


To whom it concerns,

FertiPro N.V. updated the instructions for use of VitriFreeze ES / VitriThaw ES. A summary of the changes is listed in the table below.

Instructions for use	VitriFreeze ES / VitriThaw ES
Previous version	FP09 I46 02 R01 D.6
New version	FP09 I46 02 R01 D.7
Changes	<ul style="list-style-type: none"> - New lay-out with technical support, CE 0344 and bibliography in a separate column and the addition of the cryopreservation symbol: <div style="text-align: center; margin: 5px 0;">  </div> - Addition of "For professional use only", "Sterilised by sterile filtration" and "ready-to-use" set of media - The abbreviations "VPI", "VF1", "VF2", "VF3", "VT1", "VT2", "VT3", "VT4" and "VT5" are used instead of the complete medium name. - An extra pre-use check is added: >> VitriFreeze ES™ - Freezing 2 medium may contain small salt precipitates which do not have an impact on product performance/safety - Addition of article in Bibliography: Kartinen, N., et al. (2016) The freezing method of cleavage stage embryos has no impact on the weight of the newborns. J Assist Reprod Genet, 33(3), 393-399 - Section method is slightly adjusted and summarized for the vitrification of embryos: <ul style="list-style-type: none"> • room temperature defined as (20-25°C) • the volumes needed per medium are listed per protocol.
	<ul style="list-style-type: none"> - The first warming solution used in the warming protocol can be used at room temperature as well as 37°C. This will not affect your results, and in this way no medium need to be prewarmed before use. - The volume of VitriThaw ES - Thawing medium 2 is increased from 1ml to 3.2ml

Name: Ellen Van Vlierberghe
 Function: Regulatory Affairs Associate
 Date: 06/08/2019
 Signature and stamp:

Ellen Van Vlierberghe
 Regulatory Affairs Associate
 FertiPro N.V.

