BMS Bare Metal Coronary Stent

A Description

The GENOSS BMS Bare Metal Coronary Stent is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to de novo or restenotic lesions with reference vessel diameters of 2.00–5.00 mm and ≤28 mm in length using direct stenting or predilatation. The GENOSS BMS consists of a balloon expandable stent pre-mounted on a rapid exchange delivery system. The stent body is intended as a permanent implant. It is made from a cobalt chromium alloy (L-605). The delivery system is a rapid exchange PTCA catheter. It has a working length of 145cm.
To facilitate radiopacity of angio and positioning, the stent is centered between two radiopaque markers. The proximal shaft of the stent system is a hypo-tube. It has a single luer port for connecting a device to inflate/deflate the balloon, allowing it to be connected to standard inflation device. The guide wire lumen starts at the delivery system tip and ends at the guide wire exit point, 28cm from the distal end. The stent delivery system is compatible with guide wires of 0.014" (0.36mm) diameter and guiding catheters with an inner diameter of 20.056" (1.42mm). To indicate when the delivery system tip exits from the guiding catheter, the markers are located on the hypo-tube 90cm (brachial technique) and 100cm (femoral technique) from the distal end of the delivery system.

B How supplied

Device is sterilized with ethylene oxide. DO NOT use if the package is opened or damaged, or if any information provided is obscured or damaged.

C Contents

- One (1) GENOSS BMS Bare Metal Coronary Stent in a sealed, peel-open pouch.
- One (1) Instructions for Use Manual.
- One (1) Compliance Chart.

D Storage

Store in the Tyvek pouch at room temperature (1°C to 30°C) in a cool, dry, and dark place.

E Indication

The GENOSS BMS Bare Metal Coronary Stent is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to de novo or restenotic lesions with reference vessel diameters of 2.00–5.00 mm and ≤28 mm in length using direct stenting or predilatation

F Contraindications

The GENOSS BMS Bare Metal Coronary Stent is contraindicated for use in patients with:
- Patient with allergic of hypersensitive reactions about contrast medium, Co-Cr, Nikel, and Molybden
- Contraindicated patient for antiplatelet and anticoagulant:
- Patient with inhibit about compete inflation of PTCA balloon or lesions that impede the proper procedure of stent delivery system

G Warning

- This device carries an associated risk of subacute thrombosis, vascular complications and/or bleeding events. Therefore, patients should be carefully selected (see Section: Patient Selection. Individualization of Treatment.)
- This device is designed and intended for single use only. DO NOT re-sterilize and/or reuse. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure. GENOSS will not be responsible for any direct, incidental or consequential damages resulting from re-sterilization or reuse.
- DO NOT use the stent system if the outer package or inner package is damaged or opened, or any information provided is obscured.
- DO NOT use device after the "Use by" date indicated on the label.
- DO NOT attempt to remove or readjust the stent on the delivery system as it may damage the stent, polymer system and/or lead to stent embolization. The stent cannot be removed and placed on another balloon catheter.
- Administration of appropriate anticoagulant, antiplatelet and vasodilatation therapy is critical to successful stent implantation.
- When the stent system is in the body it should be manipulated while under high quality fluoroscopy.
- When multiple stents are required to treat the lesion, stents should be similar composition as the risk of corrosion increases when stents of differing metals contact one another.
- The use of GENOSS BMS Bare Metal Coronary Stent in patients with chronic total occlusions or in patients with poor flow distal to the identified lesion is not recommended.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should NOT exceed the original diameter of the vessel proximal and distal to the lesion.
- Balloon pressure should not exceed the Rated Burst Pressure. Use of a pressure-monitoring inflation/deflation device is mandatory to prevent over-pressurization.
- Use only an appropriate balloon inflation medium (e.g. 50:50 mixture by volume of contrast medium and saline.) NEVER use air or any gaseous medium to inflate the balloon.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcomes following repeat dilatation of endothelialized stents are unknown.

