

MICROCATHETER CONSIDERATIONS WITH NeVa™

1. Recommended Micro-Catheters for different sizes:

4.0 & 4.5 mm sizes: Compatible with MicroCatheters with a min ID of 0.021"		6.0 mm size: Compatible with MicroCatheters with a min ID of 0.027"	
CLEARED FOR USE	not tested	CLEARED FOR USE	not tested
Via (.021")	Trevo Trak (.021")	Via (.027")	Headway (.027")
Headway (.021")	Prowler (.021")	Phenom (.027")	XT 27 (.027")
Trevo Pro 18 (.021")	ProwlerSelect (.021")	Marksman (.0274")	Velocity (.025")
Phenom (.021")	NeuroSlider (.021")		
Rebar 18 (.021")			
Velocity (.025")			
All .027" MCs			

2. Statements and Discussion Points:

STATEMENTS

NOTES and DISCUSSION POINTS

1. The current line of NeVa™ sizes are compatible with microcatheters with ID of 0.021" or larger.

- Depending on the habits of a user, they may prefer to use the larger size NeVa (NeVa- T, 4.5 mm diameter) with a larger ID microcatheter.
- This will be specific to each user. While some feel perfectly comfortable using large diameter devices in standard MCs, others may feel the resulting friction is not desirable. It is really a matter of "operator taste" and personal preference. To ensure a positive experience, having a discussion with physicians before first use is worthwhile to understand their style and choices.
- Example: If they use the larger sizes of Solitaire or Trevo (6mm) in a .027" catheter, they may be more comfortable using the NeVa 4.0 or 4.5 mm size with a 0.027" catheter as well.

2. NeVa's unique design requires a catheter that provides good distal support.

- Distal support is a function of catheter size, catheter distal OD size as well as other choices made in catheter construction, such as braiding, and/or coiling in the catheter structure and material choices.
- Microcatheters that provide good distal support, by design, work better in tortuous, anatomically challenging situations.

3. RECOMMENDED

We have reports of NeVa being used successfully in the microcatheters listed in the CLEARED FOR USE column.

- The Trevo 18 and the Rebar 18 are the most commonly used microcatheters with NeVa so far.
- We did not test all available .021” micro-catheters for compatibility with NeVa.

4. NOT RECOMMENDED

- Prowler 21
- NeuroSlider

- We had reports of navigation or hub-loading difficulty in these catheters. These are NOT recommended to use with NeVa.

- Headway 21

- Experience with the Headway catheter has been mixed.
- We believe Headway’s specification make it less attractive as a catheter for delivering stents, stent retrievers, etc. The distal OD of this catheter is significantly smaller than many of the other .021" ID devices (2.0 Fr distal outer diameter (OD) versus 2.4 for Trevo Pro, Rebar, etc.) This results in less distal support than is necessary to deliver NeVa effectively in extremely tortuous situations.
- Nevertheless, note that some NeVa users are happy with the experience. μ As previously discussed “pushability and navigation experience” is unique to every physician.
- Whether or not to use Headway is not a discussion you need to have systematically with every account. We recommend having this discussion only if the account uses Headway 21 as the preferred microcatheter in thrombectomy.

- TrevoTrak

- This catheter has a 162 cm length. If your doctors prefer this catheter, you need to warn them that the pusher wire of NeVa is 180cm. In some anatomies, using the two devices together may result in having very little pusher wire remaining for device manipulation outside the microcatheter.

5. FURTHER RECOMMENDATIONS

- Systematically remind your physicians and the tech staff to flush NeVa and the microcatheters before use.
- Systematically remind your physicians and the tech staff to align NeVa introducer sheath with the hub of the microcatheters before loading.
- Once a MC is delivered to the distal location beyond the clot, recommend physicians to release excess strain by slightly pulling them back before loading NeVa and starting its navigation.

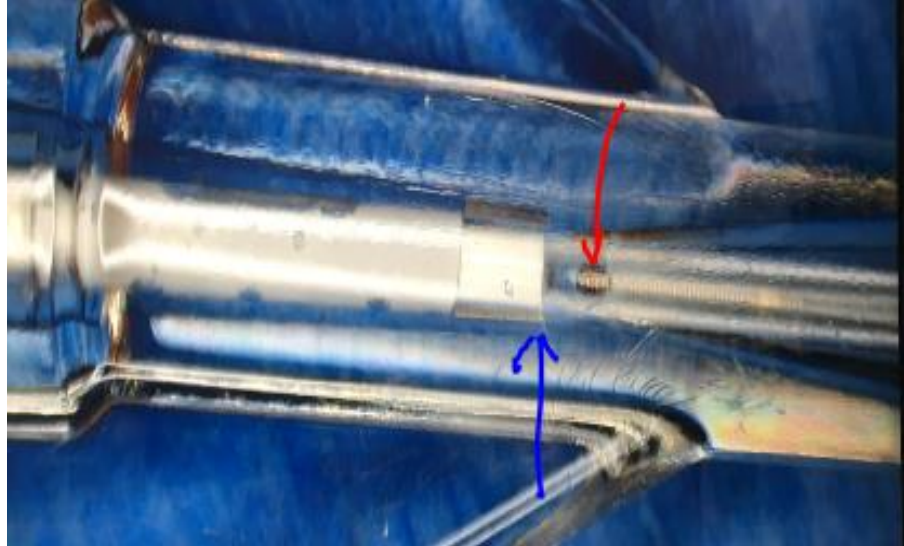
IF NeVa™ DOES NOT LOAD FROM THE INTRO SHEATH INTO THE MC

Why would this happen?

NeVa has a discontinuous design with multi-functional zones. This unique design is our selling point and makes all the difference in NeVa efficacy, allowing NeVa users to have multiple mechanisms of interaction with all types of clots.

However, due to the discontinuous design of the basket, if NeVa emerges even slightly from the sheath before loading into the hub, it will not load.

Hence, **perfect alignment of the introduction sheath with the proximal hub of the microcatheter is critical during loading** and you should underline this during account initiation/ training.



*The blue arrow indicates the location of the bottom of the catheter hub.
The red arrow indicates the distal tip of the distal marking coil of the NeVa T.*

All NeVa units get tested for loading correctly into a TREVO PRO 18 micro-catheter (0.021" ID) before packaging and sterilization), since our first commercial lots were produced in 11/07/2017.

Nevertheless, despite perfect alignment and despite the above-mentioned testing, **specifications or specification variations of different microcatheters could cause NeVa to not load into their hub.**

If this happens:

We replace the NeVa that opened and could not be used free of charge.

We will require the NeVa that could not be used as well the micro-catheter which had the problem to be returned to us for testing.