

Press release

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Redsense Medical receives FDA Clearance for the Redsense safety device for Home/Self use during home hemodialysis

The Redsense safety device is now cleared by FDA for Home/Self use and is consequently available to all patients with home hemodialysis in the US. Redsense safety device is designed to detect venous needle dislodgement during hemodialysis and its use has already improved in-clinic patient safety. Optimizing safety conditions for home hemodialysis users is a core ambition for Redsense Medical.

Dialysis equipment today is required to have a system which protects the patient from blood loss due to dislodgement of the venous needle. The commonly accepted solution is to monitor by the venous pressure alarm but a better solution has long been requested. Even with the routine supervision of medical staff still the venous needle can become dislodged: the dialysis machine will then continue to draw blood from the patient's artery however not returning blood in the loop circuit as the venous needle has become dislodged and the patient's blood ends up elsewhere. If undetected, this blood loss can have very serious consequences in only a few minutes. Redsense safety device provides a solution to this problem and detects venous needle dislodgement instantaneously; it only takes a few millilitres of blood on the sensor patch to sound the alarm.

It is well known that home hemodialysis allows for daily treatments, improving quality of life, morbidity and life expectancy. Home hemodialysis is also more cost-effective as it can free hospital beds and reduces the transport costs related to centralized dialysis care.

Being able to address the market for home hemodialysis is an important step according to, CEO Patrik Byhmer:

- This is where Redsense really can make a difference. It's very satisfying being able to increase the level of safety among the users of home hemodialysis.

More information:

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The company

Redsense Medical has offices in Sweden and in the U.S. (Chicago, IL). For more information: www.redsensemedical.com.

The product

The Redsense safety device is the results of close co-operation between medical staff and engineers. Redsense consists of two parts: a sensor patch and an alarm unit. An infrared signal is transmitted from the alarm unit to the sensor patch using fibre optic cable. In the event of bleeding, inner layers of the patch smear blood over the optical sensor, which triggers the alarm.

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