INSTRUCTION FOR USE

BIOMATRIX ALPHA
Drug Eluting Coronary Stent System

11265-000-EN Rev 05

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1. DEVICE DESCRIPTION

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

1.1. Device Component Description

- A balloon expandable intra-coronary cobalt chromium stent per ASTM F562 with a biodegradable polymer coating poly lactic acid containing the BA9 drug pre mounted onto a semi-compliant rapid exchange balloon delivery system.
- A delivery system that has two radiopaque markers, which fluoroscopically mark the ends of the stent to facilitate proper placement.
- A female Luer lock connector hub located at the proximal end of the delivery system. This hub connects to the balloon inflation lumen. The guidewire used in the procedure enters the distal tip of the catheter and exits 27.5cm proximal to the tip of the delivery system.

Table 1: BioMatrix Alpha Description

Stent Pattern	Small Vessel (SV) model	Medium Vessel (MV) model
Stent Diameters (mm)	2.25-3.0	3.5-4.0
Stent Lengths(mm)	9, 14, 19, 24, 29, 33*, 36*	
Stent Material / Coating	CoCr alloy per ASTM F562/ PLA (polylactic acid) and BA9 drug	
Delivery Catheter Design	Working Length: 142 cm Rapid Exchange (RX) compatible with 0.014”guidewires	
Guiding catheter compatibility	5F	
Balloon Catheter	Polyamide Elastomers	
Balloon Inflation Pressure Nominal Pressure (NP) Rated Burst Pressure (RBP)	8 atm/811 kPa 16 atm/1621 kPa	8 atm/811 kPa 14 atm/1418 kPa
Balloon deflation time per stent length (see table 3)	9 & 14 mm: 15 sec 19 to 29 mm: 20 sec 33 & 36 mm: : 30 sec	

**(BioMatrix Alpha DES with a length of 33 and 36 mm are only available for stent diameters from 2.5 to 3.5 mm)*

Table 2: BioMatrix Alpha stent specifications and BA9 dosage

Product Code	Nominal Expanded Inner Diameter(mm)	Nominal Unexpanded Stent Length (mm)	Nominal dose BA9 drug (µg)
BMX6-2209	2.25	9	148
BMX6-2214	2.25	14	223
BMX6-2219	2.25	19	304
BMX6-2224	2.25	24	381
BMX6-2229	2.25	29	460
BMX6-2509	2.50	9	148
BMX6-2514	2.50	14	223
BMX6-2519	2.50	19	304
BMX6-2524	2.50	24	381
BMX6-2529	2.50	29	460
BMX6-2533	2.50	33	523
BMX6-2536	2.50	36	570
BMX6-2709	2.75	9	148
BMX6-2714	2.75	14	223
BMX6-2719	2.75	19	304
BMX6-2724	2.75	24	381
BMX6-2729	2.75	29	460
BMX6-2733	2.75	33	523
BMX6-2736	2.75	36	570
BMX6-3009	3.00	9	148
BMX6-3014	3.00	14	223
BMX6-3019	3.00	19	304
BMX6-3024	3.00	24	381
BMX6-3029	3.00	29	460
BMX6-3033	3.00	33	523
BMX6-3036	3.00	36	570
BMX6-3509	3.50	9	148
BMX6-3514	3.50	14	223
BMX6-3519	3.50	19	304
BMX6-3524	3.50	24	381
BMX6-3529	3.50	29	460
BMX6-3533	3.50	33	523
BMX6-3536	3.50	36	570
BMX6-4009	4.00	9	148
BMX6-4014	4.00	14	223
BMX6-4019	4.00	19	304
BMX6-4024	4.00	24	381
BMX6-4029	4.00	29	460

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 BioMatrix Alpha stent, 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. The polymer and the drug are mixed in a 1:1 ratio at a dose of 15.6µg of drug per mm stent length.

Refer to Table 2 for the nominal dose of BA9 per stent.

