













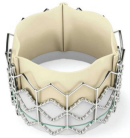













PATIENT ACCESS TO MEDICAL TECHNOLOGY IN THE EU AND US

	 EU Approval (CE mark obtained)	 US FDA Approval
 Spectra Optia Terumo BCT More than 20,000 mononuclear collection procedures have been carried out using the Spectra Optia system on patients outside the U.S.	 July 2010	  July 2012 Delayed by 24 months
 Revo MRI SureScan Medtronic The first pacemaker designed to be safe for patients to receive MRI scans, this technology improves quality of life by reducing patient concern regarding future diagnostic needs	 September 2008	  February 2011 Delayed by 29 months
 Esteem Implantable Hearing System Envoy medical The first implantable hearing system used to treat moderate to severe hearing loss, medically necessary for patients who have moderate to severe sensorineural hearing impairment and cannot tolerate an ear mold because of medical conditions	 May 2006	  March 2010 Delayed by 46 months
 Sapien Transcatheter Aortic Valve Edwards LifeSciences Provides severely compromised patients with an alternative to open-heart surgery	 September 2007	  October 2011 Delayed by 49 months
 Simplicity Renal Denervation System Medtronic A cost-effective treatment strategy for patients with treatment-resistant hypertension. The two components of the system deliver energy required to achieve safe, superior, and sustained blood pressure reductions for patients who have been unable to achieve target blood pressure levels despite multiple prescription medications	 April 2010	  Still pending Delayed by 29 months and counting
 The CoreValve System Medtronic Has been implanted in more than 26,000 people in more than 50 countries outside the U.S. and is the only transcatheter aortic valve implantation system approved for direct aortic or subclavian access	 May 2007	  Still pending Delayed by 60 months and counting

Sources: Boston Consulting Group, 2012; and other public sources