ACCESS VASCULAR

HydroMID®

Single Lumen Catheter
With MIMIX™ Technology

Instructions for use

HydroMID®

Catheter

℞ Only

Caution: Federal Law restricts this device to sale by or on the order or a licensed healthcare practitioner.

DEVICE DESCRIPTION

The HydroMID catheter is a 4 French, single lumen, midline catheter comprised of a radiopaque, hydrophilic catheter with a suture wing, Luer lock hub, and extension tubing made from materials commonly used in the manufacture of catheters. Catheters are provided packaged in kit configurations with the appropriate accessories for placement in the respective clinical environments. The maximum power injection flow rate for the lumen is indicated on the extension tube clamp.

HydroMID has been shown to be effective in reducing thrombus accumulation and thrombotic occlusions. Reduction of thrombus accumulation and thrombotic occlusions were evaluated using in vitro and in vivo models. Pre-clinical in vitro and in vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation.

INDICATIONS FOR USE / INTENDED USE

HydroMID is indicated for short-term (< 30 days) peripheral access to the venous system for intravenous therapy, including but not limited to; the administration of fluids, medications, and nutrients; the sampling of blood and blood products.

The maximum power injection flow rate for the HydroMID catheter is:

Catheter Size	Maximum Power Injection Flow Rate	Usable Length
4 Fr Single Lumen HydroMID	6 mL/sec	20 cm

CATHETER SIZING

Note: Catheter must be hydrated with sterile saline for a minimum of 5 minutes prior to insertion. Please see Insertion Instructions for complete information regarding start of infusion.

Catheter is supplied in a dry state and must be hydrated for a minimum of 5 minutes before use. Catheter hydrated length is 20 cm.

Catheter	Dry Dimensions		Hydrated Dimensions	
	Outer Diameter	Inner Diameter	Outer Diameter	Inner Diameter
4 Fr Single Lumen HydroMID	1.30 mm	0.95 mm	1.35 mm	1.00 mm

Maximum guidewire compatibility with hydrated catheter is 0.018 in. (0.46 mm).

Catheter priming volume is < 1.0 mL

CONTRAINDICATIONS

- Venous thrombosis in any portion of the vein to be catheterized.
- Conditions that impede venous return from the extremity such as paralysis or lymphedema after mastectomy.
- Orthopedic or neurological conditions affecting the extremity.
- Anticipation or presence of dialysis grafts or other intraluminal devices, including pacemakers.
- Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy.
- Preexisting skin surface or subsurface infection at or near the proposed catheter insertion site.
- Anatomical distortion of the veins from surgery, injury, or trauma.
- Inadequate antecubital veins.
- Anatomical irregularities (structural or vascular) which may compromise catheter insertion or catheter care procedures.

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing has demonstrated the HydroMID Catheter is MR Conditional.

	**MR Conditional** MRI Safety Information A person with the HydroMID 4 Fr Single Lumen Catheter may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.
Device Name	HydroMID 4 Fr Single Lumen Catheter
Static Magnetic Field Strength (B0)	3.0 T or less
Maximum Spatial Field Gradient	3,000 gauss/cm or less
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

WARNINGS

Catheter Insertion Warnings

- Refer to procedural steps for additional warnings. Due to the risk of exposure to blood-borne pathogens, care providers must adhere to guidelines for universal blood and body fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device.
- Failure to use care during trimming may result in complications.
- Do not use if package is opened or damaged.
- Do not re-sheath any needles. Place needles in puncture resistant, leak proof, sharps container per institutional protocol.
- Do not attempt to trim the catheter with the guidewire loaded as catheter or guidewire may become damaged resulting in patient injury.

- Some therapies are not appropriate for midline catheters. Follow Infusion Nurses Society current standards of practice regarding midline usage for continuous vesicant therapy, parenteral nutrition, or infusates with extremes of pH or osmolarity.

Power Injection Warnings

- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of occluded catheter.
- Exceeding the maximum allowable flow rate may result in catheter failure and or catheter tip displacement.
- Catheter indication for power injection of contrast media implies the catheter's ability to withstand this procedure but does not imply appropriateness of this procedure for a particular patient. A trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- The maximum pressure of power injectors used with the power injectable Midline must not exceed 300 psi (2,068 kPa).

PRECAUTIONS

Catheter Insertion Precautions

Refer to procedural steps for additional precautions.

