

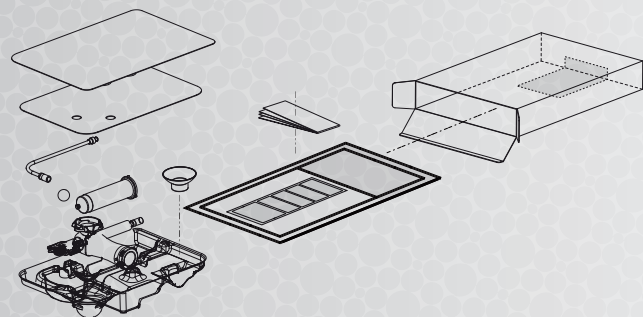


S5 kit

Storage

S5 kit is packaged in a box and sealed in a double barrier packaging which guarantees its sterility. The blister is sterile and can be put on the operating table. Single use only.

The S5 kit includes a delivery gun, an extension tube, a funnel, a ball which can be metallic or glass, a mixing vial and a lid.



Products

For any further information, please refer to the IFU.

DESIGNATION	REFERENCE (PURPLE)	REFERENCE (WHITE)
Kit S5M	T060407	T060423
Kit S5	T060410	
ADDITIONAL ITEMS APART		
Trocar 11G x 125mm	T060430	
Trocar 13G x 125mm	T060431	
Trocar Confort with chiba needle 11G x 125mm	T060432	
Trocar Confort with chiba needle 13G x 125mm	T060433	
Trocar Confort with chiba needle & Biopsy 11G x 125mm	T060434	
Trocar Confort with chiba needle & Biopsy 13G x 125mm	T060435	
TEKNIMED CEMENT RANGE	Contact us	



Classe I sterile

Patent pending



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Administration and supply-chain offices:

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Sales and engineering departments:

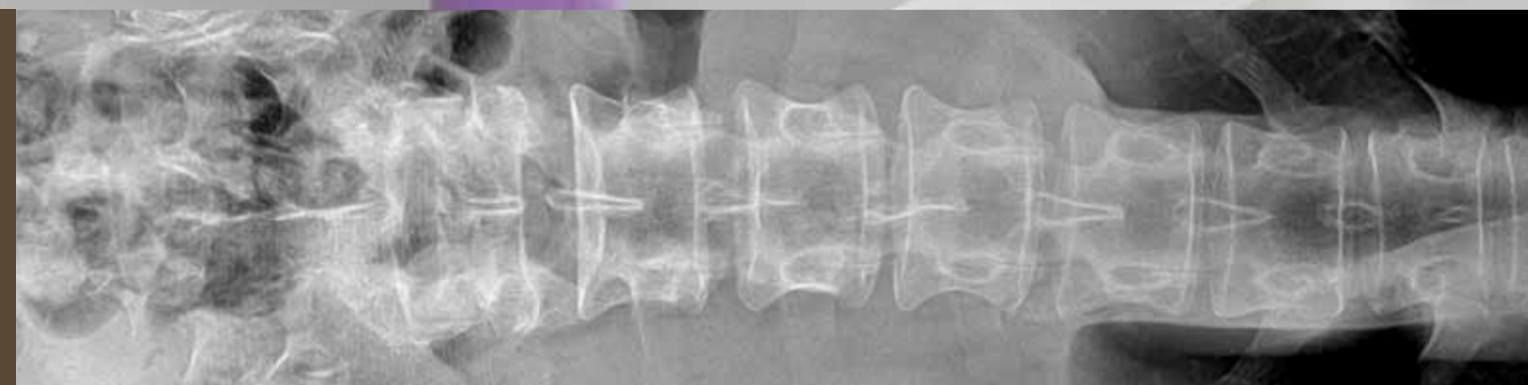
Z.I. de Montredon - 11, rue Apollo
31240 L'UNION (France)
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Fax (33) 5 34 25 27 39

