

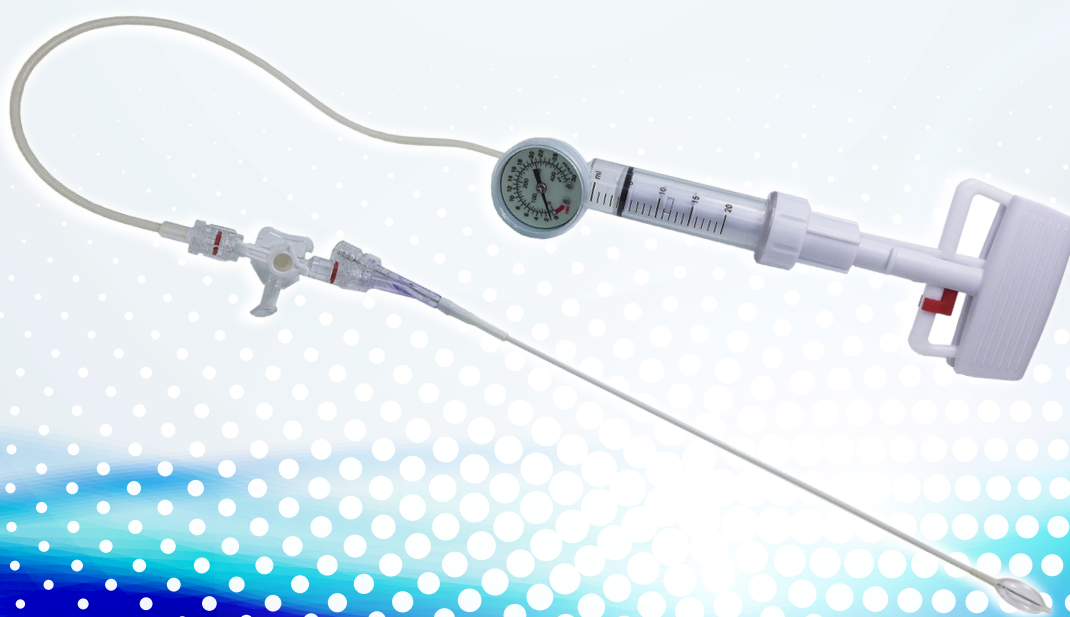
AVALON

AVALON Kyphoplasty Kit

阿凡龍®球囊椎體成型術套組

Surgical technique

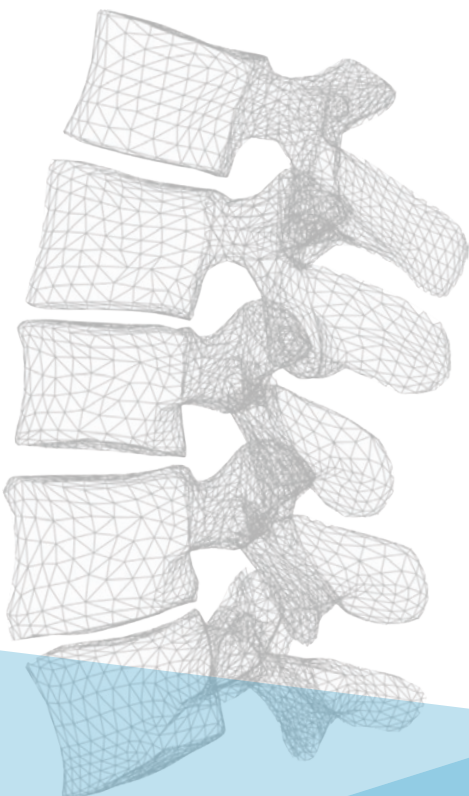
技術手冊





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Introduction | 前言

The AVALON Kyphoplasty Kit is an inflatable balloon catheter which be used to restore the vertebrae fracture and create a cavity in cancellous bone.

When successful repositioning, PMMA bone cement is injected into the cavum for stabilization and fixation.

The AVALON offers complete instruments for treating vertebral body fractures.

The comfort shaped grips allow friendly maneuverability and ensure a confidence Solutions.

Please note the instructions for use of the AVALON Kyphoplasty Kit, reliability and safety for the user. Only the cannufix instruments of the AVALON Kyphoplasty Kit may be used.

