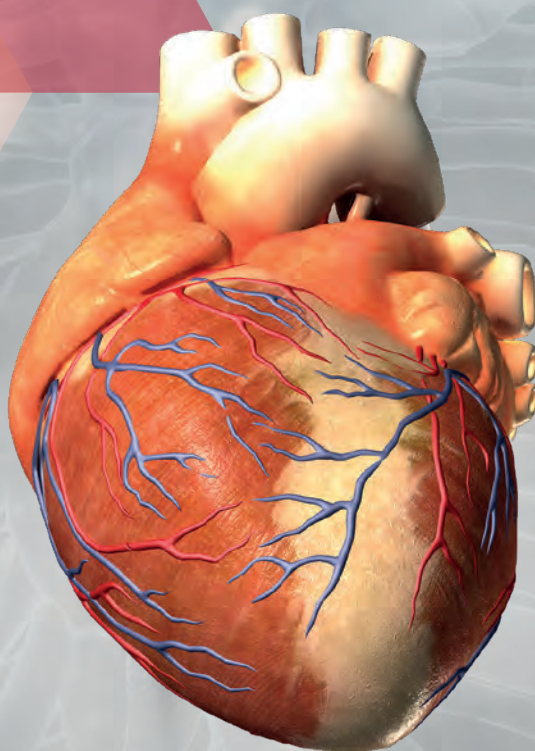


CALA

Cardiac Arrhythmia Laser Ablation



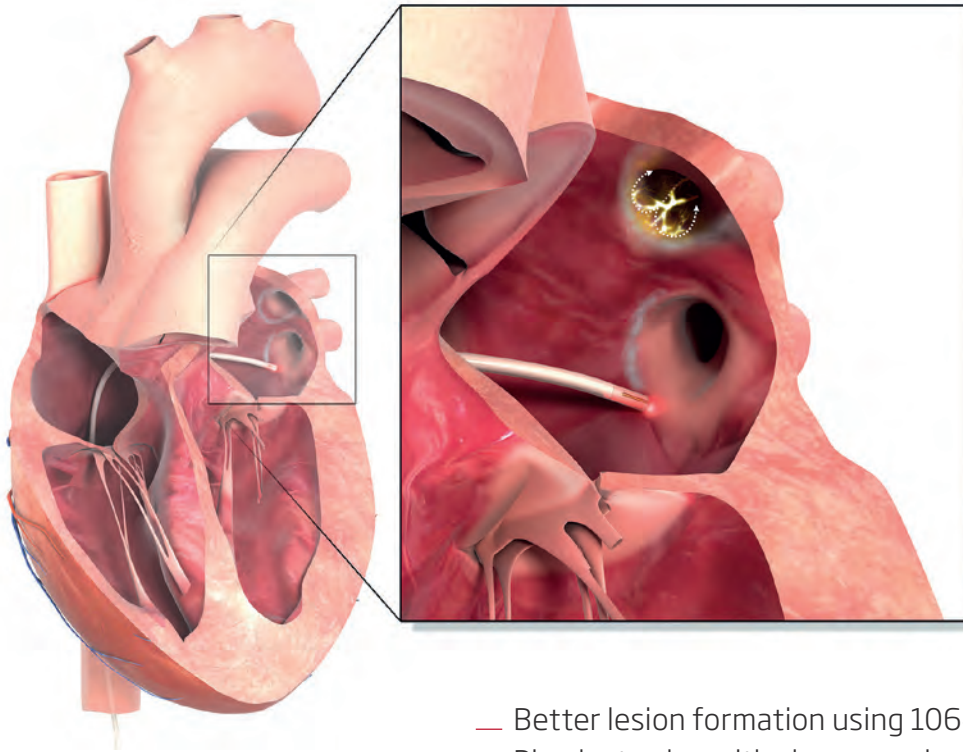
- Treats arrhythmia
- Monitors diminishing of signals during laser application via fiber tip
- Improved device for cardiac electrophysiologists

Abnormal heart rhythm

Irregularities in heart rhythm cause arrhythmia such as Atrial Fibrillation which affects almost 33 million people worldwide¹. The initial treatment with medication has proven to be ineffective in the majority of patients². Catheter ablation can reduce and eliminate the recurrence of arrhythmia events. It is a process of ablating tissues where irregular electrical signals are created or transmitted.

biolitec® has concentrated on the core business of laser treatment on soft tissue for over 20 years. This expertise has expanded to develop **CALA – Cardiac Arrhythmia Laser Ablation** – which provides effective lesions or scars that leave no remnants of electrically active myocardial tissue. A unique product with no compromises on safety and which delivers excellent results.

