

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^{1,2}

RWE

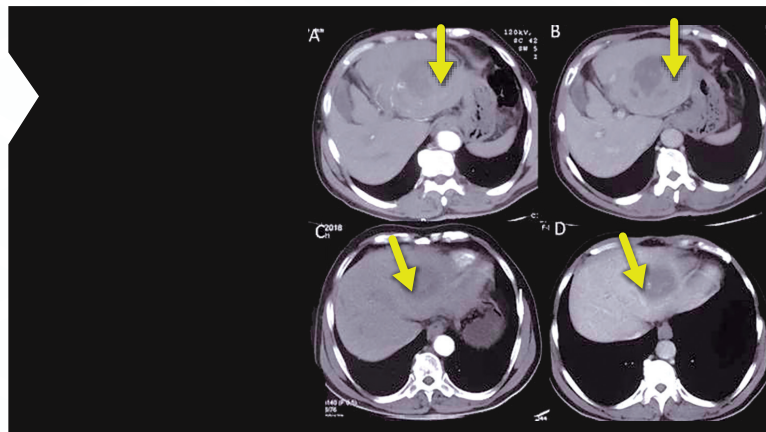
A comprehensive RWE study of PEDD for TACE and TARE among patients with HCC and liver metastases proved that despite higher baseline disease burden and complexity, patient outcomes were similar for non-PEDD patients³

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.jviro. 2015.01.029;
2. Titano, J. J. et al. End-hole Versus Microvalve Infusion Catheters in Patients Undergoing Drug-Eluting Microspheres-TACE for Solitary Hepatocellular Carcinoma Tumors: A Retrospective Analysis. *Cardiovasc Intervent Radiol* 42, 560-568 (2019)
3. Keziah Cook, Deepshekhhar 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

The complex patients' challenging clinical profile calls for the use of TriNav's PEDD approach because it may increase the amount of treatment delivered to the tumor while minimizing distribution to non-target tissue^{1,2}

Prior Embolization

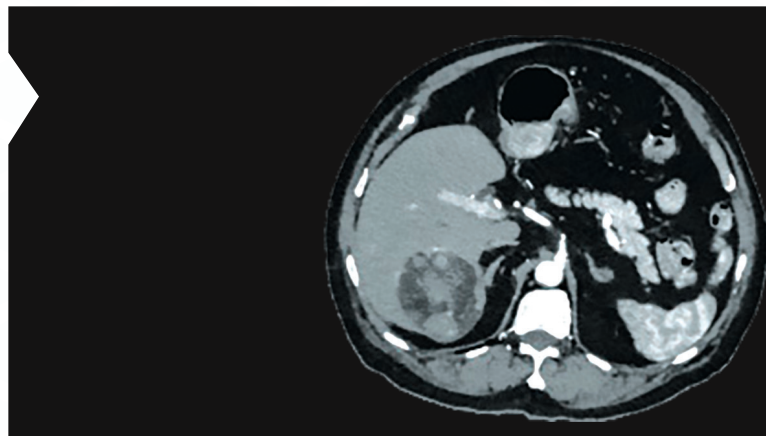
Previously embolized tumors can be more difficult to visualize and penetrate due to regions of necrosis and damaged vasculature³



Residual disease following TACE⁴

Large Tumors

Lack of particle penetration may be the cause of poor response to embolization therapies in patients with large (>5cm) tumors⁵

