



ARGENTINA MEDICAL DEVICE INDUSTRY

NOVEMBER 2007

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Market Brief: Argentina Medical Device Industry

Overview

The import market for medical equipment and devices was estimated at US\$ 115 million in 2005. This amount increases to over US\$300 million when medical instruments, implants, disposables and supplies are also included. Imports have traditionally accounted for almost 80 percent of the total market. Imports in the healthcare sector experienced a severe downturn due to the devaluation of the Argentine peso in January 2002. While the healthcare market has not completely recovered, the current economic growth is stimulating imports of goods that cannot be supplied by the local market. The United States continues to be the overall market leader with a 46 percent share of the import market in 2005. While purchases of large expensive equipment are still often postponed, U.S. companies that offer good quality at competitive prices may find significant opportunities in the Argentine market. Components and parts offer strong sales potential, in large part, because market conditions still encourage the reconditioning of equipment already in use.

The Medical Device Industry

Imports

Exports from the U.S., which have traditionally led the market for medical equipment, comprised 46 percent of the import market in 2005. Imports fell to their lowest point at US\$18.4 million in 2002. However, the market has been recovering since 2003, when it recorded 55 percent growth followed by 80 percent growth in 2004 and 127 percent growth in 2005. Imports grew 20 percent annual rate during 2006.

Medical Device Industry Market Size Table
(in millions of U.S. dollars)

	2004	2005	2006*
Imports	50.3	114.7	78.6
Imports from U.S.	17.6	54.3	23.9
Exports	12.7	28.3	13.0

(*) Jan-June Figures

Laboratory Analytical Instruments

The market for U.S. laboratory analytical instruments (LAI) is highly competitive, globalized and technologically advanced. Many companies participate in more than one market segment. Success depends heavily on selling price, the performance capabilities of an instrument, technical support, and aftermarket service.

The local market is highly concentrated with 20 or fewer firms accounting for virtually all sales in all product segments. This is not expected to change in the near future. This market is nearly entirely dominated by imports from the U.S. Total imports of the top 3 best prospect products accounted for \$25.5 Million in 2006. There is very little local production in the sector, and that which exists is for very simple applications.

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LAI products are used in Argentina by the pharmaceutical industry for drug research, testing and quality control; by science research laboratories, which include corporate, university, and governmental research labs; by the biotechnology industry; by environmental laboratories for testing air, soil, and water samples for compliance with environmental regulations; by the chemical industry for research and quality control; and by the food and beverage industry for quality control. They are also employed in industries related to the processing and/or mining of oil, gas, and various metals as well as in the production of steel.

The Argentine market for LAI products was created by government regulations on quality control and environmental protection. Usually, the distribution for these types of products succeeds the following channel:

- A. Manufacturer, Distributor, End-user
- B. Manufacturer, Subsidiary, End-user
- C. Manufacturer, End-User

Lab scientists reported that the practice by US firms of both setting up branches (Agilent, Varian, Foss), and working through distributors, have been equally effective in this market. Frequently, laboratory products are imported directly by the final user. However, end users also stated that local branches often offer a better post-sales service. The aftermarket represents an important source of income due to the lack of investment in new equipment. For example, the world's largest provider of analytical instruments for food and agricultural use, FOSS, will open its first subsidiary in Latin America. The Danish company will open a sales and service center in Buenos Aires, Argentina, from which it will manage the entire region. Argentina represents its largest market in the region. Worldwide, about 85% of milk, 80% of commercial grains and 75% of beer produced is analyzed with a FOSS product. In Argentina FOSS currently controls 85% of the commercial grain and 90% of the milk market. FOSS expects first year turnover of US\$3.5 Million and hopes to double that number within five years. Agricultural goods account for more than half of all Argentine exports; US\$21 Billion of agricultural goods were exported in 2006.

Import Market

For the last 4 years, U.S. firms exported approximately an average of US\$40.5 Million annually in laboratory instruments to Argentina and enjoy a clear leadership position in this market.

