

WORK INSTRUCTION

Title	Sporfix unit from Ultrapharma
Document number	WI01

APPROVAL

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Purpose

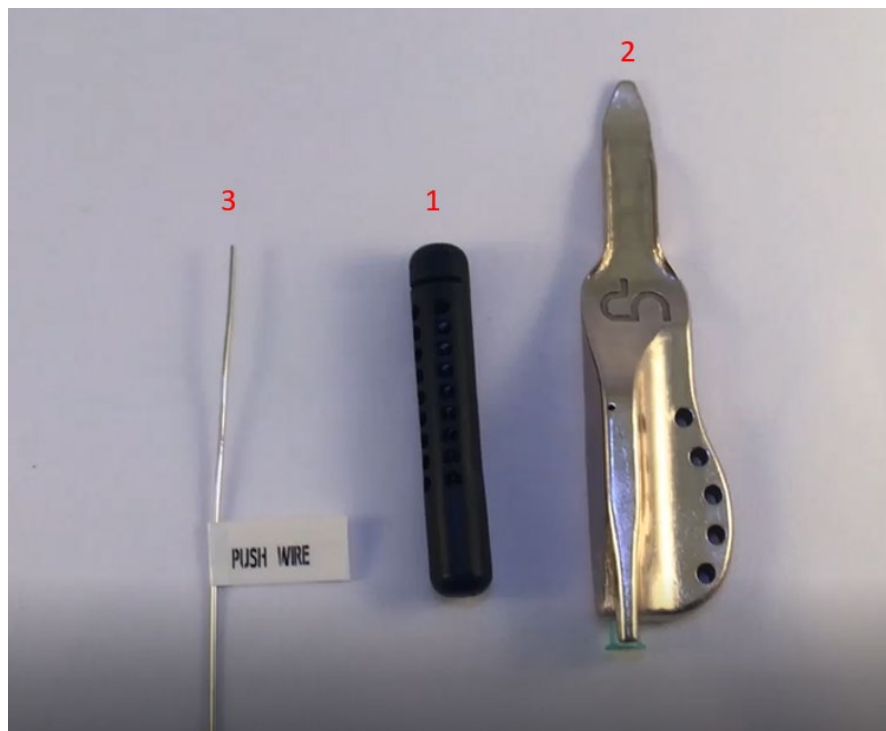
The purpose of this work instruction is to describe how to use the single use Sporfix unit and tool from Ultrapharma.

Description

The Sporfix unit (1) from Ultrapharma is used as a container for BI's (strips and ampoules) during validation of sterilization processes.

The Sporfix unit also fixes the thermo wire (temperature sensor) adjacent to the BI.

A multipurpose tool (2) is used for loading the BI into the container, for puncturing a hole for the thermo wire and for making a hook for the push wire (3) that is used fixing the Sporfix unit.



The Sporfix unit is delivered in a pouch which is traceable to a certificate as shown on the picture below



Procedure – BEFORE the sterilization process

Step 1. Create a hook at the end of the push wire using the hole of the multipurpose tool

