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Abstract*

The medical device sector is a critical driver of Costa Rica's economic development, accounting for 37 percent of total exports as of 2022. This paper analyzes the main enablers and bottlenecks in upgrading along the medical device global value chain into higher value-added segments. The mixed-method approach we use includes documentary analysis, 15 interviews with key stakeholders, and descriptive statistics of different datasets. Results indicate five enablers for upgrading: (i) a strategic location and economic, political, and social stability, education, human talent, and a favorable investment climate allowed companies to establish in Costa Rica; (ii) a shift in the strategy of the investment attraction agency toward supply chain helped identify key suppliers; (iii) the development of specialized skills and talent needed by the industry helped manufacturing more complex devices; (iv) productive development programs helped linkages emerge between multinational enterprises of medical devices and domestic firms; and (v) the existence of specialized skills enabled companies to consider Costa Rica for research and product development processes. The sector also faces three main bottlenecks that hinder its ability to continue upgrading: (i) cultural barriers and informality that restrict backward linkages; (ii) persistent skills shortages, and more bilingual graduates in science, technology, engineering and mathematics are needed; and (iii) lack of incentives that limit the ability to deepen research and development.

JEL Codes: F14, F23, O21, O47
Keywords: Costa Rica, foreign investment, medical devices, global value chain

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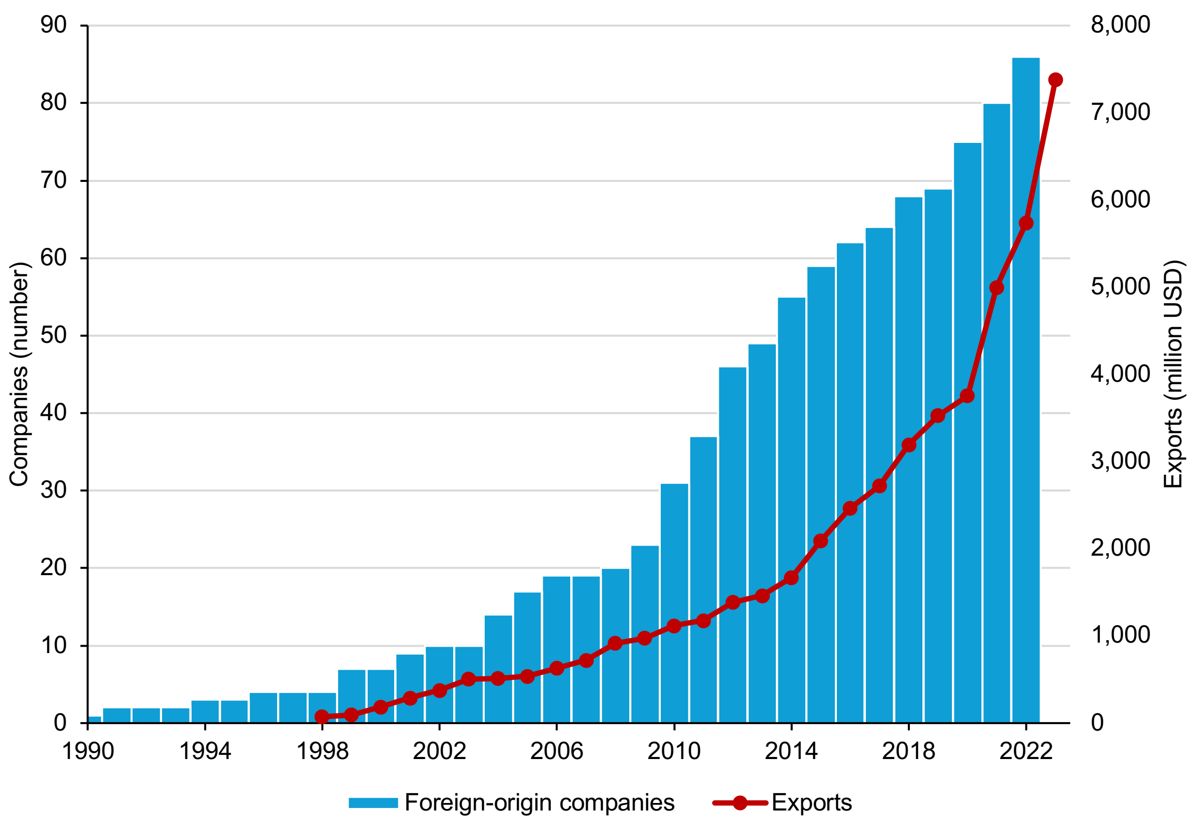
1. Introduction

In the past two decades, the medical device (MD) sector in Costa Rica has grown exponentially. In 2000, eight MD companies generated an estimated 1,500 jobs and exports, which represented 7 percent of the total exports. By 2022, the number of companies increased to 86, including 12 out of the top 30 worldwide, creating more than 50,500 jobs and exports that represented 37 percent of the total.[1] It took the country 21 years to reach US$3.5 billion, and in four years this number doubled to US$7.4 billion (Figure 1).

Figure 1. Number of Foreign-origin Firms and Exports of Medical Devices in Costa Rica, 1990—2023 (in millions of US$)



Source: Authors' elaboration using data from Procomer (http://sistemas.procomer.go.cr/estadisticas/inicio.aspx) and CINDE.
Notes: export data include all six-digit commodity codes under the four-digit codes 9018, 9021, and 9022, plus the commodity 900130 (contact lenses).

[1] Costa Rica ranks 13 out of 30 considering that Johnson & Johnson would open a production site in Costa Rica. The top 30 MD firm ranking comes from MPO ("The 2023 MPO Top 30 Medical Device Companies Report" available at https://www.mpo-mag.com/heaps/view/11657/?nav=top_nav access on March 15, 2024)

Bamber and Gereffi (2013) analyze Costa Rica's position and potential for upgrading in the MD global value chain (GVC) in 2013, finding that it exported complex MDs and that multinational corporations (MNCs) exported several sophisticated product lines. These include bovine heart valves and intravenous pumps. It also covered several market segments, including drug delivery systems and cardiovascular and orthopedic devices. Several firms—including Baxter, Boston Scientific, and Hospira—also performed a growing number of engineering processes locally. However, little is known about the challenges that the MD industry in Costa Rica faces in upgrading along the GVC into higher value-added segments. Analyzing value added in the era of GVCs can provide additional insights that cannot be obtained by analyzing exports alone. In GVCs, MNCs might perform only a fraction of all the processes used to reach the final product in each country, shaping the production landscape with components that cross borders multiple times. The phenomenon of fragmented production globally characterizes GVCs, marking a significant evolution in the organization of economic activities. This interconnected and intricate web of value-added processes has become a dominant force, influencing the strategies of nations, companies, and workers. The value of the final output produced in the country and subsequently exported minus the cost of intermediate inputs and production costs determines the DVA in gross exports.

Previous contributions in the literature include Valverde-Carbonell (2023), who identifies key country-sector pairs in Latin America with a greater chance of increasing the domestic value added (DVA) embodied in exports. The paper highlights sector D31T33 (Manufacturing n.e.c.) of Costa Rica as pushing the level of sectoral specialization. He finds that the specialization enhancement of this sector-country pair was driven by a shift in the product mix toward more complex products (MDs), representing a sectoral upgrading process. While this study highlights the importance of using value added to study GVC, there is a gap in identifying milestones within its variations.

Bamber and Gereffi (2013) use a GVC framework to analyze Costa Rica's position and potential for upgrading the GVC of MDs. Our study takes a different approach, focusing instead on explaining what allowed the country to upgrade along the GVC or limited it from doing so. We believe our exercise is useful for international policymakers

and the entry dates are from CINDE (available at https://www.cinde.org/es/sectores/manufactura-inteligente/ciencias-vida accessed on April 5, 2024).

concerned with upgrading within the MD GVS or related industries, and for local policymakers concerned with improving the MD business ecosystem. More recently, Salazar-Xirinachs (2022) identifies the main determinants of the recent growth in exports from the MD sector in Costa Rica, but does not focus on value added.

2. Methods

This study uses mixed methods that combine documentary research with qualitative in-depth interviews and quantitative data to identify and analyze the main determinants of the Costa Rican MD sector in moving along the GVC. To do so, we carried out documentary research for trend identification where we reviewed research papers, books, and policy documents (mostly from the Inter-American Development Bank, the Organisation for Economic Co-operation and Development (OECD), and the World Bank). The inclusion criteria comprised documents describing (i) theories of value-added generation (upgrading) within GVC in general or MD GVC, (ii) national public policies or public–private partnerships for foreign direct investment (FDI) attraction, retention, and heightening, and (iii) global and local trends in the MD sector. These documents provide a theoretical framework through which to understand and analyze upgrading in the local MD industry between 1995 and 2023 (see Section 3). The documents also made it possible to identify milestones in the Costa Rican MD industry.

Subsequently, we identified key informants for qualitative in-depth interviews with the objective of understanding the main enablers and bottlenecks that allowed or limited these upgrading milestones. Interviewee selection was intentional, aiming for frontline policy makers or recipients in public, private, or civil society organizations. We conducted 15 interviews with 17 sector leaders from different organizations, including the following (detailed in Table A1):

- CINDE, an FDI attraction agency
- The Costa Rican Medical Device Cluster and CRBiomed, two medical device cluster organizations
- Sistema de Banca para el Desarrollo, a risk and seed capital financial institution
- Promocor, a public–private export promotion agency
- Inteco, a certifying organism for products, processes, and services

- Sinaes, an accreditation body for university disciplines
- Academia de Centroamérica, a nongovernmental organization devoted to research on economic growth
- Ministry of Foreign Trade
- An MD entrepreneur
- IICIMED-UCIMED and Tecnológico de Costa Rica, two academic institutions

Key questions guided these semi-structured interviews of approximately one hour and a half each, adapted to the informants' expertise and the information previously collected in the documentary research (see Appendix B). The interviews were conducted between November 2023 and February 2024. Finally, the research team summarized the interview findings. To test for the different hypotheses presented by the literature and interviewees, we used quantitative trade data since 2012 from Comtrade to describe which MD products are being exported from Costa Rica.[2] We also gathered employment statistics from the most representative household survey in Costa Rica (Encuesta Continua de Empleo). To test the reasons why MD companies decide to start operations in Costa Rica, we built a database of newspaper articles with the company's reason for investing or reinvesting in the country. We searched each company's name in CINDE and *La Nación*, looking thoroughly into why they decided to invest in Costa Rica.[3] We found 137 articles, 70 of which cited specific reasons. We then grouped these reasons into different tags to determine those most cited (see Section 5.1 for results).

3. Upgrading along the Medical Devices Global Value Chain

This section describes the evolution of upgrading along the GVC using various ways to measure domestic value added in MD exports from Costa Rica. Unfortunately, no such

[2] Our definition of the MD's product space is based on Bamber and Gereffi (2013) and includes all six-digit commodity codes under the four-digit codes 9018, 9021, and 9022, plus the commodity 900130 (contact lenses).

[3] CINDE is the primary source of press releases of Greenfield investments by OEMs in Costa Rica, but its website contains news articles only since 2016, and that is the reason why we complemented it with newspaper articles published in *La Nación*. In addition, an exhaustive search was conducted on each company's website to identify the reasons behind their decision to invest in Costa Rica. However, it was not possible to find news or relevant information directly from these corporate portals.

Table 1. Upgrading Trajectories

Type of upgrading	Description
Entry into the value chain	A new actor begins to participate in the value chain
Product upgrading	Shift into the production of a higher-value product
Process upgrading	Improvements in productive efficiency leading to higher productivity
Functional upgrading	Movement to new higher-value segments in the supply chain
Chain upgrading	Leveraging knowledge developed in one sector to enter another value chain
Geographic end market upgrading	The incursion of firms into new higher-value end market segments
Forward and backward linkages	Forward and backward linkages increase the domestic component of production.

Source: Bamber and Gereffi (2013)

data exist at a sufficient level of disaggregation.[4] Therefore, we use an economic upgrading model for the MD GVC proposed by Bamber and Gereffi (2013).

Gereffi (2010, p. 171) defined economic upgrading as "the process by which economic actors—nations, firms, and workers—move from low-value to relatively high-value activities in global production networks." Bamber and Gereffi (2013) include the following potential upgrading trajectories (Table 1):

- Entry into the value chain when a new actor begins to participate in the value chain.
- Product upgrading describes the shift into the production of a higher-value product or service.
- Process upgrading describes improvements in efficiency in the production systems, such as the incorporation of more sophisticated technology.

[4] Publicly accessible data on value added comes from the OECD's Trade in Value Added (TiVA) database. TiVA is a collection of measures that provide insights into global production networks and supply chains beyond conventional trade statistics. TiVA tracks the origins of value added in exports, imports, and final demand. However, a drawback is the need for trade-in value added at the product level, because TiVA data are classified at the sector level (which can be traced back to the ISIC classification).

- Functional upgrading describes the movement to new higher-value segments in the supply chain.
- Chain upgrading describes leveraging knowledge developed in one sector to enter another higher-value segment in the value chain.
- Geographic end market upgrading describes the incursion of firms into new higher-value end market segments.
- Forward and backward linkages describe the relationship between companies, industries, or sectors within an economy, while mechanical linkages increase the domestic value added of an industry by domestically producing a larger portion of the value added that is being exported.

4. Costa Rica's Participation in the Global Medical Device Value Chain

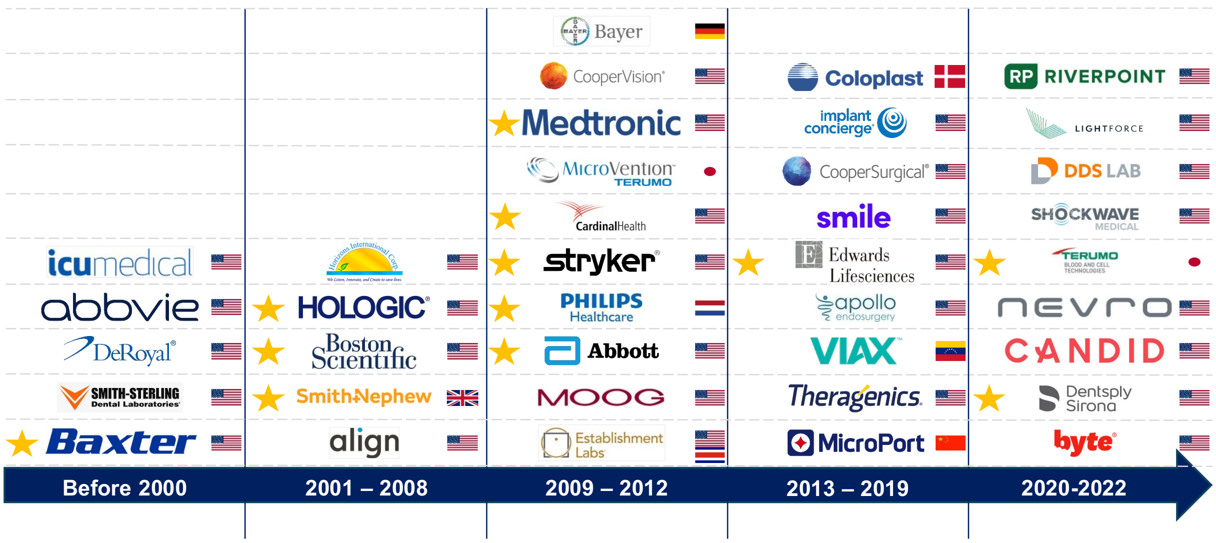
4.1 Firms Participating in the Costa Rican Medical Device Industry

The participation of large multinational companies of foreign origin with export-oriented and efficiency-seeking strategies has determined the growth of Costa Rica's participation in the MD GVS in the last 20 years. Costa Rica's entry into the MD GVC began in 1987, when Baxter Healthcare decided to open a plant in Cartago to manufacture IV solutions and drug delivery systems. Since then, 86 foreign firms have entered the MD industry in Costa Rica, which has increased its exports (Figure 1).

Figure 2 shows the moment of entry of 41 selected MD firms in Costa Rica, split into five time periods generally used in the literature (Bamber & Gereffi, 2013; Salazar-Xirinachs, 2022). It also shows the country of origin, and a star at the right of the company logo indicates that the company is one of the largest 30 MD companies worldwide. Based on the results, 31 out of the 41 firms have headquarters in the United States, but there are also OEMs from China, Denmark, Japan, the Netherlands, the United Kingdom, and Venezuela. Establishment Labs in the only MD company of Costa Rica origin. This company began operations in 2009 and eventually became the first company in the country to list on the Nasdaq.[5] By 2023, 14 of the top 30 global MD companies had production sites in Costa Rica. Milestones include the entry of Boston Scientific in 2004,

[5] Establishment Labs is now a global medical technology company focused on improving patient safety and aesthetic outcomes, initially in the breast aesthetics and reconstruction market, designing, developing, manufacturing, and marketing an innovative portfolio of silicone gel-filled breast implants.

Figure 2. Entry of Selected Companies to the Costa Rican Medical Device Industry



Source: Authors' elaboration from CINDE data.
Notes: The flag indicates the country of origin. A star by the side of the firm name indicates that the company is one of the 30 largest MD firms according to MPO ("The 2023 MPO Top 30 Medical Device Companies Report" available at https://www.mpo-mag.com/heaps/view/11657/?nav=top_nav access on March 15, 2024).

with a plant to manufacture devices for minimally invasive surgeries. Abbott's MD branch entered in 2010 with a plant to manufacture different types of cardiovascular catheters. Edwards Lifesciences entered in 2015 with a plant to manufacture heart valves, and Boston Scientific R&D entered in 2014. Since 2020, 10 OEMs and 7 suppliers have entered, including Terumo blood and cell technologies. In addition to the initial investment, our database of newspaper articles and key informant interviews (KII) demonstrate that firms usually reinvest in the country by expanding their operations.[6]

Since manufacturers tend to specialize in one or more specific end markets, the entry of a new OEM supplier helped the local MD sector diversify extensively into different market segments. It has also taken place also intensively, with the number of firms in each market segment increasing over time (see Figure A.1). This diversification accelerated considerably between 2001 and 2012 but has recently slowed down.

In the case of Costa Rica, the United States is the main destination for MD exports. Yet the exports to Japan as well as the European Economic Area and Switzerland have

[6] As further explained in Section 5.1, the Free Trade Zone regime of Costa Rica provides companies with the option to reinvest to keep the benefits. This could create an incentive to keep reinvesting in the country.

