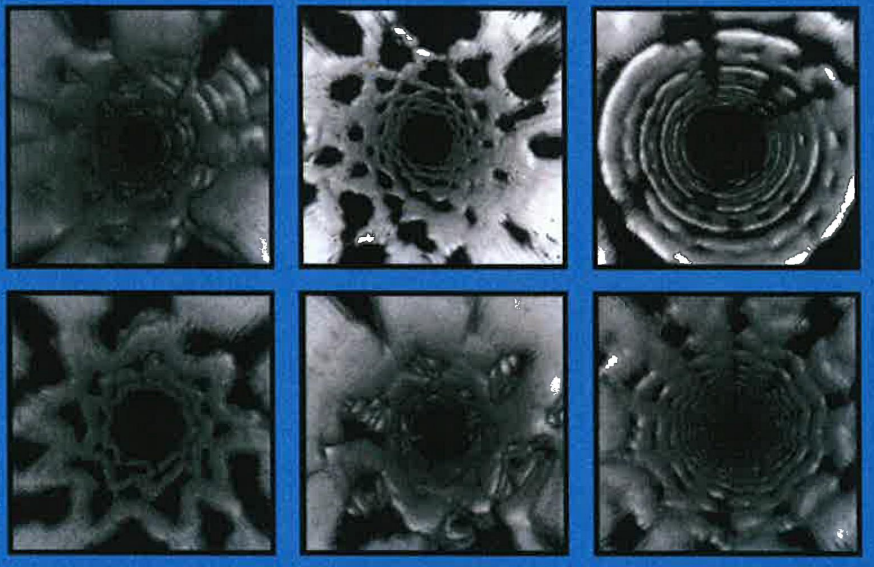
# HANDBOOK OF CORONARY STENTS

## FOURTH EDITION



*Editors*
**Patrick W Serruys • Benno J Rensing**

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Medtronic Ex-1802
Medtronic v. Teleflex

# HANDBOOK OF CORONARY STENTS

FOURTH EDITION

Serruys • Rensing

CRC

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# 13. THE GENIC®; GENIC® SV AND GENIC® LV STENT SYSTEMS

*Blue Medical Devices B.V., Helmond, The Netherlands*

Henk JM Meens and Ronald AM Horvers

**Description** The GENIC® is a balloon expandable coronary stent with a helical sinusoidal waveform geometry.

***Figure 13.1:*** *Structure of the GENIC coronary stent.*

**History**

- July–November 1999 development
- December 1999 completing animal trials
- December 1999 Development DYLYN®
- January 2000 CE Mark
- January 2000 first human implants
- May 2000 Development SV/LV
- December 2000 Development drug delivery
- January 2001 CE Mark SV/LV
- March 2001 CE Mark DYLYN®

