A-SPINE

AVALON Kyphoplasty Kit

English

I-BFS-003-DE

繁體中文

I-BFS-001-CT

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EN

AVALON Kyphoplasty Kit
Instructions for Use

IMPORTANT NOTICE
The users of the AVALON Kyphoplasty Kit acknowledge that they have read and agreed to the statement in this insert, which is considered contractual.

INTRODUCTION
AVALON Kyphoplasty Kit is a minimally invasive procedure designed to repair vertebral compression fractures (VCFs) by reducing and stabilizing the fractures. It has been clinically shown to reduce the fracture, relieve back pain, and improve quality of life.
Unlike other treatments, balloon kyphoplasty utilizes orthopaedic balloons to restore vertebral body height and correct angular deformity. Through a bilateral approach, balloons are guided through working cannulae into the vertebra and carefully inflated to create void.
After reduction, the balloons are deflated and removed. The resulting cavity (void) allows for a controlled deposition of bone cement forming an internal cast and stabilizing the fracture.

INDICATIONS
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.

CONTRAINDICATIONS
- 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

PRECAUTIONS
- The AVALON Kyphoplasty Kit must be used only by surgeons having undergone the necessary training in surgery of which must be in accordance with the medical and surgical indications, the potential risks and limitations related to this type of surgery, the contraindications, precautions, and complications.
- Prior to clinical use of these devices, the operating surgeons should thoroughly understand all aspects of the surgical procedure and limitations of the system. The AVALON Kyphoplasty Kit is limited for use by surgeons familiar with the pre- and post-operative treatment, surgical technique, cautions and potential risks related with such spinal surgery. The sufficiency of knowledge of surgical technique, adequate reduction, selection and placement of devices, pre and post-operative patient management are considered essential factors to the delivery of a successful surgical treatment.
- X-ray guidance or other image guiding system is recommended to facilitate precise positioning, and reduction in order to avoid or minimize the risk of complications.

- In some rare cases, progression of degenerative disease may be so advanced that the expected service life of such device may be substantially decreased. In such case, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

POSSIBLE ADVERSE EVENTS
Patients should be advised prior to surgery the possible adverse events of such surgeries including:
Adverse events:
The complication rate with balloon kyphoplasty has been demonstrated to be low (< 1 % procedure- and cement-related). As with all surgical procedures, there are risks associated with the procedure, including serious complications, and though rare, some of which can be fatal.
- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae
- Rupture with fragmentation of the inflatable portion of the AVALON Kyphoplasty Kit resulting in retention of a fragment within the vertebral body
- Rupture of the AVALON Kyphoplasty Kit causing contrast medium exposure, possibly resulting in an allergic reaction or anaphylaxis
- Deep or superficial wound infection
- Retropulsed vertebral body bone fragments which may cause injury to the spinal cord or nerve roots resulting in radiculopathy, paresis or paralysis
- Bleeding or hematoma

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements:
- Cardiac arrest
- Cerebrovascular accident
- Myocardial infarction
- Pulmonary embolism

Other reported adverse events relevant to the anatomy being treated with acrylic bone cements include:
- Deep or superficial wound infection
- Fistula
- Hematoma
- Hemorrhage
- Heterotopic new bone formation
- Extravasation of bone cement potentially resulting in but not limited to:
  - Compression or irritation of nerve structures, such as the spinal cord or nerve roots, causing radiculopathy, parasthesia, paraplegia or paralysis and/ or;
  - Introduction into the vascular system resulting in embolism of the lung and/ or heart or other clinical sequelae.
  - Pyrexia due to allergy to bone cement
  - Short-term conduction irregularities
  - Thrombophlebitis
  - Transitory fall in blood pressure

Possible adverse events including but not limited to the above, may necessitate further surgical treatment.

STERILIZATION, PACKAGE & STORAGE
- The devices of the AVALON Kyphoplasty Kit are supplied sterile by E.O. sterilization.
- It is necessary to exchange our product before using if the packaging has been broken without reason.
- The devices are delivered in individual packages. The device, package, and insert must be intact at the time of receipt. All legal information required for this type of device is given in the labeling and the insert of each package.
- Devices should be stored away from the corrosive environments such as salt air, moisture.
- Do not expose the devices directly to the sun, too high/low temperature.

