## **»**TriNav



# Precisely targeting the tumor for improved therapeutic delivery

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Improving the T:N\* ratio is especially important in complex patients

A complex patient profile can include:

Prior Embolization Large Tumor Multi-Focal Disease Borderline Liver Function Hypovascular Tumors

\*Tumor-to-Normal

Both Clinical and Real World Evidence (RWE) support use of Pressure-Enabled Drug Delivery™ (PEDD™) in complex patients

#### Clinical

Multiple studies of different therapeutics make up a growing body of evidence that supports how TriNav's PEDD approach can increase the T:N ratio and improve patient outcomes <sup>1,2</sup>

#### RWE

A comprehensive RWE study of PEDD for TACE and TARE among patients with HCC and liver metastases proved that despite higher baseline disease burden and complexity, patient outcomes were similar for non-PEDD patients<sup>3</sup>

- 1. 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.doi: 10.1016/j.jviv. 2015.01.029;
- 2. Titano, J. J. et al. End-hole Versus Microvalve Infusion Catheters in Patients Undergoing Drug-Eluting Microspeheres-TACE for Solitary Hepatocellular Carcinoma Tumors: A Retrospective Analysis. Cardiovasc Intervent Radiol 42, 560-568 (2019);
- 3. Keziah Cook, Deepshekhar Gupta, Yunjuan Liu, Chris Miller-Rosales, Fangzhou Wei, Edward Tuttle, Steven C. Katz, Richard Marshak & Alexander Y. Kim (2024) 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, 40:4, 591-598, DOI: 10.1080/03007995.2024.2322057

TriNav's PEDD<sup>™</sup> approach helps increase the amount of the treatment delivered to the tumor while reducing distribution to non-target tissue<sup>1</sup>



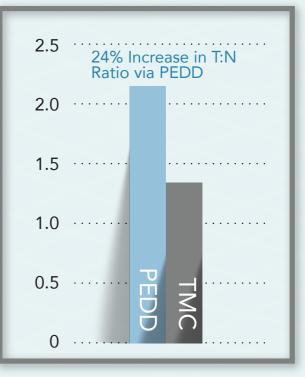
#### TriNav's PEDD significantly improves the T:N ratio, resulting in better patient outcomes

Multiple studies with different therapeutics make up a growing body of evidence that supports how TriNav® with SmartValve® technology can provide more precise tumor targeting while protecting background tissue.<sup>1,2,3</sup>

#### Clinical Evidence Helps target the tumor for

precise therapeutic delivery<sup>3</sup>

24% Increase in T:N Ratio



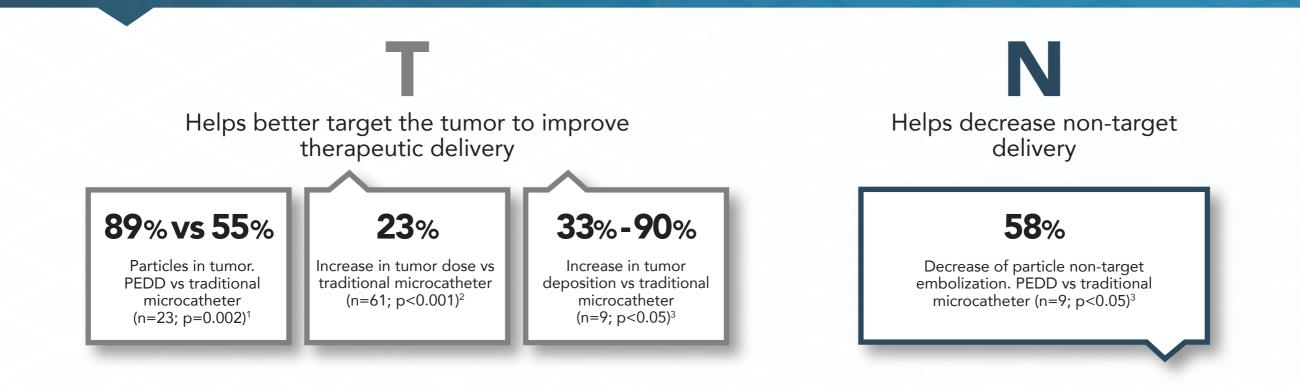
TMC - Traditional Microcatheter



- 1. 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.doi: 10.1016/j.jviv. 2015.01.029
- 2. Titano, J. J. et al. End-hole Versus Microvalve Infusion Catheters in Patients Undergoing Drug-Eluting Microspeheres-TACE for Solitary Hepatocellular Carcinoma Tumors: A Retrospective Analysis. Cardiovasc Intervent Radiol 42, 560-568 (2019);

3. d' Abadie P, et al. Antireflux catheter improves tumor targeting in liver radioembolization with resin microspheres. Diagn Interv Radiol 2021; 27:768-7733.

