NEUROVASCULAR INTERVENTIONS – EU ANALYSIS AND MARKET FORECASTS
**Executive Summary**

The table above provides the key metrics for neurointerventional devices for cerebrovascular applications in the five European Union (5EU) markets (France, Germany, Italy, Spain, and UK).

**Sales of Neurointerventional Devices by Region**

The figure below illustrates the sales of neurointerventional devices for the treatment of cerebrovascular disease. In this report, the neurovascular interventions market encompasses embolization, revascularization, mechanical thrombectomy, and access/support devices. In 2013 in the 5EU, the neurovascular interventions market was approximately $207m. We estimate the 2014 sales of neurointerventional devices for cerebrovascular applications to be $213m across the 5EU countries covered in this report, which are France, Germany, Italy, Spain, and the UK. Embolization, revascularization, and mechanical thrombectomy devices can be used for a wide range of cerebrovascular indications including intracranial aneurysms and arteriovenous malformations (AVMs), dural arteriovenous fistulas (DAVFs), atherosclerotic disease, and stroke. Endovascular therapy for neurovascular applications is rapidly expanding and provides effective results.

By the end of the forecast period, sales of neurointerventional devices will slowly grow to $254m at a Compound Annual Growth Rate (CAGR) of 3%, as shown in the figure below.
Executive Summary

Neurovascular Interventions Market Revenue ($m), 5EU, 2013 and 2020

2013
Total: $207m

- 23% France
- 24% Germany
- 18% Italy
- 21% Spain
- 14% United Kingdom

2020
Total: $254m

- 25% France
- 24% Germany
- 20% Italy
- 18% Spain
- 14% United Kingdom

Source: GlobalData

5EU = France, Germany, Italy, Spain, and UK

The key drivers for this market during the forecast period are:

- The increased use of remodeling techniques such as stent-assisted and balloon-assisted coiling, and the adoption of flow diverters for the treatment of challenging/complex aneurysms (wide-neck, large, and giant aneurysms).
- Improved recanalization rates with mechanical thrombectomy systems, where the need for chemical thrombolysis is eliminated, thereby reducing the risk of intracranial hemorrhage.
- The cost savings for healthcare payers resulting from the reduced need for repeat procedures.

In the 5EU, Germany and France are leading the way in the market and have the largest forecast market shares in 2020.

Neurovascular Interventions Market in the 5EU Markets

The neurovascular interventions market in the 5EU is a vast market that consists of innovative and emerging technologies. Rapid advances in the field of neurovascular interventions along with the development of minimally invasive techniques have greatly expanded the potential of therapeutic applications. Embolization devices including bare metal and bioactive/coated coils, aneurysm remodeling devices (stents and occlusion balloons), flow diversion devices, and liquid embolic agents can be used to treat intracranial aneurysms and AVMs, and optimize outcomes. Low-profile stent and balloon systems can be used
Executive Summary

Neurovascular Interventions– EU Analysis and Market Forecasts

Executive Summary

To revascularize plaque-burdened arteries in the cerebrovasculature. Mechanical thrombectomy devices including distal and proximal devices and stent retrievers can improve recanalization rates and provide predictable outcomes in the setting of acute ischemic stroke (AIS). In addition, the next generation of access/support devices such as microcatheters, steerable guide catheters and guidewires, and distal access guide catheters has been developed to improve navigation, trackability, and flexibility as well as provide stable access, especially through tortuous anatomy.

As shown in the figure below, the four device segments within the neurovascular interventions market are expected to grow steadily in the future as the next generation of device platforms enters the market, long-term clinical data become available, appropriate treatment guidelines and reimbursement rates are established, and high selling prices decrease.

In 2013, the embolization, revascularization, and mechanical thrombectomy device markets in the 5EU were estimated to be approximately $137m, $17m, and $6m, respectively. The access/support devices market was estimated to be approximately $46m in 2013. The embolization and mechanical thrombectomy device markets present greater opportunity and potential for growth. The embolization device market has the largest share in the 5EU neurovascular interventions market, accounting for over 60% of the market. The revascularization market is forecast to have the lowest growth in the market.

