BIOMATRIX NEOFLEX™
Drug Eluting Coronary Stent System
INSTRUCTION FOR USE

1. DEVICE DESCRIPTION 3
1.1. Device Component Description 3
1.2. Drug Component Description 5
2. INDICATIONS 6
3. CONTRAINDICATIONS 7
4. ANTIPLATELET REGIMEN 8
5. WARNINGS 8
6. PRECAUTIONS 10
6.1 Drug Interactions – Precautions 10
6.2. Stent Handling – Precautions 11
6.3. BioMatrix NeoFlexPlacement – Precautions 12
6.4 Stent / System Removal – Precautions 12
6.5. Post Implantation – Precautions 13
6.6 Magnetic Resonance Imaging (MRI) – Precautions 13
7. INDIVIDUALIZATION OF TREATMENT 14
8. USE IN SPECIAL POPULATIONS 14
9. OPERATOR'S MANUAL 15
9.1. Inspection Prior to Use 15
9.2. Materials Required 15
9.3. Delivery System Preparation 15
9.4. Stent Delivery Procedure 16
9.6. Delivery System Removal Procedure 18
9.7. Further Dilatation of Stent Segments 18
10. Potential Adverse Events 19
11. HOW SUPPLIED 19

12. SYMBOLS USED IN LABELING 21
13. WARRANTY 22

1. DEVICE DESCRIPTION

The BioMatrix NeoFlex™ Drug Eluting Coronary Stent System (BioMatrix NeoFlex DES) is a Drug Eluting Stent (DES) System for coronary use with a biodegradable polymer coating. The DES is a combination product comprised of two key components: the stent (which includes the active pharmaceutical ingredient BA9™ (Biolimus A9) incorporated into a polymer coating), and the delivery system.

1.1. Device Component Description

- A balloon expandable intra-coronary 316L stainless steel stent with a biodegradable polymer coating Poly-lactic Acid containing the BA9™ drug pre-mounted onto a semi-compliant rapid exchange balloon delivery system.
- The delivery system has two radiopaque markers, which fluoroscopically mark the ends of the stent to facilitate proper stent placement.
- At the proximal end of the delivery system is a female Luer lock connector hub. This hub connects to the balloon inflation lumen.

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

Table 1: Device Description

Stent Pattern:	**6-crown model**	**9-crown model**
Stent Diameters (mm):	2.25 – 3.0	3.5 – 4.0
Stent Lengths (mm):	8, 11, 14, 18, 24, 28, 33*, 36*	
Stent Material / Coating:	316L stainless steel stent / Poly-lactic Acid (PLA) and BA9 drug	
Delivery Catheter Working Length:	142 cm	
Guiding catheter compatibility	5F	
Stent Delivery Balloon:	Polyamide Elastomer	
Balloon Inflation: Nominal Inflation Pressure:	6 atm / 608 kPa	6 atm / 608 kPa
Rated Burst Pressure:	16 atm / 1621 kPa	14 atm /1418 kPa

Balloon Deflation Time Per stent length	08-14 mm : 15sec 18-28 mm : 20sec 33-36 mm : 30sec

*** BioMatrix NeoFlex with a length of 33 and 36 mm is only available for diameters from 2.5 to 3.5mm.**

1.2. Drug Component Description

- The BA9 drug (USAN/INN: *umirolimus*) is a semi-synthetic sirolimus derivative with increase lipophilicity. The BA9 drug, as provided on the BioMatrix NeoFlex DES, inhibits smooth muscle cell proliferation within the stent proximity.
- Poly-lactic acid (PLA) is combined with the BA9 drug and acts as the carrier to control the release of the drug from the stent.

Table 2: Nominal BA9 Drug Dosage

Product Code	Nominal Expanded Inner Diameter (mm)	Nominal Unexpanded Stent Length (mm)	Nominal Dose of BA9 drug (µg)
BMXP-2208	2.25	8	133
BMXP-2211	2.25	11	178
BMXP-2214	2.25	14	225
BMXP-2218	2.25	18	292
BMXP-2224	2.25	24	384
BMXP-2228	2.25	28	453
BMXP-2508	2.5	8	133
BMXP-2511	2.5	11	178
BMXP-2514	2.5	14	225
BMXP-2518	2.5	18	292
BMXP-2524	2.5	24	384
BMXP-2528	2.5	28	453
BMXP-2533	2.5	33	521
BMXP-2536	2.5	36	566
BMXP-2708	2.75	8	133
BMXP-2711	2.75	11	178
BMXP-2714	2.75	14	225
BMXP-2718	2.75	18	292
BMXP-2724	2.75	24	384
BMXP-2728	2.75	28	453
BMXP-2733	2.75	33	521
BMXP-2736	2.75	36	566

