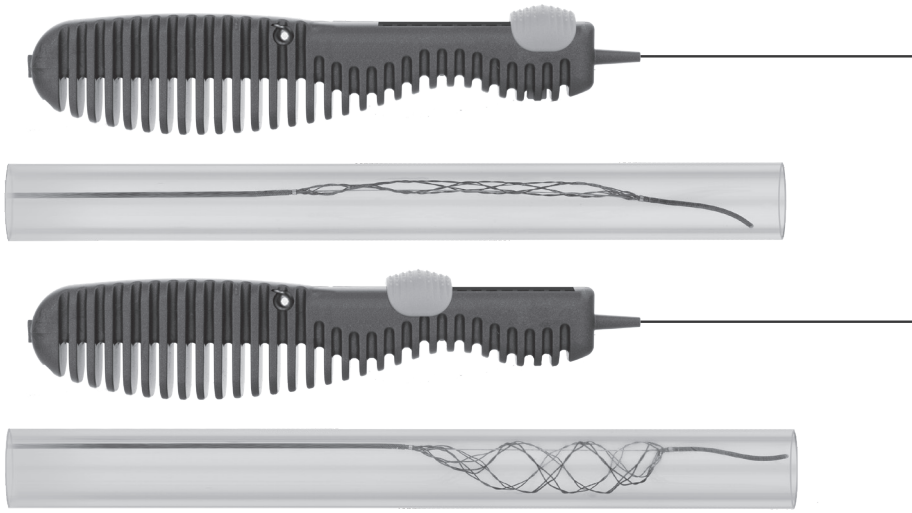
TIGERTRIEVER™

INSTRUCTIONS FOR USE



TIGERTRIEVER™ **25**

TIGERTRIEVER™ **21**

TIGERTRIEVER™

TIGERTRIEVER™ **17**

TIGERTRIEVER™ **17** ULTRA

TIGERTRIEVER™ **13**

REVASCULARIZATION DEVICE

RAPID MEDICAL™

Manufacturer

Rapid Medical Ltd.
Carmel Building, P.O. Box 337, Yokneam 2069205 Israel
Tel: +972-72-250-3331
Fax: +972-72-250-3332

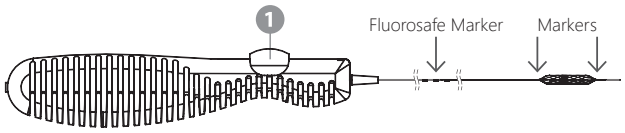


Figure 1: Tigertriever (1)-SLIDER

Device Description

The Tigertriever is intended to restore blood flow in patients experiencing ischemic stroke due to large intracranial vessel occlusion. The device is designed for use in the neurovasculature such as the internal carotid artery, M1 and M2 segments of the middle cerebral artery, basilar, and the vertebral arteries.
The Tigertriever is comprised of a collapsible, fully retrievable, fine wire construction mounted on a wire shaft that expands to comply with the vessel diameter. It is delivered through an intracranial microcatheter. The Tigertriever is provided with a peelable loading sheath.

Indication for Use

The Tigertriever is designed for use in flow restoration of patients with ischemic stroke due to large intracranial vessel occlusion. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA theraphy are candidates for treatment.

The Tigertriever Device should only be used by physicians trained in interventional neuroradiology and treatment of ischemic stroke.

Contraindications

Using the Tigertriever is contraindicated for 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 device. Patients with angiographic evidence of carotid dissection.

Using the Tigertriever 13 in smaller and more distal vessels carries a higher risk of perforation, hemorrhage, and/or ischemia due to parent vessel or perforator injury.

Complications

Potential complications include, but are not restricted to hematoma and hemorrhage at puncture site, infection, dissection, vessel perforation, emboli, thrombus, hemorrhage, ischemia, vasospasm, change in mental status, vascular occlusion, pseudo aneurysm formation, post procedure bleeding, distal embolization including to a previously uninvolved territory, adverse reaction to antiplatelet/anticoagulation agents or contrast media, device deformation/collapse/fracture/malfunction, arteriovenous fistula and neurological deficits, including stroke and death.

The device should be introduced through a microcatheter with a minimum inner diameter as in the table below.

Table 1: Compatibility
The Tigertriever was introduced in bench top model test using the following microcatheters:

Model	Commercial Name	Manufacturer
Tigertriever 25	Velocity®	Penumbra®
Tigertriever 21	Headway™ 21	MicroVention™
Tiger 17 (TRPP5166)/ Tiger 17 Ultra	Headway™ 17	MicroVention™
Tiger 17 (TRPP7166)	SL-10®/Headway™ 17	Stryker® MicroVention™
Tigertriever 13	Headway™ Duo 167 cm	MicroVention™

Warnings

1. Do not perform more than three recovery attempts in the same vessel using Tigertriever devices. Do not use each Tigertriever device for more than two restoration recovery attempts.
2. The appropriate anti-platelet and anti-coagulation therapy should be administrated in accordance with standard medical practice.
3. Do not torque the device.
4. Do not retrieve the device when encountering excessive resistance. Instead, resheath the device into the microcatheter and then remove the entire system under aspiration. If resistance is encountered during resheating, discontinue and remove the entire system under aspiration.
5. Discard after procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
6. In case of resistance during Tigertriever advancement to the target site do not continue. Assess possible cause using fluoroscopy. If the cause cannot be determined, withdraw device. Moving the Tigertriever against resistance may result in damage to the vessel or device.
7. Do not use a device that appears damaged.
8. Recommended vessel diameter for usage is between 1.5-6 mm.
9. Do not treat patients with known stenosis proximal to the deployment site.