TriNav<sup>®</sup>, the only technology helping your complex patients by increasing the T:N ratio with the PEDD<sup>™</sup> approach



- 1. Titano, J. J. et al. End-hole Versus Microvalve Infusion Catheters in Patients Undergoing Drug-Eluting Microspeheres-TACE for Solitary Hepatocellular Carcinoma Tumors: A Retrospective Analysis. Cardiovasc Intervent Radiol 42, 560-568 (2019);
- 2. d' Abadie P, et al. Antireflux catheter improves tumor targeting in liver radioembolization with resin microspheres. Diagn Interv Radiol 2021; 27:768-7733.

3. 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.doi: 10.1016/j.jviv. 2015.01.029

TriNav<sup>®</sup>: Improving care for complex patients, improving tumor response and safety

Better tumor targeting may result in a better response

#### 100% vs 77%

#### 89% vs 34%

Objective response rate, PEDD vs traditional microcatheter (n=88; p=0.019)<sup>1</sup>

Pathological response vs. traditional microcatheter (n=23; p=0.026)<sup>1</sup>

- 1. Titano, J. J. et al. End-hole Versus Microvalve Infusion Catheters in Patients Undergoing Drug-Eluting Microspeheres-TACE for Solitary Hepatocellular Carcinoma Tumors: A Retrospective Analysis. Cardiovasc Intervent Radiol 42, 560-568 (2019);
- 2. Keziah Cook, Deepshekhar Gupta, Yunjuan Liu, Chris Miller-Rosales, Fangzhou Wei, Edward Tuttle, Steven C. Katz, Richard Marshak & Alexander Y. Kim (2024) 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, 40:4, 591-598, DOI 10.1080/03007995.2024.2322057



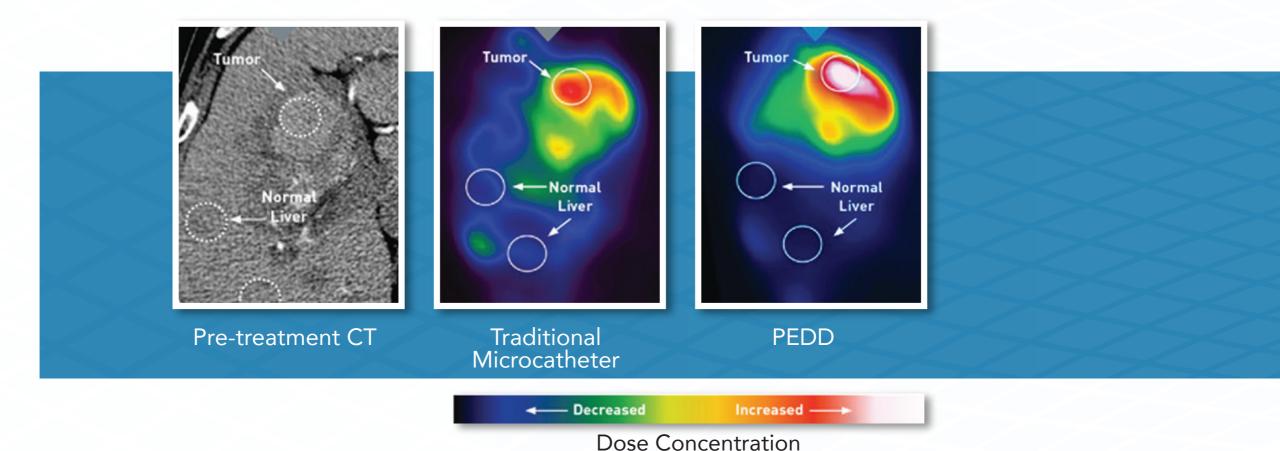


Decreasing non-target delivery may result in better safety

In a comprehensive RWE study, matched cohort analyses of TARE patients with Hepatocellular Carcinoma (HCC) (n=72) and with CRC liver metastases (CRCLM) (n=50) demonstrated that:<sup>2</sup>

