SYMETREX®
LONG TERM HEMODIALYSIS CATHETER
INSTRUCTIONS FOR USE

WARNING:

This catheter is for single product and patient use only. DO NOT RE-USE, REPROCESS OR RESTERILIZE. Re-use of a single use device carries with it the potential risk of contamination of the device and/or risk of patient/user infection or cross infection including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination, cross-contamination and/or cross-infection may lead to injury, illness, or death of the patient. Resterilization or reprocessing of the device may not be effective and may compromise the structural integrity of the device and/or lead to device failure, which in turn may lead to patient injury, illness or death. The manufacturer shall not be liable for any damages caused by re-use, reprocessing or resterilization of this device or accessories. Federal (USA) law restricts this device to be used by or under the direction of a physician.

DEVICE DESCRIPTION:

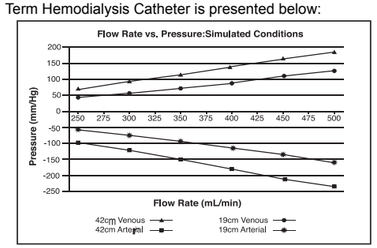
The Symetrex® Long Term Hemodialysis Catheter is a chronic,15.5 French, dual lumen, radiopaque catheter made of polyurethane. It has a polyester retention cuff and two female luer adapters. The retention cuff promotes tissue ingrowth to anchor the catheter in the subcutaneous tunnel. The luer adapters are identical in color to indicate the reversibility of this catheter. This catheter features symmetrical side channels with a distal tip configuration designed to separate the intake flow from the output flow in both directions.

RECIRCULATION RATES:

The Symetrex® Long Term Hemodialysis Catheter has less than 1% recirculation in Forward and Reverse flow when tested in vitro.

FLOW RATE VS. PRESSURE PROFILE:

The Flow Rate vs. Pressure profile of the Symetrex® Long Term Hemodialysis Catheter is presented below:



Flow Rate vs. Pressure Data was obtained in vitro using a glycerin/water analog with a viscosity of ≈2.75 cP.

INDICATIONS FOR USE:

The Symetrex® Long Term Hemodialysis Catheter is a symmetric tip dual lumen catheter designed for chronic hemodialysis. It may be inserted percutaneously. Catheters with greater than 37 cm implant length are indicated for femoral placement.

CONTRAINDICATIONS:

Do not use this catheter in thrombosed vessels or for subclavian puncture when ventilator is in use.

This device is contraindicated whenever:

- Used for any purpose other than indicated in these instructions.
- The presence of other device related infection, or septicemia is known or suspected.
- Severe chronic obstructive lung disease is present.
- Tissue factors in the localized area of device placement will prevent proper device stabilization and/or access.
- Venous thrombosis or vascular surgical procedures have occurred at the prospective placement site.
- Post irradiation of prospective insertion site.

WARNINGS & GENERAL PRECAUTIONS:

