



# 科妍生物科技股份有限公司

## SciVision Biotech Inc.

### 106年度法人說明會

研發部 專案經理  
陳俊彰 博士

# 免責聲明

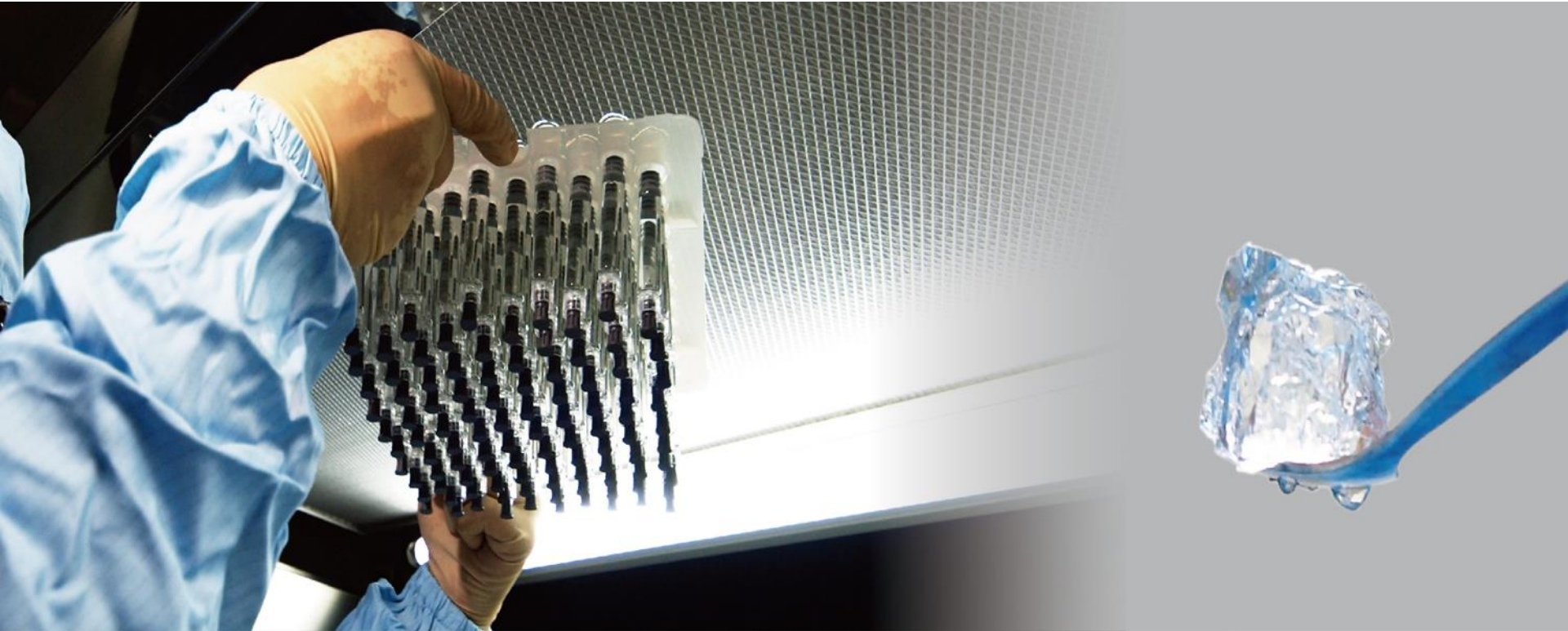
本簡報及同時發佈之相關訊息所提及之預測性資訊包括營運展望、財務狀況以及業務預測等內容，乃是建立在本公司從內部與外部來源所取得的資訊基礎。本公司未來實際所可能發生的營運結果、財務狀況以及業務成果，可能與這些明示或暗示的預測性資訊有所差異。其原因可能來自於各種因素，包括但不限於價格波動、競爭情勢、國際經濟狀況、匯率波動、市場需求以及其他本公司無法掌控之風險等因素。

本簡報中對未來的展望，反應本公司截至目前為止對於未來的看法。對於這些看法，未來若有任何變更或調整時，本公司並不負責隨時再度提醒或更新。

# 簡報大綱

1. 公司與產品介紹
2. 營運現況

科妍生物科技股份有限公司  
SciVision Biotech Inc.



透明質酸技術的領導者

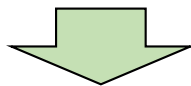
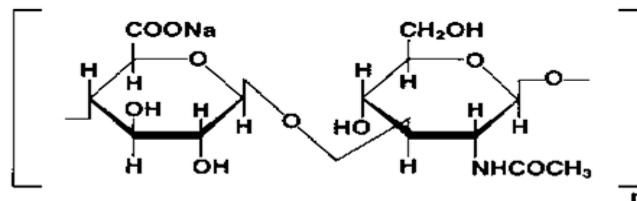
*The Leading Technology  
of Hyaluronic Acid ~*

# 科技生研

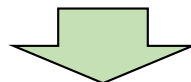


- 2001年11月12日創立
- 2013年11月12日臺灣證交所掛牌上市(股票代號1786)
- 公司定位為**專業醫藥級透明質酸研發製造公司**
- 位於臺灣高雄市前鎮區高雄加工出口區南一路1號與南六路9號
- 工廠樓地板面積19,781.85平方米(5,984坪)
- 工廠及制程設備均符合醫療器材品質管制系統標準(ISO 13485)、優良製造規範(cGMP)、美國食品藥物管理局(US FDA)及國際醫藥品稽查協約組織(PIC/s GMP)等之規範。
- 醫療器材產品(包含皮下填補劑、關節腔注射劑、可吸收防沾黏凝膠)  
年產能1,200萬支針劑

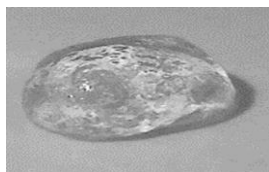
# 核心技術



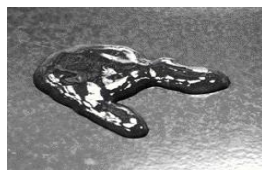
## 透明質酸交聯平臺專利技術 (Crosslinked Hyaluronic Acid Platform, CHAP<sup>®</sup>)