- Do not advance a guidewire past the level of the axilla without the use of real-time imaging guidance.
- Do not use sharp objects to open the package as damage to the device may occur.
- Catheter insertion should be performed only by a licensed and qualified healthcare practitioner.
- If catheter and accessories show any sign of damage (crimped, crushed, cut, etc.), do not use.
- If using an introducer sheath other than the one provided, verify that the catheter fits easily through the sheath.
- Do not insert the stiff end of the floppy-tipped guidewire into the vein.
- Exercise care when advancing the catheter or guidewire to avoid trauma to the vessel intima. Do not use clamps, toothed or ribbed forceps. Do not use clamps or other instruments with teeth or sharp edges on the catheter or other instruments to advance or position catheter as catheter damage may occur.

- Avoid sharp or acute angles during insertion which may compromise catheter functionality.
- Do not use sharp instruments near the extension tubes or catheter shaft.
- Following institutional policy, secure catheter externally to prevent catheter movement, migration, damage, kinking, or occlusion.
- Ensure that gloves are free of residue.
- It is recommended that only Luer lock accessories be used with the HydroMID. Repeated over-tightening may reduce hub connector life. Do not use hemostats to secure or remove devices with Luer lock hub connections.
- If resistance is met while attempting to flush catheter, follow institutional protocol for occluded catheters.
- When discarding used accessories, follow institutional protocol.
- Prior to dressing the catheter and access site, inspect both to assure that they are completely dry of cleansing agents.
- Apply a sterile end cap or needleless connector to the catheter hub to prevent contamination when not in use.
- Patients must be educated regarding the care and maintenance of their Midline. The healthcare provider is responsible for this patient instruction.
- Cyanoacrylate based tissue adhesives must not be used with HydroMID as these may cause failure of the device.

Catheter Use Precautions

- Acetone and polyethylene glycol-containing ointments should not be used with catheter components containing polyurethane (extension tubing), as these may cause failure of the device.
- Incompatible drug delivery within the same lumen may cause precipitation. Flush catheter lumen following each infusion.
- It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein.
- The HydroMID catheter bench testing included ten (10) power injection cycles.
- Do not use scissors to remove the dressing, as this may possibly cut or damage the catheter.
- Prior to dressing the catheter and access site, inspect both to assure that they are completely dry of cleansing agents.
- Apply a sterile end cap or needleless connector to the catheter hub to prevent contamination when not in use.
- Catheter use, care, or removal is to be undertaken only by trained, qualified healthcare provider.

- Use of force to remove the catheter may lead to catheter separation. Hold the catheter distal to the suture wing during removal.
- Avoid blood pressure measurement or the application of a tourniquet to an arm with an implanted device since occlusion or other damage to the device may occur.
- Avoid pressure on the inner surface area or axilla of the cannulated arm while using crutches.
- Do not reinsert a catheter that becomes partially retracted during normal use or catheter maintenance (following the initial device insertion).
- Remove the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, possible embolism, and surgical removal.
- Cyanoacrylate based tissue adhesives must not be used with HydroMID as these may cause failure of the device.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Intended for Single Patient use. DO NOT REUSE. HydroMID is a single use device and should never be re-implanted. Reuse carries with it the attendant concerns of cross-infection regardless of the cleaning or sterilization method. Re-sterilization of incompletely cleaned devices may not be effective. Any device that has been contaminated with blood must not be reused or re-sterilized.

POTENTIAL COMPLICATIONS

The following complications may be associated with the device or procedure.

- Air embolism
- Bleeding
- Brachial Plexus or other Nerve Injury
- Catheter Dislodgement
- Catheter Embolism
- Catheter Erosion through Skin/Vessel
- Catheter Fragmentation
- Catheter Malposition
- Catheter Migration
- Catheter Occlusion
- Catheter Retraction
- Catheter Rupture
- Death
- Extravasation/Infiltration of Infusate
- Embolism
- Endocarditis
- Exit Site Necrosis
- Fibrin Sheath Formation
- Foreign Body Rejection
- Hematoma
- Hemorrhage
- Hemothorax
- Infection
- Inflammation/Phlebitis
- Intolerance Reaction to Contrast Media
- Malposition
- Myocardial Erosion
- Nerve Damage
- Pain
- Pericardial Effusion
- Pleural Effusion
- Pneumothorax
- Pulmonary Embolism
- Sensitivity or Allergy
- Sepsis
- Sub-intimal Venous or Myocardial Injection
- Thoracic Duct Injury
- Thromboembolism
- Thrombophlebitis
- Vascular Thrombosis
- Vessel Damage
- Vessel Stenosis

HOW SUPPLIED

Catheter and accessories are supplied sterile. Product is sterilized by ethylene oxide (EO) except where labeled otherwise. Product should be stored in a cool, dry, dark place. DO NOT use if package is damaged or open or if labeling is incomplete or illegible.