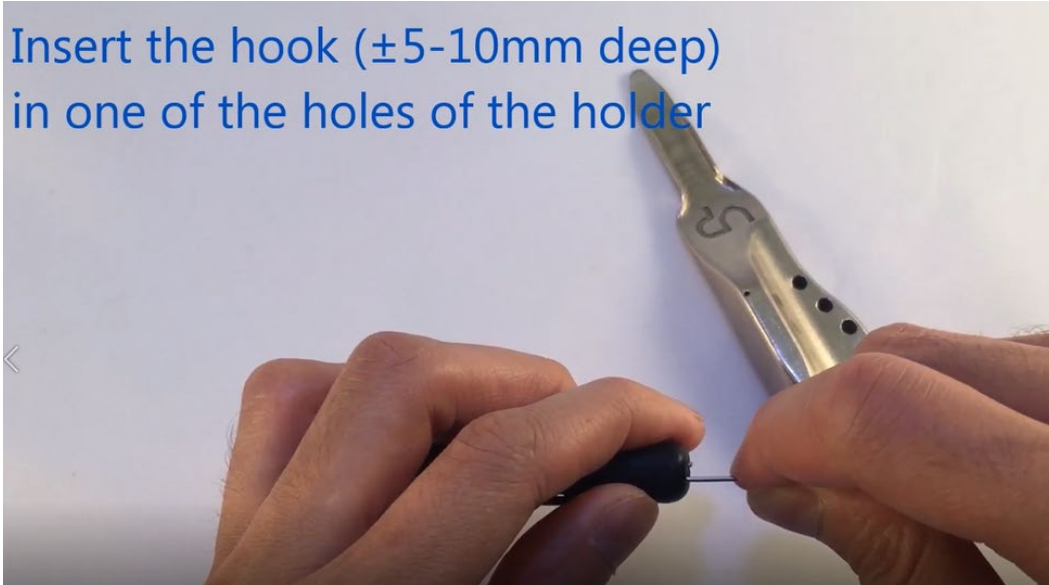


Create a hook at the end of
the pushwire using the tool

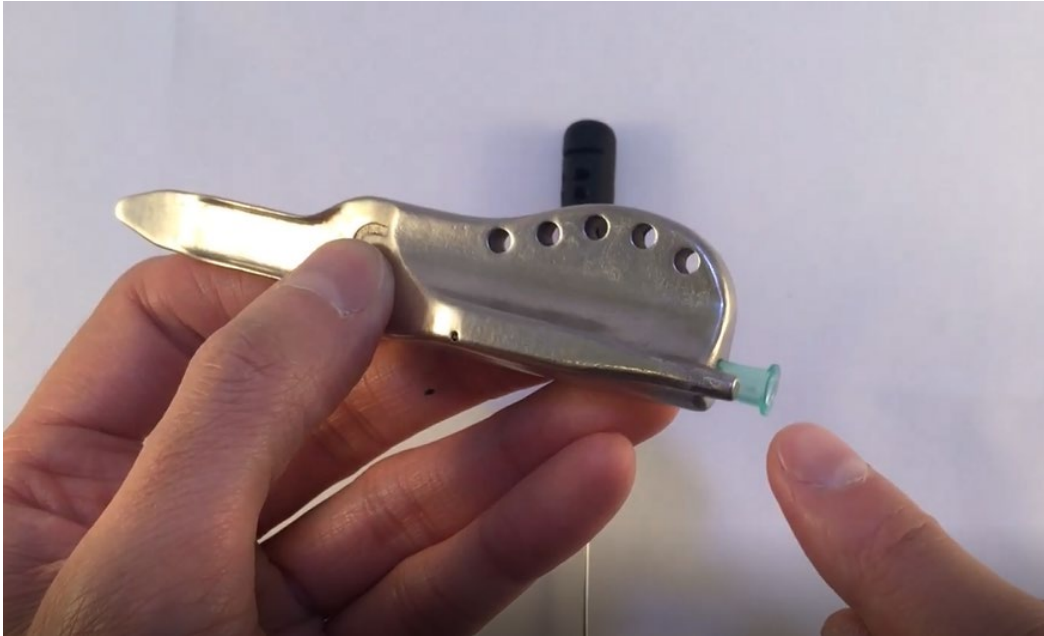


