EMBASSY OF PAKISTAN, ALGERIA TRADE AND INVESTMENT WING

PRODUCT REPORT / MARKET INTELLIGENCE REPORT

SUBJECT: <u>DEMAND OF SURGICAL INSTRUMENTS IN ALGERIA</u>

1. INTRODUCTION:

Algeria's healthcare sector is experiencing significant growth, leading to an increased demand for surgical instruments. The country primarily relies on imports to meet this demand, sourcing surgical instruments, the product group of HS code 9018 "Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraph apparatus, other electro-medical apparatus and sight-testing instruments", from various international suppliers. Germany is a leading supplier of surgical instruments to Algeria, accounting for a substantial portion of imports. India is another major exporter, contributing significantly to Algeria's surgical instrument imports. Pakistan also plays a crucial role in supplying surgical instruments to Algeria.

2. PRODUCTION:

The production of surgical instruments in Algeria is relatively limited, with the country relying heavily on imports to meet its medical device needs. However, there are a few notable local manufacturers contributing to the sector. SARL PROMEDAL (Progress Medical Algeria) is an Algerian private company specializing in the production and distribution of single-use medical devices and Hikma Pharmaceuticals is operating four manufacturing plants in Algeria, Hikma specializes in producing medicines, including cephalosporins, general formulations, penicillin, and oncology products.

Despite these local efforts, the majority of surgical instruments are imported. As of recent data, Algeria has 74 importers of surgical instruments, with a total of 1,316 export-import shipments recorded. The Algerian government has implemented measures to promote local production and reduce dependency on imports. Since January 1, 2009, Algeria has imposed a ban on imports of drugs and medical devices that are also produced locally, aiming to encourage domestic manufacturing.

3. CONSUMPTION:

Algeria's surgical instruments market is experiencing significant growth, driven by healthcare reforms, increased government spending, and a rising demand for advanced medical technologies. The surgical instruments market in Algeria is expected to grow at a compound annual growth rate (CAGR) of 6-8% from 2024 to 2030. By 2029, the medical devices market, encompassing surgical instruments, is projected to reach a volume of approximately \$1.68 billion. The Algerian government's focus on enhancing healthcare facilities and services is a primary driver of increased demand for surgical instruments. The adoption of minimally invasive surgeries and the need for precision tools are boosting the demand for specialized surgical instruments. Instruments such as forceps and retractors are widely used across various surgical fields, contributing significantly to market consumption.

4. IMPORT MARKET ANALYSIS:

The consumption of surgical instruments in Algeria is on an upward trajectory, supported by governmental healthcare initiatives, a growing patient population, and technological advancements in medical procedures. However, addressing challenges related to cost, training, and accessibility is essential to sustain and further accelerate this growth.

Algeria imports surgical instruments from a diverse range of countries. According to available data, the leading suppliers are:

HS-9018-Surgincal Instruments Top Exportering Countries to Algeria					
USD "000					USD "000"
Years	2019	2020	2021	2022	2023
France	39,672	33,102	41,411	54,967	52,386
Germany	40,112	33,323	27,601	34,541	39,892
India	5,412	4,463	6,739	6,276	12,898
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Turkye	1,274	562	1,767	1,639	1,730
Pakistan	1,140	798	1,790	912	1,374
Thailand	1,337	1,045	1,123	1,408	1,169
Source: ITC Trademap					

5. SPECIFIC QUALITY/PACKAGING/LABELLING REQUIREMENTS:

Importing surgical instruments into Algeria necessitates adherence to specific quality, packaging, and labelling requirements to ensure compliance with national regulations and standards.

- Certificates of Conformity: Importers must provide certificates of conformity and quality from independent third parties, verifying that the surgical instruments meet Algerian standards. These certificates are part of the mandatory documentation for customs clearance.
- Compliance with Technical Standards: Surgical instruments must comply with technical requirements set by Algerian authorities, particularly those outlined in the Ministerial Decree of October 30, 2008, which specifies conditions for the import of medical devices for human use.
- **Protection and Safety:** Packaging must ensure the protection of surgical instruments during transportation and storage, maintaining their sterility and functionality. While specific Algerian regulations on packaging materials may not be detailed, adherence to international best practices is advisable.
- **Documentation Inclusion:** All necessary documentation, including certificates of conformity and quality, should be included within the packaging to facilitate inspection and verification by Algerian customs authorities.
- Language: All imported products, including surgical instruments, must be labelled in Arabic. This regulation is strictly enforced to ensure accessibility and compliance with national standards.
- **Product Information:** Labels should clearly display essential information such as the product name, manufacturer details, country of origin, and any relevant usage instructions or warnings. While not mandatory, including labels in French can be beneficial due to its widespread use in Algeria.