The HydroMID Catheter is supplied in a dry state and must be hydrated before use**.**

The HydroMID catheter is supplied in a foil pouch and the kit components are supplied in a separate pouch. The contents within these pouches are sterile. However, the outside of these pouches are not sterile. Remove pouches from outer packaging outside of sterile field. Using aseptic technique, transfer contents of the foil pouch INTO sterile field established by opening the kit component pouch.

OPERATIONAL INSTRUCTIONS

The HydroMID is to be inserted, manipulated, and removed only by a qualified, licensed healthcare practitioner. The techniques and procedures provided below do not represent all medically acceptable methods, nor are they intended to substitute the experience or judgment of a clinician in treating any one patient.

Strict aseptic technique must be used during all techniques related to catheter use, insertion, manipulation, and removal. Before use, carefully examine the product to verify that it has not expired and has not been damaged in shipment or during removal from packaging.

CAUTION: Do not use sharp objects to open package.

INSTRUCTIONS FOR USE

Catheter Insertion Instructions

Identify Vein and Insertion Site

1. Select a vein by assessing patient anatomy and condition. Common veins used for insertion include the basilic, brachial, and cephalic veins.
2. Measure distance along vein track between selected insertion site and the desired catheter tip location.

NOTE: According to Infusion Nursing Society Standards, the current recommended tip location is at or below the axillary line.
NOTE: The external measurement can never exactly duplicate the internal venous anatomy.

Prepare Catheter

NOTE: Catheter should be prepared before venous access.

1. Prepare sterile field and supplies.
2. Open outer packaging and remove non-sterile pouches containing catheter and kit components.
3. Using sterile technique, transfer the contents of the foil catheter pouch onto the sterile field.
4. Leave catheter in its protective sheath for hydration steps.

NOTE: Catheter must be hydrated for a minimum of 5 minutes before insertion.

5. Attach a 10 mL sterile saline syringe to the catheter.
6. Leaving catheter in protective sheath, flush catheter.

NOTE: To ensure full hydration, all air must be evacuated from protective sheath during flush. This can be achieved by retracting the suture wing approximately 1 cm from the sheath and occluding the other end during flush.
NOTE: After flush, carefully reinsert catheter hub into sheath to prevent saline from leaking out.

7. Once all air is evacuated from the sheath, lock catheter clamp and remove syringe. Lay in sterile field.
8. Wait at least 5 minutes. Leave catheter in protective sheath during this time.
9. After at least 5 minutes, hydration is complete and the catheter may be removed from the sheath for further preparation.

NOTE: Complete hydration may be confirmed by observing that catheter is free of curling and is able to be straightened.

Venous Access

1. Position patient with arm extended outward from body at 90-degree angle, or as tolerated.
2. As necessary, apply tourniquet to upper arm above intended insertion site.
3. Insert introducer needle, bevel up, into selected vein and confirm vessel entry.
   NOTE: Follow clinical practice guidelines, standards or institutional procedures in the use of ultrasound guidance when gaining access to veins that are not visible or palpable.
4. Insert flex tip of guidewire through the needle and into the vein to the desired position based on standard clinical practice guideline and standards or institutional procedures.
5. Release tourniquet, if used.
6. Gently remove needle and discard per institutional protocol.

Introducer Sheath and Dilator Placement

1. Advance tearaway sheath assembly over guidewire. Using a slight twisting motion, advance assembly into vein.
   NOTE: If needed, nick insertion site with scalpel.

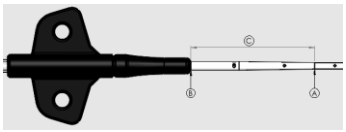
Catheter Insertion

1. After 5 minute hydration, trim the catheter to the desired length. Note the length for later recording on the Patient Information Card.
   NOTE: It is recommended that the catheter is inserted to the zero mark on the catheter shaft.
2. Rotate locking collar of dilator to unlock dilator from sheath.
3. Withdraw the dilator and guidewire, leaving sheath in place.

