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TRIO-CT® TRIPLE LUMEN CATHETER HEMODIALYSIS, APHERESIS, AND INFUSION

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Trio-CT® Triple Lumen Catheter is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis and apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring.
- The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media.

DESCRIPTION:

- The Trio-CT® Triple Lumen Catheter is a short-term (less than 30 days) dialysis catheter made of thermosensitive polyurethane. The catheter has three separate lumens allowing continuous blood flow. The venous (blue) and arterial (red) lumens may be used for hemodialysis and apheresis treatments. The middle (purple) lumen is independent from the two dialysis lumens, and may be used for intravenous therapy, power injection of contrast media, central venous pressure monitoring, blood draws and infusion of medications.

CONTRAINDICATIONS:

- This catheter is intended for short-term (less than 30 days) vascular access only and should not be used for any purpose other than indicated in these instructions.

This device is also contraindicated:

- When the presence of device related infection, bacteremia, or septicemia is known or suspected.
- When the patient's body size is insufficient to accomodate the size of the implanted device.
- When the patient is known or is suspected to be allergic to materials contained in the device.
- If the prospective insertion site has been previously irradiated.
- If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. If local tissue factors may prevent proper device stabilization and/or access.

POTENTIAL COMPLICATIONS:

- Air Embolus
- Bacteremia
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Erosion through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Central Venous Thrombosis
- Embolism
- Endocarditis
- Exit Site Infection
- Exsanguination
- Hematoma
- Hemorrhage
- Hemothorax
- Intolerance Reaction to Implanted Device
- Laceration of the Vessel
- Laceration of Vessels or Viscus
- Lumen Thrombosis
- Mediastinal Injury
- Perforation of the Vessel
- Pleural Injury
- Pneumothorax
- Retroperitoneal Bleed
- Right Atrial Puncture
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery
- Septicemia
- Spontaneous Catheter Tip Malposition or Retraction
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thoracic Duct Laceration
- Vascular Thrombosis

- Before attempting the insertion, ensure that you are familiar with the potential complications and their emergency treatment should any of them occur.

IMPORTANT INFORMATION PERTAINING TO POWER INJECTION:

- Contrast media should be warmed to body temperature (37°C) prior to power injection.
- **Warning:** Failure to warm contrast to body temperature prior to power injection may result in catheter failure.
- Vigorously flush the catheter using a 10cc or larger syringe and sterile normal saline prior to and immediately following the completion of power injection studies. This will ensure the patency of the catheter and prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. Do Not proceed with the power injection study until occlusion has been cleared.
- **Warning:** Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Use only the lumen marked “power injectable” for power injection of contrast media.
- Do Not exceed the maximum flow rate of 5cc/sec.
- **Warning:** Power injector machine pressure limiting feature may not prevent over pressurization of on occluded catheter.
- **Warning:** Exceeding the maximum flow rate of 5cc/sec may result in catheter failure and /or catheter tip displacement.
- **Warning:** The indication of power injection of contrast media implies the catheter’s ability to withstand the procedure, but does not imply the appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- **Warning:** If local pain, swelling, or signs of extravasation are noted, the injection procedure should be stopped immediately.

WARNINGS:

- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the catheter and guidewire must be removed together.
- This catheter is for Single Use Only.

- Do not resterilize the catheter or accessories by any method.

- Re-use may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
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STERILE | EO

- Do not use catheter or accessories if package is opened or damaged.

- Do not use catheter or accessories if any sign of product damage is visible.

CATHETER PRECAUTIONS:

- Do not use sharp instruments near the extension tubing or catheter lumen.
- Do not use scissors to remove dressing.
- Catheter will be damaged if clamps other than what is provided with this kit are used.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the luers and hub of the catheter.
- Examine catheter lumen and extensions before and after each treatment for damage.
- To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.
- Use only Luer Lock (threaded) Connectors with this catheter in order to avoid inadvertent disconnection.
- Repeated overtightening of bloodlines, syringes and caps will reduce connector life and could lead to potential connector failure.
- Do not infuse incompatible drugs simultaneously through the same lumen; precipitation could occur.
- Do not infuse against a closed clamp or forcibly infuse a blocked catheter.
- To avoid damage to vessels and viscus, prolonged infusion pressures must not exceed 25 psi (172 kPa).
- Subclavian only. Pinch-off Prevention: Percutaneous insertion of the catheter must be made into the axillary-subclavian vein at the junction of the outer and mid-third of the clavicle lateral to the thoracic outlet. The catheter must not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle and can lead to damage or fracture and embolization of the catheter. Fluoroscopic or radiographic confirmation of catheter tip placement can be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle.[1]
- Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumens.
- Recirculation in femoral catheters was reportedly significantly greater than in internal jugular catheters.[5]
- Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein.[2]
- Discard biohazard according to facility protocol.

