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1.1 Market Overview & Growth Trend

The world market for intracranial stents was valued at $130 million in 2010, a growth rate of 30% over its 2009 level of $100 million. The market has been growing at an average annual growth rate of 35% over the past five years.

In the past few years, intracranial stents have provided a significant advancement in the endovascular treatment of many lesions. Currently, the most common indications for their use are intracranial aneurysms either to assist coiling of wide-necked aneurysms or as stand alone flow diverting devices. They are also increasingly used for the treatment of intracranial occlusive disease either chronic like in intracranial atherosclerotic disease (ICAD) or acute as in acute ischemic attacks (AIS).
1.2 Device Application Segmentation

The use of stents to repair aneurysms is the most established application accounting for 65% of the market. Until recently stents were used as scaffolds to assist coil embolization in wide-neck aneurysms in stent-assisted coiling procedures, currently accounting for 42% of the total market.

The use of stents as mono-therapy flow diverting devices for aneurysm repair is gaining momentum and currently accounts for 23% of the market, almost all 2010 revenue have been achieved in Europe with some limited revenue realized in international markets.

In April 2011 the FDA granted Covidien's Pipeline Embolization Device a pre-marketing authorization (PMA) for the endovascular treatment of adults with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments.

The use of stents in the cerebral ischemia setting currently accounts for 35% of the market. Until recently the main indication was for the revascularization of symptomatic atherosclerosed cerebral arteries of 70% or more blockage during intracranial angioplasty and stenting operations. More recently, retrievable stents like the Solitaire FR have been successfully used to disrupt or retrieve clots in acute ischemic stroke (AIS) cases.
1.3 Geographic Segmentation

The European market is the most advanced in terms of stent application to the intracranial vasculature and accounts for 46% of the global market followed by the US with 35% share. The rest of the world markets are relatively under penetrated.

The market for intracranial stens is still in its early stages of development and regulatory approval is key for market development. In Europe, regulatory approval simply relates to the fact that the device will be inserted in the cerebral circulation.

The Neuroform EZ and the Enterprise are the only two commercially approved stents in the US for aneurysm assisted coiling, both under humanitarian device exemption (HDE) clause. In April 2011 Covidien received premarketing approval (PMA) for the Pipeline Embolization Device as a monotherapy treatment for large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments.

Stryker Wingspan is currently the only stent commercially approved in the US for cerebral ischemia, however the Pharos Vitesse from DePuy and the Solitaire FR from Covidien are far along the registration pathways and one of them is expected to enter the US market shortly.

The recent re-launch of the Solitaire FR from Covidien in October 2009 in Europe as a revascularization and clot retrieval device in acute ischemic stroke (AIS) cases opens a new arena for intracranial stent use in the cerebral ischemia setting.