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LIMITLESS POSSIBILITIES

Vivo ISAR

Polymer Free Sirolimus Eluting Coronary Stent System

Instructions for Use

Manufacturing Facility

Translumina Therapeutics LLP
Plot No. #12, Pharmacity, Selaqui, Dehradun 248 011
Uttarakhand, India.
Phone:+ 91 135 2699944, +91 1352699795
Fax: + 91 135 2699944, +91 1352699795
Email: info@translumina.in
Web: www.translumina.in

Registered Office

Translumina Therapeutics LLP
Ground Floor Metro Tower, LSC
MOR Land, New Rajender Nagar.
New Delhi-110060, India
Customer Care No.: +91 11 2874 2874
Email: info@translumina.in
Web: www.translumina.in

EC REP

CMC Medical Devices & Drugs S.L.,
C/HoracioLengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054, Fax: +34952330100
Email: mmateos@cmcmedicaldevices.com, Web: www.cmcmedicaldevices.com

CE 1434

DOC.NO.: VISR.IFU.11-21.Rev.05

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1. **Product Description:**

   The Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System consist of a Cobalt Chromium stent mounted on a stent delivery system.The stent is coated with a formulation of Sirolimus drug in a polymer free delivery matrix of hydrophobic carrier Probucol and Shellac Resin.

2. **Contents of Sterile Package**

   1 nos. Polymer Free Sirolimus Eluting Coronary Stent System consisting of a Cobalt Chromium (L605) Coronary stent mounted on a Stent Delivery System

3. **General Description of Medical Device**

   The Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent is a precision Laser cut mesh made of medical grade metal alloy – L605 (Cobalt Chromium). The Stent is crimped on a Balloon expandable delivery system. The Vivo ISAR Stent System is coated with a Sirolimus matrix, which consists of equal share (1:1) of Sirolimus drug and hydrophobic carrier – Probucol. The Drug loading is nominal 2.6 µg/mm^2 with maximum drug load of 600 µg on a 4.00 x 48 mm stent. The Drug coated stent is pre-mounted on a stent delivery system (Balloon catheter) which has two radiopaque markers for accurate positioning under fluoroscopy. The Vivo ISAR Polymer Free Sirolimus Eluting Stent is delivered by inflation of balloon and stent is expanded into the vascular wall at target lesion in coronary artery. The Medical device acts as a scaffold and is a permanent implant. The target lesion should be properly prepared before the implantation of stent by means of a suitably sized balloon dilatation catheter. After implantation, neointimal growth and reendothelialization occurs at the implantation site.

   The Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System is available in lengths of 8 mm to 48 mm and in diameters of 2.00 mm to 4.00 mm. The Medical Device is sterilized with Ethylene Oxide Gas and is intended for single use only.

   Remarks: Re-use of single use device can create a potential risk for the user which may lead to injury, illness or death of the Patient. It may lead to contamination and/or compromise on functional capability as per its performance characteristics.

Device Component Description

Available Stent Lengths (mm)	8, 12, 16, 18, 21, 24, 28, 32, 36, 40, 44, 48 mm
Available Stent Diameters (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00 mm
Stent Material	L 605 Cobalt Chromium Alloy stent
Strut Thickness (µm)	Small Vessel – 68 µm, Medium vessel – 79 µm
Strut width (µm)	Small Vessel – 88 µm, Medium vessel – 98 µm
Stent Surface	Sandblasted Microporous Surface
Delivery System Length (mm)	143 cm (1430 mm) ± 5 cm
Stent Delivery System (SDS)	The Stent delivery system is a rapid exchange catheter with a balloon located at the distal tip. The distal shaft comprises of two lumens, one is used for inflation of the balloon and the other permits the use of a guide wire to enable advancement of the catheter to and through the stenosis to be stented. The balloon provides an expandable segment of known diameter at specific pressure. The proximal shaft is made of a stainless steel hypotube. Proximal visual markers located approximately 90 cm to 100 cm from the distal tip aid catheter positioning without fluoroscopy assistance
Stent Delivery Balloon	A semi-compliant polyamide Balloon, nominally about 1 mm longer than the stent with two platinum iridium radiopaque marker located in the catheter shaft to indicate balloon positioning and expanded stent length.
Balloon Inflation Pressure	Nominal Inflation Pressure: 11 ATM / 11.15 Bar Rated Burst Pressure: 16 ATM / 16.21 Bar
Guiding Catheter Diameter (min)	Minimum 5 French (1.67mm)
Guide Wire Compatibility (max)	0.014" (0.36 mm)
Catheter Shaft Outer Diameter	Proximally: 1.9 French (0.825mm) Distally: 2.7 French (0.594mm)

Drug Component Description:

Active pharmaceutical ingredient (API): Sirolimus Drug

Sirolimus is a macrocyclic lactone produced by Streptomyces hygroscopius.

Appearance: white to off-white powder.

Solubility: Freely soluble in chloroform, acetone and acetonitrile and insoluble in water

Molecular Formula: $C_{51}H_{79}NO_{13}$

Molecular Weight: 914.2

CAS Registry no.; 53123-88-9

Chemical name: (3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)-

9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-hexadecahydro-9,27-dihydroxy-3-[(1R)-2-

[(1S,3R, 4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy-6,8,12,14,20,26-

hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4] oxaazacyclohentriacontine-1,5,11,28,29(4H,6H,31H) -pentone.