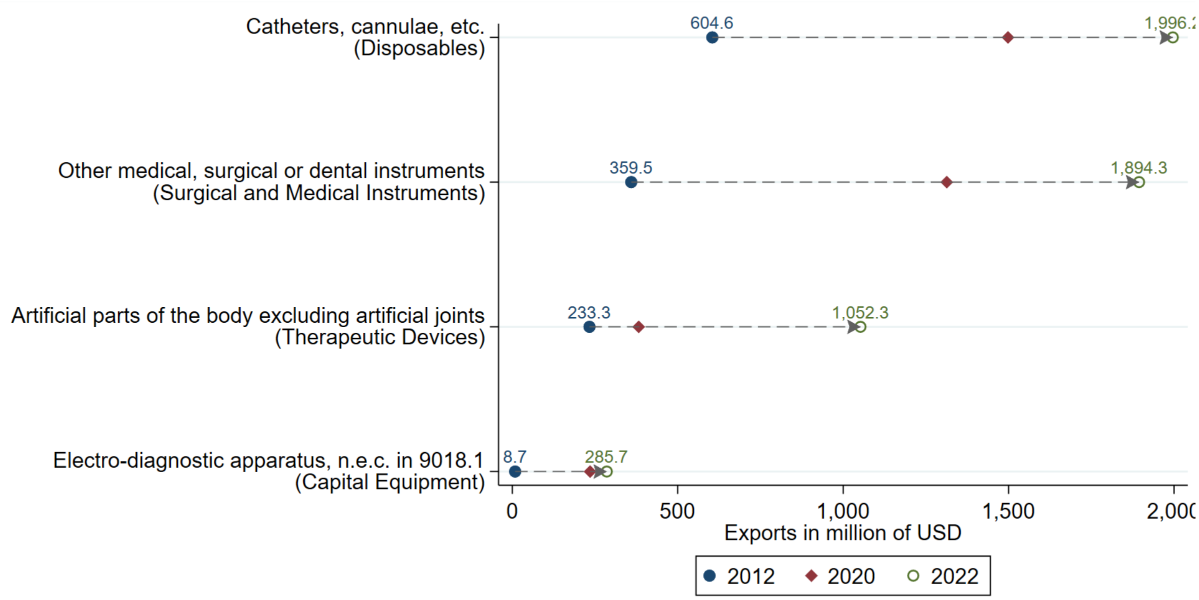
multiplied by a factor of 65.6 and 5.6 since 2012, respectively (see Figure A.2). This is important from a value-added perspective because these are markets with stringent health regulations, increasing the value added of the devices manufactured locally. Exports to Latin American countries doubled between 2012 and 2022 but still represented just 2 percent in 2022. By classification from lower to higher unitary value (see Box A.1 and Figure A.3), disposables were the most exported product category in 2001, but they have been gradually displaced in the last 20 years by medical and surgical instruments and therapeutics. Exports of capital equipment products have increased in the last decade.

4.2 Main Medical Devices Exported from Costa Rica

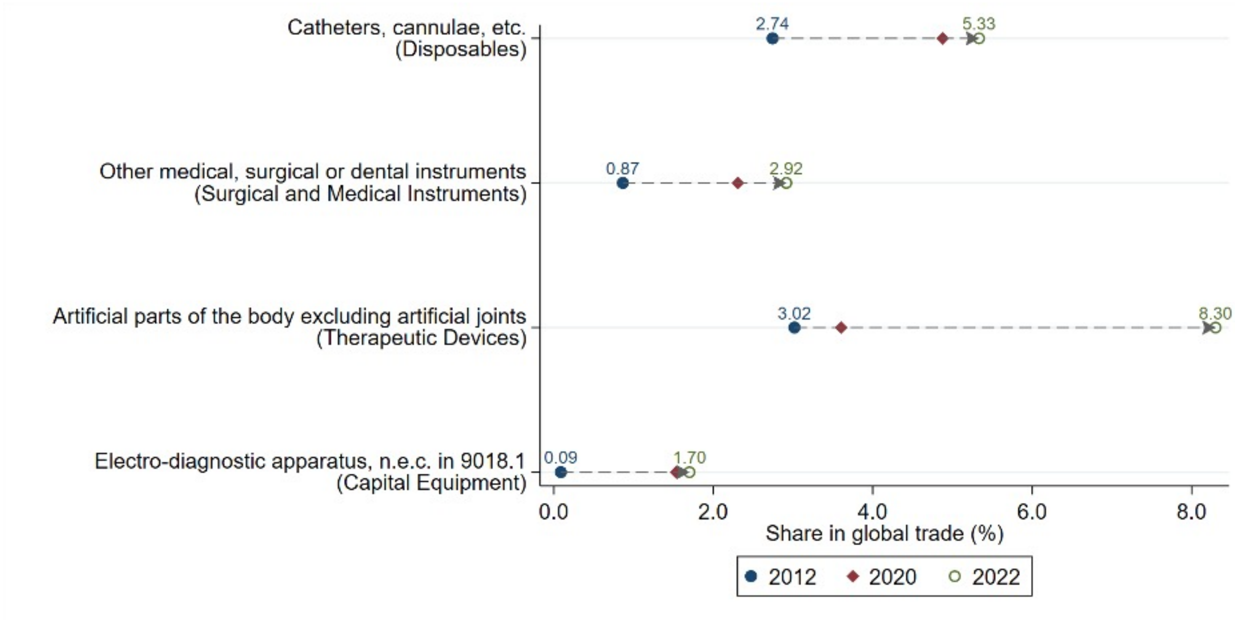
Medical device complexity varies considerably even within the same category, highlighting the importance of further analyzing the MDs exported from Costa Rica. The growth of three products (catheters, cannulas, and similar products; other medical, surgical, or dental instruments; and artificial parts of the body excluding artificial joints) explains almost 100 percent of the total growth in exports between 2020 and 2021 (Figure 3, panels A and B, and Table A3).

Figure 3. Exports of Medical Devices in Costa Rica, 2012, 2020, and 2022 (in millions of US$)

Panel A. Most Exported MDs



Panel B. Share in Global Trade of Costa Rican Exports



Source: Authors' elaboration from COMTRADE data.
Notes: This figure shows in percentage points the exported value from Costa Rica for each product specified in the vertical axis divided by the value traded globally in 2012, 2020, and 2022.

4.2.1 Catheters

According to Panel A, the highest volume of exported devices are catheters. Catheters are sterile thin tubes of different lengths and sizes made with medical-grade materials, often silicone but also polymers (polyurethane, PET, polyimides), and sometimes coated with a hydrophilic surface (a slippery film). By 2022, Costa Rican exports of catheters represented 5.3 percent of the global trade of catheters, positioning the country as the seventh largest exporter of catheters worldwide. Catheters are also Costa Rica's main export product overall (among all products, even agriculture). Figure A.4 shows that 63.4 percent of catheters exported from Costa Rica in 2022 went to the United States, followed by European countries. Since the United States is the largest buyer, Figure A.5 also shows the main source countries of U.S. imports, led by Mexico (which represented 36.9 percent of all catheters imported to the United States), followed by Costa Rica (13.6 percent). Dominican Republic is the seventh largest source country (3.1 percent). The most common types of catheters exported from Costa Rica are "IV drug delivery systems" and "other types of catheters" (see Figure A.6). According to shipment data from TradeDataPlus.com, Baxter and Abbott Costa Rica are the largest exporters of catheters, accounting for 78.2 percent of exports. Baxter's production specializes in seven MDs related to irrigation and transport of fluids from an external source to the human body (Bastos-Vega et al., 2022). Abbott is the largest exporter of coronary dilatation catheters.

4.2.2 Heart valves and heart occluders

The third most exported MD from Costa Rica is "artificial parts of the body excluding artificial joints" (HS code 9021.39). In the case of Costa Rica, HS code 9021.39 includes mostly biological heart valves and heart occluders. Costa Rica is the third largest exporter in this category, with its exports representing 8.3 percent of the global trade in 2022. Figure A.7 shows that 60.4 percent of exports in this category from Costa Rica goes to the United States (followed by European countries). Again, since the United States is the largest buyer, Figure A.8 also shows the main source countries of U.S. imports, led by Ireland (which represented 62.7 percent of imports to the United States), followed by Costa Rica (13.3 percent). Mexico is fourth with 4.1 percent, and Brazil is 12th with less than 0.1 percent.

A heart occluder is a device that is placed in the heart to treat a heart defect known as a patent foramen ovale (PFO).[7] The occluder is a Class III device that requires biocompatible materials because it remains permanently implanted in the heart. Prosthetic heart valves are artificial valves used to replace damaged or diseased heart valves. Shipment data from TradeDataPlus.com indicates that Edwards Lifesciences, Abbott, and Boston Scientific are the largest exporters in this category (accounting for around 64.8 percent of the exports). Surgical prosthetic heart valves (see Figure A.9), are either mechanical or biological, and which Edwards Lifesciences is a leading manufacturer. In Costa Rica, Edwards Lifesciences began with a dry plant assembling heart valve parts, receiving all the raw materials from its headquarters in Irvine, CA. Two years later, through an expansion to a wet plant, it moved to manufacturing a transcatheter heart valve and then to surgical valves. Surgical BHVs are either of porcine origin or are synthesized from a sheet of bovine pericardium mounted on a frame or stent and covered by fabric, which serves as a sewing ring. BHVs assembly requires significant expertise and manual assembly labor. In Costa Rica, Edwards imports around 95 percent of its raw materials from the United States, include the animal tissues for

[7] According to the Mayo Clinic, a patent foramen ovale (PFO) is a hole in the heart that didn't close the way it should after birth. The hole is a small flaplike opening between the upper heart chambers.

BHVs where no local provider exists (possibly due to scale, traceability, and cattle farming practices needed by the OEMs).

4.3 Costa Rica's Competitiveness by Medical Device

Figure A.10 shows the remaining HS codes for MDs. This figure highlights that while the country seems to be competitive on average in the MD industry, considerable variation remains in Costa Rica's competitiveness across the different devices. Some devices are left in the, such as syringes, whose exports decreased to a nonsignificant value between 2012 and 2022.[8] But other devices enter the market as their export value increased from a nonsignificant to a significant value due to the entry of a new OEM which affects the types of new devices that begin to be exported.[9] The figure also highlight future opportunities for export expansion as the country has not yet exported several devices whose manufacturers can be attracted through FDI (e.g., dental drill engines).

The following two sections describe the main enablers and bottlenecks that Costa Rica faces to continue advancing in the global value chain of MDs. They explain some of the upgrading milestones that the Costa Rican MD industry experienced and were constructed from the analysis of the qualitative in-depth interviews with key stakeholders.

5. Upgrading in the Costa Rica's Medical Device industry: Main Determinants Contributing to the Growth in Domestic Value-Added

5.1 Innate and Acquired Factors

[8] Syringe exports from Costa Rica decreased continuously since 2017 to a value of US$1.32 million by 2022. We tried to understand why Costa Rica syringe exports decreased to a nonsignificant value. We asked the KII about this phenomenon and searched news articles, but unfortunately, we were not able to find an answer. A hypothesis is that OEMs moved the production of this high-volume, low-value-added device to a lower-cost facility.

[9] Theragenics is a manufacturer of needles and sutures for special surgeries (see https://www.comex.go.cr/sala-de-prensa/comunicados/2014/agosto/theragenics-instalar%C3%A1-planta-de-manufactura-m%C3%A9dica-en-costa-rica/ visited on March 15, 2024). Exports of orthopedic appliances have also expanded considerably following a large investment from Medtronic that began in 2020 to increase production capacity. Contact lenses (not included in the original Bamber and Gereffi classification of MDs) entered the market in 2012 following the entry of CooperVision. Artificial teeth entered the market in 2014 following the entry of Viax Dental Lab. Regarding capital equipment (panel E), four products entered the market. Electro-cardiographs in 2019, ultrasonic scanning apparatus and computed tomography in 2021 following the entry of Terumo, and x-rays parts and accessories in 2022.

Innate and acquired factors explain why MD companies and their suppliers have chosen to operate in Costa Rica. The country entered the MD GVC in 1987 when Baxter began operations. Its participation strengthened with the entry of 86 OEMs and suppliers. The success in attracting FDI in MD is also reflected in other knowledge-intensive sectors like advanced manufacturing and corporate services (including shared services, contact centers, and back office). The significance of these results made UNCTAD (2002) name Costa Rica one of the six most successful countries that had made large strides in improving its export competitiveness based on increased FDI inflows and upgrading in the composition of its exports. FDI inflows to Costa Rica increased from US$162 million in 1990 to US$3.0 billion in 2022, ranking first in the Greenfield FDI Performance Index for two consecutive years (2022 and 2023) as the country that attracts the most FDI relative to its gross domestic product (GDP).[10] Thus, the question of why MD OEMs and suppliers decided to invest in Costa Rica is broader and includes which features have made the country more attractive to FDI.

Case studies from Costa Rica provide hypotheses explaining the country's results in attracting FDI in the high-tech (Spar, 1998; Larraín et al., 2000; Rodríguez-Clare, 2001; UNCTAD, 2002; Cordero & Paus, 2009; Comex, 2012; Román et al., 2014; Oviedo et al., 2015) and MD sectors (Alfaro, 2024; Bamber & Gereffi, 2013).[11] We describe these key policies below, while taking into consideration that "Costa Rica's recent string of achievements in the technological area are the result of a series of mutually reinforcing policies and events (some of them dating back to the nineteenth century) that have converged in recent years" (Rodríguez-Clare, 2001, p. 312).

Costa Rica's political and social stability and strong emphasis on education are the basis for democracy and development. Costa Rica is the oldest democracy in Latin America. Spar (1998) is the best source of information describing Intel's site-selection

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[10] This increase in FDI could be related to nearshoring (a business strategy of relocating some or all the company's operations to a country closer to its headquarters), a phenomenon that accelerated since trade relations between the United States. and China deteriorated in 2018 and soon after the arrival of COVID-19 in 2020. Unfortunately, there is no evidence that this is happening locally, and as shown throughout this section, it also responds to innate and acquired factors of Costa Rica. FDI data according to UNCTAD (see https://unctadstat.unctad.org/datacentre/dataviewer/US.FdiFlowsStock accessed August 7, 2024), and Greenfield FDI Performance Index according to FDI Intelligence (see https://www.fdiintelligence.com/content/data-trends/costa-rica-again-tops-list-of-fdi-overachievers-82539 accessed August 7, 2024).

[11] Another interesting research area with numerous studies is related to the determinants of FDI, but we will not describe it here.

process in Costa Rica, a decision that marked a pivotal shift in FDI attraction policy. The study mentions (p. 13) that Costa Rica, "Occasionally described as the 'Switzerland of the Americas' (...) has a long history of political and social stability, rare commodities in most of Central and South America. The country has been a full-fledge democracy since 1948 and has had none of the uprisings or civil unrest that plague many of its neighbors... Civility, property rights and the rule of law are solidly established in the country, which has only seen two periods of armed conflict (1917-1919 and 1948-1949) since declaring itself as a sovereign republic in 1838. Unique to the world, Costa Rica has not had a military since its turn to democracy in 1948." This democracy has been built on education.

Costa Rica's emphasis on education began early in the 19th century, when the country had a literacy rate among the highest in the Americas. This commitment to education was later reinforced with the accession to make primary education constitutionally mandatory, the creation of the first public university of the 20th century in 1940, and the creation of three more in the 1970s. The public universities generated the supply of scientists and engineers needed for the industrial sectors that grew in the 1960s and 1970s, and for the state-owned companies in agriculture, electricity, industry, infrastructure, telecommunications, and water supply. Thanks to these investment policies in education, Costa Rica's adult literacy rate is close to 100 percent, and primary school enrollment is nearly universal. However, the country still has high dropout rates of students at the secondary and tertiary levels. A considerable number of people have some knowledge of English, a result of the introduction of foreign language instruction in primary schools in 1994 and the prevalence of English-speaking tourists. These educational results are considerably better than most of its peer countries at the same distance or less from the United States, as reflected in the EF English Proficiency Index (EPI).[12]

The legacy of a protectionist development strategy known as import substitution bequeathed institutions and incentives to promote the growth of non-traditional exports through subsidies and partial tax exemptions. The import substitution strategy aimed to protect the domestic manufacturing sector from competition outside the

[12] Available at https://www.ef.com/wwen/epi/ accessed on August 22, 2024. See also https://www.elfinancierocr.com/economia-y-politica/costa-rica-tiene-el-segundo-mejor-ingles-en/424U4DD7CFDF7PBWRLTZGQSUD4/story/ accessed on August 22, 2024.

Central American Common Market. Despite its increased tariff and non-tariff barriers to international trade, the strategy was accompanied by institution building that promoted the growth of nontraditional exports through subsidies and partial tax exemptions.[13] The Export Processing Zone regime emerged in 1981, allowing companies to import all their inputs and equipment tax free and avoid paying income tax for eight years, paying only 50 percent of taxes due for the next four years. This system was designed to attract FDI and would eventually become one key element in the attraction of high-tech multinationals.

A shift in the development model toward a process of trade liberalization included institution building and adjustments to existing institutions and incentives. The "demonstrations of openness and liberalization" (Spar, 1998, p. 3) began in 1982, when Costa Rica experienced the worst economic crisis in its history. With no majority opposition and driven by international organizations, the crisis led to a widespread consensus that the development model needed to shift to a process of trade liberalization. Adjustments to existing institutions and incentives included the creation in 1983 of the first public entity responsible for formulating and implementing foreign trade policy, the Ministry of Exports (Minex).

The Export Contract, active between 1984 and 1999, provided fiscal incentives where exporters enjoyed an income tax holiday, tax-free imports of equipment and inputs, and received a generous subsidy equivalent to 10 percent of the value of their exports. This system was designed to help domestic companies change their strategy from one designed for the domestic and Central American Common Market to one of competition in open and competitive world markets. Costa Rica further liberalized its trade policies and entered into both bilateral and multilateral free trade agreements. By 1990, Costa Rica formalized its accession to the General Agreement on Tariffs and Trade (GATT)—which later became the World Trade Organization (WTO)—and by 1995 it had signed its first free trade agreement with Mexico, later resulting in 15 trade agreements signed to date. By 1990, the export processing zones were reformed into free trade zones

[13] Since 1968, there was a center (Cenpro) aimed at promoting exports and streamlining international trade procedures. Since 1976, there was also an Export Promotion Law intended to complement Cenpro's efforts by promoting non-traditional exports to markets outside Central America through subsidies on export value, partial exemptions from import duties, and partial exemptions from some domestic taxes on imported raw materials used in the production of goods destined for export.

(FTZs). FTZs wave custom duties and provide tax incentives to companies establishing export-driven manufacturing operations (see Table A.3), and "have resulted in one of the better export processing zone systems in the developing world" (FIAS, 1996, p. vi). To support this process, the government also invested in upgrades to the national airport, ports, and customs systems to enhance international trade infrastructure.

Geopolitical interests, influenced by the Cold War rivalry between the United States and the Soviet Union, also played an important role in creating initiatives which helped Costa Rica stand out in a turbulent region and to attract FDI.[14] The first initiative was the Caribbean Basin Initiative (CBI), of which Costa Rica was a member from its inception, enjoying duty-free access to the U.S. market (zero import duties for nearly all manufactured and agricultural products). The CBI was part of a comprehensive foreign policy program of the Reagan administration "to promote economic revitalization and facilitate the expansion of economic opportunities for the Caribbean Basin region." It granted certain trade preferences and other benefits to countries in the region beginning in 1984. These tariff and trade measures were intended to promote economic revitalization and expand private sector opportunities in the Caribbean Basin Region. The second initiative was CINDE, founded in October 1982 by prominent businesspeople and financed by USAID grants within the CBI program.

Baxter entry in 1987. Baxter's first contact with Costa Rica was through an executive who visited the country as a tourist, at a time when Baxter was concerned with the potential disruptions that hurricanes could cause to its operations in the Caribbean (Cornick & Trejos, 2018). Close to the United States but not subject to the impact of hurricanes, Costa Rica became a candidate as an investment destination. And was eventually chosen after the corporation conducted a series of studies on countries that offered lower costs and had a strategic location for the distribution of Baxter's products.[15] Costa Rica's proximity to Dominican Republic, Puerto Rico, and the United

[14] Central America in the 1980s was plagued by internal political conflicts and influenced particularly by the Cold War rivalry between the United States. and the Soviet Union. USAID had a geopolitical interest in promoting changes in economic models as part of its strategy of external economic aid for the development of countries as an element of the fight against communism. The United States sought to combat the expansion of communism in the region through various economic assistance programs, of which Costa Rica took advantage as the oldest democracy in the region.
[15] See https://www.nacion.com/economia/baxter-planea-expansion/LT6JJVP3PRFDPP37V2JD4QJJNE/story/ visited on March 15, 2024.

