

To whom it concerns,

FertiPro N.V. updated the instructions for use of SpermFreeze. A summary of the changes is listed in the table below.

Instructions for use	SpermFreeze
Previous version	FP09 I11 R01 C.5
New version	FP09 I11 R01 D.1
Changes	<ul style="list-style-type: none"> - New lay-out - All product names of products marketed by FertiPro with the addition of "TM" - Addition of "<i>For professional use only</i>". - Addition of underlined sentences in "Before freezing" in section "SpermFreeze™ and sperm preparation": <i><u>In case of very low sperm concentration it is advisable to concentrate the sperm before freezing. Sil-Select Plus™ can be applied before freezing to remove debris and to enrich the concentration of motile cells in a sample. This may increase the sperm quality after thawing and will reduce the number of straws to be frozen. In case of very high sperm concentration, sperm can be diluted with FertiCult™ Flushing medium before freezing, if preferred.</u></i> - Rewording of point 8 and 9 of the freezing method: <i>"Freeze vertically for 15 minutes, just above the level of the liquid nitrogen. Store in liquid nitrogen"</i> Is replaced by: "<i>Place the straws horizontally on a styrofoam board in a liquid nitrogen bath to allow for freezing in vapour phase. Leave for (at least) 15 minutes. Transfer straws quickly into liquid nitrogen and store at -196°C</i>"

Name: Ellen Van Vlierberghe
 Function: Regulatory Affairs Associate
 Date: 25/10/2018
 Signature and stamp:


