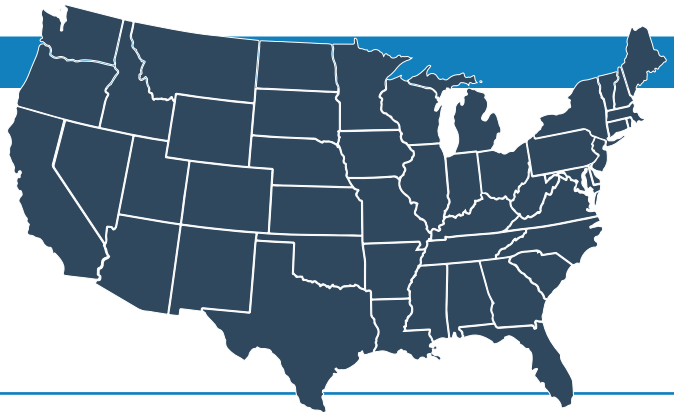
TriNav® INFUSION SYSTEM

REAL-WORLD EVIDENCE SUPPORTS USE OF TRINAV® IN COMPLEX PATIENTS

Claims* analysis demonstrated that **TriNav** and the **Pressure-Enabled Drug Delivery™ (PEDD™)** approach was used disproportionally to treat challenging and complex patients – and achieved the same or better results.[1,2]

Study Design

- Data from a large claims database* covering more than **300 million patient lives** over the period 01/01/2020 – 03/31/2024
- > 96% of US payers
- Study compared **603 PEDD™ patients** to **16,210 non-PEDD patients** with HCC or secondary liver metastases treated with TACE or TARE



TriNav Patient Type

- More complex
- Have more comorbidities and liver-related adverse events
- Higher healthcare resource utilization prior to the embolization procedure
- Greater burden of disease

Patients in the PEDD cohort had a higher disease burden

Mean ± Standard Deviation or %	PEDD N=603	Non-PEDD N=16,210	SMD
Charlson Comorbidity Index (CCI)	7.1 ± 2.3	6.0 ± 4.7	0.29
Outpatient visits in 3 months prior to index	6.5 ± 5.6	5.0 ± 4.7	0.28
Any systemic treatment prior to index	24.5%	16.1%	0.21

Treatment

Significantly more doxorubicin was delivered in the TACE cohort: **13.9 doses** with PEDD vs. **9.48 doses** with non-PEDD, p<0.01

*** Administrative claims from Clarivate Real World Data Repository Jan-1, 2020 – Mar-31, 2024.**

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OUTCOMES

Matched Cohort Analysis

Outcome	PEDD N=603	Non-PEDD N=603	p-value
30-day post-procedure inpatient visits, TACE subgroup	8.0%	20.5%	< 0.05
Fatigue overall	20.9%	26.4%	< 0.05
Fatigue, TARE subgroup	20.4%	27.4%	< 0.05
Any clinical complications post-index, TARE subgroup	59.2%	64.9%	0.07
Gastric ulcer	1.8%	4.7%	0.09
Jaundice, HCC subgroup	3.7%	7.3%	0.09

Cost Reduction

Among all patients, PEDD use translated to per-patient costs avoided:

$3,135 reduced in patient visits

$4,599 reduced charges related to clinical complications

Summary

- Despite higher level of baseline disease burden, PEDD use was associated with improved post procedure outcomes
- While more doxorubicin was delivered in TACE procedures, fewer in-patient visits were seen in that cohort
- PEDD use was associated with improved safety in matched cohorts analysis
- Overall, the benefits of PEDD procedures translated to lower resource burden via reduced hospitalizations and complications

Indications for Use: The TriNav, TriNav FLX, and TriNav LV Infusion Systems are intended for use in angiographic procedures. They deliver radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.[3,4,5]

Contraindications: The TriNav, TriNav FLX, and TriNav LV Infusion Systems are not indicated for use in the vasculature of the central nervous system (including the neurovasculature) or central circulatory system (including the coronary vasculature).[3,4,5]

Rx Only. For the safe and proper use of the TriNav, TriNav FLX, and TriNav LV Infusion Systems, refer to their individual Instructions for Use.

1. Cook K, Gupta D, Liu Y, et al. Real-world evidence of Pressure-Enabled Drug Delivery for trans-arterial chemoembolization and radioembolization among patients with hepatocellular carcinoma and liver metastases. Current Medical Research and Opinion. 2024;40(4):591-598.
2. Gupta et al, Clinical Outcomes of Pressure-Enabled Drug Delivery for TACE and TARE; SIO-2025 poster
3. TriSalus™ TriNav® Infusion System Instructions for Use.
4. TriSalus™ TriNav® FLX Infusion System Instructions for Use.
5. TriSalus™ TriNav® LV Infusion System Instructions for Use.

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