Unmet Needs Remain a Challenge

Management of patients with intracranial aneurysms and AVMs, atherosclerotic disease, and stroke is complex and challenging, reiterating the need for effective therapies. There are many dimensions in the struggle to provide better care for patients with cerebrovascular disease including: a lack of physician practice, performance, and training guidelines; complications of surgical therapy such as cerebral artery bypass and aneurysm clipping; treating challenging indications such as AVMs and stroke; a lack of clinical data; and improve ease of access in tortuous vasculature.

The neurointerventional field would greatly benefit from multispecialty and multinational collaboration on developing guidelines on effective treatment practices and strategies for various cerebrovascular indications. For example, the
optimal treatment strategy for unruptured intracranial aneurysms (UIAs) remains undefined. In addition, complex aneurysm morphologies and sizes such as wide-neck, wide-neck bifurcation, and large and giant aneurysms are challenging to treat due to the high recanalization rates and severe periprocedural complications. Intracranial AVMs are one of the most challenging indications to treat given the lack of curative therapies. AVMs are characterized by a complex angioarchitecture, where the timing of development and the nature of the lesion is not well understood. Currently, there is no single treatment that has been proven to be effective for treating intracranial AVMs.

Minimally invasive techniques including stenting and balloon angioplasty can be used to open occluded arteries and restore normal blood flow. However, there are post-procedural complications such as thrombosis, chronic inflammation, and in-stent restenosis (ISR) associated with stenting. In addition, the need for prolonged dual antiplatelet therapy can increase the risk of bleeding and incur additional costs to healthcare providers. Also, the management of AIS has been a source of frustration and dismay for physicians and patients alike, given the lack of effective treatments. Conventional therapy for treating AIS consists of chemical thrombolysis with intravenous (IV) administration of a thrombolytic agent. IV thrombolysis is limited by low rates of complete recanalization and increased risk of intracranial hemorrhage, often leading to poor outcomes.

Given the challenges in treating the various cerebrovascular indications, device manufacturers need to develop effective therapies that ensure long-term outcomes and increase patient safety. Neurovascular interventions using embolization, revascularization, and mechanical thrombectomy devices can reduce the risk of complications such as hemorrhage and thromboembolism, and improve outcomes. The development of innovative devices such as flow diverters has enabled treatment of complex aneurysms that otherwise would be left untreated.

**Key Players in the Neurovascular Interventions Market**

The neurovascular interventions market is a dynamic market dominated by key players such as Covidien, Johnson & Johnson (J&J), Stryker Corporation, Terumo Corporation, Penumbra, and BALT Extrusion. The competitive landscape consists of large, mid-size, and small companies that have developed various neurointerventional devices to target cerebrovascular disease. The key players in the market have developed a broad and comprehensive portfolio of neurointerventional devices for various cerebrovascular indications ranging from the treatment of complex intracranial aneurysms to AIS.

GlobalData believes that as the next generation of neurointerventional devices enters the market, the current key players will need to retain and acquire market share by improving the clinical performance of their existing products. In addition, the current
players need to expand into, or increase their presence in the emerging markets, in order to take revenue away from their competitors in the future.

**Neurovascular Interventions Market Future Outlook in the 5EU Markets**

The neurovascular interventions market in the 5EU markets is a vast and dynamic market that enables medical device companies to customize and develop innovative platforms for a variety of cerebrovascular indications/segments. The rapid advancements in the field of neuroendovascular therapy have led to the development of innovative embolization, revascularization, mechanical thrombectomy, and access/support devices.