阿凡龍®球囊椎體成型術是一種微創手術，可復位與穩定骨折部位，適用於修復椎體壓迫性骨折(VCFs)。臨床應用證實可將骨折處復位、緩解背痛，並提升生活品質。

阿凡龍®球囊椎體成型術套組是包含了數個用於定位壓迫性骨折椎體的器械。系統運用充氣球囊導管在鬆質骨內產生立體空腔，使骨折復位。重新定位受損椎體後，使用醫療級的人工骨水泥(聚甲基丙烯酸甲酯)注入椎體內空腔以固定椎體。

阿凡龍®球囊椎體成型術套組提供完整的器械工具治療脊椎骨折。本產品器械工具附有舒適握柄，易於操作且深得顧客信賴。為確保阿凡龍®球囊椎體成型術套組能被可靠與安全的使用，請詳閱使用說明書。請搭配使用阿凡龍®球囊系統的專用工具。

Procedure designed to 手術目的

- > Relieve pain
- > Reduce and stabilize the fracture
- > Restore vertebral height
- > 緩解疼痛
- > 骨折復位與固定
- > 椎體高度重建

Design Rationale 設計原理

- > Easy to use, minimally invasive tools for gaining access to the fracture
- > Use the balloon to restore the vertebrae fracture and create a cavity
- > 便於操作，使用微創工具到達骨折部位。
- > 使用球囊在椎體內產生一個空腔，骨折復位。

Recommendations 使用建議

- > Painful osteoporotic or osteolytic compression fractures in the thoracic or lumbar vertebrae stemming from :
 - ◆ Primary osteoporosis
 - ◆ Secondary osteoporosis
 - ◆ Multiple myeloma
- > 由下列症狀導致的骨質疏鬆或溶骨性胸椎壓縮性骨折、腰椎壓縮性骨折：
 - ◆ 原發性骨質疏鬆
 - ◆ 續發性骨質疏鬆症
 - ◆ 多發性骨髓瘤

Indications

適應症

- > AVALON Kyphoplasty Kit is intended to be used as conventional bone tamps for the reduction of fractures and/ or creation of a void in cancellous bone in the spine.
- > 阿凡龍®可充氣球囊導管系統使鬆質骨夯實，用於減少脊柱中鬆質骨骨折或製造在鬆質骨區域的空間。

Contraindications

禁忌症

- > Any active or suspected latent infection
- > Any mental or neuromuscular disorder which might create unacceptable risk of fixation failure or complications post-operatively
- > Metal sensitivity, documented or suspected
- > Pregnancy
- > Excessive local inflammation reaction
- > 任何疑似潛伏感染症狀
- > 任何可能在手術後產生不可接受的固定失敗或併發症風險導致精神或神經肌肉疾病
- > 金屬過敏
- > 懷孕
- > 局部炎症反應過度

