

# Medinol – new products and a new solo approach

*Cardiovascular News* spoke to Jacob (Kobi) Richter and Judith Richter of Medinol at EuroPCR 2002. Kobi is Medinol's chairman and chief technology officer, while Judith is the Israeli company's CEO. Medinol, founded in 1992, is recognised in the industry as a highly innovative company, which leverages insights from other sectors for the design and manufacture of its stents. The company is currently best known for the invention of the NIR stent (marketed until mid-2001 in Europe by Boston Scientific). Since then the company has gained CE marks for its new products and is now marketing directly to healthcare institutions.

## An idea rich company

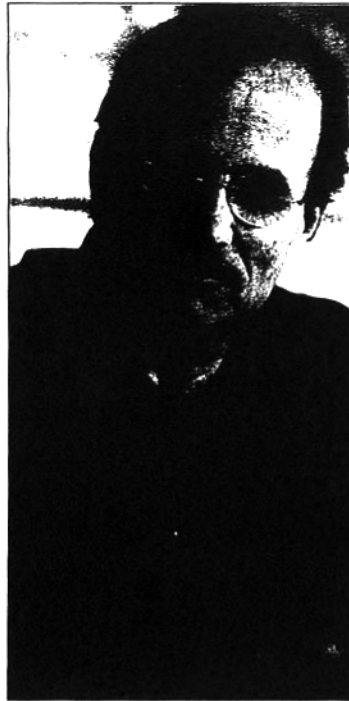
Medinol has evolved from a leading designer, manufacturer and developer of stents into a developer and manufacturer of complete angioplasty systems, while expanding its operations to include supplying goods to hospitals. The company now uses its own marketing subsidiaries based in Europe along with some distribution agents. The manufacture of catheter delivery and balloon systems is considered important, and there is no outsourcing of any activity. Staying abreast of the technology is also seen as important. In this way Medinol has complete control of its business. The Medinol team, including Kobi and Judith Richter, were at EuroPCR 2002 to meet the European market and present the company's new stent system – NIRflex, which gained a CE mark in early 2002.

The company, already known for the NIR stent and its flexible closed cell design, has developed a proprietary manufacturing process by which multiple stents are simultaneously etched photochemically on a flat metal sheet. "We have a good in-

house understanding of medicine and technology that enables us to design stents in a unique proprietary way", said Kobi Richter.

Kobi pointed out that the stent itself is the most important part of any angioplasty system: "This is the only permanent implant. In 1993, the only coronary stents available were the Palmaz, Palmaz-Schatz and the GRI coil stent. The diamond cells of the Palmaz provided rigidity and could support anything, but it could go nowhere, while the GRI could go anywhere but support nothing. It seemed that to provide flexibility and deliverability you needed to sacrifice support."

Then Medinol developed the NIR stent, which used a flexible closed cell system. This provides flexibility when the stent is delivered through the vascular conduit and the support and radial force needed after expansion. In this way Medinol secured the patent for the flexible closed cell stent that – until the recent break-up – was marketed by Boston Scientific, which was market leader in the coronary stent business in Europe (1996) and the US



Kobi Richter

(1998) within three months of the NIR stent launch. Kobi explained: "We are no longer the loving couple with Boston but a single parent."

## NIRflex

NIRflex and NIRflex Royal are the new stents that Medinol was promoting at EuroPCR. "The revolutionary geometry of NIRflex answers the needs of patients and physicians with a breakthrough in stent performance: optimal flexibility and enhanced scaffolding provided simultaneously," said Kobi Richter. NIRflex and NIRflex Royal received CE marks in March 2002 and are in clinical trials in the US.

"Open cell stents, when flexed, leave a gaping area that promotes tis-

sue prolapse. The flexible closed cell design of NIRflex provides extreme flexibility without sacrificing scaffolding." The design also outperforms others in terms of its suitability as a matrix for drug elution. For post procedure follow-up Medinol's stent also outperforms others. Kobi explained that the NIRflex Royal stent is fused with gold to provide unsurpassed visibility, enhancing stent placement and diagnosis during angiography.

Medinol, recently completed enrolment into its NIR TOP trial, the first study with NIRflex and NIRflex Royal premounted on Medinol's own delivery system. A total of 305 patients have been enrolled in 15 leading investigational sites in Canada, Europe and Israel. Patients' follow-up is currently on going. The NIR TOP is designed to compare the acute and long-term results between the two products. One month clinical follow-up results are expected in the autumn of 2002 followed by six-month angiographic results.

## In the pipeline: the NIRflex product portfolio

Medinol's product portfolio includes additional stenting solutions for different applications, currently in various stages of animal and human testing.

### Coronary

- NIRflex and NIRflex Royal (CE marked)
  - NIRSIDE, which allows for stenting of the bifurcation, or side branch, without committing the physician to unnecessary stenting of the branch itself
- Judith explained: "Physicians prefer longer stents, with the flexibility to stay, to cover longer vessels which may need a curve. We have therefore

developed a very long stent with two inflection points – we replaced the 'U' connector with a 'Z' connector".

Kobi said, "By next year, we will have expanded our products portfolio, looking into bifurcation, our next generation of stents and three more non-coronary stents for the carotids, the renal arteries and lower extremities."

### Neurovascular

- NIRvascular, specifically developed and optimised for carotid artery applications
- "This is very smooth and with very continuous scaffolding, to prevent embolisation – you cannot just extrapolate from coronary."

### Renal

- NIRflex Renal, a coronary stent designed to fit the renal artery with the challenge of tough ostial lesions
- "The need is for a flexible stent as this can release emboli and vulnerable plaque. Therefore the stent has a very thin wire."

### Peripheral

- NIRflex Peripheral, for iliac applications
- NIRtinol, a self-expanding stent for external-iliac and superficial femoral artery application.

### Drug eluting stents

Medinol has been monitoring developments in drug-eluting stents with interest. Judith said that the company will see how the market matures, but "our intention is to come up with a product that is specifically designed for drug delivery by optimising separately both the mechanical support of the stent and the biological activity of the drug".