愛德華瑟皮恩三優創乾式經導管心臟瓣膜系統

Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

衛部醫器輸字第 037718 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用

使用說明

醫師必須接受愛德華公司相關訓練，才可執行經導管心臟瓣膜的植入手術。負責植入手術的醫師應具備執行主動脈瓣膜球囊成形術和標準心導管技術的經驗。由醫師依據患者的解剖結構及相關風險，選擇合適的路徑植入經導管心臟瓣膜。

名稱	20 mm	23 mm	26 mm	29 mm
	型號/目錄編號			
愛德華瑟皮恩三優創乾式經導管心臟瓣膜系統 Edwards SAPIEN 3 Ultra RESILIA - Edwards Commander Kit	S3URCM20AP	S3URCM23AP	S3URCM26AP	S3URCM29AP
Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜 (Transcatheter Heart Valve)	9755RSL20	9755RSL23	9755RSL26	9755RSL29
Edwards Commander 輸送系統 (Delivery System) [1]	9750CM20	9750CM23	9750CM26	9750CM29
Edwards eSheath+ 導引器套組 (Introducer Set)	914ESP			916ESP
壓折器 (Crimper)	9600CR			
擴張裝置 (Inflation Device)	96402			-
Locking Syringe	-			96406
[1]包括裝填器、Qualcrimp壓折器配件(Crimping Accessory)及兩件式壓折器擋片(Crimp Stopper)				

1.0 裝置介紹

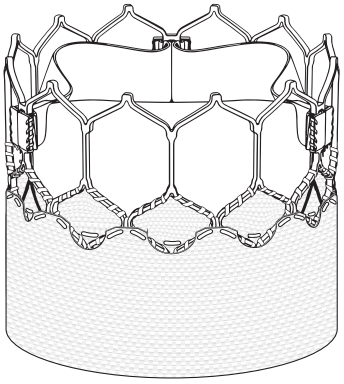
Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜系統

Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜 (THV) 系統由 Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜和輸送系統組成。

- **Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜 - (圖 1)**

Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜 (transcatheter heart valve) 的組成包括：一組可藉球囊擴張、不透射線的鈷鉻合金支架、利用牛心包膜組織製作的三葉 RESILIA瓣膜、以及聚對苯二甲酸乙二酯 (polyethylene terephthalate，簡稱 PET) 材質的內層和外層織物裙緣。

RESILIA 組織：RESILIA 組織以 Edwards Integrity Preservation 的創新技術製成，該技術具有穩定的覆蓋防鈣化處理程序，可阻斷已知會與鈣結合的殘留醛基。這項技術也結合甘油封存組織技術，取代傳統的戊二醛溶液等液體溶液的儲存方式。這種儲存方法可避免組織暴露於戊二醛儲存液常見的殘留游離醛基。



9755RSL

圖 1：Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜

表 1

瓣膜尺寸	瓣膜高度
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm
29 mm	22.5 mm

經導管心臟瓣膜適合植入的原生瓣環尺寸範圍，係以心臟收縮時、在瓣環基部 (basal ring) 測得之主動脈瓣環三度空間面積推算而得。有關原生瓣膜內植入 Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜的尺寸測定建議如下表：

表 2

原生瓣環尺寸 (TEE)	原生瓣環尺寸 (CT)		經導管心臟瓣膜 (THV) 尺寸
	面積	面積換算直徑	
16 - 19 mm	273 - 345 mm^2	18.6 - 21 mm	20 mm
18 - 22 mm	338 - 430 mm^2	20.7 - 23.4 mm	23 mm
21 - 25 mm	430 - 546 mm^2	23.4 - 26.4 mm	26 mm
24 - 28 mm	540 - 683 mm^2	26.2 - 29.5 mm	29 mm
瓣膜尺寸建議是依據經食道心臟超音波 (TEE) 或電腦斷層 (CT) 測量的原生瓣環尺寸推算。選擇瓣膜尺寸時應考慮患者的解剖構造因素和多種成像方式。 **註：應考慮與尺寸不足和過大的相關風險。**			

經導管心臟瓣膜尺寸建議是依據經食道心臟超音波 (TEE) 或電腦斷層 (CT) 測量的原生瓣環尺寸推算。選擇經導管心臟瓣膜尺寸時應考慮患者的解剖構造和多種成像方式。

註：應考慮尺寸不足和過大的相關風險，以將瓣周漏、移位和/或瓣環破裂的風險降至最低。

*由於二度空間影像的限制，二度空間的經食道心臟超音波影像應以三度空間的面積測量結果補足。

對於功能失效的人工生物瓣膜內 (尺寸 19 - 25 mm 的 INSPIRIS RESILIA 主動脈瓣膜除外) 植入 Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜的尺寸測定建議如下表：

表 3

外科瓣膜真內徑 (ID) [1]	經導管心臟瓣膜內植經導管心臟瓣膜 (THV-in-THV) (原生瓣環尺寸)	經導管心臟瓣膜 (THV) 尺寸
16.5 - 19.0 mm	18.6 - 21.0 mm	20 mm
18.5 - 22.0 mm	20.7 - 23.4 mm	23 mm
22.0 - 25.0 mm	23.4 - 26.4 mm	26 mm
25.0 - 28.5 mm	26.2 - 29.5 mm	29 mm

註：外科瓣膜 (Surgical valve) 的「真內徑」(True ID) 可能小於標籤所示的瓣膜尺寸。對於在經導管心臟瓣膜內植經導管心臟瓣膜 (THV-in-THV)，應考慮原生瓣環尺寸，以確定植入適當尺寸的經導管心臟瓣膜。對於功能衰竭的無支架人工生物瓣膜，應考慮原生瓣環的尺寸建議。應確定功能失效的人工生物瓣膜尺寸，以便植入適當尺寸的經導管心臟瓣膜；且最好使用電腦斷層、磁振造影和/或經食道心臟超音波進行尺寸測量。

依據實驗室測試，在 INSPIRIS RESILIA 尺寸 19 - 25 mm、功能失效的主動脈外科人工生物瓣膜內植入 Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜的尺寸測定建議如下表：

表 4

INSPIRIS RESILIA 主動脈瓣膜 (型號 11500A)* 標示尺寸	**經導管心臟瓣膜 (THV) 尺寸**
19 mm	20 mm 或 23 mm
21 mm	23 mm 或 26 mm
23 mm	23 mm 或 26 mm
25 mm	26 mm 或 29 mm

*INSPIRIS RESILIA 型號 11500A、尺寸 19 - 25 mm 的主動脈瓣膜採用 VFit 技術，包含可擴張環帶與螢光鏡可見的尺寸標記，設計用於日後進行經導管心臟瓣膜內植經導管心臟瓣膜 (valve-in-valve) 手術。目前並無臨床資料，可得知 INSPIRIS RESILIA 主動脈瓣膜型號 11500A 之經導管心臟瓣膜內植經導管心臟瓣膜手術或擴張特性。尚未評估過組織向內生長對 INSPIRIS RESILIA 主動脈瓣膜之擴張特性的影響。

警告：切勿在 INSPIRIS RESILIA 尺寸 19 – 25 mm 的主動脈瓣膜內進行獨立球囊主動脈瓣膜成形術。這可能會擴張主動脈瓣膜，造成功能失效、冠狀動脈栓塞或瓣環破裂。

註：INSPIRIS RESILIA 型號 11500A、尺寸 27 - 29 mm 的主動脈瓣膜未採用 VFit 技術，因此應遵循表 2 的外科瓣膜真內徑尺寸。

註：展開經導管心臟瓣膜所需的確切體積，可能依人工生物瓣膜的內部孔徑而異。諸如鈣化和血管組織生長等因素可能在成像中不能準確地顯現，並且可能將功能衰竭的人工生物瓣膜有效內徑減少至小於「真內徑」(True ID) 一個尺寸。

應考慮和評估這些因素以確定最合適的經導管心臟瓣膜尺寸，達到經導管心臟瓣膜公稱的展開和充足錨固。請勿超出額定破裂壓力。有關擴張參數請參閱表 5。

- **Edwards Commander 輸送系統 (圖 2)**

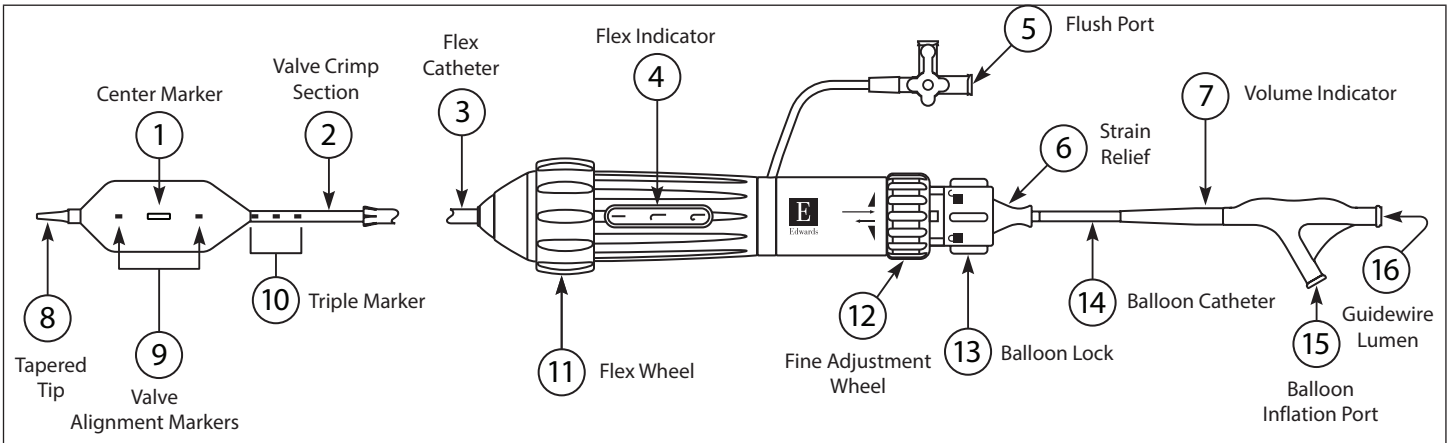
Edwards Commander 輸送系統用於置放人工生物瓣膜。

其包括一組 flex 導管，用於協助調整瓣膜相對於球囊的位置、追蹤定位經導管心臟瓣膜。輸送系統的錐形末梢有助於通過原生瓣膜。把手的 Flex 控制環可控制 Flex 導管的彎曲狀態，球囊鎖定裝置及微調環則能協助瓣膜定位與調整瓣膜定位在原生瓣環的位置。輸送系統的導引線管腔內附有一通管針。球囊導管具有不透射線的瓣膜定位標記，標示出球囊的有效長度。不透射線的球囊中央標記可協助瓣膜的定位。球囊近端、不透射線的三重標記則可在展開時標示出 Flex 導管的位置。

展開經導管心臟瓣膜時的擴張參數：

表 5

型號	**標稱球囊直徑 (Nominal Balloon Diameter)**	**標稱擴張體積 (Nominal Inflation Volume)**	**額定破裂壓力 (Rated Burst Pressure，簡稱 RBP)**
9750CM20	20 mm	11 mL	7 atm
9750CM23	23 mm	17 mL	7 atm
9750CM26	26 mm	23 mL	7 atm
9750CM29	29 mm	33 mL	7 atm