Step 2. Insert the hook in either of the two holes of the Sporfix unit

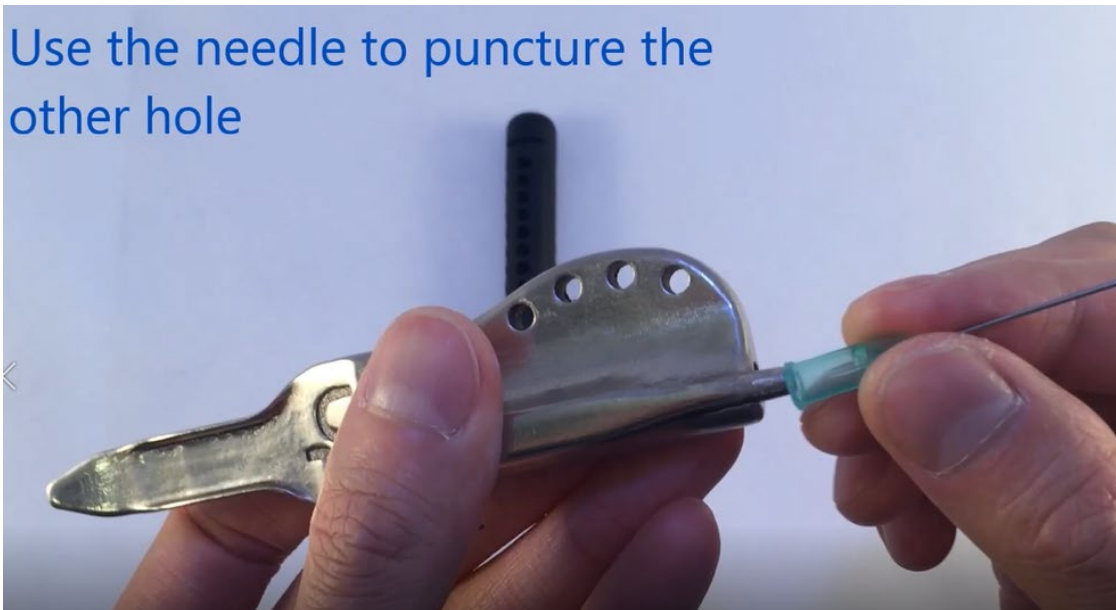
Insert the hook ($\pm 5-10$ mm deep)
in one of the holes of the holder