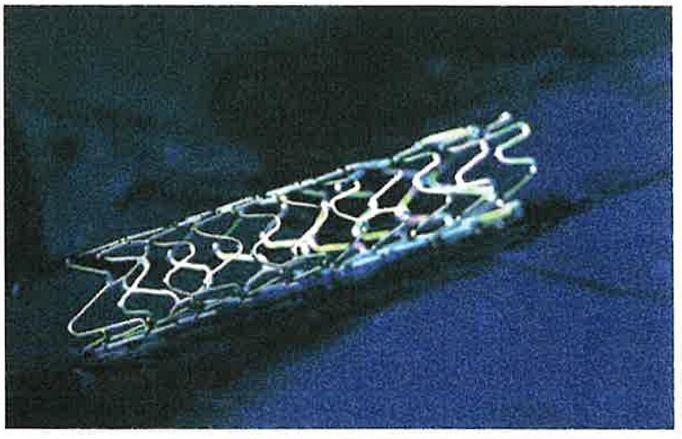


***Figure 13.2:*** *Expanded 18 mm GENIC coronary stent.*

| GENIC® coronary stent technical specifications | |
|---|---|
| Material composition: | 316 L medical grade |
| Radiopacity: | Moderate |
| Ferromagnetism: | Non-ferromagnetic |
| MRI: | MRI safe |
| Metallic surface area | |
| expanded: | 14% at dia 3.0 mm |
| unexpanded: | 28% |
| Metallic cross-sectional area: | 0.14 $mm^2$ |
| Stent design: | Helical sinusoidal waves |
| Strut design: | Rectangular with rounded edges |
| Strut dimensions: | 0.11–0.12 mm wide |
| Strut thickness: | 0.10 mm |
| Profiles | |
| expanded: | 2.5–4.0 mm |
| crimped: | < 1.0 mm (3.0 × 28) |
| Longitudinal flexibility | |
| Balloon/stent assy: | Excellent |
| Expanded stent: | Excellent |
| Shortening (expansion): | 3–4% (3.0 × 18) |
| Expansion range: | 2.3–4.5 mm |
| Recoil: | 3–5% (all sizes) |
| Radial force: | Excellent |
| Available diameters: | 2.5, 3.0, 3.5 and 4.0 |
| Available lengths | |
| Mounted: | 10, 14, 18, 22 and 28 |
| Available sizes: | Full matrix |
| Recrossability: | Excellent |
| Other types: | Under development |

| GENIC® LV coronary stent technical specifications | |
|---|---|
| Material composition: | 316 L medical grade |
| Radiopacity: | Moderate |
| Ferromagnetism: | Non-ferromagnetic |
| MRI: | MRI safe |
| Metallic surface area | |
| expanded: | 14% at dia. 4.0 mm |
| unexpanded: | 30% |
| Metallic cross-sectional area: | 0.17 $mm^2$ |
| Stent design: | Helical sinusoidal waves |
| Strut design: | Rectangular with rounded edges |
| Strut dimensions: | 0.10–0.13 mm wide |
| Strut thickness: | 0.11 mm |
| Profiles | |
| expanded: | 4.0–5.0 mm |
| crimped: | ≤ 1.1 mm (all sizes) |
| Longitudinal flexibility | |
| Balloon/stent assy: | Excellent |
| Expanded stent: | Excellent |
| Shortening (expansion): | 4–5% (4.5 × 22) |
| Expansion range: | 3.7–5.5 mm |
| Recoil: | 3.5–5.5% (all sizes) |
| Radial force: | Excellent |
| Available diameters: | 4.0, 4.5 and 5.0 |
| Available lengths | |
| Mounted: | 18, 22 and 28 |
| Available sizes: | Full matrix |
| Recrossability: | Excellent |
| Other types: | Under development |

| GENIC® SV coronary stent technical specifications | |
|---|---|
| Material composition: | 316 L medical grade |
| Radiopacity: | Moderate |
| Ferromagnetism: | Non-ferromagnetic |
| MRI: | MRI safe |
| Metallic surface area | |
| expanded: | 14% at dia 4.0 mm |
| unexpanded: | 26% |
| Metallic cross-sectional area: | 0.11 $mm^2$ |
| Stent design: | Helical sinusoidal waves |
| Strut design: | Rectangular with rounded edges |
| Strut dimensions: | 0.08 × 0.10 mm wide |
| Strut thickness: | 0.09 mm |
| Profiles | |
| expanded: | 2.0–2.5 mm |
| crimped: | ≤ 0.9 mm (all sizes) |
| Longitudinal flexibility | |
| Balloon/stent assy: | Excellent |
| Expanded stent: | Excellent |
| Shortening (expansion): | 2–3% (2.5 × 14) |
| Expansion range: | 1.8–2.8 mm |
| Recoil: | 2.5–4.5% (all sizes) |
| Radial force: | Excellent |
| Available diameters: | 2.0 and 2.5 |
| Available lengths | |
| Mounted: | 10, 14 and 18 |
| Available sizes: | Full matrix |
| Recrossability: | Excellent |
| Other types: | Under development |

## Tips and tricks for delivery

- The GENIC® coronary stent is premounted on a semi-compliant, high-pressure rapid exchange stent delivery catheter, with optimized pushability and distal flexibility, securing reliable performance.
- The GENIC® coronary stent is positioned between two platinum iridium balloon markers.
- The GENIC® coronary stent delivery system is compatible with a 5 Fr guiding catheter.
- After delivery the GENIC® coronary stent conforms to the natural anatomy of the coronary artery.

## Indications for use

- The very flexible GENIC® coronary stent can be applied in a wide range of procedures, from straight stent procedures to procedures in complex tortuous paths and direct stenting.
- The GENIC® coronary stent enables side branch access without decrease of robustness in the design.