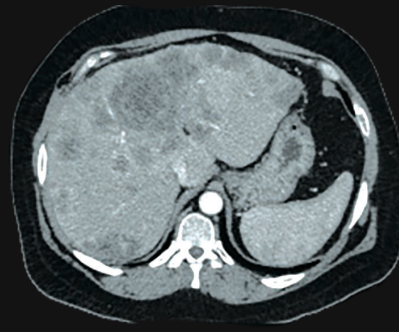


Pre-treatment CT showing 7x6cm biopsy proven HCC in segment 6/7

1. Titano, J. J. et al. End-hole Versus Microvalve Infusion Catheters in Patients Undergoing Drug-Eluting Microspheres-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.jv. 2015.01.029;
3. Chen S, Peng Z, Zhang Y, Chen M, Li J, Guo R, Li J, Li B, Mei J, Feng S, Kuang M. Lack of Response to Transarterial Chemoembolization for Intermediate-Stage Hepatocellular Carcinoma: Abandon or Repeat? *Radiology*. 2021 Mar;298(3):680-692. doi: 10.1148/radiol.2021202289. Epub 2021 Jan 19. PMID: 33464183.3)
4. Gupta, Pankaj et al; Response Assessment Following Image-Guided Therapy of Hepatocellular Carcinoma *Journal of Clinical Interventional Radiology ISVIR* 2020; 4(02):088-097
5. Higuchi/Tsuneo; Kikuchi/Masahiro; Okazaki/Masatoshi; Hepatocellular carcinoma after transcatheter hepatic arterial embolization. A histopathologic study of 84 resected cases 1 May 1994; [https://doi.org/10.1002/1097-0142\(19940501\)73:9%3c2259::AID-CNCR2820730905%3e3.0.CO;2-P](https://doi.org/10.1002/1097-0142(19940501)73:9%3c2259::AID-CNCR2820730905%3e3.0.CO;2-P)

Multi-Focal

It can be difficult to deliver adequate treatment while minimizing injury to normal liver in patients with multiple tumors¹

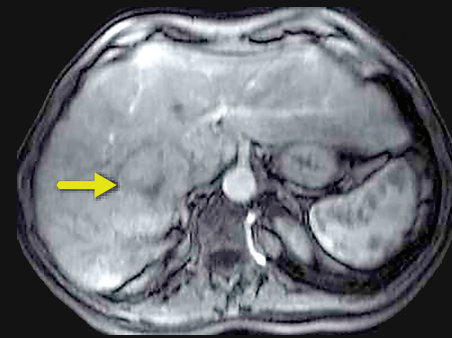


Multi-focal, poorly differentiated cholangiocarcinoma

Borderline Liver Function

In patients with borderline liver function, the challenge is to deliver an effective treatment while preserving adequate healthy liver tissue²

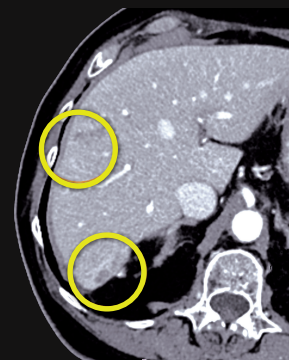
Elevated liver biomarkers are associated with poor prognosis in HCC⁴