Penetration and Inflatable Device



427-3701

Inflatable Balloon Catheter 15mm
擴張球囊導管



427-3706

Inflatable Balloon S Catheter 20mm
S 型擴張球囊導管



427-1403

Introducer
導入器



427-3801

Inflation Device
壓力注射器



427-0206

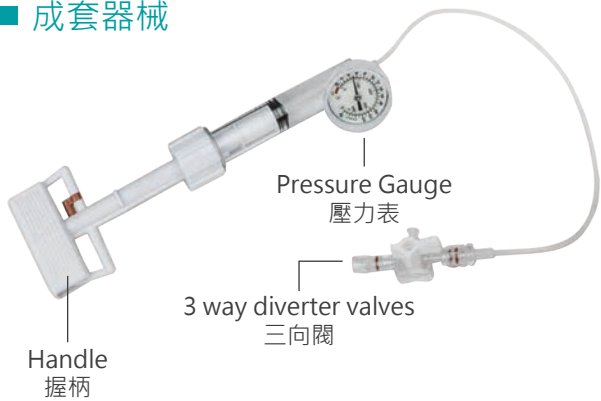
Dilator (8G)
擴張器



427-1904

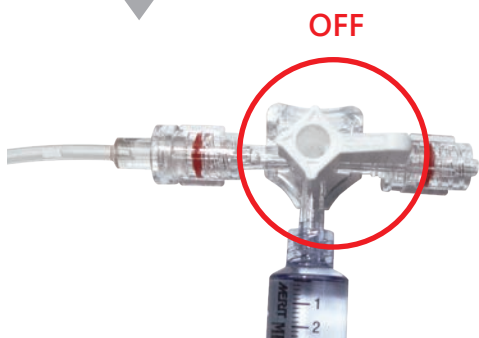
3.5mm Drill
鑽頭

■ 成套器械



10c.c. 注射空針
Syringe

Prepare | 壓力注射器術前準備



1

- 10c.c. syringe filled with contrast media.
- 將10c.c.針筒填滿顯影劑。

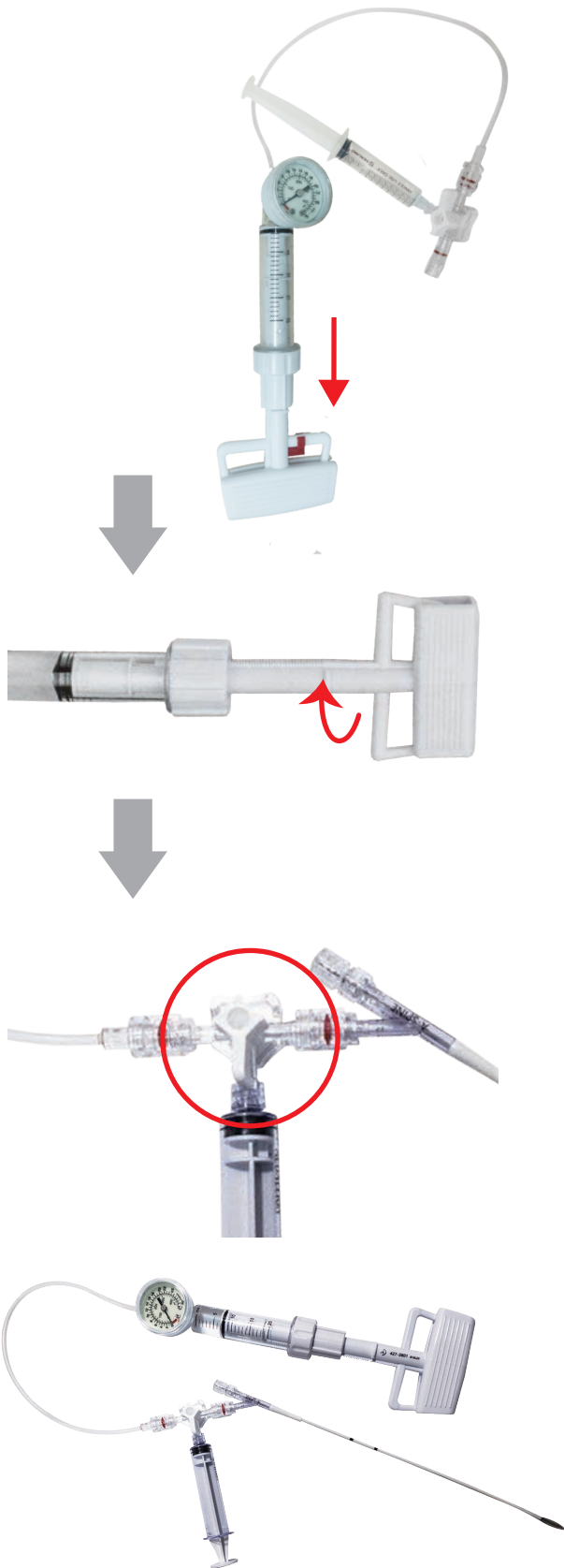
2

- Connect syringe with 3 way diverter valves and turn the "off" label to unconnected direction.
- 針筒連接上三向閥，將off的旋鈕轉到未連接物品的方向。

3

- Take off the red seal to unlock position for quickly moving device grip to achieve pumping function.
- 移除 " 紅色解鎖器 "，可快速推進幫浦，以利抽取顯影劑。

Prepare | 壓力注射器術前準備



4

- Point the syringe down and pull the handle of inflation device(427-3801) in a downward direction to fill the cylinder with contrast media.

- 針筒朝下，壓力注射器(427-3801)向下方拉出握把，抽入顯影劑。

5

- Turn the handle to right to remove air from the cylinder.