2. INDICATION

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

3. CONTRAINDICATIONS

The BioMatrix Alpha DES is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients with lesion(s) that prevent complete inflation of an angioplasty balloon.
- Patients with known sensitivity to BA9 or its derivatives.
- Patients with known allergies to Cobalt, Chromium, Nickel, Molybdenum or any metallic component in use in CoCr ASTM F562 alloy.
- Patients with known sensitivity to contrast agents that cannot be controlled prophylactically prior to BioMatrix Alpha stent implantation.
- Off-label use (i.e.: outside of the approved indication for use).

4. ANTIPLATELET REGIMEN

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

Physicians and/or Health Care Professionals (HCPs) 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

- Judicious selection of patients is necessary since the use of this device carries the associated risk of thrombosis, vascular complications and/or bleeding events.

[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

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.
- 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.
- Use of the device in patients with history of restenosis, multiple stents, and diabetes can lead to an increased risk of restenosis.
- The extent of residual stenosis and malapposition of the stent can lead to a greater risk of restenosis.
- Ensure that the inner packaging has not been damaged or opened as this may indicate a breach of the sterile barrier.
- **This stent deployment device must not be reused in another procedure**. The performance characteristics of the balloon are degraded during use.
- This product is not intended or approved for use in peripheral applications.
- When multiple tandem stents are required, stent materials should be of similar composition to avoid dissimilar metal corrosion.
- Direct stenting is not recommended as it could lead to suboptimal clinical outcome and / or a failure to cross the lesion with the stent.
- 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.
- The safety and effectiveness of overlapping BioMatrix Alpha stents have not been established

6. PRECAUTIONS

6.1. Drug Interactions

- Consideration should be given to the potential for drug interactions when deciding to place a BioMatrix Alpha 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 Alpha stent. The effect of the BioMatrix Alpha DES drug interactions on safety or efficacy has not been determined.
- There is no specific clinical data available for the interaction of the BA9 drug with other drugs. However, drugs like Tacrolimus that may act through the same binding proteins (FKBP) may interfere with the efficacy of the BA9 drug. Drug interaction studies have not been performed.
- 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

BA9 drug should be taken into consideration if the patient is treated concomitantly with systemic immunosuppressive therapy.

- Patient's exposure to the BA9 drug is directly related to the number and length of the BioMatrix Alpha stent or any other BA9 eluting stents implanted.

6.2. Stent/ System 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 package is opened or damaged. **The sterility and stability of the BioMatrix Alpha DES cannot be guaranteed once the pouch has been opened** and hence the device MUST be used promptly. Un-used devices should be returned to Biosensors International[3] and should not be re-stocked.
- The delivery system is designed to deploy the stent once, and cannot be reused. Do not use if stent coating is subjected to abrasions beyond those of normal insertion and delivery.
- Do not use if stent is exposed to abnormal rubbing or contact with objects other than the guide catheter or opened hemostasis valve prior to implantation.
- **DO NOT 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 Alpha stent is intended to perform as a system. 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.
- Exposing the stent to fluids before implantation is not recommended. Exposure to fluids prior to implantation may result in premature release of drug.
- Use only the appropriate balloon inflation media (contrast media in dilution 1:1 with normal saline). 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.
- The delivery system should not be used in conjunction with other stents.
- Do not attempt to straighten the proximal shaft (hypotube) as it may cause the catheter to break if it is accidentally bent.
- When removing the device from the packaging, care should be taken not to kink the shaft.
- 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].