Among the embolization devices, embolic coils will continue to be widely adopted for intracranial aneurysm treatment given the extensive clinical experience with such devices, and their use in both ruptured and unruptured aneurysms. Innovative coils have been developed to provide increased packing density, conformability, and stability. Liquid embolic agents such as Onyx have been, and will continue to be adopted to embolize intracranial AVMs. The adoption of emerging technologies such as flow diverters will increase only slowly in the future and is expected to take market share away from the stent-assisted and balloon-assisted coiling markets. However, the use of flow diverters is limited to niche aneurysm indications such as wide-neck, large, and giant aneurysms. In addition, the high cost of flow diverters compared with coils and remodeling devices will hinder the widespread adoption of flow diverters.

Outcomes of the Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) clinical trial demonstrating a lack of superior clinical performance of endovascular therapy versus medical therapy has limited the use of stents for treating intracranial stenosis. Stenting and balloon angioplasty are primarily performed in the setting of carotid artery stenosis. Low-profile stent systems have been designed to improve flexibility, radial strength, and conformability. Although innovative stent/balloon technologies with integrated embolic protection have been developed, GlobalData questions the widespread adoption of such revascularization devices in the future, given the lack of clinical data and appropriate reimbursement.

For AIS, mechanical thrombectomy devices provide higher recanalization rates and lower complication rates than IV thrombolysis. Stroke is a large market where there is a clinical need for effective therapies with predictable outcomes. Mechanical thrombectomy devices such as stent retrievers and proximal thrombectomy devices are primarily used in clinical practice. Stent retrievers have become the primary choice for devices used in mechanical thrombectomy procedures and will be widely adopted in the future. Due to technical challenges, while proximal aspiration thrombectomy devices such as the Penumbra...
Executive Summary

System can reduce the risk of embolic events, they are used less often in clinical practice compared with stent retrievers.

What Do Physicians Think?

Physicians believe flow diverters are innovative technologies that will be adopted for challenging intracranial aneurysms in the future. However, they question widespread adoption given the complications/challenges associated with flow diversion devices.

"Flow diverters are a great technology and there is no question about it. They are easy to implant and have very good, impressive results. You are able to get a 95% cure rate for patients treated with flow diverters.”

Physicians are optimistic about mechanical thrombectomy devices such as stent retrievers as well as their adoption in the future to treat patients with AIS.

“Thrombectomy has improved significantly . . . . I think a significant improvement and a big milestone in stroke therapy has been stent retrievers.”

Physicians want to see long-term clinical data to evaluate and compare the clinical effectiveness of neurointerventional devices/techniques for various cerebrovascular applications.

“Clinical trial outcomes do affect and change how we practice because we want to do what is best for our patients. If endovascular therapy is more dangerous for [a] patient than medical, then we prefer to do medical therapy.”

Physicians are optimistic about mechanical thrombectomy devices such as stent retrievers as well as their adoption in the future to treat patients with AIS.

“Stent retrievers are probably used in 85-90% of mechanical thrombectomy procedures . . . . When you have something in a middle cerebral artery segment or vessel that is 1-2mm, it is very hard to navigate the Merci device there.”

Physicians want to see long-term clinical data to evaluate and compare the clinical effectiveness of neurointerventional devices/techniques for various cerebrovascular applications.

“There is no clinical difference between endarterectomy and stenting. There is [a] lack of clinical data demonstrating stenting is better than endarterectomy.”
Executive Summary

As cost-containment policies are implemented, the widespread adoption of expensive neurointerventional technologies is questioned. “Cost is a major criterion when selecting a treatment modality for patients with cerebrovascular disease.”

“I think stent retrievers will be adopted widely in the future . . . . The only impediment is the cost. If the costs are lowered, then it may be widely used.”

