


References

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 Consult Instructions for Use

Indications for Use: The GORE VIATORR® TIPS Endoprosthesis is indicated for use in the *de novo* and revision treatment of portal hypertension and its complications such as variceal bleeding, gastropathy, refractory ascites, and / or hepatic hydrothorax. Refer to *Instructions for Use* at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events. 

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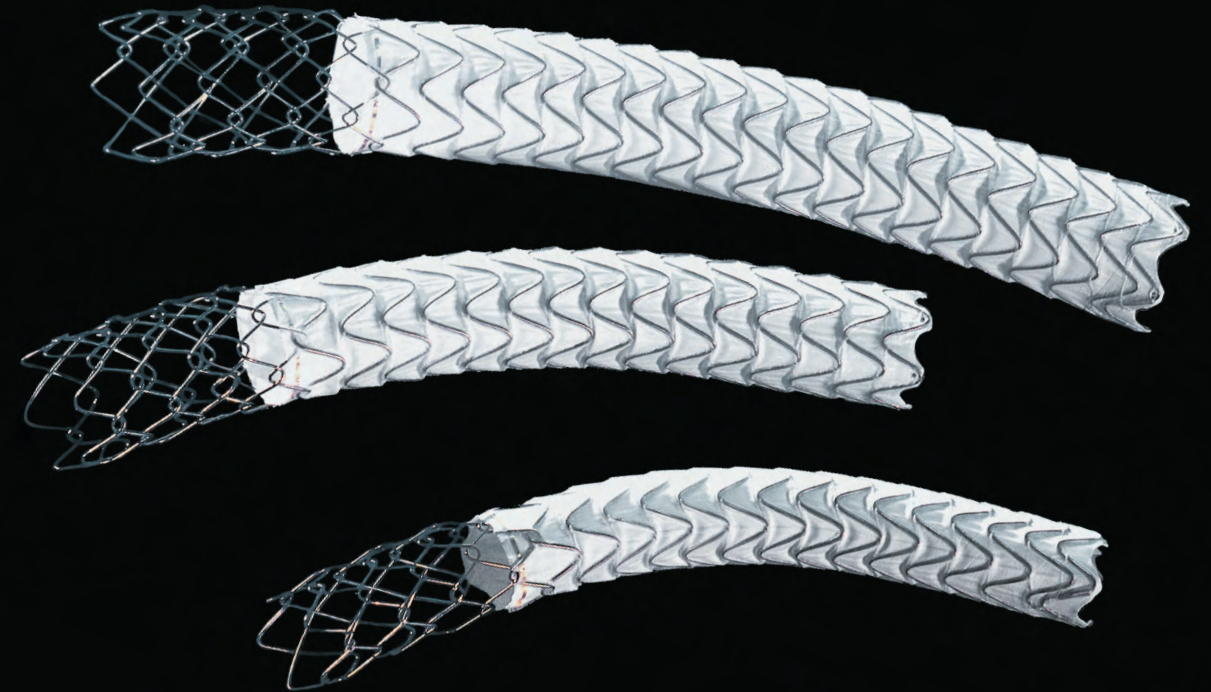


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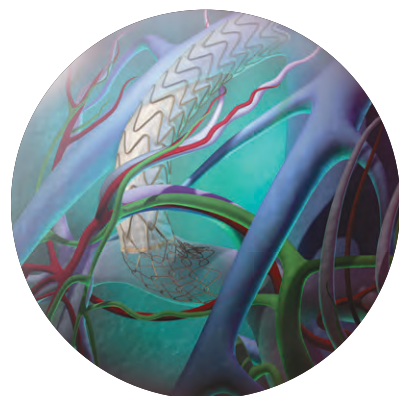
Optimized **Patency**
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PERFORMANCE through data

SUPERIOR
TIPS
PERFORMANCE





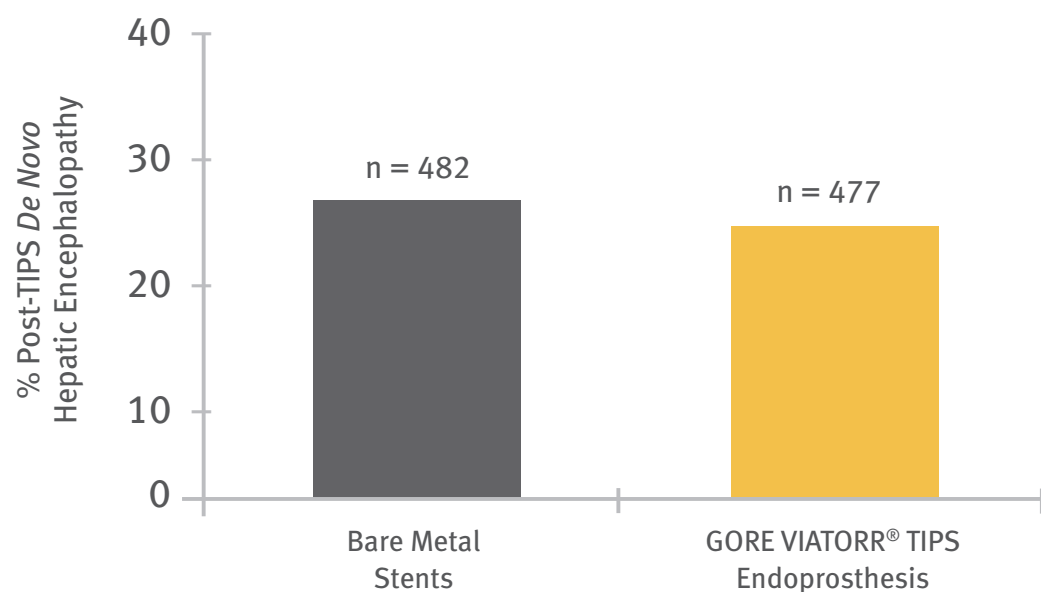
For your patients with portal hypertension, the GORE VIATORR® TIPS Endoprosthesis maintains significantly increased patency compared to bare metal stent alternatives. Highly effective in lowering portal pressure gradients in patients with refractory ascites and variceal bleeding, the GORE VIATORR® TIPS Endoprosthesis effectively treats patients over a longer period of time.