H Precautions

General precautions:
- Prior to procedure, the stent system should be visually examined to verify functionality and ensure that its size is suitable for the specific procedure which it is to be used.
- Only physicians thoroughly trained and experienced in the performance of PCTA and stent implantation should use this device.
- PTCA and stent implantation should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed in the event of a potential injury or life-threatening complication.
- If the GENOSS BMS Bare Metal Coronary Stent was removed prior to expansion, DO NOT RE-INSERT the GENOSS BMS Bare Metal Coronary Stent as the stent and/or the delivery system may have been damaged during the initial attempt to cross the lesion or during withdrawal.

Pre-and Post-Procedure Antiplatelet Therapy Recommendations:
- Antiplatelet/anticoagulation medication should be used in combination with GENOSS BMS.
- Physicians should consider the information from the current Bare-metal stent literature and the current ACC/AHA guideline recommendations on PCI concerning the selection, dosage, duration and combination of different antithrombotic drugs. Specific needs and the risk profile of individual patients may influence the antiplatelet/anticoagulation regime to be used.
- In the recently Clinical Trial, dual antiplatelet therapy (DAPT) with aspirin and a p2Y12 inhibitor was administration prior to the index procedure and then continued for at least 12 months. The protocol highly recommended continuing DAPT for 12 months in subjects who were not at a high risk of bleeding. Aspirin was recommended to be continued indefinitely to reduce the risk of thrombosis.
- The optimal duration of antiplatelet therapy, specifically p2Y12 inhibitor therapy, is unknown and BMS thrombosis may still occur despite continued therapy. Provided herein are recent recommendations for post-procedural antiplatelet therapy from the 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients With Coronary Artery Disease; see the "Oral Antiplatelet Therapy" section below. Also refer to the "Warnings" and "Clinical Studies" sections for more information on DAPT usage.

Oral Antiplatelet Therapy
- Dual antiplatelet therapy (DAPT) using a combination treatment of aspirin with a p2Y12 platelet inhibitor after percutaneous coronary intervention (PCI) reduces the risk of stent thrombosis and ischemic cardiac events but increases the risk of bleeding complications. The optimal duration of DAPT (specifically, a p2Y12 platelet inhibitor in addition to aspirin) following BMS implantation is unknown, and BMS thrombosis may still occur despite continued therapy. It is very important that the patient is compliant with the post-procedural antiplatelet recommendations.
- Per 2016 ACC/AHA guidelines 1, a daily aspirin dose of 81 mg is recommended indefinitely after PCI. A p2Y12 platelet inhibitor should be given daily for at least 6 months in stable ischemic heart disease patients and for at least 12 months in patients with acute coronary syndrome (ACS).
- Consistent with the DAPT Study2 and the 2016 ACC/AHA guidelines, longer duration of DAPT may be considered in patients at higher ischemic risk with lower bleeding risk.
- In patients at higher risk of bleeding, DAPT discontinuation may be reasonable after 3 months in stable patients or 6 months in ACS patients.
- Decisions about duration of DAPT are best made on an individual basis and should integrate clinical judgment, assessment of the benefit/risk ratio, and patient preference.
- Premature discontinuation or interruption of prescribed antiplatelet medication could result in a higher risk of stent thrombosis, MI or death.
- Prior to PCI, if premature discontinuation of antiplatelet therapy is anticipated, physicians should carefully evaluate with the patient whether a BMS and its physicians should carefully evaluate with the patient whether a BMS and is associated recommended DAPT regimen is the appropriate PCI choice.
- Following PCI, if elective non-cardiac surgery requiring suspension of antiplatelet therapy is considered, the risks and benefits of the procedure should be weighed against the possible risk associated with interruption of antiplatelet therapy.
- Patients who require premature DAPT discontinuation should be carefully monitored for cardiac events. At the discretion of the patient's treating physician(s), the antiplatelet therapy should be restarted as soon as possible.
- Exercise care during device handling to reduce the possibility of disrupting the delicate placement of the stent on the balloon and accidental breakage, bending, kinking of the stent system shaft. Special care must be taken not to handle or in any way disrupt the polymer from packaging, placement over guide wire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Take care when removing the stent system from the spiral packaging, as forceful movements may dislocate the protector and the stent.
- When removing the stent protector, always pull at the very distal end of the protector to avoid dislocation of the stent. DO NOT touch the part of the protector over the stent.
- Avoid excessive manipulation of the stent during flushing of the guide wire lumen. Special care must be taken not to handle or in any way disrupt the stent coating and the stent itself on the balloon. Manipulation, e.g. rolling the mounted stent with your fingers, may loosen the stent from the delivery system balloon and cause dislodgement. Should there be movement of or damage to the stent, DO NOT use.

