

CE
0086

Spinal Alignment System for VCF **SPASY™**

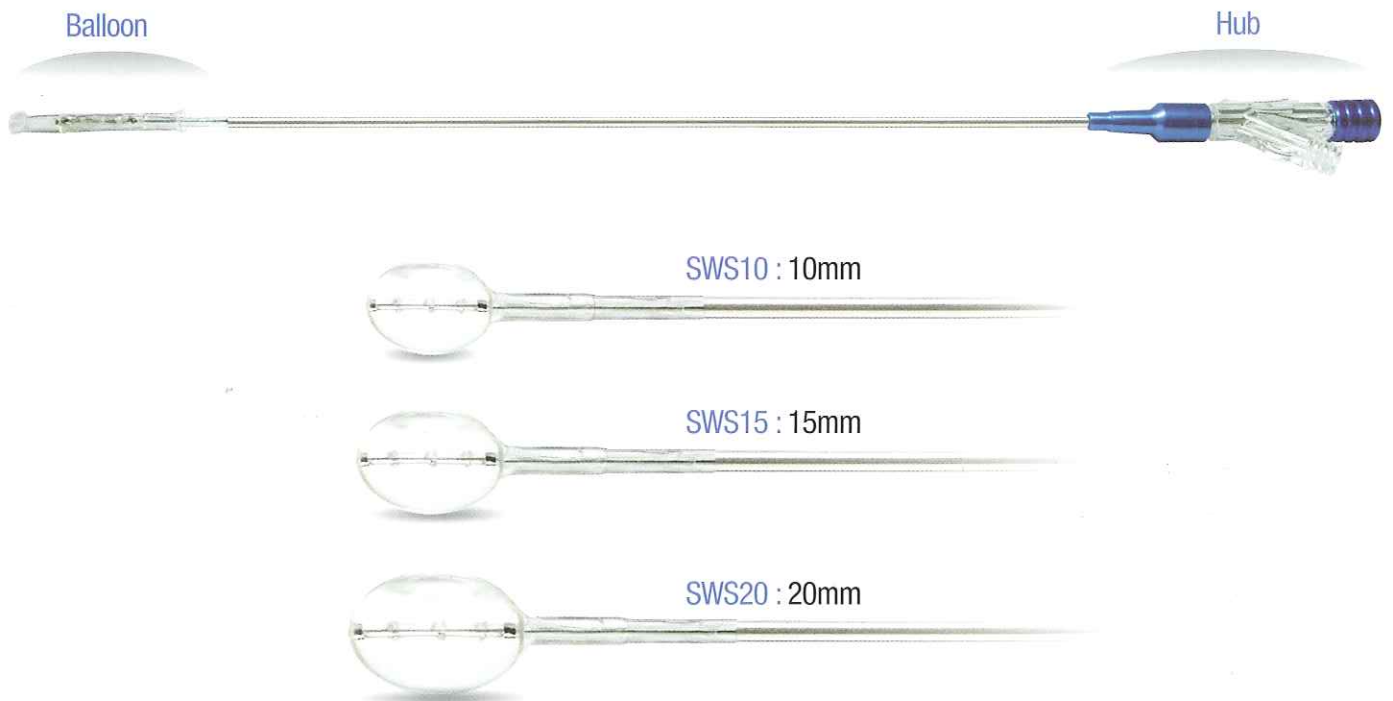
Indication

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



Special Feature

Pressure Gauge indicates the pressure of the balloon
Release Button helps to control compression and decompression by turning on “LOCK” and “UNLOCK”.