- PEDD HCC patients had fewer 30-day inpatient visits than non-PEDD patients post-procedure
- PEDD CRCLM patients had fewer overall clinical complications than non-PEDD patients post-procedure

#### Clinical experience with PEDD<sup>™</sup> delivery. PEDD helps better target the tumor while decreasing non-targeted delivery<sup>1</sup>



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1. 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.doi: 10.1016/j.jviv. 2015.01.029

#### CMS recognition of TriNav<sup>®</sup> data HCSPCS code assigned to TriNav Infusion Systems<sup>1</sup>

## The totality and consistency of the data merited the assignment of a new procedure code by CMS

- The New Technology Healthcare Common Procedure Coding System (HCPCS) code is for procedures involving the TriNav® Infusion System.
- This new code, **HCPCS C9797**, has been assigned to the Ambulatory Payment Classification **(APC) 5194-Level 4** Endovascular Procedures.
- The new code became effective on January 1, 2024, and may be reported by hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs)
- Both TriNav and TriNav LV are covered under the CMS coding



1. The Centers for Medicare & Medicaid Services. New Technology APC Decision Tracker. December 13, 2023. https://www.cms.gov/files/document/newtechnology-apc-application-decision-tracker.pdf. Accessed December 18, 2023

### TriNav<sup>®</sup>: Aligned with Unmet Need in Complex Patients

For	Interventional Radiologists who treat Complex Patients with: Prior Embolization, Large Tumors, Multi-Focal Disease, Borderline Liver Function or Hypovascular tumors	<ul> <li>Better targeting: 89% vs 55% particles in tumor, PEDD vs traditional microcatheter<sup>1</sup></li> <li>Reduced off-target delivery: 58%</li> </ul>
TriNav Infusion Systems*	help increase the T:N ratio, precisely targeting the tumor while reducing non-target embolization	 decrease in non-target embolization vs traditional microcatheter <sup>2</sup>
Because	of their unique Pressure-Enabled Drug Delivery™ (PEDD™) approach	<ul> <li>Response: 100% vs 77% overall response rate vs traditional microcatheter<sup>1</sup></li> </ul>
So That	IRs can achieve improved outcomes in patients with higher disease burden	 • Safety: fewer inpatient visits, <b>fewer overall complications</b> vs. traditional microcatheter <sup>3</sup>
*TriNav and TriNav LV		

- 1. Titano, J. J. et al. End-hole Versus Microvalve Infusion Catheters in Patients Undergoing Drug-Eluting Microspeheres-TACE for Solitary Hepatocellular Carcinoma Tumors: A Retrospective Analysis. Cardiovasc Intervent Radiol 42, 560-568 (2019);
- 2. 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.doi: 10.1016/j.jviv. 2015.01.029
- 3. Keziah Cook, Deepshekhar Gupta, Yunjuan Liu, Chris Miller-Rosales, Fangzhou Wei, Edward Tuttle, Steven C. Katz, Richard Marshak & Alexander Y. Kim (2024) 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, 40:4, 591-598, DOI: 10.1080/03007995.2024.2322057





#### TriNav<sup>®</sup> and TriNav<sup>®</sup> LV Infusion Systems with SmartValve<sup>®</sup> Technology

TriNav<sup>®</sup> LV Infusion System offers a portfolio to meet your needs – **vessel sizes from 1.5mm to 5.0mm** 

> TriNav<sup>®</sup> TriNav<sup>®</sup>LV Infusion System System

TriNav <sup>®</sup> Recommended for 1.5mm-3.5mm vessels			TriNav <sup>®</sup> LV Recommended for 3.5mm-5.0mm vessels		
Product Code	TNV-21120-35	TNV-21150-35	TVM-25120-50	TVM-25150-50	
Length	120cm	150cm	120cm	150cm	



## ≫TriNav<sup>®</sup>



# Precisely targeting the tumor for improved therapeutic delivery

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

**Indications for Use:** The TriNav 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.<sup>1,2</sup>

**Contraindications:** TriNav 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).<sup>1,2</sup>

1. TriSalus<sup>TM</sup> TriNav<sup>®</sup> Infusion System Instructions for Use 2. TriSalus<sup>TM</sup> TriNav<sup>®</sup> LV Infusion System Instructions for Use

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