INSERTION SITES:

Caution: Left sided placement in particular, may provide unique challenges due to the right angles formed by the innominate vein and the left brachiocephalic junction with the left SVC.[3,4]

- The patient should be in a modified Trendelenberg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

INTERNAL JUGULAR VEIN

- Have patient lift his/her head from the bed to define the sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.

SUBCLAVIAN VEIN

- Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib.)

FEMORAL VEIN

- The patient should lie completely on their back. Both femoral veins should be palpated for site selection and consequence assessment. The knee on the same side of the insertion site should be flexed and the thigh abducted. Place foot across the opposite leg. The femoral vein is then posterior / medial to the artery.
- **Note:** For femoral placement, monitor patient closely for thrombosis, infection, and bleeding. Femoral vein insertions should be left in place for no longer than three days.

Warning:

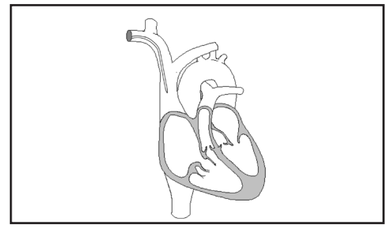
- Patients requiring ventilator support are at an increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.
- Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the initial insertion of this catheter to confirm proper tip placement prior to use.

DIRECTIONS FOR SELDINGER INSERTION

- Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician. The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician’s experience and judgment in treating any specific patient. Use standard hospital protocols when applicable.

1. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The Operating Room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask.
2. The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.

Tip Placement



3. Administer sufficient local anesthetic to completely anesthetize the insertion site.
4. Insert the introducer needle with attached syringe into the target vein. Aspirate to insure proper placement.

Note: If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that arterial bleeding has stopped and hematomas have not developed before attempting to cannulate the vein again.

5. Remove the syringe, and place thumb over the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back into advancer so that only the end of the guidewire is visible. Insert advancer’s distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

Caution: When introducer needle is used, do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.

6. Remove the needle, leaving guidewire in the vessel. Enlarge cutaneous puncture site with scalpel to facilitate passage of the dilator and catheter.
7. Thread the dilator over the proximal end of the guidewire. Dilate subcutaneous tissue and vein wall to allow easy passage of catheter into target vein.

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.

8. Remove the dilator leaving the guidewire in place.

Caution: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.

9. Irrigate catheter with saline, then clamp catheter extensions to assure that saline is not inadvertently drained from catheter. Use clamps provided.

Caution: Do not clamp the lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps, use only the in-line clamps provided.

10. Open distal extension clamp. Thread the catheter over proximal end of the guidewire.
11. Ease the catheter through the subcutaneous tissue and into the target vein.

Caution: Observe the patient carefully for signs and symptoms of cardiac arrhythmia caused by passage of the catheter into the right atrium. If symptoms appear, pull back the tip of the catheter until they are eliminated.

12. Make any adjustments to catheter under fluoroscopy. The distal tip should be located just before the junction of the superior vena cava and the right atrium.
13. Once proper placement is confirmed, remove guidewire and close slide clamp.
14. Attach syringes to all extensions and open clamps. Blood should aspirate easily from all lumens. If the lumens exhibit excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows.
15. Once adequate aspiration has been achieved, all lumens should be irrigated with saline filled syringes using quick bolus technique. Assure that extension clamps are open during irrigation procedure.
16. Close the extension clamps, remove the syringes, and place an end cap on each luer lock connectors. Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
17. To maintain patency, an anticoagulant lock must be created in all lumens. Refer to hospital locking solution protocols guidelines.

Caution: Assure that all air has been aspirated from the catheter and extensions.Failure to do so may result in air embolism.

18. Once the catheter is locked with anticoagulant locking solution, close the clamps and install end caps onto the extensions’ female luers. To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.
19. Confirm proper tip placement with fluoroscopy. The distal venous tip should be located just before the junction of the superior vena cava and the right atrium.

Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

CATHETER SECUREMENT AND WOUND DRESSING:

20. Suture the catheter to the skin using the suture wing. Removable suture wing may be used to minimize movement at exit site. Do not suture the catheter tubing.

Warning: Do not suture through any part of the catheter.

Caution: Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

21. Cover the insertion site with an occlusive dressing leaving extensions, clamps, luers, and caps exposed for access by the staff.
22. Catheter must be secured/sutured for entire duration of implantation.