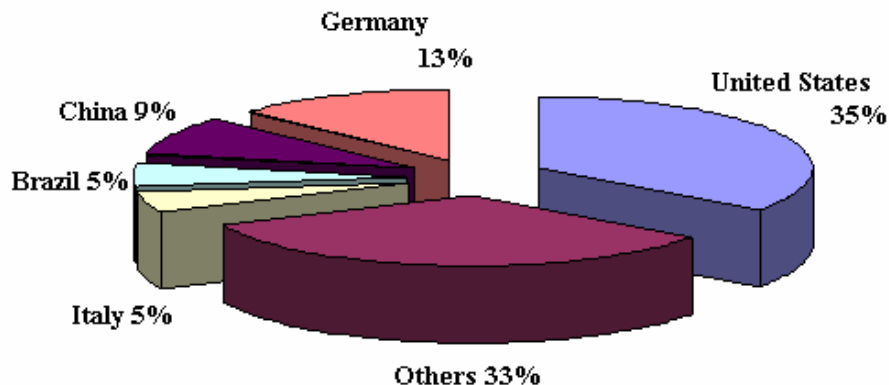
Overall 2004 to August 2007

1. HS 90262090000 Instruments for Checking pressure: US\$40,319,052
2. HS 90268000000 Instruments for measuring/checking variables de liquids gases: US\$24,466,091
3. HS 90261019000 Flow meters: US\$23,896,775
4. HS 90271000000 Gas or Smoke Analysis: US\$18,168,666
5. HS 90221999900 Apparatus Base on X-ray for other use, ex: Medical: US\$17,416,409
6. HS 90272012000 Liquid Chromatographs: US\$16,857,890
7. HS 90261029900 Level Meters or Controls (non metal and not for combustibles): US\$14,830,109
8. HS 90304090000 Specially designed telecommunications instruments: US\$14,194,309
9. HS 90269090000 PARTS for Instruments for measuring/checking variables de liquids gases: US\$14,263,973
10. HS 90262010000 Instruments and apparatus for measuring and checking pressure

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(Manometers): \$13,755,421

Laboratory Analytical Instruments Market Share – 2006



Source: Argentine Customs

Medical Instruments and Accessories

The import market for medical instruments and accessories was estimated at US\$28 million in 2006. Instruments include surgical instruments and surgery sets, microscopes and magnifying glasses, as used in ophthalmologic surgery, and parts. Imports in the healthcare sector experienced a severe downturn due to the devaluation of the Argentine peso in January 2002. While the healthcare market has not completely recovered, the current economic growth is stimulating imports of goods that cannot be supplied by the local market. The Argentine economy has experienced a significant recovery in the last four years, with a growth rate of 8.5 percent in 2006. The United States continues to be the overall market leader with a 40 percent share of the import market in medical instruments in 2006. Imports have traditionally accounted for almost 75 percent of the total market, a significant portion of which consists of surgery sets sold by subsidiaries of U.S. and European companies in Argentina. While there is some local manufacturing of surgical instruments, imports from Pakistan and India have increasingly gained market share and replaced local production. U.S. companies that offer high quality products at competitive prices may still find niche opportunities in the Argentine market.

While the market is expected to continue growing and importing critical inputs for their practice, the high import cost of some medical products cannot be completely passed on to the Argentine patient, who already struggles with decreasing purchasing power and less generous healthcare plans. As a result, purchases of more innovative or expensive technology will often be postponed. Imports of surgical products have, however, increased since 2003, after the devaluation. This is related to an increasing number of surgical procedures offered to cater to a niche demand from a growing influx of tourists requiring healthcare services. These foreigners are attracted by a world-renowned expertise in professional medical services and the reduced cost of treatments and surgeries, including implants. Within the past few years, demand for plastic surgery in Argentina has increased significantly. It is now ranked third behind the United States and Mexico in terms of the number of plastic surgeries performed each year, increasing 60% (or about 50,000 surgical candidates) since 2003. Some renowned plastic surgeons estimate that approximately 30% of their

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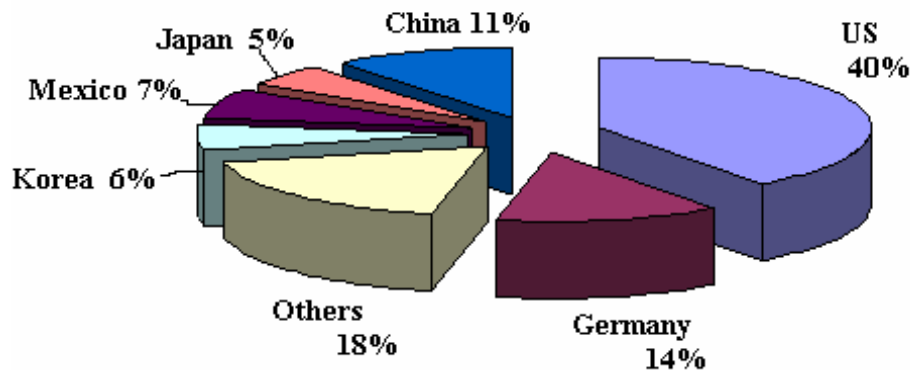
patients are tourists. Although popular at the moment, plastic surgery is only one of the many medical services available in Argentina. Many people travel to Argentina to receive cardiovascular, dental and ophthalmologic treatments, which are easily accessible at a fraction of the price of services in the United States.

