INSTRUCTION FOR USE

Chroma
Coronary Stent System

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1. DEVICE DESCRIPTION

The Chroma™ Coronary Stent System is a Bare Metal Stent (BMS) System for coronary use composed of a cobalt chromium platform mounted on the balloon and its associated delivery system.

1.1 Device Component Description

The Chroma includes:

- A balloon expandable intra-coronary cobalt chromium stent pre mounted onto a semi-compliant rapid exchange balloon delivery system.
- A delivery system that has two radiopaque markers, which fluoroscopically marks the ends of the stent to facilitate proper placement.
- A female Luer lock connector hub located at the proximal end of the delivery system. This hub connects to the balloon inflation lumen.

The guidewire used in the procedure enters the distal tip of the catheter and exits 27.5 cm proximal to the tip of the delivery system.

Table 1: Chroma Description

Stent Pattern	Small Vessel (SV) model	Medium Vessel (MV) model
Stent Diameters (mm)	2.25-3.0	3.5-4.0
Stent Lengths(mm)	9, 14, 19, 24, 29, 33*, 36*	
Stent Material	CoCr alloy	
Delivery Catheter Design	Working Length: 142 cm Rapid Exchange (RX) compatible with 0.014”guidewires	
Guiding catheter compatibility	5F (0.056”)	
Balloon Material	Polyamide Elastomers	
Balloon Inflation Pressure Nominal Pressure (NP) Rate Burst Pressure (RBP)	 NP: 8 atm/811 kPa RBP: 16atm/1621 kPa	 NP: 8 atm/811 kPa RBP: 14atm/1418 kPa
Balloon deflation time per stent length (Table 3)	9 and 14 mm: 15 sec 19 to 29 mm: 20 sec 33 and 36 mm : 30 sec	

** (lengths 33 & 36 mm are not available for stent diameters 2.25 and 4.0 mm)*

Table 2: Chroma stent specifications

Product Code	Nominal Stent Diameter(mm)	Nominal Stent Length (mm)
BCR-2209	2.25	9
BCR-2214	2.25	14
BCR-2219	2.25	19
BCR-2224	2.25	24
BCR-2229	2.25	29
BCR-2509	2.50	9
BCR-2514	2.50	14
BCR-2519	2.50	19
BCR-2524	2.50	24
BCR-2529	2.50	29
BCR-2533	2.50	33
BCR-2536	2.50	36
BCR-2709	2.75	9
BCR-2714	2.75	14
BCR-2719	2.75	19
BCR-2724	2.75	24
BCR-2729	2.75	29
BCR-2733	2.75	33
BCR-2736	2.75	36
BCR-3009	3.00	9
BCR-3014	3.00	14
BCR-3019	3.00	19
BCR-3024	3.00	24
BCR-3029	3.00	29
BCR-3033	3.00	33
BCR-3036	3.00	36
BCR-3509	3.50	9
BCR-3514	3.50	14
BCR-3519	3.50	19
BCR-3524	3.50	24
BCR-3529	3.50	29
BCR-3533	3.50	33
BCR-3536	3.50	36
BCR-4009	4.00	9
BCR-4014	4.00	14
BCR-4019	4.00	19
BCR-4024	4.00	24
BCR-4029	4.00	29

2. INDICATION

The Chroma stent is indicated for improving coronary luminal diameter for the treatment of lesions in coronary arteries with a reference diameter ranging between 2.25mm and 4.0mm. Stents with length 33 and 36mm are only available for artery diameters ranging between 2.5mm and 3.5mm.

3. CONTRAINDICATIONS

The Chroma stent is contraindicated for use in the following situations:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients with lesion(s) that prevent complete inflation of an angioplasty balloon.
- Patients with known sensitivity to contrast agents that cannot be controlled prophylactically prior to Chroma stent implantation.
- Patients with known allergies to Cobalt, Chromium, Nickel, Molybdenum or any metallic component in use in CoCr ASTM F 562 alloy.
- Off-label use (i.e.: outside of the approved indication for use).

