

The **gold** standard
just went **platinum**



Featuring the hit...
"Get the Lead Out"

*Newest data show a 20% complication rate in abandoned noninfected leads**

Spectranetics

we get your blood flowing™

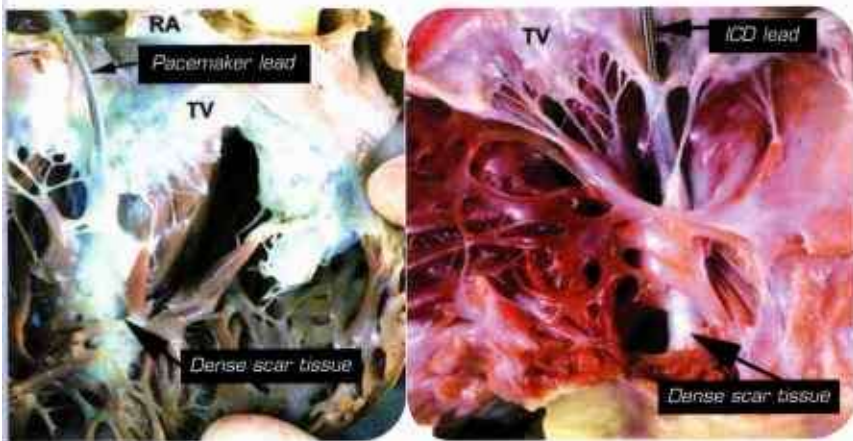
Coronary Artery
Disease Therapy

**Cardiac Lead
Removal Systems**

Peripheral Vascular
Disease Therapy

CVX-300™
Technology

“Get the Lead Out...”



The issue with the removal of cardiac leads is the dense scar tissue holding them in place.



Before a new pacemaker goes in, old cardiac leads should come out. The potential downside of abandoning old leads is simply too problematic.

A recent study shows a 20% patient complication rate when cardiac leads are left behind, resulting in higher morbidity and cost.¹

“With the lead extraction technique available, the issue of the removal of all unwanted pacemaker leads should be addressed.”

It is time to get the lead out.

The FDA's Office of Device Evaluation, in its annual report for fiscal year 1998, listed the **SLS** as one of the **“Significant Medical Device Breakthroughs.”**

These are “...**first-of-a-kind** e.g., they use a new technology or energy source, or they provide a major diagnostic/therapeutic advancement such as reducing hospital stays, replacing the need for surgical intervention, reducing time needed for diagnostic determination, etc.”



Using the CLEARs excimer laser technology, the dense scar tissue surrounding pacemaker and ICD leads is effectively removed resulting in safe lead extraction.

...with the only proven, physician-reviewed Cardiac Lead Removal System (CLeaRS™).

The Spectranetics CLeaRS system uses "cool" ultraviolet excimer laser energy to ablate scar tissue holding problematic cardiac leads in place. The old "rip and tear" mechanical method of cardiac lead removal is very traumatic to the patient and often dangerous.

CLeaRS becomes the gold standard

When introduced in 1998, CLeaRS quickly became the gold standard within the industry. Using CLeaRS resulted in:

- *Faster procedures*, reducing average procedure times to 1.5 hours from 3.5 hours with mechanical methods.^{2,3}
- *Better outcomes*, reducing complications to 1.4% from 2.5% with mechanical methods.²
- *More effective lead removal*, increasing success rates to 94% from 65% with mechanical methods.²

The gold standard goes platinum

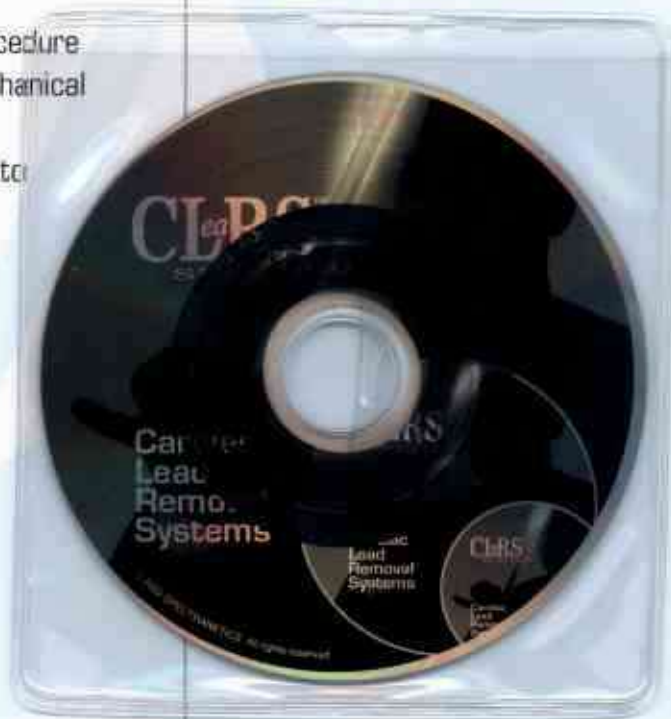
With recent enhancements to the SLS catheter and the LLD traction platform, the CLeaRS gold standard went platinum. Now CLeaRS:

- has an average cardiac lead removal time of 4 minutes.⁴
- has reduced complications to 1.0%.^{4,5}
- is even more successful at 98%.^{4,5}

Refer your patients to physicians who use CLeaRS, the platinum standard.

There is no safer or more effective way to remove problematic cardiac leads.

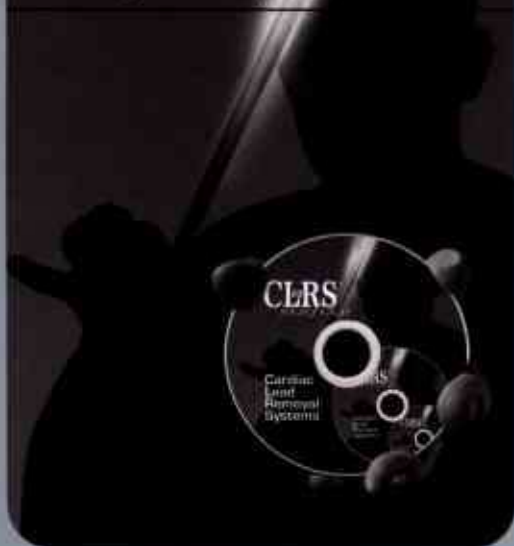
Before a new pacemaker or ICD goes in, make sure the old cardiac leads come out.



Pop in this platinum CD

This CD examines the pathology of cardiac lead removal and how CLeaRS works from the patient's point of view. It also contains a bibliography of papers on cardiac lead removal and the CLeaRS technology. For the CLeaRS centers of excellence nearest you, call + 31 33 43 47 050.

The gold standard
just went platinum



Indications for cardiac lead removal

NASPE: Class 1 (life-threatening)

- Septicemia
- Endocarditis
- Lead migration

NASPE: Class 2 (significant morbidity)

- Pocket infection
- Lead migration
and erosion
- Vein thrombosis
- Chronic draining
sinus
- Lead replacement

NASPE: Class 3

- Pain
- Malignancy
- Lead replacement

More than 250 hospitals around
the world use CLearS technology
to remove problematic pacemaker
and defibrillator cardiac leads.

Well over 15,000 patients have
been successfully treated.

This technology uses the "cool" ultraviolet excimer
laser to precisely ablate scar tissue holding cardiac
leads in place. It is proven to be successful 98% of
the time.^{4,5}

When you refer patients to physicians who use
CLearS, complications diminish and long-term
success rates climb.

¹Bohm, A., et al: Complications Due to Abandoned Noninfected
Pacemaker Leads; PACE, 24:1721-1724, December 2001

²Pacing Lead Explant with the Excimer Sheath (PLEXES) clinical trial
FDA panel presentation, 1997

³Colavita, P.G., et al: Intravascular Extraction of Chronic Pacemaker
Efficacy and Follow-up; PACE, Vol. 16: 2333-2336, December 1993

⁴23rd NASPE Annual Scientific Session, Abstract: Lead Extraction:
Initial Experience Using a New Laser-Sheath; Kennergren, C., Tyres, F.,
May 2002

⁵Kennergren, C., et al: Cardiac Lead Extraction with a Novel Locking
Stylet. Journal of Interventional Cardiac Electrophysiology; 4:501-503,
December 2000

Pathology photos courtesy of Dr. Andrew Epstein: Gross and
Microscopic Pathological Changes Associated With Nonthoracotomy
Implantable Defibrillator Leads; Circulation, 1998; 98:1517-1524

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