Reclaim the rhythm with CALA



Pulmonary vein isolation procedure using CALA Fiber

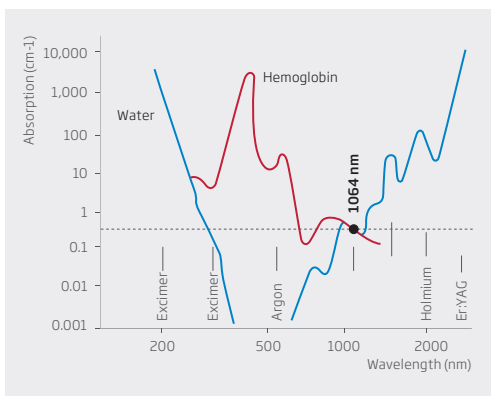
- Better lesion formation using 1064 nm laser
- Pin electrodes with closer spacing provide increased mapping resolution

Conditions treated

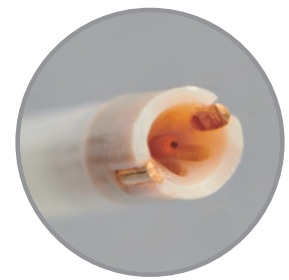
- Atrial Fibrillation
- Atrial Tachycardia
- Atrial Flutter
- Ventricular Tachycardia
- Atrioventricular Nodal Re-entrant Tachycardia (AVNRT)
- Accessory Atrioventricular Pathways (AP)
- Inappropriate Sinus Tachycardia

Why laser energy?

- Achieves transmural lesion using 1064 nm laser³
- No interference with intracardiac electrograms
- Less chance of thrombus formation³
- Myocardium is ablated by light absorption instead of catheter surface temperature that conducts energy

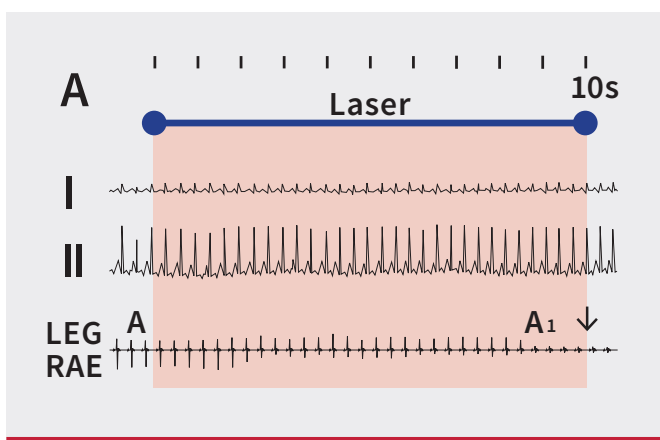


Laser for a precise ablation



Fiber tip electrodes with irrigation ports

- Lower chance of electrical reconnection
- Increased quality of life for patients⁴
- Reliable results⁴
- Reduced complications



A snippet of electrogram recording showing the diminishing electrograms during laser application. The Right Atrial Electrogram (RAE) is attenuating when laser is fired (A-A1) and abolished at the arrow mark⁵

Benefits of fiber tip electrodes

- Electrogram recordings via electrode without noise during laser application
- Monitors diminishing of signals during laser application via fiber tip⁵
- High resolution mapping helps in targeting discrete segments of the conduction system

LEONARDO FPS 1064 with LEONARDO FLOW pump for irrigation

- 1064 nm diode laser with max. output of 20 W
- Fiber Protection System (FPS) protects the tissue and catheter from char formation
- Irrigation helps in creating larger lesions

References

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biolitec® laser and pump

Model	LEONARDO® FPS 1064
REF	LF1064nm20W
Wavelength	1064 nm
Power	20 W (1064 nm)
Fiber diameter	≥ 360 µm
Aiming beam	635 nm, max. 4 mW
Treatment mode	CW mode
Power supply	110 - 240 VAC, 50 / 60 Hz, 450 VA
Dimensions (H × W × D)	approx. 28 cm × 37 cm × 9 cm
Weight	approx. 8.5 kg

Model	LEONARDO® FLOW pump
REF	400100500
Volume Flow	Low Flow 1 - 30 ml / min High Flow 1 - 60 ml / min (High flow is always >Low flow) Flush Flow 40 - 80 ml / min
Air bubble	Auto stop of flush when air bubbles are detected
Maximum Tubing pressure	Max. 5 bar
Power supply	110 - 240 VAC, 50 - 60 Hz
Dimensions	262 mm × 285 mm × 155 mm
Weight	approx. 6.7 kg

Fiber

REF	Product	Packaging Unit	Length [m]	Compatible Introducer (Recommended)
503100500	CALA Fiber, IC	1	3	8,5 Fr

CALA fiber is compatible with most models and makes of Electrophysiology recording systems

Tubing set

REF	Product	Packaging Unit
400100510	Live Cool tubing set	1

Sheath

400100590	Agilis™ NxT Steerable Introducers 8.5 F 71 cm Small Curl Dual-Reach™ Bi-directional (SJM REF: 408309)
400100600	Agilis™ NxT Steerable Introducers 8.5 F 71 cm Medium Curl Dual-Reach™ Bi-directional (SJM REF: 408310)
400100610	Agilis™ NxT Steerable Introducers 8.5 F 71 cm Large Curl Dual-Reach™ Bi-directional (SJM REF: G408324)

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of minimally invasive laser therapies



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All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated) delivered sterile for immediate use.

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