Sirolimus is an immunosuppressive agent. Sirolimus inhibits T-lymphocyte activation and proliferation that occurs in response to antigenic and cytokine (Interleukin [IL]-2, IL-4, and IL-15) stimulation by a mechanism that is distinct from that of other

immunosuppressants. In cells, sirolimus binds to the immunophilin, FK Binding Protein-12 (FKBP-12), to generate an immunosuppressive complex. This complex binds to and inhibits the activation of the mammalian Target of Rapamycin (mTOR), a key regulatory kinase. This inhibition suppresses cytokine-driven T-cell proliferation, inhibiting the progression from the G1 to the S phase of the cell cycle. The sirolimus is intended to reduce restenosis as ancillary medicinal substance to coronary intervention using the Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System.

Balloon Delivery Catheter:

The delivery catheter is a high pressure, semi-compliant balloon delivery catheter that has two radiopaque markers, which fluoroscopically mark the ends of the stent to facilitate proper stent placement. The Nominal pressure for inflation is 11 ATM and Rated Burst Pressure is 16 ATM.

The active balloon length is closely sized to the length of the stent to prevent over-expansion of the tissue proximal or distal to the stent.

At the proximal end of the system is a female luer lock connector hub. This hub connects to the balloon inflation lumen. The guide wire enters the distal tip of the catheter and exits 25 cm proximal to the tip. The surface of catheter is partially coated with hydrophilic polymer coating which generates lubricity when wet.

Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System has a coating consisting of single layer. The Drug coating and drug carrier matrix is expected to degrade within 30 days for release. The drug coating is applied abluminal, leaving the luminal side of the stent free from drug as such enhancing endothelial coverage.

4. Individualization of Treatment

The risks and benefits of Sirolimus-eluting stent should be considered for each patient before (using) implanting Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System. Physicians are responsible for assessing patient appropriateness for undergoing stent implantation prior to procedure. When establishing patient exclusion criteria, the risk associated with antiplatelet therapy should be taken into consideration.

Special consideration is required to be taken for patients with recent active gastritis, peptic ulcer disease, hemorrhagic diathesis or other disease conditions such gastro-intestinal ulceration or cerebral circulatory disorders which restrict use of platelet aggregation inhibition therapy and anti-coagulant therapy. Judicious selection of patients is necessary since Percutaneous Coronary Intervention with the use of stents carries the risk of stent thrombosis, vascular complications and/or bleeding events. The occurrence of thrombosis after stent implantation is influenced by various anatomical and procedure dependent factors. These include small vessel diameter, complex vessel anatomy, intro-procedural thrombosis and dissection after stent implantation. Continued presence of thrombosis or dissection should be treated as a sign of subsequent thrombotic occlusion and should be closely monitored for the first month after treatment. Patients should be maintained on clinically adequate post-procedural antiplatelet therapy (aspirin and thienopyridine, or appropriate antiplatelet agents).

5. Intended Use:

Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System is intended for use in treatment of:

- Symptomatic coronary artery disease due to discrete de novo or restenosis lesion in native coronary artery.
- Symptomatic coronary artery disease due to culprit lesion in saphenous vein graft.
- Coronary lesion in patients undergoing primary or rescue PCI for acute ST segment elevation myocardial infraction (STEMI)
- Coronary lesion having athero thrombotic appearance in patients with non-ST-elevation acute coronary syndromes (unstable angina and non-ST-segment elevation myocardial infraction).

6. Indications of Use:

The Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter and reducing restenosis for treatment of coronary artery lesions in native coronary arteries ranging from 2.00 to 4.00 mm. The safety and efficacy of Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System has been established for indicated use.

Remarks: Before implantation of Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System, the stent length and diameter should match the related vessel morphology of target lesion.

7. Contraindications:

Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System is contraindicated in following patient groups:

- Patients in whom anti-platelet and/or anti-coagulation therapy is contraindicated.
- Patients with lesions that possibly cannot be treated successfully with PTCA or stent implantation.
- Patients with known sensitivity to Sirolimus and its derivatives, the carrier Probucol and procedural co-medication.
- Patients with known allergy to components of L605 Alloy used for Stent (including major elements like Cobalt, Chromium, Nickel and Tungsten).
- Patients with known sensitivity to contrast agents.
- Patients who have heavily calcified lesion or such lesions that prevents complete inflation of an angioplasty balloon or proper placement of stent or delivery catheter.
- Patients with extreme vessel tortuosity that may impair stent placement.

Recommendations: It is strongly recommended not to implant Polymer Free Sirolimus Eluting Coronary Stent System in pregnant women. Effects of Sirolimus drug during lactation have not been evaluated, therefore it is strongly recommended

to avoid breast feeding when this stent is implanted.

8. Warnings

- Judicious selection of patients is necessary since Percutaneous Coronary Intervention with the use of stents carries the risk of stent thrombosis, vascular complications and/or bleeding events. Hence patients should be maintained on clinically adequate post-procedural antiplatelet therapy (Aspirin and Thienopyridine, or appropriate antiplatelet agents).
- Only physicians who have received appropriate training should perform stent implantation.
- Any advancement after introduction of the delivery catheter into the vessel should be done under high resolution fluoroscopy. When resistance is felt during manipulation, determine the cause of the resistance before proceeding.
- Proper judgment is necessary to select lesion for direct stenting since insufficiently prepared lesion may lead to stent dislodgement.
- Ensure that the aluminium pack and blister pouch have not been damaged or opened as this may compromise the stability and the sterile barrier.

