

## Valued customer,

We want to inform you on the following changes regarding FertiPro's sperm freezing media:

## SpermFreeze™:

The instructions for use were updated to include the cryopreservation of sperm from testicular biopsies (TESE) again.

With the CE-marking according to the Regulation (EU) 2017/745, this was omitted from the intended use due to an insufficient amount of clinical data to support this. The past years, efforts were made to collect additional clinical data, making it possible to extend the intended use again.

In this regard, in order to keep our technical file updated, if you are able to share clinical data on the cryopreservation of sperm from TESE, please contact <u>ra@fertipro.com</u>.

## SpermFreeze<sup>™</sup> and SpermFreeze<sup>™</sup> SSP:

The instructions for use were updated to include the SpermFreeze Box as an accessory of SpermFreeze $^{TM}$  and SpermFreeze $^{TM}$  SSP.

The SpermFreeze Box is a box to standardize the cryopreservation of human semen samples, by offering a standardized height of the sperm freezing straws in the liquid nitrogen vapor phase.

If additional information is required, please send your question(s) to ra@fertipro.com.