Precautions

1. The Tigertriever Device should only be used by physicians trained in interventional neuroradiology and treatment of ischemic stroke.
2. The device is intended for single use only. Do not resterilize and/or reuse.
3. Store in a dry place at room temperature in its designated box.
4. Use by "Use By" date.
5. Carefully examine device and package before use to identify possible damages.
6. Do not use opened or damaged packages.
7. Do not use kinked or damaged devices.
8. Upon removal from package, inspect device to ensure it is not damaged.
9. Use the Tigertriever in conjunction with fluoroscopic visualization and proper anticoagulation and anti-platelet agents.
10. Precautions should be taken in order to facilitate the safe disposal of the device and its accessories.

Directions for Use

1. Administer anti-coagulation and anti-platelet medications per standard medical care.
2. Introduce an 8FR or larger neurovascular balloon guiding catheter.
3. Aided by angiographic fluoroscopy, determine the deployment location and its diameter.
   Selectively access the occluded vessel using a microcatheter with an RHV flushed with heparinized saline. With an aid of a guidewire advance the micorcatheter until the end of the microcatheter is positioned distaly to the thrombus, so that the usable length of the Tigertriever 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 micro catheter.

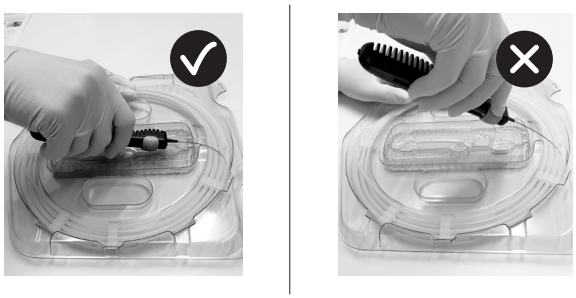


Figure 2: Removal of the Tigertriever from the tray

4. Remove the Tigertriever from the tray according to the above figure.
5. Carefully advance the Tigertriever until the mesh completely extends from the loading tube.
6. Slowly expand the device by sliding the Slider (1) backwards. Do not over inflate. Make sure the device is not damaged.
7. Soak the open mesh in heparinized saline.
8. Deflate the device carefully by advancing the Slider until the mesh reaches its minimal form (figure 3).

Figure 3: Mesh in minimal form

9. Pull back until the tip is just inside the end of the loading tube (figure 4).

Figure 4: Tip at the end of the loading tube

10. Insert the loading tube into the microcatheter's RHV and tighten it.
11. Slowly advance about 50cm of the Tigertriever through the loading tube into the microcatheter. Loosen the RHV, slide the loading tube back to the device handle, and retighten the RHV as needed.
12. Resume slowly advancing the device. Once the fluorosafe marker reaches the RHV, begin fluoroscopic imaging. Advance the device under fluoroscopic visual control until the tip extends out of the microcatheter.
13. Unsheathe the device slowly while following the tip of the device and distal and proximal markers for accurate deployment.

Important: the proximal marker remains stationary during device expansion while the distal marker and tip move slightly backwards. As a result the proximal marker should be positioned proximally to the thrombus.

14. Under fluoroscopic visual control slowly expand the device by sliding the *Slider* (1) backwards.
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 to prevent relative movement between the microcatheter and the device.

Retrieving the Tigertriever

17. Inflate the guide catheter balloon to occlude vessel as specified in Balloon Guide Catheter labeling.
18. Slowly withdraw the microcatheter and the Tigertriever device as a unit to the guide catheter tip while appling aspiration to the guide catheter with a 60cc syringe. If needed, adjust the size of the device under fluoroscopic visual control.
19. Apply vigorous aspiration to the guide catheter using syringe and recover Tigertriever device and microcatheter inside guide catheter. If needed partially deflate the device prior to inserting it into GC. Contniue aspirating guide catheter until the device and microcatheter are nearly withdrawn from the guide catheter.
20. 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.
21. Aspirate the guide catheter to ensure the guide catheter is clean of any thombus material.
22. Deflate balloon guide catheter.
23. If additional flow restoration attempts are desired:
    - **i.** The procedure may be attempted up to a total of 3 times in the same vessel.
    - **ii.** If a new device is used repeat the steps described above.
    - **iii.** If the same Tigertriever device is used, then:
        - **a.** Clean the device with heparinized saline solution. Do not use solvents or autoclave
        - **b.** Carefully inspect the device for damage. Do not use the device if it is damaged or not clean. Soak the device in heparinized saline until next use.
        - **c.** Repeat the above starting from step 6.
24. If necessary, there is an extra loading device available on the tray. Make sure that the device is clean and in its minimal shape before introducing it.

Symbol Glossary

	Attention, see instructions for use		Manufacturer
	Single use only. Do not reuse		Consult instructions for use
STERILIZE	Do not resterilize		Keep away from sunlight
REF	Catalogue Number		Keep Dry
STERILE EO	Single sterile barrier system with protective packaging inside. Sterilized using Ethylene Oxide		Do not use if package is damaged
LOT	Lot number		Non-pyrogenic
	Use by		

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