Stent Placement precautions
- The GENOSS BMS is recommended to use a maximum number of 2 stents to be implanted in single procedure.
- DO NOT apply negative pressure to the stent system at any time prior to placement of the stent across the target lesion. This may cause premature dislodgment of the stent.
- Use only guide wires with a diameter of 0.014" (0.36mm).
- Use guiding catheters with a minimum inner diameter of ≥ 0.056" (1.42mm).

Handling precautions
- Exercise care during device handling to reduce the possibility of disrupting the delicate placement of the stent on the balloon and accidental breakage, bending, kinking of the stent system shaft. Special care must be taken not to handle or in any way disrupt the polymer from packaging, placement over guide wire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Take care when removing the stent system from the spiral packaging, as forceful movements may dislocate the protector and the stent.
- When removing the stent protector, always pull at the very distal end of the protector to avoid dislocation of the stent. DO NOT touch the part of the protector over the stent.
- Avoid excessive manipulation of the stent during flushing of the guide wire lumen. Special care must be taken not to handle or in any way disrupt the stent coating and the stent itself on the balloon. Manipulation, e.g. rolling the mounted stent with your fingers, may loosen the stent from the delivery system balloon and cause dislodgement. Should there be movement of or damage to the stent, DO NOT use.

Stent Placement precautions
- The GENOSS BMS is recommended to use a maximum number of 2 stents to be implanted in single procedure.
- DO NOT apply negative pressure to the stent system at any time prior to placement of the stent across the target lesion. This may cause premature dislodgment of the stent.
- Use only guide wires with a diameter of 0.014" (0.36mm).
- Use guiding catheters with a minimum inner diameter of ≥ 0.056" (1.42mm).

Stent Placement precautions
- The GENOSS BMS is recommended to use a maximum number of 2 stents to be implanted in single procedure.
- DO NOT apply negative pressure to the stent system at any time prior to placement of the stent across the target lesion. This may cause premature dislodgment of the stent.
- Use only guide wires with a diameter of 0.014" (0.36mm).
- Use guiding catheters with a minimum inner diameter of ≥ 0.056" (1.42mm).
- When inserting and positioning the stent system, ensure that the hemostatic rotating valve of the guiding catheter is fully open. A partially opened hemostatic rotating valve might damage the stent or dislodge it from the centered location on the balloon.
- If any resistance is felt at any time during lesion access, DO NOT force the passage, stop the procedure and determine the cause of resistance before proceeding. If the stent system is unable to reach the lesion easily, the procedure should be aborted. In this case, refer to the instructions for "Removal of an unexpanded stent"
- During the procedure, make sure that the guide wire exit port of the delivery system, 29cm from the distal tip of the delivery system, remains in the guiding catheter.
- An unexpanded stent should not be subsequently moved in and out through the distal end of the guiding catheter as stent damage or stent dislodgement from the balloon may occur.
- DO NOT apply excessive force while attempting to cross the lesion. This may damage the stent and/or dislodge it from the dilatation balloon. If the stent system is unable to cross the lesion easily the unexpanded stent system should be removed according to the instructions. In this case, refer to the instructions for "Removal of an unexpanded stent.
- DO NOT inflate the balloon if vacuum cannot be held, as this indicates a leak in the delivery system. If a vacuum cannot be held, follow the instructions for the "Removal of an unexpanded stent"
- Avoid barotrauma outside the stent margins during post-dilatation. Placement of the stent has the potential to compromise side branch patency.
- Implanting stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g. CABG, further dilatation or placement of additional stents)
- DO NOT post-dilate the stent to more than the maximum expanded diameter recommended in the table "Available sizes."
- Additional expansion of a deployed stent may cause a flow limiting dissection. This may be treated by implantation of another stent. When multiple stents are implanted, the ends should overlap slightly.
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. 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.
- 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 can include bleeding, hematoma or pseudoaneurysm.
- The use of brachytherapy treatment, mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters to treat in-stent restenosis of a GENOSS BMS Bare Metal Coronary Stent is not recommended.