SWMVP

Bone Marrow Needle



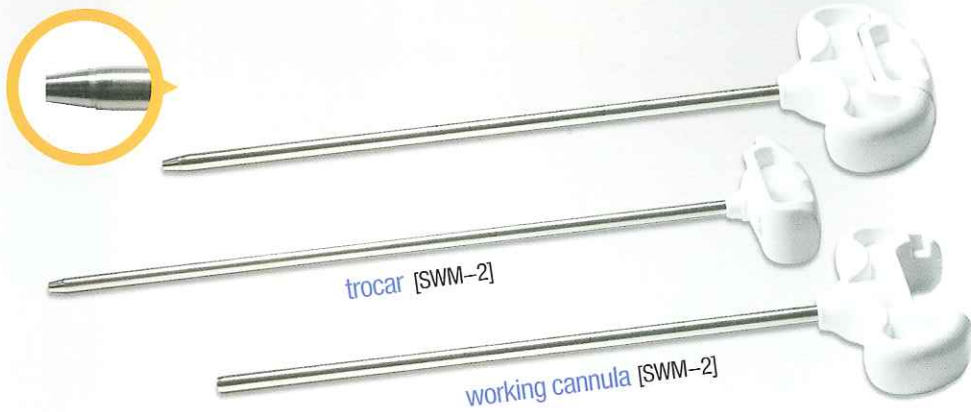
SWM-1

Guide Wire



SWM-2

Cannula



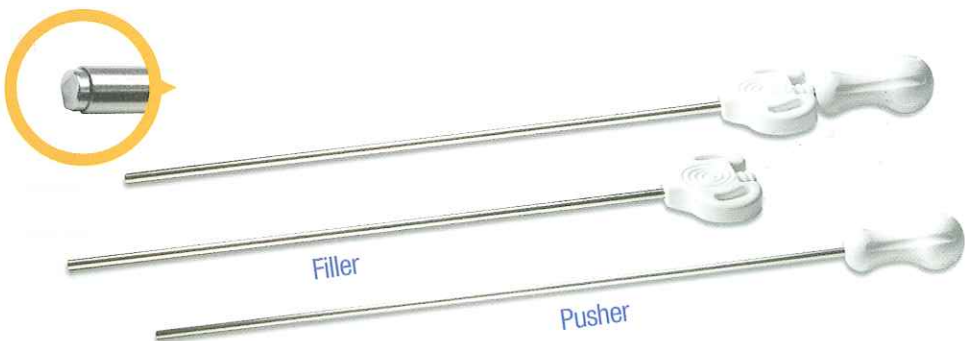
SWM-3

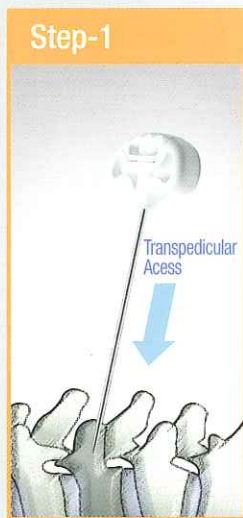
Bone Drill



SWM-4

Bone Cement Filler

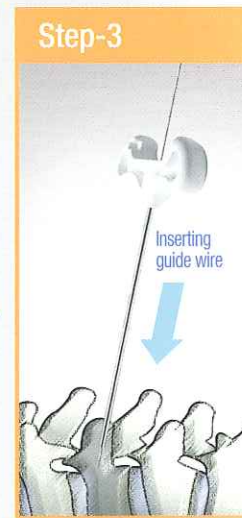




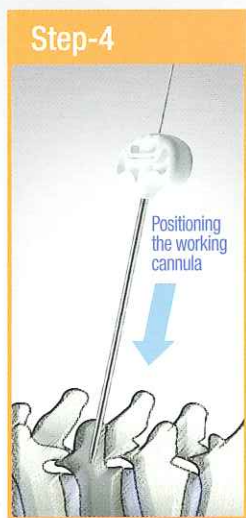
Transpedicular with the bone puncture needle(SWMVP) up to 5mm into the vertebral body.



Pull the stylet out the bone puncture needle(SWMVP)



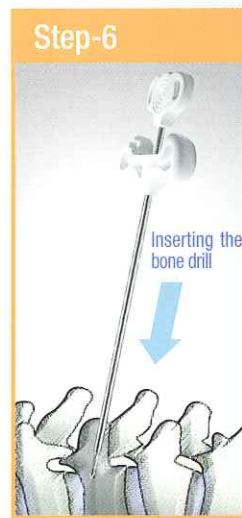
Insert the guide wire(SWM-1).



Remove the bone puncture needle(SWMVP) from the vertebral body, Insert the cannula(SWM-2) over the guide wire(SWM-1) into vertebral body.



Remove the guide wire(SWM-1) & trocar(SWM-2), only the working cannula(SWM-2) remains in the vertebral body.



Insert the bone drill (SWM-3) into the working cannula and make the room in the vertebral body for the balloon catheter. Check under C-arm and ensure the lumen of the working cannula to be free of bone particles.



Move the bone cement applicator(SWM-4) back and forth through the cannula(SWM-2) several times to prevent the balloon from bursting due to sharp bone fragments. The bone cement applicator (SWM-4) must then be removed.

Step-1

Filling the cylinder with contrast agent



Pull the handle of the balloon expander(SWMP) to fill the cylinder with approx. 20cm³ of contrast agent.
Then move the seal to the "lock" position.

Step-2



The seal of the balloon expander (SWMP) remains locked Turn the handle to the right just before "0" marking to remove air from the cylinder.

Step-3



Connecting Balloon Catheter/ Removing residual air from the system
Remove the cover of the balloon Catheter(SWS10 or SWS15 or SWS20). The 3way valve points to the open connection with "off)



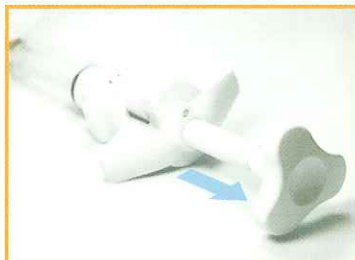
Removing air from the cylinder

Step-4



To remove the remaining air, turn the handle of the balloon expander(SWMP) to the right. The balloon inflates.

Step-5



To Remove the air from the balloon Catheter(SWS10 or SWS15 or SWS20), move the locking mechanism to the "unlock" position. Pull the handle of the balloon catheter and move the locking mechanism to the "lock" position.

1Kit Composition

Part No	Description	EA / Kit
Balloon Catheter	SWS10 SWS15 SWS20	1 EA
Balloon Expander	SWMP	1EA
Bone Marrow Needle	SWMVP	1Set
Guide Wire	SWM-1	1EA
Cannular	SWM-2	1Set
Bone Drill	SWM-3	1EA
Bone Cement Filler	SWM-4	2Sets

2Kit Composition

Part No	Description	EA / Kit
Balloon Catheter	SWS10 SWS15 SWS20	2 EA
Balloon Expander	SWMP	2EA
Bone Marrow Needle	SWMVP	1Set
Guide Wire	SWM-1	2EA
Cannular	SWM-2	2Sets
Bone Drill	SWM-3	1EA
Bone Cement Filler	SWM-4	6Sets

Ordering Information

Spec	Ordering No.
10mm	SWS10
15mm	SWS15
20mm	SWS20

Balloon Specification

Part No	Initial Length (mm)	PSI Rating	Maximum Diameter (mm)	Maximum Length (mm)	Maximum Volume (cc)
SWS10	10	440	14	16	4
SWS15	15	440	17	22	4
SWS20	20	440	19	34	6



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