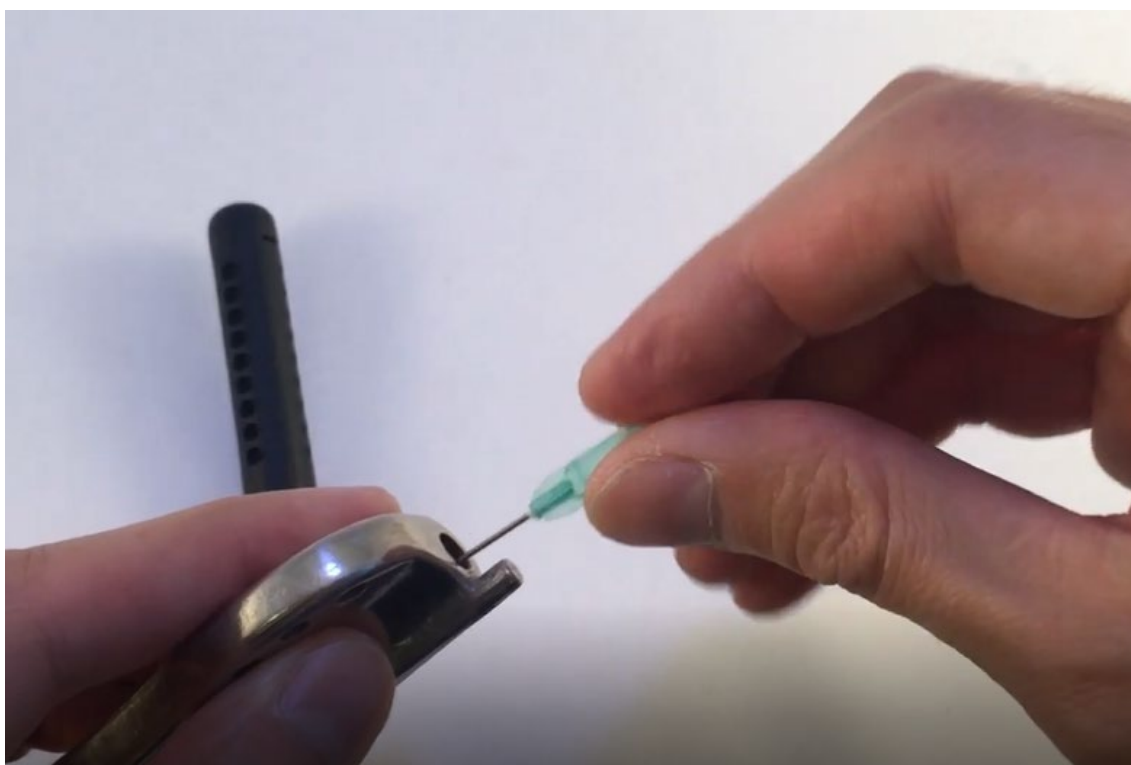


Step 3. Use the needle of the multipurpose tool to puncture the other hole of the Spofix unit



Use the needle to puncture the other hole



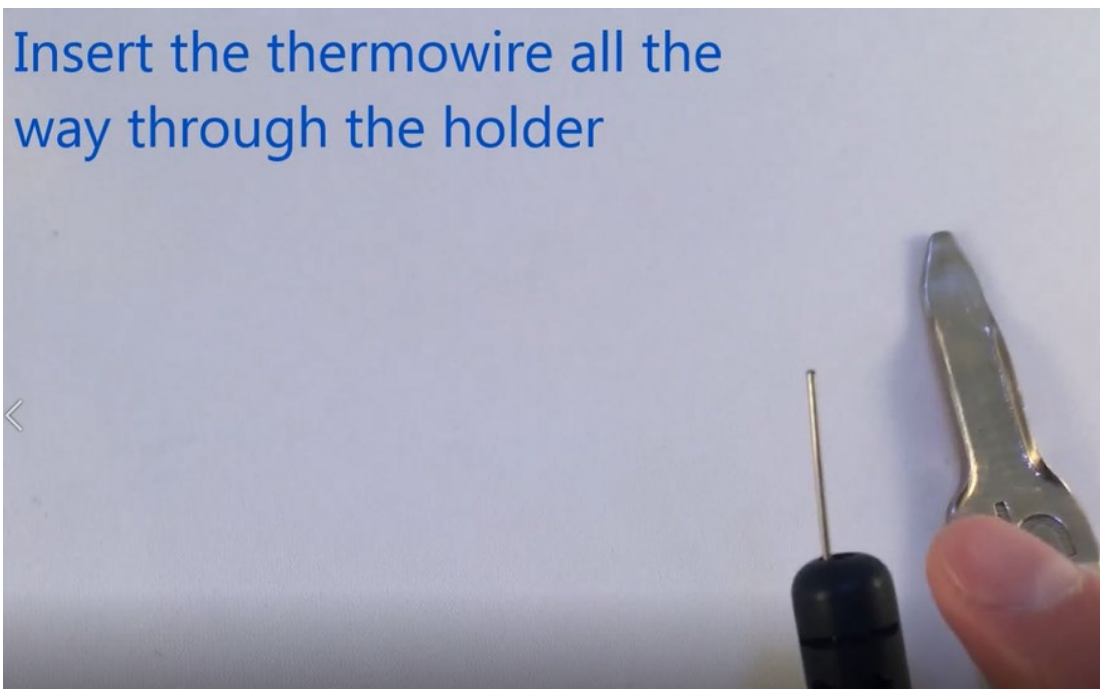


Step 4. Insert the thermocouple all the way through the Sporfix unit

Insert the thermowire all the way through the holder



Insert the thermowire all the way through the holder



Step 5. Insert the tip of the multipurpose tool into the slit of the Sporfex unit