States created logistical synergies for Baxter's manufacturing operations. Baxter was a pioneer in Costa Rica at a time when the country was undergoing trade liberalization, but before CINDE prioritized the MD sector and before the current FTZ regime.[16] No new MD investments took place until 1991, one year after the EPZs were transformed into the FTZ regime of 1990.

The existence of an "aggressive, effective and knowledgeable foreign investment promotion agency" with a successful high-tech FDI attraction strategy that has built confidence among global investors. CINDE was founded in October 1982 as a nonprofit investment promotion agency supported by the Costa Rican government and financed by USAID grants within the CBI program. CINDE accompanied and supported the beginning of the transition to the new export promotion model. Its broad mission was to assist the country's economic development, but over time, CINDE acquired relevant expertise for FDI attraction.

While there is no paper studying the counterfactual scenario of FDI attraction without CINDE, the literature using Costa Rica as a case study have highlighted CINDE's positive role in FDI attraction. Spar (1998) highlights CINDE as a facilitator and a coordinator in Intel's site selection process. One of the factors that made Intel choose Costa Rica for the location of its plant was "the existence of an aggressive, effective and knowledgeable foreign investment promotion agency like CINDE" (Rodríguez-Clare, 2001, p. 316). Alfaro (2024) refers to CINDE as a significant driving force in attracting FDI in the MD industry; Román et al. (2014, p. 29) characterizes CINDE as a high-performance organization; and Cornick and Trejos (2018) highlights CINDE's role as a success story of a productive development strategy.

The existence of strong and growing demand attracts OEM foreign suppliers to set up operations in the country. The growth of the sector and the presence in Costa Rica of some of the top global manufacturers, along with the increased volume and complexity of their operations and the sector's strong growth prospects, attracts foreign suppliers to set up operations in the country. OEMs also push their global suppliers to

[16] For a more in-depth description of Baxter's activities in Costa Rica, see Abbate et al. (2010) and Bastos-Vega et al. (2022).

co-locate close to its production sites; a practice known as follow sourcing (Humphrey, 2003).

Overall, the decision of the early MD company to choose Costa Rica as a destination can be explained by demand-seeking and efficiency-seeking strategies of multinational MDs-led corporations of U.S. origin (Bamber & Gereffi, 2013, p. 35); a stable democracy with a relatively good quality of life; a good investment climate, including a strong tradition of peace and democracy, and high standards of intellectual property protection. Commitment to protecting natural resources, sustainable environmental policies, and energy from almost 100 percent renewable sources. Stable policies, with continuity and strategic vision adapted to changing global conditions regarding foreign trade, investment attraction, and export promotion led by the three key institutions: The Ministry of Foreign Trade (Ministerio de Comercio Exterior, or Comex), CINDE, and Procomer.

Evidence from press releases. As can be seen, many factors explain the country's success in attracting high-tech FDI. To help test the hypothesis raised in the Costa Rican case studies, we built a database of newspaper articles with the company's reason for investing or reinvesting in the country. Table 2 shows that the most frequently cited reasons are related to "human talent," followed by "strategic location" and "education." Human talent embodies the workforce's quality, availability, specialization, and soft skills. Education refers to educational standards, technical knowledge, and qualifications, including being bilingual. Strategic location is related to the country's geographic proximity to the United States. Another relevant reason is the country's economic and political stability, which creates a trustworthy environment for companies to make investment decisions, and the country's sustainability features, including Costa Rica's commitment to environmental policies and the promotion of renewable energy. Infrastructure and competitiveness are mentioned less frequently, hence highlighting the importance of improvement in those areas.

Table 2. Frequency of Reasons Why Original Equipment Manufacturers of Medical Devices in Costa Rica Mentioned for Establishing Operations in Costa Rica

Reason Group	Counter	Keywords
Human talent	29	Excellent workforce; quality of its professionals; exceptional quality of talent; interesting availability of talent; human talent; talented workforce; availability of professionals with experience in MDs; talented human resource; quality of workforce; human talent with great capacity to learn and innovate; quality of human resource; professional talent; young workforce; local talent; talented and bilingual; workforce; valuable human resource; human talent; human talent; workforce excellence; highly talented people; skilled labor; large pool of talent
Strategic location	27	Geographic location; proximity; strategic location (proximity to the United States); attractive geography; strategic location; proximity to U.S. and Latin American employees and customers; geographic location; location; proximity to the United States; strategic location; strategic location; strategic location.
Education	20	High standards of education and skilled human resource; high level of English literacy; high level of education; high level of education; skilled human resource; skilled technical personnel; highly skilled workforce; highly skilled workforce; technically skilled talent; level of education; strong education system; education; education; skilled labor force; skilled human talent; human talent with the necessary technical competencies; highly skilled workforce
Stability	14	Very stable regulatory environment; security; economic and political stability; stability; economic and social stability; stable economic conditions that the country offers; stable political environment; political, social, and economic stability; political and social stability; political stability
Cluster consolidation	13	Ecosystem; Existence of cluster; Costa Rica is a hub for MD manufacturers; experience in MD manufacturing; good manufacturing practices in production of MDs; experience in MDs; cluster consolidation; existence of cluster; highly specialized local talent
Investment climate	10	Costa Rica is a country that understands and supports the MD industry; extensive network of suppliers; solid supply chain; business conditions; ease of support; economic environment; cultural openness; investment climate; good investment conditions; economic environment.
Company's own	10	Relocation of operations; great potential of our workers, managers, and manufacturing associates; Strategic expansion; Previous plans; growth in demand; Increase in sales (high demand); Relocation of operations; talented team; Costa Rican team; high demand.
Business environment	8	Business environment; business climate; good business climate; favorable business environment; favorable business environment; business environment
Sustainability	7	Sustainability policies; carbon neutrality 2030; renewable energy sources; sustainability; environmental and human rights advocacy; commitment to sustainability; collaboration and leadership in environmental sustainability
Costs	4	Low cost; cost-competitive; cost; cost-competitive environment; cost-competitive environment
Infrastructure	2	Infrastructure; infrastructure
Competitiveness	1	Country competitiveness
Free Trade Zone Regime	1	Taxes
Linkages	1	Linkages
Security	1	Security

Source: Authors' elaboration.

Costa Rica has an innately strategic location in relation to the United States, sharing the CST time zone and being just three to four hours away by air from major cities like Miami, Houston, and Atlanta. Moreover, its mountain range protects the capital and metropolitan area from direct impacts of hurricanes. The country also has direct and close access to ports in both the Pacific Ocean and the Caribbean Sea. Additionally, "Costa Rica's strategic location as a connector between North and South America provides manufacturers with direct access to both markets" (Alfaro, 2024).

Costa Rica's strategic location, economic and political stability, consolidated MDcluster, and education are important features in choosing the country as a destination. Yet, there are also differences. The literature emphasizes the role of human talent less than the role of education, but this is not the case for companies. The literature also highlights CINDE as crucial in the development of industry, but companies did not cite CINDE as a direct reason for investment. Additionally, companies also mention the influence of the FTZs. It is possible that CINDE and the FTZs are important at an earlier decision-making stage when companies are selecting countries.

5.2 Strategy Shift

A shift in the strategy of the foreign investment attraction agency from sectorial to supply chain helped to secure the entry of key suppliers allowing to thrust the domestic value added. Strategic suppliers of MD firms began setting up their operations in Costa Rica in 1991, helping to increase DVA by creating locally additional backward linkages and forward linkages the entry of sterilization firms allowed devices to exit Costa Rica straight to the buyer with the highest value-added. The strong and growing demand partly explains the entry of suppliers. But the second driver, well explained by Cornick and Trejos (2018), was CINDE's creation of its After Care Division.

In the 1980s, CINDE aimed this expertise mainly toward agriculture and unskilled intensive manufacturing sectors, especially apparel assembly plants (after all, Costa Rica was recovering from a 12 percent unemployment rate during 1982). Eventually, CINDE realized that the country was losing competitiveness in unskilled labor-intensive industries to other members of the CBI. Moreover, the North American Free Trade Agreement (NAFTA) would give Mexico better access to the U.S. market than CBI members (Rodríguez-Clare, 2001). CINDE decided to focus on sectors that were a better match for Costa Rica's better educated population, including electrical, electronic, and telecommunications. These sectors not only required more skilled workers but were also experiencing fast growth in the United States. Strong competitiveness pressures were forcing companies to search for low-cost locations around the world. It was thought that these sectors were a particularly good match for Costa Rica because of its good supply of technicians and engineers at relatively low cost, as well as the widespread knowledge of English, the country's well-known political stability and democracy, and its developed legal system and low levels of corruption. There was also a high quality of life, with good access to health services, nightlife and cultural amenities, and natural resources.

CINDE's high-tech FDI strategy emerged naturally after the entry of electronic giants like DSC Communication Corporation in 1995 and Intel in 1997, confirming that "attracting high-tech multinationals was feasible and potentially effective as part of Costa Rica's development strategy" (Rodríguez-Clare, 2001, p. 317).[17] Additionally, FIAS (1996) found that "there is a basis for substantial expansion of foreign direct investment in the electronics industry in Costa Rica… Such products draw heavily on the main advantage that Costa Rica has to offer the world electronics industry: a labor force that is relatively well educated in relation to its cost." Spar (1998, p. 14) also mentions "a very well educated low-wage labor pool. This is a central and critical distinction." By 1998, CINDE stated its objective to position Costa Rica as "the emerging electronics manufacturing center in the Americas."

In the ensuing years, additional research led CINDE to include the MD sector among its targeted sectors. As had happened earlier with the electronics sector, success came early, this time in the form of the decision by Abbott Laboratories to establish a sophisticated US$60 million manufacturing plant in the country in 1998 and Baxter's decision to expand its presence in the country with a US$30 million investment.

Two key organizational changes occurred that eventually led to the service model that allowed CINDE to identify the need and opportunity to establish sterilization

[17] For a detailed examination of Intel's site selection process see Spar (1998) and Rodríguez-Clare (2001).

services for the MD industry. First, budget cuts in 2000 led CINDE to transition toward a sectoral specialization, which enabled it to build in-depth knowledge of the sectors on which it focuses, and of the needs and requirements of companies operating in those sectors. Sector specialists plus a Business Intelligence Unit ensure that when CINDE approaches a company, it knows everything it needs to know to make a convincing case for investment in Costa Rica.

Second, in 2008, CINDE created an After Care Division to facilitate the installation and start-up of operations of firms that decide to invest in Costa Rica and meet their needs once operations start. The After Care Division ensures that CINDE knows what that investor needs to prosper in Costa Rica and to expand and upgrade its operations. The Division identifies opportunities for local and foreign suppliers to operate in Costa Rica and facilitate agglomeration economies and spillover effects.

According to Cornick and Trejos (2018), it was the combined skills of sector specialists, business intelligence, and after-care services that allowed CINDE to identify the need for sterilization services and the impact of those services in terms of the sector's costs, competitiveness, and potential for expansion. An opportunity was identified: while the MD sector was thriving, there were no sterilization services in Costa Rica. This imposed a cost on all companies operating in Costa Rica, as production had to be sent for sterilization elsewhere, increasing inventory costs and extending the production cycle. Moreover, lack of sterilization services prevented the installation in Costa Rica of distribution centers and the logistics and marketing functions associated with them.

Working in cooperation with manufacturers already operating in Costa Rica, CINDE mapped the sterilization industry and set out to systematically approach the companies in it, one by one, and convince at least one to open a plant in Costa Rica. This strategy resulted in Steris (originally knew as BeamOne) opening its electron-beam sterilization plant in 2008. Between 2010 and 2011, Steris opened a second electron-beam sterilization operation as well as an ethylene oxide operation. In 2010, Sterigenics, another sterilization provider, began offering its services in Costa Rica.

Today, CINDE regularly approaches not only firms that are the ultimate target of its effort to attract business to Costa Rica, but also their key suppliers. The aim is to anchor the investments as the costs of moving an operation from one location to another are higher if there is a well-developed supply chain in the first location. CINDE also actively promotes changes to the investment climate to align it to the needs of the companies installed in Costa Rica.

While the establishment of sterilization services made the MD firms operating in Costa Rica more competitive, perhaps the most important impact was that it made the country more attractive to new firms not previously established in the country and allowed them to undertake more ambitious operations. This hypothesis is validated by the large number of new firms that have opened plants in Costa Rica since 2008 and the complexity of their operations, as in the case of St. Jude Medical and Abbott Vascular (Crespi et al., 2014, Box 9.4). The entry of the sterilization firms is also an example of CINDE's successful role in red tape advising to attract FDI. Sterilization, particularly ethylene oxide sterilization, produces chemical waste that could potentially affect human health. According to KII, CINDE had to coordinate with the Ministry of Health for the sterilization suppliers to obtain a health permit. This coordination also allowed other OEMs to build sterilization plants. For example, Baxter opened one in 2008 and required health permits. KII also mentioned migration permits for foreign workers and building permits with the local governments as examples of red tape advice.

5.3. Specialized Skills and Talent

The development of specialized skills and human talent needed by the MD industry facilitated the production of more complex devices (Table A.4). The quality of the human capital involved in production is essential to MD business success because the industry is highly regulated due to the severe consequences of human error and potential for liability suits. The MDs manufactured in the country have become increasingly complex. Local manufacturing of Class III products has increased, indicating a growing confidence in the capabilities of Costa Rican plants to follow strict regulatory protocols.

In Costa Rica, while initially firms like Baxter had to train their workers from the ground up, subsequent plant operators and managers in the industry were recruited from the electronics sector, some of whom were trained by Intel. Initially, MD companies hired blue-collar workers from other industries (garment and electronics) and bore the training costs. The supply of white-collar workers, such as engineers, came from the academy and the industry itself.

According to the MD Cluster Costa Rica, there is good availability of junior to mid-level workers trained in public and private universities (with varying quality among the latter). However, senior-level talent is more limited and tends to be comprised of former employees of Baxter and Intel. Costa Rica has made continuous efforts to build technical capacity that complements training funded by MD companies (one- to two-week induction training and constant on-the-job supervision and development). The country has coordinated efforts by publicly funded secondary and post-secondary educational institutions (including nine years of primary and secondary school plus three years of technical education, the Instituto Nacional de Aprendizaje (INA), the Instituto Tecnológico de Costa Rica (TEC), and the University of Costa Rica) and complemented by the private sector. Technical high schools offer degrees needed by the MD industry. INA now offers a one-week introductory course to the MD sector, covering good manufacturing practices, working in cleanrooms, and documentation. Since 2014, TEC has been offering a master's degree in MDs jointly with the University of Minnesota and the University of Zaragoza.[18]

In addition to training human capital, a tangible benefit of sustained growth in the MDs industry in Costa Rica is significant knowledge transfer due to the presence of several leading global MD manufacturers and a unique generation of specialized talent. In 2011, the industry employed approximately 12,500 people (Bamber & Gereffi, 2013, p. 42). By 2015, 19,328 people were working in the MD industry, and by 2023 there were 55,699. Labor mobility between MD firms in the country has increased the availability of

[18] Around 136 public technical high schools (nine years primary and secondary, plus three years technical education) located around Costa Rica offer degrees needed by the MD industry. The degrees include industrial electronics (2,988 graduates), administration (2,868), precision mechanics (1,418), among many others.[18] Additionally, MD firms have worked with the Instituto Nacional de Aprendizaje (INA) to train line operators, material handlers and technicians. INA now offers a one-week introductory course to the MD sector, covering good manufacturing practices, working in cleanrooms and documentation. While the program now has 564 graduates, it is unclear how often it is offered. Private institutions, like SMD, also offer educational programs. Since 2014, TEC has offered a master's degree in medical devices jointly with the University of Minnesota and the University of Zaragoza. By 2023, there were around 120 students graduated with this master's degree across nine cohorts. Regarding the supply of professional engineers and microbiologists, graduates in these careers have increased since 2014 and the supply is almost equally split between the public sector (of which TEC and the University of Costa Rica are the most important) and the private sector. Data on graduates comes from Hipatia.cr available at https://hipatia.cr/dashboard/talento-tecnico accessed April 5, 2024.

local human capital with specialized skills and talent needed. Companies that settle in Costa Rica can quickly access experienced workers, facilitating new companies' rapid assimilation of advanced practices and knowledge, and shortening the learning curve for implementing advanced processes.

The current context presents unique advantages for companies interested in manufacturing more complex MDs, such as Class III or capital equipment, in terms of finding specialized talent in the local labor market. Unlike in the past, when acquiring qualified professionals turned to academia or other industries, today, companies can tap into a talent pool with experience in the MD industry.

5.4 Productive Development Programs

Productive development programs helped create linkages between MNEs or MDs in Costa Rica and local firms. These linkages increase the DVA embodied in gross exports by producing domestically a larger fraction of the value added that is being exported. To increase the DVA in exports, it should not matter whether the linkage is with a domestic firm, or a foreign firm established in Costa Rica. However, the literature has separately analyzed each type of firm. For example, Monge-González and Rivera (2022) characterize the linkages between local suppliers and MNCs in the MD sector. Using 2008 to 2019 as the study period and data from the Central Bank of Costa Rica on productive chains for the MD sector, they confirm that linkages between OEMs and domestic firms are taking place and maturing. Local purchases by MNEs of MDs in Costa Rica have increased from 7 to 16 percent of the total value purchased (both in Costa Rica and abroad), of which 58 percent are purchases from domestic firms (fluctuating between 53 and 65 percent over the period analyzed). The value of local purchases has multiplied eightfold in that period.

Grupo Vargas (GV) was often cited in our interviews (and often cited by newspapers) as a success story in terms of generating new backward linkages.[19] GV invested continuously over five years "until we were able to convince Allergan that we were capable of printing locally what they were importing from their suppliers abroad," said Marco Vargas, commercial manager of GV, in an interview a local TV show.[20] These

[19] See, for example, https://www.nacion.com/economia/negocios/grupo-vargas-reconvirtio-su-imprenta-para-vender-a/6C5JAHC3XJBBVDFXDPCQBNNPIE/story accessed
[20] See https://www.youtube.com/watch?v=qFl8I5sx3I0 accessed

investments included certifications, specialized quality control equipment, procedures, and certifications of good manufacturing practices.[21]

Some linkages with MNCs of MDs in Costa Rica can be partially explained by public policy and the involvement of the private sector to promote linkages. (Morales-Sandova et al., 2019) analyze eight cases of the medical equipment sector in Germany and Costa Rica found that German suppliers generated linkages through existing networks within the sector that help link MNCs with suppliers, where MNCs participate in different clusters of a specific sector that facilitates linkages between suppliers. According to the study, Costa Rica has institutions that help link local suppliers with MNCs, and the extent to which these policies successfully generate and promote linkages depends on the support provided by the institutional ecosystem.

In 2019, the MD industry formed the Medical Devices Cluster Costa Rica. It brings together MD companies with operations in Costa Rica with the aim of articulating efforts, creating synergies, and fostering co-creating spaces that allows Costa Rica to keep strengthening and developing the MD Ecosystem. One of the five priority areas of the Cluster is developing local suppliers and supporting productive chains.