Store the device at 25°C in the original package. The Device is packed in Aluminium Foil Pouch. After opening of Aluminium pouch, use the device within 12 hours. Do not store the device only in Tyvek pouch as it may affect the Device.

9. Precautions

9.1. General Precautions

- The device should only be used at medical facilities by physicians who are adequately trained and experienced in performing vascular interventions (including cases of life-threatening complications).
- The DES should only be considered for implantation in lesions which do not show any signs of severe narrowing after balloon dilation.
- This device carries an associated risk of thrombosis, vascular complications and/or bleeding events. Therefore, careful selection of patients is critical. The long-term effects of DES and the risks associated with these implants are unknown. The limited availability of long-term clinical data should be considered before making a risk/benefit assessment for the patient prior to implantation.
- Stent thrombosis is a low-frequency event that is frequently associated with myocardial infarction (MI) or death. The rate of stent thrombosis for DES does not differ significantly from expectations for a current generation DES.
- The patient's exposure to the drug and drug delivery matrix is directly related to the number of stents and the stent length implanted.
- Potential interactions of our system with other DES have not been evaluated and should be avoided whenever possible.

9.2. Stent Handling Precautions

- This device is designed and intended for single use only. Do not re-sterilize and/or re-use. Re-use 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.
- Do not use the stent system if the outer package and/or inner package are/is damaged or opened, or if any information provided is obscured or damaged. Ensure that the inner package has not been opened or damaged as this may indicate that the sterile barrier has been breached.
- Do not use device after the 'use by date' indicated on the label.
- Use the device immediately after opening Tyvek pouch.
- Entire operation of opening and using device should be done aseptically.
- Do not inflate or create vacuum in the Balloon catheter prematurely since it may lead to stent dislodgement.
- Do not attempt to remove or readjust the stent on the delivery system as it may damage the stent, drug coating system and/or lead to stent embolization. The stent must not be removed from its dedicated delivery system and placed on another balloon catheter.
- Do not expose and/or suspend the stent within any liquid solution on the sterile field prior to the preparation and the insertion as the drug carrier coating may be susceptible to damage or premature drug elution.
- Care should be taken that the stent or its coating is not damaged or affected and the stent does not dislodge from the balloon. Direct touching of stent or its contact with liquids should be strictly avoided, since this can cause negative effects on the stent coating.
- 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.
- If the stent system was removed prior to expansion, do not re-insert as the stent and/or the delivery system may have been damaged during the initial attempt to cross the lesion or during withdrawal (refer to the "**Special Retrieval Techniques**" section for instructions).
- If a balloon rupture occurs before a complete stent expansion is achieved, the defective balloon should be pulled back and the stent should be completely embedded in the vessel wall by the use of an additional balloon catheter.

- Use stents with a similar composition (metallic alloy) when multiple stents are required to treat the lesion as the risk of corrosion increases when stents of dissimilar metals contact one another.
- Do not attempt to straighten the proximal shaft (hypotube) as it may cause the catheter to break if it is accidentally bent.
- Manipulate the stent system under angiographic guidance when it is in the body.
- Do not exceed the original diameter of the vessel proximal and distal to the lesion when inflating the balloon to reduce the potential for vessel damage.
- Balloon pressure should not exceed the Rated Burst Pressure (RBP). Use of a pressure-monitoring device is mandatory to prevent over-pressurization of the Balloon.
- 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 as it may increase the risk associated with the procedure.
- Administration of appropriate anticoagulant, antiplatelet and vasodilation therapy is critical to successful stent implantation.
- Use of DES outside of the specified indications is prohibited. The use of DES in patients and lesions outside the labelled indications may have an increased risk of adverse events, including stent thrombosis, stent embolization, myocardial infarction (MI) or death.

9.3. Stent Placement Precautions

- Do not introduce negative pressure or pre-inflate delivery system prior to stent deployment other than as directed.
- Always select an appropriate size of the stent as an undersized stent may result in inadequate expansion of the lesion while an oversized stent may lead to inadequate expansion of the stent or damage to the vessel wall.
- Always verify whether the stent is well apposed against vessel wall because incomplete stent apposition may lead to stent thrombosis.
- When treating multiple lesions in the same vessel, stent the distal lesion prior to stenting the proximal lesion. Stenting in this order avoids crossing the proximal stent with the distal stent and reduces the chances for dislodgement.
- Do not expand the stent if it is not properly positioned in the vessel. (See **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 the device label. Use of pressure higher than specified may result in balloon rupture with possible intimal damage and dissection.
- If the stent system is unable to reach/cross the lesion easily, stop the procedure and follow the instructions listed under "**Removal of an Unexpanded Stent**" subsection.
- Do not apply negative pressure to the stent system at any time prior to the placement of the stent across the target lesion.
- Do not apply excessive force while attempting to cross the lesion. Do not force the passage if any resistance is felt at any time during lesion access.
- Determine the cause of resistance before proceeding. Do not attempt to move an unexpanded stent in and out through the distal end of the guiding catheter. Ensure that the rotating haemostatic valve of the guiding catheter is fully open when inserting and positioning the stent system.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion and could cause an acute closure of the vessel and require additional intervention (e.g. coronary artery bypass grafting, further dilation or placement of additional stents).
- An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged or dislocated. In case of stent dislodgement, 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.
- 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 listed under the "**Removal of an Unexpanded Stent**" subsection.
- Do not post-dilate the stent to more than the maximum expandable diameter.
- Avoid barotrauma outside the stent margins during post-dilation.
- Additional expansion of a deployed stent may cause a flow limiting dissection. This may be treated by implanting another stent. When multiple stents are implanted, the ends should overlap slightly.
- Complication may include bleeding, hematoma or pseudoaneurysm.

