



## **Redsense Medical ready for the European markets**

**Redsense Medical's product for blood loss detection during hemodialysis received considerable attention at the Annual Dialysis Conference in Denver, US, last week. This revolutionary device is now approved for sale in Europe and granted the CE mark.**

According to standards, dialysis equipment must provide a system to protect the patient from blood loss from venous needle dislodgement. Figures about reported annual deaths due to venous needle dislodgement in the US vary between 5 and 10.

For several reasons, companies producing dialysis equipment have long searched for a better solution than the method used today: venous pressure monitoring. The problem with this method is that medical staff believes it will detect venous needle dislodgement. Most likely, it won't.

The lack of a reliable solution has led some clinics to use moisture detectors such as enuresis pads. But these products don't have blood detection as "intended use" and their reliability is uncertain. They have never been clinically tested.

Extra surveillance is another way to make up for the lack of adequate alarms. Normally, medical staff can move around between rooms but in some clinics, rooms with patients in dialysis must at all times be attended by a nurse. Extra surveillance demand resources.

At home, there's no surveillance at all. In nocturnal home hemodialysis, which provides many benefits for both patients and for the health care system, the added safety of a tried and tested alarm becomes even more valuable.

The clinical trial included 213 dialysis treatments with 40 patients involved. The Swedish Medical Products Agency has approved the product as a class I product according to the Medical Device Directive 93/42/EEC. The FDA approval process required for sales in the US is expected to finish in a few months time.

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*Company: After a number of incidents with venous needle dislodgement during hemodialysis at a dialysis clinic in Sweden, the clinic's technicians contacted a company specializing in medical technology. This co-operation between medical staff and engineers resulted in the start-up of Redsense Medical in 2006. Redsense Medical has offices in Sweden and in the US (Seattle, WA).*

*Product: Redsense is a blood loss detection device comprising two parts: a sensor patch and a base unit. Connected to the base unit by a small wire, the sensor patch employs fiber optic technology to continuously monitor the venous needle access point. If the needle dislodges and bleeding begins the alarm will be raised by the base unit worn on the patient's arm.*

*More information: [www.redsensemedical.com](http://www.redsensemedical.com)*