Key opinion leader
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2 Introduction

Cerebrovascular disease is a major global public health and economic problem that is associated with high mortality and morbidity. Neurovascular interventions using embolization, revascularization, and mechanical thrombectomy devices have been adopted in clinical practice to address the challenges of conventional therapies, as well as improve outcomes and patient prognosis. Endovascular therapy including coil embolization, stent/balloon-assisted coiling, and flow diversion techniques can be used to treat ruptured intracranial aneurysms and unruptured intracranial aneurysms (UIAs). Emerging technologies such as flow diverters have been used to treat challenging intracranial aneurysms such as wide-neck, large, and giant aneurysms. Embolization with liquid embolic agents can be used as an adjunct or primary therapy for intracranial arteriovenous malformation (AVM) and dural arteriovenous fistula (DAVF) treatment. Revascularization of occluded/narrow intracranial and extracranial arteries can be performed using minimally invasive devices such as stents and angioplasty balloon catheters. However, the number of revascularization procedures performed has decreased from previous years due to a lack of clinical data demonstrating the benefits of stenting compared with surgical and medical therapy for treating patients with carotid artery disease and intracranial atherosclerotic disease (ICAD).

For patients with acute ischemic stroke (AIS), mechanical thrombectomy devices including stent retrievers and proximal aspiration thrombectomy devices have emerged as viable and effective alternative solutions to conventional chemical thrombolysis. Access devices such as microcatheters, guide catheters, and guidewires enable the delivery of embolization, revascularization, and thrombectomy devices to the target site.

This report focuses on the neurovascular interventions market in the 5EU markets (France, Germany, Italy, Spain, and UK) for treating cerebrovascular disease including intracranial aneurysms and AVMs, atherosclerotic disease, and AIS. In the report, the neurovascular interventions market is forecasted for the 5EU markets, where the unmet needs for treating cerebrovascular disease are identified while providing an understanding of physicians’ perceptions and decision-making processes. This report also evaluates the adoption of various neurointerventional devices in the future.
Introduction

2.1 Catalyst

Modern developments in endovascular interventions have led to a paradigm shift in the treatment of cerebrovascular disease towards endovascular therapy. Technological and scientific advancements in the field of neurovascular interventions have expanded the potential for therapeutic applications. Neurovascular interventions using embolization, revascularization, and mechanical thrombectomy devices can provide sustained clinical outcomes and address the unmet needs of the market. Management of patients with intracranial aneurysms and AVMs, atherosclerotic disease, and stroke is complex and challenging, reiterating the need for effective therapies. Conventional therapies used to treat patients with cerebrovascular disease do not translate to improved, long-term clinical outcomes.

Complex aneurysm morphologies and sizes such as wide-neck, wide-neck bifurcation, and large and giant aneurysms are a challenging subset of lesions to treat. These lesions are difficult to treat due to high recanalization rates and severe periprocedural complications. In addition, there is a lack of an optimal treatment strategy for treating intracranial unruptured aneurysms. Intracranial AVMs are characterized by a complex angioarchitecture, where there is currently no single treatment that has been proven to be effective. Although low profile stent and balloon systems have been developed for the revascularization of vessels characterized by atherosclerosis, a lack of clinical data demonstrating superior performance to surgical and medical therapy as well as post-procedural complications have hindered widespread adoption. Also, the management of AIS is challenging due to a lack of effective treatment options and the unpredictability of outcomes. Intravenous (IV) thrombolysis is the first line of therapy for eligible patients with AIS. However, low complete recanalization rates and an increased risk of hemorrhagic complications warrant the need for alternative therapies.

The challenges and clinical unmet needs of treating intracranial aneurysms and AVM, atherosclerotic disease, and stroke reiterate the need for therapies that provide long-term outcomes and increase patient safety. As more long-term clinical data that demonstrate the superior therapeutic benefits and appropriate reimbursement become available, and the cost of devices decrease, the adoption of innovative neurointerventional devices by the medical community will increase in the future. This report looks at the current neurovascular interventions market for cerebrovascular disease and evaluates the adoption and opportunities for this technology in the 5EU markets.
Appendix

13.8 About MediPoint

MediPoint is the flagship product for GlobalData’s Medical team. Each MediPoint report is built from the ground up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading KOLs. Running throughout each report in the series, “What Physicians Think” quotes provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

13.9 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team. GlobalData has offices in New York, San Francisco, Boston, London, India, Korea, Tokyo, and Singapore.

13.10 Disclaimer

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