9.4. Stent / System Removal Precautions

Stent introduction into the coronary artery is limited to one time only as dislodgement may occur. Should unusual resistance be felt at any time during either lesion access or removal of the stent delivery system pre-stent implantation, carefully attempt to pull the stent delivery system back through the guiding catheter. If resistance is felt in doing so, or if resistance is felt during the removal of the stent delivery system post-stent deployment, the delivery system and guiding catheter must be removed as a single unit.Failure to follow these instructions may potentially result in loss 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 can include bleeding, hematoma or pseudoaneurysm.

9.5. Post-implantation Precautions

- Care must be exercised when crossing a newly deployed stent with a coronary guide wire, IVUS catheter, OCT catheter, balloon or other stent delivery system to avoid disruption of the stent geometry.
- Patients should be maintained on clinically adequate post-procedural antiplatelet therapy (Aspirin, Thienopyridine or other appropriate antiplatelet agents) according to the current guidelines. In case of need, dual antiplatelet therapy can be discontinued earlier, but not before one month.
- Magnetic Resonance Imaging (MRI)

Non-Clinical testing has demonstrated that the metallic platform of Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system is MR-conditional. They can be scanned safely, post implantation under following conditions:

- Static Magnetic field strength of 1.5and 3.0 Tesla
- Spatial Gradient field of 36T/m and less

An MRI scan should not be performed on a patient after stent implantation until there is adequate neointimal growth of the stent because of a potential for stent migration. For a conventional drug coated stent this period is usually considered to be eight weeks. Because of the reduced neointimal formation associated with the Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system, the period of vulnerability may be longer, but there is currently insufficient information to provide a specific recommendation.

9.6. Special Retrieval Techniques and Precautions

When removing the delivery system and guiding catheter 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.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating haemostatic valve to secure the delivery system to the guiding catheter, then remove the guiding catheter and deliverysystem as a single unit.
- Failure to follow these steps and/or applying excessive force to the delivery system can potentially result in stent dislodgement or damage to the stent and/or delivery system components.
- It is necessary to retain guide wire position for subsequent artery/lesion access, leave the guide wire in place and remove all other system components.

Removal of an Unexpanded Stent

- If removal of the stent system is required prior to deployment, ensure that the guiding catheter is coaxially positioned relative to the delivery system and avoid any acute angle between the floppy part of the delivery system and the guiding catheter.
- Slowly pull back the stent system into the guiding catheter. The entry of the stent into the guiding catheter must be performed slowly under fluoroscopic control to avoid dislodgement of the stent from its position on the delivery system balloon.
- Caution: If resistance is felt when pulling the stent system into the guiding catheter, remove the stent system and the guiding catheter as a single unit (proceed as directed).
- The lesion must be pre-dilated again or otherwise prepared before a second attempt at stenting is undertaken using a new stent system.

9.7. Use of Multiple Stents

- The patient's risk factors are related to exposure to Sirolimus, Probucol and are also related to the number of stents implanted. Use of more than two stents has not received adequate clinical evaluation. With use of more than two stents, the patient will receive larger amounts of drug than the experience and is reflected in the product testing.
- To avoid the possibility of dissimilar metal corrosion, do not implant stents of different materials in tandem where overlap or contact is possible. The possible interactions of Vivo ISAR Stent with other drug-eluting or coated stents have not been evaluated and should be avoided whenever possible.
- When placing more than one stent, it is recommended that the distal stent is placed first. If a further stent has to be placed distally, care must be taken to ensure that the guidewire is not positioned between the vascular wall and the stent.
- If additional Vivo ISAR stents are implanted, please make sure that a severe stent-end overlap is avoided. Overlapping stents may lead to a delayed re-endothelization.

9.8. Pre and Post Antiplatelet Therapy Recommendations

- Antiplatelet/anticoagulation medication should be used in combination with Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System.

- Physicians should consider the information from the current drug-eluting 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.
- Dual Antiplatelet Therapy (DAPT) with aspirin and a p2Y12 inhibitor administration is recommended prior to the index procedure and then continued for a minimum of 6 months. The DAPT protocol is highly recommended for continuing DAPT for 12 months in pateintswho are not at a high risk of bleeding. Aspirin is recommended to be continued indefinitely to reduce the risk of thrombosis.
- The optimal duration of antiplatelet therapy, specifically P2Y12 inhibitor therapy, is unknown and DES 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.

9.9. 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 DES implantation is unknown, and DES 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 guidelines1, 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 DES and its 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.