Additionally, in 2003, Costa Rica launched a productive development program (PDP) known as Costa Rica Provee, a program that promotes backward linkages between MNCs and local firms that was later transformed into the Linkages Division of Procomer. According to Cornick and Trejos (2018), the role of the Linkages Program gradually evolved from generic to industry-focused linkage promotion, and from matchmaking to business development. While Procomer initially had simply identified local capabilities and tried to match them to the demands of multinationals operating

[21] Grupo Vargas (GV) is a family firm started in 1941 as a small printing office for local newspapers that eventually became the biggest labels press in Costa Rica by selling to MNCs in the food and beverage sector, especially beers and pineapples, and later diversified to thermoforming and folding boxes. GV realized that MD MNCs in Costa Rica were importing the printed materials (instruction books, labels they require, the folding boxes where the product goes, etc.) from their suppliers around the world. These investments included certifications, specialized quality control equipment, procedures, certifications of good manufacturing practices, that require everyone entering the plant to take off their watch, earrings, rings, protect themselves from their hair, so that no one product that is leaving the plant (even if it is a brochure, an instruction brochure, a folding box, or a thermoformed packaging) has a hair, "this would be terrible for these companies where there is no margin for error, the product must be 100 percent good, and that takes getting used to. It is a whole culture that must be acquired in companies." Today, GV has a manufacturing plant in the FTZs Multiplx in Coyol, Alajuela and is a supplier to the most important global companies installed in Costa Rica that produce all their literature.

in FTZs, since 2010 Procomer started identifying MNCs' needs, then surveying local capabilities. If such capabilities were lacking but developing them was deemed feasible, it worked with potential suppliers to do so and in cooperation with a large set of other public institutions organized under an Inter-Ministerial Linkages Commission with private sector and academic participation. This coordination was important as the task of developing suppliers clearly was beyond what Procomer could do by itself. Broad policies were needed to achieve these new policy goals, and the context was favorable to achieving broader policy coordination. The new strategy was explicitly demand driven and focused the Linkages Program exclusively on tradables, with a special emphasis on high-value-added linkages. While Costa Rica Provee was successful in promoting new linkages and creating new exporters from local SMEs (Rodríguez-Álvarez et al., 2013), to this day most local purchases by MNCs are unrelated to public policy efforts to promote them—according to Cornick and Trejos (2018) and our KII.

6. Main Bottlenecks to Movement into Higher Value-Added Segments

6.1 Cultural Barriers and Informality

Cultural barriers and informality are restricting backward linkages between medical device multinational corporations and domestic companies. Although local purchases by MNEs of medical devices in Costa Rica have increased, the literature suggests that linkages between MD OEMs and local companies are limited (Bamber & Gereffi, 2013; Cornick & Trejos, 2018; Gereffi et al., 2019; Monge-González & Rivera, 2022). Monge-González and Rivera (2022) differentiate between specialized inputs (that become part of the final product or service and, therefore, of the GVC), non-tradable services (i.e., maintenance services, electricity), and standardized inputs (i.e., generic ones such as packaging materials). They do so because specialized inputs make it possible to scale up the GVC, increase the DVA of exports, and further enhance productivity spillovers to domestic supplier companies. They find that local purchases of specialized inputs by MD MNCs represent just under 2 percent of total purchases. Moreover, the relative importance of domestic suppliers has decreased from 76 to 47 percent vis-à-vis an increase in the weight of foreign providers in Costa Rica. Regarding sales of specialized inputs by domestic suppliers to MNEs of medical devices in Costa Rica, 75 percent correspond to distribution services of medical articles, orthopedics, specialized textiles and equipment of various kinds, followed by 15 percent of wholesale trade of medical articles.

According to Cornick and Trejos (2018), significant, albeit low-value-added linkages between local companies and MNCs developed spontaneously. MNCs inevitably purchase nontradables locally, including cleaning services, food, security, and some logistics, as well as the supplies required to provide such services. Likewise, MNCs will necessarily buy water, electricity, and telecommunications services from local suppliers, and in some cases, they are likely to purchase packaging materials locally as well. What did not happen spontaneously was the development of significant linkages in tradable goods and services that would have involved local companies gradually climbing up the value chain and providing increasingly complex, knowledge-intensive inputs, parts, finished products and services to MNCs (Cornick & Trejos, 2018).

Why do linkages remain insufficient (or at least that is the perception) even if PDPs and a Cluster initiative are supporting their creation? From the Medical Device Cluster Costa Rica perspective, the main challenge for generating more backward linkages is that local providers need to have robust, equivalent, and comparable quality systems. Yet, quality systems are underused in Costa Rica. Most of the sales take place in the national or regional markets where no certification is required, and firms are not used to follow processes and norms or keep records of the suppliers. Informality among firms is common in Costa Rica, where highly productive firms that generate well paid jobs coexist with low productive firms that generate low quality informal jobs. While there are no studies for Costa Rica, an article points out that 10 percent of the population of informal firms in Brazil could be able to jump the threshold of minimum capacities to participate in a dynamic value chain.[22] In this sense, firms interested in becoming suppliers for an MD MNC must adapt, and the cluster recognizes that this comes with a learning curve and a change in culture. According to the Cluster's president, "It is a process of learning and support. Any company needs an adjustment process to become a supplier."

[22] See https://www.crhoy.com/opinion/confrontando-la-informalidad-y-el-dualismo-productivo-en-costa-rica/ accessed

Safety regulations push MD firms to be a particularly demanding sector in terms of quality checks, and MNCs usually must work backwards with suppliers to have in order much of the paperwork that might eventually be requested by the U.S. Food and Drug Administration (FDA), for example. While MNCs participating in the Costa Rican MD industry do not always need an ISO 13485 or a GMP certification, these MNCs do require a chain of good practices and operational excellence from suppliers that allows them to demonstrate that their supplier is suitable for that specific product. This means keeping electronic quotes to provide materials traceability, quality standards for materials and products, etc. When certifications are required, suppliers often see the certification system as cumbersome or onerous. Sometimes internal organizational changes must be implemented or specialized software must be purchased to keep track of decisions and acquisitions along the supply chain.

Another explanation is the limited supply of MNC-ready local suppliers (Cornick & Trejos, 2018). In some cases, technical capabilities may be lacking. In others, the binding constraints involve questions of scale, availability of finance, willingness to incur risks, or lack of general quality certifications and/or sector-specific and relatively costly certifications. Additionally, the availability of qualified personnel at competitive salaries seems to be an increasingly significant constraint.

Unfortunately, these constraints on creating more linkages cannot be alleviated by investing more money in the Linkages Program, but rather through long-term, broad policies that address both the demand and the supply side of local (tradable) goods and services (Cornick & Trejos, 2018). The Cluster and the Academia de Centroamérica point to another element: the design of the PDPs itself. Procomer offers over ten PDPs. One of them, Programa Crecimiento Verde, provides non-refundable funds and technical guidance for micro, small, and medium-sized businesses to obtain certifications or to implement changes in the production process.[23] The Sistema de Banca para el Desarrollo (SBD) offers loans and targeted financial services to companies typically underserved by traditional banking institutions such as small and medium-sized enterprises (SMEs), entrepreneurs, and sectors such as agriculture, tourism, and innovation. SMEs could potentially use SBD to obtain certifications. Yet, “successful

[23] See https://www.procomer.com/exportador/programas/crecimiento-verde/ accessed

suppliers of MNCs in the MD sector in Costa Rica are often from medium to large companies," according to the Cluster president. GV, for example, was a medium-sized firm when it started supplying to Allergan. The local legislation (Reglamento a la Ley de Fortalecimiento de las Pequeñas y Medianas Empresas, Ley N° 8262) establishes thresholds for the classification of companies by size based on the company's assets, annual sales, number of employees, and economic activity. "One option is to relax the threshold to allow more companies to be classified as an SME" mentioned Ricardo Monge in the interview. The government could do this without needing legislative approval. "The mistake we are making is that we are penalizing companies that have managed to reach a certain size and there are no public programs to which they can apply to obtain financing or other types of support so that they can chain themselves." Apparently, all the pieces of the puzzle are there but someone must put them together. From his perspective, a coordinating body using a cluster approach to value chains should be responsible to do it (Monge-González, 2018).

Promoting backward linkages is a pending task. "If it is not possible to develop a local supplier, that FDI supplier will eventually arrive in the country," mentioned a KII. One example is GV, which offers thermoformed services but not to the MD companies because there are other foreign firms in Costa Rica offering such services (that is why they specialized in digital instructions for use printing and packaging). Another example is coatings. A coating of Teflon or a hydrophilic material (which becomes slimy if it touches a liquid), is used in most devices that are insertable. There was no coating supplier in Costa Rica. FDI met the need. Precision Coating entered in 2012, and Specialty Coating Systems entered in 2015. While developing a supplier from scratch is a different story than supporting a firm to make the jump to become a supplier of an MNC, it is worth asking why Costa Rica did not have a coating firm despite the need.

6.1 Human Capital Needs

More bilingual STEM graduates are needed to continue growing in the manufacturing and assembly stages. KII mentioned the need for additional bilingual graduates in science, technology, engineering, and mathematics (STEM) subjects. Bilingualism is essential (investment primarily comes from the United States and Europe after all), but an analysis of the local labor surveys shows that only one-fourth of college or university graduates could speak and write in English in the last quarter of 2023.[24]

There are supply and demand side challenges in the formation and retention of human capital for innovation amid the linkage of industry with academia and other research stakeholders. On the supply side, public universities enroll most freshmen in the country, but a particular concern is their preference for social science and humanities careers. Figure A.12 shows that fewer freshmen enrolled in STEM careers than in non-STEM careers. While the difference is not relatively large, it seems from the declarations by KII that the numbers should be more skewed toward STEM. The OECD has noted that the education system has not kept pace with ongoing structural transformation toward high technology- and skill-content sectors, resulting in skills shortages despite high levels of unemployment (OECD, 2018). The OECD also highlighted the need for significant tertiary education reforms given that Costa Rican public universities have a high degree of autonomy and few incentives to respond to labor market needs (OECD, 2018). The small number of STEM graduates poses a significant obstacle to Costa Rica's ambition of developing a more high-tech, knowledge-intensive economy (OECD, 2016, 2017, 2018).

Why are more freshmen in non-STEM than in STEM careers? According to the KII, this is partly because opening additional spots in some STEM careers is expensive (for example, in engineering which requires installing expensive equipment in new laboratories), but also because few students are seeking a STEM career.

On the demand side, students' preference for other fields of study limits public universities from opening additional spots in STEM. Students might not be interested in pursuing a career in STEM just because of personal preferences, or due to a lack of information on prospective income dynamics. In this regard, the MD sector has not provided comprehensive and systematic information about employment opportunities, including earnings potential and potential career paths. Making available this information could encourage people to study English and pursue a STEM career.

[24] This percentage has fluctuated over time between 23 percent and 36 percent with a downward trend. Also see Figure A.11.

Increasing soft skills, the share of English-speaking workers, highly specialized profiles in regulatory areas, and post-graduates is a priority for MNCs. The lack of skills in crucial areas such as technical problem-solving, process improvement, and communication is a central concern for companies.[25] The absence of competencies in project management and economic analysis, or financial engineering, has also become a prominent obstacle requiring attention and development. Additionally, companies increasingly indicate English skills as a fundamental requirement for their workers.

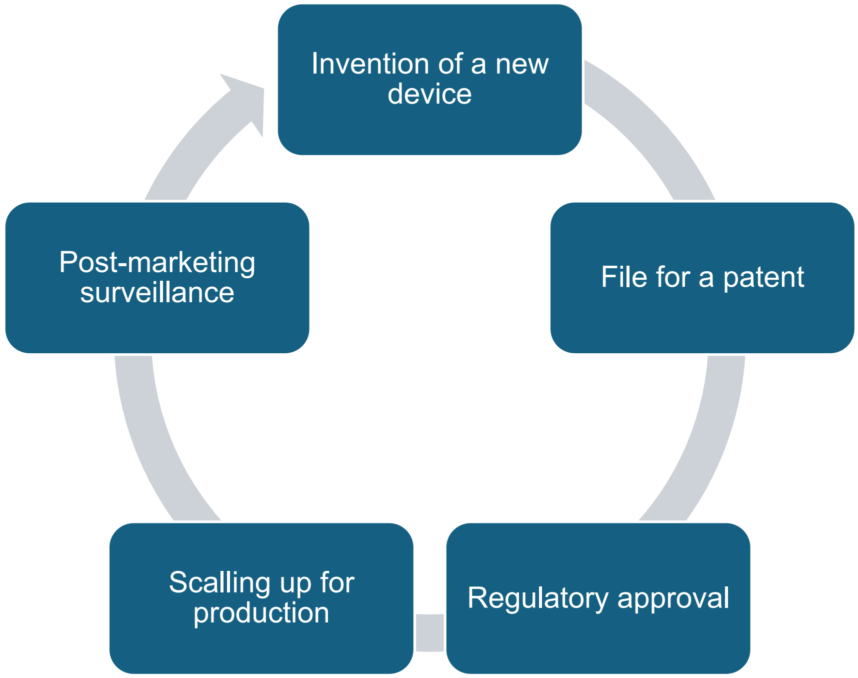
Since investment primarily comes from the United States, Canada, and Europe, bilingualism has become essential.[26] The need for highly specialized profiles, especially in regulatory areas, is an additional challenge. The lack of training in regulatory issues and the shortage of specific skills in clinical research exacerbate the gap between the current academic offerings and industry demands. This mismatch is accentuated in emerging areas of the industry, such as project management and economic analysis. The absence of master's and potentially doctoral programs in STEM disciplines hinders progress toward research and development. Closing these gaps will require significant investment in specialized academic programs that meet the changing demands of the industry and foster the growth of the human capital necessary for innovation in MDs.

7. Life Cycle of New Medical Devices and Opportunities for Local Firms

During the research and product development (R&D) stage, new products are conceptualized, prototypes are produced and tested, and potential manufacturing capabilities are assessed. Figure 4 illustrates each of the R&D phases based on Gelijns (1989) and WHO (2010) to identify opportunities where local firms could participate further, with further details below.

[25] Interview with a representative of MNC located in Costa Rica
[26] Interview with FDI attraction organization

Figure 4. The Life Cycle of a New Medical Device



Source: Authors' elaboration based on Gelijns (1989) and WHO (2010).

7.1 Lifecycle of New Medical Devices

7.1.1 Invention of a new device

Innovations are generally categorized into two broad groups—radical and incremental—and this is also the case for MDs. The invention of MDs is often incremental rather than radical. Radical innovations usually require large-scale investments in R&D due to their resource-intensive nature, which is why they typically occur in large firms. But usually, small firms and individuals produce most of the innovations in the early stages of developing a new class of MDs, and larger firms play an especially important role later in the development process (sometimes through the acquisition of small firms). In this regard, biomedical, clinical, and bioengineering research provides an important contribution to the knowledge base underlying MD development. Physician-researchers also play an important role in the invention of MD prototypes. Not only do they identify the clinical need for a new device or for improvements in existing devices, but they may also be the innovators and builders of the original prototype.

7.1.2 File for a patent

A patent application may be filed after a product is invented. Yet, the value of patent protection in MD development is less evident than in the pharmaceutical R&D process. In the device area, it is easier to invent around a patent, and the R&D time is shorter (10 to 15 years for drugs and 3 to 7 years for devices). Furthermore, the large-scale investments needed by some devices may prevent competitors from entering the market.

7.1.3 Regulatory approval

Regulatory schemes focused mainly on safety and efficacy testing practices govern the development of new devices. The FDA divides MDs into three classes based on their risk and the level of regulatory control needed. Class III devices are typically high-risk and require pre-market approval (PMA). Devices are automatically placed in Class III unless the sponsor successfully petitions the FDA to reclassify it as “substantially equivalent” to a device already on the market—known as a 510(k) submission. Devices may be found to be substantially equivalent only if the new technological features of a device can be shown not to decrease its safety and efficacy. This may be demonstrated through descriptive, performance, and even clinical data. If successful, a 510(k) allows sponsors to market the device without going through the more rigorous PMA process. Between 2003 and 2007, the FDA reviewed roughly 93 percent of MDs through a 510(k), and 7 percent underwent the full PMA process (GAO, 2009).

The PMA process, or in some instances a 510(k) submission, requires manufacturers to provide detailed scientific evidence, including clinical trial data, to demonstrate that their device is safe for its intended use. Clinical trials involve subjects (patients), an Institutional Review Board (IRB), and laboratories or physicians who carry out the clinical trials. The IRB examines the investigational plan and approves clinical studies for their institution. In addition to clinical evaluations, clinical testing usually involves an initial pilot stage and a technical testing stage. During the pilot stage, the prototype's design and materials are further developed and tested. During the technical testing stage, for example, the electrical and mechanical components of infusion pumps are subject to technical evaluations, and bench tests are performed to determine a pump's accuracy and reliability. After the technical development has become stabilized, a series of safety and efficacy evaluations of the final initial product can begin. Based on the results of clinical investigations, a device may be approved for marketing.

7.1.4 Scaling up for production

During clinical studies, much industrial effort may be directed toward scaling up for production. The necessary production capacity may vary widely, ranging from 10 to 100,000 devices a year. Process development—that is, establishing the manufacturing parameters—takes place in conjunction with input from the engineers at the manufacturing plants to determine the most efficient means of production.

7.1.5 Post-marketing surveillance

After an MD receives PMA and is marketed, the FDA and manufacturers continue to monitor its performance in real-world settings to detect adverse device reactions. The FDA receives reports on device hazards from health professionals and manufacturers and device manufacturers are required to keep records of complaints as part of GMP regulations. During production, a team of engineers continues to improve upon the production process in a process known as sustaining engineering. These engineers work in close contact with the product development teams. This stage is also characterized by constant improvement to existing devices as patents expire and new substitutes enter the market. Such improvements could include material enhancements (such as using or substituting original materials for new biocompatible coatings, antimicrobial surfaces, and advanced polymers), design improvements (such as redesigning handles of surgical tools for better grip and comfort during use), usage enhancements (such as transitioning to digitally interactive instructions for use or including a mobile app support), and technology advancements (such as increasing the accuracy of sensors used in devices like glucose monitors or heart rate monitors), among others.

7.2. Costa Rica Participation in Research and Development

Programa Estado de la Nación (2023) studies 55 domestic and foreign-owned firms with different roles (OEMs, manufacturing contractors, and suppliers) and found that 42 percent of the companies carry out R&D activities in the country.[27] This is a large increase

[27] The study results are available at https://hipatia.cr/dashboard/id-stat accessed October 3, 2024. Also see https://estadonacion.or.cr/dispositivos-medicos/ accessed October 3, 2024.

compared to 2013, when only a small number of OEM firms in Costa Rica were performing additional manufacturing R&D focused on improving the production process (sustaining engineering) and establishing the new production process for new products (process development) to be launched directly from Costa Rica (Bamber & Gereffi, 2013, p. 33). Most MD companies initially focused their presence on manufacturing activities. Subsequently, some companies invest and transfer R&D operations to Costa Rica. Such local R&D has been possible thanks to the existence of specialized engineers who graduated from academic programs with guaranteed quality and receive further training from the industry.

Furthermore, the presence of organizations with the installed capacity of laboratories has made notable advances in developing preclinical studies in MDs, including animal studies. Although local laboratories may not have specific certifications, their participation is concentrated in the initial testing phases, followed by the submission of accredited results for external certification, particularly before entities such as the FDA. An illustrative example of this progress is the collaboration between the National University and Boston Scientific, where over 40 contracted preclinical studies have been developed. This joint effort has allowed for preclinical studies even in institutions such as UCIMED, marking a milestone in the involvement of MD companies in the country. Such collaborations demonstrate the growing capability of local laboratories and companies' willingness to outsource preclinical studies, supporting innovation and product validation in Costa Rica's MD sector.

Establishment Labs is an exceptional example of an MD company that develops its R&D fully from Costa Rica, from prototyping to sustaining engineering. The limitations for conducting certain types of tests in the country are due to the need for laboratories to perform such analyses. The robust availability of talent and investment by companies in developing advanced technologies positions Costa Rica as an emerging player in the development and innovation of MDs.