• **Regulatory Compliance:** Any changes to the labelling or packaging of approved medical devices must be promptly communicated to Algerian regulatory authorities to maintain compliance and ensure that all information remains accurate and up-to-date.

6. TECHNICAL STANDARDS:

- In Algeria, the regulation of surgical instruments falls under the broader category of medical devices, overseen by the Ministry of Health, Population, and Hospital Reform (MSPRH). To ensure safety, efficacy, and quality, surgical instruments must comply with specific technical standards and regulatory requirements.
- The National Agency for Pharmaceutical Products (ANPP): An independent administrative authority whose primary task is the registration of all medicines and medical devices in the Algerian market. The agency is mandated to provide a crucial link in monitoring the control of quality, safety, efficacy and referential value of pharmaceutical products and medical devices for the use of human medicine.
- Pasteur Institute Algeria (IPA) has exclusive import and distribution rights for serums and vaccines. It plays a critical role in epidemiological surveillance: acting as the national reference point for the identification of infectious and parasitic disease and tasked with the development of tools and training schemes to counter these disease categories.
- National Laboratory for Control of Pharmaceutical Products (LNCPP), Algeria's national pharmaceutical regulator undertakes quality control and evaluation duties alongside research and training functions. It also enjoys World Health Organization (WHO) status as an Africa and the Middle East—wide reference laboratory.
- Central Pharmacy for Hospitals (PCH) is responsible for the acquisition, stock management, regulation and supply of pharmaceuticals to the country's public health institutions. It is also in charge of maintaining strategic and contingency drug stocks and it engages in local production as well. It has a different procurement directorate specialized by product category, but the central purchasing unit of PCH is the one in charge of all local and foreign purchases. The mode of procurement for the PCH is open bidding (public tender) for international and local vendors alike. Examples on some recent public tenders announced by the PCH can be found on this link: http://www.sante.dz/pch.htm
- SAIDAL: Founded in April 1982 following the restructuring of the Algerian Central Pharmacy (PCA), SAIDAL became a public company in 1989 following the implementation of economic reforms. Based in Algiers, state-run SAIDAL is the largest pharmaceuticals group in the country and ranks among the biggest in Africa. The firm operates six production divisions and three distribution centers, as well as a research and development hub and a bioequivalence center. It aims to raise production capacity to 300m units.
- **Regulatory Framework:** Executive Decree 23-101 (March 2023): This decree has streamlined the sale of medical devices in Algeria. Devices already on the market can continue to be sold without immediate registration with the Algerian National Agency of Pharmaceutical Products (ANPP). However, registration with the ANPP is mandatory by November 2024.
- **ISO** Certifications: Manufacturers are encouraged to implement quality management systems compliant with international standards such as ISO 9001:2015 and ISO 13485:2016. These certifications demonstrate a commitment to maintaining consistent quality in the design, production, and distribution of medical devices, including surgical instruments.
- Comprehensive Dossiers: Manufacturers must prepare detailed technical documentation for each device, encompassing design specifications, clinical data, risk assessments, and

- evidence of compliance with applicable standards. This documentation is critical for the registration process and for demonstrating conformity with regulatory requirements.
- Certification of Conformity: Products must meet Algerian standards, which define the technical, safety, and quality requirements for market approval. Conformity assessments are conducted to verify that products adhere to these standards, ensuring they are safe and effective for use.
- National Register of Medical Devices: Surgical instruments must be registered with the National Register of Medical Devices before being placed on the Algerian market. The registration certificate is valid for three years from the date of issuance. The process involves submitting comprehensive technical documentation and may require an import license, typically issued within 30 days.
- Ongoing Compliance: Manufacturers are responsible for continuous monitoring of their devices' performance and safety after they enter the market. This includes reporting adverse events, implementing corrective actions when necessary, and ensuring that any changes to the device are communicated to regulatory authorities.
- Import Bans on Locally Produced Devices: Since January 1, 2009, Algeria has imposed a ban on the import of medical devices, including surgical instruments, that are also produced locally. This policy aims to promote domestic manufacturing and reduce reliance on foreign products.