1 Levine GN, et al. 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients With Coronary Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2016; doi:10.1016/j.jacc.2016.03.513. For full text, please refer to the following website: http://content.onlinejacc.org/article.aspx?doi=10.1016/j.jacc.2016.03.513

2 Mauri L, et al. Twelve or 30 Months of Dual Antiplatelet Therapy After Drug-Eluting Stents. N Engl J Med. 2014;371:2155–66.

9.10. Brachytherapy

The safety and effectiveness of the Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System in patients with prior brachytherapy of the target lesion have not been established. The safety and effectiveness of use of brachytherapy to treat in-stent restenosis in Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System have not been established. Both vascular brachytherapy and Vivo ISAR stent alter arterial biology, and the combined vascular responses of these two treatments have not been determined.

10. Use in Conjunction with Other Procedures

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters in conjunction with Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System implantation have not been established.

11. Use in Special Population

11.1. Pregnancy

Pregnancy Category C: There are no adequate and well controlled studies in pregnant women or men intending to father children. Effective contraception should be initiated before implanting a Vivo ISAR stent and for 12 weeks after implantation. The Vivo ISAR Stent should be used during pregnancy only if the potential benefit outweighs the potential risk to the embryo or foetus.It is not possible to state the effects of Vivo ISAR on the unborn child. Tests have not been conducted with pregnant women or men who intend fatherhood. Contraindications and risks are unknown.

11.2. Lactation

A decision should be made whether to discontinue nursing prior to stent implantation, taking into account the importance of the stent to the mother.Sirolimus is excreted in trace amounts in milk of lactating rats. It is not known whether sirolimus is excreted in human milk. The pharmacokinetic and safety profiles of sirolimus in infants are not known. Because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants from sirolimus, a decision should be made whether to discontinue nursing or to implant the stent, taking into account the importance of the stent to the mother.

11.3. Paediatric Use

The safety and efficacy of the Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System in paediatric patients have not been established.

11.4. Geriatric Use:

Clinical studies of the Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System did not find that patients age 65Years and over differed with regard to safety and efficacy compared to younger patients.

11.5. Gender

Clinical evaluation studies of Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System did not find any significant differences in safety and effectiveness for male and female patients.

11.6. Ethnicity

Clinical studies have not been completed to study any differences in safety and effectiveness due to ethnicity, either by individual category or when grouped.

11.7. Non-Coronary Use

The safety and effectiveness of our product Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System has not been established in the cerebral, carotid or peripheral vasculature.

11.8. Lesion/Vessel Characteristics

The safety and effectiveness of the Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system have not been established in the following patient populations:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameter < 2.0 mm or >4.0 mm.
- Patients with lesions located in the in saphenous vein grafts, in the unprotected left main coronary artery system, ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease or poor overflow distal to the identified lesions.
- Patients with tortuous vessels in the region of the obstruction or proximal to the lesion.
- Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow.
- Patients with multi vessel disease.
- Patients with lesions longer than 48mm and requiring more than on Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system.
- Patients with chronic total occlusions
- Patients with in-stent restenotic lesions.

12. Directions for Use

12.1. Access to Package Holding Sterile Stent Delivery System

- Tear open outer foil pouch to reveal second inner pouch of Tyvek.
- Note: DO NOT drop or hand inner pouch into sterile field.
- Remove inner pouch from outer foil pouch.
- Peel open inner pouch using aseptic technique to reveal sterile package.
- Pass or drop the procedure into the sterile field using an aseptic technique.

12.2. Inspection Prior to Use

Prior to using the Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent is located between the radiopaque balloon markers. Do not use if there is any damage to the packaging.

12.3. Materials Required

Appropriate Guiding catheter(s) minimum size 5F

2-3Nos.	10-20 cc Syringes
1000µ/500cc	Sterile Heparinised Normal Saline (Hep NS)
1	0.014" x 175 cm (minimum length) Guidewire
1	Rotating Haemostatic valve with minimum 0.096" inner diameter
	Contrast medium diluted 1:1 with sterile(normal) saline solution
1	Inflation Device with three-way stopcock
1	Torque Device
1	Guide wire Introducer

12.4. Preparation

- AVOID manipulation of stent during flushing of the guidewire lumen, as this may disrupt the placement of the stent on the balloon.

- DO NOT apply negative or positive pressure to the balloon during the delivery system preparation.
- Rinse the catheter with sterile heparinized normal saline solution.
- Flush the guide wire lumen with HepNS.

12.5. Guide wire Lumen Flush

- Remove protective cover from the tip
- Connect a syringe containing heparinized normal saline to an appropriately sized flushing needle. Carefully apply the needle to the distal tip of the delivery system and flush the guide wire lumen until fluid exits the guide wire port.
- Remove the syringe and the flushing needle.
- Leave the prepared stent system at ambient pressure.

12.6. Delivery System Preparation

1. Prepare the inflation device or syringe with diluted contrast medium.
2. Attach the inflation device/syringe to the stopcock; attach to inflation port.
3. With tip down, orient Delivery System vertically.
4. Open stopcock to Delivery System; pull negative for 30 seconds; release to neutral for contrast fill.
5. Close stopcock to Delivery System; purge inflation device/syringe of all air.
6. Repeat steps 3 to 5 until all air is expelled
7. Note: If air is seen in shaft, repeat Balloon Preparation steps 3 to 5 to prevent uneven stent expansion.
8. If a syringe was used, attach a prepared inflation device to stopcock.
9. Open stopcock to Delivery System.
10. Leave the inflation device or syringe on neutral.

12.7. Delivery Procedure

1. Prepare the vascular access site according to standard practice.
2. Pre-dilate the lesion with a PTCA catheter.
3. Maintain neutral pressure on the inflation device. Open the rotating hemostatic valve as widely as possible.
4. Backload the delivery system onto the proximal portion of the guidewire while maintaining the guide wire position across the target lesion.
5. Advance the stent delivery system over the guidewire to the target lesion. Use the radiopaque balloon markers to position the stent across the lesion; perform angiography to confirm the position of the stent.

   NOTE. If during the process of moving the Delivery System into position you notice the stent has moved on the balloon, do not deploy the stent. The entire system should be removed as a single unit. See Precautions –**Stent/System Removal Precautions** for specific Delivery System removal instructions.
6. Tighten rotating hemostatic valve. Stent is now ready to be deployed.

12.8. Deployment Procedure

1. Before deployment, reconfirm the correct position of the stent relative to the target lesion via radiopaque balloon markers
2. Attach the inflation device (only partially filled with contrast media) to a three-way stopcock and apply negative pressure to purge the air bubble if any.

3. Turn the stopcock on the catheter to the off position and purge the inflation device of air. Close the side port of the stopcock.

4. Under fluoroscopic visualization, inflate the balloon to at least the nominal pressure to deploy the stent, but do not exceed the labelled rated burst pressure of 16 bar. Maintain inflation pressure for 15-30 seconds for full expansion of the stent. 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. Stent wall contact should be verified through routine angiography or intravascular ultrasound.
5. Fully cover by entire lesion and balloon treated area (including dissection) with the Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system, allowing for adequate stent coverage into healthy tissue proximal and distal to lesion.
6. If more than one Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system is needed to cover the lesion and balloon treated area, adequately overlap the stents, taking into account stent foreshortening. Ensure no gaps between to stents by positioning the balloon marker bands of the second Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system inside the deployed stent prior to expansion.
7. Deflate the balloon by pulling a vacuum with the inflation device. Make certain that the balloon is fully deflated stent prior to move the catheter.
8. Confirm that the stent is adequately expanded by angiographic injection through the guiding catheter.

   NOTE: The inner diameter of the stent should not be less than the reference diameter of the target vessel. The Stent should be expanded to a diameter slightly above one of the neighbouring non-diseased vessel, or one which corresponds it.

12.9. Removal Procedure

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

12.10. Disposal Procedure

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

13. Vivo ISAR: Product matrix and Nominal Sirolimus content (Table)

Ref No.	Length (mm)	Diameter (mm)	Nominal Sirolimus Content (µg)	Nominal Probucol Content (µg)
VISR-2008	8	2.00	100	100
VISR-2208	8	2.25	100	100
VISR-2508	8	2.50	100	100
VISR-2708	8	2.75	100	100
VISR-3008	8	3.00	100	100
VISR-3508	8	3.50	100	100
VISR-4008	8	4.00	100	100
VISR-2012	12	2.00	150	150
VISR-2212	12	2.25	150	150
VISR-2512	12	2.50	150	150
VISR-2712	12	2.75	150	150
VISR-3012	12	3.00	150	150
VISR-3512	12	3.50	150	150
VISR-4012	12	4.00	150	150
VISR-2016	16	2.00	200	200
VISR-2216	16	2.25	200	200
VISR-2516	16	2.50	200	200
VISR-2716	16	2.75	200	200
VISR-3016	16	3.00	200	200
VISR-3516	16	3.50	200	200
VISR-4016	16	4.00	200	200
VISR-2018	18	2.00	225	225
VISR-2218	18	2.25	225	225
VISR-2518	18	2.50	225	225
VISR-2718	18	2.75	225	225
VISR-3018	18	3.00	225	225
VISR-3518	18	3.50	225	225
VISR-4018	18	4.00	225	225
VISR-2021	21	2.00	263	263
VISR-2221	21	2.25	263	263

Ref No.	Length (mm)	Diameter (mm)	Nominal Sirolimus Content (µg)	Nominal Probucol Content (µg)
VISR-2521	21	2.50	263	263
VISR-2721	21	2.75	263	263
VISR-3021	21	3.00	263	263
VISR-3521	21	3.50	263	263
VISR-4021	21	4.00	263	263
VISR-2024	24	2.00	300	300
VISR-2224	24	2.25	300	300
VISR-2524	24	2.50	300	300
VISR-2724	24	2.75	300	300
VISR-3024	24	3.00	300	300
VISR-3524	24	3.50	300	300
VISR-4024	24	4.00	300	300
VISR-2028	28	2.00	350	350
VISR-2228	28	2.25	350	350
VISR-2528	28	2.50	350	350
VISR-2728	28	2.75	350	350
VISR-3028	28	3.00	350	350
VISR-3528	28	3.50	350	350
VISR-4028	28	4.00	350	350
VISR-2032	32	2.00	400	400
VISR-2232	32	2.25	400	400
VISR-2532	32	2.50	400	400
VISR-2732	32	2.75	400	400
VISR-3032	32	3.00	400	400
VISR-3532	32	3.50	400	400
VISR-4032	32	4.00	400	400
VISR-2736	36	2.75	450	450
VISR-3036	36	3.00	450	450
VISR-3536	36	3.50	450	450
VISR-4036	36	4.00	450	450
VISR-2740	40	2.75	500	500
VISR-3040	40	3.00	500	500
VISR-3540	40	3.50	500	500
VISR-4040	40	4.00	500	500
VISR-2744	44	2.75	550	550
VISR-3044	44	3.00	550	550
VISR-3544	44	3.50	550	550
VISR-4044	44	4.00	550	550
VISR-2748	48	2.75	600	600
VISR-3048	48	3.00	600	600
VISR-3548	48	3.50	600	600
VISR-4048	48	4.00	600	600