Medical Instruments and Accessories Market Size (in millions of U.S. dollars)

	2005	2006	2007*
Imports	20.7	28	8.6
Imports from U.S.	8.1	11.3	2.8
Exports	3.4	4	0.95

(*) Jan-April Figures

Medical Instruments and Accessories Market Share - 2006



Source: EXInet based on Argentine Customs statistics

The medical instruments import market grew to US\$28 million in 2006. Imports from the U.S., which have traditionally led the market for medical products, comprised 40 percent of the import market in 2006, with US\$11.3 million. Imports from Germany amounted to US\$3.9 million, followed by China with US\$2.9 million in exports, Mexico with US\$ 1.9 million (although mostly by one company: Johnson & Johnson), Korea with US\$1.5 million and Japan with US\$ 1.2 million. Imports from neighboring Brazil amounted to US\$0.63 million, mostly related to parts or general instruments. Under the Mercosur customs union, of which both Argentina and Brazil are members, imports from Brazil are duty free.

The import market for medical instruments has been recovering since 2003 after reaching its lowest point during the 2002 peso devaluation at US\$4.5million. The market grew dramatically in

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2005 US\$20.7 million, surpassing pre-devaluation levels. Imports continued to grow another 35 percent in 2006, with U.S. imports reaching US\$8.6 million and maintaining its traditional share of the market. Total imports during the first quarter of 2007 have already reached US\$8.6 million, with imports from the U.S. amounting to US\$2.8 million (and Argentine exports amounting to approximately US\$1 million). Imports are expected to stabilize during 2007 with a slight projected increase of 5 percent.

While imports from the US continue to lead the market, simpler instruments, such as non-electrical scalpels are either sourced locally or mainly imported from India and Pakistan as well as from Germany.

Key Suppliers

More than two thousand companies sell medical products in Argentina, of which 25 percent are manufacturers and 75 percent are importers. However, it is difficult to estimate how many are exclusively focused on the medical instrument subsector. Large U.S., Japanese and European companies are either established in Argentina with subsidiaries or are represented by local importers/representatives. There is local production of instruments, which, although they are durable, are generally considered less technologically advanced. However, local companies have been making advances and are supplying instruments for arthroscopy, fixation instruments for videoendoscopy surgery, etc. This market niche is also supplied by imports from Brazil, India and Pakistan. Among the leading international suppliers of instruments established in Argentina are: Johnson & Johnson, Alcon, Carl Zeiss, Mallinckrodt Medical, Boston Scientific, Biomet, and Stryker Corporation. These companies account for about 30 percent of the market, or US\$8.6 million. Other international companies established in Argentina are B.Braun Medical and Synthes.

The following is a list of companies exporting to Argentina:

U.S.: Scanlan International, Medtronic Safamor Danek, Tava Surgical, Implant Innovations, Blacstone Medical, Hu Friedy Manufacturing Co, Arthrex, Zimmer, Teleflex Medical

Germany: Reda Instrumente Gmbh, Martin Medizin Technik, Aesculap, Nopa Instruments, Gimmi, Rebstock Instruments

Brazil: Edlo Productos Medicos, Hexagon

Italy: Mikai Manufacturing:

France: Groupe Lepine

Pakistan: Tecno Instruments, Weldon, Surgiwell, Pakistan Scissors, Ekal Surgicals, Professional Hospital Furnishers

Medical Disposables

The import market for medical disposables was estimated at US\$ 90 million in 2006. Basic disposables include gloves, needles, syringes, bandages, gauzes, basic catheters, tubes (Levin, PVC, nasal/oral), IV admin sets, etc. This niche sector characterized by large volumes and low profit margins is well supplied mostly by Asian companies. However, the higher-end disposable market, such as those specifically designed for hemodynamics, cardiovascular and neurological surgeries, sutures, among others, are the best prospects for U.S. firms.

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The United States continues to be the overall market leader with a 17.4 percent share of the import market in medical disposables in 2006. Imports in the overall medical product sector have traditionally accounted for almost 75 percent of the total market. U.S. companies that offer high quality products at competitive prices may still find niche opportunities in the Argentine market.