   NOTE: If desired, unlock catheter clamp and advance guidewire into catheter then clamp the catheter to lock the guidewire in place.
   NOTE: The guidewire should not extend past the catheter tip.

4. Insert the catheter into the sheath.
5. Advance the catheter slowly to desired tip location.

   NOTE: The HydroMID catheter features a tapered catheter design. Resistance may be felt approximately 4cm distal of catheter hub when introducing the catheter into the sheath due to an increase in outer diameter. The introducer may be partially split, but not removed, to facilitate insertion of the catheter past this point if necessary.

	# of Lumens	**A** OD (Fr)	**B** OD at Suture Wing (Fr)	**C** Taper Length (cm)
HydroMID 4 Fr Single Lumen	1	4	5.5	6

6. Holding the catheter steady, slowly withdraw the peelable sheath approximately 1 cm from the insertion site. Grasping the wings of the sheath firmly, peel apart by applying equal pressure to both wings. Peel the sheath away from the catheter by using a forward motion.
7. Slowly advance the catheter to the desired position.

   NOTE: It is recommended that the catheter is inserted to the zero mark on the catheter shaft.

8. Remove guidewire while holding suture wing in place.
9. Attach syringe and aspirate gently and observe blood return.
10. Flush and lock the catheter with sterile saline per institutional protocol, but no less than 2.5 times the catheter priming volume (priming volume 1 mL).
    NOTE: Follow institutional protocol for placement of needleless connector and flush/clamping sequence.
11. Dispose sheath, guidewire, and syringe per institutional protocol.

    NOTE: ***Do not infuse for an additional 15 minutes after hydration.*** Catheter testing was performed using the assumption that the catheter insertion and securement steps would take 15 minutes after hydration.

Catheter Securement

NOTE: Make best efforts to minimize catheter movement during stabilization.

1. Prepare securement site, removing any antiseptic residue present.
2. Refer to securement device manufacturers' placement instructions for skin preparation and securement.

Confirm Catheter Patency

1. Attach a 10 mL sterile normal saline syringe to hub and open clamp.
2. Aspirate for adequate blood return and flush catheter to ensure patency.
3. Close clamp and detach syringe. Discard per institutional protocol.
4. Attach a cap or needleless connector to the catheter hub following institutional protocol.

   NOTE: Never leave catheter uncapped after placement.

5. Cover site with transparent dressing.

NOTE: Flush catheter after EVERY use. When not in use, the catheter should be flushed per institutional protocol, to ensure patency.

CATHETER MAINTENANCE

The catheter should be maintained in accordance with institutional policies. Recommended care for the HydroMID can be found below.

General Care of Catheter

- Use aseptic technique during catheter care and use.
- Use Standard and Universal Precautions during catheter care procedures.
- Never leave catheter uncapped. Follow institutional protocols for needleless connector changes.
- Do not use clamps or instruments with teeth or sharp edges on the catheter as catheter damage may occur.

Care of Insertion Site and Dressing

- Insertion site, catheter securement device, and external measurement should be examined routinely and with each dressing change.
- A sterile, occlusive dressing covering the entire insertion site, catheter securement device, and a portion of the extension tube is recommended.
- Follow Institutional protocol for dressing change. It is recommended that dressings be changed weekly and as needed.
- To maintain unobstructed flow, make sure there are no kinks in catheter or IV tubing.
- All efforts should be made to keep both the insertion site and dressing clean, dry, and intact.

Dressing Removal

1. Stabilize catheter and Luer lock hub during dressing removal to prevent accidental dislodgement.
2. Separate dressing away from Luer lock hub and catheter and toward insertion site. As you separate, keep any tape and dressing close to patient's arm to avoid dislodging catheter.

Catheter Integrity Assessment

1. Before any injection/infusion, the integrity of the catheter should be assessed.
2. Examine and palpate catheter tract and insertion site for complications.
3. Using a 10 mL sterile normal saline (NS) syringe, flush small amount of sterile normal saline per institutional protocol, but no less than 2.5 times the catheter priming volume (priming volume 1 mL), then aspirate slowly for brisk blood return. Difficulty in withdrawing blood

may indicate catheter compression, kink, malposition, and/or obstruction. Discard syringe according to institutional protocol.

