New crossing techniques for ilio caval occlusion

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Disclosure

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I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [x] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
The Unmet Need in Chronic Venous Occlusions (CVOs)

Although many chronic venous occlusions may be crossed and treated with blunt recanalization using a guidewire and catheter, there are reports of failures requiring advanced techniques higher than 20% of the cases depending on location (iliofemoral native CVO > SVC CTO > chronic venous stent occlusion > hemodialysis CVO)

CVOs crossing could be time consuming with long intervention time and high radiation exposure

Non-steerable, non-dedicated sharp recanalization devices are associated with complications and lower technical success rates (including trans-septal needle, radiofrequency wires, Chiba-needle, etc.)

The Traversa
Venous Recanalization Controlled

**Designed for Versatility**
Ability to cross long occlusions 3-25 cm

**Designed for Speed**
Cross in < 30 min*

**Designed for Success**
Improve success rate from 90% to 100%**

*opposed to 3-6 hours for standard of care
** Compared to standard guidewire use

Unique anchoring mechanism incorporated with a crossing tool provides total control during recanalization.

The Traversa

Anchor
Steering and Penetration mechanism

Handle
Traversa
INDICATIONS

• Recanalization of discrete lesions of the peripheral and central venous vasculature (FDA) – Confirmed by FDA Pre-Submission

• These include:
  • Occluded venous stents
  • Chronic DVT/PTS w/ or w/o occluded stents
  • Central Venous Occlusions from Dialysis Access
  • Arteriovenous Fistulas for Dialysis Access
Main Results – Benchtop Studies

Iliac vein model
Successful Animal Studies

- Created rapid occlusion model
- Crossed 5, 6 cm & 8 cm lesions that was uncrossable with standard guidewire recanalization
- Rapid occlusion crossing (<30 min)
- Accurate control of needle (torque-ability and steerability)
- Demonstrated balloon support
- Proven artificial CVO model
Traversa successfully navigated from distal mid-stent access to proximal cap and exited allowing guidewire placement.

Then navigated from IJ access 15 cm down. Final crossing performed by steering needle and advancing the wire.

Attempted previous recanalization 4 times and failed.

“The needle strength along with the durability of the outer catheter together allowed for a technically successful recanalization” – Minhaj Khaja, MD.
Device Performance

Initial Entry and Advancement

Rounding the corner

Final Wire placement
Successful Clinical Case – 16 May 2023
Klinikum Hochsauerland

1. Patient Profile:
   1. 39-year-old woman
   2. **Severe PTS** in right arm
   3. Inability to carry young children
2. Failed previous attempt with competing product
3. Traversa’s Success:
   1. After advancing with NaviCross as far as possible, Traversa entered
   2. Wire passed cleanly after 4th needle advancement
   3. Patient pain-free immediately post-procedure
TRAVERSA SVC RECANALIZATION
Clinical Program

**Study for Regulatory Clearance – Confirmed by FDA Pre-Submission**
- Technical Success
- Safety
- 30 patients

**Post-Market Reimbursement Study**
- 200-266 patients (80-90% power)
- Demonstrate improvement in success rate (from 90% to 99%)
  - Shorter procedural time (<30 min)
  - Economic variables
- Multi-center (10-15 sites)
THANK YOU