1. 中央標記
2. 瓣膜壓折部
3. Flex 導管
4. Flex 指標
5. 沖洗口
6. 應力消除裝置
7. 體積指示器
8. 錐形末梢
9. 瓣膜定位標記
10. 三重標記
11. Flex 控制環
12. 微調環
13. 球囊鎖定裝置
14. 球囊導管
15. 球囊擴張口
16. 導引線管腔

圖 2：Edwards Commander 輸送系統

其他配件

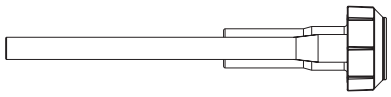


圖 3：裝填器

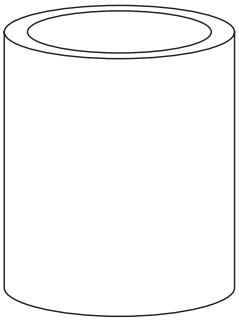


圖 4：Qualcrimp 壓折器配件

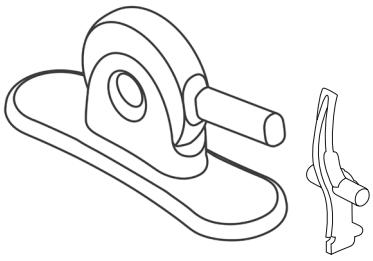


圖 5：Edwards 壓折器及壓折器擋片

- **裝填器 (圖 3)**

裝填器用於協助將輸送系統放入套管。

- **Edwards Sheath (套管)**

關於裝置的敘述，請參考套管使用說明。

- **Qualcrimp 壓折器配件 (圖 4)**

Qualcrimp 壓折器配件用於經導管心臟瓣膜的壓折。

- **Edwards 壓折器及壓折器擋片 (圖 5)**

Edwards 壓折器可縮小經導管心臟瓣膜的直徑，並將其裝上輸送系統。壓折器由外殼和壓縮裝置組成，壓縮裝置可利用位於外殼的把手闔起。兩件式壓折器擋片用於壓折經導管心臟瓣膜至預期直徑。

- **擴張裝置**

具有鎖定機制的擴張裝置用於展開經導管心臟瓣膜。

註：為達到適當體積，使用輸送系統時應搭配愛德華公司提供的擴張裝置。

2.0 用途

人工生物瓣膜適用於需要心臟瓣膜置換的患者。輸送系統和配件適用於將人工生物瓣膜通過經股動脈、經房中膈、鎖骨下/腋窩進入途徑的放置。

3.0 適應症

1. Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜系統適用於原生鈣化性主動脈瓣狹窄，並對於開放性外科手術具有任何或所有風險程度的心臟病患者。
2. Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜系統適用於，患者先前植入的主動脈經導管人工生物瓣膜、或主動脈瓣或二尖瓣外科人工生物瓣膜功能衰竭(狹窄、閉鎖不全或複合性)導致有症狀心臟病，並經由心臟科團隊，包含心臟外科醫師，判定對於開放性外科手術具有高度或更高風險 (亦即，依據胸腔外科醫師學會 (STS) 風險評分及 STS 風險計算式未測量之其他臨床合併症，預期術後 30 天的手術致死率風險 ≥ 8%) 的患者。

4.0 禁忌症

Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜系統禁用於出現下列情況的患者：

- 無法耐受抗凝血/抗血小板治療，或患有活動性細菌型心內膜炎 (active bacterial endocarditis) 或其他活動性感染(active infections)。

5.0 警語

- 為避免節律導線穿孔的風險，務必全程觀察節律導線的傳輸情形。
- 本裝置基於設計、用途及銷售目的，以無菌狀態供應且僅限單次使用。切勿再次滅菌或重複使用本裝置。目前並無資料證明，本裝置經重新處理後無菌性、無致熱原性及功能是否仍符合標準。
- 不正確的瓣膜尺寸測定，可能會導致瓣周漏、移位、栓塞、殘留壓力差（患者-人工生物瓣膜不匹配）和/或瓣環破裂。
- 患者鈣質代謝功能有所改變時，鈣化退化可能會加快瓣膜的劣化速度。
- 輸送前，經導管心臟瓣膜必須隨時保持濕潤，而且為避免瓣葉組織受損而影響瓣膜功能，除專用運送保存液及無菌生理食鹽水溶液外，不可讓瓣膜接觸其他溶液、抗生素、化學物質等。若經導管心臟瓣膜的瓣葉在流程中受到不當操作或損傷，必須更換整組經導管心臟瓣膜。
- 冠狀動脈疾病具臨床意義的患者，進行瓣膜植入手術時應特別謹慎。
- 若患者已安裝人工生物瓣膜，植入瓣膜之前應接受審慎評估，確保瓣膜正確定位並適當展開。
- 如果防變造封條毀損、溫度指示裝置啟動、瓣膜受損或超過有效期限，無菌性或瓣膜功能可能受損，切勿使用該組瓣膜。
- 切勿不當操作輸送系統；若包裝無菌屏障及組件開啟或毀損（例如，扭結或拉伸）、無法沖洗、超過使用期限，切勿使用該組輸送系統及配件裝置。
- 取出輸送系統前未將其伸直，可能會造成患者受傷。
- 對鈷、鎳、鉻、鉬、鈦、錳、矽、甘油、牛組織及/或聚合材料過敏的患者，可能會因這些材質而引發過敏反應。
- 患者接受瓣膜植入手術後，應由醫師依據個別患者的狀況，決定是否維持抗凝血/抗血小板藥物的治療（有禁忌症時除外），以減少瓣膜血栓形成或血栓栓塞事件的風險。尚未測試過在不使用抗凝劑的情況下，使用本裝置。
- 在治療功能衰竭的人工生物瓣膜時，應避免使用球囊瓣膜成形術，這可能會導致生物瓣膜材質栓塞和瓣葉的機械性破壞。
- 植入前必須確認經導管心臟瓣膜的方向是否正確。
- 通路特性，例如嚴重阻塞或圓周向鈣化、嚴重扭曲、血管直徑小於 5.5 mm（尺寸為 20、23 和 26 mm 的 SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜）或 6.0 mm（尺寸為 29 mm SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜），可能阻礙套管安全放置，應在手術前仔細評估。

6.0 注意事項

- 目前尚未確立經導管心臟瓣膜的長期耐用性，因此建議定期接受醫療後續追蹤，以評估瓣膜狀況。
- 如果導管推進通過血管組織時阻力顯著增加，應停止推進並探究阻力的原因，再繼續進行。請勿強行通過，這可能會增加血管併發症的風險。相較於 SAPIEN 3，扭曲/較困難的血管解剖結構使用 SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜的系統推力可能較高。
- 切勿過度擴張展開的球囊，以免瓣葉無法適當接合，而影響瓣膜功能。
- 有人工瓣膜感染或心內膜炎風險的患者，建議術後給予適當的抗生素預防治療。
- 經導管置換功能衰竭的二尖瓣人工生物瓣膜的其他注意事項包括：腔靜脈內有裝置或血栓或其他異常，導致無法安全採用經股靜脈途徑通過心房中膈；具有心房中膈堵塞裝置或鈣化，導致無法安全通過心房中膈。
- 若原有植入手術時使用腱索保留技術，在進行二尖瓣置換時務必特別注意，避免勾到瓣膜下結構(subvalvular apparatus)。
- 依據主治醫師對於風險及效益的考量，可將瓣膜植入相對年輕的患者。雖然瓣膜的長期耐用性仍尚待持續進行臨床研究。
- 目前尚未確認下列患者接受經導管心臟瓣膜植入手術的安全性及效能：
  - 非鈣化主動脈瓣環

- 心室功能嚴重異常，射出分率 <20%
- 先天性單尖型主動脈瓣
- 任何位置已裝有人工生物瓣環
- 嚴重二尖瓣環鈣化（MAC）、嚴重（> 3+）二尖瓣閉鎖不全或 Gorlin 症候群
- 惡血質，定義為：白血球減少（WBC < 3000 cells/μL）、急性貧血（Hb < 9 g/dL）、血小板減少（血小板計數 < 50,000 cells/μL），或有出血體質或凝血病變病史
- 肥厚性心肌症（HOCM），不論有無阻塞
- 主動脈狹窄，特徵為併發主動脈瓣流速偏低、瓣膜兩側壓力差異過小
- 心臟超音波顯示心臟內有明顯團塊、血栓或贅生物
- 已知曾對阿斯匹靈、肝素、ticlopidine（Ticlid）或 clopidogrel（Plavix）過敏或有禁忌症，或對顯影劑敏感，因此無法充分接受前置用藥
- 嚴重的主動脈疾病，包括腹部主動脈或胸腔動脈瘤，定義為最大管腔直徑 5 cm 以上；顯著扭曲（超急性彎曲）、主動脈弓動脈粥狀瘤（尤其是增厚 [> 5 mm]、突出或潰爛），或腹部或胸腔主動脈或狹窄（尤其是伴隨鈣化或表面不規律）、嚴重「展開」和胸腔主動脈扭曲
- 靠近冠狀動脈開口的大面積鈣化主動脈瓣葉
- 併發的瓣周漏，其中功能失效的生物瓣膜未牢固地固定在原生瓣環中或結構不完整（例如線型支架斷裂）
- 位於主動脈瓣位置失效的生物瓣膜，其部分分離的瓣葉可能會阻塞冠狀動脈開口

- 鎖骨下/腋下通路的風險低且可接受，然而當醫師判定採用經股動脈路徑的風險較高，則應考慮採用鎖骨下/腋下路徑。
- 對於左腋窩方法，自主動脈弓至左鎖骨下角度約 ≥ 90° 會造成銳角，可能導致套管扭結、鎖骨下/腋窩分割和主動脈弓受損。
- 對於左/右側窩方法，應確保手術過程左內乳動脈（LIMA）/右內乳動脈（RIMA）內具有血流，並監測同側橈動脈的壓力。
- 「THV 植入於功能衰竭的生物瓣膜」設定的剩餘壓差可能高於使用相同尺寸的裝置，在原生主動脈瓣環植入瓣膜所觀察到的數值。患者在術後若平均壓差升高，應密切追蹤。務必確認既有的生物瓣膜製造商、型號和尺寸，以便植入合適的瓣膜，避免發生假體不符的情形。此外，必須採用術前影像檢查，儘可能確認內徑的準確度。
- 使用都卜勒心臟超音波進行 TAVR 裝置效能的程序後和追蹤評估，可能會受到用於決定平均壓差、EOA 和人工生物瓣膜與假體不符等測量值的白努利公式之既有限制影響。這些限制可能會導致 TAVR 植入後，過度高估或低估瓣膜效能測量值。因此，應使用 TAVR 後心臟超音波確立基準點，作為未來追蹤回診的比較基礎。適當時可在重新進行處置之前，經由心臟導管進行確認性直接壓力測量。

