Interview: Malan de Villiers – Managing Director, Southern Medical, South Africa



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The managing director of Southern Medical, Malan de Villiers illustrates the sheer diversity of the company's current activities and portfolio within South Africa as a leading implant devices company, while depicting his vision on the South African medical device market. He also reveals the competitive and regulatory challenges in the local and international market as well as the next priorities for the group.

To begin, Malan, please describe your initial aspirations in establishing Southern Medical and illustrate exactly how far the group has progressed now under your leadership?

The Southern Group of companies formed in 1987 and consists of a number of disciplines from the medical devices sector, which are managed by Graham Blackbeard and myself. Graham is the managing director of **Southern Implants,** the parent company manufacturing dental implants and associated prosthetic devices. We built on some of the technologies from Southern Implants and broadened the scope of the Southern Group to include separate companies specialized in different disciplines. **Southern Medical**, is a leading spinal and orthopedic device company. **Medika SA** was formed in 2002 to produce and distribute locally advanced wound care and

biological skin replacements products. Medika SA also partners with Mölnlycke, the Swedish based world leading wound care device company which had a relatively small footprint in South Africa, but is now expanding rapidly. The fourth company is **Southern ENT**, which specializes in cochlear implants and is the only company in the group that only distributes imported products into the South African market. **Skin Rejuvenation Technologies**, is a medical devices manufacturer specialized in cosmeceuticals. We leveraged the R&D effort that we have in the wound care and biological skin replacement fields and applied that to cosmeceuticals. Furthermore, we provide aesthetic fillers and other aesthetic devices as well as ophthalmic and visco-surgical devices.

Our activities are quite diverse, but each company is separate and specialized in a specific discipline of medical devices. We are proud to be one of the first local medical devices entrants in South Africa and the first company to be ISO 13485 certified. We also have FDA approval and have carried out clinical trials for FDA PMA premarket approval for certain ranges of products. We specifically target the key opinion leaders of the specific disciplines that we are focusing on. We have a very strong R&D focus as we do not merely produce generic products—we are looking to add value and provide solutions to our specific fields. Traditionally, we've insourced all our operations, even packaging, as we like to have control over the full process enabling the delivery of a quality product directly to the end-user. We are strong in manufacturing, processing, which includes the supply chain, and distribution. More than 50% of our income is derived from exports, which is mainly comprised of dental implants—the largest portion of our turnover. We do partner with distributors in many countries, but we are direct in the UK, Australia and collaboratively direct in the US.

Spanning the group's product portfolio, which segments have displayed the most promising growth prospects?

All of them. Dental implants remain one of the strongest components of our portfolio. Spinal orthopedics are also successful and we have high hopes for the future, although the market is very competitive and presents unique difficulties in comparison to other segments. This discipline requires extensive instrumentation. Aside from the actual device, we have to deliver the whole system to enable the surgeon to place the implant.

Our wound care division is growing fast with unique products including biological skin replacement products, for example. Additionally, our ophthalmic products have strong potential too, as there is a real need due to the limited presence of ophthalmic devices manufacturers in South Africa. Finally, the cosmeceutical area is highly competitive, but we have a unique product offering. Therefore, we are also doing well in this segment.

We won many prizes, such as innovation prizes, the Proudly South African reward, and we have been awarded the designation as exporter of the year. We remain one of the most active South African group of device companies.

Considering the rather remote location of the country, how are South African manufacturers generally perceived abroad?

Although we initially thought that our location may be a disadvantage, we noticed that South African manufacturers are well perceived at a global level. South Africa is viewed as the springboard into the African continent. The biggest challenge is to make sure that all our products are regulatory compliant in the markets we are entering. Our FDA and ISO 13485 certifications, in addition to the CE mark, play a crucial role in our continued success. These certifications put the South African manufacturers on the same base as foreign companies. Finally, our contribution to the industry in terms of R&D and conferences, presentations, also enhances the country's reputation and should be expanded upon.

Was it hard to create a brand identity in mature markets, such as the United States—the most developed medical devices market in the world?

The FDA registration in the United States is a trade barrier for foreign companies. However, many people are familiar with our products as a well-known South African brand, which helped us to enter markets like Australia and the United States. South Africa has traditionally produced quality surgeons and practitioners many of whom practice abroad and are familiar with our products. South African medical schools are well rated and concerned about maintaining or developing that recognition into the future.

Leveraging your background as an inventor and engineer, how would you evaluate South Africa as a platform for launching new medical device technologies?

The South African medical devices landscape has evolved significantly. Before, there was no regulation and it was therefore much easier for South African and foreign companies to conduct clinical trials inside South Africa without necessarily having the same compliance requirements that they would have been subjected to elsewhere. The medical devices regulations are going to come into force within the next six months and will bring the medical devices sector in line with the rest of the world. Some of our medical schemes require FDA registration as a minimum. This makes it difficult for a South African company that does not view the US as its immediate market. In this case, this requirement is unfair and we are looking forward to local device regulations. When new technologies are involved, medical funders have to instill barriers in order to avoid over-usage. If

we are not going to launch a device in the US, it is however inappropriate to incur the FDA registration cost.

Southern Implants is among only a handful of other local manufacturers to possess a thriving domestic and export business. In your opinion, what hurdles are preventing South Africa from truly cultivating a stronger local manufacturing base?

The big problem for South African companies now that devices are to be regulated is the regulatory environment. We do not have accredited bodies in South Africa that can certify to ISO 13485. For South African companies to be able to export to Europe we have to get auditors out from Europe on an annual basis. As a result local companies spend an excessive amount on regulatory compliance, which is very difficult for early stage companies to do. We are pursuing the creation of a local regulatory avenue so that new players can have an easier regulatory pathway. There is a lot of expertise in South Africa and a reservoir of talent is available. As one of the few leading medical device companies we receive a large number of applications for employment from highly skilled local engineers and biologists.

What are the challenges to maintain market share, especially with the entrance of multinationals into the market shortly after the creation of the group?

We have seen a steady increase of entrants to the competitive South African market. A few years ago the products that came to South Africa and Africa, were not necessarily of the same standard as in the rest of the world (sometimes being discontinued ranges of multi-national companies). Now emerging economies from the Middle East or India are bringing in very competitively priced products. Quality of cheap imports is difficult to evaluate. We maintain a product quality to meet very high standards and that is how we compete. It is very difficult for local companies to compete in the consumables market due to pricing. Even though South Africa has a weak currency and should have cheap labour and costs, it is still difficult to compete with these economies. They serve economies so large in scale, that it allows them to bring extremely cheap products into the country.

You are leading several other companies within the group, how have you managed to stay on top of all these work streams without diluting your contributions and impact on each individual entity?

I have a very strong partner who leads the Southern Implants company and strongly focuses on that. For each of the other companies, we have highly qualified general managers and strong management teams. My primary area of focus is R&D because I love finding solutions to problems.

I am happy to operate within different companies in that capacity.

And looking forward to the 3 to 5 years, where will we find Southern Medical?

Many of our domestic efforts are well established and the focus for the group is now to turn more towards exports for growth. Fortunately and unfortunately the rand has weakened. We become more competitive with a weaker currency and if you have a high quality product coming out of a weak currency environment you have a strong competitive positioning.

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