Insert the tip of the tool into the holder



Insert the tip of the tool into the holder



Step 6. Fold the spore strip

Fold the spore strip



Fold the spore strip





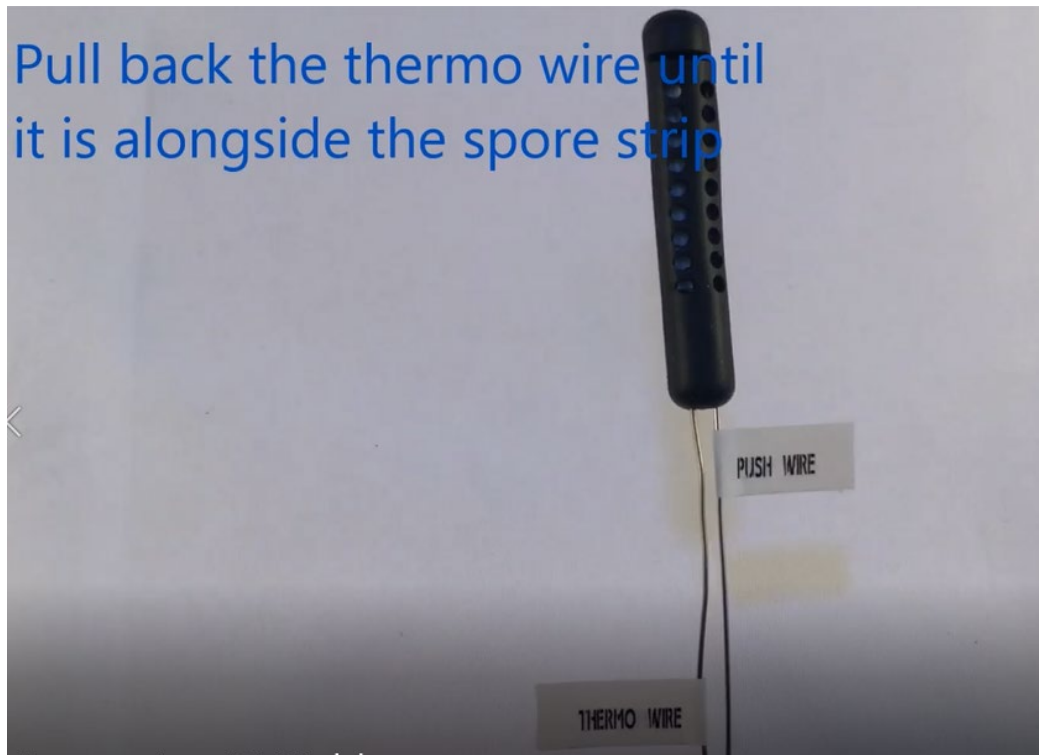
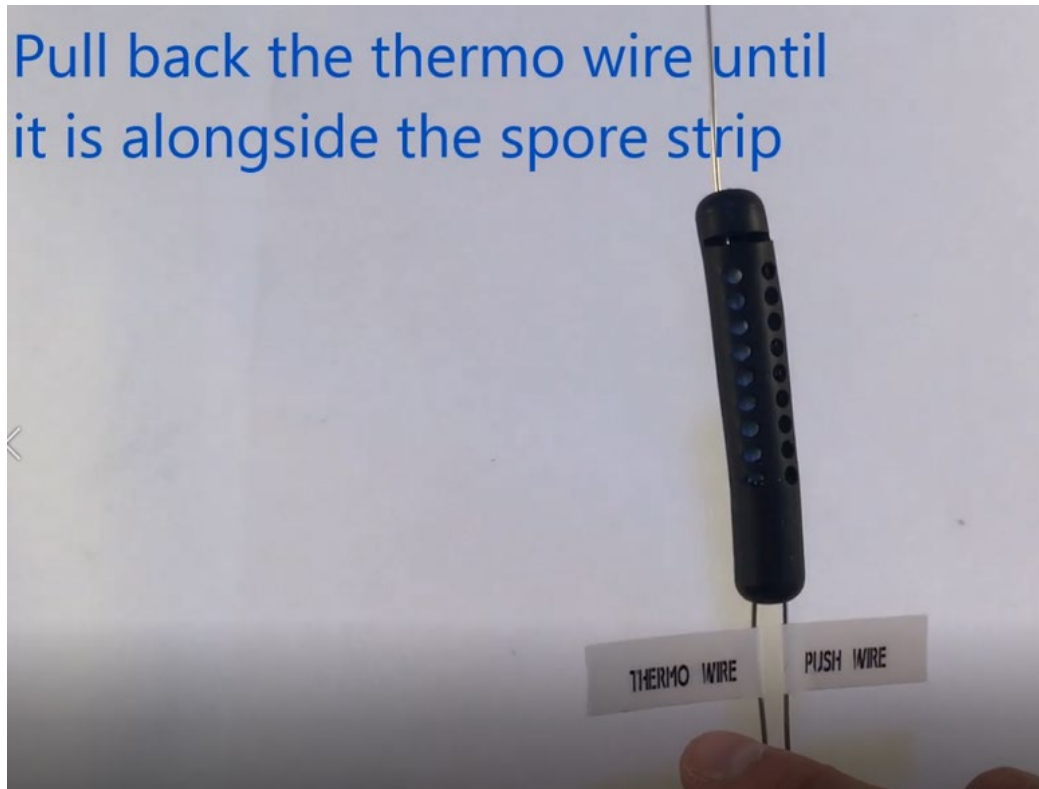
Step 7. Insert the spore strip into the Sporfix unit using the multi-purpose tool