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

6.3. Stent 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 Preparation of the Stent / Stent Delivery System.
- **The labeled stent diameter refers to the expanded stent inner** diameter at its nominal pressure.
- Implanting a stent may lead to dissection of the vessels distal and/or proximal to the stent and may cause acute closure of the vessel, requiring additional intervention (e.g. CABG, further dilatation, placement of additional stents or other).
- When treating multiple lesions, distal lesions should be stented first followed by proximal lesion stenting. Stenting in this order obviates the need to cross the proximal stent when placing 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) Do not use the device if proper positioning within the lesion cannot be achieved.
- Placement of a stent has the potential to compromise side branch patency.
- **Do not exceed rated burst pressure as indicated on product labeling material.** Use of pressures higher than specified on the product labeling material may result in a ruptured balloon with possible intimae damage and dissection. Over inflation may lead to stent fracture.
- **Do not attempt to pull an unexpanded stent back through the guiding catheter, as dislodgement of the stent from the balloon may occur. Remove as a single unit as described in section 6.4 Stent/System Removal Precautions.**

6.4 Stent / System Removal – Precautions

Should unusual resistance be felt at any time during either lesion advancement or removal of the stent delivery system into the guiding catheter if the stent failed to be implanted, the entire system should be removed as a single unit (see below). This must be done under direct fluoroscopic visualization.

When removing the stent delivery system as a single unit:

- Do not attempt to retract an unexpanded stent into the guiding catheter while engaged in the coronary arteries.
- Stent damage or dislodgement may occur.
- Vessel damage may occur.
- Ensure complete balloon deflation. If unusual resistance is felt during stent delivery system withdrawal, pay particular attention to the guiding catheter position. In some cases it may be necessary to slightly retract the guiding catheter in order to prevent unplanned guiding catheter movement and subsequent vessel damage. In cases where unplanned guiding catheter movement has occurred, a coronary tree angiographic assessment should be undertaken to ensure that there is no damage to the coronary vasculature.

- Position the proximal balloon marker just distal to the guiding catheter tip.
- Advance the guide wire into the coronary anatomy as far distally as safely possible. **NOTE**: If this is necessary to maintain 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 an unexpanded stent back through the introducer sheath. When the distal tip of the guiding catheter reaches the distal end of the introducer sheath, remove sheath, guiding catheter, and delivery system as a single unit and replace sheath as per hospital protocol.**
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

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

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 MRI Information – Precautions

CoCr (ASTM F 562) as used in BioMatrix Alpha stent is a non ferromagnetic alloy that does not interact with MRI. Based on literature evaluation, a patient with a BioMatrix Alpha stent can be scanned safely, immediately after placement of this implant. The following statements were assessed:

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

7 INDIVIDUALISATION OF TREATMENT

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

8 USE IN SPECIAL POPULATION

The safety and effectiveness of the BioMatrix Alpha stent has not been established in the following patient populations.

- Pregnancy: There is no data available for use of the BioMatrix Alpha 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 Alpha stent has not been established.

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

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 before opening. Do not use after the expiration date. If the integrity of the sterile package has been compromised (e.g., damage to the package), contact Biosensors. Do not use if any defects are noted.
2. Carefully remove the system from the package and inspect the delivery catheter for bends, kinks, 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 displaced from its original position on the balloon. Verify that the stent is positioned between proximal and distal balloon markers.
5. Note the position of the stent relative to the delivery system markers for use as reference under fluoroscopy.

Do not use if any defects are noted.

9.2 Material Required

1	Appropriate guiding catheter with minimum inner diameter of 0.056" / 1.42mm for the SV model and for the MV model.
1	Pre-dilatation balloon catheter, if needed
1	10-20 ml syringe
1000 IU	Heparin per 500 ml Normal Saline (HepNS)
1	Guidewire, 0.014 inch / 0.36 mm maximum diameter x 190 cm minimum length
1	Rotating haemostatic valve
N/A	Contrast medium diluted 1:1 with normal saline
1	Inflation device
1	Three-way stopcock

9.3 Preparation of the Stent/ Delivery System

1. Prepare inflation device/syringe with diluted contrast medium.

2. Attach the inflation device to the three-way stopcock; attach to balloon inflation port hub. DO NOT apply negative or positive pressure to the balloon at this time as it can cause premature dislodgement of the stent.
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 0.5mm smaller than the stent and a balloon length equal to or shorter than the target lesion length and shorter than the length of the stent to be implanted.
3. The safety of using the mechanical atherectomy devices (directional atherectomy catheters) or laser angioplasty catheters to treat in-stent stenosis has not been established.
4. Immediately prior to back loading the stent delivery catheter onto the guide wire, 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.