Stent/Delivery System Removal precautions
- Should unusual resistance be felt at any time during either lesion access, crossing the lesion or removal of the delivery system (pre-or post-implantation), the stent system/delivery system must be removed as directed either in "Removal of an unexpanded stent" or in "Removal of the stent system delivery system and the guiding catheter as a single unit" sections below.
- Failure to follow correct removal steps for the delivery system or for an unexpanded stent system and/or applying excessive force to the stent system can potentially result in loss or damage to the stent and/or delivery system components.

Post-implant precautions
- Exercise care when crossing a newly deployed stent with an intravascular ultrasound (IVUS) catheter, a coronary guide wire, a balloon catheter or any other device to avoid disrupting the stent placement, apposition, stent geometry of the GENOSS BMS Bare Metal Coronary Stent.

I Potential Adverse Events / Complications

Possible adverse events associated with PTCA and stent placement include, but are not limited to
- Cardiac events: Myocardial infarction or ischemia, abrupt closure of coronary artery, restenosis of treated artery (greater than 50% obstruction), cardiogenic shock, angina, tamponade, perforation or dissection of coronary artery or aorta, cardiac perforation, emergency cardiac surgery, pericardial effusion, aneurysm formation.
- Arrhythmic events: Ventricular tachycardia, ventricular fibrillation, atrial fibrillation, bradycardia.
- Stent system events: Failure to deliver stent to intended site, stent dislodgement from the delivery system, stent misplacement, stent deformation, stent embolization, stent thrombosis or occlusion, stent fracture, stent migration, inadequate apposition or compression of stent/s, inflation difficulties, rupture or pinhole of the delivery system balloon, deflation difficulties, withdrawal difficulties, embolization of catheter material.
- Respiratory events: Acute pulmonary edema, congestive heart failure, respiratory insufficiency or failure.
- Vascular events: Access site hematoma, hypotension/hypertension, pseudoaneurysm, arteriovenous fistula formation, retro-peritoneal hematoma, vessel dissection or perforation, restenosis, thrombosis or occlusion, vasospasm, peripheral ischemia, dissection, distal embolization (air, tissue debris, thrombus).
- Neurologic events: Permanent (stroke) or reversible (TIA) neurologic event, femoral I nerve injury, peripheral nerve injury.
- Bleeding events: Access site bleeding or hemorrhage, hemorrhage requiring transfusion or other treatment.
- Death

J Patient Selection. Individualization of Treatment

Judicious selection of patients according to the intended use is necessary since the use of this device carries the associated risks of complications listed in Potential Adverse Events/Complications section. The risks and benefit should be considered for each patient before use of the GENOSS BMS Bare Metal Coronary Stent.
Patient selection factors to be assessed should include a judgment regarding risk of long-term antiplatelet therapy. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease and patients with high risk of bleeding in which anticoagulation therapy would be contraindicated. Antiplatelet drugs should be used in combination with GENOSS BMS Bare Metal Coronary Stent. Physician should use the information from the current drug eluting stent literature and specific antiplatelet/anticoagulation regime to be used for their patients in general practice.
It is very important that the patient is compliant with the post procedure antiplatelet recommendation. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, myocardial infarction or death. Prior to PCI, if a surgical or dental procedure is anticipated that requires early discontinuation of antiplatelet therapy, the interventionalist and patient should carefully consider whether a Bare Metal Coronary Stent and its associated recommended antiplatelet therapy is the appropriate PCI choice. Following PCI, should a surgical or dental procedure be recommended, the risk and benefits of the procedure should be weighed against the possible risk associated with premature discontinuation of antiplatelet therapy.
Patients who require premature discontinuation of antiplatelet therapy secondary to significant bleeding, should be monitored carefully for cardiac events and, once stabilized, have their antiplatelet therapy restarted as soon as possible per the discretion of their treating physicians. Premorbid conditions that increase the risk of poor initial result or the risk of emergency referral for bypass surgery (diabetes, renal failure, and severe obesity) should be reviewed, a review of the vessel location, reference vessel size, lesion length, qualitative target lesion characteristics, and the amount of myocardium in jeopardy from acute or subacute thrombosis must also be considered.
Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3mm, intra-procedural thrombus and dissection following stent implantation. In patients who have undergone coronary stenting, the persistence of thrombus or dissection should be considered a marker for subsequent thrombotic occlusion. Following PCI, the patients should be monitored very carefully during the first month after stent implantation.

