

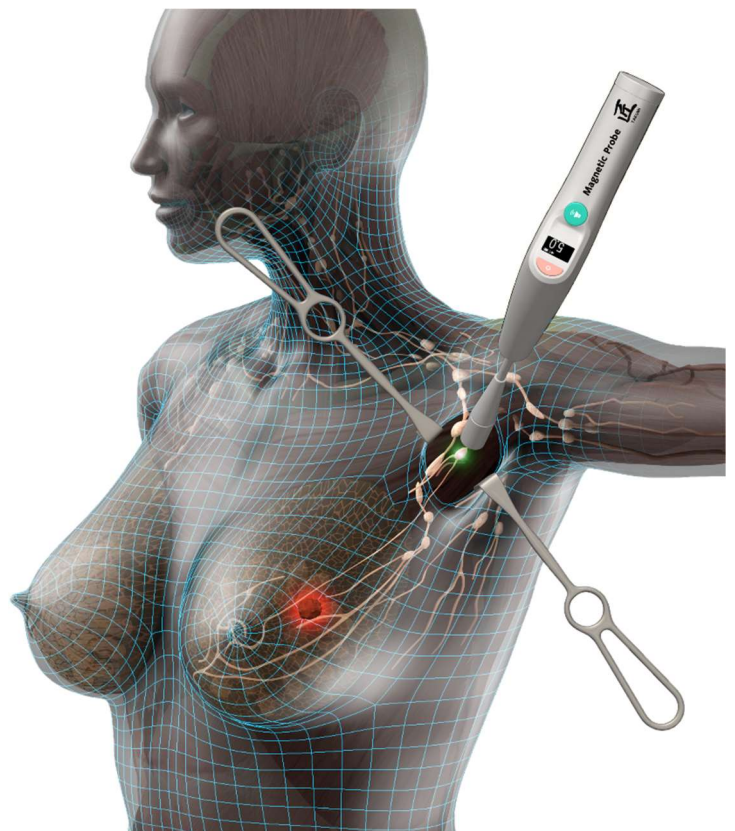


Concept

TAKUMI is a magnetic probe for sentinel lymph node identification, designed to be used in conjunction with a magnetic nanoparticle tracer or fluid during sentinel lymph node biopsy (SLNB).

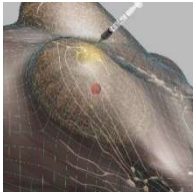
Unlike conventional radioisotope methods, SLNB with magnetic tracers and a probe like TAKUMI enable even small- to medium-sized medical institutions to accurately and objectively diagnose cancer metastasis.

Where similar devices require a cable-connected external unit, we fit all components of TAKUMI – including the permanent magnet and Hall sensor – into a compact, lightweight, handheld device, to be operated by one person alone. Application is kept simple and straight-forward, with only three buttons and an easy-to-understand LED display.

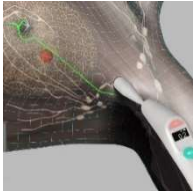


CE Marking of Conformity was acquired in July, 2019 (NB: 0344, EC Certificate No.: 4201663CE01).

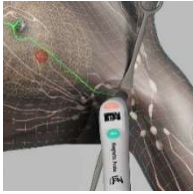
Application



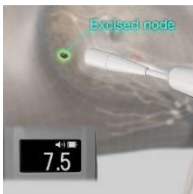
Injection of magnetic tracer at areola or in tumor vicinity. Tracer particles travel through lymph vessels & accumulate in SLN



SLN identification by holding TAKUMI to skin surface prior to surgery & determination of optimal incision site. Numeric value on display & sound change when in proximity of SLN containing magnetic nanoparticles



Approaching SLN through incision site to confirm numeric value change via TAKUMI's display & sound, and through visual inspection



Excision of SLN and recording of values measured

Description & Specifications

Device group	Medical device for inspection & diagnosis
Name	Magnetometer
Shape	Handheld, cordless and battery-powered
Size & weight	W:300mm x H:95mm x D:34mm, 150g
Power input & supply	1.5VA, 3V DC
Temperature, humidity	<ul style="list-style-type: none"> • Transport: -10~50°C, 30~75% Transport device in the case provided • Operation: 10~40°C, 30~75% • Storage: 10~40°C, 30~75%. Avoid condensation during storage
Shelf life	1 year. Operational warranty period under storage conditions
Appurtenances	Checker to ensure operational capability
Optional accessories	Titanium retractors
Operating precautions	<ul style="list-style-type: none"> • Device is not sterile. When used in contact with body tissue/fluid, device is to be covered with single-use sterile sheath • For accurate & safe measurement, contact part of device should not be placed within 70mm of cardiac pacemaker and/or other active devices, as well as 40mm of metallic/magnetic objects • Do not reassemble and/or remodel any part of device to keep basic performance & safety • Do not operate in environments that are hot, humid, dusty, exposed to direct sunlight, used to store chemicals and/or where gas is generated
Safety device	N/A
Other	Device is reusable