TAKHOSUS SPINE

Feasibility Study Prepared By Haroon F. Choudhri, MD, FAANS



HIGH TECH MEDICAL MANUFACTURING

An experienced team of Spine Professionals joining to develop a world class line of Spinal Implants.

There is a need for high-quality implants that are manufactured within the GCC.

We intend to manufacture an existing product line with many years of clinical success to reduce GCC import costs, create jobs, increase local manufacturing revenue generation, and boost economic multiplier effects.





Executive Summary



Products

Takhosus Spine is a brand new venture which will manufacture a full range of implants and instruments for use in spinal surgery.

Implants will be manufactured from a variety of materials including titanium, stainless steel, and PEEK (Poly-Ether-Ether-Ketone).

Implants are made to be used in a wide range of spinal surgeries in all areas of the spine.

Customers

The target audience for Takhosus Spine are spine surgeons and hospitals/clinics that perform spinal surgeries.

Our product line will include plates, screws and interbody cages of the highest quality and design for use in the Cervical, Thoracic and Lumbar spine regions from Anterior, Posterior and Lateral approaches.

Future of Company

Although the spinal implant manufacturing business is highly competitive, we are confident that there is a need for high-quality implants that are manufactured within the GCC.

We intend to use an existing product line with many years of clinical success to enhance it with recently patented designs and to incorporate the input from regional key opinion leaders.

Mission Statement & Legal Structure



Mission Statement

Takhosus Spine aims to revolutionize the field of spine surgery by offering innovative and superior products.

The company's mission is to leverage the extensive knowledge and experience of our leadership team to manufacture the highest quality spine surgical implants and instruments which will provide surgeons with state-of-the-art implants that improve patient outcomes, reduce postoperative complications, and increase surgeons' procedural efficiency.

Legal Structure

Takhosus Spine is a Limited Partnership (LP).

Principal Members





Haroon F. Choudhri, MD, FAANS

CEO & Partner Takhosus Spine and Spine Surgeon



Andy Elsbury, MBA, BSME, MSIE

Owner & Partner Takhosus Spine, Founder & President NEXXT Spine



Keith Cunnion

Executive with extensive experience in medical sales & Sales team development leadership



Paul Beckwith

Medical device entrepreneur with vast experience developing manufacturing facilities

MARKET RESEARCH



Market Research: Industry

This project has been developed to meet the important and unfilled need for a comprehensive, top quality, full service spinal implant company within the GCC. Takhosus Spine will accomplish goals of furthering supply chain resilience and reduce the need for import of the growing volume of Spinal Implants consistent with the outlined goals of Vision 2030.

In 2023, MEA spending on spinal implants was \$293,000,000 USD, the majority of which was imported. In addition to creating many jobs and export revenues, the majority of this expenditure can be converted from import costs to local manufacturing revenue generation with its associated tax base and economic multiplier effects.



Market Research: Customers



Spinal implants are ultimately used in patients who will undergo spinal surgery and represent our highest priority. The implants themselves are typically selected by spine surgeons and purchased by hospitals and clinics with reimbursement from insurance companies in many cases.

Understanding this complex array of decision makers and payors while keeping patient outcomes as our highest priority is one of our greatest strengths. All interested parties have important needs and goals, which at times may seem conflicting, that must be carefully balanced to achieve satisfactory results for all.



Market Research: Company Advantages

Takhosus Spine has the following **advantages** versus our competitors:

- World class expertise in 3D printing titanium and CNC machining of titanium and PEEK
- Extensive experience in engineering instruments, implants, and introducing them to market.
- Significant input from Surgeons at the highest levels of company functioning and product design
- Unique Intellectual property and patents
- Strong partnership with a leading US spine manufacturing company: NEXXT Spine







Market Research: Regulations

Takhosus Spine has a complete and tested portfolio of implants at launch which are all FDA approved for use in the United States.





PRODUCT LINES



Product Lines: Anterior Cervical Products







NEXXT MATRIXX[®] Cervical



HONOUR[®] Orb Cervical







STRUXXURE® ACP

Product Lines: Posterior Cervical Products

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SAXXONY® Posterior Cervical Thoracic Fixation System





Cross Connectors



Rod to Rod Connectors



Head to Head Connectors



Offset Connectors

Product Lines: Thoracolumbar Products





Product Lines: Lateral Lumbar





Product Lines: Anterior Lumbar







STRUXXURE[®]-A Plate

NEXXT MATRIXX[®] ALIF

NEXXT MATRIXX[®] SA ALIF

MARKETING AND SALES

Market Research Appendix starts at Slide 28.



Growth Strategy

To grow the company, Takhosus spine will employ the following strategies:

- Seek favorable consideration from Government tenders per GCC regulations and agreements concerning products manufactured within the GCC
- Conduct multiple medical education events and become a partner in surgeon training to extend awareness of our product line
- Leverage our extensive, existing relationships with surgeons in KSA, UAE, Oman and Kuwait
- We will offer state of the art instruments with cost effective alternatives with potential to create custom implant sets as complete offerings for hospital chains and ministries to allow them to realize substantial cost savings and improved workflow with no loss of quality in exchange for sizable purchase volume.