7.0 可能發生的不良事件

整體手術過程（包括裝置導入、心導管手術、局部清醒鎮靜麻醉及/或全身麻醉）的相關潛在風險：

- 死亡（Death）
- 中風/暫時性腦缺血（Stroke/transient ischemic attack），叢發性或神經學缺陷（clusters or neurological deficit）
- 癱瘓（Paralysis）
- 永久殘疾
- 呼吸功能不全（Respiratory insufficiency ）或呼吸衰竭（respiratory failure）
- 出血，必須接受輸血或進行處置
- 心血管損傷，例如血管、心室、心房、膈膜、心肌或瓣膜構造的穿孔或剝離，可能需要進行處置
- 心包積液（Pericardial effusion）或心包填塞（cardiac tamponade）
- 胸腔出血
- 栓塞，例如氣體、鈣化瓣膜組織或血栓
- 感染，例如敗血症（septicemia）及心內膜炎（endocarditis）
- 心臟衰竭（Heart failure）
- 心肌局部缺血（Myocardial ischemia）或梗塞（infarction）
- 腎功能不全（Renal insufficiency）或腎臟衰竭（renal failure）
- 傳導系統（Conduction system）缺損，可能必須使用永久性心律調節器
- 心律不整（Arrhythmias），包括心室纖維顫動（ventricular fibrillation，簡稱 VF）和心室頻脈（ventricular tachycardia，簡稱 VT）
- 腹膜後出血（Retroperitoneal bleed）
- 動靜脈（AV fistula）瘻管或假性血管瘤（pseudoaneurysm）
- 再次手術
- 局部缺血（Ischemia）或神經損傷（nerve injury），或臂神經叢損傷（brachial plexus injury）或腔室症候群（compartment syndrome）
- 血管再狹窄

- 肺水腫（Pulmonary edema）
- 肋膜積液（Pleural effusion）
- 出血（Bleeding），必須輸血或進行處置
- 貧血（Anemia）
- 血管血栓/阻塞（Vessel thrombosis/occlusion）
- 實驗室檢驗值異常（包括電解質失衡）
- 高血壓（Hypertension）或低血壓（hypotension）
- 對麻醉、顯影劑或裝置材質或牛心包膜組織產生過敏反應
- 血腫
- 暈厥（Syncope）
- 導管插入部位疼痛或改變（例如，傷口感染、血腫和其他傷口護理併發症）
- 無法耐受運動或虛弱（Exercise intolerance or weakness）
- 發炎（Inflammation）
- 心絞痛（Angina）
- 血管迷走神經反應（Vasovagal response）
- 心雜音（Heart murmur）
- 發燒（Fever）

經導管主動脈瓣置換術（TAVR）、人工生物瓣膜及相關裝置與配件的其他相關潛在風險包括：

- 心跳停止（Cardiac arrest）
- 心因性休克（Cardiogenic shock）
- 緊急心臟手術（Emergency cardiac surgery）
- 心臟衰竭（Cardiac failure）或心輸出量偏低（low cardiac output）
- 冠狀動脈血流受阻/血流通過瓣膜兩側時受到干擾
- 裝置引發血栓（Device thrombosis），必須進行處置
- 瓣膜血栓（Valve thrombosis）
- 裝置栓塞（Device embolization）
- 裝置移位或位置錯誤（migration or malposition），必須進行處置
- 左心室出口通道阻塞（LVOT obstruction）
- 瓣膜在預期以外位置展開
- 瓣膜狹窄（Valve stenosis）
- 血管痙攣（Vessel spasm）
- 瓣膜結構退化（脫落、破裂、鈣化、瓣葉撕裂/自支架裂開、瓣葉縮回、人工瓣膜組成的縫合線斷裂、增厚、狹窄）
- 裝置退化（Device degeneration）
- 跨瓣或經瓣膜滲漏（Paravalvular or transvalvular leak）
- 瓣膜逆流（Valve regurgitation）
- 溶血（Hemolysis）
- 裝置移除（Device explants）
- 非結構性功能障礙
- 輸送系統及/或配件出現機械性故障，包括球囊破裂和末梢分離
- 非緊急的再次手術
- 植體引發產生過敏/免疫反應（Allergic/immunologic reaction）
- 二尖瓣損傷（Injury to mitral valve）

8.0 操作說明

8.1 系統相容性

表 6

產品名稱	20 mm 系統	23 mm 系統	26 mm 系統	29 mm 系統
	型號			
Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜 (Transcatheter Heart Valve)	9755RSL20 (20 mm)	9755RSL23 (23 mm)	9755RSL26 (26 mm)	9755RSL29 (29 mm)
Edwards Commander 輸送系統 (Delivery System)	9750CM20	9750CM23	9750CM26	9750CM29
Edwards eSheath+ 導引器套組 (Introducer Set)	914ESP			916ESP
擴張裝置 (Inflation Device)	96402			96406
Edwards 壓折器 (Crimper)	9600CR			
Qualcrimp 壓折器配件、壓折器擋片及裝填器皆由愛德華提供				

其他設備：

- 醫師選用的球囊導管
- 20 cc 或容量更大的針筒
- 50 cc 或容量更大的針筒
- 高壓型三向調節閥 (2 組)
- 標準心導管室設備與耗材，此外應有一般心臟瓣膜手術室設備與耗材
- 螢光鏡 (適用於經皮冠狀動脈介入治療的固定式、移動式或半移動式螢光鏡系統)
- 執行經食道或經胸腔心臟超音波的設備
- 交換長度為 0.035 英吋 (0.89 mm) 的超硬型導引線
- 暫時性心律調節器 (PM) 與節律導線
- 適用時，用於穿越心房中膈和中膈造口的器材
- 無菌沖洗盆、生理食鹽水、肝素食鹽水溶液、15% 稀釋的不透射線顯影劑
- 準備瓣膜及配件的無菌工作台

8.2 瓣膜的處理及準備

準備及植入裝置期間，必須持續使用無菌操作技術。

8.2.1 SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜

SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜以無菌且無致熱原形式供應。包裝包含一個內含鋁箔袋的紙盒。鋁箔袋內有一個以 Tyvek 蓋密封的托盤。托盤內是包含瓣膜的瓣膜固定器。

1. 移除防變造標籤以打開紙盒。
2. 在非無菌區內，從紙盒取出鋁箔袋。打開鋁箔袋之前，請檢查包裝有無損壞或密封破裂或遺失的情況。在非無菌區內打開袋並取出托盤。

   警告，請勿在無菌區內打開鋁箔袋，因為可能會破壞無菌狀態。鋁箔袋僅作為保護層。只有瓣膜固定器可進入無菌區。

   註：如果程序期間打開鋁箔袋且未使用瓣膜，請棄置瓣膜。
3. 托盤會標示型號、尺寸和序號。應確認型號、尺寸和序號，與瓣膜包裝和瓣膜植體資料卡上的號碼相符。
4. 在無菌區附近，拿著托盤底部，撕開托盤的蓋子。
5. 瓣膜固定器和內容物為無菌。將瓣膜固定器移往無菌區。

   注意：瓣膜固定器的內容物必須使用無菌技術處理。從托盤小心取出瓣膜固定器，確保不會接觸到托盤邊緣的非無菌黏合劑。

8.2.2 瓣膜浸泡/沖洗程序

8.2.2.1 SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜

1. 為浸泡瓣膜，準備一 (1) 組無菌沖洗盆及裝有至少 500 ml 的無菌生理食鹽水。
2. 托住底部並開啟蓋子，打開瓣膜固定器。從瓣膜固定器小心取出瓣膜，不碰觸到組織。檢查瓣膜確認支架或組織有無受損跡象。
3. 將經導管心臟瓣膜放入裝有無菌生理食鹽水的無菌沖洗盆。確認無菌生理食鹽水完全覆蓋瓣膜至少 2 分鐘，以濕潤瓣葉。瓣膜應留至於無菌生理食鹽水內，以免組織乾燥。

   注意：浸泡盆中不可放入其他任何物品。瓣膜應保持濕潤，以防止組織乾燥。

8.2.3 準備系統

1. 目視檢查各項組件是否受損。確認輸送系統是否完全伸直，球囊導管是否完全推入 Flex 導管。

   警告：為了避免球囊囊體受損，應確保球囊囊體的近端未受到彎折。

2. 使用含有肝素的食鹽水溶液，經由沖洗口沖洗輸送系統。
3. 小心地移除輸送系統的遠端球囊護罩。從導引線管腔遠端取出通管針，將其放在一旁。
4. 以含有肝素的生理食鹽水沖洗導引線管腔，再將通管針插回導引線管腔的遠端。

   註：若未將通管針放回導引線管腔內，可能導致管腔在瓣膜壓折過程中受損。

5. 將輸送系統放到預定位置 (應力消除裝置末端對齊球囊囊體的兩個白色標記之間)，確認球囊近端護罩覆蓋 Flex 導管末梢。旋開裝填器管的護蓋，以添加肝素的食鹽水溶液沖洗裝填器護蓋。將裝填器護蓋放到球囊近端護罩並裝上 Flex 導管，護蓋內側朝向遠端末梢。
6. 將球囊導管完全推入 Flex 導管。
   移除球囊囊體藍色部分的球囊近端護罩。
7. 將三向調節閥接上球囊擴張口。在 50 cc 或容量更大的針筒裝入部分 15-20 mL 稀釋顯影劑，然後將其接上三向調節閥。
8. 在愛德華公司提供的擴張裝置裝入超出所示擴張體積的過量稀釋顯影劑。鎖定擴張裝置後，接上三向調節閥。
9. 關閉通往愛德華公司提供之擴張裝置的三向調節閥。使用 50 cc 以上的針筒抽真空，抽出系統的空氣。慢慢鬆開針筒活塞推桿，確保顯影劑流入輸送系統管腔。重複操作，直到去除輸送系統內所有氣泡為止。讓輸送系統內的壓力歸零。

   警告：確保球囊中沒有殘留的液體，以避免在手術過程中可能造成瓣膜對齊的困難度。

10. 關閉通往輸送系統的調節閥。轉動愛德華公司提供之擴張裝置旋鈕，輸送顯影劑到針筒內，並達到展開瓣膜所需的適當體積。
11. 關閉通往 50 cc 或容量更大針筒的調節閥。取下針筒。確認擴張體積是否正確，並鎖定愛德華公司提供的擴張裝置。

注意：在經導管心臟瓣膜展開前，愛德華公司提供的擴張裝置必須維持鎖定狀態，盡可能降低球囊提前擴張而導致經導管心臟瓣膜未能適當展開的風險。

8.2.4 將瓣膜裝上輸送系統並壓折

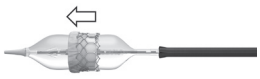
1. 為充分沖洗 Qualcrimp 壓折器配件，請準備額外兩 (2) 組裝有至少 100 mL 無菌生理食鹽水溶液的無菌沖洗盆。
2. 將 Qualcrimp 壓折器配件完全浸入第一組沖洗盆，輕輕加壓，確保配件吸滿食鹽水溶液。緩慢旋轉 Qualcrimp 壓折器配件至少 1 分鐘。在第二個沖洗盆重複前述步驟。
3. 從浸泡/沖洗盆取出瓣膜。
4. 轉動壓折器的把手，直到開口完全打開為止。將兩件式壓折器擋片裝於壓折器底座並卡入定位。
5. 壓折器在打開的狀態下，將瓣膜輕輕放入壓折器開口。對瓣膜進行漸進式壓折，直到瓣膜緊貼 Qualcrimp 壓折器配件內側為止。

   註：20 mm 瓣膜不需要這個步驟。

6. 將 Qualcrimp 壓折器配件放在瓣膜上方，確保瓣膜與 Qualcrimp 壓折器配件邊緣對齊。
7. 將經導管心臟瓣膜及 Qualcrimp 壓折器配件放入壓折器開口。將輸送系統沿著軸線插入經導管心臟瓣膜壓折部分的瓣膜內 (球囊囊體遠端 2-3 mm 處)，輸送系統上的瓣膜方向說明如下：

