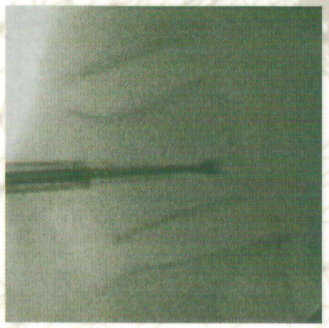
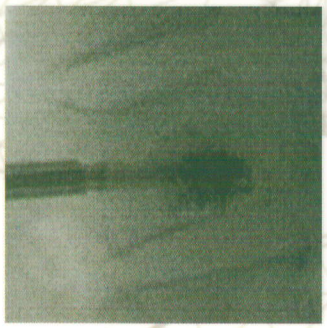
VESSEL-X®

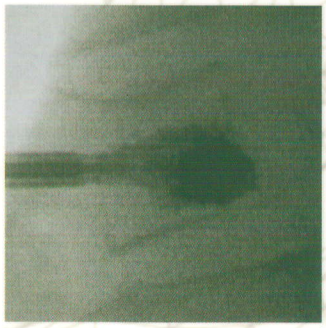
Bone Filling Container System

Vesselplasty

A-Spine Holding Group Corp.







The inflation process of Vessel-X® is filled by bone filler materials (BFMs) in Vertebral body while performing vesselplasty procedure under fluoroscopy
The image is kindly permit by Dr. Bambang Darwono for A-Spine use.

Vesselplasty

An approved novel vertebral osteoplasty technique, designed to implant a Vessel-X® , a non-stretchable fabric in the trabecular bone to form a treating step by filling the bone filler materials. Its purpose not only to restore the height of a vertebral body but also solve the common/ fatal problem of cement leakage in the vertebral body.

1. Bambang Darwono Vesselplasty : a novel concept of percutaneous treatment for stabilization and height restoration of vertebral compression fractures. *Journal of Musculoskeletal Research* , 2008; 11: 2 p71-79.
2. Bambang Darwono Vesselplasty. a novel concept of percutaneous treatment for stabilization and height restoration of vertebral compression fractures. -technical consideration in *Emerging Techniques in Spine Surgery by Arvind Bhave. Chapter 1.10: 79-86* 2009 Jaypee Brothers Medical Publishers (P) Ltd.
3. Lucia Flors, et al.Vesselplasty: a new technical approach to treat symptomatic vertebral compression fractures. American Journal of Roentgenology 2009; 193 (1) : 218-226
4. Zheng Z. The disaster complication of percutaneous vertebroplasty and kyphoplasty- cement leakage and its preventive way. *In the second Chinese congress on minimally invasive spine surgery & Changsha international summit on endoscopic spine surgery.* 2007; 173-178. [Chinese]
5. Zheng, Z. et al. Percutaneous vertebral augmentation with the vessel-x bone void filling container system: a preliminary clinical trial. Chinese Journal of Minimally Invasive Surgery 2007;7 (2). [Chinese]

Indication:

- Painful osteoporotic vertebral compression fractures refractory to in medical treatment.
- Traumatic vertebral compression fracture.
- Benign or Malignant tumor: vertebral hemangioma, spinal metastasis.
- Non-traumatic spine disease: vertebral osteonecrosis.
- Reinforced or stabilized the weakened vertebral body prior surgery.