Product Code	Nominal Expanded Inner Diameter (mm)	Nominal Unexpanded Stent Length (mm)	Nominal Dose of BA9 drug (µg)
BMXP-3008	3.0	8	133
BMXP-3011	3.0	11	178
BMXP-3014	3.0	14	225
BMXP-3018	3.0	18	292
BMXP-3024	3.0	24	384
BMXP-3028	3.0	28	453
BMXP-3033	3.0	33	521
BMXP-3036	3.0	36	566
BMXP-3508	3.5	8	133
BMXP-3511	3.5	11	178
BMXP-3514	3.5	14	225
BMXP-3518	3.5	18	292
BMXP-3524	3.5	24	384
BMXP-3528	3.5	28	453
BMXP-3533	3.5	33	521
BMXP-3536	3.5	36	566
BMXP-4008	4.0	8	133
BMXP-4011	4.0	11	178
BMXP-4014	4.0	14	225
BMXP-4018	4.0	18	292
BMXP-4024	4.0	24	384
BMXP-4028	4.0	28	453

2. INDICATIONS

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

The BioMatrix NeoFlex DES with stent length up to 28 mm is also indicated for use in patients with:

- ST elevated myocardial infarction (STEMI)
- Acute Coronary Syndromes (ACS) including ACS-STEMI, ACS-NSTEMI and Unstable Angina
- Diabetes Mellitus

3. CONTRAINDICATIONS

The BioMatrix NeoFlex DES is contraindicated for use in:

- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients with complex lesion(s) that prevent complete inflation of an angioplasty balloon.
- Patients with known sensitivity to the BA9 drug or its derivatives.
- Patients with a known allergy to stainless steel, nickel or other metal ions found in 316L.

- Patients with known sensitivity to contrast agents that cannot be controlled prophylactically prior to BioMatrix NeoFlex stent implantation.
- Off-label use (i.e. outside of the approved indications for use). Patient outcomes may not be the same as the results observed in clinical trials.

4. ANTIPLATELET REGIMEN

Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical for a successful long term result of the implantation.

Physicians should take into consideration information from clinical trials with BA9 DES as well as currently available guidelines and the specific needs of individual patients to determine the 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

- BioMatrix NeoFlex indication for use of the 33 and 36 mm stent lengths in patients with STEMI, ACS or Diabetes Mellitus have not been established.
- 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 physicians who have received appropriate training should perform implantation of the stent. Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.

[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 restenosis 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.
- The inner packaging provides a sterile barrier; therefore it is essential to ensure that it has not been damaged or opened.
- **This stent deployment device must not be reused in another procedure**. The performance characteristics of the balloon are degraded during use.
- When multiple tandem stents are required, stent materials should be of similar composition to avoid dissimilar metal corrosion.

- Direct stenting is not recommended.
- Stent occlusion may require repeat dilations of the target lesion. The long-term outcome following repeat dilations of the target lesion is presently unknown.
- 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.
- Use in patients with history of restenosis, multiple stents, extent of residual stenosis, diabetes and malapposition of the stent are at risk for restenosis.

6. PRECAUTIONS

6.1 Drug Interactions – Precautions

- There is no specific clinical data available for the interactions of the BA9 drug with other drugs. Drug interaction studies have not been performed. However, drugs like Tacrolimus that may act through the same binding proteins (FKBP) may interfere with the efficacy of the BA9 drug. The BA9 drug is metabolized by CYP3A4. Strong inhibitors of CYP3A4 (e.g. ketoconazol) might cause increased BA9 drug exposure to levels associated with systemic effects, especially if multiple stents are deployed. Systemic exposure of the BA9 drug should be taken into consideration if the patient is treated concomitantly with systemic immunosuppressive therapy.

- Consideration should be given to the potential for drug interactions when deciding to place a BioMatrix NeoFlex stent in a patient who is taking a drug that could interact with the BA9 drug or when deciding to initiate therapy with such a drug in a patient who has recently received a BioMatrix NeoFlex stent. The effect of BioMatrix NeoFlex DES drug interactions on safety or efficacy has not been determined.
- Patient's exposure to BA9 is directly related to the length of the BioMatrix NeoFlex™ stent and number of BA9 eluting stents implanted.

(See Table 2 for nominal BA9 content per BioMatrix NeoFlex stent. If another BA9 eluting stent has been or will be used please refer to its IFU.)

