

Product Fact Sheet

Sirius Pintuition® Localization System



Product name

Sirius Pintuition Localization System

Manufacturer

Sirius Medical Systems B.V.
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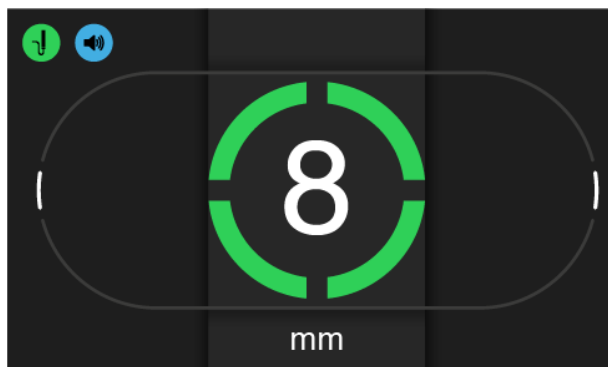
Summary

Sirius Pintuition, powered by GPSDetect™ software, is the only wire-free localization technology designed to provide navigational guidance in an easy-to-use and intuitive system. It provides real-time directional feedback using audio and visual guidance for unmatched precision to locate tumors more easily and accurately. The Sirius Pintuition Seed can be placed percutaneously using radiological guidance (x-ray or ultrasound) up to 180 days prior to a planned surgery.

GPSDetect™



Navigational Guidance



TargetLOC™



Features

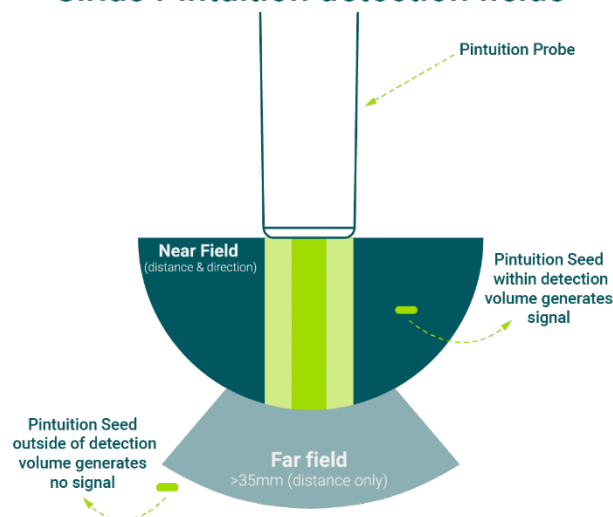
Feature	Description
Pintuition Seed	
Size	1.65mm x 5.20mm
Type	Solid and robust; cannot break during implantation
Material	Magnet in a medical grade biocompatible Titanium encasing
Delivery System	14-gauge, preloaded, 12 and 20cm with ultrasound enhanced tip
Implantation	Unlimited implant term
Intended tissue	Soft tissue including lymph nodes
Image guidance	Ultrasound or X-ray
MRI	Conditional up to 3.0T (with image artefact)
Pintuition Base Unit	
Navigational Guidance	GPSDetect™ software provides Real-time, directional feedback using audio and visual navigation
Precision	TargetLOC™ Visual target guidance that provides precise alignment above the seed
Distance Detection	True distance towards the seed in mm
Accuracy	Up to 1 mm; no tissue contact required
Detection Depth	50mm
Pinpoint Detection	Accurate regardless of seed orientation
Probe type	Reusable; cover with standard sterile probe cover
Calibration	Once per procedure
Regulatory Status	CE-marked (Seed and Detector)

Technical Specifications

Specification	Description
Pintuition System (Probe and Base Unit)	
Operating Principle	The Pintuition Probe contains a smart grid of multiple sensitive sensors that continuously measure the magnetic presence of the Pintuition Seed. The base unit software processes the measurements and provides navigational guidance, TargetLOC™ and the distance in millimeters using varying audio and visual feedback.
Distance accuracy	0-20 mm +/-1mm 20-30 mm +/-2mm 30-40 mm +/-4 mm 40-50 mm +/-5 mm
Operating Environment	Temperature: 15 – 25 °C Relative Humidity: 15% - 90%, non-condensing Altitude: <3000 meters
Storage and transport	Temperature: -25 – 70°C Relative Humidity: <90% non-condensing
Operating, Storage and Transport	Atmospheric Pressure: 70 - 106 kPa
Protection against electrical shock	Class I Protectively Earthed
Service life	5 years
Electromagnetic Emissions	The Pintuition Detector is Designed in accordance with IEC 60601-1-2 (Edition 4). The System does not use RF energy for its intended function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Pintuition detector is suitable for use in all establishments other than domestic.
Electromagnetic Immunity	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Mains power quality expected of a typical hospital and/or commercial environment.
Pintuition Base Unit	
Dimensions	26 x 16 x 32 cm (W x H x D)
Weight	6 kg
Information on display	- Distance in millimeters (when seed is detected) - Navigational guidance & TargetLOC™ - Probe connected status - Audio volume adjustment - Calibration indications - Error codes

Specification	Description
Ingress protection	IP3X
Power Lead Connector	IEC 60320 C13
Power Cable Length	2.5m (includes country specific connector)
Rated input	100-240 V AC ~ 50/60 Hz 1.2A
Pintuition Probe (Applied Part; type BF)	
Dimensions	Ø 18mm (tip) 180 mm (length)
Weight (including cable)	165 g
Probe Cable Length	3m
Ingress protection	IP44
Cleaning and disinfection	The Pintuition Probe and cable must be cleaned and disinfected immediately after each use. Use only non-protein fixing VAH-listed, legally marketed disinfectant wipes with proofed cleaning effect, suitable for plastics (such as Incidin Oxy Wipe S, Ecolab #3082280).

Sirius Pintuition detection fields



Articles

Ref.	Item	Qty
SPS12	Sirius Pintuition Seed 14G x 12cm	10
SPS20	Sirius Pintuition Seed 14G x 20cm	10
SPP	Sirius Pintuition Probe	1
SPBU	Sirius Pintuition Base Unit	1