Distributed by

Manufactured by



S5 kit



Mixing & injection system
for vertebroplasty Bone Cement



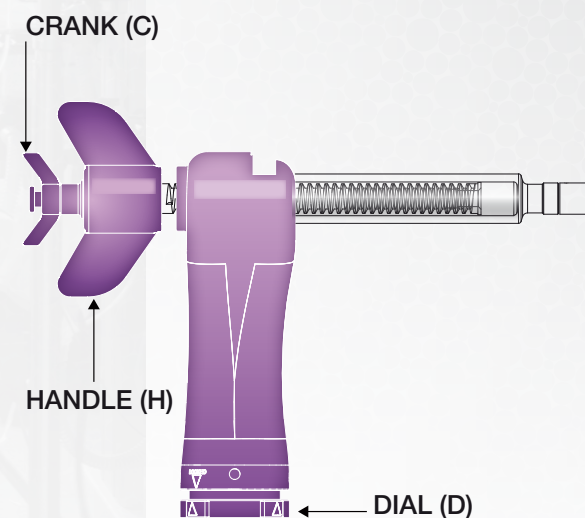
S5 kit

The first bone cement delivery gun equipped with an automatic pressure-overload safety feature. Teknimed brings bone cement preparation and delivery to a new level with a Safe, Simple, Robust complete kit specifically designed to treat vertebral compression fractures by vertebroplasty or kyphoplasty.

As the cement viscosity increases over time, the pressure generated inside the syringe is simultaneously increases. The maximum pressure tolerated by the delivery gun can be controlled to progressively perform the augmentation

procedure preventing rapid and massive injection of cement into vertebral body. As soon as the pressure inside the syringe reaches the initial maximum pressure tolerated by the delivery gun, the automatic security mechanism is activated and the cement cannot be injected anymore. At this time, the surgeon increases the maximum pressure by turning "the crank" and continues the injection with "the handle" until the security system is activated again. The injection procedure is progressively carried out, adapting the delivery system to the bone cement viscosity.

S5 device is designed by, and for medical professionals Teknimed is committed to supplying surgeons with the most innovative solutions for vertebral augmentation procedures throughout the entire range of Teknimed cements.

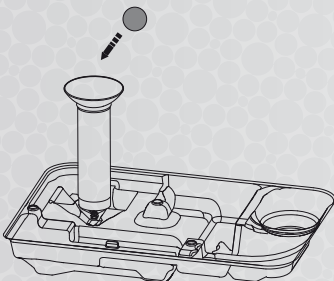


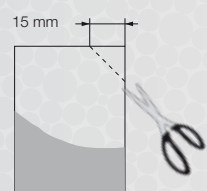
CRANK (C) to adjust the injection force.
HANDLE (H) to inject the cement.


Advantages


- SAFE INJECTION
- SECURE MECHANISM
- ROBUST INSTRUMENTATION
- SIMPLE SHAKE TO MIX
- AUTOMATIC PRESSURE CONTROL

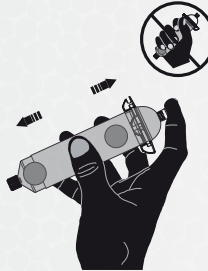
Use

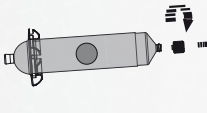
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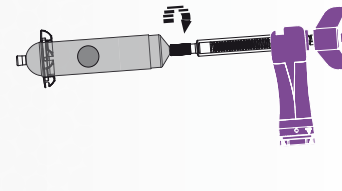
Place the mixing vial into the indicated location within the tray.
Place funnel and then the ball into the mixing vial.
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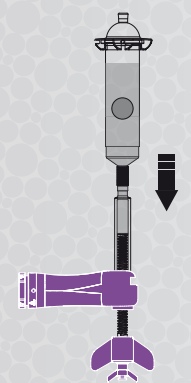
Cut the corner of the pouch.
- 

