

Magnetic Resonance Imaging Certificate

The optional ALN Vena Cava Filter is made of a magnetic medical grade 316 L stainless steel.

A non-clinical test, conducted in accordance with the ASTM F2052 standard, has demonstrated that the ALN Vena Cava Filter is "MR-conditional". A patient implanted with this filter can safely undergo MRI examination under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial magnetic field gradient of 720-Gauss/cm or less
- Maximum SAR of 3 W/kg for a 15-minute examination.

During the non-clinical test, the ALN Vena Cava Filter generates a 0.7°C increase in temperature for a 3 W/kg SAR during 15 minutes, on a 3-Tesla MRI (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

The quality of the MRI image may be impaired if the point of interest is located at the exact or approximate filter placement site. In this case, it may be necessary to optimize the machine parameters in order to improve the image. In all cases, see the MRI machine's user manual when conducting an examination on a patient implanted with an ALN Vena Cava Filter.

29 November, 2012

Alain NIGON
President



Magnetic Resonance Imaging Certificate

The optional ALN Vena Cava Filter with hook is made of a magnetic medical grade 316 L stainless steel.

A non-clinical test, conducted in accordance with the ASTM F2052 standard, has demonstrated that the ALN Vena Cava Filter with hook is "MR-conditional". A patient implanted with this filter can safely undergo MRI examination under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial magnetic field gradient of 720-Gauss/cm or less
- Maximum SAR of 3 W/kg for a 15-minute examination.

During the non-clinical test, the ALN Vena Cava Filter with hook generates a 0.7°C increase in temperature for a 3 W/kg SAR during 15 minutes, on a 3-Tesla MRI (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

The quality of the MRI image may be impaired if the point of interest is located at the exact or approximate filter placement site. In this case, it may be necessary to optimize the machine parameters in order to improve the image. In all cases, see the MRI machine's user manual when conducting an examination on a patient implanted with an ALN Vena Cava Filter with hook.

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