NOTE: Nominal Probucol content on the Device is same as Sirolimus Drug. The Formulation has 1:1 (w/w) proportion of Sirolimus to Probucol on the Device.

14. Adverse Events

Potential Adverse Events with Procedure

Potential adverse events which may be associated with Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent System implantation include but are not limited to:

- Cardiac events: MI 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 and aneurysm formation.
- Arrhythmic events: ventricular tachycardia, ventricular fibrillation, atrial fibrillation and 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 and embolization of catheter material.
- Respiratory events: acute pulmonary Edema, congestive heart failure and respiratory insufficiency or failure.
- Vascular events: access site hematoma, hypotension/hypertension, pseudoaneurysm, arteriovenous fistula formation, retroperitoneal hematoma, vessel dissection or perforation, restenosis, thrombosis or occlusion, vasospasm, peripheral ischemia, dissection and distal embolization (air, tissue debris and thrombus).
- Neurologic events: permanent (stroke) or reversible (TIA) neurologic event, femoral nerve injury and peripheral nerve injury.
- Bleeding events: access site bleeding or haemorrhage, haemorrhage requiring transfusion or other treatment.
- Allergic reactions to contrast media, antiplatelets, anticoagulants, L-605 cobalt chromium alloy and its components, sirolimus or sirolimus derivatives, probucol and shellac resin.
- Death.
- Infection and sepsis.

Potential adverse events related to

Potential adverse events related to Sirolimus

Potential adverse events related to oral administration of sirolimus include, but are not limited to, abnormal liver function tests, anaemia, arthralgia, diarrhoea, hypercholesterolemia, hypersensitivity (including anaphylactic/anaphylactoid type reactions), hypertriglyceridemia, hypokalaemia, infections, interstitial lung disease, thrombocytopenia, leukopenia, lymphoma and other malignancies.

Potential adverse events related to Probucol

Potential adverse event related to oral administration of Probucol, it decreases both LDL and HDL cholesterol.Probucol can have undesired effect of lowering HDL in patients with heart disease. It promotes resolution of cholesterol xanthomata. Potential adverse events related to administration of probucol are generally mild but are not limited to Gastrointestinal discomfort like Diarrhoea, Angioneurotic oedema, cardiac arrhythmias and prolonged QT intervals in ECG. The arrhythmia events are likely to increase in patients who are also taking tricyclic antidepressants or class I or III antiarrhythmic agents or phenothiazines. In rare cases, swelling on face, hands, feet or mouth is observed, Common side-effects of probucol on patients includes dizziness or fainting.

15. Drug Interactions

A complete study of possible interactions of Sirolimus in association with treatment accompanying has not been established. Sirolimus is metabolized by CYP3A4-isoenzyme. Strong inhibitors of CYP3A4 (e.g. ketoconazole) may cause increased sirolimus exposure to levels associated with systemic effects, especially if multiple stents are deployed. It is rather improbable that interactions with other drugs will occur due to significant lower dosage compared to oncological indicated Sirolimus therapy. Systemic exposure of sirolimus should also be taken into consideration if the patient is treated concomitantly with systemic immunosuppressive therapy.

While no specific data are available, drugs like tacrolimus, which act through the same binding protein (FKBP) may interfere with the efficacy of sirolimus.

Probucol lowers the level of cholesterol in blood by increasing LDL catabolism. It may inhibit cholesterol synthesis and delay cholesterol absorption. The major interaction of probucol with various drugs lead to increased risk or severity of QT prolongation. The drug is a lipid modifying agent and it is not recommended to use with following medicines like Bepridil, Cisapride, Dronedarone, Foscarnet, Levomethadyl, Mesoridazine, Pimozide, Piperaquine, Sparfloxacin, Terfenadine, Thioridazine, Ziprasidone. In some cases, using Probucol is not usually recommended but may be required when both medicines are prescribed together. The Dose may be adjusted for each of the Drug by Physician. The List of medicines are given but not limited to them only – Acecainide, Ajmaline, Amiodarone, Amisulpride, Anagrelide, Apomorphine, Aprindine, Aripiprazole, AripiprazoleLauroxil, Arsenic Trioxide, Astemizole, Azimilide, Bretylium, Buprenorphine, Buserelin, Ceritinib, Chloral Hydrate, Chloroquine, Chlorpromazine, Clarithromycin, Clofazimine, Clozapine, Crizotinib, Dabrafenib, Dasatinib, Degarelix, Delamanid, Deslorelin, Deutetrabenazine, Disopyramide, Dofetilide, Dolasetron, Domperidone, Donepezil, Droperidol, Efavirenz, Encorafenib, Enflurane, Entrectinib, Erythromycin, Escitalopram, Fingolimod, Flecainide,

