Supernova
Revascularization Device

Instructions for Use

Supernova Revascularization Device

DEVICE DESCRIPTION

The Gravity Supernova Revascularization Device is a stent-based thrombus retrieval device with a collapsible, fully retrievable, self-expanding laser cut stent which is mounted on a wire shaft for delivery. The Gravity Supernova Revascularization Device is offered in two different sizes: 4mm x 43mm and 6mm x 47mm. The Gravity Supernova Revascularization Device will be intended for general intravascular use for the neuro vasculature such as the Internal Carotid Artery (ICA), M1 and M2 segments of the middle cerebral artery, basilar, and the vertebral arteries.

INTENDED USE

The Supernova Revascularization Device is intended to restore blood flow and remove thrombus in the cerebral vasculature.

INDICATIONS FOR USE

The Supernova Revascularization Device is indicated for temporary use to restore blood flow in the cerebral vasculature of patients suffering from an acute ischemic stroke.

SUMMARY OF CHARACTERISTICS

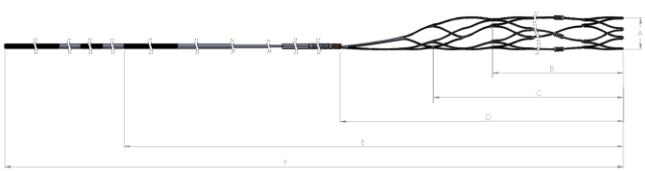

Figure 1: Supernova Revascularization Device

Table 1: Product Specifications for Gravity Supernova

Catalog Number	Stent Maximum Diameter A	Target Vessel Diameter		Stent Working Length B	Cell Coverage Length C	Proximal Marker to Distal Marker Length D	Length from Distal Tip to Fluorosafe Marker E	Delivery Catheter ID	Device Total Length F	Radiopaque Markers
	mm	Minimum (mm)	Maximum (mm)	mm	mm	mm	cm	in	cm	
GRVY-004-043-TH	4	1.5	4	39	43	50	145	0.021	205	12
GRVY-006-047-TH	6	2	5.5	43	47	55	145	0.021	205	15

Device selection is based on the sizing recommendation listed in this table and the diameter of the smallest vessel at the thrombus site.

HOW SUPPLIED

Sterile: The device is sterilized with Ethylene Oxide. Non-pyrogenic.

Contents: One (1) Gravity Supernova Revascularization Device.

Storage: Store product in a dry, cool place.

CONTRAINDICATIONS

The Gravity Supernova Revascularization Device is contraindicated for use in:

- Patients with known hypersensitivity to nickel-titanium.
- Patients with stenosis and/or pre-existing stent proximal to the thrombus site that may preclude safe recovery of the Gravity Supernova Revascularization Device.
- Patients with angiographic evidence of carotid dissection.

WARNINGS

- The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.
- Prescription only – device restricted to use by or on the order of a physician.
- Administer IV t-PA as soon as possible for all patients who are indicated to receive the drug. Do not cause delays in this therapy.
- Per IV t-PA manufacturer labeling, IV t-PA should be administered within 3 hours of stroke symptom onset.
- Do not torque the Gravity Supernova Revascularization Device.
- For vessel safety, do not perform more than 3 recovery attempts in the same vessel using Gravity Supernova Revascularization Device.
- For each new Gravity Supernova Revascularization Device, use a new microcatheter.
- Contents supplied STERILE, using an ethylene oxide (EO) process. Nonpyrogenic. DO NOT USE if the sterile barrier is damaged or opened prior to the intended use.
- Store in a cool, dry, dark place.
- Do not autoclave.
- Do not expose device to solvents.
- DO NOT USE after the labeled “Use By” date.
- The Gravity Supernova Revascularization Device is intended for SINGLE USE only. DO NOT RESTERILIZE AND/OR REUSE. Reuse and/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. Re-sterilization and/or reuse may create a risk of contamination of the device and/or cause patient infection or cross-infection, including the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to patient injury, illness, or death.
- Use Gravity Supernova Revascularization Device in conjunction with fluoroscopic visualization and proper anticoagulation agents.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution between guide catheter and microcatheter and between microcatheter and device or guidewire.

PRECAUTIONS

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with possible complications which may occur during or after the procedure.