Seek favorable consideration from Government tenders per GCC regulations and agreements concerning products manufactured within the GCC



Substantial synergies for host countries with supply chain resilience, jobs, taxes, and education opportunities

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Growing domestic market for medical devices and spine implants in particular



Our model will heavily incorporate design surgeons from within the region

### **Financial Feasibility**



Takhosus Spine is owned by its principal investors, Haroon F. Choudhri, MD, FAANS & Andy Elsbury BSME, MSIE, MBA. Funds required to start operations and allow for equipment purchase, site procurement in Riyadh, and initial operations will be \$10,000,000 USD.

We currently have \$5,000,000 USD reserved to start the company and anticipate that after securing loans for \$5,000,000 USD for launch, an additional \$15,000,000 USD will be required over the first 5 years to conduct marketing, education and distribution network development as well as to run the factory and cover the labor and material expenses over the first 5 years.

Our experience, funding and intellectual property will position us well for a successful launch. Our conservative financial projections for the first 5 years are presented in **Appendix A**.



### **Financial Feasibility - Competitors**



The spine market is dominated by several large players, however, there remains substantial opportunity for new companies with cutting edge technology and marketing.

In particular, a company based within the GCC with full design and manufacturing capabilities will be able to seek preferred vendor status for government tenders within the GCC.

The spine market is expected to continue to expand and there is no comprehensive spine company manufacturing a full line of implants within the GCC. Detailed market analysis of sales volume for KSA and UAE are available in **Appendices B & C**. Limited Design and Manufacturing Integration

**Stryker**<sup>®</sup> Medtronic Johnson Johnson

#### Full Design and Manufacturing Vertical Integration



### **Financial Feasibility – Competitors**

#### The Orthopaedic Industry Annual Report

Medtronic leveraged improving procedure volumes in the U.S. and implant pull through from its digital ecosystem to offset VBP and currency headwinds. DuPuy Synthes and Stryker fell behind the competition in the enabling technology segment, which hurt their spine performance. Globus Medical surprised many observers by using its plentiful cash reserves to double down on the spine market. The company will have to buck a trend of failed M&A integrations in the segment by meshing two very different cultures.

ATEC dominated the mid-tier spine market with better than 40% growth in 2022. This part of the market also saw consolidation in the merger between Orthofix and SeaSpine. The combined Orthofix organization is still a single-digit market share player in spine,but closed the gap on companies like ATEC and ZimVie. Over the next five years, ZimVie is likely to take a few steps back as it exists unprofitable geographies and rationalizes its portfolio. The company plans to use its legacy fusion business to fuel growth in areas such as motion preservation and minimally invasive surgery.



### Financial Feasibility – Market

The Orthopaedic Industry Annual Report

Exhibit 61: Spine Sales Trajectory – 2017 to 2026 (\$Millions)



We project that the global spine market will grow to \$10 billion in 2023, as its growth accelerates slightly to +2.2%. We expect an expanding patient population and adoption of new treatment options to drive the market to \$10.9 billion by 2025.

### **Technical Feasibility**

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Our team possesses extensive knowledge about all aspects of the Spinal Implant business. Starting with theoretical principles and design, our team has developed a wide range of spine surgical implants and instruments and hold numerous patents and other intellectual property in this space.

In terms of manufacturing, we have designed and developed multiple factories and utilized a full range of manufacturing instruments from lathes to milling to anodization with a special expertise as a global leader in the latest technology of 3-D printing using titanium. We have experience with quality control testing, post-processing, packaging, graphic design and order fulfillment.

Our International sales expertise is wide ranging and led by a highly experienced team. Finally, our surgeon partners have a strong track record of thousands of successful surgeries with spine implants from around the world.