## Why I like my stent

- The unique geometric design of the GENIC® combines the well-appreciated flexibility of coil stents with the proven robustness of the tubular stents. The superb crimping technology enables direct stenting even through 5 Fr guiding catheters.
- The GENIC® coronary stent is designed to provide optimal flexibility mounted on the stent delivery system.
- Due to this optimal combination, the GENIC® coronary stent and its stent delivery system has an extremely low profile and an excellent crossing performance.
- The helical sinusoidal waveform geometry conforms to the natural dynamic tortuous coronary anatomy and prevents stretching of the vessel. This excellent flexibility allows placement in very dynamic coronary anatomy with less stress on the coronary vessel wall preventing restenosis at the extremities.

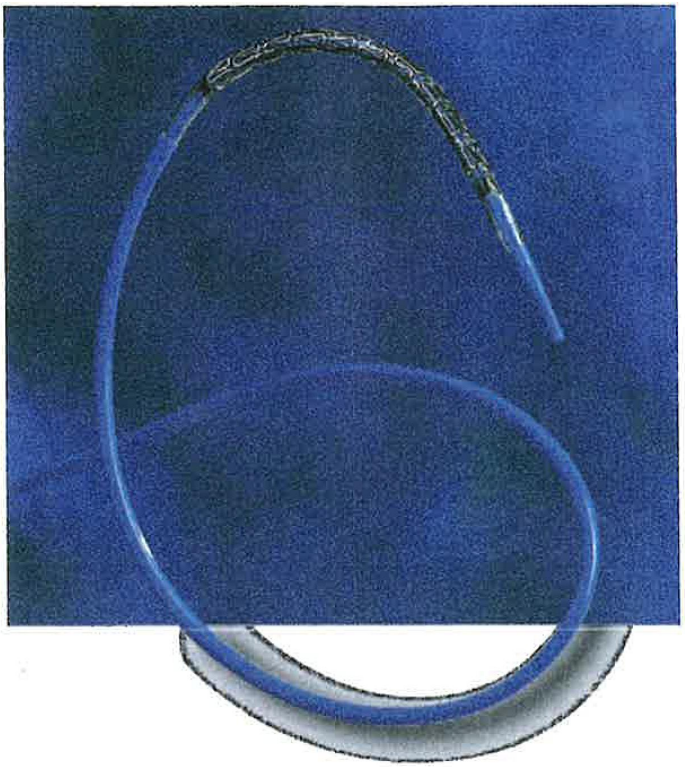
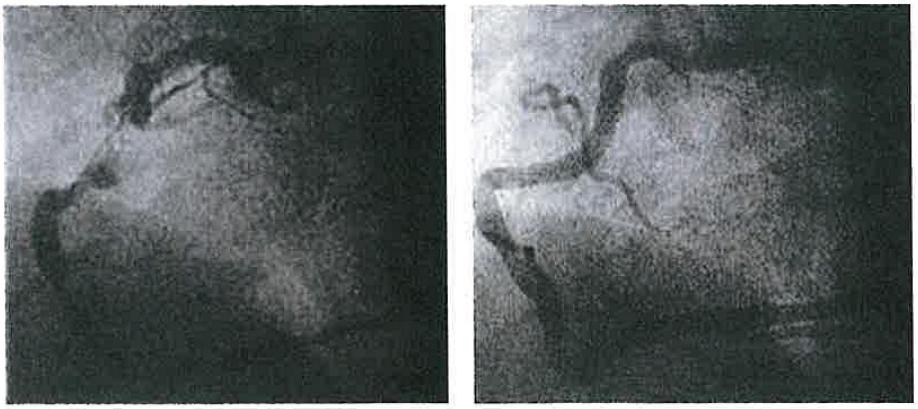


***Figure 13.3:*** *Flexibility of the GENIC coronary stent delivery system.*



*(a)* *(b)*

***Figure 13.4:*** *(a) Complete stenosis in tortuous proximal right coronary artery; (b) after GENIC stent implantation. This shows the excellent conformability to the vessel wall of the expanded stent.*

(a) (b)

