Overview of the U.S. Orthopedics Market
The orthopedics accounts for about 29 percent of the U.S. medical device industry sales, and is projected to experience a growth rate of 13-14% per year between 2004 and 2011. There should be ample opportunities for both machine tool manufacturers who sell machine tools to OEMs, subcontractors, and job shops; and Swiss subcontractors who have the capability to machine parts out of materials such as austenitic stainless steels, cobalt-chromium alloys, and titanium alloys. In addition, subcontracting opportunities exist for the production of tools and instruments that are used to insert each of the various orthopedic implant systems.

The trend in device manufacturing is that OEMs are outsourcing a larger portion of their production and assembly operations to contract manufacturers. There are a number of factors that are driving this trend. Market pressure to reduce prices and shorten lead times are two leading factors. In response, manufactures are focusing their efforts on R&D investment, regulatory issues, and product marketing. OEMs are thus outsourcing a lot of production and assembly operations to partners who can provide supply chain economies of scale and good operational support. Another leading factor is the trend toward integrated testing starting from the early product development stage and continuing through to clinical validation. The integrated testing process includes materials, components and complete devices, and is expected to become the industry norm. Swiss subcontractors who can provide services that meet these OEM needs will have opportunities to acquire new business.
The U.S. orthopedic device market can be divided into two broad categories:

1. Large bone trauma devices and large joint devices.
   In the U.S. orthopedic device market, many companies have focused almost exclusively on the first category and over the years this has resulted in considerable industry consolidation. As a result, the large bone and large joint category has become a highly concentrated market which is dominated by the leading OEM companies. These companies include DePuy (J&J), Zimmer, Stryker, Synthes, Biomet, Smith & Nephew, and Wright Medical. These companies comprise about two-thirds of the overall U.S. orthopedic device market.

2. Upper and lower extremity devices. This market is fragmented and remains unconsolidated despite the fact that it is a significant part of the overall orthopedic industry.

Although the leading seven companies comprise about two-thirds of the U.S. orthopedic device market, there is a considerable number of small- and medium-size companies that make up the remaining one-third.

There is a wide range of instruments used in the numerous orthopedic implant procedures available today. Each implant system usually has a special set of instruments that is used in the surgical procedure to insert a particular implant system. The number and type of instruments included in a set varies by implant system. For instance, instrument sets for knee and hip implant procedures may have more than 100 instruments, while revision procedure sets may only have about 50 instruments. Instrument systems can generally be categorized as: (1) Implant-specific instruments which are used exclusively for a specific brand of implant, such as certain reamers, broaches, and high-precision knee cutting blocks; or (2) Procedure-specific instruments which are intended for a specific type of procedure, such as a minimally invasive hip implant procedure, but are also compatible with the implant systems of various other companies.
In the case of implant-specific instruments, the shape, size, and other attributes of each implant system are unique. As such, in order to ensure precise fitting and alignment during the surgical procedure to insert an implant system, unique instruments must also be used. This being the case, when a medical device company develops a new implant system, it usually develops custom designed instruments to insert the implant system. Medical device companies then supply these complete implant-specific instrument sets to end users (e.g. outpatient centers, hospitals, and physicians) in an effort to promote the use of the implant.

In the case of procedure-specific instruments, complete implant procedure instrument sets usually contain an assortment of instruments that are designed for a specific type of procedure, but can be used with the implant systems of various other companies.1

Manufacturing Trends

To stay competitive in the medical device market, it is important for companies to maximize investments in R&D and also develop good relationships with their material suppliers. In order to do this, more and more OEMs are focusing their efforts on R&D, design, regulatory issues, and marketing of new medical devices, and they are outsourcing a larger share of their manufacturing and assembly operations to contract manufacturers. In addition, both OEMs and contract manufacturers are requiring shorter lead times from their suppliers for engineering and development projects.

Medical device OEMs are very good at creating and developing new medical products, but they may not be as proficient at managing their global manufacturing and supply chain logistics. As such, medical device OEMs

need partners who can help them create market opportunities by combining the OEM’s product innovation with the partner’s operational proficiency. Contract manufacturers have been assisting OEMs for many years in other sectors by reducing costs through outsourced manufacturing services. Medical device OEMs are now beginning to work with contract manufacturers both to reduce costs and enhance business performance through improved supply chain economics. The swing to end-customer driven demand requires a supply chain that is quick to respond and at the same time can deliver quality, flexibility, and the lowest total landed cost. The trend is clear that medical device OEMs will need to find partners who can work collectively to combine the OEM’s product innovation together with the contract manufacturer’s operational innovation that will create market opportunities.2

There is also a trend in medical device manufacturing toward integrated design and testing. Rising demands by patients for their ever increasing quality of life needs combined with more and more complex devices designed to meet these needs are creating new procedures in orthopedic design and testing. Design engineers have begun to incorporate testing throughout the entire development process from the beginning concept stage to clinical validation as testing abilities have continued to improve. The overall trend for the full integration of testing is expected to become the norm and will include materials, components and complete devices. One way that test system suppliers have been able to keep pace with the increasing complexity of orthopedic device designs is by assimilating advanced test technologies and techniques previously used in the automotive and aerospace industries.

There is also a growing trend in the medical device manufacturing industry to allow customers to decide where they would like to have their products produced. For example, Pacific Plastics & Engineering, a privately held California based manufacturer of specialized devices for medical companies, gives its customers the option to have their products produced in the U.S., or at plants in India or Taiwan (for at least

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25 percent less). Other medical device manufacturers, such as United Plastics Group in Illinois and the Tech Group division of West Pharmaceuticals Services in Pennsylvania, also offer customers a choice between more expensive domestically produced products or cheaper products made in lower cost foreign markets. A spokesman from the Tech Group states that between 15 and 25 percent of the company’s clients choose to have devices manufactured at Tech Group plants in Latin America while the other 75-85 percent choose Tech Group plants in the U.S. Driving this trend is the need to reduce costs on one hand, and maintain high quality on the other. U.S. companies are willing to pay extra for precision products which require more talented tooling making; however, there is a trend to manufacture less complicated devices and molds in lower cost locations like India, China and Latin America. Industry experts believe that giving the client the option to choose is exactly what customers want.3

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Swiss Business Hub USA, the trade promotion arm of the Swiss Embassy and the Swiss Consulates in the USA, will publish in October 2007 the third amended and updated edition of it’s well renowned report «The American Market for Medical Technologies – Opportunities and Challenges for Swiss Companies». For a copy of this report please send an e-mail to martin@SwissBusinessHub.org or contact Osec business network Switzerland at (044) 365 5151 or (021) 613 35 70

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