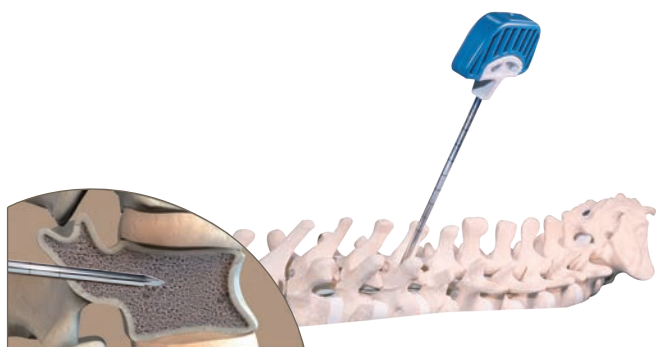
- 向右旋轉握柄，排除壓力注射器內多餘空氣。

6

- Connect the balloon catheter (427-3701, 427-3706) with 3 way diverter valves. Turn the "off" label to the direction of syringe for preventing contrast media from flowing back into syringe.

- 將擴張球囊導管接上三向閥，並把off的旋扭轉到針筒的方向，避免顯影劑回流至針筒。

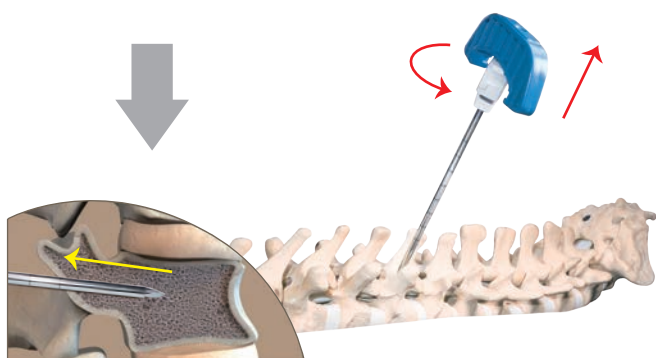
Instrumentation procedure | 手術步驟



1

- Initially penetrate into the vertebral body with the Trocar. (427-0206)

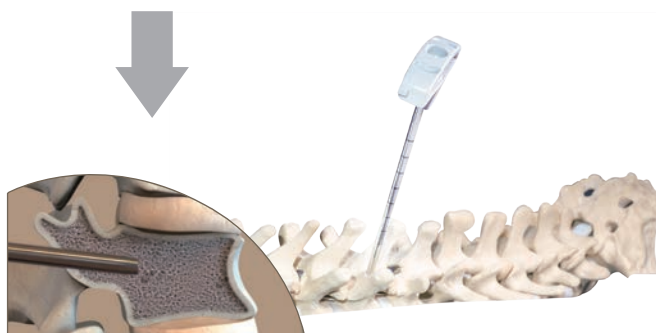
- 先使用擴張器 (427-0206) 插入椎體。



2

- Remove the needle of Trocar from the vertebral body.

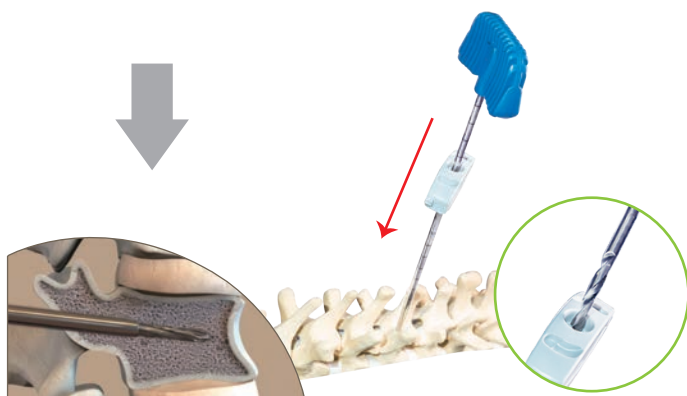
- 從椎體移除三椎尖針。



3

- Leave the working channel alone.

- 撤出擴張器內的穿針握柄，留下工作通道。

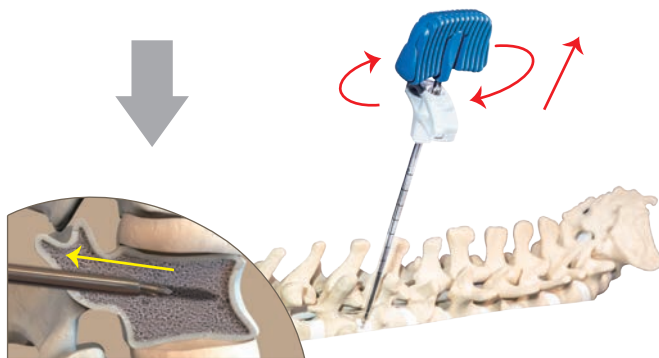


4

- Insert the drill. (427-1904)