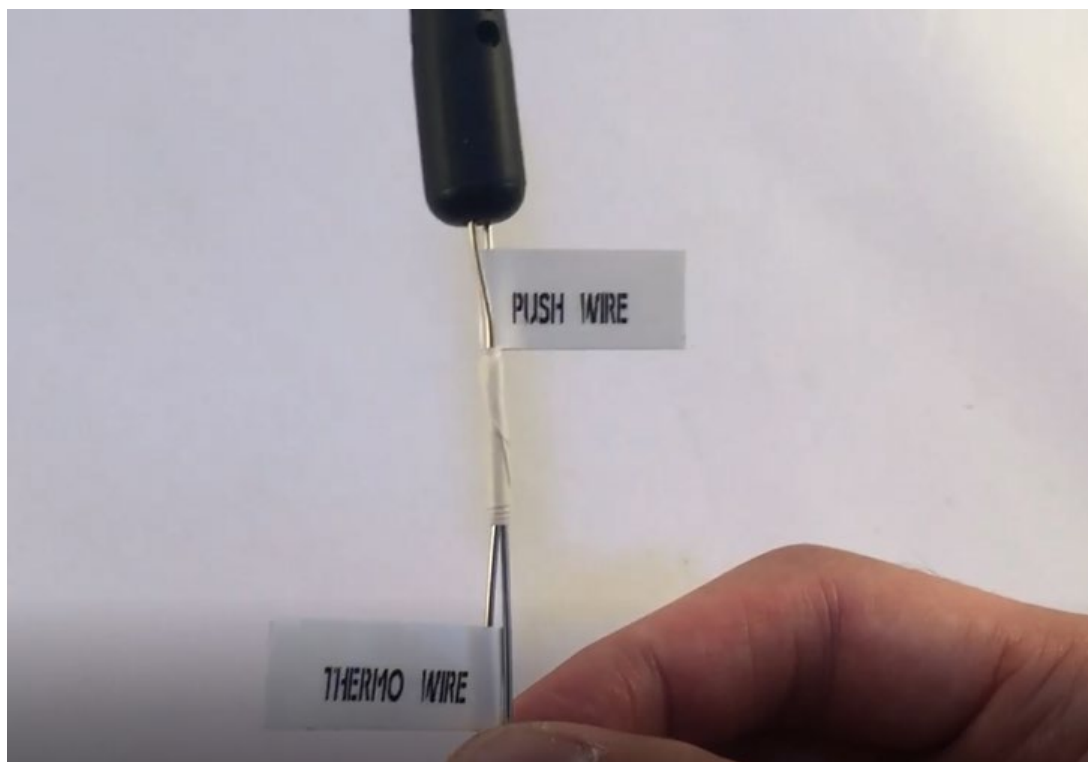
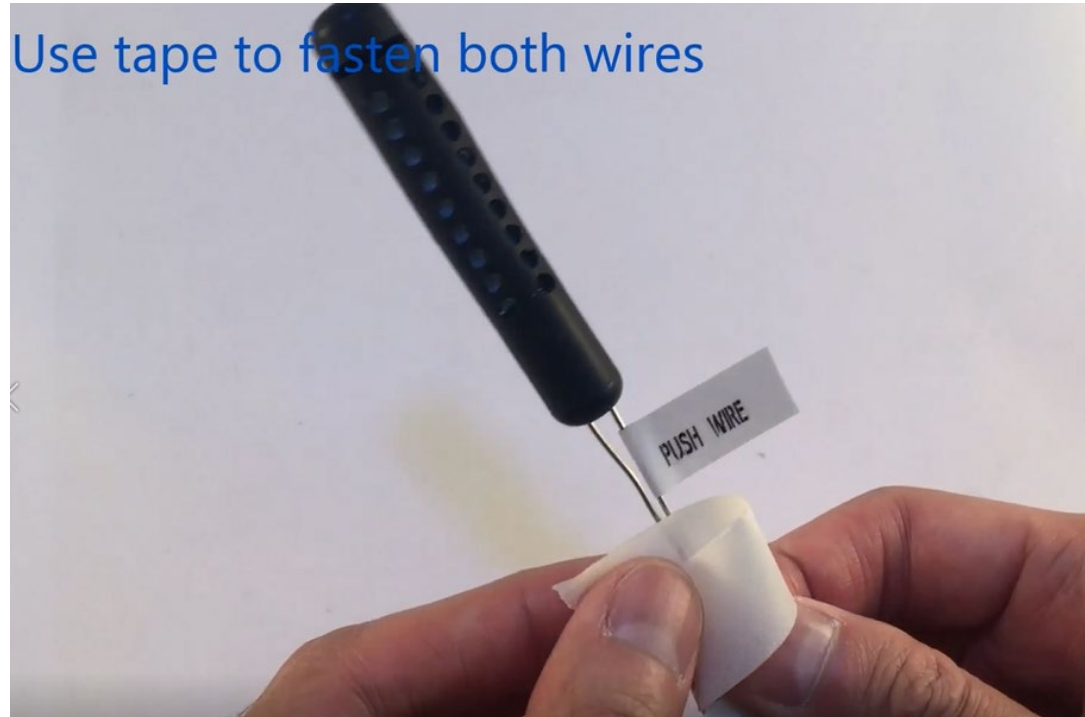
Insert the spore strip into the holder using the tool