- To reduce the risk of vessel damage, adhere to the following recommendations:
  - Take care to appropriately size device to vessel diameter at the intended deployment site.
  - Do not perform more than three (3) retrieval attempts in the same vessel using Gravity Supernova Revascularization Device.
  - Maintain device position in the vessel when removing or exchanging microcatheter.
- To reduce risk of kinking/fracture, adhere to the following:
  - Immediately after unsheathing Gravity Supernova Revascularization Device, position microcatheter tip marker just proximal to shaped section. Maintain microcatheter tip marker just proximal to shaped section of Gravity Supernova Revascularization Device during manipulation and withdrawal.
  - Do not rotate or torque Gravity Supernova Revascularization Device.
  - Use caution when passing Gravity Supernova Revascularization Device through stented arteries.

- The Gravity Supernova Revascularization Device should only be used by physicians trained in interventional neuroradiology and treatment of ischemic stroke.
- Carefully inspect the sterile packaging and the Gravity Supernova Revascularization Device prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components.
- The Gravity Supernova Revascularization Device is not to be used after the expiration date imprinted on the product label.
- Refer to the appropriate intravenous tissue plasminogen activator (IV t-PA) manufacturer labeling for indications, contraindications, warnings, precautions, and instructions for use.
- Do not advance or withdraw Gravity Supernova Revascularization Device against resistance or significant vasospasm. Moving or torquing device against resistance or significant vasospasm may result in damage to vessel or device. Assess cause of resistance using fluoroscopy and, if needed re-sheath the device to withdraw.
- Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.
- If Gravity Supernova Revascularization Device is difficult to withdraw from the vessel, do not torque the Gravity Supernova Revascularization Device. Advance microcatheter distally, gently pull the Gravity Supernova Revascularization Device back into microcatheter and remove Gravity Supernova Revascularization Device and microcatheter as a unit. If undue resistance is met when withdrawing the Gravity Supernova Revascularization Device into the microcatheter, consider extending the Gravity Supernova Revascularization Device using the Abbott Vascular DOC guidewire extension (REF 22260) so that the microcatheter can be exchanged for a larger diameter catheter such as a DAC™ catheter. Gently withdraw the Gravity Supernova Revascularization Device into the larger diameter catheter.
- Administer anticoagulation and anti-platelet medications per standard institutional guidelines.

COMPLICATIONS

Possible complications include, but are not limited to, the following:

- Acute Occlusion
- Air Embolism
- Death
- Dissection or perforation
- Distal embolization
- Emboli
- False Aneurysm Formation
- Hematoma or hemorrhage at the puncture site
- Infection
- Intracranial Hemorrhage
- Ischemia
- Pain/headache
- Stroke
- Thrombosis
- Vessel Spasm

PROCEDURE

Prior to the procedure, carefully examine all equipment and materials to be used during the procedure, including the Gravity Supernova Revascularization Device, to verify proper functioning. Verify that the Gravity Supernova Revascularization Device size is suitable for the specific procedure for which it is intended.

In addition to the Gravity Supernova Revascularization Device, the following standard materials may also be required:

- 0.014" (0.36 mm) guidewire
- Torque device
- Hemostasis valve with 8Fr inner lumen
- Introducer sheath (8 Fr)
- Contrast medium
- Sterile saline
- Inflation device with manometer
- Luer lock syringe for purging

Handle the Gravity Supernova Revascularization Device with extreme caution in order to avoid any damage to the device.

DEVICE PREPARATION, DELIVERY, & POSITIONING

1. Administer anticoagulation and anti-platelet medications per standard institutional guidelines.
2. Aided by angiographic fluoroscopy, determine the deployment location and its

diameter.