- 插入鑽頭 (427-1904)。

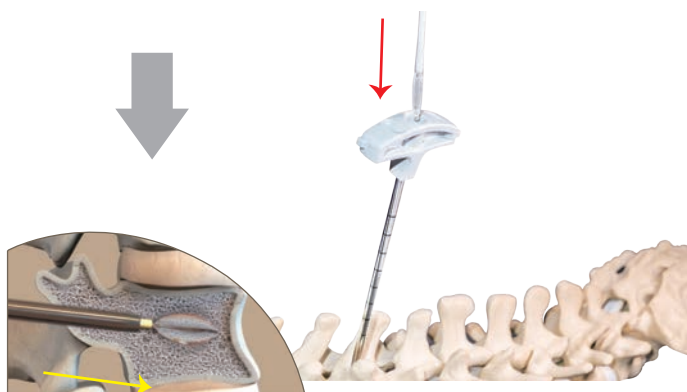
Instrumentation procedure | 手術步驟



5

- When creat a channel, Remove the Drill.

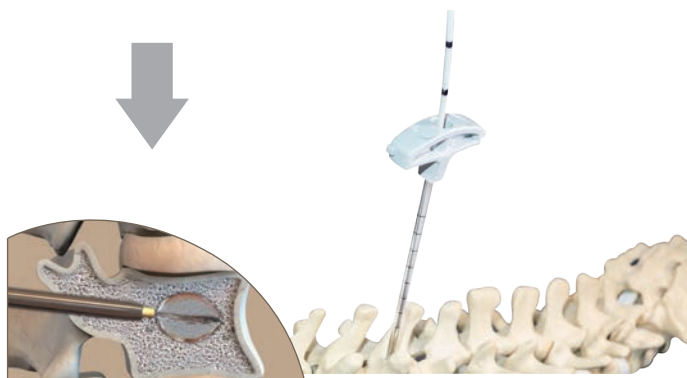
- 在椎體製造一個通道後，即可抽出鑽頭。



6

- Insert the Balloon Catheter (427-3706) and Inflate the Balloon with contrast media.

- 插入球囊導管.(427-3706) · 將顯影劑注入球囊。



NOTE :

Inflatable Balloon Catheter 20mm

Maximum Volume : 6ml

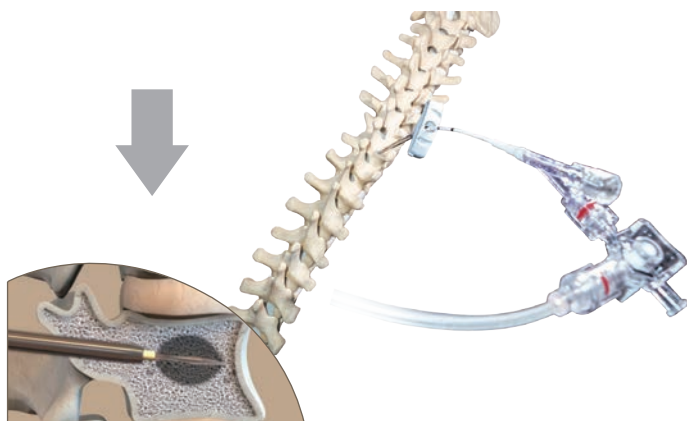
PSI Rating: 400

Inflatable Balloon Catheter 15mm

Maximum Volume : 4ml

PSI Rating: 400

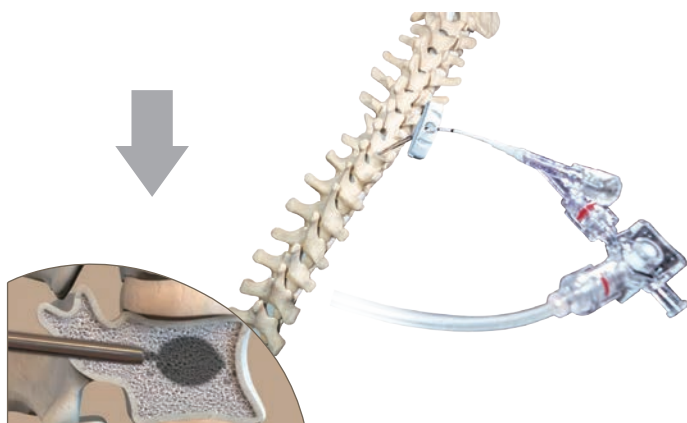
Instrumentation procedure | 手術步驟



7

- When the balloon expands, it forms a cavity in the vertebral body.
- Pull the handle of the Inflation Device (427-3801) downward to remove the contrast agent from the balloon.