DESIGN RATIONALE

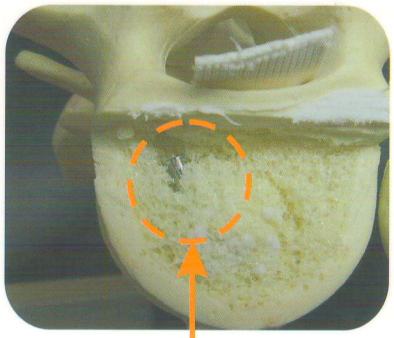
A Novel Concept and Technique

- The minimal invasive technique provides the fast recovery rate, low infection rate and short hospital stay for the client.
- Vesselplasty is a term applied as minimally invasive surgical procedure to facilitate pre-deployed Vessel-X® container to treat vertebrae or disc disorders actively or passively.
- A novel concept of Vessel-X® is to provide a controllable shape in solving the unexpected effect of uncontrollable cement leakage.
- Vessel-X® is currently made of non- stretchable fabric and that is less or equal to 100 μm of surgical mesh. Owing to its nature of non-stretchable fabric and pore size, bone filler materials can generate a complete mass in a restricted shape and has interdigitation effect with the trabecular bone.
- The restored height of the fractured vertebrae and the increased volume of bone filler material from injecting to the Vessel-X® is strongly correlated.

Interdigitation Effect

Intercross with Trabecular Bone

The restricted penetrating volume of viscosity BFMs from the Vessel-X® container is well interdigitated with surrounding trabecular bones, this phenomenon called interdigitation effect. This results "a better cement placement in the vertebral body" and "it could be leakage controllable technique in percutaneous vertebral augmentation." (Zheng, et al. Spine 2007:32 (19))



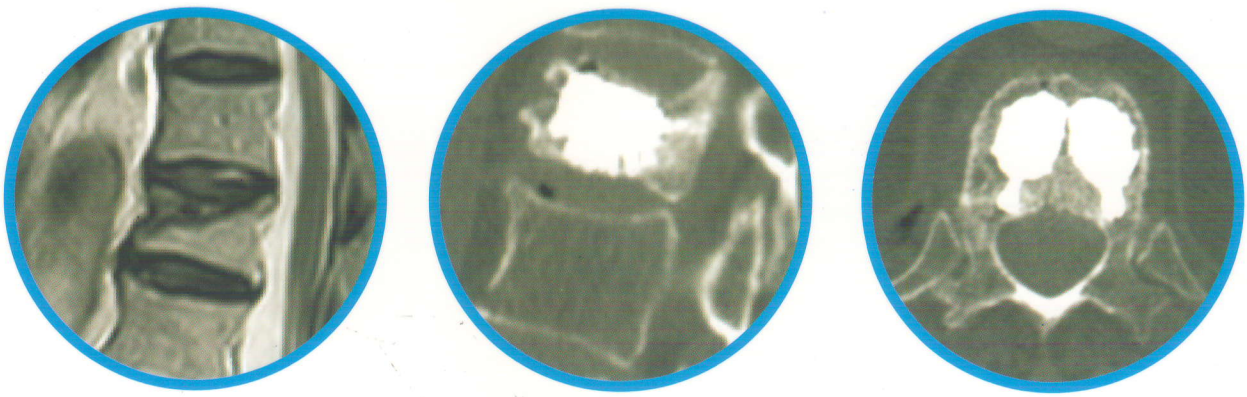
Thread connect part
(Ti-6Al-4V Alloy)

Vessel-X® inflated progress

Deflated configuration in size 20 of Vessel-X®

1.5 ml cement injected into the size 20 of Vessel-X®

3.5ml cement injected into the size 20 of Vessel-X®



A VCFs case was diagnosed and treated with vesselplasty procedure under fluoroscopy by Prof. Vilio Tempesta, MD., kindly permits A-Spine to use.

Vessel-X® Bone Filling Container System

Implant set			Two layers per tray
BVFX-UD20 BVFX-UD25 BVFX-UD30	Unit Kit	• Vessel-X® D20/25/30 • Guide Pin • Bone Access Needle • Stylet • Precision Drill	
BVFX-SD20 BVFX-SD25 BVFX-SD30	Standard Kit	• Vessel-X® D20/25/30 x2 • Guide Pin • Bone Access Needle x2 • Precision Drill	

A complete kit contains one of implant sets and delivery sets, please see the ordering form for further information.

Delivery set		One tray
T-CCD1-T301	CCD Basic • Deliver after mixed bone cement.	
T-C303	CCD Plus - All in One • Advantageous closed mixing device. • Work only with the use of Osteo-G® series, as DBVF-PB208 and DBVF-PP208.	
CCD plus with pre-loaded Osteo-G® series	Ready to use Revolution • Pre-loaded Osteo-G® Series in CCD plus. • User friendly- Simply mix and deliver. • Available for DBVF-KB208 and DBVF-KP208.	

