

Step-1



Filling the cylinder with contrast agent



Pull the handle of the balloon expander(SWMP) to fill the cylinder with approx. 20cm<sup>3</sup> 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"



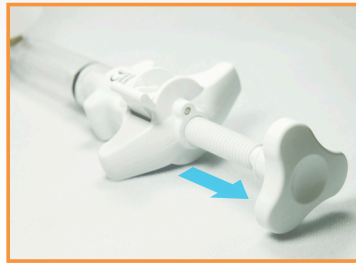
Removing air from the cylinder

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	300	14	16	4
SWS15	15	300	17	22	4
SWS20	20	300	19	34	6

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# Spinal Alignment System for VCF SPASY™

Indication

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



SPASY™

SWMP Balloon Expander

Special Feature

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



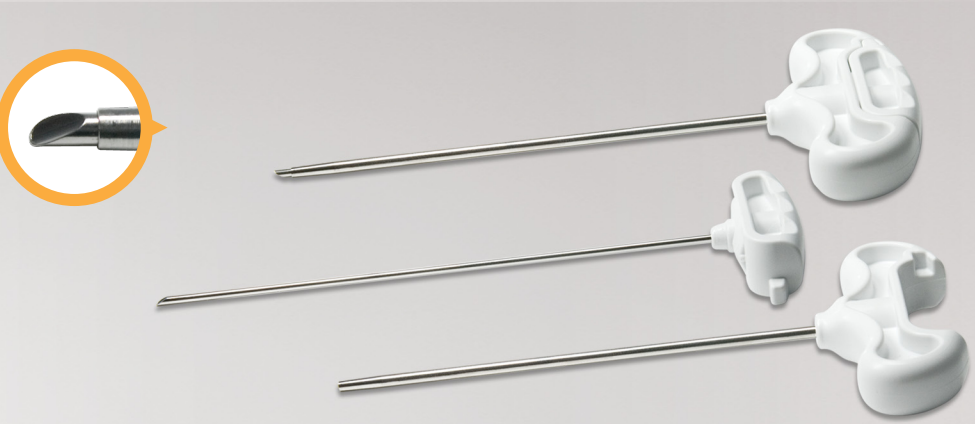
SPASY™

SWS10/15/20 Balloon Catheter



SWMVP

Bone Marrow Needle



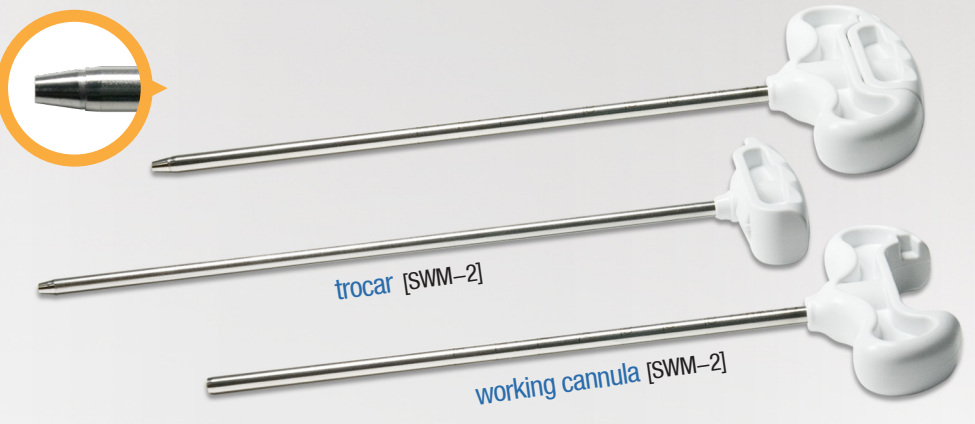
SWM-1

Guide Wire



SWM-2

Cannula



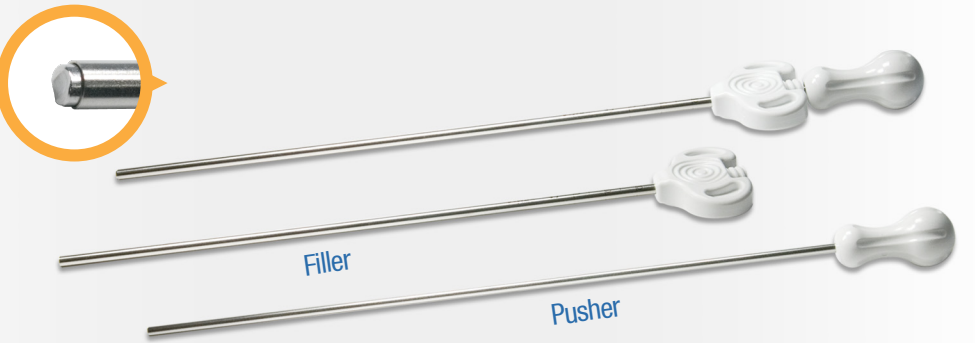
SWM-3

Bone Drill



SWM-4

Bone Cement Filler



SPASY™

Surgical Technique - Bone Access System

Step-1



Transpedicular  
Access

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

Step-2



Removing  
the stylet

Pull the stylet out the bone  
puncture needle(SWMVP)

Step-3



Inserting  
guide wire

Insert the guide wire(SWM-1).

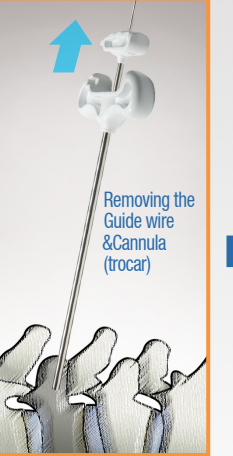
Step-4



Positioning  
the working  
cannula

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

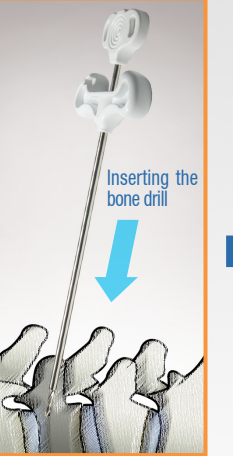
Step-5



Removing the  
Guide wire  
&Cannula  
(trocar)

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

Step-6



Inserting the  
bone drill

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.

Step-7



Smoothing/  
deburring  
the cavum

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.