   順行法：瓣膜的流入側 (外層裙緣端) 朝向輸送系統的近端。

   逆行法：瓣膜的流入側 (外層裙緣端) 朝向輸送系統的遠端。



8. 將球囊囊體沿著軸線放入經導管心臟瓣膜內的中心位置。壓折經導管心臟瓣膜，直到達到兩件式壓折器擋片上的 Qualcrimp 壓折器配件擋片為止。
9. 從經導管心臟瓣膜上輕輕取下 Qualcrimp 壓折器配件。從壓折器擋片取下 Qualcrimp 壓折器配件擋片，將最終擋片留在原位。
10. 將經導管心臟瓣膜置於壓折器開口中新。將經導管心臟瓣膜彎折到底，直到其接觸最終擋片為止，並維持 5 秒鐘。

    註：確認瓣膜壓折部分與瓣膜維持在同一軸線。確保壓折期間，經導管心臟瓣膜完全位於壓折器鉗口內。

11. 重複將瓣膜壓折到底兩次，總共進行三次壓折，每次維持 5 秒鐘。
12. 拉回球囊囊體，並鎖定在預定位置。
13. 以含有肝素的生理食鹽水沖洗裝填器。立即將經導管心臟瓣膜推入裝填器，直到完全位於裝填器內為止。

注意：經導管心臟瓣膜維持彎折到底或停留於裝填器的時間不可超過 15 分鐘，以免瓣葉受損而影響瓣膜功能。

14. 將裝填器護蓋裝回裝填器，經由沖洗口再次沖洗輸送系統，然後關閉通往輸送系統的調節閥。
取出通管針，然後沖洗輸送系統的導引線管腔。

注意：經導管心臟瓣膜植入前必須保持濕潤，以免瓣葉受損而影響瓣膜功能。

警告：植入前，必須確認經導管心臟瓣膜的安裝方向是否正確，以防止嚴重患者傷害風險。

8.3 預先撐開原生瓣膜與送入瓣膜

預先撐開原生瓣膜與送入瓣膜兩項步驟，應在血液動力學監控下採取局部清醒鎮靜麻醉及/或全身麻醉方式進行；執行手術的心導管室/複合式手術室，必須配備螢光鏡與心臟超音波等造影設備。

程序期間給予肝素，使活化凝血時間 (ACT) 維持在 250 秒以上。

在治療功能衰竭的人工生物瓣膜時，應避免使用球囊瓣膜成形術，這可能會導致生物瓣膜材質栓塞和瓣葉的機械性破壞。

注意：使用過量顯影劑可能導致腎臟衰竭，進行程序前應測量患者的肌酸酐濃度，並監控顯影劑的用量。

注意：手術可能需要切開動脈，且因動脈切開範圍較大，可能須以手術方式縫合穿刺部位。

8.3.1 基準點參數

1. 進行血管攝影，使螢光鏡的視野與瓣膜垂直。
2. 以經導管心臟瓣膜的支架高度為依據，評估左側及右側冠狀動脈口至主動脈瓣環的距離。
3. 插入心律調節器 (pacemaker，簡稱 PM) 導極，妥善放置。
4. 設定刺激參數直到 1:1 擷取率，測試節律。

8.3.2 預先撐開原生瓣膜

依據選定球囊主動脈瓣膜成形術導管的使用說明，由醫師決定是否預先撐開原生主動脈瓣膜。

注意：球囊在瓣膜成形術期間無法完全擴張時，不應進行瓣膜植入。

8.3.3 送入瓣膜

1. 使用標準心導管技術進入通路。
2. 依照使用說明準備 Edwards 套管，並將其插入。
3. 將裝填器插入套管，直到裝填器無法繼續前進為止。
4. 推進輸送系統，使 Edwards 標誌朝向正確方向 (朝沖洗口相反方向彎曲輸送系統)，通過套管直到瓣膜從套管伸出。

   註：操作全程均須維持 Flex 導管的正確方向。朝沖洗口相反方向彎曲輸送系統。

   注意：對於髂股通路，為降低髂血管受損風險，當套管末梢尚未越過下腔靜脈（IVC）分叉部位時，不可推進經導管心臟瓣膜通過套管。

   注意：經導管心臟瓣膜停留於套管的時間不可超過 5 分鐘，否則瓣葉可能會受損並影響瓣膜功能。
5. 在血管組織的直線段開始瓣膜定位，解除球囊鎖定裝置，並將球囊導管直接向後拉，直到部分警告標記出現為止。抽回時切勿超過警告標記。

   警告：為了避免球囊囊體受損，應確保球囊囊體的近端未受到彎折。

   啟動球囊鎖定裝置。

   使用微調環將經導管心臟瓣膜移至瓣膜定位標記間的位置。

   注意：當球囊鎖定裝置未啟動時，切勿轉動微調環。

   警告：切勿讓經導管心臟瓣膜超過遠端瓣膜定位標記，以免瓣膜無法適當展開或造成經導管心臟瓣膜栓塞。

   注意：瓣膜定位時應維持導引線位置，以免導引線位置改變。

   警告：如果閥門對齊不是直線段，則執行此步驟可能會遇到困難，這可能導致輸送系統損壞且無法為球囊充氣。利用交替的螢光鏡檢視畫面，可以幫助評估解剖結構的曲率。如果瓣膜在對準期間經歷過度張力，則需要將輸送系統重新定位到血管組織的不同直線部分，並減輕系統中的壓縮（或張力）。
6. 推進導管，必要時使用 Flex 控制環，並越過瓣膜。

   註：確認 Edwards 標誌方向，以確保正確連接。朝沖洗口相反方向彎曲輸送系統。
7. 解除球囊鎖定裝置，將 Flex 導管末梢收入三重標記中央。啟動球囊鎖定裝置。
8. 以原生瓣環為參考基準，確認經導管心臟瓣膜位於正確位置。
9. 必要時使用 Flex 控制環調整經導管心臟瓣膜的軸向性，並以微調節環調整經導管心臟瓣的位置。
10. 展開前，應確認瓣膜已正確置放於瓣膜定位標記間，且 Flex 導管末梢在三重標記上方。

11. 開始展開經導管心臟瓣膜：

- 解除愛德華公司提供之擴張裝置的鎖定狀態。
- 開始迅速節律；一旦收縮壓降至 50 mmHg 以下，開始擴張球囊。
- 利用緩慢且受到控制的擴張方式，以愛德華公司提供之擴張裝置的全部體積注入球囊，展開經導管心臟瓣膜，並維持此狀態 3 秒鐘，然後確認擴張裝置活塞筒徹底排空，以確保球囊完成擴張。
- 排空球囊。球囊導管徹底排空後，關閉心律調節器。

8.3.4 移除系統

1. 視需要，在縮回裝置時伸直輸送系統。確認 Flex 導管末梢固定於三重標記上方。將裝填器回縮到輸送系統近端，並從套管移除輸送系統。

   註：對於鎖骨下-腋窩方法，將輸送系統留在套管內，直到準備好將全部裝置一併移除為止。

   注意：為避免患者受傷，取出輸送系統前應將其伸直。

2. 等活化凝血時間降至適當程度，便可移除所有裝置。關於移除裝置的方法，請參考 Edwards 套管的使用說明。
3. 縫合導管插入部位。

9.0 供應方式

無菌：SAPIEN 3 Ultra RESILIA 瓣膜、輸送系統及配件經環氧乙烷氣體滅菌後供應。

瓣膜以不含致熱源的狀態供應，並採用防變造密封包裝，。

9.1 儲存

經導管心臟瓣膜必須儲存於 10°C 至 25°C (50°F 至 77°F)。瓣膜均以密封包裝運送，箱內備有溫度指示裝置，用以偵測經導管心臟瓣膜是否曾暴露於極端溫度。

輸送系統應儲存於陰涼、乾燥處所。

10.0 磁振造影安全資訊

與磁振造影有條件相容

非臨床測試證實，Edwards SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜與磁振造影有條件相容。在下列條件下，患者在植入本裝置後即可接受安全掃描：

- 靜磁場強度為 1.5 T 或 3.0 T
- 最大空間梯度場為 3000 gauss/cm (30 T/m)
- 磁振造影系統回報的最大全身平均特定吸收率 (SAR) 為 2 W/kg (正常操作模式)

在前述掃描條件下，預期 SAPIEN 3 Ultra RESILIA 經導管心臟瓣膜在連續掃描 15 分鐘後，體內溫度最高幅度低於 1.9°C。

依據非臨床測試，以 3.0 T 的磁振造影系統進行掃描時，自旋回波 (spin echo) 造影由裝置產生的假影超出植體最多至 9.0 mm，梯度回波 (gradient echo) 造影則為 23 mm。在梯度回波影像內的假影會使裝置管腔變模糊。

目前尚未評估植體在 1.5 T 或 3.0 T 以外磁振造影系統的表現。

對於瓣膜內植入瓣膜 (valve-in-valve) 或存在的其他植入物，在磁振造影前請參閱外科瓣膜或其他裝置的 MRI 安全資訊。

11.0 患者資訊

每個經導管心臟瓣膜皆隨附患者植體卡。植入後，請填妥所有必要的資訊，並將植體卡交給患者。序號請見包裝。患者就醫時，這張植體卡可供醫護專業人員瞭解患者植入的裝置種類。

12.0 回收的經導管心臟瓣膜與裝置的處置

取出的經導管心臟瓣膜應置入適當的組織固定液，例如 10% 福馬林或 2% 戊二醛，再送回公司。這種情況下不須冷藏。如需索取移除工具組，請聯絡愛德華公司。

使用過的裝置應視為醫院廢棄物及生物危害性物質，並以相同方式處理及處置。處理這類裝置並無特殊風險。

13.0 參考文獻

[1] Bapat V, Attia R, Thomas M. Effect of Valve Design on the Stent Internal Diameter of a Bioprosthetic Valve:A Concept of True Internal Diameter and Its Implications for the Valve-in-Valve Procedure.JACC:Cardiovascular Interventions.Vol. 7, No. 2 2014: 115-127.

