

## FerriScan<sup>®</sup> R2-MRI Fact Sheet - Myelodysplastic Syndrome and Iron Overload

Myelodysplastic syndrome (MDS) is a group of diseases characterised by ineffective haematopoiesis, morphological dysplasia, peripheral blood cytopaenias and a high risk of developing acute myeloid leukaemia. It is a disease that mainly affects elderly patients; the average age at diagnosis being between 65 and 70 years.

The primary reason for iron overload in patients with MDS is transfusion therapy, approximately 20 – 30 % of patients requiring regular transfusions. However, some MDS patients will already have excess iron levels before commencing transfusion therapy, due to an increased absorption of dietary iron which can be characteristic of the condition.

### Monitoring Iron Overload in MDS

The most widely available technique for diagnosing and monitoring iron overload in MDS patients is serum ferritin, even though it does not always accurately reflect tissue iron levels. A definitive diagnosis of iron overload requires more evidence than elevated serum ferritin alone.

In addition, there is substantial variation in ferritin levels between patients with equivalent iron burden. Other factors present in patients with MDS such as infection, inflammation, cancer or liver damage may result in significant elevation of ferritin concentration, even in the absence of iron overload.

The patented FerriScan R2-MRI technique offers an accurate and safe method of monitoring liver iron content. The liver is the primary site of iron storage and therefore provides a reliable measure of total body iron loading.

### FerriScan R2 MRI

The FerriScan analysis technique is applied to R2-MRI acquired images of the liver, creating a map of liver iron concentration (LIC) and providing a mean LIC value calculated from a cross-section of liver tissue.

The use of FerriScan for monitoring LIC in MDS patients has been included in a number of international patient management guidelines.

*Iron Overload in Myelodysplastic Syndromes: a Canadian consensus guideline* states:

*“The most accurate and precise MRI technique for measurement of LIC was developed by St Pierre et al, who found mean liver proton relaxation rates (R2) correlated strongly with LIC, as determined by biopsy across a broad range of LIC values.”*

### Key FerriScan Features

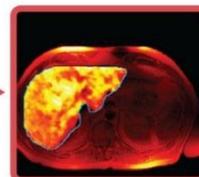
- ✓ FerriScan provides an accurate, validated MRI-based measurement of liver iron concentration
- ✓ FerriScan is non-invasive, requires no contrast agents and has a scan time of approximately 10 minutes
- ✓ FerriScan has high sensitivity and specificity for measuring LIC
- ✓ Image analysis and LIC reporting is performed at a central ISO 13485 certified Service Centre
- ✓ FerriScan has international regulatory clearance (USA, Europe, Australia)
- ✓ Results are available within a target time of two business days
- ✓ FerriScan can measure LIC over the entire range encountered in clinical practice<sup>3</sup>
- ✓ FerriScan results are clinically validated to be unaffected by inflammation, fibrosis or cirrhosis
- ✓ FerriScan requires no breath-hold and may therefore be used for paediatric patients
- ✓ Results are accurate, reliable and reproducible over time and between MRI centres and models of scanner
- ✓ There is no requirement for customers to purchase new software or hardware
- ✓ FerriScan is suitable for 1.5 Tesla MRI scanners

### FerriScan<sup>®</sup> Service Model



Patient referred for 10 min MRI scan at a validated Radiology Centre

MRI data is securely transmitted to the Resonance Health Service Centre



FerriScan analysis and quality checks performed

Liver Iron Concentration Report available for secure download by Radiology Centre within target time of 2 business days