應用CHAP技術可做成各種  
型態及應用範疇之產品



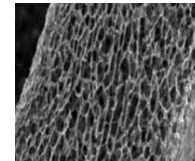
可吸收防  
沾黏凝膠



一針劑型關  
節腔注射劑



皮下填  
補劑



其他新型運用範疇產品

# 發明專利

## 發明專利說明書 公告本

(19) 中华人民共和国国家知识产权局



(12) 发明专利

(10) 授权公告号 CN 101724164 B  
(45) 授权公告日 2011.12.14

(21) 申请号 200810172328.6 1-5.  
(22) 申请日 2008.10.31 审查员 张娜  
(73) 专利权人 科妍生物科技股份有限公司  
地址 中国台湾高雄市  
(72) 发明人 陈拓成 陈丽凤  
(74) 专利代理机构 北京律盟知识产权代理有限公司  
责任公司 11287  
代理人 刘国伟

(51) Int. Cl.  
C08J 3/24 (2006.01)  
C08L 5/08 (2006.01)  
C08L 5/1515 (2006.01)  
(56) 对比文件  
CN 101244290 A, 2008.08.20, 权利要求  
1-5.  
CN 1774272 A, 2006.05.17, 全文。  
CN 101153061 A, 2008.04.02, 全文。  
US 2007/0026070 A1, 2007.02.01, 权利要求  
36-38.  
CN 101244290 A, 2008.08.20, 权利要求

权利要求书 1 页 说明书 12 页

(54) 发明名称  
交联透明质酸的制造方法  
(57) 摘要

本发明涉及一种制造交联透明质酸的方法，其包含在约 10℃ 至约 30℃ 的低温下使包含透明质酸的溶液进行交联反应超过约 18 小时，本发明的方法不需纯化步骤即可降低交联剂的含量。

(本说明书记载之序及标题等，请勿任意更改，※记载部分请勿填写)

※ 申请案号: 97136520  
※ 申请日期: 97.09.23  
IPC 分类: C08B  
C08J3/24 (2006.01)  
C08L5/08 (2006.01)

一、发明名称: (中文/英文)

交联透明质酸之製造方法

METHOD FOR PRODUCING CROSS-LINKED HYALURONIC ACID

二、申请人: (共 1 人)

姓名或名称: (中文/英文)

科妍生物科技股份有限公司  
SCIVISION BIOTECH INC.

代表人: (中文/英文)

韓開程  
HAN, KAI-CHENG

住居所或營業所地址: (中文/英文)

高雄市 806 前鎮區 高雄出口工業區 南六路 9 號  
9, SOUTH 6TH RD., K.E.P.Z., TAIWAN, R.O.C.

國籍: (中文/英文)

中華民國 R.O.C.

(18) 日本國際特許 (IP) (12) 特許公報 (32) (11) 特許案號

(46) 特許日 平成 25 年 11 月 13 日 (2013.11.13) (44) 登錄日 平成 25 年 8 月 16 日 (2013.8.16) 特許第 5340093 号 (P5340093)

(61) 附圖: COB 37/08 (2008.01) F1 COB B 37/08 Z

(62) 發明人: 陳拓成 (2008.10.31) 陳麗鳳 (2008.10.31)

(73) 專利權人: 科妍生物科技股份有限公司 (2008.10.31) 台灣高雄市前鎮區高雄出口工業區南六路 9 號

(72) 發明人: 陳拓成 (2008.10.31) 陳麗鳳 (2008.10.31)

(74) 專利代理人: 謝志強 (2008.10.31) 謝志強 (2008.10.31)

(51) 國際分類: C08J 3/24 (2006.01) C08L 5/08 (2006.01) C08L 5/1515 (2006.01)

(52) 國際分類: C08J 3/24 (2006.01) C08L 5/08 (2006.01) C08L 5/1515 (2006.01)

(53) 優先權案號: 97136520 (2008.09.23) 97136520 (2008.09.23)

(54) 發明名稱: 交聯透明質酸之製造方法

(57) 摘要: 本發明涉及一種製造交聯透明質酸的方法，其包含在約 10℃ 至約 30℃ 的低温下使包含透明質酸的溶液進行交聯反應超過約 18 小時，本發明的方法不需純化步驟即可降低交聯劑的含量。

(73) 專利權人: 科妍生物科技股份有限公司 (2008.10.31) 台灣高雄市前鎮區高雄出口工業區南六路 9 號

(72) 發明人: 陳拓成 (2008.10.31) 陳麗鳳 (2008.10.31)

(74) 專利代理人: 謝志強 (2008.10.31) 謝志強 (2008.10.31)

(51) 國際分類: C08J 3/24 (2006.01) C08L 5/08 (2006.01) C08L 5/1515 (2006.01)

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(72) 發明人: 陳拓成 (2008.10.31) 陳麗鳳 (2008.10.31)

(74) 專利代理人: 謝志強 (2008.10.31) 謝志強 (2008.10.31)

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(52) 國際分類: C08J 3/24 (2006.01) C08L 5/08 (2006.01) C08L 5/1515 (2006.01)

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(74) 專利代理人: 謝志強 (2008.10.31) 謝志強 (2008.10.31)

中國



(12) United States Patent  
Chen et al.

(16) Patent No.: US 9,371,402 B2  
(45) Date of Patent: Jun. 21, 2016

(54) METHOD FOR PRODUCING CROSS-LINKED HYALURONIC ACID

(75) Inventors: Tor-Chern Chen, Kaohsiung (TW); Li-Su Chen, Kaohsiung (TW)

(73) Assignee: SCIVISION BIOTECH INC., K.E.P.Z. (TW)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 351 days.

(21) Appl. No.: 13916449

(22) Filed: Dec. 12, 2011

(56) Prior Publication Data  
US 2012/0005206 A1 Apr. 19, 2012

Related U.S. Application Data  
(63) Continuation-in-part of application No. 12/385,502, filed on Apr. 9, 2009, now abandoned.

