

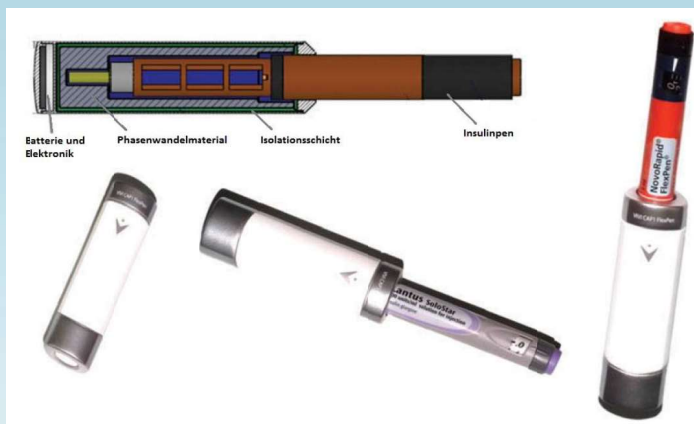
VIViCap Protects Insulin in Disposable and Reusable Pen Devices From Degradation During Exposure to Extreme Temperature Conditions.

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Background

Exposure to extreme cold or heat leads to insulin degradation in a very short time with loss of glucose-lowering efficacy. Therefore, insulin vials and cartridges have to be kept at 4-8 °C (~ 39°F to 47°F) until use. Once opened, the insulin supposed to be stable for 28 to 30 days at room temperature. ViVi-Cap (TempraMed Inc.) is a reusable storage device, which is available for the majority of existing disposable (D-Cap) and reusable (R-Cap) pen devices in the US and EU. It works without external power supply requirements based on an ultra-high vacuum insulation and an additional heat consumption by a calorimetry-based phase-change technology.

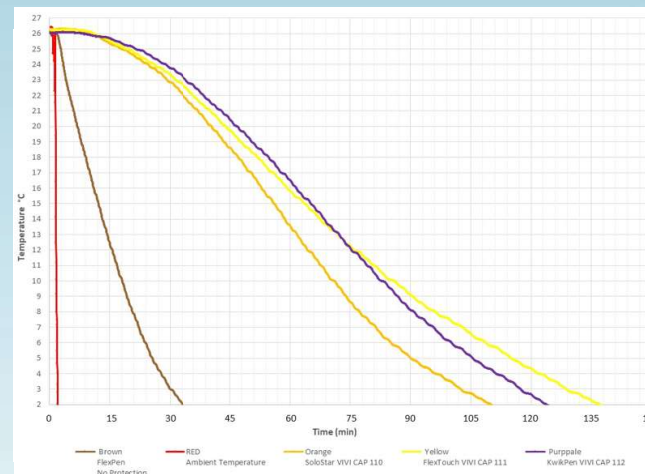
Fig.1: ViViCap design



Methods

Five disposable insulin pens (FlexPen, Insulin aspart) were kept for one week under extreme temperature conditions for 5 days (each day: 8 h at 50 °C and 16 h at 22 °C) either without protection, in a frio device (freshly prepared each day) and in the ViViCap. Samples were taken every day and insulin degradation was determined in accordance with US pharmacopoeia by appropriate HPLC methods for insulin aspart, and high and low molecular weight degradation molecules. Each experiment was performed in triplicate.

Fig.2: Temperature changes, when pens are exposed to very cold temperature (-20 °C)



Conclusions

ViVi-Cap was superior to the other tested conditions with respect to stabilizing insulin aspart during storage under extreme temperature conditions. The device provides an easy to use solution for maintaining insulin efficacy under daily life conditions.

Results

Insulin aspart without protection was shown to have more than 2 % impurities already after one day (Frio: 2 days, ViViCap: >5 days). High molecular weight products appeared in measurable quantities after two days without protection (Frio: 3 days, ViViCap > 5 days, $p < 0.01$ against the other 2 storage conditions). In a second experiment, unprotected insulin aspart pens were exposed to -20 °C and reached the critical temperature of 2 °C after 37 min. When protected by the ViViCap device, this temperature was reached after 150 min.

Fig.3: Impurities [%] over time [h] of unprotected pens (red), pens in a Frio Coolbag (grey) and in the ViViCap (green) during exposure to high temperature (50 °C)

