
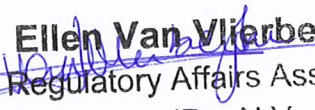


To whom it concerns,

FertiPro N.V. updated the instructions for use of FertiVit Cooling/Warming. A summary of the changes is listed in the table below.

Instructions for use	FertiVit Cooling / FertiVit Warming
Previous version	FP09 I46 03 R01 A.2
New version	FP09 I46 03 R01 A.3
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: 10px 0;">  </div> - Addition of "<i>For professional use only</i>", "<i>Sterilised by sterile filtration</i>" and "<i>ready-to-use</i>" set of media - Addition of article in Bibliography: Papatheodorou, A., et al., How does closed system vitrification of human oocytes affect the clinical outcome? A prospective, observational, cohort, noninferiority trial in an oocyte donation program. <i>Fertil Steril</i>, 2016. 106(6): p. 1348-1355. - Section preliminary steps is slightly adjusted and summarized for the vitrification of oocytes and embryos: <ul style="list-style-type: none"> • room temperature defined as (20-25°C) • the volumes needed per medium are listed per protocol. - The first warming solution used in the 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. - FertiVit Cooling/Warming can be used with open and closed vitrification device. We still advise to use a closed vitrification device in order to comply with European regulations defining medical safety requirements for cryopreservation of human cells. The use of closed vitrification devices avoid direct contact between the embryo and liquid nitrogen during cooling and long-term storage.

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