| (12) | Choudhri                                                                                                                                                                                                                                                                                                                                                                                            | (10) Patent No.: US 11,759,324 B2<br>(45) Date of Patent: Sep. 19, 2023                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |  |  |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| (54) | INTERVERTEBRAL IMPLANTS HAVING<br>POSITIONING GROOVES AND KITS AND                                                                                                                                                                                                                                                                                                                                  | (56) References Cited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |  |  |
|      | METHODS OF USE THEREOF                                                                                                                                                                                                                                                                                                                                                                              | U.S. PATENT DOCUMENTS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |  |  |
| (71) | Applicant: Haroon Fiaz Choudhri Alpine NI                                                                                                                                                                                                                                                                                                                                                           | 6,261,296 B1* 7/2001 Aebi A61B 17/025                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |  |  |
|      | (US)                                                                                                                                                                                                                                                                                                                                                                                                | 7,303,583 B1* 12/2007 Schar A61F 2/442                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  |  |  |
| (72) | Jacometers - Hanson Flor Chaudhal Alaine MI                                                                                                                                                                                                                                                                                                                                                         | 2002/0116009 A1* 8/2002 Fraser A61B 17/025                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |  |
| (72) | (US)                                                                                                                                                                                                                                                                                                                                                                                                | 606/99<br>2004/0122518 A1* 6/2004 Rhoda A61F 2/4611                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |  |  |
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| (*)  | Notice: Subject to any disclaimer, the term of this<br>patent is extended or adjusted under 35                                                                                                                                                                                                                                                                                                      | 623/17.11<br>2005/0216084 A1* 9/2005 Fleischmann A61F 2/4611                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |
|      | U.S.C. 154(b) by 148 days.                                                                                                                                                                                                                                                                                                                                                                          | 623/17.11<br>2006/0235520 A1* 10/2006 Pages A61B 17/025                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |  |  |
| (21) | Appl. No.: 17/462.117                                                                                                                                                                                                                                                                                                                                                                               | 2008/0206508 AL* 12/2008 Mancon AGLE 2/447                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |  |
|      |                                                                                                                                                                                                                                                                                                                                                                                                     | 62/23/23/2<br>62/23/23/2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |  |  |
| (22) | Filed: Aug. 31, 2021                                                                                                                                                                                                                                                                                                                                                                                | 2011/0082552 A1* 4/2011 Wistrom A61F 2/4425<br>623/17.16                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |  |  |
| (65) | Prior Publication Data                                                                                                                                                                                                                                                                                                                                                                              | 2012/0116513 A1* 5/2012 Carpenter A61F 2/4611<br>623/17.16                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |  |
|      | US 2023/0068626 A1 Mar. 2, 2023                                                                                                                                                                                                                                                                                                                                                                     | 2014/0100657 A1* 4/2014 McCormack A61B 17/1735<br>623/17.11                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |  |  |
|      |                                                                                                                                                                                                                                                                                                                                                                                                     | 2017/0079805 A1* 3/2017 Costabile A61F 2/447                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |
| (51) | Int. Cl. (200( 01)                                                                                                                                                                                                                                                                                                                                                                                  | * cited by examiner                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |  |  |
|      | A61F 2/44 (2006.01)<br>A61F 2/46 (2006.01)                                                                                                                                                                                                                                                                                                                                                          | Primary Examiner — Matthew J Lawson<br>(74) Attorney Agent or Firm —                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |  |
|      | A61F 2/30 (2006.01)                                                                                                                                                                                                                                                                                                                                                                                 | THOMASIHORSTEMEYER, LLP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |  |  |
| (58) | <ul> <li>(2013.01); A61F 2/42 (2013.01); K61F</li> <li>22455 (2013.01); K61F 2/4411 (2013.01);</li> <li>K61F 2002/3008 (2013.01); A61F 2002/3012;</li> <li>(2013.01); K61F 2002/3013;</li> <li>2002/30593 (2013.01); A61F 2002/30138;</li> <li>(2013.01); A61F 2002/3013;</li> <li>(2013.01); K61F 2/423; K61F 2/445; K61F 2/445;</li> <li>K61F 2/441;</li> <li>K61F 2/445]; K61F 2/445;</li> </ul> | incring spinal implants are provided. The implants can be<br>implanted inn intervented spectra between adjusted sup-<br>rior and inferior vertebrae. The implant includes a superior<br>implant startification baving one or more superior positioning<br>grouves configured to receive a corresponding superior<br>positioning and land interior implant archice having one or<br>more inferior positioning grooves configured to receive a<br>corresponding inferior positioning rail when the implant is<br>implanted in the intervertibut space. |  |  |  |
|      | See application file for complete search history.                                                                                                                                                                                                                                                                                                                                                   | 30 Claims, 12 Drawing Sheets                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |
|      |                                                                                                                                                                                                                                                                                                                                                                                                     | 1300                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |  |
|      |                                                                                                                                                                                                                                                                                                                                                                                                     | 1310<br>1310<br>1310                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |  |

### **Expertise in Robotics**



Our team has extensive experience with automated manufacturing processes and incorporation of robotic technology in instrument production.

With our substantial experience using robots and navigation technology during spine surgery, we plan to partner with other experts to develop our own surgical robotic platform in the future.



# TAKHOSUS NEEDS



### **Equipment Needs (Multiple of Each)**

- Citizen L20
- Citizen M20
- Citizen M32
- Willemin 408MT-FULL 5-Axis
- HASS UMC-1 5-Axis
- MLAB 3D Printer
- EOS 3D Printer
- Automated and Hand Blasters

- Laser Marking
- De-ionize System
- Air Filtration System
- Air Conditioning
- Anodization Line
- Passivation Line
- Air Compressor
- Laser Welding Machine

- CMM
- CONTRACER
- Stress Testing Station
- Optical Comparators
- Machine Shop Quality Gauges

More detail in **Appendix D** 

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### **Property and Plant**

- 3+ Acres of Land
- 40,000 sqft building
- Cement Floors Rated for Precision Machining
- Proximity to Airport and Strong Work Force
- AMPLE Amps of Power
- Air Purification System
- Loading Dock Access
- Water Treatment System
- Parking



