Neutron Reperfusion Catheter

Instructions for Use

Gravity Medical Technology, Inc.

Neutron Reperfusion Catheter

DEVICE DESCRIPTION

The Neutron Reperfusion Catheter is a non-tapered, single lumen, variable stiffness catheter equipped with coil reinforcement. The catheter is inserted into the target vasculature under angiographic visualization and is designed to be used for general intravascular use, introduction of diagnostic or therapeutic devices, and aspiration of embolus and thrombus. The distal segment is designed to facilitate vessel selection with the hydrophilic coating for navigation through the vasculature. A radiopaque marker provides the user with visual confirmation of the distal tip under fluoroscopy. The proximal end of the catheter utilizes a luer fitting to allow attachment of accessories and infusion of liquids through the system. The Neutron Catheter is packaged with an introducer sheath to assist introducing the catheter into the Y-connector.

Model Number	Working Length	ID	OD	Hydrophilic Coating
NTRON-~~072~~ 070 -136-~~TII~~	136cm	.070”	.085”	60cm
NTRON-~~072~~ 070 -125-~~TII~~	125cm			
NTRON-~~072~~ 070 -115-~~TII~~	115cm			

INDICATIONS FOR USE

The Neutron Reperfusion Catheter is indicated for injection of intravascular fluids, the introduction of interventional devices into the peripheral and neuro vasculature, and removal/aspiration of soft emboli and thrombi from the arterial system, including the peripheral and neuro vasculature.

INTENDED PURPOSE

The Neutron Reperfusion Catheter will be intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents.

Additionally, the Neutron Reperfusion Catheter will be intended for use in the revascularization of patients, intended to remove/aspirate emboli and thrombus from the peripheral and neuro vasculature.

INTENDED USER

The Neutron Reperfusion Catheter should only be used by physicians trained in interventional procedures. Medical specialist including, but not limited to, Interventional Neuroradiologist (INR), Interventional Neurosurgeons, Interventional Neurologist, and others trained to perform treatment in the neuro and peripheral vasculature via endovascular techniques.

CONTRAINDICATIONS

There are no known contraindications.

COMPATIBILITY

Refer to the product label for device dimensions. Refer to labeling provided with other medical technologies to determine compatibility.

WARNINGS

Contents supplied sterile using an ethylene oxide (EO) process. Do not use if the sterile barrier is damaged. Do not reuse, reprocess, or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to the transition of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness of death of the patient.

Not intended for use with power injectors.

Do not advance, retract or use any component of the Neutron Catheter against resistance without careful assessment of the cause using fluoroscopy. Forced advancement or torquing the Neutron Catheter may result in damage of the catheter and cause vessel damage.

If flow through the catheter becomes restricted, do no attempt to clear the catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace the catheter.

The device must be disposed according to the national regulations and laws for clinically contaminated materials after use.

PRECAUTIONS

The Neutron Catheter should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.

Carefully inspect all devices prior to use. Verify size, length and condition are suitable for the specific procedure. Ensure the catheter’s labeled outer diameter is smaller than the treatment vessel diameter. Do not use a device that has been damaged in any way. Damaged device may cause complications.

Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.

To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.

Use the product prior to the “Use By” date located on the packaging label.

To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.

Torquing the catheter may cause damage which could result in kink or separation of the catheter shaft.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to:

- Access site complications
- Allergic or Anaphylactic reaction
- Aneurysm perforation or rupture
- Death
- Embolism (air, foreign body, plaque, thrombus)
- Hematoma
- Hemorrhage
- Infection
- Ischemia
- Neurological deficits
- Pseudoaneurysm
- Stroke
- Transient Ischemic Attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

PREPARATION FOR USE

1. Using standard sterile technique, gently remove the Neutron Reperfusion Catheter and packaging card from the pouch by grasping the packaging card and slowly pulling the card out of the pouch.
2. Remove the Neutron Reperfusion Catheter from the packaging card.
3. Carefully inspect the Neutron Reperfusion Catheter for any damage or kinks. If any damage is observed, replace it with a new device.
4. Connect a rotating hemostasis valve (RHV) to the hub of the catheter and flush the inner lumen with heparinized saline.
5. Hydrate the coating of the Neutron Reperfusion Catheter by submerging the catheter into a saline solution for a minimum of 30 seconds to activate the coating prior to use.
6. Prep guidewire and microcatheter per appropriate IFU.
7. Insert the guidewire into the microcatheter and insert the guidewire/microcatheter system into the ID of the Neutron Reperfusion Catheter.
8. Introduce the catheter system into the guide catheter or femoral sheath. A peel-away introducer sheath is provided in the package to provide support and facilitate the introduction of the Neutron Reperfusion Catheter distal tip into the guide catheter or femoral sheath. If the peel-away introducer sheath is used, remove it after the Neutron Reperfusion Catheter distal tip has been introduced into the guide catheter or femoral sheath.
9. Under fluoroscopic guidance and conventional catheterization techniques, advance the catheter system until the desired position is attained.
10. Remove the guidewire and microcatheter prior to the introduction of compatible devices or aspiration of thrombus.

ASPIRATION OF THROMBUS

1. The Neutron Reperfusion Catheter should be placed proximally to the thrombus in the desired vessel.
2. To retrieve thrombus, apply aspiration to the catheter using a 60cc locking syringe.
3. Continue aspirating through the catheter until the thrombus is withdrawn or physician determines further aspiration is ineffective.
4. As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.

SYMBOL LEGEND

REF	Catalogue number		Caution	MD	Medical Device
LOT	Lot Number		Do Not Re-Use		Single Sterile Barrier System with Protective Packaging Outside
	Non-pyrogenic		Keep Dry		Single Sterile Barrier System with Protective Packaging Inside
	Manufacturer		Keep Away from Sunlight		Do Not Re-Sterilize
	Use-by date		Consult Instructions for Use	STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged				

Manufacturer: Gravity Medical Technology (Thailand) Co., Ltd Bangkok Thailand