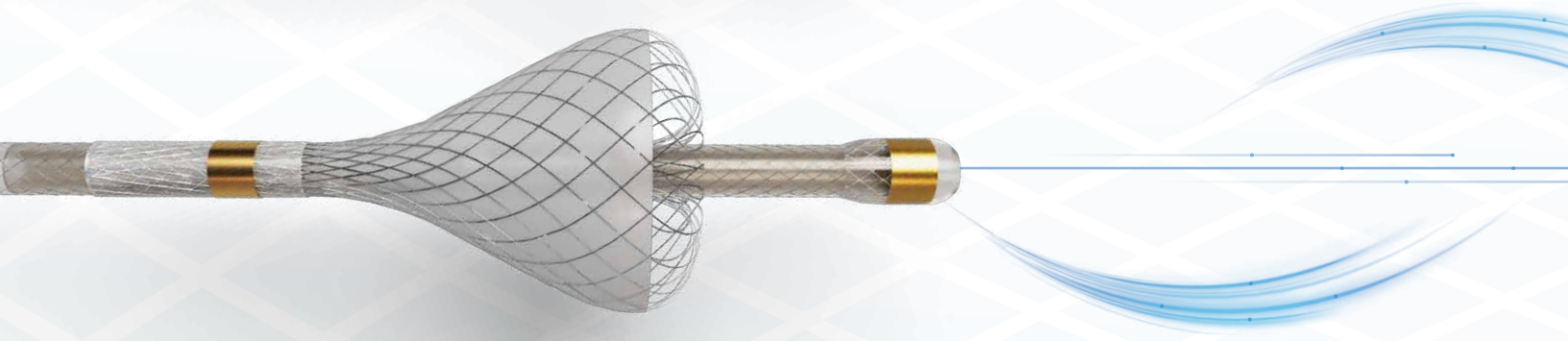
TriNav®
INFUSION SYSTEM

A revolution in precision embolization

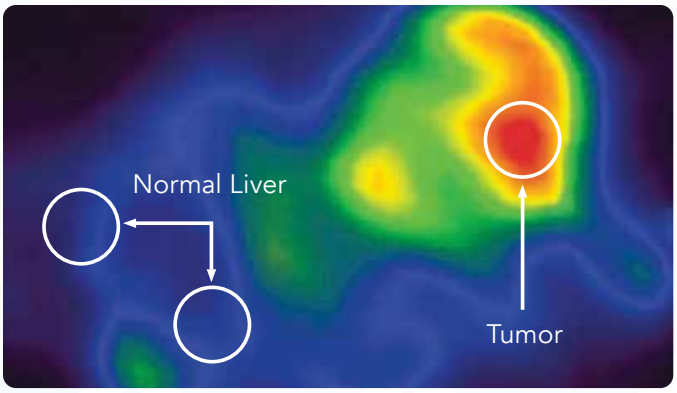


TriSalus
LIFE SCIENCES®

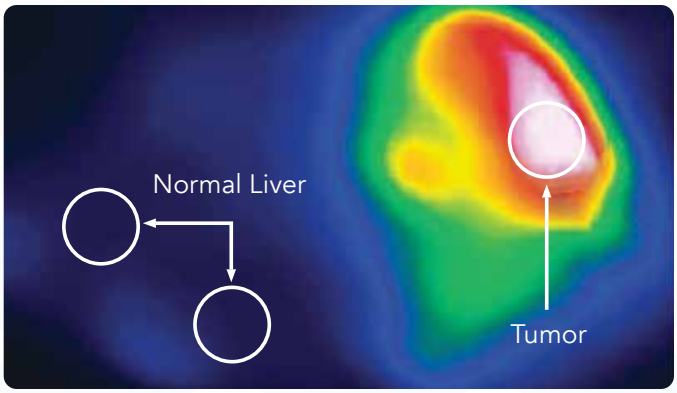
Overcome challenges that can impede therapeutic delivery and improve the T:N ratio in complex patients

When treating complex liver cancer patients, delivering more therapy to the tumor and less to normal tissue is often the goal. However, intratumoral pressure (ITP) can prevent therapeutics from penetrating solid tumors.[1]