### **Personnel Needs**





# APPENDICES



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#### Income Statement

|                           | Year 1        |                 | Year 2        |                 | Year 3        |                 | Year 4        |                 | Year 5        |                 |  |
|---------------------------|---------------|-----------------|---------------|-----------------|---------------|-----------------|---------------|-----------------|---------------|-----------------|--|
| Revenue                   | Avg Per Unit  | Total           |  |
| Volume/ Procedures        | 4,0           | 4,000           |               | 8,000           |               | 12,000          |               | 16,000          |               | 20,000          |  |
| Gross Revenue             | \$1,000.00    | \$4,000,000     | \$1,000.00    | \$8,000,000     | \$1,000.00    | \$12,000,000    | \$1,000.00    | \$16,000,000    | \$1,000.00    | \$20,000,000    |  |
| -Discounts                | 0.00          | <u>\$0</u>      |  |
| Net Revenue               | \$1,000.00    | \$4,000,000     | \$1,000.00    | \$8,000,000     | \$1,000.00    | \$12,000,000    | \$1,000.00    | \$16,000,000    | \$1,000.00    | \$20,000,000    |  |
| Direct Costs              |               |                 |               |                 |               |                 |               |                 |               |                 |  |
| Direct Labor              | \$358.80      | \$1,435,200     | \$179.40      | \$1,435,200     | \$119.60      | \$1,435,200     | \$89.70       | \$1,435,200     | \$71.76       | \$1,435,200     |  |
| Raw Material              | \$80.00       | \$320,000       | \$80.00       | \$640,000       | \$80.00       | \$960,000       | \$80.00       | \$1,280,000     | \$80.00       | \$1,600,000     |  |
| Assemble/Pack             | \$10.00       | \$40,000        | \$10.00       | \$80,000        | \$10.00       | \$120,000       | \$10.00       | \$160,000       | \$10.00       | \$200,000       |  |
| Sterilize                 | \$10.00       | \$40,000        | \$10.00       | \$80,000        | \$10.00       | \$120,000       | \$10.00       | \$160,000       | \$10.00       | \$200,000       |  |
| Distribution Costs        | <u>\$1.00</u> | <u>\$4.000</u>  | <u>\$1.00</u> | \$8.000         | <u>\$1.00</u> | <u>\$12.000</u> | <u>\$1.00</u> | <u>\$16.000</u> | <u>\$1.00</u> | \$20.000        |  |
| Subtotal                  | \$459.80      | \$1,839,200     | \$280.40      | \$2,243,200     | \$220.60      | \$2,647,200     | \$190.70      | \$3,051,200     | \$172.76      | \$3,455,200     |  |
| Overhead                  |               |                 |               |                 |               |                 |               |                 |               |                 |  |
| R & D                     | \$0.00        | \$0             | \$0.00        | \$0             | \$0.00        | \$0             | \$0.00        | \$0             | \$0.00        | \$0             |  |
| Product Commercialization | \$12.50       | \$50,000        | \$6.25        | \$50,000        | \$4.17        | \$50,000        | \$3.13        | \$50,000        | \$2.50        | \$50,000        |  |
| Manager Salary            | \$62.50       | \$250,000       | \$31.25       | \$250,000       | \$20.83       | \$250,000       | \$15.63       | \$250,000       | \$12.50       | \$250,000       |  |
| Indirect Salary           | \$200.00      | \$800,000       | \$100.00      | \$800,000       | \$66.67       | \$800,000       | \$50.00       | \$800,000       | \$40.00       | \$800,000       |  |
| Rent/Mortgage             | \$90.00       | \$360,000       | \$45.00       | \$360,000       | \$30.00       | \$360,000       | \$22.50       | \$360,000       | \$18.00       | \$360,000       |  |
| Reps (Or ZB) Commission   | \$125.00      | \$500,000       | \$62.50       | \$500,000       | \$41.67       | \$500,000       | \$31.25       | \$500,000       | \$25.00       | \$500,000       |  |
| Banking                   | \$1.25        | \$5,000         | \$0.63        | \$5,000         | \$0.42        | \$5,000         | \$0.31        | \$5,000         | \$0.25        | \$5,000         |  |
| QuickBooks                | \$0.25        | \$1,000         | \$0.13        | \$1,000         | \$0.08        | \$1,000         | \$0.06        | \$1,000         | \$0.05        | \$1,000         |  |
| ІТ                        | \$5.00        | \$20,000        | \$2.50        | \$20,000        | \$1.67        | \$20,000        | \$1.25        | \$20,000        | \$1.00        | \$20,000        |  |
| Insurance                 | \$2.50        | \$10,000        | \$1.25        | \$10,000        | \$0.83        | \$10,000        | \$0.63        | \$10,000        | \$0.50        | \$10,000        |  |
| Dose Audits               | \$25.00       | \$100,000       | \$12.50       | \$100,000       | \$8.33        | \$100,000       | \$6.25        | \$100,000       | \$5.00        | \$100,000       |  |
| Accounting                | \$5.00        | \$20,000        | \$2.50        | \$20,000        | \$1.67        | \$20,000        | \$1.25        | \$20,000        | \$1.00        | \$20,000        |  |
| Legal                     | \$2.50        | \$10,000        | \$1.25        | \$10,000        | \$0.83        | \$10,000        | \$0.63        | \$10,000        | \$0.50        | \$10,000        |  |
| Shipping                  | \$7.50        | \$30,000        | \$3.75        | \$30,000        | \$2.50        | \$30,000        | \$1.88        | \$30,000        | \$1.50        | \$30,000        |  |
| Regulatory                | \$5.00        | \$20,000        | \$2.50        | \$20,000        | \$1.67        | \$20,000        | \$1.25        | \$20,000        | \$1.00        | \$20,000        |  |
| CAD License               | \$1.88        | \$7,500         | \$0.94        | \$7,500         | \$0.63        | \$7,500         | \$0.47        | \$7,500         | \$0.38        | \$7,500         |  |
| Marketing/Website         | \$25.00       | \$100,000       | \$12.50       | \$100,000       | \$8.33        | \$100,000       | \$6.25        | \$100,000       | \$5.00        | \$100,000       |  |
| Travel                    | \$25.00       | \$100,000       | \$12.50       | \$100,000       | \$8.33        | \$100,000       | \$6.25        | \$100,000       | \$5.00        | \$100,000       |  |
| Miscellaneous             | \$5.00        | <u>\$20.000</u> | \$2.50        | <u>\$20.000</u> | \$1.67        | <u>\$20.000</u> | \$1.25        | <u>\$20.000</u> | \$1.00        | <u>\$20.000</u> |  |
| Subtotal                  | \$600.88      | \$2,403,500     | \$300.44      | \$2,403,500     | \$200.29      | \$2,403,500     | \$150.22      | \$2,403,500     | \$120.18      | \$2,403,500     |  |
| Total Expenses            | \$1,060.68    | \$4,242,700     | \$580.84      | \$4,646,700     | \$420.89      | \$5,050,700     | \$340.92      | \$5,454,700     | \$292.94      | \$5,858,700     |  |
| Net Income                | (\$61)        | (\$242,700)     | \$419         | \$3,353,300     | \$579         | \$6,949,300     | \$659         | \$10,545,300    | \$707         | \$14,141,300    |  |
| Profit Margin             | -6            | 5%              | 4             | 2%              | 5             | 8%              | 6             | 6%              | 719           | 6               |  |