4. ANTIPLATELET REGIMEN

Physicians and/or Health Care Professionals (HCPs) should use information currently available in bare-metal stent (BMS) literature as well as the specific needs of individual patients to determine the specific antiplatelet/anticoagulation regimen to be used for their patients in general practice. (Ref: ACC/AHA/SCAI PCI Practice Guidelines [1], [2]).

Specific consideration should be given to the risk of antiplatelet therapy. For patients with a heightened risk of bleeding (e.g. patients with recently active gastritis or peptic ulcer disease), stenting is generally avoided as anticoagulation therapy would be contraindicated.

5. WARNINGS

- Judicious selection of patients is necessary since the use of this device carries the associated risk of thrombosis, vascular complications and/or bleeding events. Hence, patients should be maintained on clinically adequate post-procedural antiplatelet therapy (Refer to section 4.0: Antiplatelet regimen).
- Only physician who have received appropriate training should perform implantation of stent. Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery (CABG) is accessible.

[1] Frederick G. Kushner & al. 2009 Focused Update of ACC/AHA/SCAI. Circulation 2009, 120:2271-2306

[2] WilliamWijns & al. Guidelines on myocardial revascularization. European Heart Journal (2010) 31, 2501–2555

- Subsequent blockage may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- Use of the device in patients with history of restenosis, multiple stents, and diabetes can lead to an increased risk of restenosis.
- The extent of residual stenosis and malapposition of the stent can lead to a greater risk of restenosis.
- The inner packaging provides a sterile barrier; therefore it is essential to ensure that it has not been damaged or opened.
- **This delivery system must not be reused in another procedure.** The performance characteristics of the balloon are degraded during use.
- This product is not intended or approved for use in peripheral applications.
- DO NOT resterilize and/or reuse this device or related delivery system, as this can compromise performance and can lead to device/delivery system failure and procedure complications with severe injury or patient death. Reuse, reprocessing and resterilization bear the risk of cross contamination and patient to patient infection.

6. PRECAUTIONS

6.1 System Handling – Precautions

- The content of the device is supplied sterile unless package is open or damaged. Do not use if package is opened or damaged. Take notice of Chroma expiration date.
- **The sterility and stability of the Chroma cannot be guaranteed once the pouch has been opened** and hence the device MUST be used promptly. Unused devices should be discarded or returned to Biosensors International™ and should not be re-stocked.
- The delivery system is designed to deploy the stent once, and cannot be reused.
- Do not expose delivery catheter to organic solvents, e.g. isopropyl alcohol. Such an exposure can degrade delivery catheter performance.
- When removing the device from the packaging, care should be taken not to kink the shaft.
- Do not use if stent is exposed to abnormal rubbing or contact with objects other than the guide catheter or opened hemostasis valve prior to implantation.
- Do not remove stent from its delivery catheter as removal may damage the stent and/or lead to stent embolization. Chroma Stent System is intended to perform as a system.
- The delivery system should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon.

- Do not manipulate (eg.: “roll”) the mounted stent with your fingers as this action may loosen the stent from the balloon and cause subsequent dislodgement.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.
- Do not attempt to straighten the proximal shaft (hypotube) as it may cause the catheter to break if it is accidentally bent.
- **In the event that the stent is not successfully deployed, the stent and delivery system should be returned to Biosensors International.**
- The use of mechanical atherectomy devices (directional atherectomy catheters) or laser angioplasty catheters to treat in-stent stenosis have not been established.
- When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different metals in contact with each other may increase the potential for corrosion.