6.2. Stent Handling – Precautions

- **For single use only.** Do not resterilize or reuse.
- Do not use a product that has reached or exceeded its labeled expiration date.
- Do not use if packaging has been damaged or opened. **The sterility and stability of the BioMatrix NeoFlex DES cannot be guaranteed once the pouch has been opened.** Once the package has been opened the device MUST be used promptly. Un-used devices should be returned to Biosensors International™[3] and should not be re-stocked.
- Do not use if stent coating is subjected to abrasions beyond those of normal insertion and delivery.
- Do not use the system if the stent is exposed to abnormal rubbing or contact with objects other than the guide catheter or the open hemostasis valve prior to implantation.
- **Do not rub or scrape the stent coating.**
- Do not remove stent from its delivery catheter as removal may damage the stent and/or lead to stent embolization. BioMatrix NeoFlex stent 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 "roll" the mounted stent with your fingers as this action may loosen the stent from the balloon and cause subsequent dislodgement, or cause some loss of drug coating.
- 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.
- Exposing the stent to fluids before implantation is not recommended. Exposure to fluids prior to implantation may result in premature release of drug.

- Do not expose delivery catheter to organic solvents, e.g. isopropyl alcohol. Such an exposure can degrade delivery catheter performance.
- In the event that the stent is not successfully deployed, the stent and delivery system should be returned to Biosensors International[3].

6.3. BioMatrix NeoFlex Placement – Precautions

Do not prepare, introduce negative pressure, or pre-inflate the delivery system prior to stent deployment other than as directed. Use balloon purging technique described in Section 9.3 Delivery System Preparation.

The labeled stent diameter refers to the expanded stent inner diameter.

Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).

Beware that the direct stenting is not recommended (as per section 5. WARNINGS) and could lead to suboptimal clinical outcome and / or a failure to cross the lesion with the stent.

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 in placement of the distal stent and reduces the chances for dislodging the proximal stent.

Use of Multiple Stents: The extent of the patient's exposure to drug and polymer is directly related to the number of stents implanted.

Do not expand the stent if it is not properly positioned in the vessel. (See 6.4. Stent / System Removal – Precautions)

Placement of a stent has the potential to compromise side branch patency.

Do not exceed rated burst pressure as indicated on product compliance card. Use of pressures higher than specified on the product label may result in a ruptured balloon with possible intimae damage and dissection.

6.4 Stent / System Removal – Precautions

Should unusual resistance be felt at any time during either lesion access or removal of the stent delivery system prior to the stent being implanted, the entire system should be removed as a single unit.

[3] Please contact the Sales and Customer Service of your region or local distributor for return of goods

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.

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.
- Stent damage or dislodgement may occur. Advance the guidewire into the coronary anatomy as far distally as safely possible.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.

NOTE: If it is necessary to maintain the guidewire position, the guidewire must either be converted to an exchange wire length or a second guidewire must be inserted.

- Tighten the rotating hemostatic valve to secure the delivery system to the guiding catheter. Remove the guiding catheter and stent delivery system as a **single unit**.

Do not attempt to pull the guiding catheter and delivery system through the introducer sheath. When the distal tip of the guiding catheter reaches the distal end of the femoral sheath, remove sheath, guiding catheter, and delivery system as a single unit and replace sheath per hospital protocol.

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. 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.

6.5. 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.

6.6 Magnetic Resonance Imaging (MRI) – Precautions

Non-clinical testing has demonstrated that the BioMatrix NeoFlex DES is MR Conditional. A patient with a BioMatrix NeoFlex stent can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial gradient field of 720-Gauss/cm or less

- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the BioMatrix NeoFlex DES (single and two stents overlapping) produced a temperature rise of less than or equal to 2.1°C at a maximum MR system reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla, 128 MHz MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI). The effect of performing MRI procedures using higher levels of RF energy on the BioMatrix NeoFlex stent has not been determined. The effect of heating in the MRI environment on more than two overlapping stents, **drug or polymer coating is unknown**.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the BioMatrix NeoFlex DES.

7. INDIVIDUALIZATION OF TREATMENT

The risks and benefits of drug-eluting stents should be considered for each patient before use of the BioMatrix NeoFlex stent. Physicians are responsible for assessing patient appropriateness for stent implantation prior to procedure.

8. USE IN SPECIAL POPULATIONS

The safety and effectiveness of the BioMatrix NeoFlex DES has not been established in the following patient populations:

- Pregnancy: There are no data available for use of the BioMatrix NeoFlex stent in pregnant women.
- During Lactation: The effects of the BA9 drug during lactation have not been evaluated.
- Pediatric use: The safety and efficacy of the BioMatrix NeoFlex stent has not been established.