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#### Saudi Arabia Spinal Surgery Devices Market Analysis (1/2)

The Saudi Arabia spinal surgery devices market is expected to register a CAGR of 3.2% over the forecast period, (2022-2027).

The outbreak of COVID-19 in the country has affected the spinal surgery devices market in many ways as it has limited the intensive care unit (ICU) beds and ventilation sites owing to the necessity of postponing elective and/or complex spinal surgeries. For instance, according to the study report titled 'The Saudi Spine Society guidelines on spinal surgery during the COVID-19 pandemic' published in June 2020, the Saudi Spine Society (SSS) Scientific Committee developed a basic protocol in 2020 in which the spine surgery candidates were categorized into category A (immediate), category B (urgent), and category C (elective). All the category A and B surgical procedures were carried out as usual, with only effect on category C (elective) which was strongly recommended to be postponed. Due to the postponement of surgeries the spinal surgery devices market had a negative impact. Also, the COVID-19 lockdown had a clear impact on the volume and mechanisms of injuries. For instance, as per the study in 2020 titled "The Impact of COVID-19 Lockdown on Injuries in Saudi Arabia: Results From a Level-I Trauma Center" published in July 2021, the ICU admissions were significantly reduced by 57% during the lockdown period in Saudi Arabia. Due to the decrease in the accidents and injuries during the lockdown period, the market was negatively impacted. However, the market is expected to gain traction over the coming years because of declining COVID-19 cases and the resumption of elective surgeries.

#### Saudi Arabia Spinal Surgery Devices Market Analysis (2/2)

The factors such as increasing adoption of minimally invasive spinal surgeries and technological advancements in spinal surgeries are expected to positively impact the market in the forecast period. With recent developments like spinal navigation technology, newer minimally invasive techniques are expected to become available, enabling the integration of emerging technology in spinal surgery devices. Such advances will result in smaller incisions, less trauma to normal tissues, faster healing time, and quicker recovery. For instance, according to the Ministry of Health, Kingdom of Saudi Arabia, Health Activities report 2020, the total surgical interventions in Ministry of Health hospitals were reported as 3,98,188 out of which 6,709 cases are of neurosurgeries. This significant amount of surgical interventions will positively impact the spinal surgery devices market as majority of spinal surgery devices are used during the neurosurgery procedures.

However, the stringent regulatory process for new product approvals and expensive treatment and procedures are the major factors that may restrain the market's growth.

#### Slide 33

#### Saudi Arabia Spinal Surgery Devices Market Trends (1/2)

This section covers the major market trends shaping the Saudi Arabia Spinal Surgery Devices Market according to our research experts:

#### Cervical Fusion Segment is Expected to Dominate the Market Over the Forecast Period

Cervical fusion is one of the common types performed during spinal fusion procedures. Spinal fusion is surgery to permanently connect two or more vertebrae in the spine, and eliminate motion between them. The growth of the cervical fusion segment is mainly attributed to the increasing adoption of minimally invasive surgeries, the rising obese population, and the increase in road accidents in Saudi Arabia.