Two clinical studies were conducted in the United States to evaluate the GORE VIATORR® TIPS Endoprosthesis for use in *de novo* TIPS and TIPS revision. These studies demonstrated that primary patency of the GORE VIATORR® Device group was superior to that of the WALLSTENT® Device group ($p < 0.001$) at six months, with no significant differences in mortality or risk of encephalopathy*. Independent research since commercialization has yielded results that complement these original studies**.

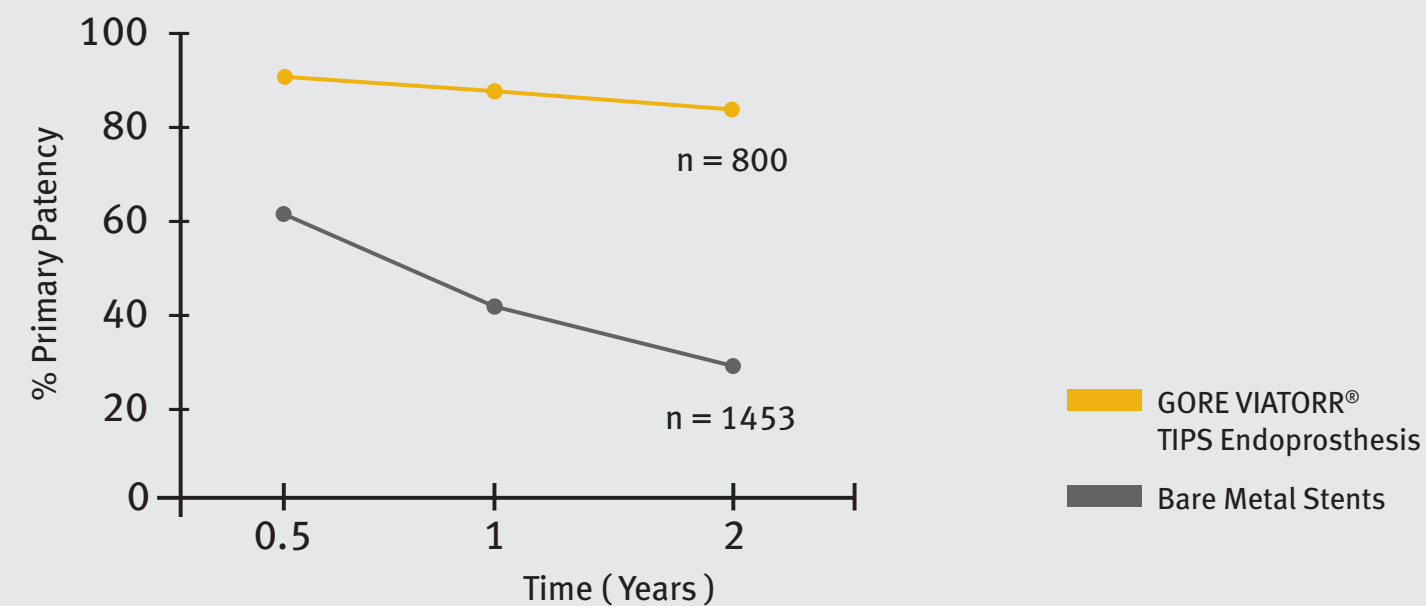
* On file with Gore PMA P040027

** Data on file

Post-TIPS *De Novo* Hepatic Encephalopathy^{1, 2, 4, 6, 7, 8, 10, 12, 15, 18, 19, 21}



Primary Patency¹⁻²⁵



GORE VIATORR® TIPS Endoprosthesis Primary Patency

YEAR	AUTHOR	N	PRIMARY PATENCY %		
			0.5 YEAR	1 YEAR	2 YEAR
2007	Bureau ¹	39			76
2006	Amarapurkar ²	11	90.9		
2006	Rossle ³	100		90	84
2006	Tripathi ⁴	157	93	92	89
2005	Barrio ⁵	20	100	100	
2005	Echenagusia ⁶	12		100	88.8
2005	Vignali ⁷	113	91.9	79.9	75.9
2004	Angeloni ⁸	32		76.3	
2004	Charon ⁹	100		84	
2004	Hausegger ¹⁰	71	87.4	80.8	
2004	Maleaux ¹¹	56		89.3	
2004	Rossi ¹²	53		83.8	
2002	Otal ¹³	20		80	
2001	Cejna ¹⁴	16	82		
Weighted Average			91.5	86.2	83.1