TriNav® Infusion Systems leverage the Pressure-Enabled Drug Delivery™ (PEDD™) approach to atraumatically open collapsed vessels and help deliver more therapy where you need it, and less where you don't.[2,3,4]

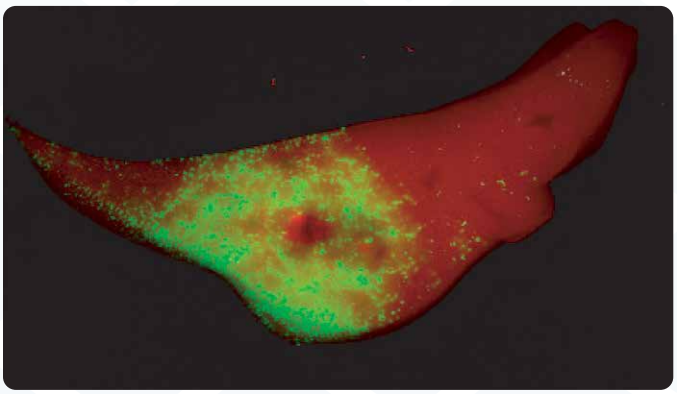


Therapy distribution with traditional microcatheter.[4]

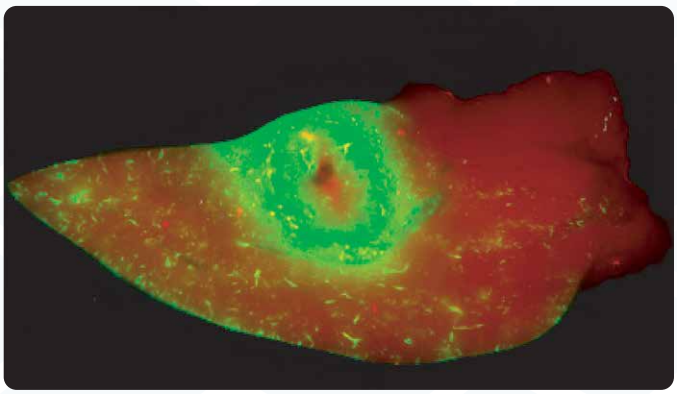


Therapy distribution with PEDD.[4]

In a prospective clinical study, PEDD was shown to increase tumor targeting by mean 68% while reducing non-target embolization by mean 58% (n=9, $p<0.05$).[4]



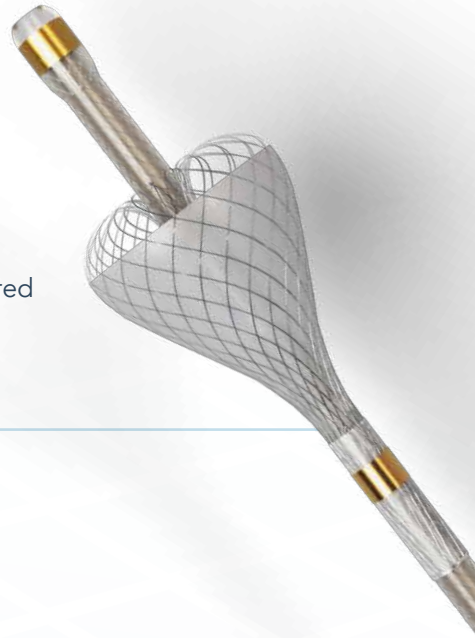
Delivery via traditional microcatheter



Delivery via TriNav

In a preclinical study, physicians achieved a **2.2x increase** in total tumor penetration in lobar deliveries using TriNav (n=17, p=0.004).[5]

WHY TRINAV?