For instance, according to the Ministry of Health, Kingdom of Saudi Arabia, Statistics and Indicators, the total road accidents in 2020 reported were 25,561. During these accidents majorly spine deformities can be observed which can be resolved through spinal fusion surgeries like cervical fusion. Hence, the demand for spinal surgery devices is expected to raise during the study period through this segment.

Many products available in the market provide conventional, yet effective treatments to patients suffering from lumbar spinal stenosis, along with alternative advanced treatments for decompression spine surgery. The major market players manufacture both anterior and posterior dynamic stabilization devices for the lumbar spine. Several clinical trials for new products are in process, which is likely to drive the growth in the coming future. Furthermore, there have been significant advancements in the field of minimally invasive that contributes toward the market expansion. Hence, the market studied is likely to be impact by the aforementioned factors over the forecast period.

Saudi Arabia Spinal Surgery Devices Market Trends (2/2)

Total Number of Road Traffic Injuries (In Thousands), By Age, Saudi Arabia, 2020



Source: Ministry of Health, Kingdom of Saudi Arabia, 2020



#### Saudi Arabia Spinal Surgery Devices Industry Overview

The spinal surgery devices market is moderately competitive and consists of international players that are operating in Saudi Arabia. Additionally, mid-size to smaller businesses are growing their market presence by offering new technologies with greater usability in response to the increasing technology breakthroughs and product innovations. Some of the major players that are operating in the Saudi Arabia spinal surgery devices market are Globus Medical Inc., Johnson & Johnson Services Inc, Medtronic, NuVasive Inc, Orthofix Holdings Inc, Tina Medix Technologies Int. Co., Baxter, Styker, Medos International SARL and ZimVie.

### Saudi Arabia Spinal Surgery Devices Market Leaders

- 1. Johnson & Johnson
- 2. NuVasive, Inc.
- 3. Medtronic
- 4. Styker
- 5. ZimVie

### Saudi Arabia Spinal Surgery Devices Market News

- In March 2022, Zimmer Biomet Holdings, Inc. completed its spinoff of ZimVie, Zimmer Biomet's former Dental and Spine business. ZimVie is a global life sciences leader in the dental and spine markets that develops, manufactures, and delivers a comprehensive portfolio of products and solutions.
- In September 2021, Medtronic PLC announced the latest additions of Catalyft PL and PL40, Space-D Access System, and Accelerate Graft Delivery System with Grafton DBF to its minimally invasive spine surgery ecosystem.

Source: https://www.mordorintelligence.com/industry-reports/saudi-arabia-spinal-surgery-devices-market

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#### **UAE Spinal Surgery Devices Market Analysis (1/3)**

The United Arab Emirates spinal surgery devices market is expected to register a CAGR of 5.8% during the forecast period.

The COVID-19 pandemic had a significant impact on the country's healthcare systems with significant consequences not only for COVID-19-infected patients but also for others, which resulted in the cancellation of spinal surgeries to manage and reserve resources, and many hospitals experienced a shortage of professionals to assist with these surgeries. For instance, as per an article published by NCBI, in June 2021, about 80% of elective surgical cases were postponed in the country to avoid the spread of coronavirus among the population. This has impacted the demand for spinal surgery devices in the country. However, with the released COVID-19 restrictions, spine surgical procedures have increased which has propelled the demand for surgical devices. Thus, the market has witnessed significant growth after the pandemic and is expected to gain its full potential over the forecast period.

Factors such as the increasing cases of spine injuries and technological advancements in spine surgery are boosting the market growth.

#### **UAE Spinal Surgery Devices Market Analysis (2/3)**

Besides, the incidence of obesity and spinal injuries is increasing as the population with a higher body mass index (BMI) is more vulnerable to spine-related disorders and back pain. The demand for spinal surgeries among obese patients is likely to increase the risk of spinal injuries or deformations which in turn is anticipated to fuel the market growth over the forecast period. For instance, according to an article published in MDPI, in September 2021, it has been observed that non-traumatic spinal cord injuries, such as spinal cord compression, tumor in the spinal cord, inflammatory causes or autoimmune causes, damage from radiation, infection or disruption of blood to the spinal cord, are much more common among the population living in the United Arab Emirates.

Furthermore, minimally invasive spine surgery (MISS) offers an alternative to conventional open surgical techniques for treating a variety of spinal problems, including spinal stenosis, degenerative disc disease, herniated discs, scoliosis, and others. These minimally invasive spine surgeries offer numerous possible benefits such as smaller incisions, less cutting into soft tissues (including ligaments and muscles), outpatient possibilities, reduced post-operative pain, and quicker recovery. Such benefits offered by minimally invasive spine surgery are anticipated to increase its adoption among surgeons, which is expected to augment the market growth over the forecast period.

