HANDBOOK *of* CORONARY STENTS

Third Edition

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34. The NIR and NIROYAL Coronary Stents

Medinol/SciMed Life Systems, Maple Grove, MN, USA

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Description

General

The NIR Stent was developed based on many physicians' 'wish list' for new functional features in order to overcome shortcomings of first generation devices. The two most important features of the coronary stent are basic to its use: the radial force with which it supports the vessel, and its flexibility, one of the major determinants of its trackability into the target lesion before deployment. The basic contradiction between flexible structure that enable good trackability and rigid structure that result in optimal support, brought the developers of first generation stents to select one property while compromising on the other. A typical comparison of features resulting from that forced decision is:

Stent	Radial support	Flexibility
Palmaz–Schatz	High	Low
Gianturco–Roubin	Low	High

Our primary goal in designing the NIR Stent was to overcome this compromise by a new design for the stent, with a secondary goal to optimize other clinically important features.

Transforming geometry

A design goal was defined noticing that the two features are not required simultaneously, but rather at two mutually exclusive time slices.

- Flexibility is required only during insertion and until deployment of the stent at the target lesion.
- Rigidity is required to supply long term support to the vessel wall only from the moment of deployment and on.

It was thus defined that the desired geometry should be flexible upon insertion and will change after deployment to be rigid upon expansion.

Figure 34.1: *The NIR stent before expansion, showing the differentially elongating cells. The cell inside the curve is shorter than its counterpart outside the curve, as shown by the converging lines at their border. This feature is enabled by the vertical loop component of the cell that opens on the outside cell (A) and closes on the inside cell (B).*

Trackability and flexibility

The flexibility of a stent, a long stent especially, is a major parameter in determining its trackability into the naturally curved and tortuous anatomy of diseased coronary arteries. In order to track into such anatomies the stent on its delivery system has to curve around corners or it will latch on the opposing vessel wall. The flexibility depends on the ability of the stent to elongate differentially such that the stent wall outside of the curve be longer than the wall inside the curve. Inability or high resistance to such differential elongation will not allow the stent to flex. The design of the NIR stent is based on uniform cells each of which is capable of elongating or foreshortening as demonstrated in Figure 34.1.

Other important features that facilitate the trackability of the stent are:

1. The stent has no 'free internal points' loops or ends internal to the tubular structure that are not connected longitudinally to their neighbors and thus can flare out and generate internal ridges that will latch on plaque surface upon insertion (Figure 34.2).
2. The stent has a very low profile and crimps easily and securely on the balloon

owing to the original structure with struts slightly open (see Figure 34.1) that leaves a lot of room for crimping until struts touch each other (see Figure 34.2).

3. Most of the struts are along the insertion direction of the stent and thus will not catch on plaque the way a typical coiled stent would (see Figure 34.2).

NIR stent technical specifications

Material composition:	Stainless steel
Degree of radio-opacity:	Moderate
Ferromagnetism:	Nonferromagnetic (MRI safe)
Metallic surface area (metal: artery, expanded):	11–18%
Degree of recoil (shape memory):	<1%
Strut design:	Square, transform from flexible to rigid
Strut thickness:	0.004 inch (0.1 mm)
Non-expanded profile:	<0.04 inch (<1.0 mm)
Longitudinal flexibility:	High upon insertion, low after expansion
Percentage shortening on expansion:	<3%
Currently available diameters:	2–5 mm
Currently available lengths:	9, 16, 25 and 32 mm
Other non-coronary types:	Peripheral stents for peripheral vessels, biliary, renal and other uses; lengths: 14, 19, 39 and 59 mm. Expanded diameter range: 5–12 mm

NIR stent delivery system

Mechanism of deployment:	Balloon expandable
Minimal internal diameter of guiding catheter:	0.064 inch (1.6 mm), 6F
Premounted on delivery catheter:	Yes
Available bare (unmounted):	Yes
Protective sheath/cover:	No
Position of radio-opaque markers:	Proximal and distal to stent
Further balloon expansion recommended:	No
Recrossability of implanted stents:	Excellent
Sizing diameter:	Matching target vessel diameter

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