Warning: There is a danger of pulling the catheter hub/tubing from the suture wing if excessive force is applied.

23. Record catheter length and catheter lot number on patient’s chart.

HEMODIALYSIS TREATMENT

- The anticoagulant locking solution must be removed from the arterial and venous lumens prior to treatment. Aspiration should be based on dialysis unit protocol.
- Before dialysis begins, all connections to catheter and extracorporeal circuits should be examined carefully.
- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.
- If a leak is found, the catheter should be clamped immediately.

Caution: Only clamp catheter with in-line clamps provided.

- Necessary remedial action must be taken prior to the continuation of the dialysis treatment.

Caution: Excessive blood loss may lead to patient shock.

- Hemodialysis should be performed under physician's instructions.
- Increased recirculation will occur if the arterial and venous lines are reversed during a dialysis treatment.

INFUSION

- The anticoagulant locking solution must be removed from the infusion lumen prior to treatment. Aspiration should be based on dialysis unit protocol.
- Before infusion begins all connections should be examined carefully.
- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.
- If a leak is found, the catheter should be clamped immediately.

Caution: Only clamp catheter with in-line clamps provided.

- Necessary remedial action must be taken prior to the continuation of the infusion treatment.

Note: Excessive blood loss may lead to patient shock.

- Infusion treatment should be performed under physician's instructions.

POWER INJECTION PROCEDURE

1. Remove the end cap from the catheter.
2. Using a 10cc or larger syringe aspirate for adequate blood return to remove locking solution and to assure patency. Discard syringe.
3. Attach a 10cc or larger syringe filled with sterile normal saline and vigorously flush the catheter with the full 10cc of sterile normal saline.
   a.) **Warning:** Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
4. Detach syringe.
5. Attach the power injection device to the catheter per manufacturer's recommendations.

Warning: Do not power inject through a catheter that exhibits signs of clavicle-first rib compression or pinch-off, as it may result in catheter failure.

Warning: Always use connector tubing between power injector syringe and catheter. Do not attempt to connect power injector directly to the catheter. Damage may result.

6. Complete power injection study taking care not to exceed the flow rate limits.

Warning: Exceeding the maximum indicated flow rate of 5cc/sec may result in catheter failure and/or catheter tip displacement.

Warning: Power injection machine or pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may result in catheter failure.

7. Disconnect the power injection device.
8. Flush the catheter with 10cc of sterile normal saline, using a 10cc or larger syringe.
9. Lock the lumen marked "power injectable" per institutional protocol for central lines.
10. Replace the end cap on the catheter.

CENTRAL VENOUS PRESSURE MONITORING (CVP)

- CVP Monitoring is intended to be preformed through the distal purple lumen.
- Use your institution's protocols for central venous pressure monitoring procedures.
- Prior to conducting central venous pressure monitoring:

1. Ensure proper positioning of the catheter tip.
2. Flush catheter vigorously with sterile normal saline.
3. Ensure the pressure transducer is at the level of the right atrium.

- It is recommended that a continuous infusion of saline (3cc/hr) is maintained through the catheter while measuring CVP.

Warning: CVP Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

Warning: CVP Monitoring should not be performed during hemodialysis or apheresis.

CATHETER LOCK

- If the catheter is not to be used immediately for treatment, follow the suggested catheter patency guidelines.
- To maintain patency between treatments, a catheter lock must be created in each lumen of the catheter.
- Follow hospital protocol for anticoagulant locking solution concentration.

1. Draw anticoagulant locking solution into syringes, corresponding to the amount designated on each extension. Assure that the syringes are free of air.
2. Remove end caps from the extensions.
3. Attach a syringe containing anticoagulant locking solution to the female luer of each extension.
4. Open extension clamps.
5. Aspirate to ensure that no air will be forced into the patient.
6. Inject anticoagulant locking solution into each lumen using quick bolus technique.

Note: Each lumen should be completely filled with anticoagulant locking solution to ensure effectiveness.

7. Close extension clamps.

Caution: Extension clamps should only be open for aspiration, flushing, and dialysis treatment. If clamp is opened, blood may enter the distal portion of the catheter, ultimately resulting in a thrombus.

8. Remove syringes.
9. Attach a sterile end cap onto the female luers of the extensions.

- In most instances, no further anticoagulant locking solution is necessary for 48-72 hours, provided the lumens have not been aspirated or flushed.