Typical HCC in a patient with chronic hepatitis C.³

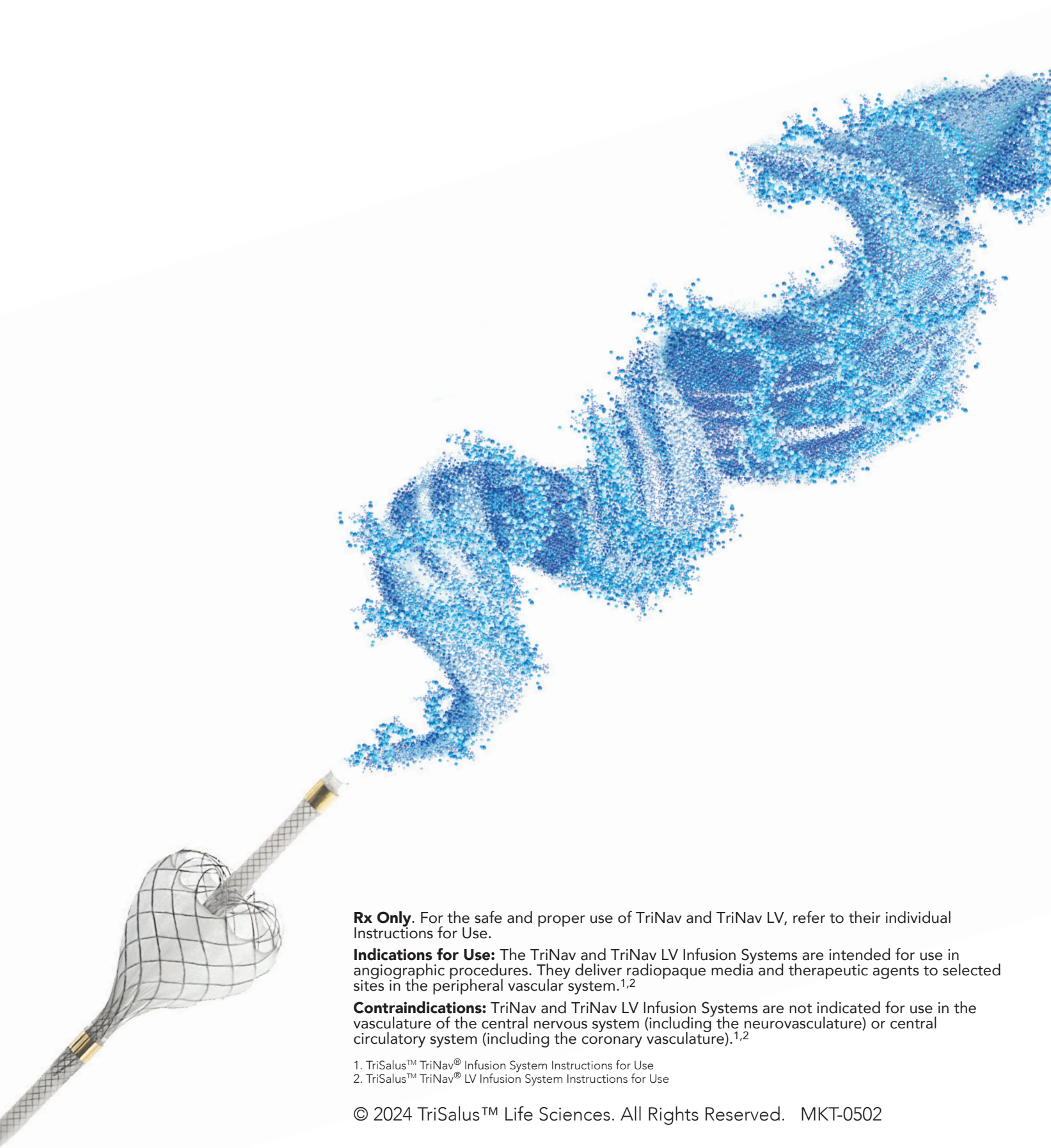
Hypovascular Tumors

It can be challenging to achieve adequate particle penetration into hypovascular tumors⁵



Metastatic renal cell carcinoma, with hypovascular liver metastases

1. Tomozawa, Yuki et al. Long-Term Toxicity after Transarterial Radioembolization with Yttrium-90 Using Resin Microspheres for Neuroendocrine Tumor Liver Metastases *Journal of Vascular and Interventional Radiology*, Volume 29, Issue 6, 858 - 865
2. 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>
3. Ramalho M, Matos AP, AlObaidy M, Velloni F, Altun E, Semelka RC. Magnetic resonance imaging of the cirrhotic liver: diagnosis of hepatocellular carcinoma and evaluation of response to treatment - Part 1. *Radiol Bras.* 2017 Jan-Feb;50(1):38-47. doi: 10.1590/0100-3984.2015.0132. PMID: 28298731; PMCID: PMC5347502.
4. Wang, F., Gao, S., Wu, M. et al. The prognostic role of the AST/ALT ratio in hepatocellular carcinoma patients receiving thermal ablation combined with simultaneous TACE. *BMC Gastroenterol* 23, 80 (2023). <https://doi.org/10.1186/s12876-023-02719-1>
5. Wasan, Harpreet S Adams, Richard Amin, Pradip Ades, Steven et al. First Line selective internal radiotherapy plus chemotherapy versus chemotherapy alone in patients with liver metastases from colorectal cancer. (FOXFIRE, SIRFLOX, and FOXFIRE-Global): a combined analysis of three multicentre, randomised, phase 3 trials. *The Lancet Oncology*, Volume 18, Issue 9, 1159 – 1171



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.^{1,2}

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).^{1,2}

1. TriSalus™ TriNav® Infusion System Instructions for Use
2. TriSalus™ TriNav® LV Infusion System Instructions for Use