6.2 Stent Placement – Precautions

- Do not prepare, introduce negative pressure or pre-inflate the delivery system prior to stent deployment in other mean than as directed. Use balloon purging technique described in section 9.3 Preparation of the Stent / Delivery System.
- The labeled stent diameter refers to the expanded stent inner diameter at its nominal pressure.
- Implanting a stent may lead to dissection of the vessels distally, and/or proximally, to the stented portions, and may cause acute closure of the vessel, requiring additional intervention (e.g. CABG, further dilatation, placement of additional stents or other).
- When treating multiple lesions, distal lesions should be stented first followed by proximal lesion stenting. Stenting in this order obviates the need to cross the proximal stent and reduces the chances for dislodging the proximal stent.
- Do not deploy the stent if it is not properly positioned within the lesion. Do not use the device if proper positioning within the lesion cannot be achieved.
- **Do not exceed rated burst pressure as indicated on product label.** Use of pressures higher than specified on the product label may result in a ruptured balloon with possible intimae damage and dissection.
- Do not attempt to pull an unexpanded stent back through the guiding catheter, as dislodgement of the stent from the balloon may occur. Remove as a single unit as described in section 6.3 Stent/System Removal Precautions.

6.3 Stent / Stent System Removal – Precautions

- Should unusual resistance be encountered at any time during either lesion access or when withdrawing the delivery system into the guiding catheter prior to stent implantation, the delivery system and the guiding catheter should be removed as a single unit. This must be done under direct fluoroscopic visualization.

When removing the stent delivery system as a single unit:

- Do not attempt to retract an unexpanded stent into the guiding catheter while engaged in the coronary arteries.
- When removing the delivery system and guiding catheter as a single unit, the following steps should be executed under direct visualization using fluoroscopy:
- Ensure complete balloon deflation. If unusual resistance is felt during stent delivery system withdrawal, pay particular attention to the guiding catheter position. In some cases it may be necessary to slightly retract the guiding catheter in order to prevent unplanned guiding catheter movement and subsequent vessel damage. In cases where unplanned guiding catheter movement has occurred, a coronary tree angiographic assessment should be undertaken to ensure that there is no damage to the coronary vasculature.
- DO NOT retract the delivery system into the guiding catheter.
- Position the proximal balloon marker just distal to the guiding catheter tip.
- Advance the guide wire into the coronary anatomy as far distally as safely possible. NOTE: If this is necessary to maintain guide wire position, the guide wire must be either converted to an exchange wire length or a second guide wire must be inserted.
- Tighten the rotating hemostatic valve to secure the delivery system to the guiding catheter, and remove the guiding catheter and delivery system as a single unit
- **Do not attempt to pull an unexpanded stent back through the introducer sheath. When the distal tip of the guiding catheter reaches the end of the introducer sheath, remove sheath, guiding catheter and delivery system as a single unit and replace sheath as per hospital protocol.**

- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Failure to follow these steps and/or applying excessive force to the stent delivery system can potentially result in stent dislodgement or damage to the stent and/or delivery system components.

6.4 Post Implantation – Precautions

- Care must be exercised when crossing a newly deployed stent with adjunct devices to avoid disrupting stent placement, apposition, and/or geometry.

6.5 MRI Information - Precautions

CoCr alloy as used in Chroma stent is a non-ferromagnetic alloy that does not interact with MRI. Based on literature evaluation, a patient with a Chroma stent can be scanned safely, immediately after placement of this implant. The following statements were assessed:

- Magnetic field interactions with the stent implant during MRI does not result in movement of the implant resulting in tissue damage or misplacement when tested at 1.5 Tesla in accordance with ASTM F2052
- Only minimal heating after 15 minutes were observed for the implant, which was tested in a 1.5-Tesla MR system, producing a whole body averaged specific absorption rate (SAR) of 2.0 W/kg in accordance with F2182
- The stent does not present imaging difficulties. Chroma does not create artifacts due to distortion of the magnetic field during MRI when tested at 1.5 T in accordance with ASTM F2119.
- The effect of performing MRI procedures using higher levels of RF energy on the Chroma stent has not been determined. The effect of heating in the MRI environment on overlapping stents is unknown.