愛德華瑟皮恩三優創乾式經導管心臟瓣膜系統

Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

愛德華 eSheath+導引器套組 (Edwards eSheath+ Introducer Set)

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

使用說明

本產品必須由受過介入治療技術訓練且擁有相關經驗的醫師操作使用。操作時應採取安裝血管通道套管的標準技術。

1. 裝置介紹

愛德華 eSheath+導引器套組包括：

1. 一組擴張式套管(eSheath+) (圖 1)，提供進入目標血管的通道，同時持續防止血液流出，並暫時擴張血管直徑供裝置通過。

2. 具親水性塗層的導引器 (圖 2)用於協助套管進入血管及其追蹤定位。

3. 具親水性塗層的擴張器 (圖 3) 用於擴張血管以容納套管。

4. 擴張工具 (圖 4) 用於在裝置準備時預先擴張套管。

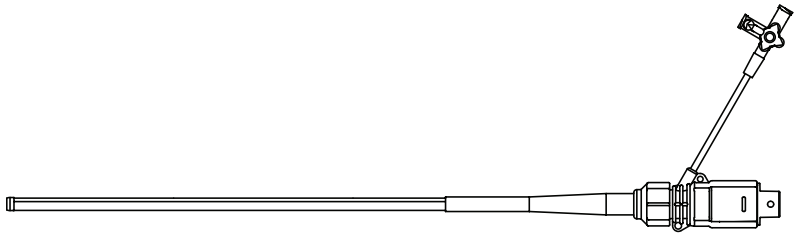


圖 1：套管

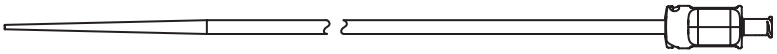


圖 2：導引器

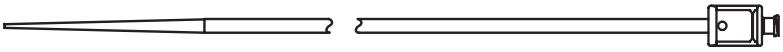


圖 3：擴張器

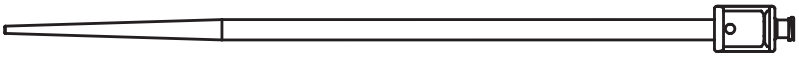


圖 4：擴張工具

	914ESP	916ESP
Sheath 內徑(擴張前)	14F (4.6 mm)	16F (5.3 mm)
Sheath 外徑(擴張前)	6.0 mm	6.7 mm
相容的 THV	20 mm 23 mm 26 mm	29 mm
導引器外徑	14F	16F
擴張器外徑	16F	18F

2. 適應症

Edwards eSheath+ 導引器套組適用於導入及移出與Edwards 經導管心臟瓣膜搭配使用的器材。

3. 禁忌症

目前沒有已知的禁忌症。

4. 警告

本裝置基於設計、用途及銷售目的，僅限單次使用。切勿再次滅菌或重複使用本裝置。目前尚無資料證明，本裝置經重新處理後無菌性、無致熱原性及功能是否仍符合標準。

為避免損傷血管，愛德華eSheath+導引器套組必須搭配相容的 0.035" (0.89 mm) 導引線使用。

切勿不當操作本裝置；若包裝或其他組件喪失無菌狀態、開啟或毀損(例如扭結或拉伸)、超過保存期限，亦不可使用。

5. 注意事項

- **擴張工具不包含親水性塗層。請勿做為擴張器使用。**
- **套管會暫時擴張血管直徑供裝置通過，因此應確認血管構造能容納套管擴張後的最大直徑。**
- **經由套管放入、操作或抽出裝置時，必須維持套管位置的方向。**
- **為防止損傷套管，在套管附近組織進行穿刺、縫合或切割時應小心謹慎。**
- **如果血管內的直徑小於 5.5 mm 或 6 mm 由於可能分別排除安全放置 14F 及 16F Edwards eSheath+ 導引器套組，應謹慎使用。**
- **扭曲或鈣化血管可能阻礙導引器套組安全進入，應謹慎使用。**

6. 可能發生的不良事件

標準導管插入技術與血管攝影可能引起的併發症包括、但不限於：麻醉劑或顯影劑引發過敏反應；血管穿孔或剝離之類的損傷；血管進入部位的損傷，可能必須進行血管修復；血栓及/或血塊移位，可能因而形成栓塞；遠端血管阻塞；中風；局部缺血及/或死亡。

7. 操作說明

1. 目視檢查導引器、擴張器、擴張工具及套管，確認表面沒有缺損及損壞。

2. 以含有肝素的生理食鹽水、經由導引線管腔沖洗導引器和擴張器。

3. 以含有肝素的生理食鹽水對整段導引器、擴張器及套管進行水合處理，以活化親水性塗層。

4. 沾濕擴張工具的表面。

5. 以含有肝素的生理食鹽水、經由沖洗口沖洗套管；沖洗後關閉沖洗口。

6. 在用於手術前，使用擴張工具預先擴張部分可擴張的套管部分。
註: 在預擴張套管之後，使用前應檢查整段可擴張部分是否毀損。

7. 在移除擴張工具後，以含有肝素的生理食鹽水、再次經由沖洗口沖洗套管；沖洗後關閉沖洗口。

8. 將導引器完全插入套管，並順時鐘方向轉動，將導引器中心固定在套管中心。

9. 利用標準導管插入技術，形成進入血管的通道，並視需要使用擴張器撐開以容納套管通過。

10. 適當地調整套管方向並全程維持這個方向。利用標準技術插入套管組件，同時利用螢光鏡影像追蹤其進展。
註: 套管有效長度的近端錐形構造直徑較大。

11. 如果可能的話，利用縫合環將套管縫於定位。

12. 透過逆時鐘方向轉動，將導引器中心自套管解開，從套管移除導引器。

13. 將裝置放入套管。
註: 手術進行期間，應依照標準介入治療技術，不時以含有肝素的生理食鹽水沖洗套管。

14. 完成手術並取出裝置後，應先移除縫線，然後在不扭轉的情形下完全取出套管，而且不可將其再次插入。

8. 供應方式

愛德華 eSheath+導引器套組以經環氧乙烷滅菌處理的袋裝形式供應。

9. 儲存

愛德華 eSheath+導引器套組應儲存於陰涼、乾燥處所。

10. 裝置處置

使用過的套管套組應視為醫院廢棄物及生物危害性物質，並以相同方式處理及處置。處理這類裝置並無特殊風險。

製造業者名稱：Edwards Lifesciences LLC

製造業者地址：One Edwards Way, Irvine, CA 92614, USA「Made (部分製程) in USA/ Singapore」

醫療器材商名稱：台灣愛德華生命科學股份有限公司

醫療器材商地址：臺北市中山區民生東路三段2號9樓之1

Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

TWFDA License No. 037718

Carefully read the original manufacturer's instructions for use prior to use and follow the instructions

Instructions for Use

Implantation of the transcatheter heart valve should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in balloon aortic valvuloplasty and standard heart catheterization techniques. It is at the physician's discretion to choose the appropriate access route to implant the transcatheter heart valve based on the patient anatomy and associated risks.

Name	20 mm	23 mm	26 mm	29 mm
	Model/Catalogue Number			
Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System Edwards SAPIEN 3 Ultra RESILIA — Edwards Commander Kit	S3URCM20AP	S3URCM23AP	S3URCM26AP	S3URCM29AP
Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	9755RSL20	9755RSL23	9755RSL26	9755RSL29
Edwards Commander Delivery System [1]	9750CM20	9750CM23	9750CM26	9750CM29
Edwards eSheath+ Introducer Set	914ESP			916ESP
Crimper	9600CR			
Inflation Device	96402			-
Locking Syringe	-			96406
[1]Including a loader, a Qualcrimp crimping accessory, and a 2-piece crimp stopper				

1.0 Device Description

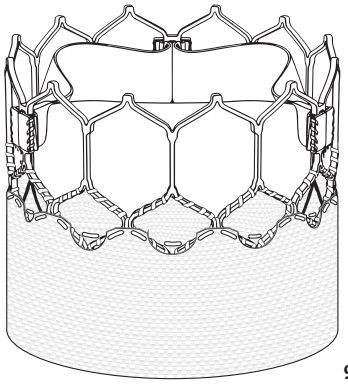
Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

The Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve (THV) system consists of the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valves and delivery systems.

- **Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve - (Figure 1)**

The Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobaltchromium frame, trileaflet RESILIA bovine pericardial tissue valve, and polyethylene terephthalate (PET) inner and outer fabric skirts.

RESILIA Tissue: RESILIA tissue is created with a novel technology called Edwards Integrity Preservation which incorporates a stable capping anti-calcification process to block residual aldehyde groups that are known to bind with calcium. The technology also incorporates tissue preservation with glycerol, which replaces the traditional storage in liquid-based solutions such as glutaraldehyde. This storage method eliminates tissue exposure to the residual unbound aldehyde groups commonly found in glutaraldehyde storage solutions.



9755RSL

Figure 1: Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

Table 1

Valve Size	Valve Height
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm
29 mm	22.5 mm

The transcatheter heart valve is intended to be implanted in a native valve annulus size range associated with the three-dimensional area of the aortic annulus measured at the basal ring during systole. Sizing recommendations for implanting the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valves in a native valve annulus are provided in the table below:

Table 2

Native Valve Annulus Size (TEE)	Native Valve Annulus Size (CT)		THV Size
	Area	Area Derived Diameter	
16-19 mm	273-345 mm^2	18.6-21 mm	20 mm
18-22 mm	338-430 mm^2	20.7-23.4 mm	23 mm
21-25 mm	430-546 mm^2	23.4-26.4 mm	26 mm
24-28 mm	540-683 mm^2	26.2-29.5 mm	29 mm
Valve size recommendations are based on native valve annulus size, as measured by transesophageal echocardiography (TEE) or computed tomography (CT). Patient anatomical factors and multiple imaging modalities should be considered during valve size selection. **Note: Risks associated with undersizing and oversizing should be considered.**			

Transcatheter heart valve size recommendations are based on native valve annulus size, as measured by transesophageal echocardiography (TEE) or computed tomography (CT). Patient anatomy and multiple imaging modalities should be considered during transcatheter heart valve size selection.

NOTE: Risks associated with undersizing and oversizing should be considered to minimize the risk of paravalvular leak, migration, and/or annular rupture.

*Due to limitations in two-dimensional images, 2-D TEE imaging should be supplemented with 3-D area measurements.

Sizing recommendations for implanting the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valves in a failing bioprosthesis, except for the INSPIRIS RESILIA aortic valve sizes 19-25 mm, are provided in the table below:

Table 3

Surgical Valve True Inner Diameter (ID) [1]	THV-in-THV (Native Valve Annulus Size)	THV Size
16.5-19.0 mm	18.6-21.0 mm	20 mm
18.5-22.0 mm	20.7-23.4 mm	23 mm
22.0-25.0 mm	23.4-26.4 mm	26 mm
25.0-28.5 mm	26.2-29.5 mm	29 mm

NOTE: Surgical valve 'True ID' may be smaller than the labeled valve size. For THV-in-THV, the native valve annulus size should be considered to determine the appropriate THV size to implant. For a failing stentless bioprosthesis, consider sizing recommendations for a native valve annulus. The dimensions of the failing bioprosthesis should be determined so that the appropriate THV size can be implanted; and it's best to determine by using computed tomography, magnetic resonance imaging, and/or transesophageal echocardiography.

Sizing recommendations for implanting the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valves in a failing INSPIRIS RESILIA aortic surgical bioprosthesis in sizes 19-25 mm, based on bench testing, are provided in the table below:

Table 4

INSPIRIS RESILIA Aortic Valve (model 11500A)* Labeled Size	THV Size
19 mm	20 mm or 23 mm
21 mm	23 mm or 26 mm
23 mm	23 mm or 26 mm
25 mm	26 mm or 29 mm

*INSPIRIS RESILIA aortic valve model 11500A sizes 19-25 mm incorporate VFit technology which consists of expandable bands and fluoroscopically visible size markers designed for potential future valve-in-valve procedures. Clinical data are not currently available on the INSPIRIS RESILIA aortic valve Model 11500A valve-in-valve procedure or expansion feature. The impact of tissue ingrowth on the expansion feature of the INSPIRIS RESILIA aortic valve has not been assessed.

WARNING: Do not perform stand-alone balloon aortic valvuloplasty procedures in the INSPIRIS RESILIA aortic valve for the sizes 19-25 mm. This may expand the valve causing aortic incompetence, coronary embolism or annular rupture.

Note: INSPIRIS RESILIA aortic valve model 11500A sizes 27-29 mm do not incorporate VFit technology and therefore, the surgical valve True ID sizing provided in Table 2 should be followed.

Note: Exact volume required to deploy the THV may vary depending on the bioprosthesis inner diameter. Factors such as calcification and pannus tissue growth may not be accurately visualized in imaging and may reduce the effective inner diameter of the failing bioprosthesis to a size smaller than the 'True ID'.