7.3 Main Bottlenecks to Deepen R&D

A lack of incentive limits the ability to deepen R&D through collaborative projects between public universities and the MD industry. Public universities are “not ready for joint projects”, mentioned KIIs. The academic sector is the main source of investment in

R&D in Costa Rica, of which the public universities have the largest share (Monge-González, 2016, p. 94) and publish the most according to data from Hipatia. Yet, collaboration between public universities and the business sector is scarce (OECD, 2016, 2023). This is partly explained by the way public research is funded (OECD, 2020, 2023). Around 90 percent of the funding for public universities comes from the government's Special Fund for Higher Education (FEES), which totaled US$1.1 billion in 2023.[28] Despite its size, FEES does not have an attached steering, monitoring, and evaluation framework (OECD, 2018, p. 155).

Furthermore, there are no centralized and independent external evaluation mechanisms (OECD, 2020, p. 60). Moving toward competitive and performance-based funding and establishing a connection with the business sector as one of the eligibility criteria could increase incentives for public universities to pursue research and innovation that benefit both the university and the MD industry. A similar observation is shared by other studies (OECD, 2020, 2023). Additionally, grants that encourage joint research projects between academia and the private sector are scarce. Overall, the absence of financial incentives that foster cooperation between companies and public universities hinders the development of joint research projects that could lead to significant MD advances in incremental innovation, conceptualization of new products, and materials, or even adapting existing MDs for emerging markets.

Variability in public universities' internal regulations creates confusion and further limits companies' access to effective collaboration. Currently, only TEC has regulations on spin-offs, and research hours are not consistently recognized in all cases.[29] Established limits restrict universities' ability to allocate resources to joint research, and the system is not adapted for selling research services. Efforts such as those by CONARE in harmonizing concepts and analyzing intellectual property policies aim to improve this situation (Argüello-Arce, 2021), but gaps persist.

Information asymmetries and myths also hinder collaboration between public universities and the MD industry. From the business perspective, the myth is that "academia does not want to collaborate with me." In contrast, from academia, there is a

[28] 1 USD = 508 CRC. The value comes from https://semanariouniversidad.com/universitarias/asi-quedo-distribuido-el-fees-de-2024/ accessed April 5, 2024.
[29] Interview with FDI attraction organization.

fear that "companies will profit from everything I do, and I will end up losing." Although there has been a shift in universities' willingness to collaborate with industry, significant cultural gaps persist when establishing meaningful collaborations between public universities and the MD industry. The academic and industrial sectors need greater awareness and openness to foster a culture of collaboration in which knowledge exchange and active participation are key elements.

Finally, the absence of financial incentives, such as grants, to foster academy-industry cooperation and few certified laboratories (e.g., with good laboratory practices) restrain further linkages. The near nonexistence of certified laboratories means that their results are not valid for FDA approval, but limited access to funding and an unpredictable level of demand also reduce the chances of investing in obtaining certifications.

A 2023 study by the local think tank Programa Estado de la Nación found similar reasons why companies (either OEMs, manufacturing contractors, or local suppliers, domestic or not) do not carry out more R&D locally. For some companies, whether to invest in R&D depends on the corporate decisions of multinational companies. For other companies, the MNC's strategic plan does not contemplate carrying out R&D in Costa Rica, or these activities are only carried out in (or near) the headquarters in a developed country. These are the reasons why the country has little direct margin of maneuver.

However, there are other reasons why companies are not carrying out R&D locally for which the country could have more margin of maneuver. Companies cite a shortage of suppliers with specific certifications and highly skilled talent (see Table A.5 for a list of these profiles). Furthermore, the lack of tax incentives to support investment in R&D is in stark contrast to the norm in OECD economies (OECD, 2023) and even in the region, where Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Peru, and Uruguay have implemented tax incentives to support R&D investment. Ecuador, Mexico, Peru, and Uruguay have implemented tax credits or income tax deductions that are contingent upon expenditures related to R&D or technological innovation (ECLAC/Oxfam, 2019).

The study also examined the challenges confronting companies that engage in R&D. First, the shortage of human resources with postgraduate degrees and novel skills is identified as a significant impediment to the effective transition toward higher value-added segments. Additionally, companies have emphasized the challenges posed by the weak interconnections between them, the government, and academia and the difficulties associated with the lack of agility in carrying out procedures, including the difficulty in importing R&D inputs and the scarcity of specialized laboratories with the requisite quality certifications for this activity.

7.4 Further Opportunities for Costa Rica.

There are several opportunities for Costa Rica at each stage of R&D. First, local entrepreneurs in the health and technological areas can play an important role since most new MDs are incremental innovations and small firms and individuals produce most of these innovations. Yet, Costa Rica has no local funding that promotes close interactions between clinicians and the industry, and few institutions are conducting research in the areas of biomedical, clinical, and bioengineering. In the United States, funding in these areas is also relatively small and must be complemented by private investment, but Costa Rica has no organizations that provide private investment in these areas. An important question that arises is how to attract private investment in this area.

Procomer has been working with the ecosystem to promote efforts to connect entrepreneurs with international funding through the K-Global financing platform. The organization is aiming to bring local entrepreneurs to the next level and provide them with the needed tools to develop formal investment projects with an adequate accounting and financial structure so that local entrepreneurs can gain access to international funding. However, the challenge is obviously how to keep these business ideas in Costa Rica, as the incentive structure and tax benefits push entrepreneurs to open an office in the United States or other developed nations. U.S. investors prefer to adhere to U.S. rules rather than to those of a developing country. The FTZ and local taxes do not provide incentives to bring investors to Costa Rica, taxing them instead whenever they have earnings.

Second, local law firms specializing in patent applications and regulatory approval could take advantage of an opportunity, as filing for a patent requires non-clinical processes and legal technical knowledge available in Costa Rica. One important limitation, however, is the firms closely guard their intellectual property, and the process for filing for a patent can be carried out only in their headquarters.

8. Discussion and Conclusions

This section develops a strengths, weaknesses, opportunities, and threats (SWOT) analysis to further understand the factors influencing Costa Rica's MD sector.

Strengths. Costa Rica's strengths for the MD sector include the presence of manufacturing giants like Abbott, Baxter, Edwards Lifesciences, Philips, Boston Scientific, and another 36 original equipment manufacturers (OEMs) and 45 suppliers that provides strategic services such as sterilization and coating. The establishment of anchor companies, such as Intel and Baxter, marked significant milestones that contributed to economic development and changed the international perception of Costa Rica. This shift facilitated the entry of other global MD giants, creating a thriving ecosystem and demonstrating a successful track record in the MD industry, providing a solid foundation for further growth and development.

Costa Rica's political, economic, and social stability creates a favorable environment for business operations and investment in the MD sector, which is completely risk-adverse due to fatal health consequences. Years of investing in human capital are paying off, and the country's human talent and education induces firms to establish operations in the country. Additionally, the productive development programs of the FTZ and collaborative endeavors involving CINDE, Procomer, and Comex played pivotal roles in positioning Costa Rica in the MD industry. Free trade agreements, especially with China, the European Union, and the United States, further strengthened market access. Positioned strategically in the Western Hemisphere, Costa Rica enjoys proximity to the United States and a natural shield against adverse climatic events. Its strategic location creates synergies with other manufacturing plants, and facilities nearshoring opportunities.

Moreover, the country's ability to upgrade products, attract international suppliers, and offer complementary services, such as sterilization, has been instrumental in inducing functional upgrading. The efforts mainly moved forward by CINDE to fill gaps in the value chain led to the arrival of sterilization companies, marking a turning point in export capabilities, and adding significant value to the products; these capabilities helped Costa Rica with the infrastructure and capacity to effectively distribute finished MDs to final markets. Costa Rica's strategic evolution in attracting investments beyond final production enhanced its position on the global map of finished product exports.

The presence of skilled and versatile human capital has been a cornerstone of Costa Rica's success in the MD industry. Over the years, the accumulation of experience has resulted in a pool of professionals with both technical and managerial expertise. The adaptability of talent to changing industry demands, coupled with the resilience of Latin American professionals, positions Costa Rica as an attractive destination for research, development, and innovation.

Weaknesses. Regulatory, logistical, and infrastructure capacity obstacles present formidable challenges in the successful development of bioMDs. Addressing issues such as traceability systems, operationalizing regulations for clinical trials, and establishing accredited laboratories for valid international studies are pivotal for advancing the industry; given this aspect, the industry depends to a considerable degree on imported inputs, which could impact cost-effectiveness and supply chain resilience. Financial and regulatory challenges within the local companies' supply chains further highlight the need for diversified funding sources and increased awareness and support for certifying local suppliers as part of the value chain. The slow integration of local suppliers faces challenges in meeting quality standards and expanding the production capacity of these suppliers, an aspect that has been solved by attracting international suppliers for the MNC in the country.

The current rate of local academic capacity for producing bilingual STEM graduates is falling behind with the industry’s need to continue growing. Human capital challenges, particularly in English language skills, technical problem-solving, and specialized profiles, underscore the need for tailored training to address industry demands. Overcoming information asymmetries and regulatory limitations between academia and industry is crucial for effective collaboration and knowledge transfer. The "obscurity" period from 2010 to 2015 highlighted the vulnerability of research activities, emphasizing the importance of stable legal frameworks for fostering innovation and retaining skilled professionals. To bridge these cultural divides, it is imperative to introduce economic incentives and financing mechanisms, fostering a collaborative culture that promotes knowledge exchange and active participation between academia and industry.

Local immigration policies limit the company's ability to hire and attract engineers and STEM graduates from neighboring countries in response to the scarcity of local talent. Costa Rica does not benefit from immigration policies like those of Ireland, as it belongs to the European Union (EU) and immigration policies in the EU are more relaxed than those in Costa Rica.

R&D capabilities and the R&D environment are another weakness. There are still some challenges to promoting R&D and innovation in the country. The current FTZ regime has no specific incentives for R&D, nor are there tax credits for R&D investments. There are no financial incentives to invest in innovation, and the limited seed capital and risk capital constrain the financing options for spinoffs and entrepreneurs, impeding the growth of innovative ventures. Inadequate intellectual property legislation exposes companies to risks of theft or infringement, threatening their competitiveness and discouraging innovation.

Opportunities. In view of the polarization between the United States and China since 2018, the biggest opportunity for Costa Rica is nearshoring, as the United States will continue to lead the consumption of MDs (van den Heuvel et al., 2018). Companies see Costa Rica as a manufacturing hub and a center for continuous development, sustaining engineering, and R&D activities. Incorporating advanced technologies in MD manufacturing showcases Costa Rica's dynamism and adaptability in addressing industry challenges. Given this, there is an opportunity to enhance the manufacturing of Class III devices, research and product development, and post-sales services through various elements: (i) sustaining engineering and process development in R&D, (ii) exploring incremental innovation R&D and conducting clinical trials, (iii) R&D linked to adapting developed-world products for emerging markets, and (iv) Offering training, consulting, maintenance, and repair services for MD equipment. Other opportunities include exporting to other markets such as Latin America, increasing the production and exports of capital goods, and improving distribution.

Future trends in the MD industry could lead manufacturers to integrate devices with services and data intelligence through wearables, smart device apps, the internet of things (IoT), cloud-based data and analytics, and blockchain (Dalgaard et al., 2023; van den Heuvel et al., 2018). In this regard, another opportunity lies in software development, where Costa Rica also has a relevant presence.

The lack of intersectoral coordination and defined institutional frameworks poses a significant obstacle to fully harnessing the industry's potential. Establishing a national productivity council and implementing a coordinated local supplier development strategy is essential to overcoming these challenges and fostering a more agile and growth-oriented industry. Moreover, cultural gaps between academia, the national productive sector, and the MD industry hinder collaborative efforts. The absence of grants and funds for joint research projects further exacerbates these gaps. Given this, establishing partnerships with multinational OEMs presents opportunities for accessing knowledge transfer, advanced technology, specialized expertise, and global distribution networks, thereby boosting competitiveness and value-added capabilities.

Creating a robust ecosystem and the ongoing commitment to innovation and human capital development would allow the country to evolve within the GVC. Structural challenges in investment and innovation for multinational companies and local ventures in the life sciences industry underscore the necessity of tailored incentives. This aspect could leverage technological advancements and rapid technological progress to open doors to R&D and develop novel, high-value MDs, positioning Costa Rica to capitalize on these advancements, given the country's track record in MDs.

Strengthening the innovation ecosystem and introducing targeted incentives will be crucial for the long-term success of both multinational and local ventures in the life sciences industry. Given demographic shifts, such as the aging population, the opportunity to exploit global demand for MDs creates avenues for the Costa Rican MD industry to expand its exports, increase value added, and explore new markets.

Threats. While nearshoring is an opportunity, it could also become a threat if it promotes investments in other sectors that use inputs in production similar to those used by the MD industry (for example, semiconductors could also use workers with similar soft skills and technical abilities, or land in industrial parks under the FTZ regime). This could potentially create a crowding-out effect against MDs.

Global competition in the manufacturing of MDs in Asia, Europe, and Latin American counterparts like Mexico and the Dominican Republic poses challenges, especially regarding pricing and productivity. This stiff competition could influence manufacturing site locations. Fluctuations in local currency rates may lead to variations in the cost of wages, imported materials, and equipment, affecting profitability and competitiveness. This instability could make it difficult for companies to predict and manage their expenses effectively. Populism in the region, artificial intelligence, automation, and new technologies, including digital instructions for use, could also threaten the country's position and linkages within the sector.

The global minimum tax introduced under Pillar 2 of the Base Erosion and Profit Shifting Project (BEPS) is based on the Global Anti-Base Erosion (GloBE) Model Rules that a jurisdiction can introduce to impose a top-up tax on the low-taxed income of in-scope taxpayers up to 15 percent. Costa Rica's accession to the OECD in May 2021 implies challenges to the current FTZ regime, specifically to the full income tax credit that it offers certain companies. Pillar 2 could impact the financial operations of Costa Rican MD firms because changes in tax policies may increase operating costs and reduce profitability for these companies. Not only Costa Rica and MD companies would be affected by this OECD-promoted policy; other OECD countries and firms would also be affected. Under Pillar 2, firms are subject to the global minimum tax if they have a consolidated revenue of more than EUR 750 million and if they benefit from shifting profits to low or no-tax locations where they have little or no economic activity or erode tax bases through deductible payments like interest or royalties.[30] If an MNE operates in a country where the local tax rate is below 15 percent, the parent country (or another jurisdiction where the MNE is headquartered) can impose a top-up tax to bring the effective tax rate up to 15 percent. Yet, some large countries (e.g., Brazil, China, India, Russia, Turkey, and the United States) have not yet fully enacted Pillar 2 legislation, and other countries offer incentives that are consistent with global tax rules and are not seen as harmful tax practices. For example, Ireland provides a 25 percent tax credit for

[30] These are firms whose consolidated revenue is larger than a certain threshold (EUR 750 million).

qualifying R&D activities. Countries may introduce or expand R&D tax credit schemes to support innovation and technological development, while still maintaining compliance with Pillar 2. The OECD allows countries to provide R&D incentives if they meet certain economic substance and transparency requirements.

Finally, the rapid evolution of emerging technologies, such as digital health and artificial intelligence, presents a threat as it may disrupt traditional MD markets. Given this aspect, companies need to adapt quickly to these changes to remain competitive and meet evolving customer demand. Despite these challenges, the sustained interest in R&D investment indicates the potential for growth and advancement in Costa Rica's MD sector. Costa Rica is a player in the MD industry, contributing to its economic growth and the advancement of the global healthcare sector.

The MD sector in Costa Rica faced five enablers for moving along the global supply chain of MDs. First, innate characteristics (a strategic location) and acquired factors (economic, political and social stability, education, human talent, and a favorable investment climate) motivated foreign investors to start operations in Costa Rica. Second, a shift in the strategy of the investment attraction agency (from sectoral to supply chain) helped secure the entry of key suppliers. Third, the development of specialized skills and talent needed by the MD industry helped upgrading toward the production of more complex devices. Fourth, productive development programs helped linkages emerge between MNEs of MDs in Costa Rica and local firms. Finally, the existence of specialized skills enabled companies to consider the country for research and product development processes.

The sector is also facing three main bottlenecks that limit its ability to continue upgrading. First, cultural barriers and informality are restricting backward linkages between MD multinational corporations and domestic companies, despite the existence of productive development programs. Second, skills shortages persist, and there are not enough bilingual STEM graduates to continue growing in the manufacturing and assembly stages. Finally, the lack of incentives limits the ability to deepen R&D through collaborative projects between public universities and the MD industry.

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Appendix A: Additional Tables and Figures

Table A.1. Key Informants for Interviews

Interview	Name	Position	Organization
1	Federico Rivera Daniel Calvo Jimena Fletes	President Principal Business Development Partner Executive Director	Medical Device Cluster of Costa Rica
2	Rafael Corrales	CEO	Arenal Medical
3	Fanny Chan Sebastián Ospina Henao	Research and Development Director Coordinator	Research Institute of Medical Sciences (UCIMED)
4	Gabriella Couto	Founder	Costa Rican Cluster for Biotechnology, Medical Devices and Life Sciences (CRBIOMED)
5	Ricardo Monge	President	Central America Academy
6	Ronald Brenes Brenes	Course Director master's degree in medical device engineering	Costa Rica Institute of Technology
7	Erick Mora Gloriana Lang	Life Science Lead Innovation and Development Lead	Costa Rican Investment Promotion Agency (CINDE)
8	Gabriela Castro	Former director of public policy for Foreign Direct Investment	Comex
9	Marcial Chaverri	Director of Creation of New Exporters and Access to Financing	Promotora de Comercio Exterior (Procomer)
10	Laura Ramírez Saborío Angélica Cordero Solís	Executive Director Director of Evaluation and Accreditation	Sistema Nacional de Acreditación de la Educación Superior (SINAES)
11	David Ramírez	Innovation and Entrepreneurship Coordinator	Sistema de Banca para el Desarrollo (SBD)
12	Eduardo Loría	Commercial Coordinator	Technical Standards Institute of Costa Rica (INTECO)
13	Marco Antonio Vargas	Chief Commercial Officer	Grupo Vargas
14	Eduardo Viso	Supply Chain Manager	Philips
15	Ivania Alvarado Esteban Campos	Human Resource Manager Supply Chain Director	Edwards Lifesciences

Table A.2. Value of Medical Devices Exported in Costa Rica and the World, by Product Category and Commodity Code, 2012, 2020, and 2022 (in millions of US$)

Product category (1)	Commodity code (2)	Commodity description (3)	Costa Rica 2012 (4)	Costa Rica 2020 (5)	Costa Rica 2022 (6)	Worldwide 2012 (7)	Worldwide 2020 (8)	Worldwide 2022 (9)
Disposables	901831	Syringes	15.9	2.3	0.1	4,275.5	5,695.0	6,613.4
	901832	Needles	0.0	40.0	53.4	1,775.1	2,762.7	3,505.0
	901839	Catheters, cannulae, etc.	604.6	1,498.2	1,996.2	22,028.4	30,721.4	37,430.8
Surgical and medical instruments	901841	Dental drill engines	0.0	0.0	0.0	415.7	574.7	616.7
	901849	Dental instruments other than dental drill engines	6.6	0.1	0.2	4,022.0	4,823.4	6,865.1
	901850	Ophthalmic instruments and appliances	0.3	2.7	7.0	3,417.2	3,738.9	5,171.9
	901890	Other medical, surgical or dental instruments	359.5	1,313.1	1,894.3	41,507.1	56,869.5	64,961.6
Therapeutic devices	900130	Contact lenses	0.1	87.5	62.5	4,922.7	6,354.0	7,205.2
	902110	Orthopedic appliances	1.6	32.5	85.1	7,382.4	9,398.6	11,076.5
	902121	Artificial teeth	0.0	6.0	6.0	616.8	808.2	1,095.3
	902129	Dental fittings other than artificial teeth	0.1	0.0	0.1	1,990.3	2,872.9	4,021.4
	902131	Artificial parts of the body	0.1	1.8	0.1	5,745.5	10,153.6	12,623.2
	902139	Artificial parts of the body excluding artificial joints	233.3	382.2	1,052.3	7,729.6	10,600.7	12,679.8
	902140	Hearing aids	0.1	0.0	0.0	3,128.3	3,941.5	5,239.3
	902150	Pacemakers for stimulating heart muscles	0.0	0.0	0.0	6,025.2	4,342.3	6,130.1
	902190	Disability appliances	36.1	179.4	43.6	11,770.4	12,564.3	15,807.8
Capital equipment	901811	Electro-cardiographs	0.0	0.5	4.9	780.9	1,061.4	1,209.2
	901812	Ultrasonic scanning apparatus	0.1	0.1	62.9	4,388.6	4,815.4	5,614.8
	901813	Magnetic resonance imaging apparatus	0.0	0.0	0.0	4,509.8	4,450.9	5,296.2
	901814	Scintigraphic apparatus	0.0	0.0	0.0	328.0	309.6	328.2
	901819	Electro-diagnostic apparatus, n.e.c. in 9018.1	8.7	235.3	285.7	9,768.9	15,345.6	16,787.7
	901820	Ultra-violet or infra-red apparatus	0.0	0.0	0.1	356.8	654.3	690.3
	902212	Computed tomography apparatus	0.0	0.4	1.5	3,077.5	4,240.8	4,970.5
	902213	X-rays for dental uses	0.0	0.0	0.0	795.5	670.7	856.6
	902214	X-rays for medical, surgical or veterinary uses	0.0	0.0	0.0	5,891.0	5,766.0	5,947.5
	902219	X-rays for other uses	0.0	0.1	0.0	2,434.6	2,565.7	2,994.1

	902221	Radiography or radiotherapy apparatus for medical uses*	0.0	0.0	0.0	509.2	324.8	304.7
	902229	Radiography or radiotherapy apparatus for other uses	0.0	0.0	0.0	286.0	169.0	328.0
	902230	X-ray tubes	0.2	0.1	0.0	1,813.7	1,740.7	2,047.6
	902290	X-rays parts and accessories	0.3	0.7	3.1	7,589.4	6,921.2	7,498.2
		TOTAL	1,267.6	3,783.0	5,559.1	169,282.1	215,257.8	255,916.7

Source: Authors' elaboration using data from Comtrade.