7. INDIVIDUALIZATION OF TREATMENT

The risks and benefits described in this document should be considered for each patient before use of the CHROMA stent. Physicians are responsible for assessing patient appropriateness for stent implantation prior to procedure. Patient selection factors to be assessed should include a judgment regarding risk of antiplatelet therapy. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

8. USE IN SPECIAL POPULATION

The safety and effectiveness of the Chroma stent has not been established in the following patient populations:

- Pregnancy
- Pediatric use

Carefully consider whether it is appropriate to use the Chroma stent in the above patient populations.

9. OPERATOR'S MANUAL

9.1 Inspection Prior to Use

1. Inspect the stent delivery system package for damage to the sterile barrier before opening. Do not use after the expiration date. If the integrity of the sterile package has been compromised (e.g., damage to the package), contact Biosensors. Do not use if any defects are noted.
2. Carefully remove the system from the package and inspect the delivery catheter for bends, kinks, or other damage.

3. Carefully remove the stent guard covering the stent/balloon. The pre-attached stylet is automatically removed.
4. Inspect the stent to ensure that it has not been displaced from its original position on the balloon. Verify that the stent is positioned between proximal and distal balloon markers.
5. Note the position of the stent relative to the delivery system markers for use as reference under fluoroscopy.

Do not use if any defects are noted.

9.2 Materials Required

1	Appropriate guiding catheter with minimum inner diameter of 0.056”
1	10-20cc syringe
1000 IU	Heparin per 500 cc Normal Saline (HepNS)
1	0.014 inch / 0.36 mm x 190 cm minimum guidewire
1	Rotating haemostatic valve
1	Torque device
1	Contrast medium diluted 1:1 with normal saline
1	Inflation device
1	Three-way stopcock

9.3 Preparation of the Stent/ Delivery System

6. Prepare inflation device/syringe with diluted contrast medium.
7. Attach the inflation device to the 3-way stopcock; attach to balloon inflation port hub. DO NOT apply negative or positive pressure to the balloon at this time as it can cause premature dislodgement of the stent.
8. Open stopcock to stent delivery system.
9. Leave on neutral.

9.4 Stent Delivery Procedure

10. If physician/HCPs estimate that the lesion site requires pre-stenting preparation: Prepare vascular access site according to standard PTCA practice.
11. Pre-dilate lesion with a balloon diameter 0.5mm smaller than the stent and a balloon length equal to or shorter than the target lesion length and shorter than the length of the stent to be implanted.
12. Immediately prior to backloading the stent delivery catheter onto the guidewire flush the lumen of the delivery system with HepNS according to hospital protocol. Avoid contact with the stent.

NOTE: Fluid contact time should be limited to immediately prior to loading the delivery catheter on the guidewire.

13. Backload stent delivery system onto the proximal portion of the guidewire while maintaining guidewire position across target lesion.
14. Open rotating haemostatic valve on the guiding catheter hub as widely as possible and close when the stent has been advanced safely inside the guide catheter.
15. Advance the stent delivery system over the guidewire to the target lesion under fluoroscopic guidance. Utilize the radiopaque balloon markers to position the stent across the lesion. Perform angiographic visualization to confirm stent position.

NOTE: If resistance is felt, DO NOT FORCE PASSAGE. Resistance may indicate a problem and may result in damage to the vessel or stent, or in stent dislodgement if it is forced. Remove the stent delivery system and the guiding catheter as a single unit (see 6.3. Stent/ Stent System Removal - Precautions).

9.5 Chroma Stent Deployment

16. Consult the balloon compliance chart on the compliance card or at the back of the product box in order to determine the balloon inflation pressure appropriate for the target vessel diameter.

    CAUTION: Different compliance charts apply for different stent lengths.
17. Before deployment, reconfirm the correct position of the stent relative to the target lesion via the balloon markers.
18. Ensure that the three-way stopcock on the stent delivery system is open to the inflation device and apply negative pressure to purge the balloon of air.