- Health care professionals should always use universal blood and body fluid precautions in the care of all patients to minimize the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens. Sterile technique must be strictly adhered to during any handling of the device.
- The risk of infection is increased with femoral vein insertion.
- To minimize the risk of air embolism or extravasation, keep the catheter clamps closed at all times when not in use or when attached to a syringe, IV tubing, or bloodlines.
- Peel-away introducer must only be advanced over a guidewire.
- Do not use device if package, catheter or components show any signs of damage (crimped, crushed, cut, opened etc.).
- Do not use device if labeling is damaged or has been defaced or made partially illegible.
- Do not use sharp instruments near the extension tubing or catheter body. Catheter failure may result from contact with sharp objects. Do not use scissors to remove the dressing as this could possibly cut or damage the device.
- Do not suture through any part of the catheter. There is a danger of tearing the catheter tubing or damaging the suture wing from the bifurcate if excessive force is applied to the catheter.
- Avoid sharp or acute angles that could compromise the opening of the catheter lumens.
- Repeated over tightening of the bloodlines, syringes and caps will reduce connector life, shorten the life of this catheter and could lead to potential connector failure. Use only Luer Lock (threaded) Connectors with this catheter. Catheter should be inspected for damage before and after each treatment.
- Ensure all caps and bloodline connections are secured prior to and between treatments.
- Clamping near the luers and/or hub of the catheter should be avoided. Repeated clamping of the tubing in the same location may cause the tubing to weaken.
- Do not clamp the shaft of the catheter. Use only the line extension clamps which have been provided with the catheter.
- To help avoid air embolism, fill (prime) the device with sterile, heparinized saline or normal saline solution prior to catheter insertion.
- Do not use excessive force to flush obstructed lumen.
- Do not advance the guidewire or catheter if you meet with unusual resistance.
- Do not use force to insert or withdraw the guidewire from any component as this could cause the wire to break or unravel. In the event the guidewire should become compromised for any reason, remove the introducer needle or sheath introducer and guidewire together as a unit.
- To avoid vessel perforation and damage, do not insert or withdraw the guidewire, dilators, or valved pull-apart sheath/introducer forcibly.
- Do not insert the valved pull-apart sheath/introducer further than necessary. Depending upon patient size and access site, it may not be necessary to insert the entire length of the introducer into the vessel.
- The valved pull-apart sheath/introducer is designed to reduce blood loss and the risk of air intake.
- The valved pull-apart sheath/introducer is not intended for arterial use.
- Dilators and catheters should be removed slowly from the sheath/introducer. Rapid removal may damage the valve members resulting in blood flow through the valve.
- Caution when using this device. Be aware of sharps.
- Do not use if components or packaging are damaged, deformed, discolored, kinked or missing before, during or after the procedure including product printing.
- Do not overtighten. Do not proceed if resistance is felt or interaction between components is failing.
- Examine all connections to ensure there is not leaking.
- Discard biohazard according to facility protocol.
- Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.

CHEMICAL EXPOSURE WARNINGS:

- Do not use acetone on any part of the catheter tubing. Chlorhexidine is the preferred alternative.
- See SITE CARE Section for full list of recommended antiseptic agents.

POSSIBLE COMPLICATIONS:

- Air Embolus
- Arterial Puncture
- Bacteremia
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Death
- Deep Vein Thrombosis of the lower extremity
- Dissection or Occlusion of the Carotid Artery
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Femoral Artery Damage
- Femoral Artery Dissection
- Femoral Vein Occlusion
- Femoral Nerve Damage
- Fibrin Sheath Formation
- Hematoma
- Hemomediastinum
- Hemorrhage
- Hemothorax
- Inflammation, Necrosis, or Scarring of skin over implant area
- Laceration of the Vessel or Viscus
- Lower Extremity Ischemia
- Lumen Thrombosis
- Mediastinal Widening
- Perforation of the Vessel or Viscus
- Pleural injury
- Pneumothorax
- Pulmonary Embolism
- Recurrent Laryngeal Nerve Palsy
- Retroperitoneal Bleed
- Subcutaneous Hematoma
- Thoracic Duct Laceration
- Trauma to Right Atrium
- Tunnel Infection
- Vascular Thrombosis

INSERTION SITES:

The ideal site for inserting the Symetrex® Long Term Hemodialysis Catheter is in the right internal jugular vein. Although this catheter may be placed in the subclavian vein it is not preferred (National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI) Guideline 2, K/DOQI Update 2006). Catheter also can be placed in the Femoral Vein as required.

STERILIZED BY ETHYLENE OXIDE: Contents sterile and non-pyrogenic in unopened, undamaged package. Do not use catheter if package has been damaged or has been opened.

CAUTION:

- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Long time use of the subclavian vein may be associated with subclavian vein stenosis.

DIRECTIONS FOR CATHETER INSERTION:

Part A: Percutaneous Access (Common Steps)

Only a qualified, licensed physician or other qualified health care professional under the direction of a physician should insert, manipulate, and remove this catheter. The medical procedures, technique, and methods outlined in these Instructions For Use are not meant to be a replacement for the physician's experience and judgment in treating any particular patient nor do they represent the only medically acceptable protocols available. K-DOQI Guidelines recommend the use of fluoroscopic visualization for placement.