#### **UAE Spinal Surgery Devices Market Analysis (3/3)**

Moreover, the rising company activities in developing spinal surgery devices are also contributing to the market growth. For instance, in October 2021, NuVasive, Inc. launched Cohere TLIF-O implant and also announced the upcoming launch of the Cohere TLIF-A implant for posterior spine surgery. Also, in January 2022, Auxein Medical launched several orthopedic implants (including spinal implants) and arthroscopy systems at Arab Health. The company's implants and tools empower surgeons in more than 70 countries to carry out minimally invasive surgeries.

Therefore, owing to the factors, such as the high burden of spinal injuries, the diabetic population, and growing product launches, the studied market is anticipated to grow over the forecast period. However, the stringent regulatory process for new product approvals is likely to hinder the growth of spinal surgery devices in the United Arab Emirates over the forecast period.

#### **UAE Spinal Surgery Devices Market Trends (1/3)**

Thoracolumbar Fusion Segment is Expected to Register Significant CAGR Over the Forecast Period in the UAE Spinal Surgery Devices Market

Thoracolumbar fusion is a complex procedure that requires the use of screws that are inserted between the vertebrae to be fused, followed by the placement of bone graft material around the screws. The screws that are used during this operation are made of titanium and are usually placed for a lifetime. It provides an effective treatment option for patients suffering from lumbar spinal stenosis and advanced alternative treatment for decompression spine surgery. The physiological changes in the body of older people and prolonged exposure to risk factors increase the incidence rates of spine disorders, which may require surgical intervention.

#### **UAE Spinal Surgery Devices Market Trends (2/3)**

The thoracolumbar fusion segment is expected to witness significant growth over the forecast period owing to the factors such as the increasing numbers of spinal disorders and the growing geriatric population. Trauma falls, crashes, and traffic accidents are all common causes of spinal fusion injuries. For instance, as per an article published in NCBI, in June 2022, it has been observed that in the United Arab Emirates, a herniated or compressed disc is the most common cause of back pain, accounting for five to twenty cases per 1,000 persons each year. Also, according to the 2022 statistics published by United Nation Population Fund, about 83% of the people living in the United Arab Emirates were aged between 15-64 years, and 2% of the population was aged 65 years and above in 2022. Thus, the high number of spinal disorders cases among the population and aging population who are more prone to develop age-related problems is expected to increase the demand for spinal surgeries due to unstable spine, hence propelling the growth of the segment.

Therefore, due to the aforementioned factors, such as spinal problems and the aging population, the studied segment is expected to grow over the forecast period.

**UAE Spinal Surgery Devices Market Trends (3/3)** 

Projected Population with Diabetes (in Million), United Arab Emirates, 2021-2045







#### Arthroplasty Devices Segment is Expected to Have the Significant Market Share Over the Forecast Period (1/2)

Artificial disc replacement, also known as arthroplasty, is the replacement of a damaged spinal disc with an artificial manufactured disc. An artificial disc is developed to support the vertebrae while maintaining rotation, side-to-side bending, and back-and-forth bending.

The arthroplasty devices segment is expected to grow over the forecast period owing to the factors such as the increasing number of spinal deformities among the population that experience an unstable movement of the lumbar spine or immobilizing a painful vertebral motion.

According to an article published in the Journal of Orthopedic Translation, in September 2022, it has been observed that total disc arthroplasty, or artificial disc replacement, has become more widely used by surgeons to lower the risk of adjacent segment disease (ASD) and intersegmental immobility and it is considered as the viable treatment options for lower cervical spine following fusion (ACDF). In addition, as per the same source, artificial disc arthroplasty was primarily developed to reduce the occurrence of ASD and restore the flexible function of surgically removed intervertebral discs. This has increased the adoption of arthroplasty devices among surgeons and is commonly practiced in clinics. This is anticipated to fuel the segment's growth.

Therefore, due to the aforementioned factors the studied segment is anticipated to grow over the forecast period.

Arthroplasty Devices Segment is Expected to Have the Significant Market Share Over the Forecast Period (2/2)

Estimated Number of Population Aged 65 years or Over (in rate per 1000), by Year, United Arab Emirates, 2020-2050



Source: Sheikh Saud bin Saqr Al Qasimi Foundation, 2022



#### **UAE Spinal Surgery Devices Industry Overview**

The United Arab Emirates spinal surgery devices market is moderately competitive and consists of several major players. Moreover, with increasing technological advancements and product innovations, mid-size to smaller companies are growing their market presence by introducing new technologies with better usability. The key players operating in the market are Medtronic Meta FZ-LLC, Stryker ESCS BV, Johnson & Johnson United Arab Emirates, Karl Storz United Arab Emirates, Fujifilm Middle East FZE, and NuVasive, Inc. among others.