20. Turn the three-way stopcock on the stent delivery catheter off to the balloon port and purge the inflation device of air. Open the side port of the three-way stopcock to the delivery system.
21. Under fluoroscopic visualization, inflate the balloon to at least 8 atm to deploy the stent, but do not exceed the labeled rated burst pressure (RBP). Optimal expansion requires the stent to be in full contact with the artery wall and that the stent internal diameter matches the size of the reference vessel diameter. ENSURE THAT THE STENT IS NOT UNDEREXPANDED.
22. Deflate the balloon by pulling a vacuum with the inflation device. Make sure the balloon is fully deflated before attempting any movement of the system. Please refer to below table for deflation time per product diameter/length.

Table 3: Chroma balloon deflation time per product specification

Stent length [mm]	Time for deflation [s]
9 & 14	15
19 to 29	20
33 & 36	30

23. Confirm adequate stent expansion and balloon deflation by angiography.
24. If more than one Chroma stent is needed to cover the lesion and balloon treated area, adequately overlap the stents (at least 2 mm) to avoid potential gap stenosis.

9.6 Delivery System Removal Procedure

25. Ensure that the balloon is fully deflated.
26. Fully open the rotating haemostatic valve.
27. While maintaining guidewire position and negative pressure on inflation device, withdraw the delivery system.
28. Tighten rotating haemostatic valve.
29. Repeat angiography to assess the stented area.

9.7 Further dilation of stent segments

If an adequate expansion has not been obtained, either re-advance the delivery system or exchange for another appropriate balloon to achieve- proper stent apposition to the vessel wall.

NOTE: Post-dilation should be performed within the stented segment. DO NOT dilate beyond the stent edges.

Reconfirm stent position and angiographic result. Repeat inflations until optimal stent deployment is achieved. Final stent diameter should match reference vessel.

10. POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to:

• Abrupt vessel closure or spasm • Acute myocardial infarction • Allergic reaction to anti-coagulation and/or anti-thrombotic therapy, contrast material, stent / stent delivery system materials • Aneurysm, pseudoaneurysm or arteriovenous fistula • Arrhythmias, including VF and VT • Cardiac tamponade • Cardiogenic shock • Damage to the stent or injury to the artery requiring emergency coronary artery bypass grafting (CABG) • Death • Dissection, perforation, rupture of the artery • Emboli (blockage), distal (air, tissue or thrombotic emboli)	• Fever • Hematoma at insertion site • Hemorrhage, requiring transfusion • Hypotension/hypertension • Risk of restenosis of stented segment(s) • Infection and/or pain at the insertion site • Stent migration or embolization • Stent thrombosis/occlusion • Peripheral ischemia / peripheral nerve injury • Renal failure • Stroke or transient ischemic attack • Total occlusion of coronary artery • Unstable angina

11. HOW SUPPLIED

STERILE**:** Package contents are sterile unless package is open or damaged. This device is sterilized via electron beam radiation and is non-pyrogenic. **It is intended for single use only**. Do not use if package is open or damaged.

CONTENTS**:** One (1) Chroma Coronary Stent System.

STORAGE**:** Store in a cool, dark, dry place.

DISPOSAL: Dispose device in accordance with local regulation.

12. SYMBOLS USED IN LABELING

	Legal Manufacturer		Keep away from sunlight or heat
	Date of Manufacture		Keep Dry
	Catalog number		Do not use if package is damaged or open
	Batch code		Stent Length
	Caution, consult accompanying documents		Stent Diameter
	Do not re-sterilize		Maximum Guidewire Outer Diameter (OD)
	Do not reuse		Minimum Guiding Catheter Inner Diameter (ID)
	This product has been sterilized using irradiation		Consult Instruction for use
	Use by date Do not use this product after the indicated date (Year-Month-Day)	RBP	Rated Burst Pressure
NP	Nominal Pressure		MR Conditional

13. WARRANTY

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

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