Engineered for Precision

TriNav's PEDD technology achieved a **24% increase in the T:N ratio** compared to traditional microcatheters (n=61, p<0.001)[2]

Designed for Safety

Demonstrated reflux protection and up to **58% mean decrease in non-target embolization** via PEDD (n=9, p<0.05)[4]

Focused on Outcomes

Clinical data show patients treated with PEDD experienced:

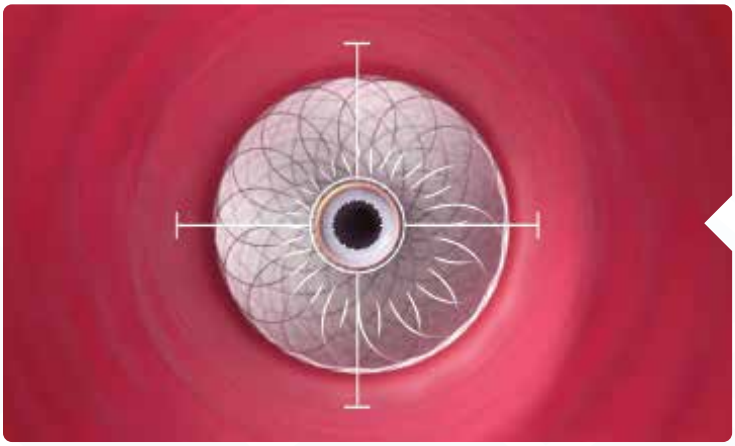
- **23% increase in tumor dose** with PEDD vs. traditional microcatheters (n=61, p<0.001)[2]
- **89% vs 34 % pathological response rate** in patients treated with PEDD vs traditional microcatheters (n=23, p=0.026)[3]
- **61% lower rate** of post-procedure in-patient visits compared to patients not treated with PEDD (8.0% vs. 20.5%)[6,7]
- **5.7% improvement** in complication rates compared to patients not treated with PEDD[6,7]

Advancing Reimbursement & Access

- Only device with **unique CMS-assigned HCPCS codes** for both mapping and treatment, supporting reimbursement for procedural planning and therapy delivery.
- Real-World Evidence shows **cost savings of up to $7.5K per case** through reductions in in-patient visits and treatment-related complications.[6,7]

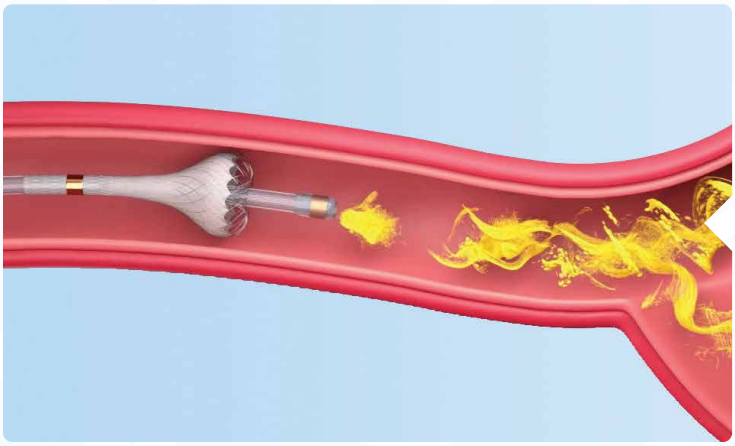
HOW TRINAV WORKS

The TriNav Infusion System, with SmartValve® technology, helps to precisely target the tumor and facilitates deeper therapy penetration while protecting against non-target embolization and reflux.[2,3,4]



Self-centers the catheter tip

In quantitative bench-top testing, the SmartValve ensured fixed centro-luminal positioning in 100% of the experiments, vs 29% when the traditional microcatheter was used.[13]



Creates turbulent flow which promotes particle mixing

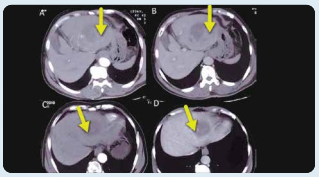
In quantitative bench-top testing, SmartValve technology was shown to consistently induce a turbulent flow pattern which promotes mixing of microspheres into the bloodstream which led to a 62% improvement in downstream microsphere administration.[13]

Helps to atraumatically **open collapsed vessels**

PEDD helps open collapsed vessels to improve tumor penetration. Blinded histopathologic evaluation of explanted livers following DEM-TACE to treat HCC showed that PEDD achieved a 33% increase to beads in the tumor compared to a traditional microcatheter.[3]

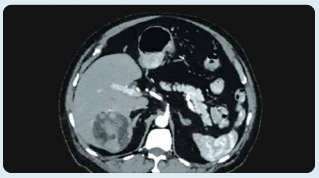
WHICH PATIENTS BENEFIT MOST FROM TRINAV?

