A magnetic resonance imaging (MRI) scan should not be performed until the implant has been completely endothelialized (approximately eight weeks) to minimize the risk of migration of the stent under a strong magnetic field. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

Instructions For Placement Of *SYMFLEX CC Coronary Stent*

Sheath, Guiding Catheter, And Guidewire Use And Selection:

Prepare the guiding catheter and guidewire according to the manufacturer's instructions. All *SYMFLEX CC Coronary Stent* delivery systems are compatible with 0.014" guidewires. Refer to product labeling for specific guiding catheter compatibility.

Selection Of Stent Size:

Careful stent sizing is important to successful stenting. In general, the stent size should be chosen to match the diameter of the reference vessel and to correspond with the length of the lesion. Slight stent oversizing is preferable to undersizing.

Caution:

The inflated balloon diameter measures slightly larger than the labeled stent diameter to allow for stent recoil upon expansion.

Preparation Of the Delivery System:

1. Remove the stent delivery system from the package. Special care must be taken not to handle the stent or in any way disrupt its

placement on the balloon. This is most important during catheter removal from packaging, placement over guidewire, and advancement through the rotating hemostatic valve and guiding catheter hub.

2. Carefully slide the protective sheath off the stent by grasping the sheath at the distal end with the thumb and finger and gently pulling it. Inspect the stent to assure it has not been damaged or displaced from its original position on the balloon.

WARNING:

- **Should there be movement of or damage to the stent, do not use.**

3. Flush balloon catheter guidewire lumen with heparinized saline in routine manner.
4. Prepare balloon lumen with 50/50 contrast-saline mixture as follows:

WARNING:

- **Do not attempt pre-inflation technique to purge balloon lumen.**
- **Do not use air or any gaseous medium to inflate the balloon.**
- **Do not pull negative pressure on inflation device before beginning the prep step.**

- a. Using a 20 cc syringe containing 5 cc of contrast-saline mixture, apply negative pressure for 20-30 seconds, allowing air removal from the balloon. An excessive amount of air released into the syringe or no air released from the balloon may indicate damage to the stent delivery system.

Caution:

Do not put bending force on the stent delivery system when applying negative pressure with the syringe.

WARNING:

- **Should there be an indication of damage to the stent delivery system, do not use.**

- b. Release pressure slowly allowing negative pressure to draw mixture into balloon lumen
- c. Detach syringe, leaving a meniscus of mixture on the hub of the balloon lumen.
- d. Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.

- e. Attach inflation device to balloon lumen directly. Apply the "meniscus to meniscus" technique to ensure that no air bubbles remain at connection. Leave at ambient pressure.

5. Moisten the stent with heparinized saline. Visually inspect the stent delivery system to ensure the stent is placed within the area between the proximal and distal balloon markers.

Caution:

Do not wipe with gauze sponges as fibers may disrupt stent.

6. Advance the stent delivery system along the guidewire through a large bore rotating hemostatic valve using conventional angioplasty techniques.

Caution:

Make sure the rotating hemostatic valve has a large bore and is fully open while passing the stent through it. If resistance is encountered, do not force passage. Resistance may indicate damage to the stent or the stent delivery system.

7. Carefully advance the stent delivery system into the hub of the guiding catheter.

Caution:

If resistance is encountered, do not force passage. Resistance may indicate damage to the stent or stent delivery system.

8. The stent delivery system can now be advanced through the guiding catheter.

Deployment Of SYMFLEX CC Coronary Stent:

1. Determine the reference vessel diameter prior to stent selection.
2. Ensure guiding catheter stability before advancing the balloon into the coronary artery.

Caution:

If initial guiding catheter position is lost, avoid pulling or pushing guiding catheter over the stent. If this is done, the distal end of the guiding catheter may damage the stent. If the stent delivery system does not readily

advance, do not force. If the stent will not advance in spite of good guiding catheter support, consider dilating proximal obstructing plaque. (See Removal of an Unexpanded Stent).

3. Position the stent across the lesion using the proximal and distal radiopaque markers on the balloon as a reference point. Optimal placement requires the proximal end of the stent to be deployed approximately 1 mm proximal to the beginning of the stenotic segment to be stented.

Caution:

Expansion of the stent should not be undertaken if the stent is not properly positioned in the stenotic segment of the vessel. If the position of the stent is not optimal, it should be repositioned or removed. (See Removal of an Unexpanded Stent).

4. Prior to stent expansion, utilize high resolution fluoroscopy to verify the stent has not been damaged or shifted during positioning.
5. Inflate the balloon to the nominal pressure to expand the stent. Refer to product labeling for the proper inflation pressure. A 15-30 second inflation is recommended for full expansion. Balloon pressure should be monitored during inflation.

Caution:

Do not exceed rated burst pressure as indicated on product label. Use of a higher pressure range than specified on the product label may result in a ruptured balloon or oversizing of the stent with possible intimal damage.

