PEDD™ DEB-TACE in Patient with HCC

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SUMMARY:

A patient initially presented with a solitary 10cm HCC tumor in segment 6 and was treated with 138mCi of resin Y90. At the 3-month visit following Y90 treatment the tumor still measured 10cm and appeared non-responsive (Images 1 & 2). Pressure Enabled Drug Delivery™ (PEDD) DEB-TACE performed using the TriNav Infusion System, followed by an infusion of Gelfoam pledgets, was used to take this large tumor to complete stasis (Image 3). The tumor appeared responsive at the 3-month follow-up visit (Image 4). This case demonstrates how TriNav's SmartValve™ can be used to achieve stasis when performing DEB-TACE by modulating pressure and preventing reflux, and how PEDD can be used to achieve a good tumor response in DEB-TACE.



Image 1 (left). Angiography showing solitary 10cm HCC tumor still present 3 months after

Image 2 (right). 3-month follow-up CT imaging shows no response to initial Y90 treatment.

Image 3 (left). Angiography showing complete stasis of tumor following PEDD DEB-TACE with TriNav (orange arrow) placed in the 1.5mm

Image 4 (right). 3-month follow-up CT imaging shows good tumor response post PEDD DEB-

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INTENDED USE: The TriNav Infusion System is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system. CONTRAINDICATIONS: TriNav is not intended for use in the vasculature of the central nervous system (including the neurovasculature) or central circulatory system (including the coronary vasculature). **Rx ONLY.** For the safe and proper use of the TriNav device, refer to the Instructions for Use