Note: The list of commodity codes includes all six-digit codes under the four-digit codes 9018, 9021, and 9022, plus 900130 (contact lenses).

Table A.3: Free Trade Zone Exemptions and Regular Tax Rate in Costa Rica for a Medical Device Firm Looking to Establish in San José and Surrounding Areas

Taxes in Costa Rica / others	Tax rate	Free Trade Zone Regime
Income tax	30 percent	6% years 1 to 8, 15% years 9 to 12, 30% after year 12
Import/export tariffs	Varies depending on the product	100% exemption
General sales tax	13%	100% exemption on local purchases of goods/services
Stamps	1%	100% exemption
Municipal license	0.3%	100% exemption for a period of 10 years
Tax on the transfer of real estate	1.5%	100% exemption for a period of 10 years
Tax on withholding of royalties, fees, and dividends	up to 25%	100% exemption
Interest tax	8%	100% exemption
Limitation of expatriates in the country	None	
Expatriate tax	All residents and non-residents working within Costa Rica's territory under an employment relationship are subject to withholdings and social security contributions. The personal income tax is increased to 15%.	
Entry requirements	Minimum investment of 150,000 USD and maintain a certain level of employment set by the company.	

Source: CINDE and Procomer (available at https://www.procomer.com/wp-content/uploads/Guia-Zonas-Francas-Ing-dic-2021.pdf accessed March 15, 2024).

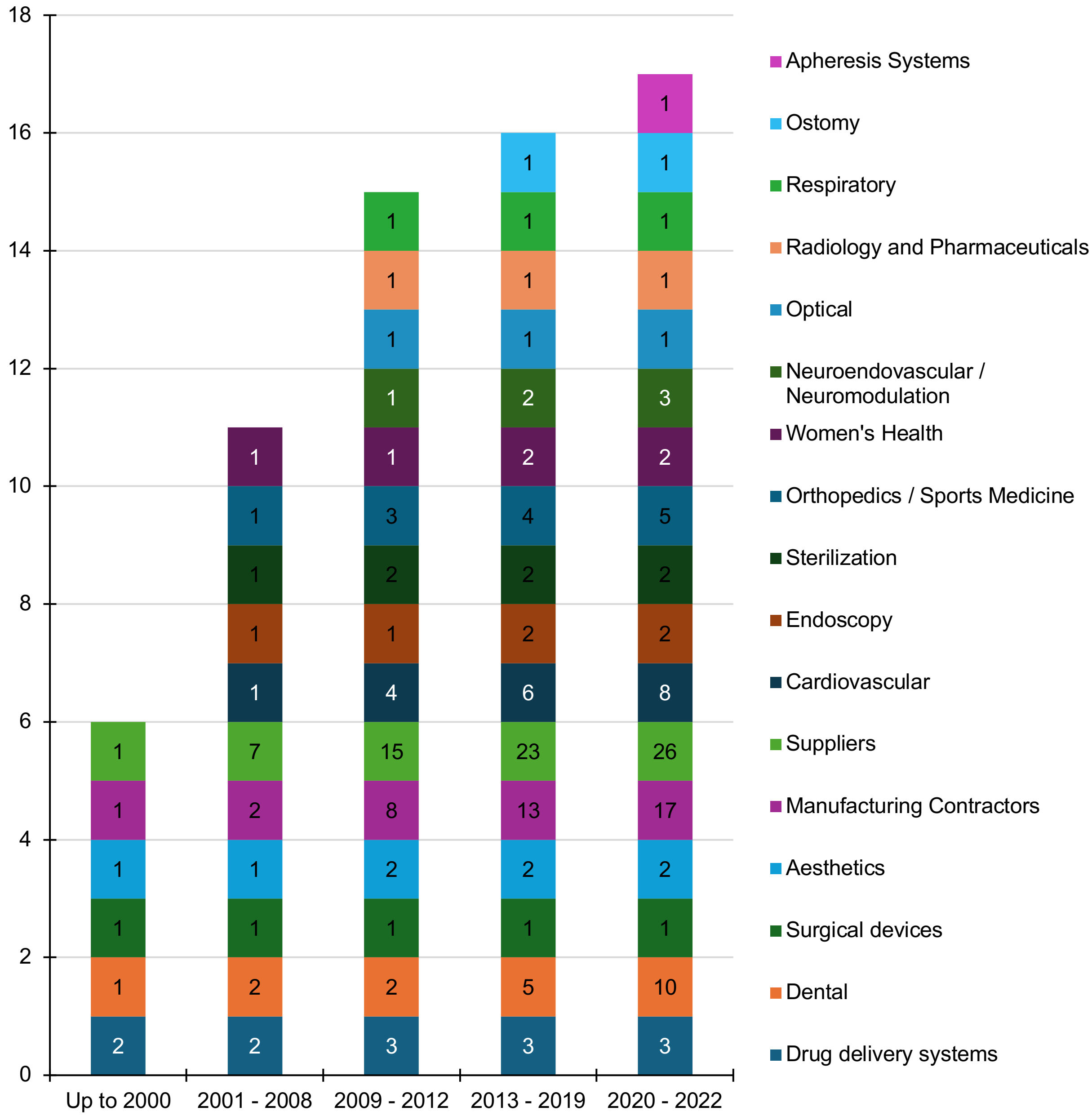
Notes: GAM stands for Great Metropolitan Area. Additional benefits and requirements may apply for other manufacturing firms, for firms looking to establish outside GAM, or for manufacturing firms whose initial investment is over 10 million USD (known as "Megaprojects").

Table A.4. Employee Profile for Select Segments of the Value Chain

Value Chain Stage	Professional Labor with Tertiary Education	Technicians and Operators
R&D	Clinicians (incremental & radical innovation) Engineers (incremental innovation) (mechanical, Electronic, biomedical, electrical, chemical, industrial, process) Product designers PhDs with industry experience and capacity in applied research Government & regulatory affairs officers Risk capital specialists (angel investors, venture capitalists)	Highly skilled technicians (prototypes)
Components	Engineers (chemical, electrical, electronic, industrial, mechanical, automation) Validation engineers Quality assurance Microbiologists	Mechanics Electricians Technicians Machine operators Manual assemblers
Assembly	Engineers (chemical, electrical, electronic, industrial, mechanical, automation) Validation engineers Quality assurance Microbiologists Compliance officers (lawyers, documentation clerks)	Mechanics Electricians Technicians Machine operators Manual assemblers
Marketing & Sales	Government & regulatory affairs officers Health economics specialists Reimbursement specialists Marketers Product specialists	

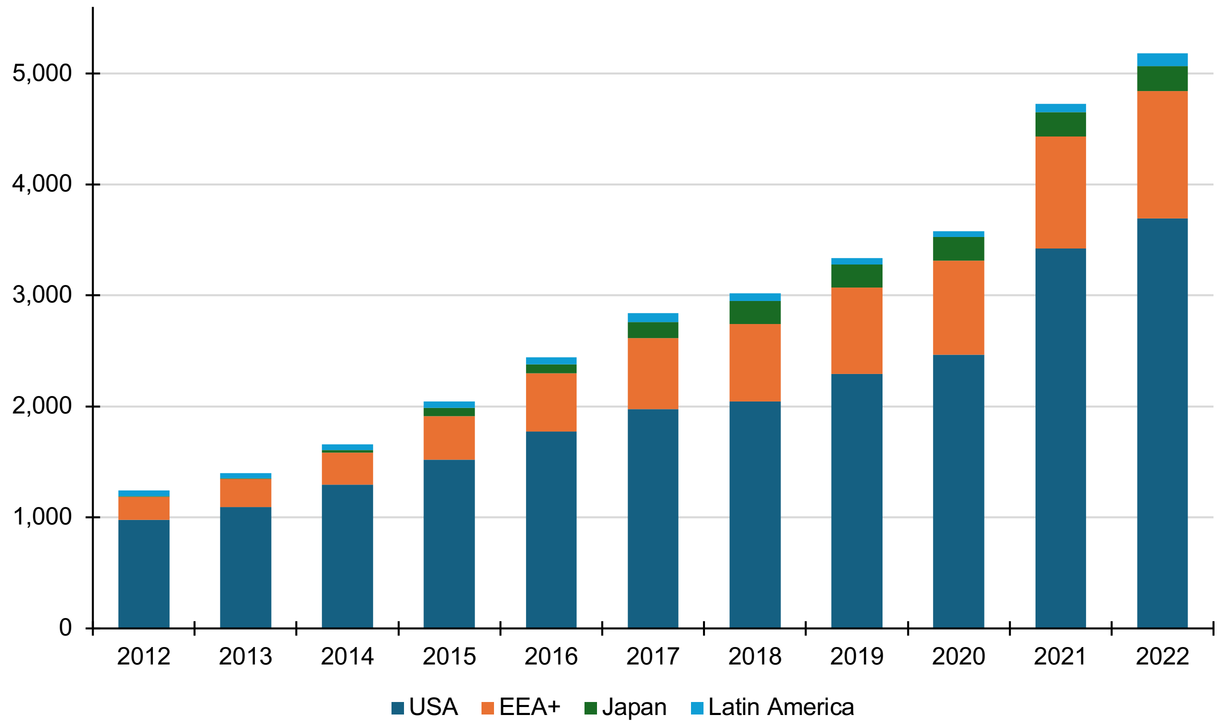
Source: Bamber and Gereffi (2013).

Figure A.1. Market Segments of the Medical Devices Sector with Presence in Costa Rica since 1987, and Number of Firms by Segment



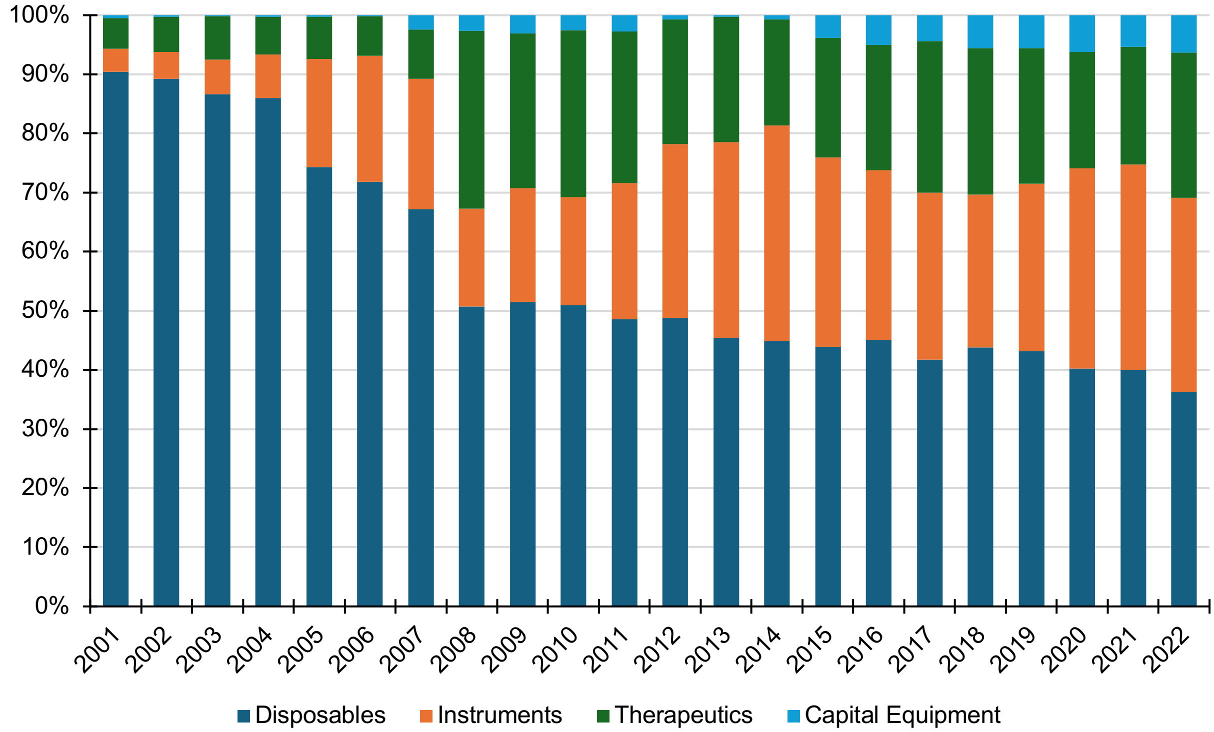
Notes: the number inside each bar is the number of firms in each market segment.
Source: Authors' elaboration using data from CINDE.

Figure A.2. Medical Devices, Costa Rican Exports by Destination, 2012 to 2022 (in millions of US$)



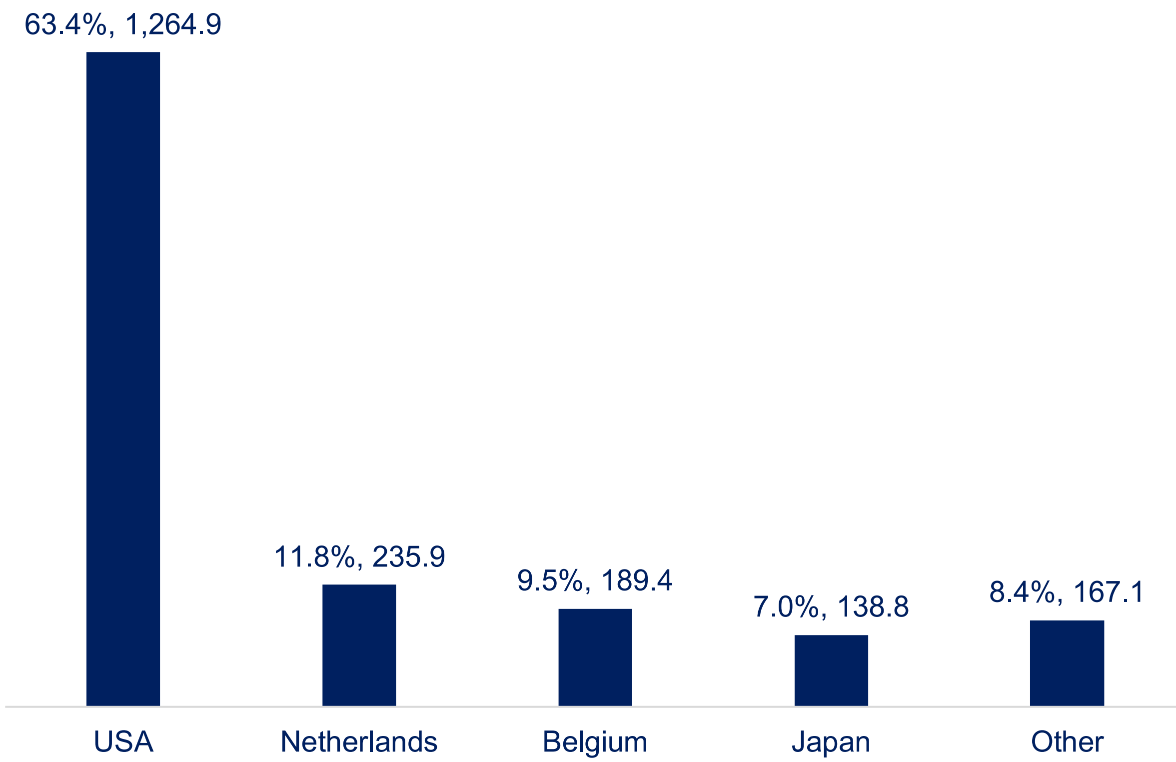
Source: Authors' elaboration using Comtrade data.
Notes: EEA+ is the European Economic Area that includes the 27 countries from the European Union plus Iceland, Liechtenstein, Norway, and Switzerland.

Figure A.3. Medical Devices, Costa Rican Exports by Product Category, 2001–22



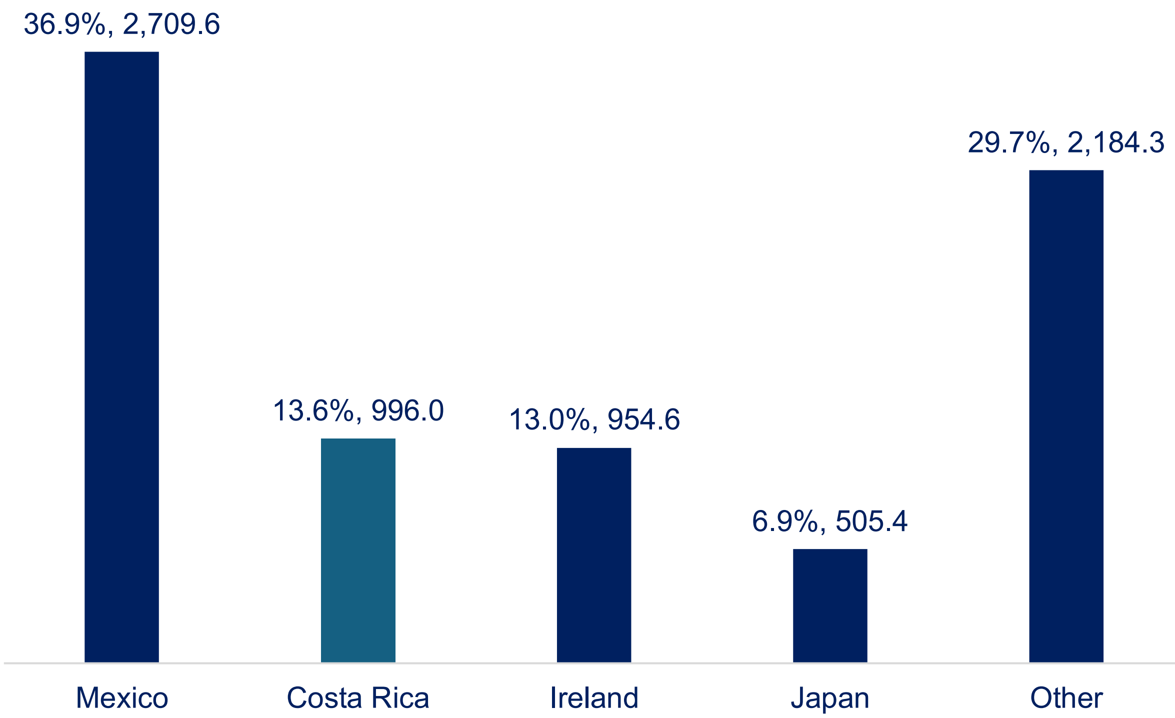
Source: Authors' elaboration using data from CINDE and Bamber and Gereffi (2013) classification.