4. Using second 10 mL syringe, flush catheter with 10 mL sterile normal saline to clear catheter.
5. Additionally, catheters that present resistance to flushing and aspiration may be partially or fully occluded. DO NOT flush against resistance. If the lumen will neither flush nor aspirate and it has been determined that the catheter is occluded with blood, replacement of catheter per institution protocol may be appropriate.

CAUTION: Remove the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, possible embolism, and surgical removal.

POWER INJECTION

WARNING: Exceeding maximum allowable flow rate may result in catheter failure and/or displacement of catheter.

1. Verify power injector is appropriately programmed and does not exceed catheter maximum flow rate below:

Catheter Size	Maximum flow rate	Maximum Pressure Setting
4 Fr Single Lumen HydroMID	6 mL/sec	300 psi [2,068 kPa]

2. Contrast media should be warmed body temperature prior to power injection.

   WARNING: Failure to warm contrast media to body temperature prior to power injection may result in catheter damage or failure.

3. Inspect catheter for damage.

   WARNING: Failure to ensure catheter patency prior to power injection studies may result in catheter failure.

4. Attach a 10 mL sterile normal saline syringe, open clamp, flush small amount per institutional protocol, but no less than 2.5 times the catheter priming volume (priming volume 1 mL) and then aspirate more than lumen volume (~ 1 mL), or until brisk blood return. Flush with remaining sterile normal saline.
5. Close clamp and remove syringe. Dispose syringe according to institutional protocol.
6. Attach syringe with 10 mL sterile saline, open clamp, and flush using pulsatile flushing technique.
7. Close clamp and detach syringe. Discard syringe according to institutional protocol.
8. Attach power injector to lumen hub per manufacturer's recommendations and open clamp.

9. Complete power injection study taking care not to exceed maximum flow rate limit (above) and close clamp.
10. Disconnect the power injector.
11. Flush and lock the catheter with sterile normal saline.

NOTE: Flush with 20 mL of saline after power injection.

BLOOD SAMPLING

1. Stop administration of infusates.
2. Using aseptic technique, swab catheter hub and allow to air dry.
3. Attach 10 mL sterile normal saline syringe, open clamp, and flush the selected lumen.
4. Use syringe to aspirate small amount of blood and fluid to verify patency and for discard volume (waste) per institutional protocol.
5. Close clamp and remove syringe. Dispose syringe according to institutional protocol.
6. Attach second syringe, open clamp, and slowly withdraw specimen. Close the clamp, remove the syringe, and transfer specimen(s) per institutional protocol.
7. Flush and lock the catheter with sterile normal saline.
8. If necessary, replace needleless connector per institutional protocol.

CATHETER REMOVAL

Catheter removal is per the discretion of the physician in conjunction with the patient's condition, therapy and the catheter site condition.

1. Position patient upright with arm at 45-degree angle outward from the body. Maintain insertion site below level of heart.
2. Remove dressing and securement device using an adhesive remover as necessary per securement device instructions to reduce trauma to the skin.
3. Cleanse exit site with appropriate antiseptic.
4. Grasp catheter near insertion site and remove slowly in small smooth increments, keeping catheter parallel to skin surface.

   NOTE: Do not grasp at Luer lock hub as damage may occur.

5. If resistance is met, follow institutional protocol for the management of difficult to remove catheters.
6. Following removal of catheter, cover insertion site with occlusive dressing for at least 24 hours.
7. Verify entire catheter has been removed by comparing catheter length to length recorded at time of insertion.
8. Dispose of catheter following institutional procedures.

TABLE OF SYMBOLS

Symbol	Meaning
	Catalog number
	Consult Instructions for Use
	Catheter is MR Conditional
	Sterilized using ethylene oxide
	For Single Use. Do Not Reuse
	Do Not Resterilize
	Legal Manufacturer
	Lot Number
Rx Only	**Caution:** Federal Law restricts this device to sale by or on the order or a licensed healthcare practitioner

Symbol	Meaning
	Caution
	Keep Dry
	Do not use if package is damaged
	Use By
	Catheter is not made with DEHP
	Catheter is non-pyrogenic
	Catheter is not made with natural rubber latex
	Single lumen catheter
	Maximum pressure setting for power injection is 300 psi

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