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FibroScan® Gains FDA Approval for Non-Invasive Liver Diagnosis

Echosens™ has announced that its FibroScan® device received 510(k) clearance from the U.S. Food and Drug Administration (FDA) on 5 April 2013 and is now ready to market its pioneering technology in the United States.

Today, 1800 FibroScan® devices are used worldwide both in research and routine clinical practice. The United States of America is the last major market to approve FibroScan®.
FibroScan® is used in the clinical management of patients with liver disease such as chronic viral hepatitis C and B and fatty liver diseases. Based on a technology called transient elastography, FibroScan® assesses liver shear wave speed (expressed in meter per second) and equivalent stiffness (expressed in kilopascal) at 50 Hz in a rapid, simple, non-invasive and totally painless way.

Initially introduced to the European market in 2003, FibroScan® pioneered the quantitative elastography medical field. It received market clearances in China (2008), Canada (2009), Brazil (2010), Japan (2011) and is currently available in 70 countries.

With more than 660 peer-reviewed publications, FibroScan® is by far the elastography device with the largest body of evidence on its clinical usefulness. Moreover, the use of FibroScan® is also mentioned in guidelines and recommendations in different regions of the world: World Health Organization, European Association for the Study of Liver (EASL), Asian Pacific Association for the Study of Liver (APASL), etc.

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