(51) Int. Cl. C08B 37/08 (2006.01)

(52) U.S. Cl. CPC: C08B 37/08 (2013.01)

(58) Field of Classification Search  
CPC: C08B 37/08 (2013.01); A61K 8/73; A61K 31/715

See application file for complete search history.  
(56) References Cited  
U.S. PATENT DOCUMENTS

Int'l. A. & Fushikami, G. H. (2005). The science of hyaluronic acid dermal fillers. *Journal of Cosmetic and Laser Therapy*, 10(1), 35-42.

U.S. 8,868,070, 9/19/08, Mono-Gain (withdrawn); Y. Takita et al., Hydrolytic degradation of hyaluronic acid, *Polymer Degradation and Stability*, 1995, pp. 269-275, vol. 68.

Hiro, J.C.F. Nishi et al., A Spectrofluorometric Procedure for the Determination of Aliphatic Epoxide under Physiological Conditions, *Analytical Biochemistry*, 1981, pp. 153-157, vol. 111.

European Search Report for 09045043.8-2115, which is a corresponding application, that cites US 2002/0497931, and U.S. Pat. No. 4,766,154, EP 1810344, US 2000/240137, EP 0970906, Jinghua et al., Characteristics of hyaluronic acid derivative films cross-linked by polyethylene glycol of low water content, *Journal of Medical College of PLA, Shanghai, CN, Feb. 1, 2009, pp. 15-15, No. 1.*

and Tomihata K. et al., Preparation of cross-linked hyaluronic acid film of low water content, *Biomaterials*, Feb. 1, 1997, pp. 189-195, vol. 18, No. 3.

European Office Action for 09045043.8-2115, which is a corresponding European application.

Chinese Office Action dated Jan. 30, 2011 for 200810172328.6, which is a corresponding Chinese application, that cites CN 101244290, and US 2007/0026070.

Chinese Office Action dated Jul. 1, 2011 for 200810172328.6, which is a corresponding Chinese application.

Jinghua et al., Characteristics of hyaluronic acid derivative films cross-linked by polyethylene glycol of low water content, *Journal of Medical College of PLA, Shanghai, CN, Feb. 1, 2009, pp. 15-15, vol. 23, No. 1.*

Tomihata K. et al., Preparation of cross-linked hyaluronic acid film of low water content, *Biomaterials*, Feb. 1, 1997, pp. 189-195, vol. 18, No. 3.

Office Action issued on Oct. 23, 2012 of the corresponding JP patent application No. 2009-219164 (cite WO 2006/011950, JP 60-210101, JP 1007-02092, and JP 1002-13049).

English abstract of Office Action issued on Oct. 23, 2012 of the corresponding JP patent application No. 2009-219164.

臺灣

日本



(12) EUROPEAN PATENT APPLICATION

(43) Date of publication: 06.10.2010 Bulletin 2010/40

(21) Application number: 09004561.8

(22) Date of filing: 30.03.2009

(84) Designated Contracting States:  
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR  
HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL  
PT RO SE SI SK TR  
Designated Extension States:  
AL BA RS

(71) Applicant: Scivision Biotech Inc.  
Kaohsiung Export Processing Zone  
Gianzhen D Kaohsiung (TW)

(54) Method for producing cross-linked hyaluronic acid

(57) A method for producing cross-linked hyaluronic acid comprising cross-linking one or more polymers at a low temperature from 10 to 30 °C for a reaction time greater than 48 hours under basic condition with a cross-linking agent to form a cross-linked hyaluronic acid, wherein the polymer is selected from the group consisting of hy-

(51) Int. Cl. C08B 37/08 (2006.01) C08L 5/08 (2006.01)

(72) Inventors:  
• Chen, Tor-Chern  
Pingting City  
Pingting (TW)  
• Chen, Li-Su  
Nanzi District (TW)

(74) Representative: Hauck Patent- und Rechtsanwälte  
Neuer Wall 50  
20354 Hamburg (DE)

aluronic acid, hyaluronate, a cross-linking agent and a mixture thereof. Whereby, a derivatives thereof in a product of the method is decreased so the product does not require purification.

歐盟

美國

# 科研與國際大廠策略結盟



雀巢®



Nestlé®



*Felixida*



曜亞國際股份有限公司  
DYNAMIC MEDICAL TECHNOLOGIES INC.





# 科妍上市產品

## Osteoarthritis Improvement

- Improvement of cartilage cell metabolism
- Inhibition of inflammation
- Promotion of synovial fluid biosynthesis



### SciVision Biotech Inc.

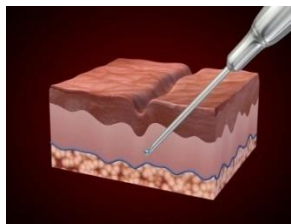
9, South 6th Rd., K.E.P.Z., Kaohsiung, 80681, Taiwan, R.O.C.  
<http://www.scivisionbiotech.com>  
service@scivision.com.tw

TEL: +886-7-823-2258  
FAX: +886-7-823-2295



## 老年照護

-關節腔注射劑



## 整形美容

-皮下填補劑



## 手術外科

-可吸收防沾黏凝膠

# 科妍產品的機會與潛力

全球市值  
13億美元  
(2016年)



透明質酸皮下填補產品  
年複合成長率12%

全球市值  
25億美元  
(2016年)



關節腔注射產品  
年複合成長率7.5%

全球市值  
24億美元  
(2016年)