CAUTION: Insert, maintain and remove catheter under strict Aseptic conditions and technique. Use standard hospital protocols when applicable.

NOTE: To reduce the number of cannulation attempts and mechanical complications, CDC Guidelines recommend the use of Ultrasound Guidance, if available. Ultrasound guidance should only be used by those fully trained in its technique.

1. Select the appropriate catheter length to achieve proper tip positioning. Proper catheter length selection is important and will be determined by patient anatomy.
2. Administer sufficient local anesthesia to the insertion area and tunnel site before attempting insertion.
3. Gain percutaneous access to selected vein by inserting introducer needle attached to syringe. When vein has been entered, remove the syringe, leaving the needle in place and place thumb over the hub of the needle to minimize blood loss and the risk of air aspiration.
4. Insert the distal end of guidewire into the needle hub and pass it into the vasculature. Guidewire should be inserted under Fluoroscopy, when desired position is reached, the depth markings should be noted.

CAUTION: The length of the guidewire inserted is determined by the size of the patient. The guidewire should be held securely during this procedure. Allowing the guidewire to pass into the right atrium or ventricle may result in cardiac arrhythmias. Patient should be placed on a cardiac monitor and monitored for arrhythmia throughout this procedure.

5. Remove needle, leaving guidewire in place.
6. Flush the tissue dilator with sterile, normal or heparinized saline solution and thread over the guidewire into the vein .
7. Prepare the peel-away introducer, flush peel-away introducer with sterile, normal or heparinized saline.
8. Remove the tissue dilator leaving the guidewire in vessel.
9. Advance the peel-away introducer over the guidewire and into the vein.

CAUTION: The valved pull-apart sheath/introducer is designed to reduce blood loss and the risk of air intake but it is not a hemostasis valve. The valve pull-apart sheath/introducer is not intended to create a complete two-way seal nor is it intended for arterial use. The valve will substantially reduce air intake. The valve will substantially reduce the rate of blood flow but some blood loss through the valve may occur.

10. Remove the peel-away dilator and guidewire and gently withdraw the dilator from the sheath.

CAUTION: Insufficient tissue dilation can cause compression of the catheter lumen against the guidewire causing difficulty in the insertion and removal of the guidewire from the catheter. This can lead to bending of the guidewire.

Part B: Tunnel Catheter (Common Steps)

1. Enlarge cutaneous puncture site with scalpel. Make secondary incision at the exit site. Ensure incision is wide enough to accommodate the catheter and dilate skin with hemostats to accommodate the cuff, approximately 1cm. NOTE: For jugular insertion, exit site is approximately 8-10cm below the clavicle on chest wall.
2. Irrigate each lumen of catheter with heparinized saline and inspect for leakage. Connect end caps to each catheter luer. NOTE: Ensure the separation of the flow is maintained through the extensions and lumens.
3. Align jaws of tunneling tool with channels of distal tip of catheter. Insert septum of distal tip of catheter into jaws of tunneling tool until the tip of the septum meets the base of the jaws. Maintain the connection between tunneling tool and catheter and slide tunneling sleeve over catheter until it stops.
4. Insert tunneler into exit site and create a short subcutaneous tunnel, emerging at the insertion site. Do not tunnel through muscle. Advance tip of tunneler through lateral portion of incision with care to prevent damage to surrounding vessels and nerves.
5. Gently lead the catheter through subcutaneous tract. Position proximal catheter allowing for standard polyester cuff placement (Approx. 2cm within tract).
6. Remove tunneler from catheter by sliding tunneling sleeve away from catheter and completely off tunneling tool. Gently remove jaws of tunneling tool from distal tip of catheter.

WARNING: To prevent severe damage to catheter tip, Do not attempt to remove tunneling tool from catheter without first removing closing sheath.

NOTE: A tunnel with a gentle arc lessens the risk of kinking. Avoid sharp or acute angles during implantation which could occlude the opening of the catheter lumen(s).