Current healthcare expenditures in Argentina amount to approximately US\$6.1 billion (versus US\$24 billion in 2000), or 4.5 percent of GDP. This dramatic decrease in annual expenditures is largely due to the currency devaluation in 2002, as the exchange rate now stands at approximately three pesos to one dollar. The devaluation coupled with rising prices has increased health care costs by over 80 percent since 2001. This severely limited the amount of critical supplies in a sector heavily dependent on imported goods, which shrank sharply during 2001-2002. According to 2003 data from INDEC, the National Bureau of Statistics and the Census, in a country with a population of 38 million, it is estimated that only 45 percent of Argentines have some type of healthcare coverage either through the public healthcare system (national, provincial, or municipal), the social security system or from private healthcare providers (“pre-pagas”), with the remainder using public hospitals.

Currently the private healthcare provider system is struggling to reschedule its huge tax debts incurred into during the last decade in order to continue operating in Argentina. A recent increase in the cost of private healthcare approved by the Argentine government was intended to palliate this effect. However, while this may improve the budgetary situation for private healthcare providers, it further limits the access to comprehensive medical services for a large portion of the population. This measure also entails a larger out-of-pocket (or co-payment) expense to cover some premium practices which may not be covered by standard healthcare plans. To alleviate the cost burdens of the sector, the national government passed Law 25590 and Decree 486/02 (Healthcare/Sanitary Emergency in force from 2002 extended by Law 26204 and Decree 1903/06 until December 31, 2007). This legislation exempts from taxes and duties imports of some critical new medical products that are not manufactured in Argentina. (Several disposable or sterile products are included in the duty exemption list. Please see Market Entry below for a list of products exempted).

The Argentine economy has recovered significantly in the last four years, with GDP growth of about 8.5 percent for 2006. While the market is expected to continue growing and importing critical inputs for their practice, the high import cost of some medical products cannot be completely passed on to the Argentine patient, who already struggles with decreasing purchasing power and less generous healthcare plans. As a result, price is a determining factor and purchases of more innovative or expensive technology are often postponed.

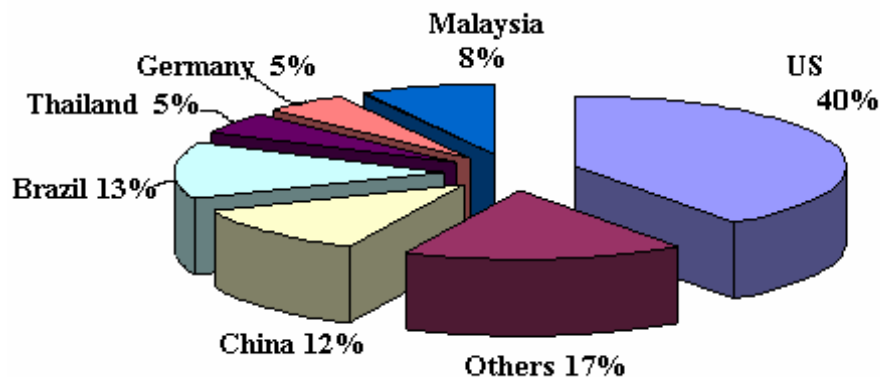
Import Market Size Table (in US\$ million)

	2005	2006	2007*
Imports	85	90	49.2
Imports from U.S	14.4	15.7	7.4

(*) Jan-Jun Figures

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Medical Disposables Market Share - %



Source: Exinet based on Argentine Customs statistics

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Market Entry

U.S. medical equipment and devices are highly regarded in Argentina. Price is the number one factor for competing in this market. After price, the two most important factors considered by local end-users are financing and performance. Successful marketing and promotion usually requires participation in local and international congresses and trade shows. Local seminars, conventions and specialty magazines are also great advertising and marketing vehicles. In addition, U.S. firms should stress their commitment to after-sales service and the timely replacement of parts. Imports of medical products must be performed by an importer registered with the ANMAT (the Argentine equivalent to the FDA) as a frequent importer of medical equipment. The importer is responsible for registration of products and must submit a product report detailing technical information, including documents that are legalized by the Argentine Consulate or Embassy in the product's country of origin. Imported products appear under the name of the local registered importer who will be responsible for the products and the registration process as a representative of the U.S. company. The U.S. company appears as the manufacturer and source of origin for the products. Requirements vary according to product classification. General requirements include:

- Registration form or certificate of free sale or an equivalent document granted by the pertinent authority in the country where the product is manufactured/commercially distributed (authenticated and translated, if appropriate)
- Authorization from manufacturer/distributor to commercially distribute the product in the market (for Class II and beyond; authenticated and translated, if appropriate).

