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Business Plan for Developing a Sustainable and Intelligent Disposable Electric Laparoscopic Stapler

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Abstract: This study examines the design and development of a new disposable electric intelligent laparoscopic stapler and its components, addressing issues in existing electric staplers, particularly insufficient power for cutting thick tissue and postoperative complications. Finite element analysis was utilized to model cutting force and tissue thickness, optimizing the device's cutting performance. The electric intelligent laparoscopic stapler integrates control, drive, transmission, execution, and communication modules, employing intelligent thickness detection and feedback mechanisms to enhance surgical precision and safety. Additionally, a degradable, absorbable hemostatic pad with excellent biocompatibility and an optimal degradation cycle was developed to minimize postoperative complications. The marketing strategy focuses on product diversification, competitive pricing, channel expansion, and technical services to strengthen the product's presence in the domestic market and support import substitution, enhancing its competitiveness. A risk analysis was conducted to address potential policy, operational, technological, and market risks, with strategies proposed for mitigation.

Keywords: Electric intelligent laparoscopic stapler; Finite element analysis; Degradable absorbable pad; Marketing strategy; Risk analysis

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1. Business description

1.1. Industry field

Advancements in surgical and minimally invasive procedures have established staplers as essential tools, replacing manual suturing for cutting, suturing, and anastomosis of body cavities and tissues [1]. Staplers improve surgical efficiency, reduce procedure times, and minimize bleeding, making them indispensable in minimally invasive surgery. Initially dominated by manual staplers, this segment faced limitations such as surgeon fatigue and inconsistent suturing, restricting their applications. Electric staplers, such as those developed by Johnson & Johnson, offer stable and consistent firing force through motorized mechanisms, reducing the burden on surgeons and ensuring seamless tissue suturing. As a result, they have gained greater

adoption [2]. However, current electric staplers sometimes experience power insufficiency when cutting thicker tissues, leading to motor failures and increased surgical risks. Additionally, traditional metal staples can cause tissue damage and lead to postoperative complications.

1.2. Product overview

The newly developed disposable electric intelligent laparoscopic stapler and its components aim to address these deficiencies. Its motion control system features an intelligent thickness sensor that automatically detects tissue thickness, adjusting compression force and speed for precise stapling with real-time feedback. This design minimizes tissue damage and enhances surgical safety. The included absorbable reinforced pad effectively prevents air leaks and bleeding, particularly in lung surgeries. The stapler adheres to Class II medical device standards set by the National Medical Products Administration, with the absorbable pad classified as Class III.

1.3. Target customers

The product is designed for use in hospitals at all levels and distribution networks, catering to surgeries in general surgery, obstetrics and gynecology, thoracic surgery, and pediatrics. It is particularly effective for organ resections involving the liver, pancreas, and kidneys. This innovative product enhances surgical efficiency, reduces intraoperative injuries and infection risks, accelerates patient recovery, and shortens hospital stays [3].

1.4. Industry life cycle

The surgical stapler industry has transitioned into an era of automation and intelligence. Since the introduction of Tristaple technology by Covidien in 2012, the market has increasingly adopted high-tech automated devices. Global companies like Johnson & Johnson and Medtronic dominate with over 80% of the market share, while domestic enterprises account for less than 10%. The growing demand for disposable and cost-effective minimally invasive surgical tools presents significant opportunities for domestic substitution. Currently, the domestic stapler market is in a growth phase, offering opportunities for increased market concentration. Competition remains moderate, but the overall market trajectory indicates robust growth potential [4].

2. Project research content

2.1. Analysis of the cutting process for different abdominal tissues

To analyze the effects of tissue thickness, cutting force, and cutting speed on surgical outcomes, gastric and pulmonary tissues with thicknesses ranging from 2.5 mm to 3.5 mm were selected. Finite element analysis was applied to calculate stress, strain, and energy distribution under varying cutting forces (10–50 N) and speeds (15–35 mm/s). The experimental results produced stress and energy distribution maps, establishing an appropriate range of cutting forces for tissues of different thicknesses.

2.2. Design of the electric intelligent stapler system

The electric intelligent laparoscopic stapler comprises a control system, drive system, transmission system, execution system, and communication module.

(1) Control system: The control system integrates hardware and software components. The hardware includes control circuits, drive circuits, thickness detection circuits, and voltage/current sampling circuits, while the software encompasses control algorithms for torque, speed, and thickness detection.

High-performance, cost-effective microcontroller units (e.g., STM32, PIC) are utilized, supported by H-bridge motor driver chips (e.g., DRV8837, SS8841) that enable forward and reverse motor rotation, emergency stops, and speed adjustments. A PWM controller regulates motor speed, with voltage sampling feedback for closed-loop control and current sampling for torque adjustment and thickness calculation, ensuring stable cutting operations [5,6]. When encountering rigid tissue, the system intelligently adjusts motor speed and torque to prevent stalling.

(2) Drive system: This system consists of a motor and reducer, which execute instructions from the control system to generate the required power.

