

在地成功經驗行銷海外市場

國產醫療器材揚名國際

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主要產品

脊椎植入產品、手術器械及其他骨科相關產品。

企業簡介

- 2001年 台灣總公司於大直設立，海外子公司於香港九龍同時成立；並於內湖科學園區籌設GMP工廠。
- 2002年 董事會改組，由賴博雄博士出任董事長。
- 2003年 通過台灣衛生署國產醫療器材優良製造規範(GMP)認可登錄。
- 2004年 通過ISO 9001/ 13485及CE Marking認證，產品項目包括脊椎固定系統、金屬與高分子聚合物椎間盤填充塊、及脊椎手術器械。
- 2005年 榮獲兩項台北生技獎，技術商品化獎(脊椎固定器與融合器)、及創新研發獎(Vessel-X[®])。台灣首家使用Invivio PEEK-Optima[®] 材料之椎間盤融合器在台上市。
- 2006年 榮獲台北生技獎，技術商品化獎(PEEK椎間盤融合器)。與德國Ulrich Medical公司(椎體置換產品)、及英國Biocomposites公司(人工骨產品)簽署台灣總代理合約。
- 2007年 榮獲台北生技獎，技術商品化獎(Vessel-X[®])。成立中國子公司“杰展醫療器材(廈門)有限公司”。
- 2008年 與德國Ulrich Medical公司簽訂脊椎產品之ODM合作協議。
- 2009年 與瑞士TRB CHEMEDICA公司(玻尿酸製劑Viscoseal[®])簽署台灣總代理合約。
- 2010年 脊椎微創產品Vessel-X[®] (治療脊椎椎體壓迫性骨折)上市。
- 2011年 脊椎固定系統SmartLoc[®]獲得美國FDA 510(k)許可。與美中互利(Chindex Medical)公司簽署中國地區總代理合約。
- 2012年 新產品AVALON[®] Kyphoplasty System上市。玻尿酸製劑Viscoseal[®] 產品取得衛生署核可上市。

國際競爭力

- 一、本公司產品涵蓋脊椎固定所需之全系列頸椎及胸腰椎產品，特色為「產品組件簡單、手術時間縮短、減少病患疼痛、達到最佳之療效」，產品質量足可與國際大廠相抗衡。
- 二、產品除自行研發外，並與國內外各大教學醫院及研究單位合作，讓產品開發與國際接軌，已取得40餘項產品專利，上市產品具有相當之國際競爭力。
- 三、以「A-SPINE」自有品牌行銷國內外，多年來積極拓展國際業務及參與國際知名的脊椎醫學會，包括NASS、EuroSpine、COA、及海外地區性的脊椎醫學會，品牌已具國際知名度。
- 四、近年來陸續取得歐盟CE、美國FDA、中國、泰國、澳大利亞、伊朗...等國家的產品銷售許可；台灣市場佔有率約在20%以上，藉由台灣成功經驗，海外行銷觸角已達二十餘個國家。
- 五、自行開發之脊椎系列產品獲德國百年骨科公司的青睞，取得該公司ODM合約，上市幾年來該合作產品已行銷全世界數十個國家及地區。



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Business Items

Spine Implants, instruments, and other orthopedics related products

Company Introduction

- 2001 A-Spine Asia Co., Ltd. (ASA) is founded and the GMP plant construction at NeiHu Technology Park begins. Subsidiary "A-Spine International Co., Ltd. is established in Hong Kong.
- 2002 The Board of A-Spine, Inc. entrusts President Life Sciences to restructure ASA and install both new board and new management team.
- 2003 Receives cGMP certification for its manufacturing plant from the DOH of Taiwan.
- 2004 Receives ISO 9001, ISO 13485 and CE Marking approvals for spine fixation system, metal and polymer disc spacers and instruments for spine surgeries.
- 2005 Awarded two Taipei Biotech Awards for Innovative Technology (Vessel-X[®]) and Technology Commercialization (Spinal Fixation Systems and Spinal Cages); launches the interbody fusion cages made from PEEK-Optima[®] Invivio.
- 2006 Awarded the Taipei Biotech Award for Technology Commercialization (PEEK cages); enters into exclusive distribution agreements with the Ulrich Medical of Germany for spine products and with the Biocomposites of UK for bone graft products.
- 2007 Awarded the Taipei Biotech Award for Technology Commercialization (Vessel-X[®]); establishes its China subsidiary operation, the Jiezhuan Medical (Xiamen) Co., Ltd. in Fujian, China.
- 2008 Enters into a partnership agreement with the Ulrich Medical of Germany for production of spine products; awarded an SBIR for innovative product development.
- 2009 Enters into an exclusive distribution agreement with the TRB CHEMEDICA of Switzerland for distributing Viscoseal[®], a sodium hyaluronate preparation, in Taiwan; receives the Partnership Award 2009 from Ulrich Medical.
- 2010 Launches Vessel-X[®] in Taiwan for addressing the VCF market.
- 2011 ASA is restructured in a management buyout deal reached with President Life Sciences; Dr. Por Lai is elected as the Chairman; receives US FDA 510(k) clearance for Smartloc[®], the Advanced Spinal Fixation System; enters into a distribution agreement with the Chindex Medical Ltd. of Shanghai for exclusive distribution of ASA's spine products in China.
- 2012 Launches Avalon[®] Kyphoplasty Kit for treating VCF in ex-Taiwan territories; launches Viscoseal[®] for synovial fluid replacement after arthroscopy in Taiwan.