防沾黏產品  
年複合成長率8.9%

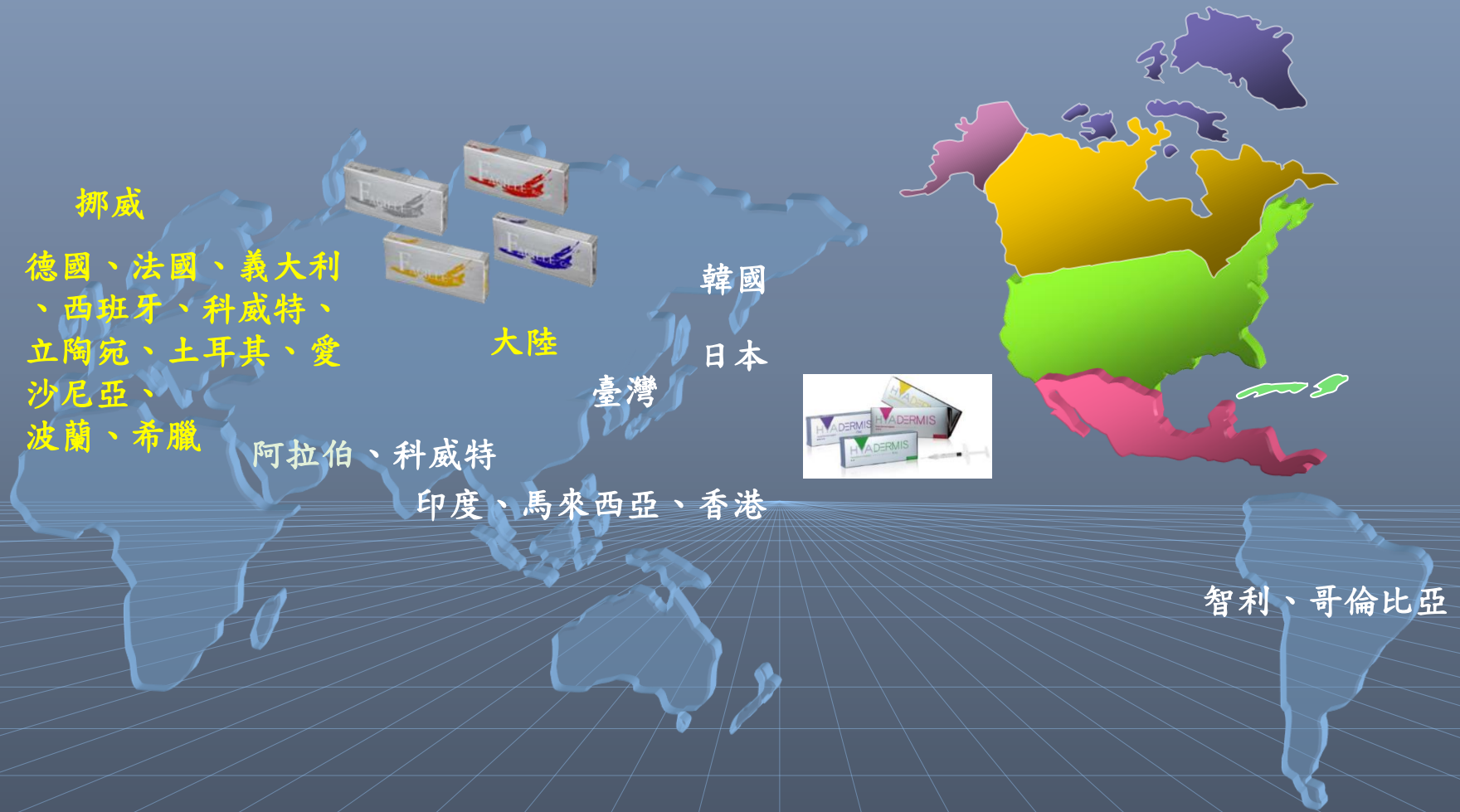
# 整形美容

## -皮下填補劑

● Blink 亮眼 ● Kiss 輕吻 ● Smile 微笑 ● Chic 別緻

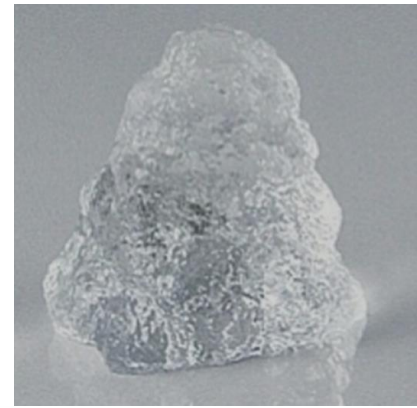


# 產品銷售區域



# HYADERMIS/ FACILLE

透明質酸皮下填補劑

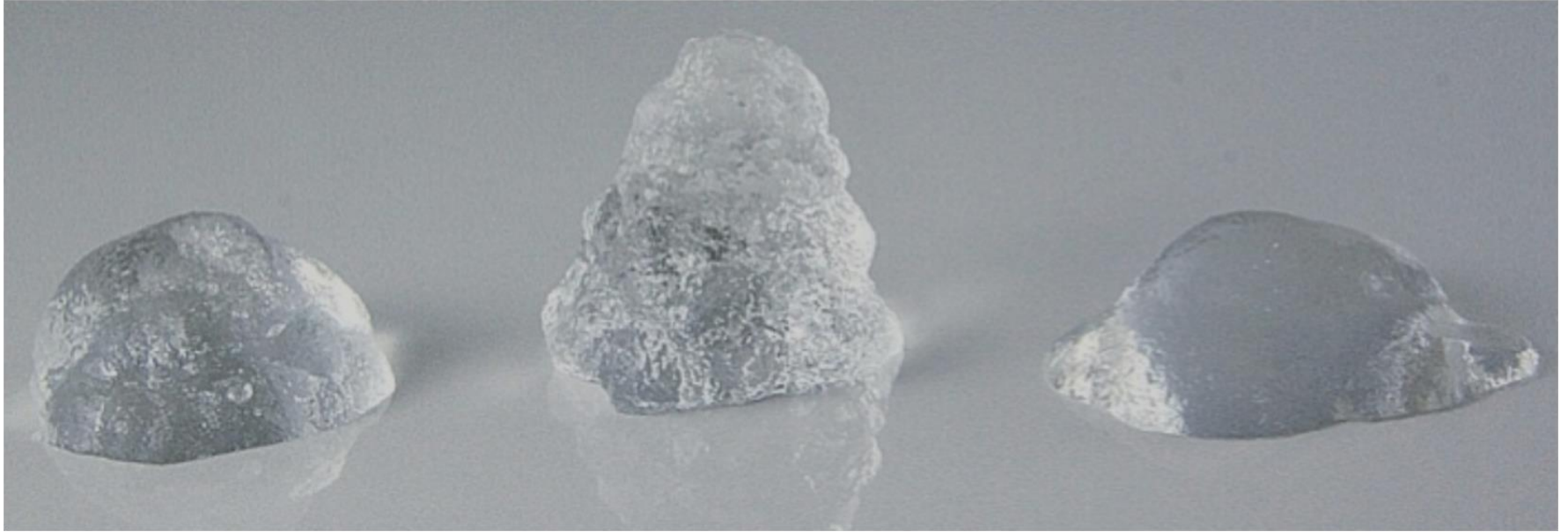


## 產品特色

- ✓ 安全性高
- ✓ 膠體結構堅固
- ✓ 不易位移
- ✓ 優異粘彈性
- ✓ 有效成分足
- ✓ 抗降解能力佳



## 支撐度試驗 (膠體結構堅固)



他牌競品 1

科妍產品

他牌競品 2

# 老年照護

## - 一針型關節腔注射劑



### Osteoarthritis Improvement

- Improvement of cartilage cell metabolism
- Inhibition of inflammation
- Promotion of synovial fluid biosynthesis

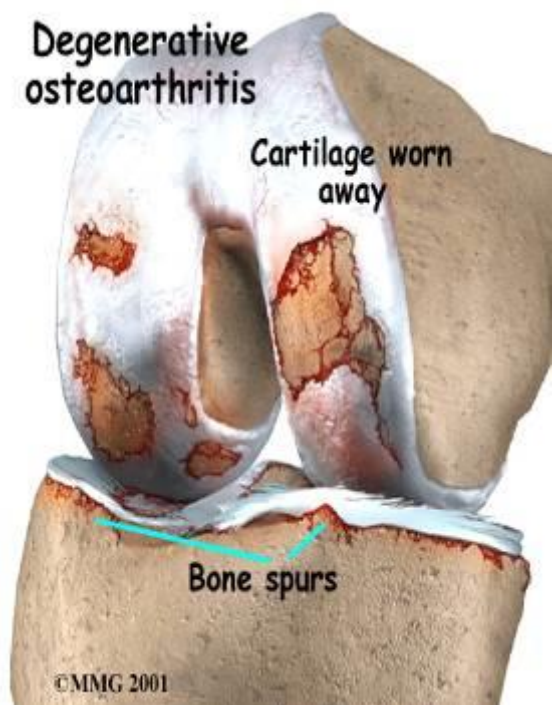


#### SciVision Biotech Inc.

9, South 6th Rd., K.E.P.Z., Kaohsiung, 80681, Taiwan, R.O.C  
<http://www.scivisionbiotech.com>  
[service@scivision.com.tw](mailto:service@scivision.com.tw)

TEL: +886-7-823-2258  
FAX: +886-7-823-2295

# 關節腔注射劑



5針劑型:連續施打5周，維持半年

3針劑型:連續施打3周，維持半年

1針劑型:施打1劑，即可維持一年





# 產品銷售區域

德國，法國，荷蘭，比利時，盧森堡，西班牙，立陶宛，波蘭，土耳其，羅馬尼亞，愛沙尼亞，希臘



約旦、沙烏地阿拉伯、臺灣、卡達、印度、馬來西亞、緬甸

澳大利亞

智利



# HYAJOINT Plus / HYAFELIC Uno

## 一針型關節腔注射劑

### 產品特色

- ✓ 一針劑型
- ✓ 高安全性
- ✓ 長效性
- ✓ 高舒適感
- ✓ 無需過度注射

**1 Injection** **HYAJOINT Plus**  
Synovial Fluid Supplement

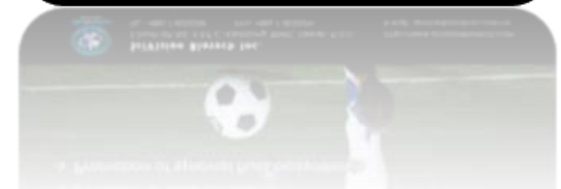
*Characteristic*

- Single injection
- Non-animal origin
- Lasting effect
- High comfort
- Needless excessive injection

**Osteoarthritis Improvement**

- ✓ Improvement of cartilage cell metabolism
- ✓ Inhibition of inflammation
- ✓ Promotion of synovial fluid biosynthesis

**SciVision Biotech Inc.**  
F. 304th St. No. 4, 2/F, 2, Xinying, Road, Taipei, R.O.C.  
Tel: +886-7-6233256 FAX: +886-7-6233295  