Part C: Catheter Insertion Technique (Common Steps)

1. Re-flush each lumen of the catheter with heparinized saline.
2. Introduce distal section of the catheter through the valved sheath introducer and advance it into the vein, grasping catheter close to the sheath and using small steps to prevent kinking if necessary.
3. Position catheter. Note: For jugular insertion, the distal tip should be placed within the right atrium confirmed by fluoroscopy for optimal flow (National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI) Guideline 2, K/DOQI Update 2006).
4. Break the sheath handle in half.
5. Peel the sheath apart, away and out of the vessel and remove the sheath from the patient.

CAUTION: To avoid vessel damage, do not pull-apart any section of the sheath until it is withdrawn from the vessel. Pull the sheath out as far as possible and tear the sheath only a few centimeters at a time.

NOTE: It is normal to experience some resistance while pulling the catheter through the slit on the valve. If alternate sheath is used, follow manufacturer's instructions.

Part D: Catheter Aspiration (Common Steps)

1. Attach syringes to both extensions and open clamps. Aspirate blood from both lumens. Blood should aspirate easily.

CAUTION: Should either side exhibit excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows. Make any adjustments to catheter under fluoroscopy.

2. Once proper blood aspiration has been established, ensure both extension lines are unclamped and flush both lumens with heparinized saline.
3. Attach syringes filled with an anticoagulant solution (per priming volume labeled on catheter) and instill the solution into the lumens of the catheter. Clamp each extension tube. Remove the syringes.
4. ALWAYS ENSURE BOTH END CAPS ARE ATTACHED TO CATHETER LUERS POST PLACEMENT.

CAUTION: Take the following steps to avoid air embolism. Ensure that the luers are closed between uses. Aspirate then irrigate the catheter with saline prior to each use. Purge air from the catheter and all connecting tubing whenever tubing connections are changed.

CAUTION: Clamp only the extension tubes with the in-line clamps provided with the Symetrex® Long Term Hemodialysis catheter. Do not use forceps and do not clamp the distal portion of the catheter.

5. Confirm final position of catheter placement with fluoroscopy or x-ray. Note: For jugular insertion, the distal tip should be placed within the right atrium confirmed by fluoroscopy for optimal flow (National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI) Guideline 2, K/DOQI Update 2006).

NOTE: Review catheter placement to ensure there is no unwanted migrating.

CAUTION: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

6. Suture the tunnel exit site and vein insertion site closed if necessary. Suture the catheter to the skin with the suture wings. To avoid occluding or cutting the catheter, do not suture through any part of the catheter tubing.
7. Apply occlusive dressing to catheter exit site and the tunneled insertion site using standard institutional protocol.

NOTE: To prevent cuff dislodgment, it is important to immobilize catheter for 7 days. Catheter must be secured/sutured for entire duration of implantation.

HEMODIALYSIS TREATMENT:

To avoid systemic heparinization, the anticoagulant solution

must be removed from each lumen prior to treatment. Aspiration should be based on dialysis unit protocol. Carefully inspect all connections and extracorporeal circuits before beginning dialysis. Early leak detection is important to prevent blood loss or air embolism. Conduct frequent visual inspections for earliest detection. Once a leak is detected, discontinue dialysis treatment and take all necessary remedial action before reinitiating treatment. Hemodialysis should be performed under physician's instructions.

To maintain patency between treatments, a lock must be created in each lumen of the catheter. It is necessary for each lumen to be completely filled in order for the lock to be effective. Follow standard institutional protocols when creating the lock.

1. Ensure that the syringes are free of air and the extension clamps are closed.
2. Remove caps from the extensions and flush catheter with saline to remove blood.
3. Attach a syringe containing anticoagulant solution (per designated priming volume as labeled on catheter) to the luer of each extension.
4. Open the extension clamps and aspirate to ensure that no air will be forced into the patient.
5. Inject lock into each lumen using quick bolus technique, remove syringes and cap luers.

PRECAUTION: Luers should be capped in between uses. Luers should only be uncapped for aspiration, flushing, and dialysis treatment.