6. Fluoroscopic visualization during stent expansion should be used in order to properly judge the optimum stent diameter as compared to the proximal and distal native coronary artery diameters. Optimal expansion and proper sizing requires that the stent be in full contact with the arterial wall.

Caution:

Inadequate expansion of the stent may result in stent movement.

Care must be taken to properly size the stent in the vessel to ensure that the stent is in full contact with the arterial wall upon deflation of the delivery balloon. The inflated balloon diameter measures slightly larger than the labeled deployed stent diameter to allow for stent recoil after expansion and balloon deflation.

Caution:

Oversizing of the stent and use of higher than recommended inflation pressures may cause vessel dissection. It is recommended that the stent size chosen closely approximates the diameter of the vessel and that recommended stent inflation pressures be used for stent deployment. If the target lesion is incompletely stented, use additional stents as necessary to adequately treat the lesion.

7. Deflate the balloon by applying negative pressure and allowing adequate time for full balloon deflation.
8. Very slowly withdraw the balloon from the stent, maintaining negative pressure and allowing movement of myocardium to gently dislodge balloon from stent. If any resistance is felt when removing the balloon from the stent, place in deflator on neutral pressure and gently remove the balloon. Maintain position of guiding catheter to prevent it from being drawn into the vessel.

NOTE:

Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement. If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, intracoronary infusions of a thrombolytic agent is recommended.

Further Dilatation Of Stented Segments:

If the deployed stent size is still inadequate with respect to the vessel diameter, a larger balloon may be used to further expand the stent to its optimal size. If the initial angiographic results are suboptimal, the stent may be further deployed using a low profile, high pressure, non-compliant balloon catheter. If required, the stented segment should be recrossed carefully with a prolapsed

guidewire to avoid dislodging the stent. All efforts should be taken to assure that the stent is not under dilated.

Caution:

Do not dilate SYMFLEX CC Coronary Stent beyond the compliance chart provided on the package. Do not dilate the 3.0 - 4.0 mm stents to greater than 5.0 mm. Do not dilate the 2.0 - 2.75 mm stents to greater than 3.25 mm.

Removal Of An Unexpanded Stent:

1. Ensure balloon is fully deflated
2. Fully open rotating hemostatic valve.
3. While maintaining guide wire position and negative pressure on inflation device, withdraw Delivery System.
NOTE: Should **unusual resistance** be felt for **any time** during either lesion access or removal of Delivery System post-stent implantation, the system should be **removed as a single unit**. See Stent/System Removal Precautions section for specific Delivery removal instructions.
4. Tighten rotating hemostatic valve.
5. Repeat angiography to assess stented area
If necessary, post dilate within stent. Balloon inflations should incorporate balloon size closely matching vessel.
6. Final stent diameter should match reference vessel. **ASSURE STENT IS NOT UNDERDILATED.**

Product Warranty And Limitations:

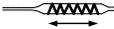
DISCLAIMER OF WARRANTY

NOTE: ALTHOUGH THE CORONARY STENT SYSTEM, HERAFTER REFFERD TO AS "PRODUCT," HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, SYMBIORPH BIOMEDICAL CORP. AND THEIR RESPECTIVE AFFILIATES (COLLECTIVELY, SYMBIORPH BIOMEDICAL CORP.) HAVE NO CONTROL OVER CONDITIONS UNDER WHICH THIS PRODUCT IS USED. SYMBIORPH BIOMEDICAL CORP., THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. SYMBIORPH BIOMEDICAL CORP. SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND SYMBIORPH BIOMEDICAL CORP. TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law. If any part of term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected.

SYMFLEX CC Compliance Data								
(ATM)		Ø (mm)						
		2.00	2.25	2.50	2.75	3.00	3.50	4.00
P	7	1.98	2.20	2.42	2.64	2.86	3.32	3.76
NOM	8	2.00	2.25	2.47	2.70	2.92	3.39	3.86
	9	2.05	2.29	2.50	2.75	3.00	3.46	3.94
	10	2.09	2.33	2.57	2.81	3.04	3.50	4.00
	11	2.12	2.37	2.61	2.86	3.09	3.58	4.07
	12	2.15	2.40	2.65	2.90	3.15	3.64	4.14
	13	2.18	2.44	2.69	2.95	3.20	3.70	4.20
	14	2.21	2.47	2.72	2.98	3.25	3.75	4.25
P	15	2.23	2.49	2.75	3.01	3.28	3.79	
MAX	16	2.25	2.52	2.78	3.04	3.32	3.83	

SYMBOL DESCRIPTION

	Batch Code		DO NOT REUSE
	EC Authorized Representative		Manufacturer
	Catalog Number		Store in Cool Temperature
	Sterilization ETO		See Instructions for Use
	Nominal Pressure		Rated Burst Pressure
	Stent Length		Stent Diameter