K Magnetic Resonance Imaging (MRI) Safety Information

Non-Clinical testing has demonstrated that the GENOSS BMS Bare Metal Coronary Stent is MR Conditional for single and overlapped conditions up to 71mm. A patient with this device can be scanned in a Magnetic Resonance system meeting the following conditions:
- Static magnetic field of 1.5T MRI, only
- Maximum spatial gradient magnetic field of 1,700 Guass/cm(extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate(SAR) or 2 W/k

Under the scan conditions defined above, GENOSS BMS Bare Metal Coronary Stent rises maximum temperature rise of 2.55°C under 1.5T, and 2.7°C under 3.0T for 15 min of continuous scanning

Image Artifact Information
Under T1 SE and GRE pulse sequence, GENOSS BMS Bare Metal Coronary Stent extended maximum 5mm artifact size compared to its original shape.

Medical Registration
It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

L Direction for use

Delivery device preparation
1) Prepare the guiding catheter and guide wire according to the instructions of the manufacturer.
2) The inner distal lumen of the GENOSS BMS permits the use of guide wires of diameters 0.36mm (0.014").
3) Especially, refer the product label and 'The apparatus before use' of item about the suitability of guiding catheter.
4) The stent size is important to transplant.
5) Select stent of appropriate length for transplant portion.
6) Selected stent should be long enough to cover for transplant portion.
Note: Inflated balloon diameter measure slightly larger than labeled stent inner diameter as the expansion considering stent recoil.
7) Gently pull out the stent delivery system from the package.
8) Place onto the thumb and forefinger at the distal end of sheath and remove protective cover that covers the stent/balloon carefully.
9) Watch stent in detail to check that stent on the balloon was not damaged, moved from its original position.
10) Check the position whether the stent is located between proximal and distal balloon marker or not.
Note: Do not use if the stent was moved or damaged.
11) Flow heparin treated saline to the guide wire lumen of stent delivery system until the liquid be come out.
12) Fill in the contrast/heparin treated saline (1:1) 5cc to 20cc syringe.
13) Attach the syringe to delivery system and add negative pressure during 20~30 seconds.
14) Add negative pressure slowly to shed mixed liquid into the balloon lumen.
15) Separate the syringe and leave the meniscus of liquid in the center of the balloon lumen.
16) Prepare inflator as standard method and remove any remaining air from the syringe and tube.
17) Attach inflator to catheter directly for preventing air bubbles remain.
18) Place on atmospheric pressure. (Neutral)
Note: Do not add negative pressure to the inflator after balloon prepared and before stent delivered.

Stent Delivery method
1) Approach to blood vessel in accordance with PTCA techniques.
2) Balloon diameter is 0.5mm smaller than stent and pre-inflate length of damaged portion equal to or shorter balloon at damaged portion.
The length of inflated balloon should be shorter than transplanted stent.
3) Maintain neutral pressure to inflator.
4) Open rotational hemostasis valve to easy the passage of the stent.
Note: Do not pass to force if there is resist. Resistance will be appeared problems, and the stent or blood vessel can be damaged if you try to force. In this case, remove the system and then examine.
5) Check the safety of guiding catheter before stent delivery system was attached into the coronary artery.
6) Push the stent delivery system into the center of the catheter carefully.
Note: Do not pass to force if there is resist before remove guiding catheter.
Resistance will be appeared problems, and the stent or blood vessel can be damaged if you try to force. In this case, maintain guide wire hold at the damaged portion and remove stent delivery system as one unit.
7) Put the delivery system to be transplanted target under direct fluoroscopic visualization.
8) Use radiopaque marker of proximal and distal of balloon for the point.
9) If the location of the stent is not selective, it should be relocated or removed.
10) Do not inflate stent if the stent is not located accordingly at target point.
11) Tighten the rotational hemostasis valve.
12) Prepare the stent exchange.