AFTER SERVICE
- In case of claim of dissatisfaction of the identification, reliability, safety, efficacy, or performance of the AVALON Kyphoplasty Kit, or the services provided by A-SPINE Asia Co., Ltd., please contact A-SPINE, the authorized distributor or dealer.
- Any defect or suspected defect in anyone of the devices should be reported to A-SPINE, the authorized distributor or dealer.
- Upon receipt of devices, devices defect or damage to the package or insert should be reported to A-SPINE, the authorized distributor or dealer for replacement.
- Any serious side effect on patient health or safety, or any life threatening issue or death caused by or associated with the use of the AVALON Kyphoplasty Kit due to component malfunction, damage, or inappropriate direction, should be reported immediately to A-SPINE, the authorized distributor or dealer by fax, e-mail or phone.
- Any claim or report listed above should contain product description, reference number, lot number, your full contact information, and the type of incident, an accurate description of the incident and consequences, and other related technical information to assist future investigation. Please indicate if a written report is required from A-SPINE, the authorized distributor or dealer.

Manufacturer

A-SPINE

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繁體中文

阿凡龍球囊椎體成型術套組

AVALON Kyphoplasty Kit

衛部醫器製字第005479號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

說明：
阿凡龍球囊椎體成型術套組包含一般使用於球囊椎體成形術中的裝置。

擴張球囊導管裝置外管內含有可移除的硬質探針(SUS 304)。
阿凡龍球囊椎體成型術套組之使用及安全性，僅限於脊椎手術之施行且輔以相關植入物之使用。

材質：
阿凡龍球囊椎體成型術套組所有接觸人體的元件以不銹鋼、TPU製成。

適應症(用途、效能)：
本產品用於協助骨水泥注入脊椎體腔。
利用擴張球囊導管在椎體內製造一個空間以協助骨水泥注入。

禁忌症
- 病患曾有對材料過敏或其他異物的過敏史
- 病患有接觸性過敏
- 骨髓炎
- 出血性因子
- 成骨不全症
- 病患的一般性醫療或心理狀況不佳或可能因實施此手術程序而惡化；主治醫師必須仔細考量這些病患的狀況
- 不適合傳統治療的患者
- 凝血病變
- 懷孕

注意事項：
- 本產品為單次使用。請勿重複使用、重新處理、重複滅菌。無論何種清潔及重新滅菌的方法，重複使用有受汙染的風險且可能造成病人感染或交叉感染。因重新處理而使得裝置效能變差的風險增加，可能導致病人受傷或死亡。
- 在操作本產品前，務必詳細閱讀使用說明與以下注意事項。
- 若包裝已打開或毀損，請勿使用，因為產品完整性（包括無菌狀態）可能已遭破。
- 請在包裝標示的使用期限前使用此裝置。
- 請勿使用已損之產品。使用前，請檢查產品與包裝，確認並未出現毀損。

- 若未接受適當使用訓練，請勿使用本產品。使用此產品之專科醫師，應熟悉特定解剖構造的生理學與病理學，並已接受特定外科技術訓練。
- 僅可使用提供高品質影像放射線設備，透過螢光透視觀察來操作本產品。
- 椎弓根的寬度至少需要5公釐，方可經由椎弓根進入椎體。插入器械時，需經由X-Ray輔助或其他造影方法，確實瞭解插入部位。

滅菌：
- 本產品經EO滅菌，手術全程應謹慎以避免污染，如發現包裝破損即不保證無菌狀態，可向本公司提出更換。

包裝、標示與儲存：
- 器械均以滅菌方式供應。
- 器械係置於個別包裝袋中，在送達時滅菌包裝及仿單必須是良好狀態方可驗收入庫。
- 處理及儲存植入物時需小心謹慎。勿將器械急劇折彎或刮傷表面，並導致裂紋及/或肉眼無法查覺的內部壓力，以致斷裂或破損。
- 器械皆應避免儲存於腐蝕性之環境中（如帶鹽分之空氣、潮濕等）。

可能發生的不良影響：
手術醫師應在術前將可能發生之不良影響告知病患：
- 神經傷害包括：導致神經根病變、輕癱或癱瘓脊髓或神經根穿刺。
- 血栓或其他物質會導致症狀性肺栓塞或其他臨床後遺症。
- 血胸或氣胸。

藥商名稱：冠亞生技股份有限公司
藥商地址：新北市永和區成功路一段80號20樓
製造廠名稱：冠亞生技股份有限公司新店廠
製造廠地址：新北市新店區復興里復興路43號 (1樓)