Fluconazole, Fluoxetine, Formoterol, Fostemsavir, Gemifloxacin, Glasdegib, Gonadorelin, Goserelin, Halofantrine, Haloperidol, Halothane, Histrelin, Hydroquinidine, Hydroxychloroquine, Hydroxyzine, Ibutilide, InotuzumabOzogamicin, Isoflurane, Isradipine, Ivabradine, Ivosidenib, Ketoconazole, Lefamulin, Lenvatinib, Levofloxacin,

Lidoflazine, Lofexidine, Lorcainide, Macimorelin, Mefloquine, Methadone, Metronidazole, Mirtazapine, Moxifloxacin, Nafarelin, Nilotinib, Octreotide, Ondansetron, Osilodrostat, Osimertinib, Oxaliplatin, Ozanimod, Panobinostat, Pasireotide, Pazopanib, Pentamidine, Pimavanserin, Pirmenol, Pitolisant, Posaconazole, Prajmaline, Procainamide, Prochlorperazine, Propafenone, Quetiapine, Quinidine, Ribociclib, Risperidone, Selpercatinib, Sematilide, Sertindole, Sertraline, Sevoflurane, Siponimod, Solifenacin, Sotalol, Spiramycin, Sulfamethoxazole, Sulpiride, Sultopride, Sunitinib, Tacrolimus, Tedisamil, Telithromycin, Trazodone, Triclabendazole, Trifluoperazine, Trimethoprim, Triptorelin, Vandetanib, Vasopressin, Vemurafenib, Vinflunine, Zolmitriptan, Zotepine, Zuclopenthixol. (Data from Mayo Clinic.org website for Probucol and its side-effects).

16. Patient Counselling Information

Cardiologist should consider the following in counselling patient about this product:

- Discuss the risks associated with stent placement
- Discuss the risks associated with a Sirolimus Eluting implant
- Discuss the risks/benefits issues for this particular patient
- Discuss alteration to current lifestyle immediately following the procedure and over the long terms.
- Discuss the risks of early discontinuation of the antiplatelet therapy.
- The following stent implantation, the patients are expected to keep the patient implant card that includes product details at all times for procedure/stent identification.

17. Packaging

Package contents: One (1) Vivo ISAR Polymer Free Sirolimus Eluting Coronary Stent system

Sterile: This device is sterilized with ETO gas, Non-pyrogenic, the contents inside the sterile barrier system are sterile.

Do not use if the package is opened or damaged.

Do not re-sterilize.

Do not reuse.

Storage: Store in cool and dry place at temperature of 25°C., Do not Freeze

Excursion Limit 15°C to 30°C

Keep away from sunlight

18. Compliance Chart, Inflation Pressure

Balloon Ø [mm]	Inflation pressure (ATM / bar /10^5Pa)														
						NP*					RBP**				
	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Ø 2.00	1.83	1.87	1.90	1.93	1.96	2.00	2.03	2.06	2.10	2.13	2.16	2.20	2.23	2.26	2.29
Ø 2.25	2.08	2.11	2.14	2.18	2.21	2.25	2.28	2.31	2.35	2.38	2.42	2.45	2.48	2.52	2.55
Ø 2.50	2.33	2.36	2.40	2.43	2.47	2.50	2.53	2.57	2.60	2.64	2.67	2.70	2.74	2.77	2.81
Ø 2.75	2.58	2.61	2.65	2.68	2.71	2.75	2.78	2.81	2.85	2.88	2.91	2.94	2.98	3.01	3.04
Ø 3.00	2.81	2.85	2.89	2.92	2.96	3.00	3.04	3.07	3.11	3.15	3.18	3.22	3.26	3.29	3.33
Ø 3.50	3.29	3.34	3.38	3.42	3.46	3.50	3.55	3.59	3.63	3.67	3.71	3.76	3.80	3.84	3.88
Ø 4.00	3.75	3.80	3.85	3.90	3.95	4.00	4.06	4.11	4.16	4.21	4.26	4.31	4.36	4.41	4.46

*Nominal Pressure ** Rated Burst Pressure

19. Conversion Chart

1 cc	1 ml		
1 French	0.0131 inch	0.33 mm	
1 bar	0.99 atm	14.5 PSI	10^5 Pa

20. Symbols

Symbol	Description
	Stent Length
	Stent Diameter
	Batch No.
	Serial No.
 YYYY MM	Manufacturing Date
 YYYY MM	Use by Date (Expiry Date)
	Sterile and method of sterilization using Ethylene Oxide
	Single use only & Do not Re-sterile
	Reference No.
	Storage Temperature
	Pyrogen Free
	Medical Device
	Contains a medicinal substance

Symbol	Description
	Rated Burst Pressure
	Manufacturer
	European Authorized Representative
	CE Mark
	Consult Instruction for Use.
	Do not use if package open or damaged
	Keep Away from Sun Light
	Keep dry.
	Nominal Pressure
	Warning/Caution
	Content of the package
	Single sterile barrier system with protective packaging outside

21. Disclaimer of Warranty and Limitation of Remedy

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