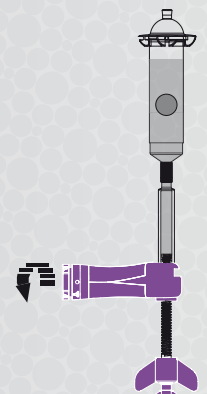
1- Pour bone cement powder first.
2- Then pour liquid monomer.
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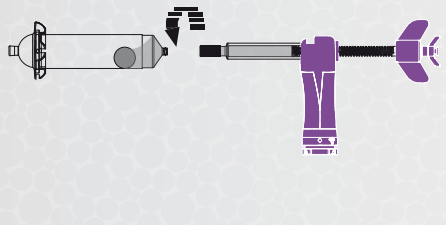
Screw the lid
- 

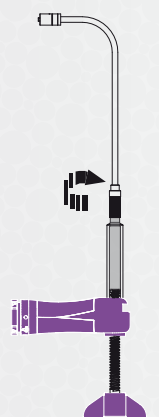
Shake up and down with 3 fingers during the required time (see IFU of bone cement).
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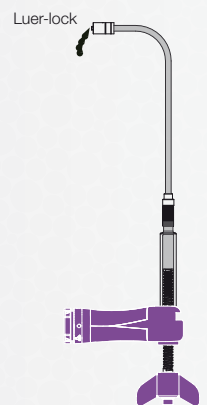
Rotate the mixing system and unscrew the cap
- 

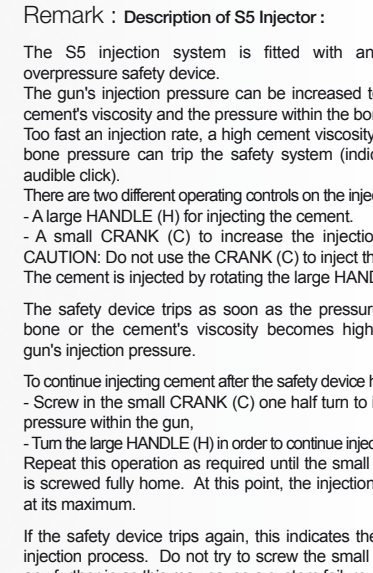
Luer-lock the cement delivery gun onto the mixing system.
- 

Turn the cement delivery gun upside down and pull out the **HANDLE (H)** to draw in the required amount of bone cement into the cement gun.
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Turn the **DIAL (D)** to the "Locked" position.
- 

Unlock the cement delivery gun from the mixing system.
- 

Luer-lock the extension tube onto the cement delivery gun.
- 

Before connecting to the trocar, turn the handle to remove the air from the extension tube, then perform one more turn to drain a first volume of cement.
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Remark : Description of S5 Injector :
The S5 injection system is fitted with an automatic overpressure safety device.
The gun's injection pressure can be increased to match the cement's viscosity and the pressure within the bone. Too fast an injection rate, a high cement viscosity or elevated bone pressure can trip the safety system (indicated by an audible click).
There are two different operating controls on the injection gun:
- A large **HANDLE (H)** for injecting the cement.
- A small **CRANK (C)** to increase the injection pressure.
CAUTION: Do not use the **CRANK (C)** to inject the cement. The cement is injected by rotating the large **HANDLE (H)**.
The safety device trips as soon as the pressure inside the bone or the cement's viscosity becomes higher than the gun's injection pressure.
To continue injecting cement after the safety device has tripped:
- Screw in the small **CRANK (C)** one half turn to increase the pressure within the gun,
- Turn the large **HANDLE (H)** in order to continue injecting cement. Repeat this operation as required until the small **CRANK (C)** is screwed fully home. At this point, the injection pressure is at its maximum.
If the safety device trips again, this indicates the end of the injection process. Do not try to screw the small **CRANK (C)** any further in as this may cause a system failure.

Indications