These factors should be considered and assessed in order to determine the most appropriate THV size to achieve nominal THV deployment and sufficient anchoring. Do not exceed the rated burst pressure. See inflation parameters in Table 5.

- **Edwards Commander Delivery System (Figure 2)**

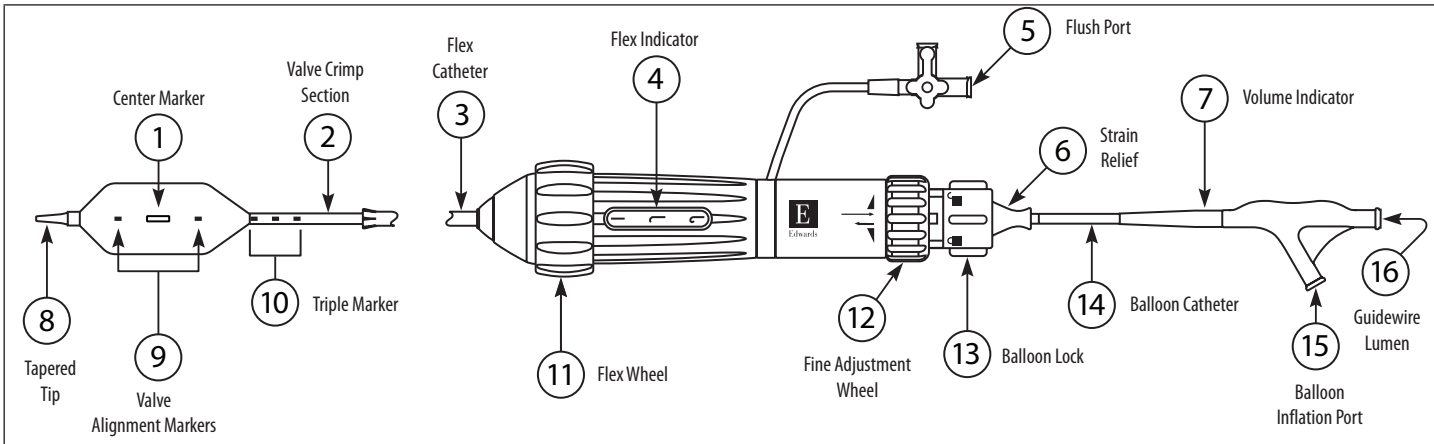
The Edwards Commander delivery system facilitates the placement of the bioprosthesis.

It consists of a flex catheter to aid in valve alignment to the balloon, tracking, and positioning of the valve. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex wheel to control flexing of the Flex catheter, and a balloon lock and fine adjustment wheel to facilitate valve alignment and positioning of the valve in the native valve annlus location. A stylet is included within the guidewire lumen of the delivery system. The balloon catheter has radiopaque valve alignment markers defining the working length of the balloon. A radiopaque center marker in the balloon is provided to help with valve positioning. A radiopaque triple marker proximal to the balloon indicates the Flex catheter position during deployment.

The inflation parameters for transcatheter heart valve deployment are:

Table 5

Model	Nominal Balloon Diameter	Nominal Inflation Volume	Rated Burst Pressure (RBP)
9750CM20	20 mm	11 ml	7 atm
9750CM23	23 mm	17 ml	7 atm
9750CM26	26 mm	23 ml	7 atm
9750CM29	29 mm	33 ml	7 atm



1. Center Marker
2. Valve Crimp Section
3. Flex Catheter
4. Flex Indicator
5. Flush Port
6. Strain Relief
7. Volume Indicator
8. Tapered Tip
9. Valve Alignment Markers
10. Triple Marker
11. Flex Wheel
12. Fine Adjustment Wheel
13. Balloon Lock
14. Balloon Catheter
15. Balloon Inflation Port
16. Guidewire Lumen

Figure 2: Edwards Commander Delivery System

Additional Accessories

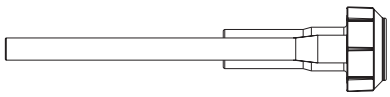


Figure 3: Loader

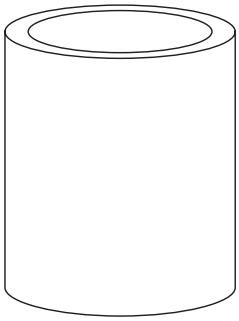


Figure 4: Qualcrimp Crimping Accessory

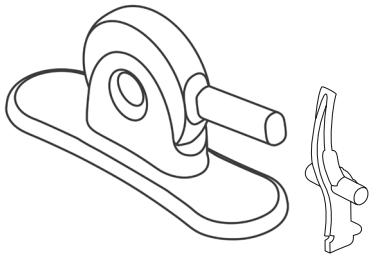


Figure 5: Edwards Crimper and Crimp Stopper

- **Loader (Figure 3)**

The loader is used to aid insertion of the delivery system into the sheath.

- **Edwards Sheath**

Refer to the sheath instructions for use for device description.

- **Qualcrimp Crimping Accessory (Figure 4)**

The Qualcrimp crimping accessory is used during THV crimping.

- **Edwards Crimper and Crimp Stopper (Figure 5)**

The Edwards crimper reduces the diameter of the transcatheter heart valve to mount it onto the delivery system. The crimper is comprised of a housing and a compression mechanism that is closed with a handle located on the housing. A 2-piece crimp stopper is used to crimp the transcatheter heart valve to its intended diameter.

- **Inflation Device**

An inflation device with locking mechanism is used during transcatheter heart valve deployment.

Note: For proper volume sizing, the delivery system must be used with the inflation device provided by Edwards Lifesciences.

2.0 Intended Use

The bioprosthesis is intended for use in patients requiring heart valve replacement. The delivery system and accessories are intended to facilitate the placement of the bioprosthesis via the transfemoral, transseptal, subclavian/axillary access approaches.

3.0 Indications

1. The Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve system is indicated for use in patients with heart disease due to native calcific aortic stenosis at any or all levels of surgical risk for open surgical therapy.
2. The Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve system is indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of an aortic transcatheter bioprosthetic or surgical aortic or mitral bioprosthetic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

4.0 Contraindications

Use of the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve system is contraindicated in patients who:

- **Cannot tolerate an anticoagulation/antiplatelet therapy or who have active bacterial endocarditis or other active infections.**

5.0 Warnings

- **Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation.**
- **The devices are designed, intended, and distributed STERILE for single use only. Do not resterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.**
- **Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-bioprosthesis mismatch) and/or annular rupture.**
- **Accelerated deterioration of the valve due to calcific degeneration may occur in patients with an altered calcium metabolism.**
- **Prior to delivery, the transcatheter heart valve must remain hydrated at all times and cannot be exposed to solutions, antibiotics, chemicals, etc. other than its shipping storage solution and sterile physiologic saline solution to prevent leaflet damage that may impact valve functionality. THV leaflets mishandled or damaged during any part of the procedure will require replacement of the THV.**
- **Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease.**
- **Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment.**
- **Do not use the valve if the tamper evident seal is broken, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed, as either sterility or valve function may be compromised.**
- **Do not mishandle the delivery system; do not use the delivery system and accessory devices if the packaging sterile barriers and any components have been opened or damaged (e.g., kinked or stretched), cannot be flushed, or the expiration date has elapsed.**
- **Patient injury could occur if the delivery system is not un-flexed prior to removal.**
- **Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, glycerol, bovine tissue, and/or polymeric materials may have an allergic reaction to these materials.**
- **Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, to minimize the risk of valve thrombosis or thromboembolic events, as determined by their physician. This device has not been tested for use without anticoagulation.**
- **Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets.**
- **The physician must verify correct orientation of the valve prior to its implantation.**
- **Access characteristics such as severe obstructive or circumferential calcification, severe tortuosity, vessel diameters less than 5.5 mm (for size 20, 23 and 26 mm SAPIEN 3 Ultra RESILIA transcatheter heart valve) or 6.0 mm (for 29-mm SAPIEN 3 Ultra RESILIA transcatheter heart valve) may preclude safe placement of the sheath and should be carefully assessed prior to the procedure.**

6.0 Precautions

- **Long-term durability has not been established for the THV. Regular medical follow-up is advised to evaluate valve performance.**
- **If a significant increase in resistance occurs when advancing the catheter through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications. As compared to SAPIEN 3, system advancement force may be higher with the use of SAPIEN 3 Ultra RESILIA transcatheter heart valve in tortuous/challenging vessel anatomies.**
- **Do not overinflate the deployment balloon, as this may prevent proper valve leaflet coaptation and thus impact valve functionality.**
- **Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis.**
- **Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include presence of devices or thrombus or other abnormalities in the vena cava precluding safe transvenous femoral access for transseptal approach; presence of Atrial Septal Occluder Device or calcium preventing safe transseptal access.**
- **Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation to avoid entrapment of the subvalvular apparatus.**

- **Based on the treating physician's consideration of risks and benefits, the valve may be implanted in relatively young patients, although the long-term durability is still the subject of ongoing clinical research.**
- **Safety and effectiveness of the THV implantation have not been established for patients who have:**
  - **Non-calcified aortic annulus**
  - **Severe ventricular dysfunction with ejection fraction < 20%**
  - **Congenital unicuspid aortic valve**
  - **Pre-existing bioprosthetic annulus in any position**
  - **Severe mitral annular calcification (MAC), severe (> 3+) mitral insufficiency, or Gorlin syndrome**
  - **Blood dyscrasias defined as: leukopenia (WBC < 3,000 cells/µL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/µL), or history of bleeding diathesis or coagulopathy**
  - **Hypertrophic cardiomyopathy (HOCM) with or without obstruction**
  - **Aortic stenosis characterized by a combination of AV low flow, low transvalvular pressure gradient**
  - **Echocardiographic evidence of intracardiac mass, thrombus, or vegetation**
  - **A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated**
  - **Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta**
  - **Bulky calcified aortic valve leaflets in close proximity to coronary ostia**
  - **A concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native valve annulus or is not structurally intact (e.g., wireform frame fracture)**
  - **A partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct coronary ostia**
- **The risks of subclavian/axillary access are low and acceptable, but subclavian/axillary access should be considered when the physician determines there is an increased risk associated with transfemoral access.**
- **For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage.**
- **For left/right axillary approach, ensure there is flow in the Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery.**
- **Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthesis are determined so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.**
- **Post-procedure and follow-up assessment of TAVR device performance by Doppler echocardiography may be impacted by inherent limitations in the Bernoulli equation used to determine measurements such as mean gradient, EOA, and bioprosthesis-patient mismatch. These limitations may lead to an overstating or understating of valve performance measurements after TAVR implantation. Therefore, a post-TAVR echocardiogram should be used to establish a baseline from which future follow-up visits are compared to. Confirmatory direct pressure measurement via cardiac catheterization may be considered, when indicated, prior to reintervention.**

7.0 Potential Adverse Events

Potential risks associated with the overall procedure including access, cardiac catheterization, local anesthesia with conscious sedation and/or general anesthesia:

- **Death**
- **Stroke/transient ischemic attack, clusters or neurological deficit**
- **Paralysis**
- **Permanent disability**
- **Respiratory insufficiency or respiratory failure**
- **Hemorrhage requiring transfusion or intervention**
- **Cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium or valvular structures that may require intervention**
- **Pericardial effusion or cardiac tamponade**
- **Thoracic bleeding**
- **Embolization, such as air, calcific valve material or thrombus**
- **Infection, such as septicemia and endocarditis**
- **Heart failure**
- **Myocardial ischemia or infarction**