PRIMING VOLUME:

The following chart outlines the priming volumes for the Symetrex® Long Term Hemodialysis Catheter. Due to the symmetrical nature of the catheter's distal tip, there is no predesignated "arterial" or "venous" lumens. The appropriate Lumen Volume (per catheter length) applies to either lumen.

Priming Volume Chart

Tip to Cuff Length	Lumen Volume
19cm	2.1cc
23cm	2.3cc
28cm	2.5cc
33cm	2.6cc
37cm	2.8cc
42cm	3.2cc

SITE CARE:

The care and maintenance of the catheter requires well-trained, skilled personnel following a detailed protocol. Catheter is compatible with ointments.

CATHETER LUER DISINFECTION: Scrub catheter luers with an appropriate antiseptic after cap is removed and before accessing. Perform every time catheter is accessed or disconnected.

WARNING: Do not use acetone on any part of the catheter tubing. Chlorhexidine is the preferred alternative.

Aqueous based povidone iodine (Betadine™*), dilute aqueous sodium hypochlorite solution (Anasept™*), chlorhexidine gluconate 4% (Hibiclens™*, Betasept™*), and Bacitracin zinc ointment (Neosporin™*) are the recommended antiseptic agents to be used with this catheter.

Clean the skin around catheter. Cover the exit site with occlusive dressing and leave extensions, luers, and caps exposed for access by dialysis staff. Wound dressings must be kept clean and dry. Patients must not swim, shower, or soak dressing while bathing unless instructed by a physician. Should the adhesion of the dressing become compromised due to moisture from profuse perspiration or other inadvertent wetting, the dressing must be changed under sterile conditions by the medical or nursing staff.

CATHETER PERFORMANCE CAUTION:

Lumen obstruction is usually evident by failure to aspirate blood from the lumen, inadequate blood flow and/or high resistance pressures during hemodialysis. The causes may include inadequate catheter tip position, catheter kink and clot. One of the following may resolve the obstruction:

- Verify the clamps are in open position when attempting to aspirate.
- Reposition patient. Have patient cough.
- Provided there is no resistance, attempt to open or move the tip by vigorously flushing the catheter with sterile normal saline.
- If thrombus develops in either lumen, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may consider using a thrombus dissolving solution (i.e. TPA) to dissolve the clot. Excessive force should not be used to flush an obstructed lumen.

INFECTION:

Catheter related infection is a serious concern of indwelling catheters. Sterile technique should always be strictly adhered to. Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate antibiotic therapy.

Per CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections:

- Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape, for the insertion of central venous catheters.
- Before central venous catheter insertion, prepare clean skin with a >0.5% chlorhexidine preparation with alcohol. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives.
- Antiseptics should be allowed to dry according to the manufacturer's recommendation prior to placing the catheter.
- After central venous catheter insertion, see SITE CARE for compatible antiseptics.

DIRECTIONS FOR CATHETER EXCHANGE:

Only a qualified, licensed physician or other qualified health care professional under the direction of a physician should insert, manipulate, and remove this catheter. The medical procedures, technique, and methods outlined in these Instructions For Use are not meant to be a replacement for the physician's experience and judgment in treating any particular patient nor do they represent the only medically acceptable protocols available. K/DOQI Guidelines recommend the use of fluoroscopic visualization for placement.

CAUTION: Hospital or unit protocol, potential complications and their treatment, warnings and precautions must be reviewed prior to catheter removal.

CAUTION: Insert, maintain and remove catheter under strict Aseptic conditions and technique.

1. If necessary, cut sutures from suture wings following hospital protocol for skin sutures.
2. Use blunt or sharp dissection to free cuff from the tissue at exit site.
3. Advance guidewire with forward motion through the venous lumen into the designated position, unless contraindicated.

NOTE: Guidewire must be the proper length so the guidewire will extend distal to the tip of the catheter for the duration of the placement procedure.

4. Hold the guidewire in place while gently pulling out the catheter over the wire.

CAUTION: Remove catheter with care. Sharp, jerking motions and undue force may tear catheter.