(atm)	(Mpa)	Balloon diameter (mm)									
		2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
9(NP)	0.91	2.02 (NP)	2.23 (NP)	2.49 (NP)	2.68 (NP)	2.99 (NP)	3.19 (NP)	3.48 (NP)	3.68	3.89	4.38	4.90
10	1.01	2.04	2.25	2.51	2.71	3.03	3.21	3.55	3.72 (NP)	3.95 (NP)	4.50 (NP)	5.00 (NP)
11	1.11	2.08	2.27	2.54	2.75	3.06	3.24	3.59	3.76	3.98	4.55	5.06
12	1.22	2.11	2.29	2.57	2.79	3.09	3.28	3.63	3.82	4.04	4.60	5.11
13	1.32	2.15	2.32	2.6	2.82	3.13	3.31	3.67	3.86	4.06	4.64	5.17
14	1.42	2.17	2.35	2.64	2.85	3.18	3.34	3.71	3.88 (RBP)	4.09 (RBP)	4.69 (RBP)	5.23 (RBP)
15	1.52	2.20	2.39	2.67	2.88	3.22	3.38	3.74	3.92	4.12	4.74	5.28
16(RBP)	1.62	2.23 (RBP)	2.43 (RBP)	2.70 (RBP)	2.92 (RBP)	3.26 (RBP)	3.43 (RBP)	3.78 (RBP)	3.96	4.18	4.79	5.33

Exchange procedure of stent
1) Use high resolution fluoroscopy to check the stent has not been moved during be damaged or be exchanged before the stent inflated.
2) Maintain inflating pressure for enough inflation of the stent during 15~30 seconds.
3) Do not exceed Rated Burst Pressure when inflated.
4) GENOSS stent should not be inflated over 0.5mm diameter of nominal expansion.
Note: Usage of high pressure about balloon inflation at small blood vessel or lesion widely spreaded blood vessel will be expanded peripheral vascular portion and can be vascular dissection at stent.
Note: The stent can be moved during the expansion of stent. Stent should be selected appropriate size to safe artery walls that completely touch when the stent deflate the balloon.

Exchange procedure of balloon
1) Deflate the balloon as adding negative pressure to inflator. Wait proper time like at least 15 seconds to deflate the balloon.
2) The long stent takes longer time to deflate.
The thing that balloon is deflated make sure that no contrast in the balloon.
3) Open the hemostasis valve to remove delivery system.
4) Maintain location of guiding catheter and wire to block flow of internal blood vessel.
5) Pull on the balloon by keeping the stent negative pressure and by watching motion of the cardiac muscle to remove balloon from stent very slowly.
6) Tighten the hemostasis valve after removing delivery system.
7) Repeat angiography and observe blood vessel and stent about proper inflation with the naked eye.
Note: If you need a second stent transplantation enough to cover wound length, Stent should be transplanted the most distant location from artery before transplantation as soon as possible.
8) Follow-up of patient and angiography evaluation of the stent location should be performed within the first 30minutes periodically after transplanting.
9) If stent transplantation is related to occur of thrombosis or suspected about thrombosis at the located stent, It is recommended injection into the coronary artery of thrombolytic.

Removal tips of stent/delivery system
1) If the removal of the stent system is needed, the guiding catheter is determine location about stent delivery system and remove stent delivery system into guiding catheter carefully.
2) If you feel unusual resistance during remove stent to guiding catheter, remove the entire system at once, i.e., the stent delivery system and guiding catheter.
3) This should be performed checking with the naked eye under fluoroscopy.
4) Note the following when the stent delivery system and guiding catheter are removed as one unit.
-Do not pull the stent delivery system into the guiding catheter.
-Maintain the guide wire position until adjacent balloon marker of the stent delivery system is combined the distal of the guiding catheter.
-The system should be pulled toward arterial sheath to descending aorta.
- According to transfer the end of guiding catheter within arterial sheath, the catheter will be flat straightly while safe removal of the stent delivery system from arterial sheath and sequential removal of the stent delivery system and guiding catheter.
-According to these orders, damage of the stent delivery system such as stent or balloon can be reduced when failed or added excessive force.