- **Renal insufficiency or renal failure**
- **Conduction system defect which may require a permanent pacemaker**
- **Arrhythmias, including ventricular fibrillation (VF) and ventricular tachycardia (VT)**
- **Retroperitoneal bleed**
- **Arteriovenous (AV) fistula or pseudoaneurysm**
- **Reoperation**
- **Ischemia or nerve injury or brachial plexus injury or compartment syndrome**
- **Restenosis**
- **Pulmonary edema**
- **Pleural effusion**
- **Bleeding requiring transfusion or intervention**
- **Anemia**
- **Vessel thrombosis/occlusion**
- **Abnormal lab values (including electrolyte imbalance)**
- **Hypertension or hypotension**
- **Allergic reaction to anesthesia, contrast media, or device materials or bovine pericardial tissue**
- **Hematoma**
- **Syncope**
- **Pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site**
- **Exercise intolerance or weakness**
- **Inflammation**
- **Angina**
- **Vasovagal response**
- **Heart murmur**
- **Fever**

Additional potential risks associated with the TAVR procedure, the bioprosthesis, and the use of its associated devices and accessories include:

- **Cardiac arrest**
- **Cardiogenic shock**
- **Emergency cardiac surgery**
- **Cardiac failure or low cardiac output**
- **Coronary artery blood flow obstruction/transvalvular blood flow disturbance**
- **Device thrombosis requiring intervention**
- **Valve thrombosis**
- **Device embolization**
- **Device migration or malposition requiring intervention**
- **LVOT obstruction**
- **Valve deployment in unintended location**
- **Valve stenosis**
- **Vessel spasm**
- **Structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis)**
- **Device degeneration**
- **Paravalvular or transvalvular leak**
- **Valve regurgitation**
- **Hemolysis**

- **Device explants**
- **Nonstructural dysfunction**
- **Mechanical failure of delivery system, and/or accessories, including balloon rupture and tip separation**
- **Non-emergent reoperation**
- **Allergic/immunologic reaction to the implant**
- **Injury to mitral valve**

8.0 Directions for Use

8.1 System Compatibility

Table 6

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	9755RSL20 (20 mm)	9755RSL23 (23 mm)	9755RSL26 (26 mm)	9755RSL29 (29 mm)
Edwards Commander Delivery System	9750CM20	9750CM23	9750CM26	9750CM29
Edwards eSheath+ Introducer Set	914ESP			916ESP
Inflation Device	96402			96406
Edwards Crimper	9600CR			
Qualcrimp Crimping Accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				

Additional Equipment:

- Balloon catheter per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment and supplies, and access to standard heart valve operating room equipment and supplies
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 in (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and accessories preparation

8.2 Valve Handling and Preparation

Maintain sterile technique during device preparation and implantation.

8.2.1 SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

The SAPIEN 3 Ultra RESILIA transcatheter heart valve is provided sterile and nonpyrogenic. The packaging consists of a carton containing a foil pouch. Within the foil pouch is a tray that is sealed with a Tyvek lid. Inside of the tray is the valve holder which contains the valve.

1. Remove the tamper evident label to open the carton.
2. Remove the foil pouch from the carton in the non-sterile field. Before opening, examine the package for evidence of damage and broken or missing seals. Open pouch and remove tray in the non-sterile field.

   WARNING: Do not open foil pouch in the sterile field, as sterility may be compromised. The foil pouch is a protective cover only. Only the valve holder may be introduced into the sterile field.

   Note: If the foil pouch is opened during the procedure and the valve is not used, discard the valve.
3. The tray is labeled with the model, size, and serial number. The model, size, and serial number should be confirmed with the number on the valve package and valve implant data card.
4. Near the sterile field, hold the base of the tray and peel the lid from the tray.
5. The valve holder and contents are sterile. Transfer the valve holder to the sterile field.

   CAUTION: The contents of the valve holder must be handled using a sterile technique. Take care when removing the valve holder from the tray to ensure there is no contact with the nonsterile adhesive on the lip of the tray.

8.2.2 Valve Soaking/Rinsing Procedure

8.2.2.1 SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

1. Setup one (1) sterile bowl with at least 500 ml of sterile physiological saline to soak the valve.
2. Open the valve holder by holding the base and lifting the lid. Carefully remove the valve from the valve holder without touching the tissue. Inspect the valve for any signs of damage to the frame or tissue.
3. Place the valve in the sterile bowl of sterile physiological saline. Be sure that the sterile physiological saline completely covers the valve for at least two minutes to hydrate the leaflets. The valve should be left in the sterile physiological saline to prevent the tissue from drying.

   CAUTION: No other objects should be placed in the soak bowl. The valve should be kept hydrated to prevent the tissue from drying.

8.2.3 Prepare the System

1. Visually inspect all components for damage. Ensure the delivery system is fully unflexed and the balloon catheter is fully advanced in the Flex catheter.

   WARNING: To prevent possible damage to the balloon shaft, ensure that the proximal end of the balloon shaft is not subjected to bending.
2. Flush the delivery system with heparinized saline through the flush port.
3. Carefully remove the distal balloon cover from the delivery system. Remove the stylet from the distal end of the guidewire lumen and set the stylet aside.
4. Flush the guidewire lumen with heparinized saline and insert the stylet back into the distal end of the guidewire lumen.

   Note: Failure to insert the stylet back into the guidewire lumen may result in damage to the lumen during the valve crimping process.
5. Place the delivery system into the default position (end of strain relief is aligned between the two white markers on the balloon shaft) and make sure that the Flex catheter tip is covered by the proximal balloon cover. Unscrew the loader cap from the loader tube and flush the loader cap with heparinized saline. Place the loader cap over the proximal balloon cover and onto the Flex catheter with the inside of the cap oriented towards the distal tip.
6. Fully advance the balloon catheter in the Flex catheter.
   Peel off the proximal balloon cover over the blue section of the balloon shaft.
7. Attach a 3-way stopcock to the balloon inflation port. Partially fill a 50 cc or larger syringe with 15-20 ml diluted contrast medium and attach to the 3-way stopcock.
8. Fill the inflation device provided by Edwards Lifesciences with excess volume of diluted contrast medium relative to the indicated inflation volume. Lock the inflation device and attach to the 3-way stopcock.
9. Close the 3-way stopcock to the inflation device provided by Edwards Lifesciences. Pull vacuum using the 50 cc or larger syringe to de-air the system. Slowly release the plunger to ensure that the contrast medium enters the lumen of the delivery system. Repeat until all air bubbles are removed from the delivery system. Leave zero pressure in the delivery system.

   WARNING: Ensure there is no residual fluid left in the balloon to avoid potential difficulty with valve alignment during the procedure.
10. Close the stopcock to the delivery system. By rotating the knob of the inflation device provided by Edwards Lifesciences, transfer the contrast medium into the syringe to achieve the appropriate volume required to deploy the valve.
11. Close the stopcock to the 50 cc or larger syringe. Remove the syringe. Verify that the inflation volume is correct and lock the inflation device provided by Edwards Lifesciences.

    CAUTION: Maintain the inflation device provided by Edwards Lifesciences in the locked position until THV deployment to minimize the risk of improper THV deployment due to premature balloon inflation.

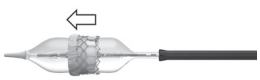
8.2.4 Mount and Crimp the Valve on the Delivery System

1. Set up two (2) additional sterile bowls with at least 100 ml of sterile physiological saline to thoroughly rinse the Qualcrimp crimping accessory.
2. Completely submerge the Qualcrimp crimping accessory in the first bowl and gently compress it to ensure complete saline absorption. Slowly swirl the Qualcrimp crimping accessory for a minimum of 1 minute. Repeat this process in the second bowl.
3. Remove the valve from the soaking/rinsing bowl.
4. Rotate the crimper handle until the aperture is fully open. Attach the 2-piece crimp stopper to the base of the crimper and click into place.
5. With the crimper in the open position, gently place the valve into the crimper aperture. Gradually crimp the valve until it fits into the Qualcrimp crimping accessory.

   Note: This step is not necessary for the 20-mm valve.
6. Place the Qualcrimp crimping accessory over the THV, making sure the THV is parallel to the edge of the Qualcrimp crimping accessory.
7. Place the valve and Qualcrimp crimping accessory in crimper aperture. Insert the delivery system coaxially within the valve on the valve crimp section (2-3 mm distal to the balloon shaft) with the orientation of the valve on the delivery system as described below:

   Antegrade approach: Inflow (outer skirt end) of the valve towards the proximal end of the delivery system.

   Retrograde approach: Inflow (outer skirt end) of the valve towards the distal end of the delivery system.



8. Center the balloon shaft coaxially within the THV. Crimp the THV until it reaches the Qualcrimp crimping accessory stop located on the 2-piece crimp stopper.

9. Gently remove the Qualcrimp crimping accessory from the THV. Remove the Qualcrimp crimping accessory stop from the crimp stopper, leaving the final stop in place.
10. Center the THV within the crimper aperture. Fully crimp the THV until it reaches the final stop and hold for 5 seconds.

    Note: Ensure that the Valve Crimp Section remains coaxial within the THV. Ensure that the THV is fully within the crimper jaws during crimping.
11. Repeat the full crimp of the THV two more times for a total of three full crimps for 5 seconds each.
12. Pull the balloon shaft and lock in the default position.
13. Flush the loader with heparinized saline. Immediately advance the THV into the loader until it is completely inside the loader.

    CAUTION: The THV should not remain fully crimped and/or in the loader for over 15 minutes, as leaflet damage may result, and impact valve functionality.
14. Attach the loader cap to the loader, re-flush the delivery system through the flush port and close the stopcock to the delivery system.
    Remove the stylet and flush the guidewire lumen of the delivery system.

    CAUTION: Keep the THV hydrated until ready for implantation to prevent damage to the leaflets which may impact valve functionality.

    WARNING: The physician must verify correct orientation of the THV prior to its implantation to prevent the risk of severe patient harm.

8.3 Native Valve Predilation and Valve Delivery

Native valve predilation and valve delivery should be performed under local anesthesia with conscious sedation and/or general anesthesia with hemodynamic monitoring in a catheterization lab/hybrid operating room with fluoroscopic and echocardiographic imaging capabilities.

Administer heparin to maintain the ACT at ≥ 250 sec during the procedure.

Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets.

CAUTION: Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored.

CAUTION: Procedure may require an arterial cut-down with surgical closure of the puncture site due to the size of the arteriotomy.

8.3.1 Baseline Parameters

1. Perform an angiogram with fluoroscopic view perpendicular to the valve.
2. Evaluate the distance of the left and right coronary ostia from the aortic annulus in relation to the valve frame height.
3. Introduce a pacemaker (PM) lead and position appropriately.
4. Set the stimulation parameters to obtain 1:1 capture, and test pacing.

8.3.2 Native Valve Predilation

Pre-dilate the native aortic valve, per the discretion of the physician, according to the instructions for use for the selected balloon aortic valvuloplasty catheter.

CAUTION: Valve implantation should not be carried out if the balloon cannot be fully inflated during valvuloplasty.