http://www.scivisionbiotech.com E-mail: service@scivision.com.tw



## Comparison of Single Intra-Articular Injection of Novel Hyaluronan (HYA-JOINT Plus) with Synvisc-One for Knee Osteoarthritis

A Randomized, Controlled, Double-Blind Trial of Efficacy and Safety

Shu-Fen Sun, MD, Chien-Wei Hsu, MD, Huey-Shyan Lin, PhD, I-Hsiu Liou, MD, Yin-Han Chen, MD, and Chia-Ling Hung, MD

Investigation performed at the Kaohsiung Veterans General Hospital, Kaohsiung City, Taiwan

**Background:** Viscosupplementation has been widely used for the treatment of knee osteoarthritis. Because we found no well-controlled trial comparing single-injection regimens of hyaluronan for knee osteoarthritis, we compared the efficacy and safety of a single intra-articular injection of a novel cross-linked hyaluronan (HYA-JOINT Plus) with a single injection of Synvisc-One in patients with knee osteoarthritis.

**Methods:** In a prospective, randomized, controlled, double-blind trial with a 6-month follow-up, 132 patients with knee osteoarthritis (Kellgren-Lawrence grade 2 or 3) were randomized to receive 1 intra-articular injection of 3 mL of HYA-JOINT Plus (20 mg/mL) (n = 66) or 6 mL of Synvisc-One (8 mg/mL) (n = 66). The primary outcome was the change from baseline in the visual analog scale (VAS) (0 to 100 mm) pain score at 6 months. Secondary outcome measures included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC, Likert scale), Lequesne index, timed "Up & Go" (TUG) test, single-limb stance (SLS) test, use of rescue analgesics, and patient satisfaction.