5. Backload stent delivery system onto the proximal portion of the guidewire while maintaining guidewire position across target lesion.
6. Open rotating haemostatic valve on the guiding catheter hub as widely as possible and close when the stent has been advanced safely inside the guide catheter.
7. 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 6.4. Stent/ Stent System Removal - Precautions).

9.5 Deployment Procedure

1. Consult the product labeling material in order to determine the balloon inflation pressure appropriate for the target vessel diameter.

CAUTION: **Different compliance charts apply for different stent lengths.**

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 8 atm to deploy the stent, but do not exceed the labeled rated burst pressure (RBP). Optimal expansion requires the stent to be in full contact with the artery wall with the stent internal

diameter matching the size of the reference vessel diameter. **ENSURE THAT THE STENT IS NOT UNDER-EXPANDED**.

6. Deflate the balloon by pulling a vacuum with the inflation device. Make sure the balloon is fully deflated before attempting any movement of the system. Please refer to below table for deflation time per product diameter/length.

Table 3: BioMatrix Alpha balloon deflation time per product specification

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

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

1. Ensure that the balloon is fully deflated.
2. Fully open the rotating hemostatic 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, either re-advance the stent delivery system or exchange for another appropriate balloon to achieve proper stent apposition to the vessel wall.

NOTE: Post-dilatation should be performed within the stented segment if needed as per Operator assessment. 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
- Acute myocardial infarction
- Allergic reaction to anti-coagulation and/or anti-thrombotic therapy, contrast material, or stent and/or delivery system materials
- Aneurysm, pseudoaneurysm or arteriovenous fistula
- Arrhythmias, including ventricular fibrillation and ventricular tachycardia

- Cardiac tamponade
- Cardiogenic shock
- Death
- Dissection, perforation, or rupture of the artery
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergency coronary artery bypass grafting (CABG) as a result of damage to the stent or injury to the vessel
- Fever
- Hematoma at insertion site
- Hemorrhage requiring transfusion
- Hypotension/hypertension
- Infection and/or pain at insertion site
- Perforation or rupture of the artery
- Peripheral ischemia or peripheral nerve injury
- Stent thrombosis /occlusion
- Stent migration or stent embolization
- Stroke or transient ischemic attack
- Renal failure
- Restenosis of stented segment
- 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 Alpha DES. They include the following:

- Nausea
- Lymphadenopathy
- Mouth ulcers
- Chest Heaviness
- Dizziness

11 HOW SUPPLIED

STERILE**:** Package contents are sterile unless package is open or damaged. This device is sterilized via electron beam radiation and is non-pyrogenic. **It is intended for single use only**. Do not use if package is open or damaged.
CONTENTS**:** One BioMatrix Alpha Drug Eluting Coronary Stent System, and one Instruction for Use.
STORAGE**:** Store in a cool, dark, dry place. Do not store above 30°C.

DISPOSAL: Dispose device in accordance with local regulation.

12 SYMBOLS USED IN LABELING

	Legal Manufacturer		Keep away from sunlight or heat
	Date of Manufacture		Keep Dry
REF	Catalog number		Do not use if package is damaged or open
LOT	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):
STERILE R	This product has been sterilized using irradiation		Do not store above 30°C
	Use by date Do not use this device after the indicated date (Year-month-day):		Consult Instruction for use
NP	Nominal Pressure	RBP	Rated Burst Pressure
	MR Conditional		

13 WARRANTY

Biosensors International warrants that its products are manufactured to the specifications set forth on its packaging, instructions for use and related literature.

This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Biosensors International neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

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