5. Immediately apply manual pressure to the puncture site after removal to control bleeding.
6. Flush each lumen of the replacement catheter with flushing solution.
7. Insert a stylet into each lumen of catheter and secure to catheter using luer lock connector.
8. Using standard technique, pass stylets and catheter over guidewire.
9. Once the guidewire exits through the luer connector, hold the guidewire securely and advance the catheter over the wire, through the existing tunnel until proper catheter tip positioning is confirmed with fluoroscopic visualization, per K/DOQI guidelines.

CAUTION: The guidewire should be held securely during this procedure. For jugular insertion, allowing the guidewire to pass into the right atrium may result in cardiac arrhythmias. Patient should be placed on a cardiac monitor and monitored for arrhythmia throughout the jugular insertion procedure. Do not advance the catheter and stiffener past the tip of the guidewire as this could cause vessel perforation and/or bleeding.

10. Once position is confirmed, slowly remove guidewire.
11. Leaving the catheter in place, gently remove stylet and immediately clamp extension lines.
12. Attach end caps.
13. Attach syringes to both extensions and open clamps. Aspirate blood from both lumens. Blood should aspirate easily. Once proper blood aspiration has been established, ensure both luers are unclamped and flush both lumens with flushing solution.

CAUTION: Take the following steps to avoid air embolism. Ensure that the internal valve of the end caps are in their closed position between uses. Aspirate then irrigate the catheter with saline prior to each use. Purge air from the catheter and all connecting tubing whenever tubing connections are changed.

CAUTION: Clamp only the extension tubes with the in-line clamps provided with the Symetrex® Long Term Hemodialysis Catheter. Do not use forceps and do not clamp the distal portion of the catheter. Do not clamp over stylets.

14. Attach syringes filled with an anticoagulant solution (per designated priming volume as labeled on catheter) and instill the solution into the lumens of the catheter. Clamp each extension line.
15. Immediately after insertion, make any adjustments to catheter under fluoroscopy. Note: For jugular insertion, the distal tip should be placed within the right atrium confirmed by fluoroscopy for optimal flow (National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI) Guideline 2, K/DOQI Update 2006).
16. ALWAYS ENSURE BOTH END CAPS ARE ATTACHED TO CATHETER LUERS POST PLACEMENT.

CAUTION: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

17. Suture incision site as needed and apply an adhesive wound dressing.
18. Suture wings to patient's skin.

FEMORAL VEIN PLACEMENT PROCEDURE:

For femoral placement, position the patient supine, and insert the catheter tip to the junction of the iliac vein and inferior vena cava.

WARNING: The risk of infection is increased with femoral vein insertion.

NOTE: Catheters greater than 37cm are intended for femoral vein insertion.

NOTE: To reduce the number of cannulation attempts and mechanical complications, CDC Guidelines recommend the use of Ultrasound Guidance, if available. Ultrasound guidance should only be used by those fully trained in its technique.

1. Assess the right and left femoral areas for suitability for catheter placement. Ultrasound may be helpful.
2. On the same side as the insertion site, have the patient flex the knee with the thigh abducted and the foot placed across the opposing leg.
3. Locate the femoral vein, posterior/medial to the femoral artery.
4. Go to Part A Percutaneous Access (Common Steps)
5. Go to Part B Tunnel Catheter (Common Steps)
6. Go to Part C Catheter Insertion Technique (Common Steps)
7. Go to Part D Catheter Aspiration (Common Steps)

CATHETER REMOVAL:

Free cuff from surrounding tissue prior to removal. Withdraw the catheter through the exit site. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops. Suture incision and apply dressing in a manner to promote optimal healing.

CAUTION: Remove catheter with care. Sharp, jerking motions and undue force may tear catheter.

Discard biohazard according to facility protocol.

STORAGE:

Store at room controlled temperature. Do not expose to solvents, ionizing radiation or ultraviolet light. Rotate inventory so that catheters are used before the expiration date on the package label.

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WARRANTY

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