**Results:** A total of 121 patients were available for the intention-to-treat analysis at 6 months. Both groups had a significant improvement in the VAS, WOMAC, and Lequesne index scores at each follow-up visit ( $p < 0.001$ ). Patients who received HYA-JOINT Plus experienced a significantly greater improvement in the VAS pain score at 1, 3, and 6 months compared with those treated with Synvisc-One (adjusted mean difference:  $-12.0$ ,  $-8.5$ , and  $-6.6$ ;  $p = 0.001$ ,  $0.033$ , and  $0.045$ , respectively). There were no significant between-group differences in any of the secondary outcomes except the WOMAC stiffness scores at 6 months, which favored HYA-JOINT Plus treatment ( $p = 0.043$ ). The TUG time did not change significantly in either group during the study ( $p > 0.05$ ), but the SLS time improved significantly in both the HYA-JOINT Plus and the Synvisc-One group ( $p = 0.004$  and  $p = 0.022$ , respectively). No significant between-group differences were observed with respect to patient satisfaction or consumption of analgesics. No serious adverse events occurred following the injections.

**Conclusions:** A single injection of either HYA-JOINT Plus or Synvisc-One is safe and effective for 6 months in patients with knee osteoarthritis. HYA-JOINT Plus is superior to Synvisc-One in terms of reducing the VAS pain score at 1, 3, and 6 months and the WOMAC stiffness score at 6 months, with similar safety.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

**Peer Review:** This article was reviewed by the Editor-in-Chief and one Deputy Editor, and it underwent blinded review by two or more outside experts. It was also reviewed by an expert in methodology and statistics. The Deputy Editor reviewed each revision of the article, and it underwent a final review by the Editor-in-Chief prior to publication. Final corrections and clarifications occurred during one or more exchanges between the author(s) and copyeditors.

Viscosupplementation with hyaluronan is a well-established treatment option for knee osteoarthritis. The goal of viscosupplementation is to reduce pain and improve

viscoelasticity of synovial fluid<sup>1,2</sup>. Hyaluronan may provide biological actions, including anti-inflammatory, antinociceptive, and anabolic effects<sup>3-6</sup>. Moreover, it has been known to

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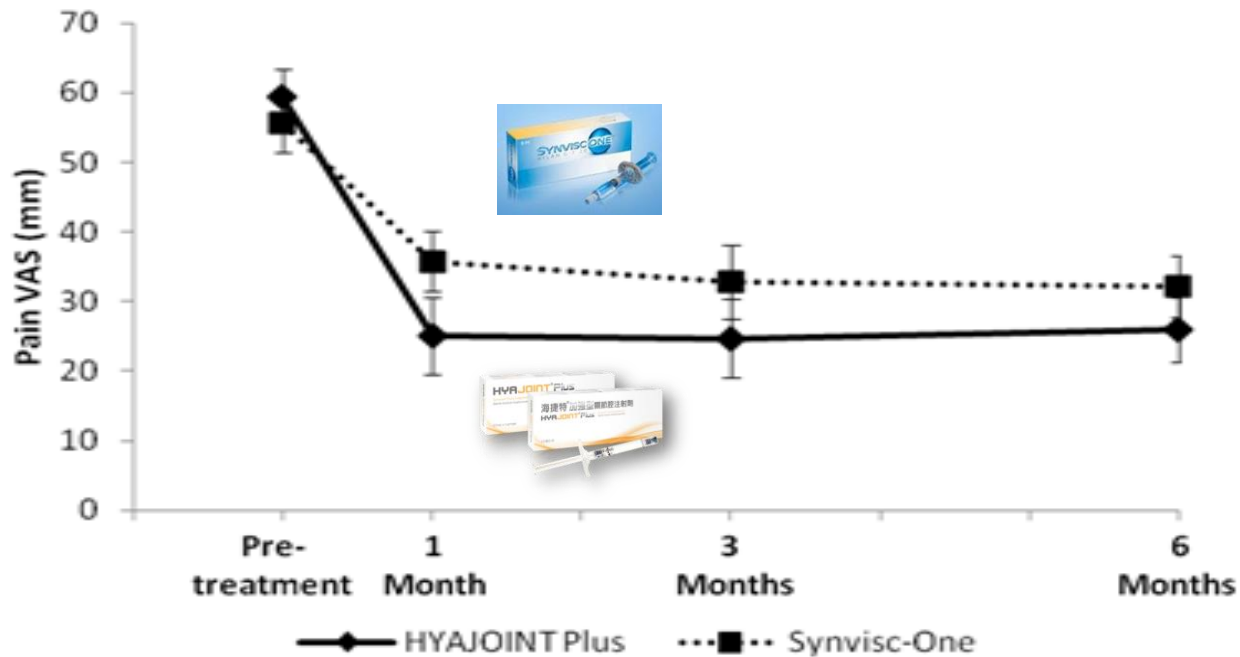
HYAJOINT Plus