3. Select Gravity Supernova Revascularization Device based on Table 1.
4. Select a suitable neurovascular guiding catheter 5Fr or larger and prepare per device instruction for use.
5. Access the occluded vessel using the guiding catheter and position catheter as close to thrombus site as possible. Connect a Rotating Hemostatic Valve (RHV) flushed with continuous heparinized saline.
    - Select a microcatheter suitable for advancing the Gravity Supernova Revascularization Device. Connect a second RHV to the hub of the microcatheter and then connect to a continuous flush. Set the flush rate per standards institutional guidelines. With the aid of a guidewire, advance the microcatheter until the end of the microcatheter is positioned distal to the thrombus. The usable length of the Gravity Supernova will extend past each side of the thrombus in the vessel. Verify the location of the distal side of the thrombus by injecting contrast media through the microcatheter. Tighten the RHV around the microcatheter and remove the guidewire.
    - Stenosis identification: A suspected stenosis can be evidenced by difficulty crossing the lesion with a wire, poor expansion of the device, or calcium on a CT image.
    - Small-caliber bifurcation identification: Carefully check whether the target occlusion crosses a small-caliber bifurcation. For instance, opacification of the collateral vessels might indicate such bifurcation. If the clot occludes a bifurcation, prefer the larger division if possible (for example, the inferior division of MCA). Perform a contrast injection through the microcatheter to evaluate the sizing of the branch where the device will be deployed.
6. Remove the Gravity Supernova Revascularization Device from the dispenser hoop.
7. Carefully advance the Gravity Supernova Revascularization Device until the device completely extends from the introducer tube.
8. Soak the open device in heparinized saline.
9. Pull back until the tip is just inside the end of the introducer tube.
10. Insert the distal end of the introducer tube into the microcatheter's RHV and tighten the RHV and verify that the fluid exits the proximal end of the introducer tube.
11. Loosen the RHV and advance about 50cm of the Gravity Supernova Revascularization Device through the introducer tube into the microcatheter.
12. Slide the introducer tube over the proximal end of the pusher wire.
13. Continue slowly advancing the device until the fluorosafe marker enters the hub of the microcatheter. Continue advancing the device under fluoroscopic visual control until its tip extends out of the microcatheter.
14. Unsheathe the device slowly by withdrawing the microcatheter in the proximal direction. Follow the tip of the device and distal and proximal markers for accurate deployment. As a result, the proximal marker should be positioned proximally to the thrombus.
15. Wait 2 minutes to allow device expansion in the thrombus.
16. Position the microcatheter until it is just proximal to the proximal marker of the device. Tighten the RHV of the microcatheter to prevent relative movement between the microcatheter and the device.
17. Tighten the RHV around the microcatheter and angiographically assess the revascularization status of the treated vessel.
18. In cases where resistance during device expansion suggests the presence of atherosclerotic plaque at the site of the clot or that the clot and device are crossing a bifurcation and extending into a smaller caliber artery, care should be used not to apply excessively prolonged deployment expansion force to the device in these locations.
19. If resheathing of the Gravity Supernova Revascularization Device is necessary proceed to the following:
    - Loosen the RHV around the microcatheter and around the pusher wire. With the aid of fluoroscopic monitoring, hold the pusher wire firmly in its position to prevent the device from moving.
    - Carefully re-sheath the Gravity Supernova Revascularization Device by advancing the microcatheter over the device until the distal markers are retracted back into the microcatheter tip.

RETRIEVAL

1. If using a balloon guide catheter, inflate the guide catheter balloon to the occluded vessel as specified in Balloon Guide Catheter labeling.
2. Loosen the RHV around the microcatheter and slowly withdraw the microcatheter and the Gravity Supernova Revascularization Device as a unit to the guide catheter tip while applying aspiration to the guide catheter with an aspiration device.
3. Apply aspiration to the guide catheter using the aspiration device and recover the Gravity Supernova Revascularization Device inside the guide catheter. Continue aspirating guide catheter until the Gravity Supernova Revascularization Device is withdrawn from the guide catheter.
4. If excessive resistance is encountered during the retrieval, partially deflate the device before continuing the retrieval and withdraw the guide catheter, microcatheter and Gravity Supernova Revascularization Device as a unit through the sheath while maintaining aspiration.
5. If stenosis or a small-caliber bifurcation were identified as described in steps 4b and 4c as mentioned above, use extra attention when withdrawing the Gravity Supernova Revascularization Device.
6. Open the guide catheter RHV to allow the microcatheter and device to exit without resistance. Use carefully to avoid interaction with the site of the intervention and to prevent air from entering the system.
7. Aspirate the guide catheter to ensure the guide catheter is clean of any thrombus material.
8. Deflate balloon guide catheter.
9. If additional flow restoration attempts are desired with:

    - The same Gravity Supernova Revascularization Device then
        - Clean the device with saline solution and carefully inspect the device for damage. If no damage is present, load the introducer tube over the proximal end of the pusher wire.
        - If there is damage, discard the device and use a new Gravity Supernova Revascularization Device starting with the device preparation steps.
    - A new Gravity Supernova device
        - Start with steps described for device preparation.

COMPATIBILITY

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

DEVICE DISPOSAL

Dispose of the device per hospital standard operating procedures.

SYMBOL LEGEND					
REF	Catalogue number		Caution	MD	Medical Device
SN	Serial Number		Do not re-use	UDI	Unique device identifier
	Date of Manufacturer		Keep Dry		Single sterile barrier system with protective packaging inside
	Manufacturer		Keep Away from Sunlight	2	Do Not Re-Sterilize
	Use-by date	#	Model Number	STERILE EO	Sterilized Using Ethylene oxide
CC	Country of Manufacture		Do Not Use if Package is Damaged		Single sterile barrier system with protective packaging outside
	Non-pyrogenic		Consult Instructions for Use		

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