SITE CARE

- Clean skin around catheter. Cover the exit site with occlusive dressing and leave extensions, clamps, and caps exposed for access by staff.
- Alcohol or alcohol-containing antiseptics (such as chlorhexidine gluconate) may be used to clean the catheter/skin site.

Alternate compatible solutions/ointments include:

- Bactroban Ointment, 2% Mupirocin, Polyethylene Glycol Ointment, N.F.
- Silvadene Cream, 1% Silver Sulfadiazine
- 10% Povidone-Iodine Ointment
- Polysporin or Triple Antibiotic Ointment
- 0.1% Gentamycin
- Hydrogen Peroxide 3% Solution
- 10% Iodophor Iodine
- Chloroprep, 2% Chlorhexidine d-Digluconate + 70% Isopropanol (Isopropyl Alcohol)
- Anasept, 0.057% Sodium Hydrochlorite
- 70% Alcohol

- Solutions should be allowed to completely dry before applying an occlusive dressing.
- Wound dressings must be kept clean and dry.

Caution: Patients must not swim, shower, or soak dressing while bathing.

- If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile conditions.

CATHETER PERFORMANCE

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems.

Warning: Only a physician familiar with the appropriate techniques should attempt the following procedures.

INSUFFICIENT FLOWS:

The following may cause insufficient blood flows:

- Occluded proximal holes due to clotting or fibrin sheath.
- Occlusion of the side holes due to contact with vein wall.

Solutions include:

- Chemical intervention utilizing a thrombolytic agent.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS:

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This is usually caused by tip malposition.

One of the following adjustments may resolve the obstruction:

- Reposition catheter.
- Reposition patient.
- Have patient cough.
- Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall.
- Never forcibly flush an obstructed lumen. If any lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may consider using appropriate agents or thrombolytic agents to dissolve the clot.

INFECTION:

Caution: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

- 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.
- If a fever occurs in a patient with a catheter in place, take a minimum of two blood cultures from a site distant from catheter exit site. If blood culture is positive, the catheter must be removed immediately and the appropriate antibiotic therapy initiated. Wait 48 hours before catheter replacement. Insertion should be made on opposite side of original catheter exit site, if possible.

CATHETER REMOVAL

Warning: Only a physician familiar with the appropriate techniques should attempt the following procedures.

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

Note: The patient should be in a modified Trendelenberg position.

1. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
2. Withdraw catheter through the exit site.
3. Apply pressure to exit site for approximately 10-15 minutes or until bleeding stops.
4. Apply dressing in a manner to promote optimal healing.

- Discard biohazard according to facility protocol.

Injector pressure not to exceed 300 psi

Max Indicated Power Injection Flow-Rate[1]	Average Max Catheter Pressure During Max Indicated Power Injection Flow Rate[2]	Average Max Burst Pressure[3]	Range of Max Burst Pressures[3]
5 ml/sec	84 psi	420 psi	332-446 psi

FLOW RATE TESTING REPRESENTS OPTIMUM LABORATORY CONDITIONS

[1] Represents maximum indicated flow rate for power injection of contrast media.

[2] Internal catheter pressure during power injection with injector safety cut-off at 300 psi and using contrast media with 11.8 cP viscosity.

[3] Max burst pressure is the static burst pressure failure point of the catheter. When catheter was occluded failure occurred at these pressures.

Flow vs. Pressure

13.5F Trio-CT Triple Lumen Catheter Average Pressure - mmHg				
Flow Rate (ml/min) Straight Catheters		200	300	400
12cm	Venous	20	30	51
	Arterial	-21	-40	-60
15cm	Venous	20	40	63
	Arterial	-26	-46	-70
20cm	Venous	21	40	62
	Arterial	-30	-50	-70
24cm	Venous	30	50	76
	Arterial	-33	-50	-80
30cm	Venous	30	51	84
	Arterial	-33	-59	-90

Note: Flow Rate vs. Pressure data was obtained in vitro using a blood analog with a viscosity of 3.47 cP.

Priming Volume Information: 13.5F Trio-CT Triple Lumen Catheter			
Part Description	Priming Volume (cc)		
Straight Catheters	Center	Arterial	Venous
13.5F X 12CM TRIO-CT	0.4	1.2	1.2
13.5F X 15CM TRIO-CT	0.4	1.3	1.3
13.5F X 20CM TRIO-CT	0.5	1.5	1.5
13.5F X 24CM TRIO-CT	0.5	1.6	1.6
13.5F X 30CM TRIO-CT	0.6	1.9	1.9

Recirculation

Average recirculation rates of 2% for normal flow, and when arterial and venous lumens are reversed.

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WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

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