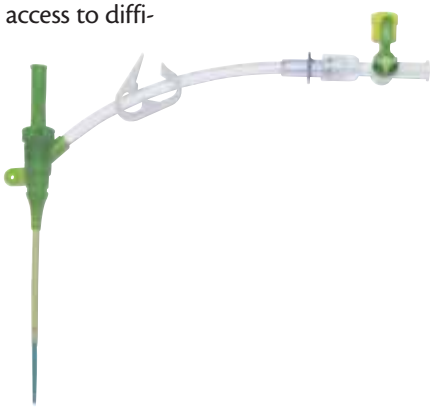
Pinnacle R/O II HiFlo

COMPANY	Terumo Interventional Systems
PHONE	(800) 862-4143
WEB	www.terumomedical.com/interventional

KEY FEATURES

- Radiopaque marker band for enhanced visibility
- Detachable, 3-way stopcock
- Shorter sheath and higher flow rate
- Larger inner-diameter side tube

Terumo Interventional Systems (Somerset, NJ) has introduced the Pinnacle R/O II HiFlo Introducer Sheath. According to the company, the new 4-cm stiff introducer sheath features the Pinnacle's recognized smooth transition, which facilitates access to difficult superficial sites that may be near a lesion site. In addition, a larger-diameter side flow tube allows a higher flow rate of fluids. The Pinnacle R/O II HiFlo also features a radiopaque marker band 5 mm from the tip for enhanced visibility, a laminar flow sheath housing with a 45° side tube take-off to improve flow dynamics, and a detachable 3-way stopcock, the company says.



Protégé RX Carotid Stent System

COMPANY	ev3 Inc.
PHONE	(800) 716-6700
WEB	www.ev3.net

KEY FEATURES

- Straight and tapered options for a customized fit in carotid vessels
- Proprietary EX.P.R.T. release technology to essentially eliminate premature deployment
- No stent shortening
- Tantalum GPS markers enhance visibility
- Cell design produces expansion force that resists compression

ev3 Inc. (Plymouth, MN) announced that it has received FDA approval for the Protégé RX Carotid Stent System. This stent system, when used in conjunction with the ev3 embolic protection systems, is indicated for the treatment of carotid artery disease in patients who are at high risk for adverse events from carotid artery surgery. The Protégé RX is available in both straight and tapered stent configurations, providing a variety of device options to address a broad range of patient anatomy present in carotid artery disease. According to the company, the safety and effectiveness of the Protégé RX Stent System is supported by the CREATE trial, a prospective, multicenter, single-arm registry that enrolled 419 patients in 31 US centers. The primary endpoint included a composite of death, MI, ipsilateral stroke, and procedure-related contralateral stroke at 30 days, and ipsilateral stroke 31 to 365 days. The major adverse event rate at 30 days was 6.3% and 7.8% at 31 to 365 days, the company says. ■