Getting more therapy to the tumor is particularly important in complex liver cancer patients. A complex patient profile can include:



PRIOR EMBOLIZATION

Previously embolized tumors can be more difficult to visualize and penetrate due to regions of necrosis and damaged vasculature.[8]

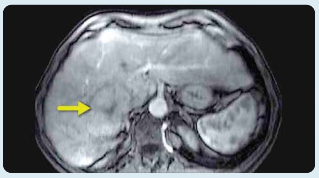


LARGE TUMORS

Lack of particle penetration may be the cause of poor response to embolization in patients with large (>5 cm) tumors.[9]

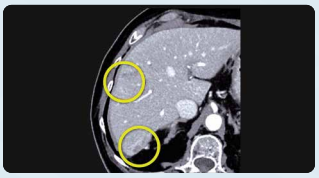
MULTI-FOCAL DISEASE

It can be difficult to deliver adequate treatment while minimizing injury to normal liver in patients with multiple tumors.[10]



BORDERLINE LIVER FUNCTION

In patients with borderline liver function, the challenge is to deliver an effective treatment while preserving adequate healthy liver tissue.[11]



HYPOVASCULAR TUMORS

It can be challenging to achieve adequate particle penetration into tumors with minimal or absent enhancement due to reduced vascularity.[12]

WHY GETTING MORE THERAPY TO THE TUMOR MATTERS

Delivering more therapy to the tumor and less to normal tissue may help ensure quality of life, lessen complications, and reduce clinical burden. In a comprehensive Real-World Evidence study, patients undergoing PEDD experienced **fewer in-patient visits and complications** post-procedure.[6,7]

Fatigue incidence was **21% lower** in the PEDD group compared to Non-PEDD (20.9% vs. 26.4%)[6,7]

Jaundice was reported in **half as many** PEDD patients compared to Non-PEDD (3.7% vs. 7.3%)[6,7]

Gastric ulcer incidence was **reduced by nearly** two-thirds with PEDD compared to Non-PEDD (1.8% vs. 4.7%)[6,7]

THE ECONOMIC AND OPERATIONAL ADVANTAGES OF USING TRINAV

Streamline reimbursement with codes for mapping and treatment. TriNav Infusion Systems are **the ONLY device with CMS-assigned HCPCS codes for both mapping and treatment**, supporting procedural planning for radioembolization cases and therapy delivery.

HCPCS Codes

C8004 Simulation angiogram with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the angiogram, for subsequent therapeutic radioembolization of tumors

C9797 Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction

In the comprehensive Real-World Evidence study, the benefits of PEDD procedures translated to lower resource burden via reduced hospitalizations and complications.[6,7]

COST REDUCTION

$3,135 reduced in-patient visits

$4,599 reduced charges related to clinical complications

SELECT THE BEST DEVICE FOR EACH UNIQUE CASE

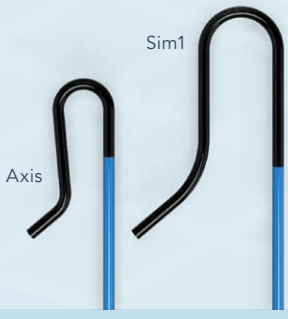
TriNav Infusion Systems provide Interventional Radiologists with a portfolio of tools to address a wide range of vessel anatomy. Because every case is different, we offer the following options to help you get the job done right.