M Warranty / Liability

The product and each component of its system (hereinafter "the product") have been designed, manufactured, tested and packaged with all reasonable care. However, GENOSS has no control over the conditions under which the product is used and a disturbance of the intended function of the product may occur for various reasons. In this respect, the warnings in this product publication/instruction for use are expressly to be considered as an integral part of this Disclaimer and provide more detailed information. For this reason, GENOSS disclaims all warranties, expressed or implied regarding the product, including but not limited to, any warranty of merchantability or fitness for a particular purpose of the product. Product descriptions or user guidelines in publications do not constitute any expressed representation or any expressed or implied warranty. GENOSS is not liable for any direct, incidental or consequential damages or medical expenses caused by any use, defect, failure or malfunction of the product whether the claim is based on contract, warranty, tort or otherwise. This does not apply in the case of intention or in the case of gross negligence of legal representatives or executive staff of GENOSS. In commercial transactions relating to merchants, the liability is limited to the compensation of typical damages; compensation for any untypical or incidental damage is excluded.
These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable in the respective country. If any clause of the Disclaimer is considered by a competent court to be invalid or to be in conflict with the applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects GENOSS's legitimate interest in limiting its liability or warranty without infringing any mandatory provisions of applicable law. No person has any authority to bind GENOSS to any warranty or liability regarding the product.

N Shelf life

3 years from the manufacturing date.

O Number of uses

This product is a disposable medical device, so it should not be reused or re-sterilized, and should be discarded according to the regulations after use.

P Product

Inflation Diameter (mm)	Stent length (mm)				
	08	13	18	23	28
2.00	GBMS-08-200	GBMS-13-200	GBMS-18-200	GBMS-23-200	GBMS-28-200
2.25	GBMS-08-225	GBMS-13-225	GBMS-18-225	GBMS-23-225	GBMS-28-225
2.50	GBMS-08-250	GBMS-13-250	GBMS-18-250	GBMS-23-250	GBMS-28-250
2.75	GBMS-08-275	GBMS-13-275	GBMS-18-275	GBMS-23-275	GBMS-28-275
3.00	GBMS-08-300	GBMS-13-300	GBMS-18-300	GBMS-23-300	GBMS-28-300
3.25	GBMS-08-325	GBMS-13-325	GBMS-18-325	GBMS-23-325	GBMS-28-325
3.50	GBMS-08-350	GBMS-13-350	GBMS-18-350	GBMS-23-350	GBMS-28-350
3.75	GBMS-08-375	GBMS-13-375	GBMS-18-375	GBMS-23-375	GBMS-28-375
4.00	GBMS-08-400	GBMS-13-400	GBMS-18-400	GBMS-23-400	GBMS-28-400
4.50	GBMS-08-450	GBMS-13-450	GBMS-18-450	GBMS-23-450	GBMS-28-450
5.00	GBMS-08-500	GBMS-13-500	GBMS-18-500	GBMS-23-500	GBMS-28-500

Q Symbols

- Manufacturer
- Date of manufacture
- Use by date
- LOT Batch code
- REF Catalogue number
- STERILE EO Sterilized using ethylene oxide
- Single Sterile barrier system with protective packaging outside
- Unique device identifier
- Do not use if package is damaged
- Keep away from sunlight
- Keep dry
- Temperature limit
- Do not re-use
- Consult instructions for use
- Caution
- MD Medical device
- UDI Unique device identifier

GENOSS Co., Ltd.
Manufacturer GENOSS Co., Ltd.
Head Office: 12F, 76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea
Part of the 1F, Gyeonggi R&DB Center, 105, Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea,
Part of the 14F, 76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea
Tel. +82-31-888-5100 www.genoss.com

MS-P3713/IFU-S0502(Rev.1,2602)