VS



Synvisc-One

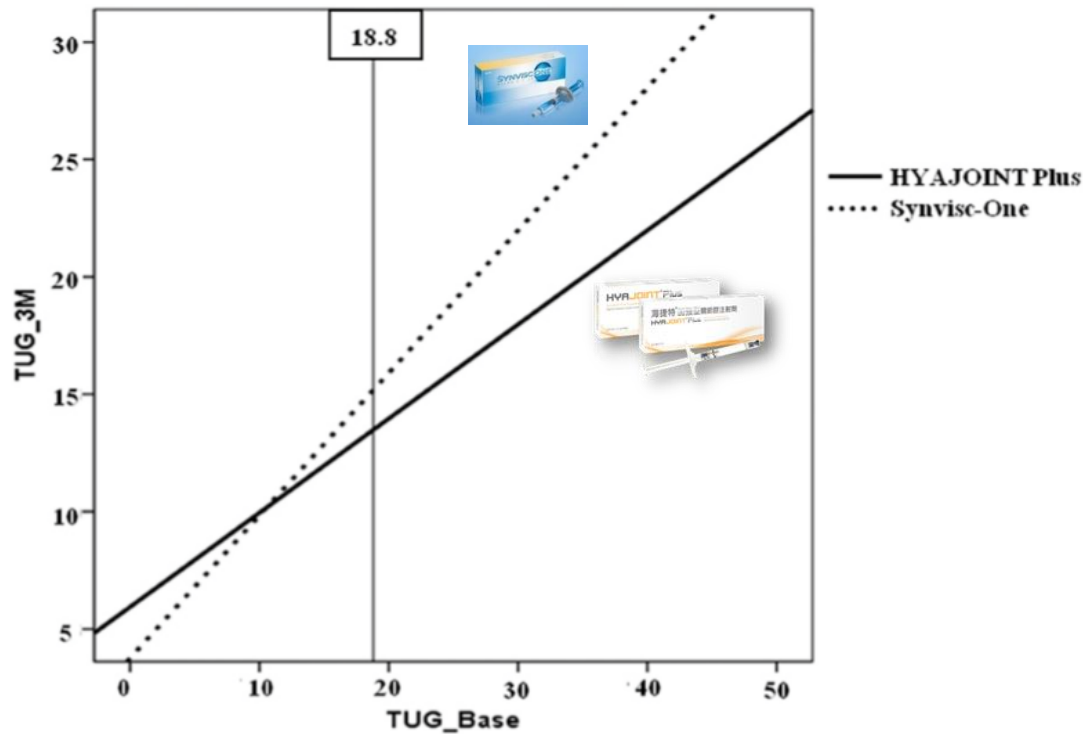
# 科妍產品減緩疼痛的效果顯著優於競爭品



**TABLE III Comparison of VAS, WOMAC, and Lequesne Index Scores Between Groups**

	HYA-JOINT Plus*	Synvisc-One*	Adjusted Mean Difference (95% Confidence Interval)	P Value†
VAS score (mm)				
Baseline	59.3 ± 15.8	55.7 ± 16.4		0.212
1 mo	25.1 ± 18.4	35.8 ± 22.1	-12.0 (-19.1, -5.0)	0.001‡
3 mo	24.7 ± 19.0	32.9 ± 24.0	-8.5 (-16.4, -0.7)	0.033‡
6 mo	26.0 ± 15.6	32.3 ± 19.6	-6.6 (-13.0, -0.2)	0.045‡
P value§	<0.001‡	<0.001‡		

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**TABLE IV Comparison of TUG and SLS Times Between Groups**

	HYA-JOINT Plus*	Synvisc-One*	P Value†
TUG time (sec)			
Baseline	12.3 ± 8.7	12.6 ± 13.3	0.902
1 mo	11.2 ± 6.1	10.4 ± 3.9	0.925
3 mo	10.9 ± 4.3	10.4 ± 3.7	HYA-JOINT Plus superior when baseline >18.8 sec
6 mo	11.1 ± 5.0	11.4 ± 5.6	
P value‡	0.078	0.23	0.145

# 手術外科

## -可吸收防沾黏凝膠



# 防粘黏產品趨勢

主成分 評比項目	醫用級(矽) 橡膠	聚-DL-乳 酸 (PLA)	殼聚糖 (幾丁聚糖) Chitosan	氧化再生纖 維素	透明質酸 鈉
原料來源	人工合成	人工合成	動物組織 萃取	人工合成 →	微生物 發酵
需二次手術取 出	需要 →	不需要	不需要	不需要	不需要
組織刺激性 (發炎反應性)	中	高	中 →	低	低
產品黏附性 (不易位移性)	低	中	中	中 →	高