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

The safety and effectiveness beyond two years, or of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters to treat in-stent stenosis has not been established.

9. OPERATOR'S MANUAL

9.1. Inspection Prior to Use

1. Verify expiration date and inspect the stent delivery system package for damage to the sterile barrier.
2. Carefully remove the system from the package and inspect the delivery catheter for bends, kinks, and 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 damaged or displaced from its original position on the balloon. Verify that the stent is positioned between the proximal and distal balloon markers.
5. Note the position of the stent relative to the proximal and distal marker bands for use as reference under fluoroscopy.

Do not use if any defects are noted.

9.2. Materials Required

1	A guiding catheter with a minimum inner diameter of 0.056"
1	Pre-dilatation balloon catheter
1	10-20 ml syringe
1000 IU	Heparin per 500 ml Normal Saline (HepNS)
1	0.014 inch/ 0.36 mm x ≥ 190 cm guidewire
1	Rotating haemostatic valve
N/A	Contrast diluted 1 : 1 with normal saline
1	Inflation device
1	Three-way stopcock

9.3. Delivery System Preparation

1. Prepare inflation device/syringe with diluted contrast medium.
2. Attach inflation device to the three-way stopcock; attach to balloon inflation port hub.

NOTE: DO NOT apply negative or positive pressure to the balloon at this time as it can cause premature dislodgement of the stent.

3. Open stopcock to stent delivery system.

4. Leave on neutral.

9.4. Stent Delivery Procedure

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

2. Pre-dilate lesion with a balloon diameter 0.5 mm 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.

3. Immediately prior to backloading the stent delivery catheter onto the guidewire, flush the guidewire lumen of the delivery system with HepNS according to hospital protocol. Avoid contact with the stent.

NOTE: Stent contact with fluid has the possibility of initiating drug release. Fluid contact time should be limited to immediately prior to loading the delivery catheter on the guidewire.

4. Backload stent delivery system onto the proximal portion of the guidewire while maintaining guidewire position across target lesion.

5. Open rotating hemostatic valve on the guiding catheter hub as widely as possible, and close when the stent has been advanced safely inside the guide catheter.

6. 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 angiography 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 section 6.4. Stent / System Removal - Precautions).

9.5. Deployment Procedure

1. 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: Please refer to the compliance chart provided with the device as the pressure indication is stent dimension specific. .

2. Before deployment, reconfirm the correct position of the stent relative to the target lesion via the balloon markers.
3. 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.
4. 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.
5. Under fluoroscopic visualization, inflate the balloon to at least 6 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 with the stent internal diameter matching the size of the reference vessel diameter. ENSURE THAT THE STENT IS NOT UNDEREXPANDED.
6. Deflate the balloon by pulling negative pressure on the inflation device. Make sure the balloon is fully deflated before attempting any movement of the system. Deflation time per stent length is given in Table 3.

Table 3: BioMatrix NeoFlex balloon deflation time per stent length

Stent Length	08-14 mm	18-28 mm	33-36 mm
Deflation time [s]	<15	<20	<30

7. Confirm adequate stent expansion and balloon deflation by angiographic injection through the guiding catheter.
8. If more than one BioMatrix NeoFlex 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

The delivery system must be withdrawn as a whole unit.

1. Ensure that the balloon is fully deflated.
2. Fully open the rotating haemostatic valve.
3. While maintaining guidewire position and negative pressure on inflation device, withdraw the delivery system.
4. Tighten rotating haemostatic valve.
5. Repeat angiography to assess the stented area.

9.7. Further Dilatation of Stent Segments

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

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

2. 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 that may be associated with the use of a stent in native coronary arteries include but not limited to:

• Abrupt vessel closure or spasm, failure to expand the stent • 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 • Increased 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

Adverse events that may be associated with BA9 drug coating.

NOTE: BA9™ drug administration is limited to intra-coronary stent delivery. The adverse effects of using this drug have not been fully characterized and may have additional side effects / complications associated with the use of the BA9™ drug at significantly higher doses than what would be delivered via the BioMatrix NeoFlex™ DES. They include the following:

- Chest heaviness
- Mouth ulcers
- Nausea
- Dizziness
- Lymphadenopathy

11. HOW SUPPLIED

STERILE, NON-PYROGENIC. This device is sterilized via e-beam sterilization.

CONTENTS: One Biosensors BioMatrix NeoFlex Drug Eluting Coronary Stent System.

STORAGE: Store in a cool dark dry place. Do not store above 25°C.

DISPOSAL: Dispose device in accordance with local regulations.

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		Do not store above 25°C
	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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