Ps. The Pre-loaded Osteo-G® Bone void filler in T-C303 is available for further requirement. Please ask your Sales representative for your need.

VESSEL-X®

Product Information

Vessel-X® and Pushing Rod

BVFX-D20, BVFX-D25, BVFX-D30
Size 20mm, 25mm, 30mm G10. Pre-deployed surgical mesh container
Restrict the cement overflow

Bone Access Needle

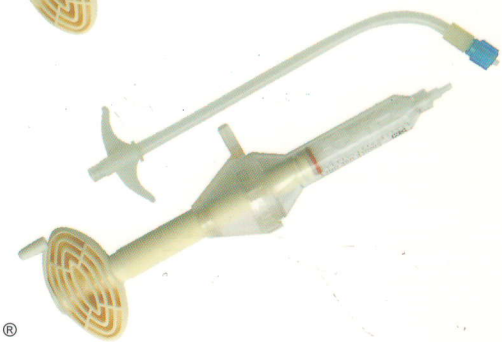
T-N201
Sharp stylet, Triangle tip for inital penetrating and accessing into the pedicle.

Precision Drill

T-D401
G10.Two fluted drill-tip. For further path created.

Controllable Cement Delivery

T-CCD1-T301
Delivering the highly viscous bone void filler materials. High precision volume control. Accurate assessment.



CCD Plus

T-C303
Ergonomic Handle Advantageous closed mixing device High precision volume and mixing control Accurate assessment User friendly

Vessel-X®
Patent status

Pending
Tw96104911
CN1526457, CN1552290, Cn1552289
US2004/0122455,US2004/0210297
US2006/0235425

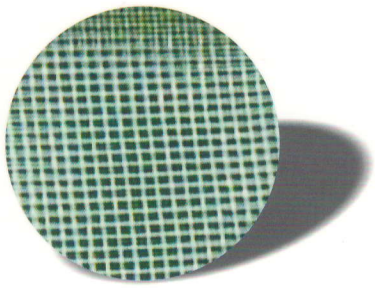
Issued
TW-554739,TW-I221091
Cn2604194
EP1495729, EP1495730,EP1495725

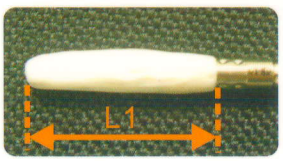
Features

Vessel-X®

Provides the strongest bond between the cement mass and trabecular bone through the interdigitation effect during expansion. Designed as an implanted and bio-compatible pioneering product. Towards its specification of Vessel-X®: **air-permeable,pre-deployable, and volume controlled**, the whole procedure becomes manageable.

Pore size of the surgical mesh provides the main interdigitation effect in the trabecular bone, those effect is produced after the volume filled by bone filler material becomes larger than capacity itself.





The Vessel-X® Container is available in single/double layers of non-stretchable PET (Polyethylene Terephthalate) fabric, with length options of 20mm, 25mm & 30mm. The length of the container will be shortened several millimeters, L1→ L2, after expansion.

A-Spine Holding Group Corp.
5F No.65,Zhouzi St.,Taipei 114 Taiwan
TEL: +886 2 8751 1790
FAX: +886 2 8751 8507
WEB: www.aspine.net
Email : service@aspine.net

Manufacture by

Central Medical Technologies,Inc.
3F,298 Rueiguang Rd.,Neihu District,
Taipei, Taiwan, R.O.C.

cGMP

Distributor:

IMPORTOR, DISTRIBUTOR & MARKETING IN
INDIA BY :-
MONTREA MEDICALS INC.
301, 3rd Floor, 16/10178, Ravinder Plaza,
Abdul Aziz Road, Karol Bagh, New Delhi-5
Ph. No.: 0091-11-28752307, 41451506
Telefax:-0091-11- 28752307
Email :- montrea@montreamedical.com
m_s_saini1@yahoo.com