#### **UAE Spinal Surgery Devices Market Leaders**

- 1. Medtronic Meta
- 2. Stryker
- 3. Johnson & Johnson



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### **UAE Spinal Surgery Devices Market News**

- In August 2022, an Emirati neurosurgeon performed a cutting-edge robotic spinal surgery in Abu Dhabi.
- In March 2022, Neuro Spinal Hospital (NSH) inaugurated its new state-of-the-art facility, the robotic Cyberknife radiosurgery center, that offers specialized care for spinal, neurosurgical, neurological, orthopedic, rehabilitation, oncology, and radiosurgery treatments with the most advanced cancer center operating from Dubai Science Park,
- In March 2022, Yas Clinic Group (YCG) conducted the first-ever robotic-assisted spine surgery in the United Arab Emirates.

Source: https://www.mordorintelligence.com/industry-reports/uae-spinal-surgery-devices-market

### **Quality Equipment**

| Quantity | Model               | Description                                 | Cost in Dollars | Total   |
|----------|---------------------|---------------------------------------------|-----------------|---------|
| 2        | VMA-2520            | Nikon Vision System CMM                     | 110,500         | 221,000 |
| 4        | HDV400-CNC -M3-2LED | Starrett Optical Comparitor                 | 35,452          | 141,809 |
| 2        | CV-2100 Series      | Mitutoyo Contracer Contour Measuring System | 65,598          | 131,197 |
| 1        |                     | General Inspection Equipment                | 500,000         | 500,000 |
|          |                     |                                             |                 | 994,005 |

#### Building

| Description             | Total   |
|-------------------------|---------|
| Office Furnature        | 79,526  |
| MFG Floor Racking       | 10,000  |
| MRP software            | 100,000 |
| Environmental Equipment | 30,060  |
| HVAC                    | 70,000  |
| MFG Furniture           | 51,126  |
| IT                      | 121,414 |
|                         | 462,126 |

#### **Engineering Software**

| Brand      | Cost in Dollars |
|------------|-----------------|
| Solidworks | \$40,000        |

#### **APPENDIX D**

#### **Manufacturing Equipment**

| Quantity | Model                        | Description                                               | <b>Cost in Dollars</b> | Total      |
|----------|------------------------------|-----------------------------------------------------------|------------------------|------------|
| 4        | 508MT                        | Willemin Five Axis Mill Turn                              | 750,000                | 3,000,000  |
| 4        | UMC-500SS                    | Hass UMC-1                                                | 150,000                | 600,000    |
| 4        | Mlab 100R                    | 3D Laser Printer MLab1 (LB1)                              | 400,000                | 1,600,000  |
| 2        | M290                         | Eos 3D Printer                                            | 1,000,000              | 2,000,000  |
| 4        | L20E IX                      | CNC Lathe - CITIZEN MODEL L20X CNC                        | 300,000                | 1,200,000  |
| 4        | L32-1M12                     | CNC Lathe - CITIZEN MODEL M32 CNC                         | 500,000                | 2,000,000  |
| 8        | CB105V                       | Citizen Cool Blaster High Pressure Pump                   | 50,224                 | 401,788    |
| 2        | Robocut C400iB               | Fanuc Wire EDM                                            | 150,000                | 300,000    |
| 2        | Pulsar III                   | Clemco hand Blast                                         | 2,000                  | 4,000      |
| 3        | BNP 160 Tumble Basket, 2-gal | Clemco Auto Blast                                         | 3,500                  | 10,500     |
| 2        | 24/BP                        | PEEK Hand Blast Cabinet (Maxiblast)                       | 14,000                 | 28,000     |
| 3        | FMSL22/8                     | Belair TUMBLER-Centrifugal Disc for finishing metal parts | 38,000                 | 114,000    |
| 4        | PRO3216                      | Ultrasonic Cleaning Equipment OWNI1012-40 W / S8 PW       | 34,860                 | 139,438    |
| 2        | Zeta Lase                    | Electrox Laser Etch                                       | 40,000                 | 80,000     |
| 1        |                              | Anodization Line                                          | 10,000                 | 10,000     |
| 1        |                              | Passivation Line                                          | 40,000                 | 40,000     |
| 3        | 502-191-150-4                | Laser Star 502-191-150-4 Laser Welder                     | 40,000                 | 120,000    |
| 1        | SB1049F                      | South Bend Manual Lathe                                   | 15,000                 | 15,000     |
| 1        | LVM-50                       | Sharp Manual Knee Mill                                    | 15,000                 | 15,000     |
| 1        | SG-618                       | Sharp Manual Surface Grinder                              | 15,000                 | 15,000     |
| 3        | KF22.5 RM3                   | Evenheat Heat Treat Oven                                  | 4,000                  | 12,000     |
| 2        | L15-22C                      | Gardner Denver Air Compressor                             | 49,445                 | 98,891     |
| 1        |                              | Mastercam                                                 | 40,000                 | 40,000     |
| 1        |                              | Parishable Tooling and Fixtures                           | 500,000                | 500,000    |
| 1        |                              | Raw Material- Rod, Powder, Plate and PEEK                 | 1,000,000              | 1,000,000  |
| 1        |                              | MFG Support Equipmentand Furniture                        | 198,571                | 198,571    |
|          |                              |                                                           |                        |            |
|          |                              |                                                           |                        | 13,542,188 |

Total including previous: 15,038,319