Step 8. Pull back the thermocouple wire until it is aligned with the spore strip



Step 9. Use thermal resistant/autoclave tape to fasten both wires



The Sporfix unit is now ready for mounting on the equipment to be sterile validated.

Procedure – AFTER the sterilization process

The Sporfix unit must be dismantled from the equipment and send to the laboratory according to procedure below. To ensure the sterile integrity use sterile gloves to perform this procedure:

1. Remove the thermal resistant/autoclave tape.
2. Pull out the thermocouple wire.
3. Cut off the push wire (welding wire) and place the Sporfix into an autoclave bag, petri dish or similar, to keep the sterile integrity during the transport to the laboratory.
4. Mark each sample with a sample id, to ensure traceability to each sample individually.
5. Send the samples to the laboratory.
6. Detach the biologic indicator strip within the Sporfix unit by tapping the top of the Sporfix unit on e.g. a table top.
7. Ensure that the BI-strip is not in the cut zone otherwise repeat 6. and cut off the bottom of the Sporfix unit.
8. Follow the laboratory procedures for the analysis.

Change log

Version	Page	Change
1.0	All	New.
2.0	All	Editorial changes. General update; BI-holder updated to actual name of the unit, corrected from BI-holder to Sporfix unit.
	4	Picture of Sporfix unit bag, replaced with the actual picture of the Sporfix unit bag.
	17	Procedure after the sterilization process updated with a more detailed description of the post-sterilization procedure steps.