Product Code	TriNav® TNV-21120-35	TriNav® TNV-21150-35	TriNav® FLX FLX-21120-35	TriNav® FLX FLX-21150-35	TriNav® LV TVM-25120-50	TriNav® LV TVM-25150-50
Recommended for	Vessel sizes 1.5-3.5mm		Vessel sizes 1.5-3.5mm; 2X more flexible material on the distal end for more tortuous anatomy		Vessel sizes 3.5-5.0mm	
Length	120 cm	150 cm	120 cm	150 cm	120 cm	150 cm
Inner Diameter	0.021 in		0.021 in		0.025 in	
Minimum Base Catheter ID	0.035 in		0.035 in		0.048 in	
Proximal Outer Diameter	2.4 F		2.4 F		2.9 F	
Maximum Guidewire Diameter	0.018 in		0.018 in		0.018 in	
Distance Between SmartValve® Marker Bands	10 mm		10 mm		12 mm	
Bead Size Compatibility	Hydrogel ≤ 500 µm Glass ≤ 110 µm		Hydrogel ≤ 500 µm Glass ≤ 110 µm		Hydrogel ≤ 500 µm Glass ≤ 110 µm	
Merit Medical FLO50™ Hemostasis Valve included (not required for use)	No		Yes		Yes	
Distal Tip Design	Standard		Flexible		Standard	
Dead Space	0.37 mL	0.44 mL	0.37 mL	0.44 mL	0.52 mL	0.61 mL
Actual Flow Rate at 1200 PSI/8274 kPa (mL/sec)*	2.6 mL/sec	2.1 mL/sec	2.6 mL/sec	2.1 mL/sec	3.6 mL/sec	3.3 mL/sec

*The observed actual flow rate values are for reference only. Infusion Medium Omnipaque 300 (Iodine 300 mg/mL), Viscosity 6.3 cP.

TriGuide Guiding Catheter

Shape	Product Code	Outer Diameter	Inner Diameter	Length
Axis	TGC-48065-Axis	5F	0.048 in	65 cm
Sim1	TGC-48065-Sim1			



READY TO DELIVER MORE THERAPEUTICS WHERE YOU WANT AND LESS WHERE YOU DON'T?

Powered by PEDD, TriNav Infusion Systems are designed to improve tumor penetration, limit delivery to nearby healthy tissue, and achieve stronger outcomes in complex liver cancer patients.[3,4,6,7]

To contact Customer Service, call **888-321-5212**
or learn more at **trinavinfusion.com**

Resources

Request a Sales Representative

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.[14,15,16] The TriGuide Catheter is intended to provide a pathway through which therapeutic devices are introduced. The TriGuide Catheter is intended to be used in the peripheral vascular system.[17]

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).[14,15,16] The TriGuide Catheter is not intended for use in vasculature of the central nervous system (including the neurovasculature) and central circulatory system (including the coronary vasculature).[17]

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

1. Kim, Hg., Yu, A.R., Lee, J.J. et al. Measurement of Tumor Pressure and Strategies of Imaging Tumor Pressure for Radioimmunotherapy. Nucl Med Mol Imaging 53, 235–241 (2019).
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4. Pasciak AS, McElmurray JH, Bourgeois AC, Heidel RE, Bradley YC. The impact of an antireflux catheter on target volume particulate distribution in liver-directed embolotherapy: a pilot study. J Vasc Interv Radiol. 2015;26(5):660-669.
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11. Jeschke, M.; Ludwig, J.M.;et al., Bilobar Radioembolization Carries the Risk of Radioembolization-Induced Liver Disease in the Treatment of Advanced Hepatocellular Carcinoma: Safety and Efficacy Comparison to Systemic Therapy with Atezolizumab/Bevacizumab. Cancers 2023, 15, 4274. https://doi.org/10.3390/cancers15174274
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13. van den Hoven A F, Lam M, Jernigan S, van den Bosch M, Buckner G D. Innovation in catheter design for intra-arterial liver cancer treatments results in favorable particle-fluid dynamics. J. Exp. Clin. Cancer Res. 2015; 34:74.
14. TriSalus™ TriNav® Infusion System Instructions for Use.
15. TriSalus™ TriNav® FLX Infusion System Instructions for Use.
16. TriSalus™ TriNav® LV Infusion System Instructions for Use.
17. TriSalus™ TriGuide® Guiding Catheter Instructions for Use.

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