8.3.3 Valve Delivery

1. Gain access using standard catheterization techniques.
2. Prepare and insert the Edwards sheath per its instructions for use.
3. Insert the loader into the sheath until the loader stops.
4. Advance the delivery system, with the Edwards logo in the proper orientation (the delivery system articulates in a direction opposite from the flush port), through the sheath until the valve exits the sheath.

   Note: Maintain the proper orientation of the Flex catheter throughout the procedure. The delivery system articulates in a direction opposite from the flush port.

   CAUTION: For iliofemoral access, the valve should not be advanced through the sheath if the sheath tip is not past the bifurcation of the inferior vena cava (IVC) to minimize the risk of ilio-vessel damage.

   CAUTION: To prevent possible leaflet damage and possible impact to valve functionality, the valve should not remain in the sheath for over 5 minutes.
5. In a straight section of the vasculature, initiate valve alignment by disengaging the balloon lock and pulling the balloon catheter straight back until part of the warning marker is visible. Do not pull past the warning marker.

   WARNING: To prevent possible damage to the balloon shaft, ensure that the proximal end of the balloon shaft is not subjected to bending.

   Engage the balloon lock.

   Use the fine adjustment wheel to position the valve between the valve alignment markers.

   CAUTION: Do not turn the fine adjustment wheel if the balloon lock is not engaged.

   WARNING: Do not position the THV past the distal valve alignment marker to minimize the risk of improper valve deployment or THV embolism.

   CAUTION: Maintain guidewire position during valve alignment to prevent loss of guidewire position.

   WARNING: If valve alignment is not performed in a straight section, there may be difficulties performing this step which may lead to delivery system damage and inability to inflate the balloon. Utilizing alternate fluoroscopic views may help with assessing curvature of the anatomy. If excessive tension is experienced during valve alignment, repositioning the delivery system to a different straight section of the vasculature and relieving compression (or tension) in the system will be necessary.
6. Advance the catheter and use the Flex wheel, if needed, to cross the valve.

   Note: Verify the orientation of the Edwards logo to ensure proper articulation. The delivery system articulates in a direction opposite from the flush port.

7. Disengage the balloon lock and retract the tip of the Flex catheter to the center of the triple marker. Engage the balloon lock.
8. Verify the correct position of the THV with respect to the native valve annulus location.
9. As necessary, utilize the Flex wheel to adjust the co-axiality of the THV and the fine adjustment wheel to adjust the position of the THV.
10. Before deployment, ensure that the THV is correctly positioned between the valve alignment markers and the Flex catheter tip is over the triple marker.
11. Begin THV deployment:
    - Unlock the inflation device provided by Edwards Lifesciences.
    - Begin rapid pacing; once systolic blood pressure has decreased to 50 mmHg or below, balloon inflation can commence.
    - Using slow controlled inflation, deploy the THV by inflating the balloon with the entire volume in the inflation device provided by Edwards Lifesciences, hold for 3 seconds and confirm that the barrel of the inflation device is empty to ensure complete inflation of the balloon.
    - Deflate the balloon. When the balloon catheter has been completely deflated, turn off the pacemaker.

8.3.4 System Removal

1. Unflex the delivery system while retracting the device, if needed. Verify that the Flex catheter tip is locked over the triple marker. Retract the loader to the proximal end of the delivery system and remove the delivery system from the sheath.

   Note: For subclavian-axillary approach, keep delivery system inside sheath until ready to remove all devices as one unit.

   CAUTION: Patient injury could occur if the delivery system is not unflexed prior to removal.
2. Remove all devices when the ACT level is appropriate. Refer to the Edwards sheath instructions for use for device removal.
3. Close the access site.

9.0 How Supplied

STERILE: The SAPIEN 3 Ultra RESILIA valve, delivery system, and accessories are supplied sterilized with ethylene oxide gas.

The valves are supplied nonpyrogenic in packaging to which a tamper evident seal has been applied.

9.1 Storage

The valve must be stored at 10 °C to 25 °C (50 °F to 77 °F). Each valve is shipped in an enclosure containing a temperature indicator to detect exposure of the valve to extreme temperature.

The delivery system should be stored in a cool, dry place.

10.0 MR Safety Information

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valves are MR Conditional. A patient with this device can be scanned safely, immediately after placement of this device under the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial gradient field of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SAPIEN 3 Ultra RESILIA transcatheter heart valves are expected to produce a maximum temperature rise of 1.9 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 9.0 mm from the implant for spin echo images and 23 mm for gradient echo images when scanned in a 3.0 T MRI system. The artifact obscures the device lumen in gradient echo images.

The implant has not been evaluated in MR systems other than 1.5 T or 3.0 T.

For valve-in-valve implantation or in the presence of other implants, please refer to the MRI safety information for the surgical valve or other devices prior to MR imaging.

11.0 Patient Information

A patient implant card is provided with each THV. After implantation, please complete all requested information and provide the implant card to the patient. The serial number is found on the package. This implant card allows patients to inform healthcare providers what type of implant they have when they seek care.

12.0 Recovered THV and Device Disposal

The explanted THV should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to the company. Refrigeration is not necessary under these circumstances. Contact Edwards Lifesciences to request an explant kit.

Used devices may be handled and disposed of in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of these devices.

13.0 References

[1] Bapat V, Attia R, Thomas M. Effect of Valve Design on the Stent Internal Diameter of a Bioprosthetic Valve: A Concept of True Internal Diameter and Its Implications for the Valve-in-Valve Procedure. JACC:Cardiovascular Interventions.Vol. 7, No. 2 2014: 115-127.

Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Edwards eSheath+ Introducer Set

Carefully read the manufacturer's manual prior to use and follow the instructions for use.

Instructions for Use

The product is intended for use by physicians trained and experienced in interventional techniques. Standard techniques for the placement of vascular access sheaths should be employed.

1. Device Description

The Edwards eSheath+ introducer set contains:

1. an expandable sheath (eSheath+) (Figure 1) that provides access into the target vessel while maintaining hemostasis and temporarily enlarges its diameter to allow for passage of a device.

2. an introducer (Figure 2) with hydrophilic coating that is used to facilitate entry and trackability of the sheath into the vessel.

3. a dilator (Figure 3) with hydrophilic coating that is used to dilate the vessel to accommodate the sheath.

4. an expansion tool (Figure 4) that is used to pre-expand the sheath during device preparation.

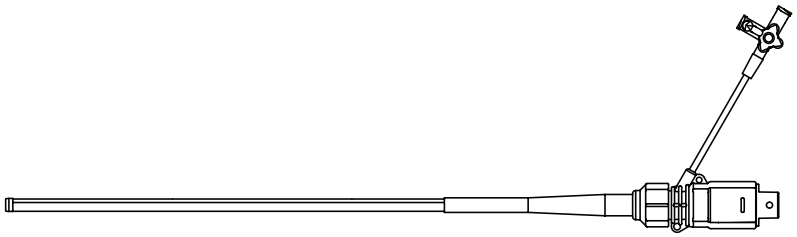


Figure 1: Sheath

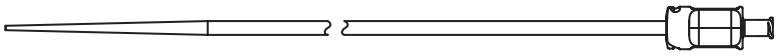


Figure 2: Introducer

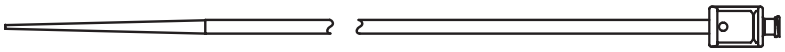


Figure 3: Dilator

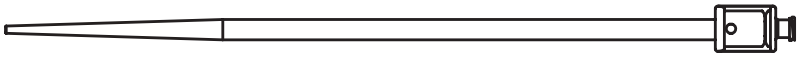


Figure 4: Expansion Tool

	914ESP	916ESP
Sheath I.D. (unexpanded)	14F (4.6 mm)	16F (5.3 mm)
Sheath O.D. (unexpanded)	6.0 mm	6.7 mm
Compatible THV	20 mm 23 mm 26 mm	29 mm
Introducer O.D.	14F	16F
Dilator O.D.	16F	18F

2. Indications

The Edwards eSheath+ Introducer Set is indicated for the introduction and removal of devices used with Edwards transcatheter heart valves.

3. Contraindications

There are no known contraindications.

4. Warnings

The devices are designed, intended, and distributed for single use only. Do not resterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.

The Edwards eSheath+ introducer set must be used with a compatible 0.035 in (0.89 mm) guidewire to prevent vessel injury.

Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (i.e., kinked or stretched, etc.), or the use-by date has elapsed.

5. Precautions

- **Expansion tool does not contain a hydrophilic coating. Do not use as a dilator.**
- **The sheath temporarily enlarges to allow the passage of devices; ensure that the vasculature can accommodate the maximum diameter of the expanded sheath.**
- **When inserting, manipulating or withdrawing a device through the sheath, always maintain orientation of the sheath position.**
- **When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.**
- **Caution should be used in vessels that have diameters less than 5.5 mm or 6 mm as it may preclude safe placement of the 14F and 16F Edwards eSheath+ introducer set respectively.**
- **Use caution in tortuous or calcified vessels that would prevent safe entry of the introducer set.**

6. Potential Adverse Events

Complications associated with standard catheterization and use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media; injury, including perforation or dissection of vessels; injury at the site of access that might require vessel repair; thrombosis and/or plaque dislodgment which may result in emboli formation; distal vessel obstruction; stroke; ischemia and/or death.

7. Directions for Use

1. Visually inspect the introducer, dilator, expansion tool and sheath for surface defects and damage.

2. Flush the introducer and dilator using heparinized saline through the guidewire lumen.

3. Hydrate the length of the introducer, dilator, and sheath with heparinized saline to activate the hydrophilic coating.

4. Wet the surface of the expansion tool.

5. Flush the sheath using heparinized saline through the flush port; close the flush port.

6. Use the expansion tool to pre-expand the partially expandable portion of the sheath prior to procedural use.
Note: After pre-expanding the sheath, inspect the length of the expandable portion for damage prior to use.

7. After removing the expansion tool, flush the sheath a second time using the heparinized saline through the flush port; close the flush port.

8. Insert the introducer completely into the sheath and turn clockwise to lock the introducer hub to the sheath hub.

9. Using standard catheterization techniques, gain access to the vessel and dilate as necessary with the dilator to accommodate the sheath.

10. Orient the sheath appropriately and maintain orientation throughout the procedure. Insert the sheath assembly using standard technique while following its progression under fluoroscopy.
NOTE: The proximal tapered end of the sheath working length is larger in diameter.

11. If possible, suture the sheath into place using the suture ring(s).

12. Remove the introducer from the sheath by turning counter clockwise to unlock the introducer hub from the sheath.

13. Insert the device into the sheath.
NOTE: The sheath should be intermittently flushed with heparinized saline throughout the procedure, per standard interventional technique.

14. After the completion of the procedure and removal of the device, remove the suture, and then remove the sheath entirely without torquing and do not reinsert.

8. How Supplied

The Edwards eSheath+ introducer set is supplied in a pouch and sterilized with ethylene oxide.

9. Storage

The Edwards eSheath+ introducer set should be stored in a cool, dry place.

10. Device Disposal

Used sheath sets may be handled and disposed of in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of these devices.

Manufacturer Name: Edwards Lifesciences LLC

Manufacturer Address: One Edwards Way, Irvine, CA 92614, USA "Made in USA / Singapore"

Name of the Medical Device Supplier: Edwards Lifesciences (Taiwan) Corp.

Address of the Medical Device Supplier: 9F-1, No. 2, Sec. 3, Minsheng East Road, Zhongshan District, Taipei City.

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