As previously noted, the national government passed Law No. 25590 (Healthcare/Sanitary Emergency in effect from 2002 to December 31, 2006, which exempts critical products from duties and taxes. This exemption applies to the imports of certain medical equipment parts and accessories that are not manufactured in Argentina. It also applies to some laboratory equipment and instruments, disposables, implants, diagnostic reagents and pharmaceuticals.

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The following medical equipment parts and accessory products (see Mercosur Harmonized System Code product description under the Market Data section above) are currently included in the import duty exemption list:

841391; 901814; 90181990; 90189094; 901813; 90182010; 84733099; 854071; 90229090; 90189099; 90181210; 90181290; 901811; 90189091; 90189031; 90189039; 90189040; 90279099; 90192010; 90192030; 90192040; 902230;

Additionally, a zero percent import duty for capital goods produced in non-Mercosur countries will remain in effect until December 31, 2008. This applies to the following medical equipment and devices:

841319001; 90181100; 90181210; 90181290; 901813; 901814; 90181910; 90181920; 90181930; 90181980, 90181990; 90182010; 90185010; 90185090; 90189010; 90189040; 90189050; 90189091; 90189093; 90189094; 90192010; 902212; 90221411; 90222110; 90222120; 902230; 90229010; 90229012; 90229019; 90279099.

Other medical equipment and devices pay import duties ranging from 0% to 16%. In these cases, an additional 0.5 percent is levied as a statistics fee.

Market Issues and Obstacles

Legislation passed in 2004 regulating medical products (Mercosur Regulations No. 3801/04 and 3804/04 and previous ANMAT Regulations 2318 and 2319/02) represent an attempt to harmonize the regulatory framework applicable to company and product authorization with the MERCOSUR Customs Union (Argentina, Brazil, Paraguay, Uruguay). This legislation establishes a unified process for the registration of medical/dental products and the registration of the manufacturing or importing company to facilitate market entry. Also applicable is ANMAT Disposicion 191/99 regarding manufacturing practices for medical products. While the new harmonized medical regulatory system has been in force since May 2, 2006, full deployment may take some time and some delays may be experienced, which may affect new product registrations. These regulations mainly affect local manufacturers and importers, although U.S. companies exporting to Argentina may be requested to provide updated product/company information (such as product certificate of free sale, which has to be authenticated and translated; authorization to commercially distribute the product in the market, etc.) to their local representative/distributor to comply with the new regulatory system.

Under the Mercosur customs union, of which both Argentina and Brazil are members, imports from Brazil enjoy a 0 percent import duty.

Prospective Buyers

While imports are mainly carried out by importers/distributors, there are some direct purchases by health care institutions that are registered to import. End users for medical equipment and products can be divided into public sector institutions, universities and private sector institutions.

The health care service sector in Argentina is a mixed system made up of four distinct service providers. The first group has the public hospitals, in place mainly for the uninsured. The second is

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the social security healthcare system (known as “obras sociales”), which is designed for people with fixed salary employment. The third is private medical insurance (“pre-pagas”), which gathers those who can afford pre-determined services. The fourth is the healthcare system for the elderly (PAMI), similar to Medicare in the U.S.

It should be noted that 56% of the healthcare sector is government-run, making the Government one of the largest local purchasers. There are approximately 285 health care organizations that offer healthcare plans at the national and provincial level under the “obras sociales” program. Universities and labor unions also offer their own healthcare programs. This system continues to be highly concentrated- out of a total of 285 organizations, 44 percent of the members are concentrated in only 10 organizations. Additionally, 54 percent of the members are located in the province of Buenos Aires. Regarding private healthcare service companies or “pre-pagas”, there are approximately 139 companies, of which 7 companies concentrate over sixty percent of market share. The “obras sociales” healthcare system provides coverage to about 16 million people, while the private healthcare system (pre-paid) covers 3.2 million people. Public hospitals are severely overburdened and serve the growing demand of patients without coverage. Therefore, most of their budgets are destined to buy critical supplies. Private healthcare providers are also under significant financial strain.

Trade Shows & Fairs

Expomedical 2008

Date: September 11th-13th, 2008

Place: Centro Costa Salguero, Buenos Aires

Description: international exhibition of medical equipment, products, and supplies

Webpage: www.expomedical.com.ar

What We Can Do for Massachusetts Companies

Massachusetts companies interested in entering South American markets or attending/visiting local trade shows, please contact the Massachusetts South America Office in Brazil at massbrazil@massbrazil.com.br.

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