# LIBRA™ INSTRUCTION FOR USE

CE 1370

**1. Introduction**

LIBRA™, Inflatable Bone Expander System for VCF with the balloon, is device intended to insert the bone cement into the cavity made by the balloon tip in the fractures of the spinal bone.

A. Balloon Expander

① Pressure Gauge: It indicates the pressure of the balloon.
② Compression Cylinder: It makes to expand and shrink the balloon.
③ Knob: It is used to control the inflation and deflation by turning it.
④ Compressor Body: It controls compression and decompression with pushing button.

B. Balloon Catheter

⑤ Balloon Tip: Expansion parts of the catheter in the vertebral body fractures.
⑥ Inner Tube: It does as a supporter of balloon positioning.
⑦ Outer Tube: It is main body of balloon catheter.
⑧ Hub: It is connected with the balloon catheter.

C. Bone Access System

① Cannula: These devices are available to drill holes for inserting the Balloon Catheter into the cavity of a vertebral body.
② Guide Wire: It is used to guide the needle, Cannula and Expander.
③ Bone Marrow Needle: It is temporarily inserted into bone with the gimlet shaped wire and pipe.
④ Bone Drill: It makes the cavity by drilling into the vertebral body for insertion of the balloon catheter.
⑤ Bone Cement Filler: These are used to fill up the cavity of the vertebral body with the bone cement.

D. The kit box includes 1 set.

E. 1 kit contains the Balloon Expander, Balloon Catheter, Guide Wire, Cannula, Bone Drill, Bone Cement Filler and Bone Marrow Needle.

F. Accessory Kits : BCD Kit (11G), BCD Kit (13G)
BE Kit (Bone Extractor A Type), BE Kit (Bone Extractor B Type)

**2. Indication**

-VCF (Vertebral compression fracture) due to Osteoporosis
-Osteolytic fracture
-Metastatic bone fractures

**3. Contraindication**

- Infection
- Pregnancy
- Mental illness
- Clotting disorders or patients in anticoagulant treatment

**4. Instruction for use**

4.1 Preparation for Kyphoplasty

a. Fill the syringe of the Balloon Expander with contrast medium of about 20cc. Generally, set up the zero scale of Inflation cylinder to 10cc.
b. After filling the contrast medium into the syringe which is connected with the Balloon Catheter, as a part of the Balloon Expander.
c. Prepare the medical equipment and medication for local or general anesthesia.

4.2 Method and Procedure for use

a. Find the approaching spot of pedicle with wire pin and mark the point with a pen.
b. Puncture up to 5mm of the vertebral body passing through the pedicle with Bone marrow needle.
c. Pull out the needle from the Bone marrow needle.
d. Push the guide wire into the Bone marrow needle up to 3/4 of vertebral body.
e. Remove the Bone marrow needle except for the guide wire.
f. Through the guide wire, push the Cannula and Expander from the starting point of vertebral body to 3mm.
g. Remain the Cannula only and remove the Guide wire and Expander.
h. Ream with the bone drill to the end of callous bone of vertebral body through the Cannula.
i. Remove the bone drill and reciprocate the bone cement filler several times through the Cannula. (For smooth balloon insertion and prevention of the balloon bursting by sharp bone)
j. Slightly inflate the balloon at suitable position in vertebral body, after insertion.
k. Pressurize the balloon to the appropriate level of reduction. (WSS10=4cc, WSS15=4cc, WSS20=6cc)
l. Remove the balloon from the vertebral body after it is deflated.
m. Inject the vertebral body with the bone cement, approximately as much as the amount of contrast medium to fill the balloon, using the Bone Cement Filler and Pusher without any leakage of the bone cement.
n. Bone Cement Filler is available to contain up to 1.5cc of the bone cement.

**5. Cautions**

a. Reuse of disposable products and parts is strictly prohibited and disposed of in accordance with the medical regulations of each country and the regulations of the hospital.
b. Do not disassemble, repair and reconstruct except the experts.
c. Use of medical devices is only for the educated and certified person
d. All components are for single-use and do not reuse.
e. Do not use if any part of the LIBRA™ or package is damaged.
f. Used products during the operation should be disposed regarding as the correct procedure and those must be fallen into disuse.
g. Reusing the used product may medically cause serious problems (autogenous infection, cross infection so on)
h. Dispose of any used product after the procedure as per the correct guidelines of hospitals and clinics.
i. Report the device to manufacturers and regulators in the event of a serious accident. Follow the submission deadline according to the harmfulness and report to the manufacturer (+82 032 684 7071, www.seawonmt.com). Regulators report in accordance with the procedures and reports appropriate to the country concerned.
j. Patient movements can cause serious side effects during the procedure, so keep patient posture fixed.
k. Do not pull with a strong force when removing the catheter from the patients, and slowly insert when inserting a catheter.

**6. Storage**

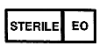
a. Do not expose the product directly to the sun, too high/ low temperature and humidity.
b. Do not keep the products at the place includes ion like salinity
c. Avoid the place for chemicals and containing gas

**7. Expiry date: 3**years from the date of E.O sterilization

**8. Symbols**

 Date of manufacture  Lot number

 EU representative  Do not reuse

 Sterilized using Ethylene Oxide

 Consult instructions for use

 Manufacturer  Use by

 Do not use if Package is Damaged.,

 Caution, consult accompanying documents

CE 1370 CE Marking

**Manufacturer and EU representative**

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