



## **New PVC-free blood bags have reached a major milestone**

**In-vitro testing with the first PVC-free blood bags has started at Karolinska University Hospital with donor blood. The blood bags and its tubings are solely produced from MELITEK's soft polyolefin materials that are manufactured at our dedicated plant south of Copenhagen.**

*"We are very excited that this major milestone is reached after several years of close work with the partners on this project and are optimistic based on our initial trials made earlier this year with water, that the bags will perform well in actual use - now we are anxious to see the outcome of the actual testing with blood and hearing the feedback from hospital staff", says Jesper Laursen, Business Director at MELITEK.*

Hans Gulliksson, Associate professor in Experimental Transfusion Medicine at Karolinska University Hospital, supervised the first blood donations for the in vitro evaluations. Donors gave blood at Skanstull donation centre in Stockholm and donors who had given their informed consent donated the blood used for the tests.

*"Introducing new medical devices is a long and thorough process. I am very happy that we're now starting in vitro testing - it is a huge milestone in the project,"* says Lena Stigh, project manager from Region Jämtland Härjedalen in Sweden.

The physical performance of the bags has already been tested with water. The bags were deemed to fulfil essential requirements when factors such as impact during centrifugation, leakages and suitable length of tubes were tested. The same tests will be carried out using blood.

The study is taking place at Karolinska University Hospital and will be conducted by a team managed by professor Petter Höglund. *"It will be exciting to see the results of the evaluation in March next year,"* says Hans Gulliksson.

Concurrently, the PVC-free blood bags will also undergo a test at Östersund hospital and four other Swedish hospitals. These tests are planned to start before Christmas and will simulate and evaluate the practical handling of the blood bags by medical staff.

There are currently no PVC-free blood bags for red blood cells on the market. The most commonly used plasticizer in blood bags for red blood cells is phthalates that is classified as a reproductive disruptor.

The PVCfreeBloodBag is a cooperation between industry and European healthcare, aimed at phasing out hazardous substances from healthcare.

Four European companies are participating in the project - MELITEK A/S in Denmark, Wipak Oy in Finland, Primo Profile in Poland and Haemotronic in Italy. Karolinska University Hospital is responsible for evaluating the bag.

MELITEK is a privately owned Danish company specialized in medical compounds based on 30 years' experience servicing the healthcare market. MELITEK offer a broad range of elastomer and polymer materials, sold under the MELIFLEX trade name) that are produced according to GMP, with an extensive medical service package and certified to ISO 10993 and USP.

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For more information about MELITEK and our meliflex products, please contact:

Jesper Laursen | MELITEK A/S | Denmark | tel. +45 70 250 255 | sales@melitek.com

*“This project has two objectives: firstly to increase demand from healthcare organisations; and secondly to demonstrate that it is possible to make a PVC-free blood bag that fulfils the relevant requirements specification,”* says Lena Stigh.

Progress towards producing a PVC-free blood bag has been successful and the work to increase demand is underway. Disseminating knowledge and raising awareness in partnership with European healthcare providers is essential for driving demand.

*“We have over the years supplied materials for many applications replacing soft PVC in medical products, and now set our goal to demonstrate that our material platform will work and offer environmental and health benefits also for blood bags. We hope this project will prove to healthcare providers, industry and the public that it is possible to substitute PVC one of the last few applications where PVC containing DEHP phthalates still remain in use”,* says Jesper Laursen.

PVCfreeBloodBag is a project within the EU’s Life+ Environmental Programme. The full title is “Public healthcare and plastic makers demonstrate how to remove barriers to PVC-free blood bags in the spirit of REACH”. It started in the autumn of 2011 and will run for four years.



*Picture: One of the new PVC-free blood bags filled with blood and ready for further tests.*

*Photographer: Andreas Johansson*

**Do you want to find out more? Contact Jesper Laursen, Business Director at MELITEK A/S.**

**Tel +45 70 25 02 55 or e-mail: [JL@melitek.com](mailto:JL@melitek.com)**

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