7. **IMPORT TARIFF:**

Importing surgical instruments into Algeria involves specific tariffs that importers must consider. The Algerian customs tariff is applied in accordance with the international Harmonized System (HS). The tariff rate levied on imported surgical instruments ranges between 5% to 30%. Those products in which Pakistan has an edge are facing duty of 3.5%. Dental instruments face 30% duty. A database provided by the Algerian customs on its website indicates the specific duty charge rate for a certain product category. The value-added tax (VAT) is 19%. Customs clearance file includes invoice with a bank domiciliation, a copy of company registers, a copy of the tax card issued by the relevant fiscal authorities. Additional documents can be required in case of a specific administrative procedure or a preferential tax regime application.

- General Tariff Rates: Algeria applies customs tariffs ranging from 0% to 30% on imported goods, depending on the product type. The exact tariff for surgical instruments can vary based on their classification under the Harmonized System (HS) codes.
- Provisional Additional Safeguard Duty (DAPS): Introduced in January 2019, DAPS applies to certain products to protect domestic industries. Duties range from 30% to 200%. It's essential to verify whether specific surgical instruments fall under this regime.
- Value-Added Tax (VAT): As of June 2021, Algeria reduced the VAT on imports of medical supplies, including surgical instruments, to alleviate financial burdens on healthcare providers.

8. NON-TARIFF BARRIERS:

Importing surgical instruments into Algeria involves specific NTBs that importers must consider.

• **Import Restrictions:** Since January 1, 2009, Algeria has imposed a ban on the import of drugs and medical devices, including certain surgical instruments, that are also produced locally. Importers should verify whether the instruments they intend to import are subject to such restrictions.

• Customs Declaration: Importers must submit a written and signed customs declaration to the relevant customs office within 21 days of the goods' arrival. The declarant can be the owner, a customs agent, or the carrier.

9. IMPORT VALUE AND VOLUME:

Algeria imports surgical instruments from a diverse range of countries. According to available data, the leading suppliers are:

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Source: ITC Trademap					

10. DISTRIBUTION CHANNELS:

The distribution of surgical instruments in Algeria follows specific channels influenced by the country's regulatory framework and market dynamics.

- Importers and distributors act as intermediaries between international manufacturers and local healthcare providers. They are responsible for managing regulatory compliance, storage, and delivery.
- The Algerian government is a significant buyer of medical devices, including surgical instruments, for public hospitals and clinics.
- Many private entities purchase directly from local distributors or international manufacturers.
- Retailers specializing in medical and surgical equipment cater to smaller healthcare facilities and individual practitioners.
- Emerging trend of online platforms offering medical supplies.
- Many international manufacturers partner with Algerian firms for exclusive rights to distribute their products.
- Health and Medical Trade Fairs: Events like SIMEM (Salon International des Équipements Médicaux) allow manufacturers and distributors to showcase products, build partnerships, and connect with potential buyers.
- Leverage Trade Events: Participate in exhibitions to increase brand visibility and network with industry players.

11. PRICES:

The pricing of surgical instruments in Algeria varies significantly based on factors such as the type of instrument, brand, quality, and whether the equipment is disposable or reusable. Additionally, import duties, taxes, and shipping costs can influence the final price.

- **Disposable Surgical Instruments:** Items like disposable scalpels or syringes are generally more affordable, with prices ranging from a few hundred to several thousand Algerian Dinars (DZD) per unit, depending on the specific product and quantity purchased.
- Reusable Surgical Instruments: High-quality reusable instruments, such as forceps, scissors, or clamps, can range from several thousand to tens of thousands of DZD per unit. For instance, surgical scissors may have varying prices based on their design and material.
- Advanced Surgical Equipment: Complex devices like electrosurgical units or specialized surgical kits are priced higher, often starting from hundreds of thousands to millions of DZD, reflecting their advanced technology and critical applications.

12. EXPORTS OF THE PRODUCT FROM PAKISTAN TO HOST COUNTRY AND COMPARISON WITH COMPETITORS IN THE MARKET

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13. REASONS FOR PAKISTAN'S LOW SHARES:

Pakistan's low export of surgical instruments to Algeria can be attributed to several factors, both external and internal.

- Complex Regulatory Environment: Algeria has stringent regulations for importing medical devices, including mandatory compliance with local standards and certifications. Pakistani manufacturers may face challenges in meeting these specific requirements.
- **Import Restrictions:** Algeria bans the import of surgical instruments that are locally produced to support domestic manufacturing, limiting the scope for Pakistani exports.
- **High Tariffs and Non-Tariff Barriers:** Duties, import taxes, and administrative procedures increase the cost of Pakistani surgical instruments, reducing their competitiveness in Algeria.