Figure A.4. Exports of Catheters from Costa Rica by Destination (MM US$, 2022)



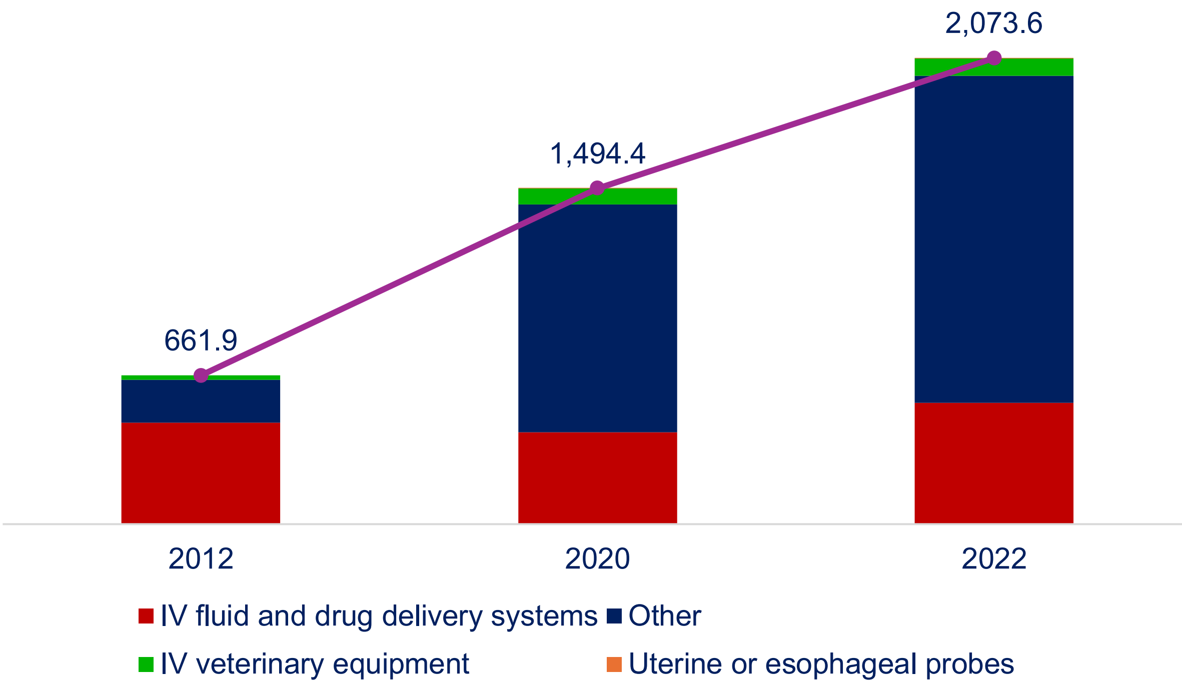
Source: Authors' elaboration.

Figure A.5. U.S. Imports of Catheters by Partner (MM US$, 2022)



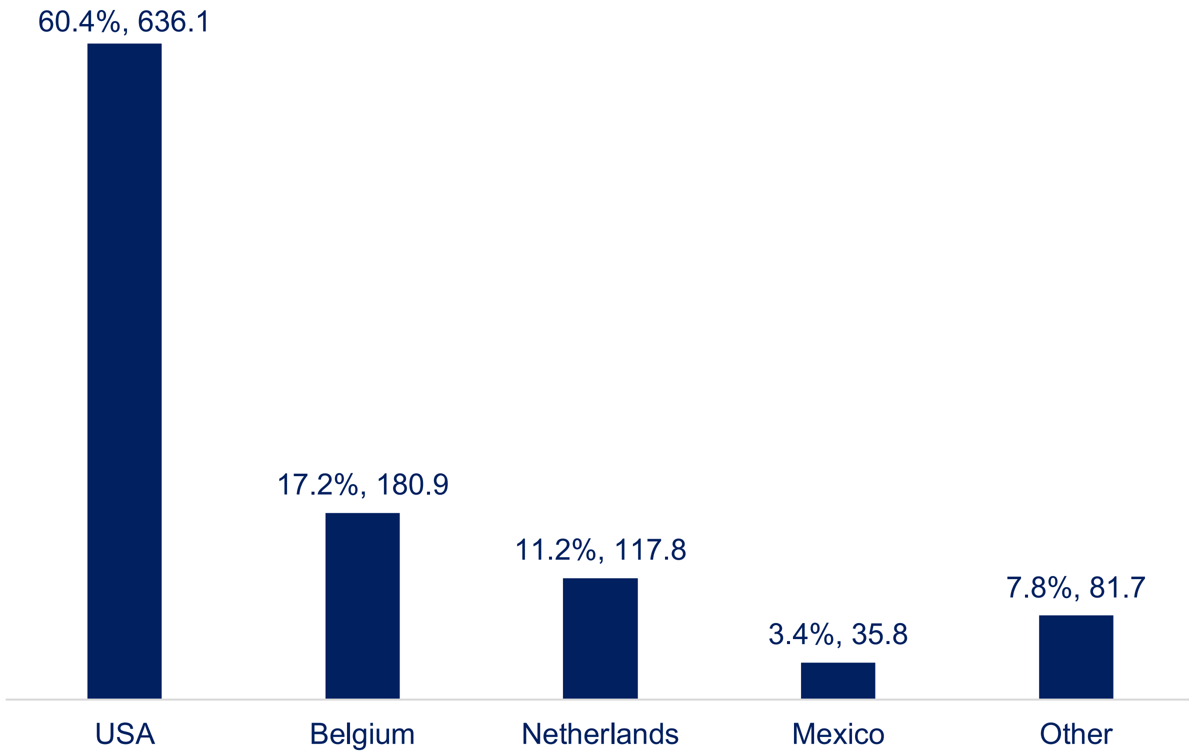
Source: Authors' elaboration using data from Comtrade.

Figure A.6. Exports of Catheters (901839) by Type (2012, 2020, 2022)



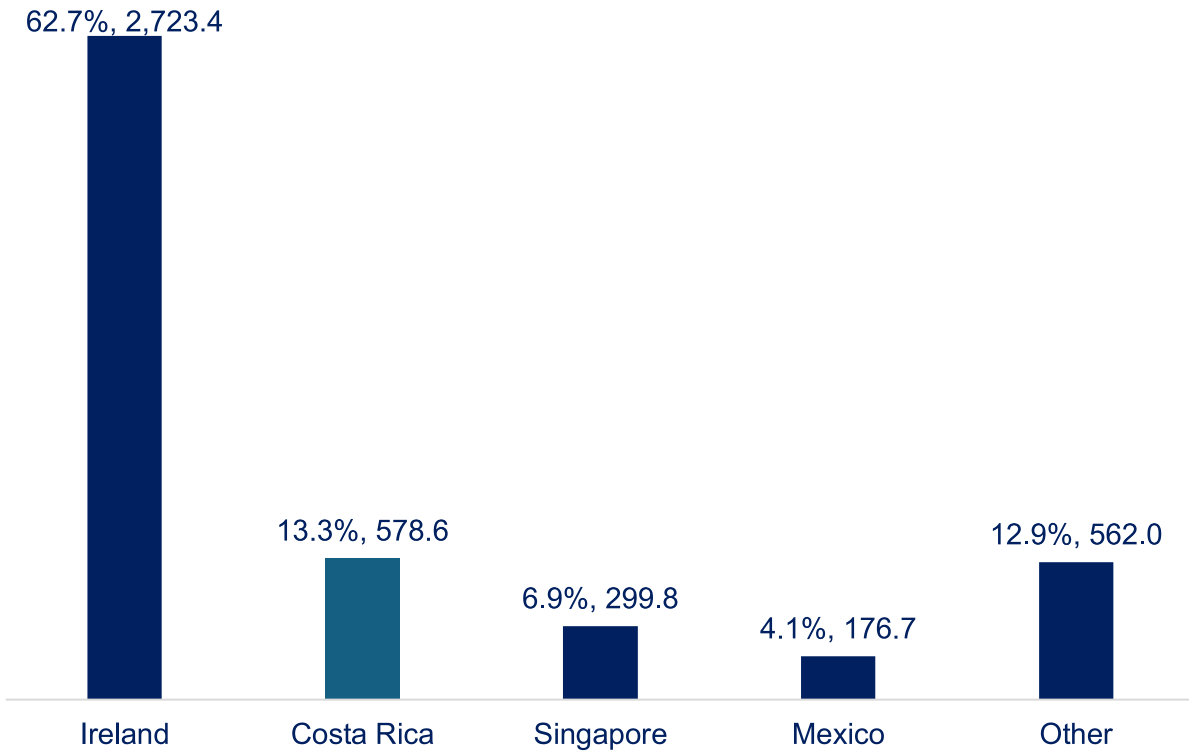
Source: Authors' elaboration using data from Procomer.

Figure A.7. Exports of 902139 from Costa Rica by Destination (MM US$, 2022)



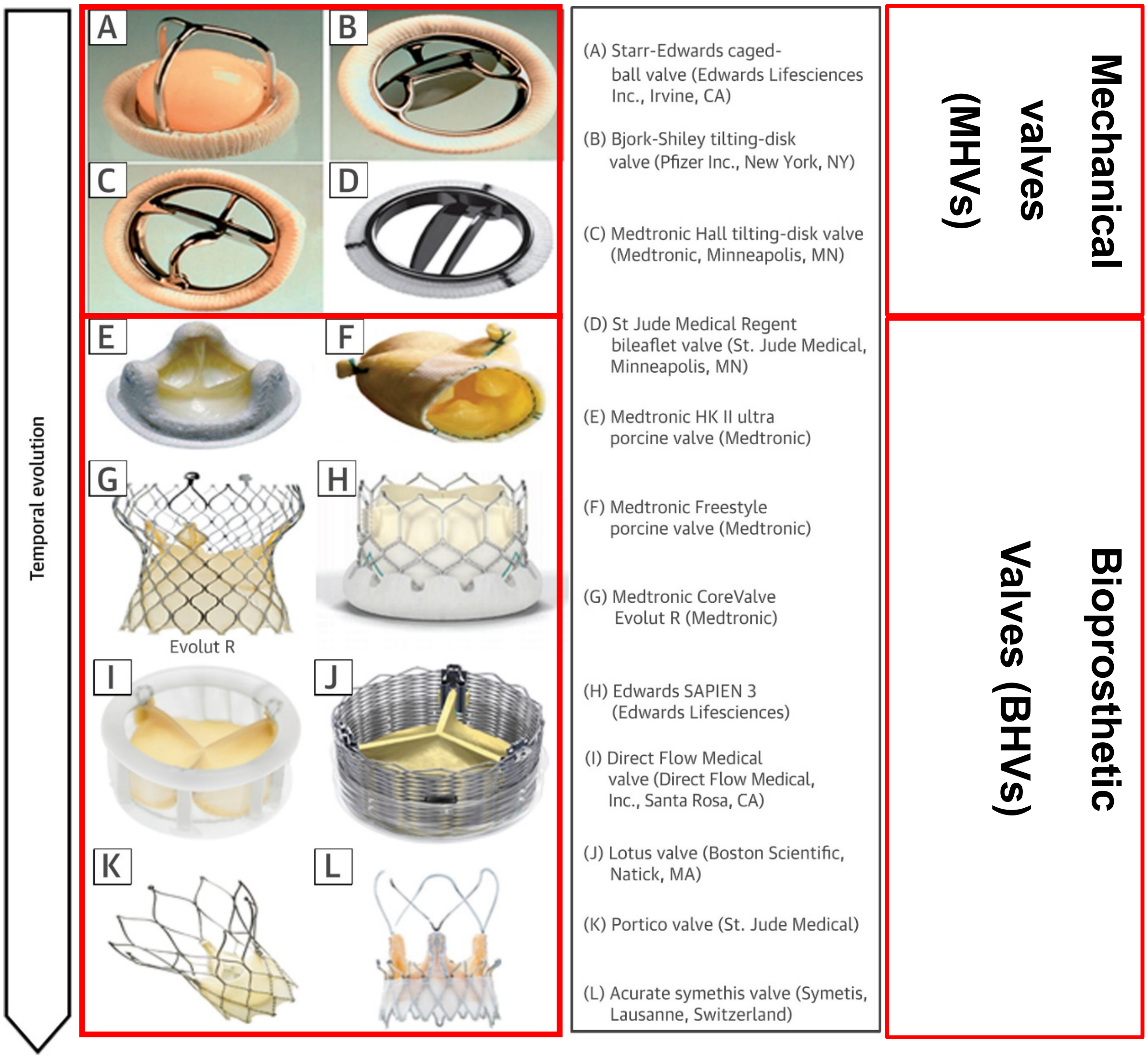
Source: Authors' elaboration.

Figure A.8. U.S. Imports of 902139 by Partner (MM US$, 2022)



Source: Authors' elaboration.

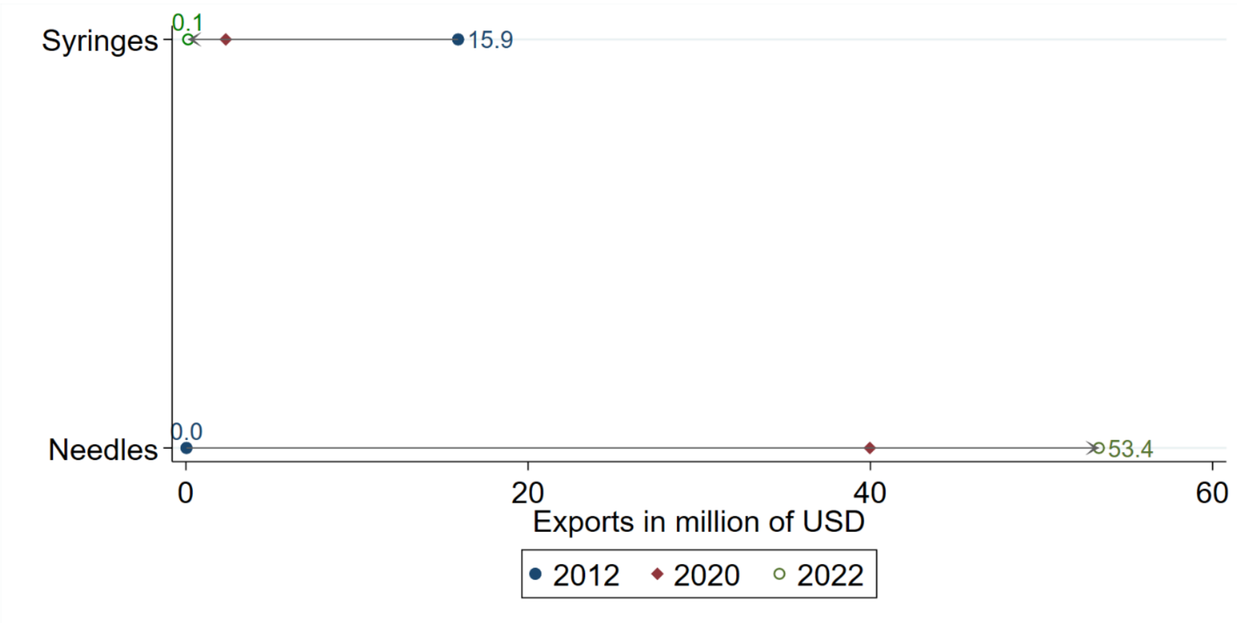
Figure A.9. Surgical and Transcatheter Prosthetic Heart Valve Examples. Evolution of Surgical and Transcatheter Prosthetic Heart Valves



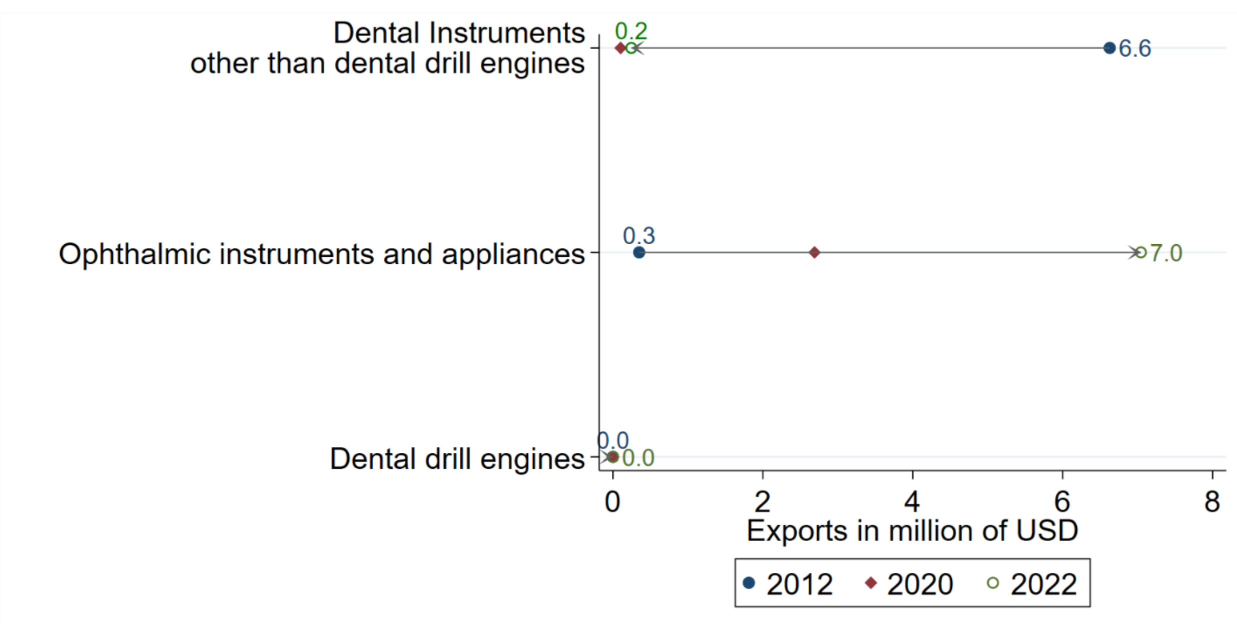
Source: Figure 1 from Dangas et al. (2016).