Export Competitiveness

- I. As the leading domestic orthopedics company in spine implants field in Taiwan, ASA has achieved the brand status for its quality spine implant products. This brand status significantly enhances ASA's export competitiveness. This competitiveness is further supported by ASA's internationally-aligned clinical and regulatory capabilities as evidenced by ASA's 60+ product licenses received from a number of regulatory agencies such as Taiwan, US, EU and China.
- II. The quality of ASA's spine implant products is indicated by the fact that these market-tested products have been in clinical uses for years by most of the domestic surgeons in Taiwan and by many international surgeons in seventeen countries. ASA's professional service team further assures the clinical utilities of the company's quality products.
- III. ASA accomplishes its innovation goals through in-house R&D and close collaborations with clinicians in the field. Such efforts have resulted in building a unique proprietary position of owning 40+ issued patents and 10+ pending ones by ASA. However, as a relatively small scale operation, ASA realizes its challenges and needs for effective partnering with academic, medical and industrial sectors as well as supports from government.
- IV. ASA's export competitiveness could not be materialized without its competent senior management team which shows more than 120 collective years of experience in international business conducts.

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營運管理

- 一、公司營運目標及績效透過董事會的定期召開與監督，由經營團隊執行，並遵循政府法令及公司治理的規範誠信運行。
- 二、「鞏固本土市佔、穩健耕耘中國、積極行銷國際、擴大代工合作」為營運策略的四大主軸；「提昇產品品質、強化研發能力、不斷推出創新產品、及有效降低成本」以維持國際競爭優勢。
- 三、人力資源管理首重「企業永續經營、人才為本」，秉持持續投資員工的承諾，建立完善的福利制度及明訂員工分紅制度，期以激勵員工。
- 四、營運管理系統導入ERP系統、人力資源管理系統、專案管理系統等，使用軟體採用合法正版，逐步朝無紙化的目標努力。
- 五、整體營運藉由完整的外部規範（GMP、ISO）及內部制度的運作，及透過具公信力的會計師事務所（PwC）進行查核簽證，讓公司營收成長率及純益率得以持續及效率地朝10%以上的目標成長，達到股東、董事會、員工、社會責任等多贏的目標。

企業特色

- 一、秉持以「創新研發及品質優先」為營運之主要理念，專注於脊椎相關產品之研發、設計、生產及銷售，為台灣首家以脊椎產品開發為主的中小企業。
- 二、以「研製自有專利技術產品、建構國際行銷網絡為優先，結合國內優質機械加工廠商做後盾，品質以嚴格後製程處理、落實100%品管為上市標準」為公司經營模式及投入方向。
- 三、公司治理及管理制度朝上市櫃公司之難型及水平運作，人力資源採取「精簡、精實」策略，具中小企業之「創新求變、機動彈性」利基。
- 四、持續與各大教學醫院、研究中心、及知名骨科醫師合作，指派研發人員參與國際性脊椎醫學會，先期掌握全球市場產品發展趨勢，以開發出更多高科技醫療產品，回饋國人，造福人群。
- 五、公司獲利員工同享，開發優質產品及擴大國際行銷以提升台灣國際競爭力，持續提供醫材救助弱勢病患及投入社會捐助，以善盡中小企業社會責任。

綜合評語

- 一、積極擴展海外市場，產品行銷20多國，外銷比重上升，營收穩定成長，產品自有品牌獲得美國FDA上市許可，另取得德國百年骨科公司認可並獲得ODM合約，產品頗具國際競爭力。
- 二、產品研發具特色，不僅取得GMP認可，亦符合ISO 9001、ISO 13485認證，並通過歐盟CE認證，除自行研發外，亦與國內外醫院合作，以確實掌握國際趨勢與客戶需求。
- 三、導入人力資源管理及專案管理系統，以提升經營管理成效，生產作業管理於內湖科學園區建立GMP工廠做為生產基地，並且依循衛生署國內GMP與ISO作為品質目標，歷年來均通過衛生署三年一度的查廠及ISO年度查核。
- 四、在企業特色方面，公司規模小，同時人資配置上採精簡策略，平均每位員工年產值約新臺幣800萬元、純益率也達到10%以上，相較於同業，其績效確實較為突出。



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Operation Management

- I. ASA continues to evolve and improve with respect to operation management. This is evidenced by its compliance with the most strict corporate governance requirements in accordance with the mandate by its Board and the direction under its management team. Its annual reports have been audited for years by the prominent firm, PWC Taiwan. Accountability, efficiency, effectiveness and transparency are the prime operation principles observed by the company.
- II. One significant result of continuing search for efficiency and effectiveness at ASA is its improvements made with gross and net profit margins in recent years amid an adverse domestic market atmosphere. The accountability of ASA's Board of Directors to its shareholders is to assure efficiency, effectiveness and transparency at ASA.
- III. ASA relies on its people to carry out business and generate profits from operations. ASA continues to invest in its people in key areas including administration, business and techniques. As required by cGMP and ISO measures, the company also routinely conducts series of training courses to ensure well preparedness of its employees.

Enterprise Characteristics

- I. At the completion of the 2011 management buyout deal, many ASA employees are now also shareholders. This has provided a great opportunity for ASA to deliver anticipated results through its incentive-based approaches to optimizing business operation and maintaining competitiveness.
- II. Medical technology industry is an innovation-driven and a highly regulated industry. ASA devotes significant efforts to assess market needs and to maintain current awareness of continuously evolving clinical and regulatory environment in order to assure its customers and shareholders of competitive products of reliable quality.
- III. Medical technology industry is committed to prudently serve medical community and patients. ASA continues to invest in its people to ensure such commitment, in particular, to develop competent teams with desired coordinating and integrating skills for working closely with the clinical community in order to translate clinical ideas into working products and services.