- Lack of Awareness: Algerian buyers may have limited awareness of the quality and competitiveness of surgical instruments from Pakistan.
- **Poor Distribution Networks:** Limited partnerships between Pakistani exporters and Algerian distributors hinder market access and penetration.
- European Dominance: Algeria has a strong trade relationship with European countries like Germany and France, known for high-quality medical devices. European products often dominate the market due to proximity and established brand reputation.
- **Price vs. Quality Perception:** While Pakistani instruments are cost-effective, they may be perceived as lower quality compared to European or American products, despite being competitive in many aspects.
- Limited Marketing Efforts: There is often insufficient promotion of Pakistani surgical instruments in Algeria, leading to low demand and recognition.
- **Geographical Distance:** Pakistan's geographical distance from Algeria increases shipping costs and delivery times compared to European suppliers.
- Algerian Protectionist Policies: Algeria prioritizes local industries and restricts imports, impacting Pakistan's ability to export surgical instruments.

14. **RECOMMENDATIONS:**

To increase surgical instrument exports from Pakistan to Algeria, a strategic approach is essential, addressing both supply-side improvements and market-entry tactics.

- **Regulatory Compliance:** Collaborate with Algerian authorities to meet local certification and quality standards.
- **Build Local Partnerships:** Partner with Algerian distributors and healthcare providers to establish a strong presence in the market. Explore joint ventures or collaborations with local manufacturers.
- Leverage Trade Agreements: Work through bilateral or multilateral trade agreements to reduce tariffs and barriers. Engage with trade bodies to negotiate favorable terms for exports.
- Focus on Niche Products: Identify surgical instruments not manufactured in Algeria and focus on exporting these.
- Enhance Product Perception: Improve branding and quality assurance to compete with European counterparts. Highlight Pakistan's global reputation as a leading surgical instrument producer.
- **Meet Algerian Standards:** Ensure compliance with Algerian regulatory standards for medical devices, including obtaining certifications like ISO 13485 and providing conformity documentation.
- **Streamline Documentation:** Work with Algerian import authorities to simplify the customs process by preparing complete and accurate documentation.
- **Invest in Branding:** Develop strong branding for surgical instruments, emphasizing their cost-effectiveness and reliability.
- Participate in Trade Events: Attend Algerian and regional medical trade fairs like SIMEM (Salon International des Équipements Médicaux) to network and showcase products.
- Target Public and Private Buyers: Build relationships with public procurement agencies and private healthcare providers in Algeria.
- Collaborate with Distributors: Partner with reliable Algerian distributors who have strong networks in the healthcare sector.
- Establish Local Offices or Representatives: Set up a local presence to better understand the market and improve customer relationships.

- **Joint Ventures:** Explore joint ventures with Algerian firms to produce or distribute surgical instruments locally.
- **Financial Incentives:** Seek government incentives and subsidies for exporters to mitigate costs.
- **Digital Presence:** Develop a robust online presence to reach Algerian buyers through digital platforms.

15. LIST OF MAJOR SURGICAL INSTRUMENT IMPORTERS IN ALGERIA:

Company Name	Contact Number	Email Address	Website
Eurl medbel Dental Address: Quartier Boushaki No 32 Bab Ezzouar	Tel: 00213 791 685 059 00213 793 243 420	medbel.dental@yaho o.com	
MEDICALEX,SARL Address: 26, rue Rachid Lafkir 16035 El Mouradia Algeria	Tel:00213 21 690551 Fax:00213 21 690551		
Sarl DREAMED Address: 21 RUE KEROUCHE SLIMANE EX CLOS ST JEAN Birkhadem, Alger(16), Algérie	Tel/fax: 00213 23 57 9585 00213 560 04 02 01 00213 667 334 519	sarldreamed@gmail.	
SARL NE Address: 5 D RUE MOHAMED BOUNAB Algiers Center, Algiers(16), Algeria	Tel: 00213 21 74 07 08 00213 555 025 766 00213 555 025 768 00213 555 025 767	krimo_epem@yahoo .fr	
ORTHO MAT TRAUM, EURL Address: 22, rue Bakkal Baghdad - 31024 Oran – Algeria,	0661 41 94 37 Tel: 041 80 21 83/84, +213 41825209 - Fax: 041 80 21 80/81	medicatdirection@g mail.com	
GROUPE MEDICO	Tel: 023 57 94 54	responsable.commer cial@groupemedico. com	
SAMIBI MEDICAL	Tel: 0770 71 95 29	samibimedical@gma il.com	Website: samibimedica l.com
EURL MEDBEL IMPORT EXPORT City Mimoni hamoud	Tel: 0791 68 50 59	info.medbel@gmail. com	Website: medbel.net

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