Figure A.10. Exports of Medical Devices' Products by Category and Product, Costa Rica (in millions of US$), 2012, 2020, and 2022

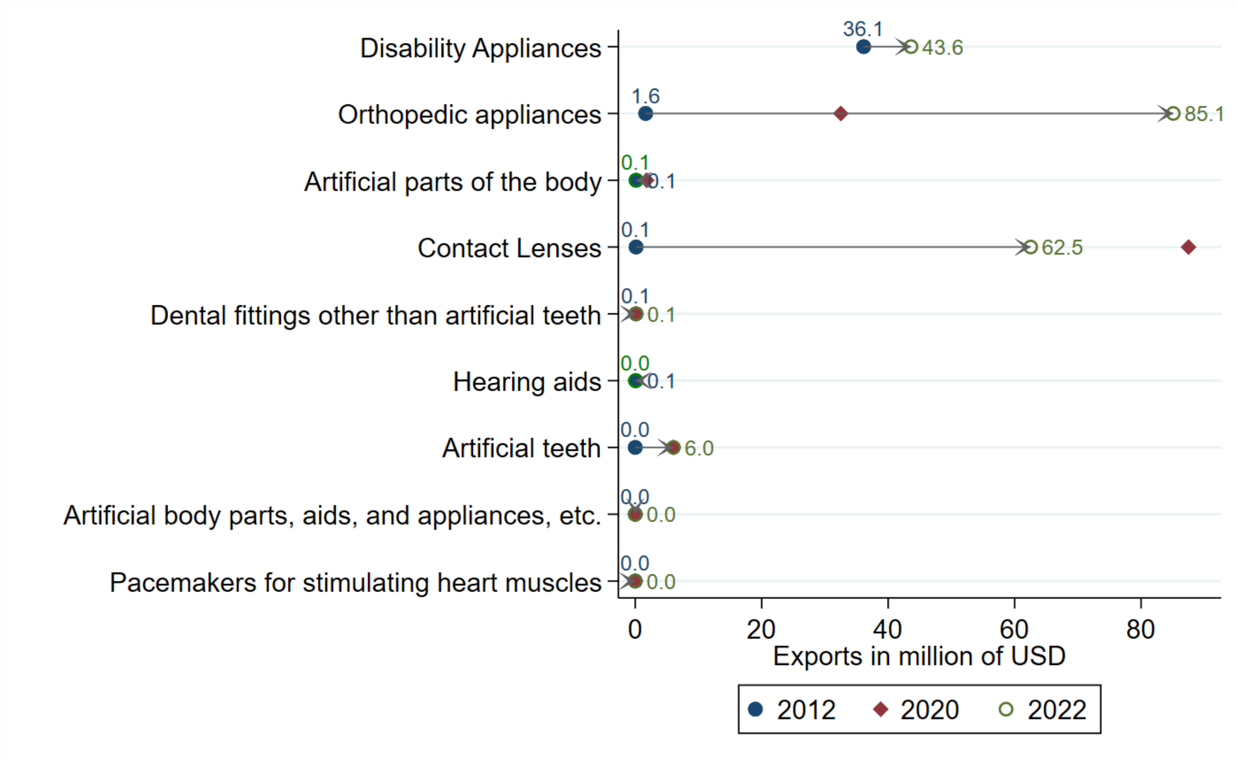
Panel A. Disposables



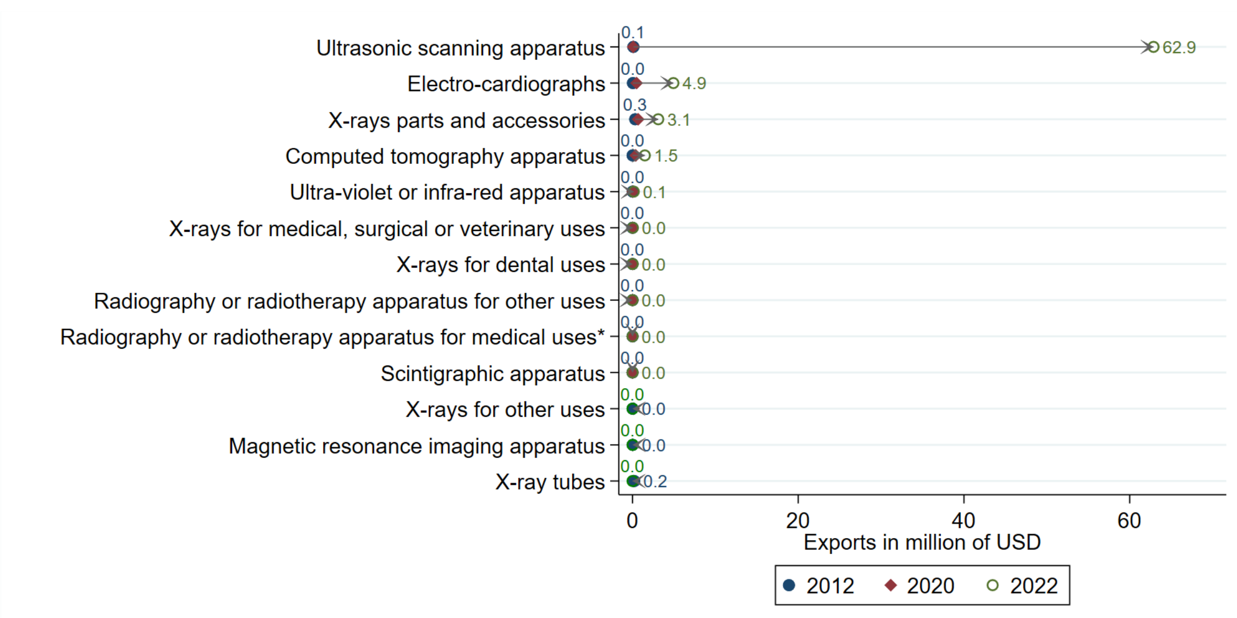
Panel B. Surgical and Medical Instruments



Panel C. Therapeutic Devices

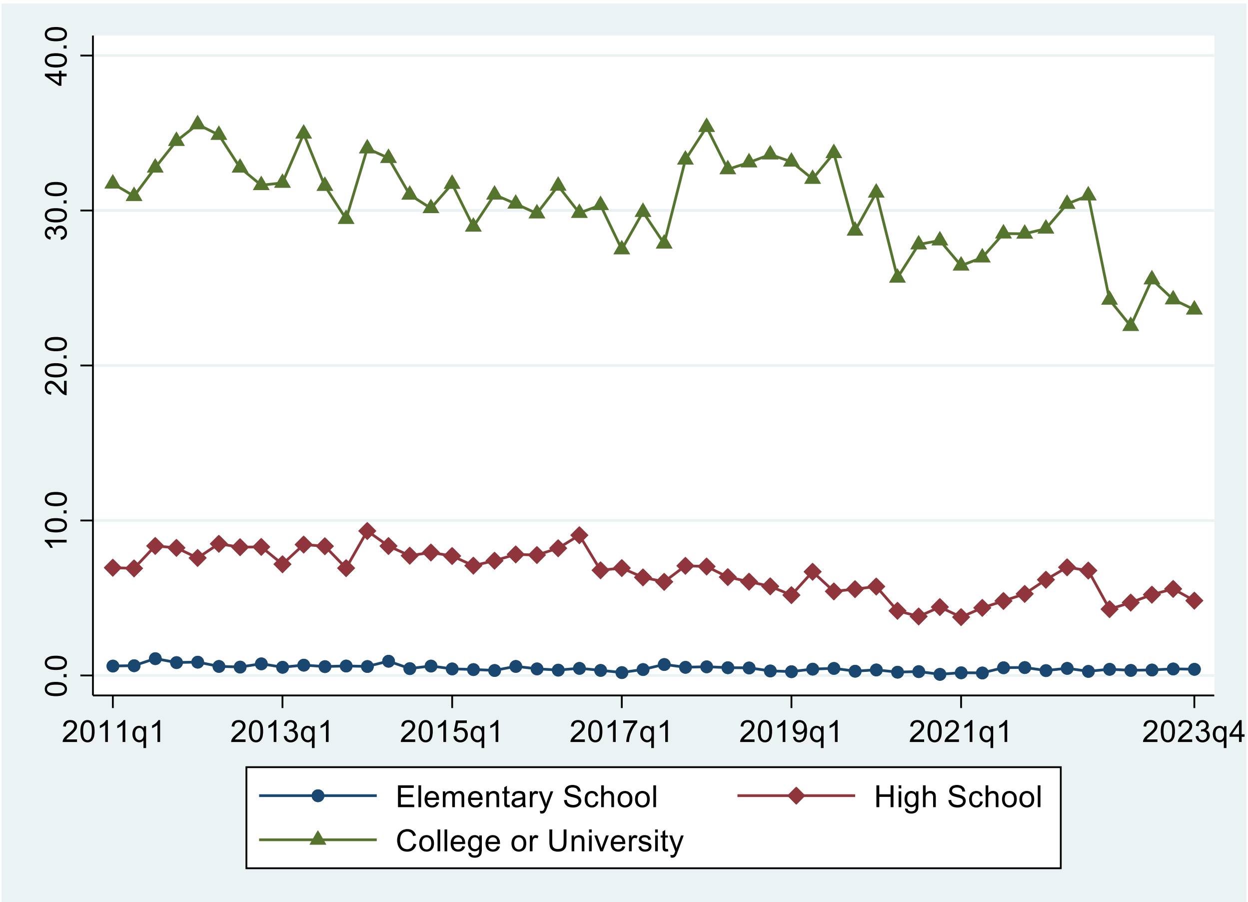


Panel D. Capital Equipment



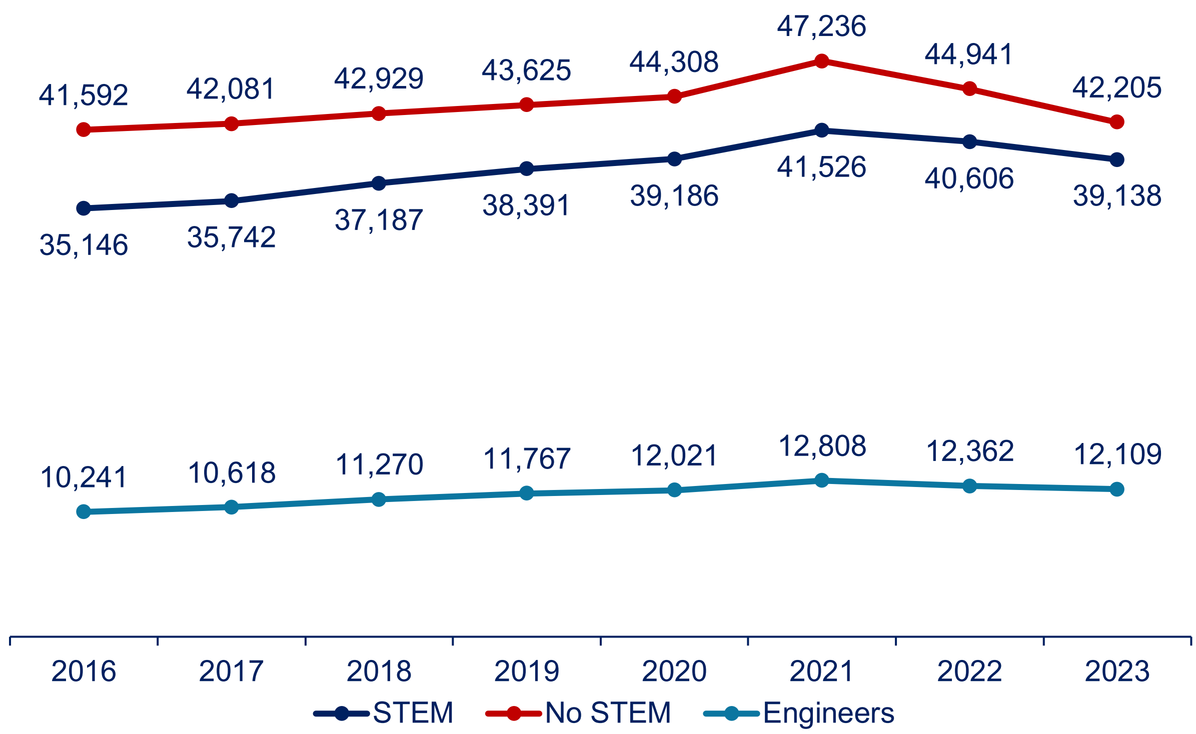
Source: Authors' elaboration using data from Comtrade.

Figure A.11. Percentage of People who Speak and Write English, by Academic Degree, from the First Quarter of 2011 to the Last Quarter of 2023



Source: Authors' elaboration using as a data source all the available quarterly rounds of the Encuesta Continua de Empleo (ECE) labor survey of Costa Rica carried by the local institute of statistics (INEC).

Figure A.12. Freshmen in Public Universities in Costa Rica



Source: Authors' elaboration from analysis of CONARE data.

Box A.1. Categories of Finished Medical Devices

Finished products can be classified into four categories. This classification is important for two reasons (Salazar-Xirinais, 2022): each category corresponds to products with increasing value-added degrees, and these categories are the basis for placing these products in the Standard Industrial Classification (SIC) that guides the collection of trade statistics:

(i) Disposables or high-volume commodities include bandages, surgical gloves, plastic syringes, catheters, and needles. These are low tech, generally single-use products that are cost driven. Manufacturing these products requires less medical expertise than other product categories, but producers must comply with specific quality standards.

(ii) Surgical and medical instruments include forceps, medical scissors, dental drills, and specialized surgical instruments used in cosmetic and endoscopic surgery. These are generally multi-use products that are sterilized between uses with different patients. Some devices may be electrically powered. The production of many surgical and medical instruments is increasingly cost-driven.

(iii) Therapeutic devices include implantable and non-implantable devices to help people manage physical illness or disability. Examples include hearing aids, pacemakers, and prosthetics. These products are aimed at specialists. Due to their prolonged use inside the body, producing implantable devices requires considerable expertise, particularly concerning biocompatibility, and obtaining regulatory approval for implantable devices is costly. This increases the value of each device considerably.

(iv) Capital equipment includes single-purchase equipment that can be used repeatedly over several years. These products require ongoing account management for accessories, services, and parts. This product category covers patient monitoring, diagnostics, and imaging equipment. It ranges from infusion pumps and blood pressure monitors to significant investments such as MRI equipment or computed tomography. Equipment requiring these large, long-term investments generally requires multiple decision-makers.

Appendix B: Interview Question Guide for the Sector

The question guide serves as a conversation guide during the interviews. The questions were formulated based on an initial review of literature about the sector in Costa Rica (Bamber and Gereffi, 2013; Gibson, 2022; Pietrobelli et.al., forthcoming; Santos and Durán, 2023, Salazar-Xirinachs, 2022; Valverde, 2023) and the evolution of global value chains (Pietrobelli, 2021; Pietrobelli et.al. 2021). The intention is to follow a process of semi-structured interviews, allowing exploration of topics raised by the interviewee as relevant to the interview continuation. The guide presents a comprehensive list of topics to be addressed during the data collection process. Prior to the interview, the research team will select the most relevant questions based on the interviewee's expertise and their relevance to specific themes.

1. Can you tell us about the role of your organization in the ecosystem of the medical devices and life sciences sector in Costa Rica?
2. From your perspective, how has the D31T33 sector evolved in Costa Rica over the last two decades?
3. What does the value chain in the medical devices sector include? a. What has Costa Rica successfully included in its production? b. What needs to be included to increase the generated value?
4. What are the determining factors that have contributed to the sector's growth in the country during the last two decades of sector development?
5. Are there identifiable obstacles that have hindered sector development during this period? a. For example, in an ideal scenario, what prevented them from growing twice as much in the sector? b. Are there missed opportunities in the sector's development over the last two decades, and what could have resulted in more positive outcomes?
6. How do you compare operating costs in CR vs. other countries in the region and the world in this sector? a. Has the sector recently benefited or been affected by the dynamics of nearshoring with significant markets like the United States? b. Has the sector recently benefited or been affected by the dynamics of friendshoring?

7. How have verticalization and integration forward and backward in the production chain been managed? a. How has market diversification and entry into higher-value segments of the medical devices sector evolved in Costa Rica?
8. How have specific challenges related to regulation and uncertainty in Costa Rica affected attracting investments and expanding the medical devices sector? a. How has technical regulation impacted the sector's process of attracting foreign direct investment? b. Are bureaucratic processes a factor in attracting FDI? And in the development and growth of sector companies? c. How has the investment attraction policy influenced identifying and filling gaps in the value chain?
9. How has coordination and collaboration between multinational companies and local suppliers impacted the sector's growth? a. Were there public-private coordination efforts that allowed the development of coordination and collaboration between multinational companies and local suppliers? b. What challenges have been identified for collaboration between these two industry actors? c. How has local chaining and the participation of local suppliers in the D31T33 sector developed? d. How has the existence of clusters contributed to knowledge exchange and sector competitiveness in the country? e. What has been the role of technology transfer in the growth and development of the medical devices industry in Costa Rica? f. Are there significant obstacles in technology transfer, and how have they been addressed? g. How has access to contact information for industry suppliers in Costa Rica been? h. What are the barriers to the effective participation of local suppliers, and how could they be overcome?
10. How do companies in the D31T33 sector in Costa Rica perceive the availability of postgraduate human resources in key disciplines such as information and communication technologies, highly specialized engineering, industrial design, electronics, mechatronics, and how has this affected their ability to move toward higher value-added segments? a. How have academic curriculum contents related to the medical devices industry evolved? b. How has the quality of engineering and business graduates evolved in relation to sector needs? c. What

identified obstacles exist for implementing changes in study plans, and how could they be overcome?

11. What are the experiences of companies regarding the links between them and academia in the D31T33 sector in Costa Rica? a. In terms of public sector support, how do companies evaluate collaboration with the government and academia in research and development initiatives? b. How have these links affected companies' ability to overcome obstacles and seize opportunities? c. Are there suggestions to strengthen this collaboration and improve government support for the sector? d. How could links between government, academia, and industry be improved to drive innovation in the D31T33 sector in Costa Rica, from the perspective of companies?

12. In terms of procedures and regulations, how do companies experience difficulties, including importing inputs for R&D? a. How has this affected the agility and competitiveness of the sector? b. What solutions do they propose to improve these processes?

13. How has the national quality system affected the development of clinical trials and laboratory accreditation in Costa Rica? a. Are there specific barriers to the implementation of quality standards, and how have they influenced the growth of the medical devices and life sciences sector? b. How have international quality standards influenced export strategies and access to international markets? c. Are there specific challenges in adapting to these standards, and how have sector companies addressed them?

14. What are the impacts of the shortage of specialized laboratories with quality certifications on the development of new technologies in the D31T33 sector in Costa Rica? a. How have companies faced this limitation, and which opportunities have been affected? b. How does this affect the capacity for innovation and the development of new technologies in the D31T33 sector in Costa Rica? c. How has laboratory accreditation and the National Quality System influenced the development of clinical trials in the sector?

15. What is companies' perception of the costs involved in R&D in the medical devices sector in Costa Rica? a. How do these costs affect or benefit companies' ability to move toward higher value-added segments?

16. What has been the experience of companies regarding access to capital for the development of research and development projects in the medical devices sector in Costa Rica? a. What is the industry's perception regarding incentives for innovation and risk-taking in research development? b. What are the main challenges in this aspect, and what suggestions do they have to improve access to financing? c. Are there specific policies that could encourage greater innovation in the sector?

17. How has access to capital (seed capital and venture capital) been for the creation of new companies and for local companies (small and medium enterprises) in the medical devices sector in Costa Rica? a. What challenges have they faced in this regard, and what measures do they propose to improve access to financing?

18. Considering the lessons learned from previous experiences, what are the best practices that could be shared to address identified challenges and maximize opportunities in the medical devices sector in Costa Rica? a. What lessons can be drawn from Costa Rica's experience in identifying and addressing critical gaps in technical capabilities to attract foreign investment?

19. Considering the current sector situation, what are the critical gaps that must be addressed to increase opportunities in the medical devices sector in Costa Rica? a. What challenges and areas of improvement have been identified to facilitate the sector's future growth in the country? b. What are the specific challenges and opportunities for specialization in highly complex medical products? c. What situations need to be addressed promptly to increase the added value of Costa Rica's production in the global sector chain? d. What situations need to be addressed in the medium and long term?