(3) Transmission system: Designed to minimize vibration and tissue damage, this module incorporates high-precision gear transmission and lead screws to efficiently convert rotational motion into linear motion.

(4) Execution system: As the primary interface for tissue interaction, the execution system includes a cutting blade and push blade. The cutting blade features an elastically designed C-shape, accommodating various surgical angles.

(5) Communication module: A Bluetooth chip is incorporated into the communication module to connect with the main control chip, allowing surgeons to monitor the stapler's real-time status via smart devices, record surgical data, and support postoperative analysis and improvement [7].

2.3. Development of a degradable absorbable reinforcement pad

A degradable absorbable pad was developed using natural cotton chemically modified to ensure excellent biosafety and tissue compatibility. The pad features a moderate degradation cycle, enabling self-absorption post-wound healing and reducing inflammation and foreign body reactions.

(1) Hemostatic performance study: The hemostatic effectiveness of the pad was validated through in vitro coagulation tests and rabbit models. Thrombin time, activated partial thromboplastin time, and other parameters were used to reveal coagulation mechanisms and establish a hemostatic efficacy evaluation system [8].

(2) Degradation performance study: *In vitro* and *in vivo* experiments were conducted to observe material degradation in simulated bodily fluids and physiological conditions. *In vivo* tests involved implanting the pad in various animal body parts, with periodic sampling and histological analysis to assess biodegradation behavior and tissue response, forming a comprehensive biodegradation evaluation system.

2.4. Technical features of the project

2.4.1. Cutting model and analysis

Cutting motion analysis was performed on abdominal tissues of varying thicknesses, establishing optimal cutting force and compression parameters to enhance the stapler's cutting performance [9].

2.4.2. PWM-based motion control

A combination of software algorithms and hardware modules enables real-time speed and torque measurements, providing precise control of the DC motor's operation for surgical stability. Voltage and current sampling ensure closed-loop feedback, dynamically adjusting motor speed and torque to achieve accurate tissue thickness

detection and pressure control [10].

2.4.3. Degradable absorbable pad

Compared to traditional metal staples, the degradable absorbable pad minimizes mechanical damage and significantly reduces stapling-related complications. The pad's design facilitates smooth staple penetration, elastic protection for tissues, and enhanced cell adhesion and proliferation, thereby promoting wound healing. This material addresses challenges faced by existing pads, such as excessive hardness, poor fixation, and prolonged degradation cycles, ultimately improving the safety and efficacy of stapler applications [11-13].

These innovations and optimizations not only meet clinical requirements but also significantly enhance the safety, efficiency, and intelligence of the product.

3. Marketing

3.1. Target market

With the ongoing development of minimally invasive surgery in China, the demand for staplers has grown steadily. In 2021, the Chinese stapler market reached 8.288 billion yuan, reflecting a 20.24% increase from 2020. Stapler products are categorized into intelligent, open, and laparoscopic staplers, with laparoscopic staplers accounting for approximately 60% of the market, followed by open and intelligent staplers at 21% and 19%, respectively. Since 2016, the laparoscopic stapler market has experienced continuous growth, reaching 4.992 billion yuan in 2021, representing 60% of the total market. Due to high technological barriers, foreign brands currently dominate the laparoscopic stapler market, contributing to elevated treatment costs. Although domestic brands account for 50% of the open stapler market, they hold only a 16% share in the laparoscopic stapler sector. Import substitution and domestic production are anticipated to drive future trends.

3.2. Business profit model

The company employs a hybrid sales approach combining direct sales and distribution channels. Direct sales provide greater control over the end-sales network and are suitable for later stages as the market matures. Distribution, however, is the primary strategy during the early stages, establishing a strong market foundation through collaboration with distributors. As the company scales, integrating direct sales with distribution will enhance customer engagement and control, ultimately transitioning toward a predominantly direct sales model [14].

3.3. Marketing strategy

Based on a SWOT analysis, the following marketing strategies have been formulated:

3.3.1. Product strategy

The company will offer a diversified product portfolio to address varied customer needs, supported by policy incentives to expand market share. A robust brand strategy will mitigate low-price competition and ensure long-term growth. Marketing efforts will emphasize professional medical publications, promotional materials, and digital media. Brand visibility will also increase through participation in medical device exhibitions and technical seminars. Specific initiatives include regular attendance at specialized exhibitions such as the China International Medical Equipment Fair, advertising in medical journals in collaboration with agents and OEM partners, and hosting industry forums and technical seminars targeting physicians.

3.3.2. Pricing strategy

A value-based pricing strategy will position the product between 5,000 and 6,000 yuan—approximately half the cost of high-end foreign brands. This approach facilitates rapid market entry while maintaining profitability to support future product development. Pricing decisions are informed by market positioning, production costs, and profit objectives, with the aim of quickly expanding market share [15].

3.3.3. Channel strategy

The channel strategy emphasizes collaboration with capable distributors to leverage their networks and regional expertise, enabling market expansion. Simultaneously, in-house sales channels will be developed to gradually reduce dependence on distributors. Additional efforts include promoting e-commerce, building customer databases, and creating multi-layered sales networks. Flexible ordering, credit, and payment policies will ensure a seamless supply chain. Regional institutions will be authorized to manage warehousing and transportation, optimizing logistics to align with market demands [16].