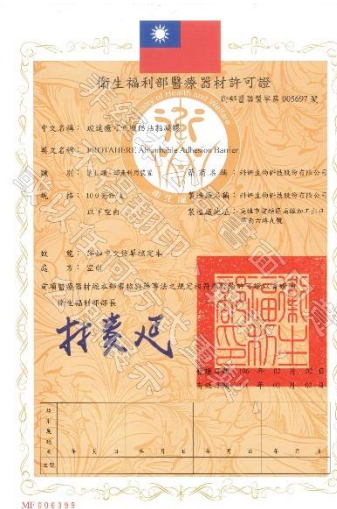
# PROTAHERE

## 可吸收防沾黏凝膠



### 產品特色

- ✓ 生物相容性高
- ✓ 有效避免或減少沾黏發生
- ✓ 安全、天然、可被人體吸收
- ✓ 操作方便迅速
- ✓ 經濟有效





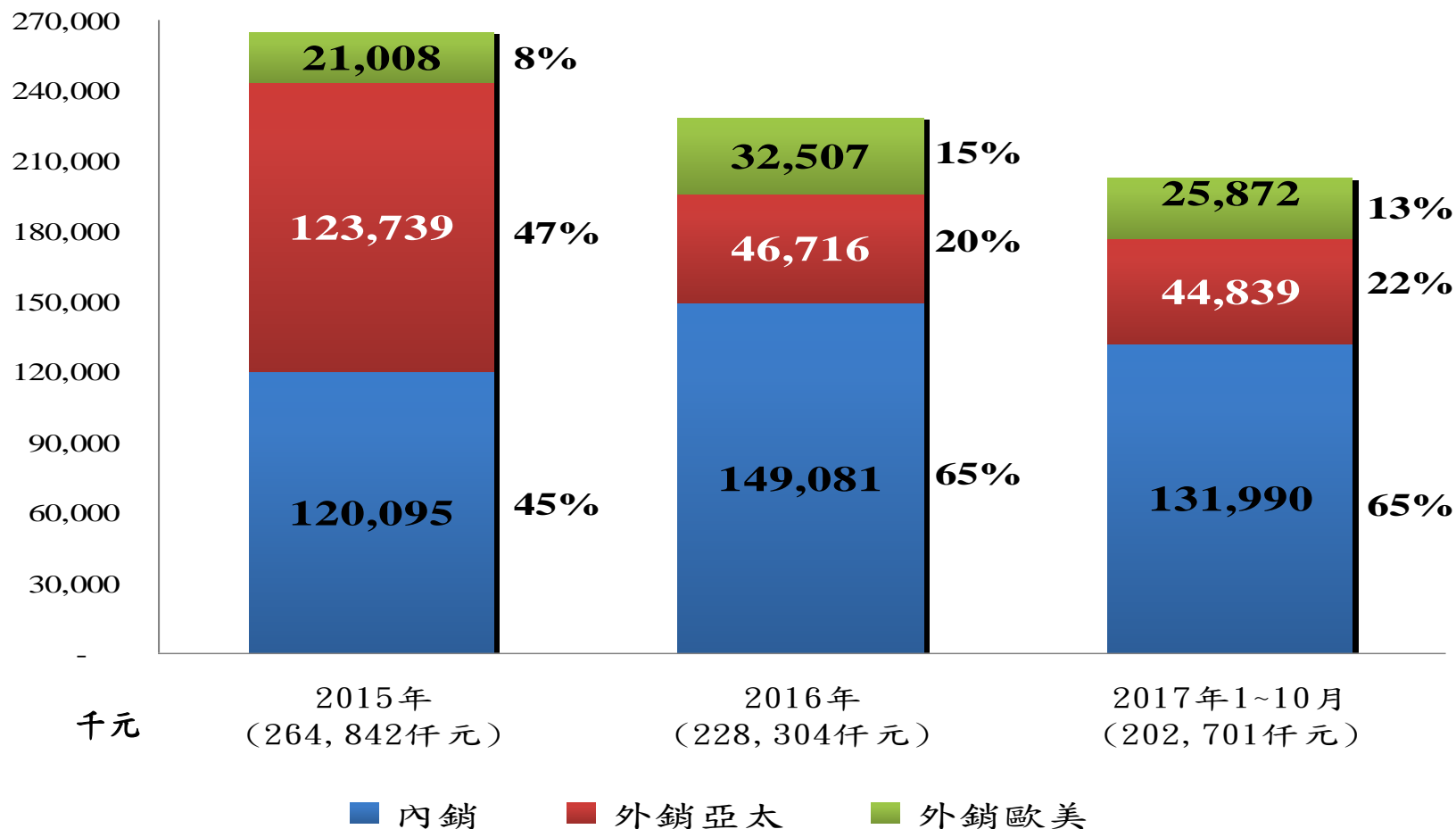
# 簡報大綱

1. 公司與產品介紹

2. 營運現況

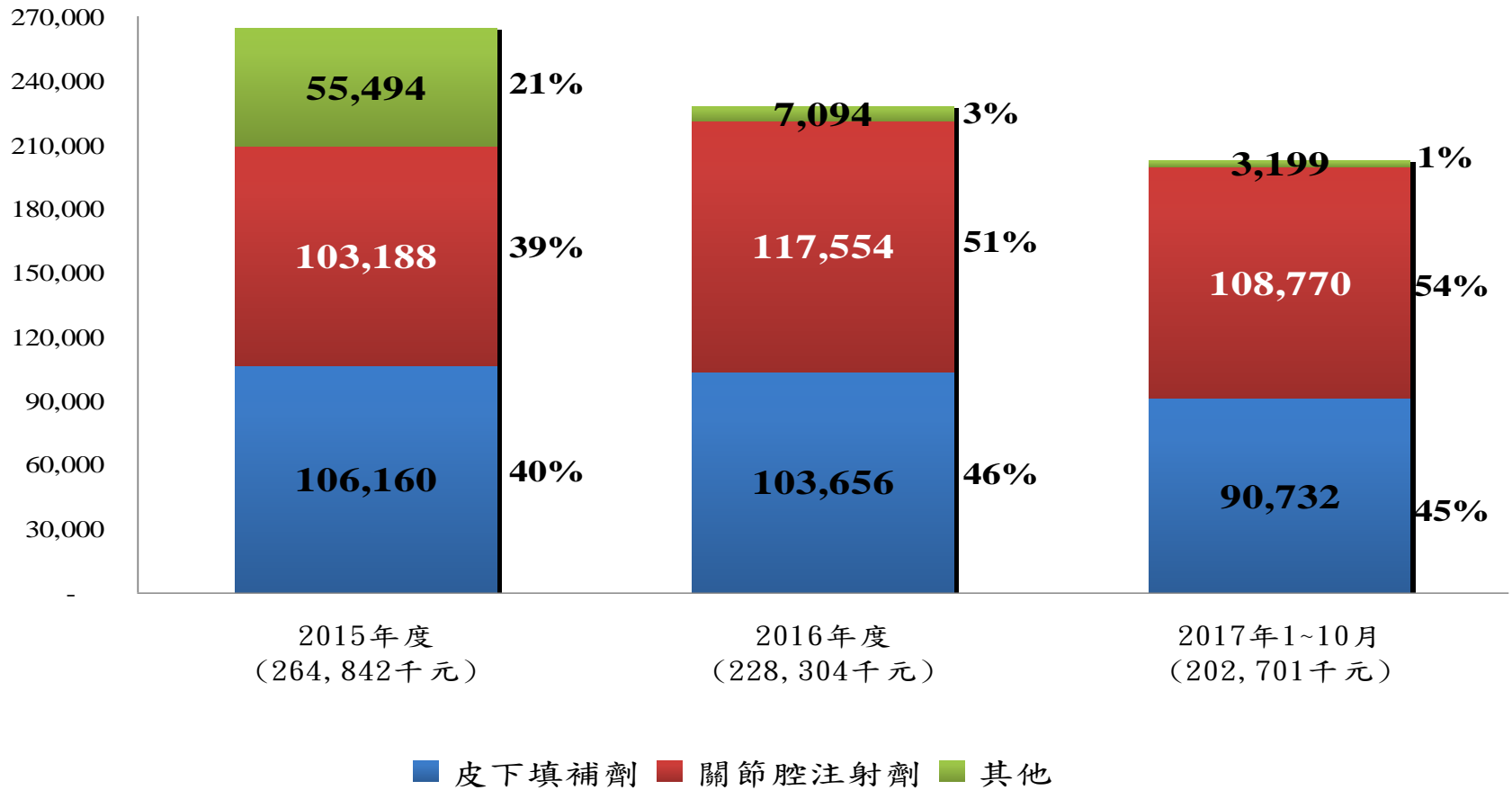
# 主要銷售地區

2015~2016年度及2017年1~10月



# 產品別營收與比重

2015~2016年度及2017年1~10月



# 願景與展望

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