- 球囊膨脹時會在椎體內製造一個空腔。
- 轉動拉出朝下的壓力注射器的握柄，抽出球囊裡的顯影劑。



8

- Pull the balloon catheter out of the cannula.
- 從通道抽出球囊。

Instrumentation procedure | 手術步驟

Prepare PMMA cement 準備骨水泥

- Preloaded 1.25c.c bone cement to the each cement Introducer (427-1403) for delivery.

- 每一個骨水泥導入器(427-1403)可以預注1.25cc的骨水泥。

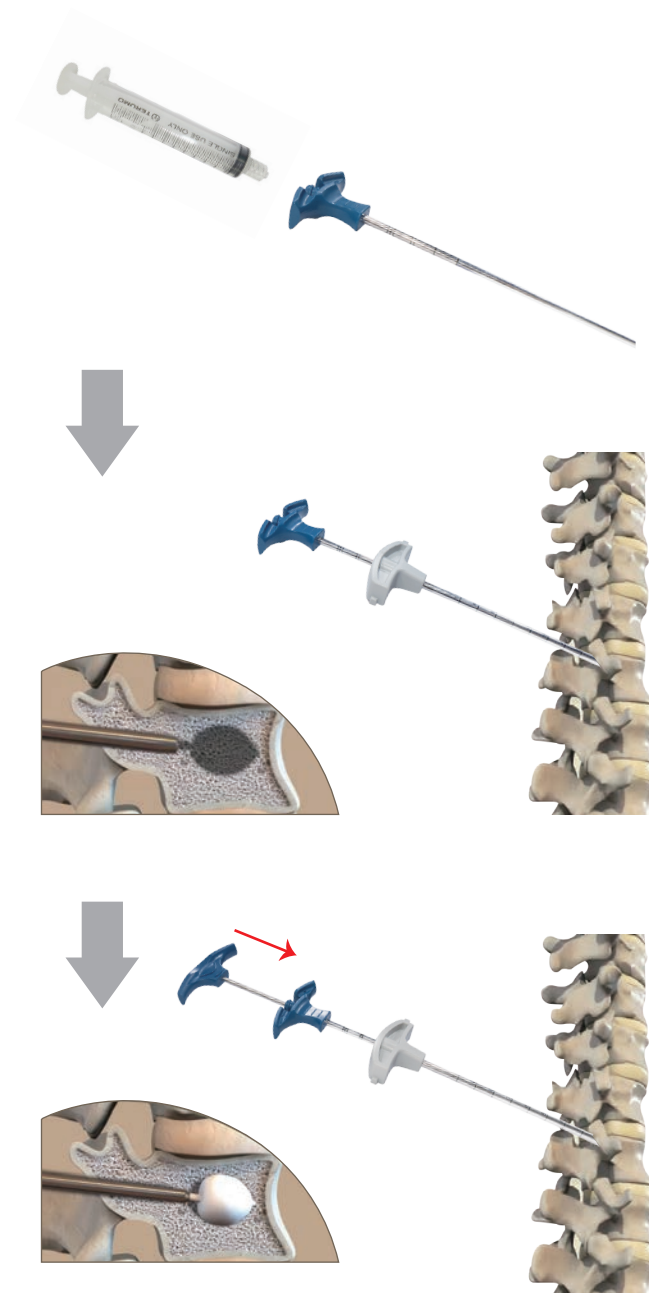
- Filling the PMMA cement with the cement Introducer and Pusher.

- 將骨水泥填滿導入器。

- Insert the Cement Introducer through the cannula.

- 將導入器插入工作通道，使用推桿將骨水泥推入椎體間。

NOTE :



Instrumentation procedure | 手術步驟



- Remove off.
- 待骨水泥完全填入後，即退出所有器械。

Outcomes | 術後

The benefits of AVALON Kyphoplasty Kit include:

- ◆ Correction spinal deformity
- ◆ Significant reduction in back pain
- ◆ Significant improvement in mobility

AVALON 球囊椎體成型術具有下列優勢：

- ◆ 矯正脊柱畸形
- ◆ 有效緩解背部疼痛
- ◆ 明顯改善活動能力



AVALON

AVALON Kyphoplasty Kit

NOTE



AVALON Kyphoplasty Kit



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T-BFS-001-EE/2022