3.3.4. Promotion strategy

The product's clinical value will be highlighted through technical workshops and interactive sessions with doctors to build trust among medical professionals. Collaborations with hospitals will facilitate product adoption, enhancing recognition and fostering brand loyalty.

3.3.5. Service strategy

High-quality service is a critical element of competitive differentiation. The company offers comprehensive services, including pre-sales consultations, product demonstrations, guidance during use, and post-sales issue resolution. If necessary, product recalls are conducted promptly. Technical services will involve academic activities for clinical doctors to emphasize the product's mechanism and efficacy, patient usage tracking, and educational initiatives to optimize treatment outcomes and user experiences.

Through these strategies, the company seeks to rapidly penetrate the market, enhance product visibility and market share, and ultimately establish brand influence and market leadership.

4. Risk analysis

4.1. Overview of current market competitiveness

The intelligent stapling platform developed in this project features a high-performance chip, microprocessor, and sensors, alongside an LED display capable of automatically detecting and calculating tissue thickness. The platform provides real-time feedback via the display, advising surgeons on the appropriate staple cartridge and automatically adjusting firing force and speed during procedures. This functionality allows for precise, customized stapling tailored to various organs and tissues, facilitating personalized treatments during minimally invasive laparoscopic surgeries where direct access to internal tissues is limited. Additionally, a degradable hemostatic pad is integrated as a reinforcement pad at the stapler's component end, effectively preventing tissue tearing, air leakage, and postoperative bleeding while promoting healing. Currently, no competing product on the market incorporates such an innovative material.

4.2. Risk analysis

4.2.1. Policy risk

(1) Factors: Changes in national industrial and tax policies related to the medical device industry may impact the company's operations. Over the long term, the positive and negative impacts of future domestic policies are expected to be balanced out [17].

(2) Countermeasures: The company will remain vigilant in monitoring policy developments, conduct in-depth research on industry-specific regulations, and adjust product structures and resource allocation accordingly to mitigate potential risks associated with policy changes.

4.2.2. Operational Risk

(1) Factors: (a) Dependence on essential raw materials and supply channels; (b) Reliance on key customers; (c) Limited diversity in the product or business structure; (d) Constraints imposed by current production conditions [18].

(2) Countermeasures: (a) Establish stable, long-term relationships with suppliers through contractual agreements and consistent payment plans, supported by annual, quarterly, and monthly supply arrangements; (b) Expand sales channels and customer bases through enhanced marketing efforts, creating a stable and efficient marketing system; (c) Intensify research and development efforts to explore new product markets; (d) Leverage regional development policies, such as the Western China Development Strategy, to seek industrial development funding in areas like the Chongqing Northern New Area; (e) Address financing challenges through appropriate channels as required.

4.2.3. Product risk

(1) Factors: (a) Lack of clarity in product labels and warnings; (b) Insufficient training for users; (c) Incorrect staple size selection; (d) Improper cartridge installation.

(2) Countermeasures: (a) Enhance product manuals, labels, and warning information to ensure clarity; (b) Collaborate with hospitals to provide comprehensive training for medical professionals on the device's operation.

4.2.4. Technological risk

(1) Factors: (a) Rapid innovation cycles in the industry; (b) High costs associated with new product development; (c) Extended research and development periods.

(2) Countermeasures: (a) Monitor domestic and international trends closely and establish robust technological collaborations with universities; (b) Strengthen the company's R&D center to cultivate in-house innovation capabilities [19].

4.2.5. Financial risk

(1) Factors: (a) Potential increases in low current interest rates, leading to higher financial expenses; (b) Changes in preferential fiscal and tax policies that may affect net profits; (c) Potential bad debts from accounts receivable, impacting cash flow and operations.

(2) Countermeasures: (a) Interest rate sensitivity is minimized by using a higher assumed borrowing rate of 8% in financial calculations, compared to the current one-year rate of 4.75%; (b) A conservative tax rate of 33% is applied in profit projections, ensuring that changes in preferential policies do not affect

calculations; (c) Hospitals, the primary sales channel, typically operate with a payment period of three to six months, reducing the likelihood of bad debts. Additionally, the company maintains adequate cash flow to sustain operations under financial strain.

4.2.6. Market risk

(1) Factors: (a) Market irregularities, counterfeit activities, and unregulated operations in hospital procurement processes; (b) Risk of reverse engineering by potential industry entrants within two to three years [20].

(2) Countermeasures: (a) Pursue recognition as a "Famous Brand Product" by the Jiangsu provincial government and enhance intellectual property protections. Collaborate with government entities to establish a well-regulated market environment; (b) Build a strong brand and corporate image through strategic public relations activities. Strengthen brand loyalty among medical professionals, develop upgraded and alternative products, and foster core competencies to enhance market competitiveness.

Disclosure statement

The author declares no conflict of interest.

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