***Figure 13.5:*** *(a) Total occlusion of proximal right coronary artery; (b) after recanalization and GENIC stent implantation.*

| **Delivery device of GENIC®** | |
|---|---|
| Mechanism of deployment: | Balloon expandable |
| Minimal internal guiding catheter: | 0.056 inch |
| Maximal guidewire diameter: | 0.014 inch |
| System: | Rapid exchange |
| Design: | Hypo tube |
| Proximal shaft: | 2.1 Fr |
| Distal shaft: | 2.6 Fr |
| Number of markers: | 2 |
| Type of markers: | Platinum iridium |
| Position of markers: | Proximal and distal balloon |
| Position stent: | Between balloon markers |
| Balloon material: | Acrylon® (thermoplastic elastomer) |
| Compliance: | Semi-compliant, high-pressure |
| Nominal: | 6 atm |
| Rated burst pressure: | 16 atm (> 4.0 mm: 14 atm.) |
| GENIC® is a registered trademark of Blue Medical Devices | |

# JOSTENT® Coronary Stent Graft

**Description**

JOMED has developed a unique stent technology which represents a new era in coronary stenting. The JOSTENT® Coronary Stent Graft combines a flexible stent with a layer of expandable PTFE graft material designed for successful management of acute cardiac situations.

The JOSTENT® Coronary Stent Graft combines all the properties of a graft and a coronary stent, yet it is as flexible as most conventional stents. The JOSTENT® Coronary Stent Graft has been constructed by using a unique sandwich technique, whereby an ultrathin layer of expandable PTFE is placed between two stents, welded at its ends.

This design provides high radial strength and longitudinal flexibility and the device can be crimped down to a low profile, very close to standard bare stents (6Fr compatible). The unique construction allows the JOSTENT® Coronary Stent Graft to effectively seal off the vessel wall. It can be safely implanted and is beneficial or even life-saving in coronary dissections, perforations, aneurysms and bypass graft lesions.

*Figure 16.8: JOSTENT® Coronary Stent Graft.*

| JOSTENT® Coronary Stent Graft technical specifications | |
|---|---|
| Material composition: | 316L stainless steel, PTFE |
| Degree of radiopacity (grade): | Moderate |
| Ferromagnetism: | Non-ferromagnetic (MRI safe) |
| Degree of recoil (shape memory): | <5% |
| Strut design: | Rounded edges |
| Wall thickness: | 0.012 inch (0.30 mm) |
| Delivery profile (crossing profile): | 0.064 inch (1.6 mm) |
| Longitudinal flexibility: | Good |
| Percentage shortening upon expansion: | <3% at 3.5 mm |
| Currently available lengths: | Stent graft length: 9, 12, 16, 19 and 26 mm |
| Currently available diameters: | 2.5 to 5.0 mm |
| Other non-coronary types: | Vascular, iliac |

### Tips and tricks for delivery (JOSTENT® Coronary Stent Graft)

- For optimal expansion use inflation pressures of min. 14–16 atm.
- Use IVUS to ensure optimal deployment.

# 17. The Lunar Coronary Stent System

*InFlow Dynamics AG, Munich, Germany*

Franz R Eberli and Stephan Windecker

| | |
|---|---|
| **Definition** | Starflex design is a homogeneous, multicellular stent structure with alternating stiff and flex segments for excellent longitudinal flexibility; the Niobium alloy stent is coated with iridium oxide, which facilitates the growth of endothelial cells and reduces the inflammatory response to stent mediated vascular injury. |

| | |
|---|---|
| **History** | • September 2000, CE mark received<br>• December 2000, clinical evaluation at Swiss Cardiovascular Center, Bern, Switzerland<br>• March 2001, multicenter registry study 'Moonlight' with six European centres<br>• March 2001, first live case with lunar coronary stent system from Inselspital, Bern, Switzerland, to Percutaneous Endovascular Therapeutics Congress, Santa Fé, Argentina |

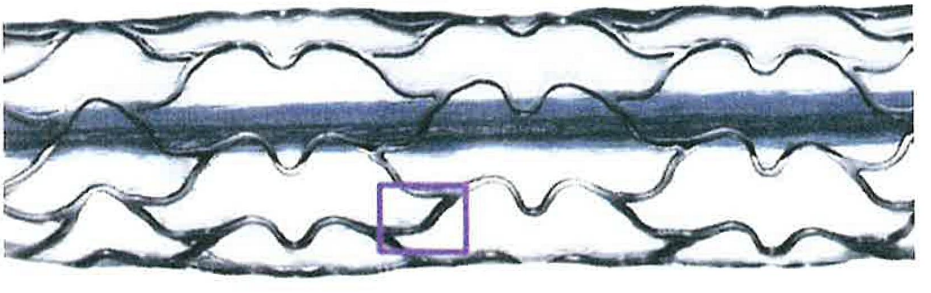
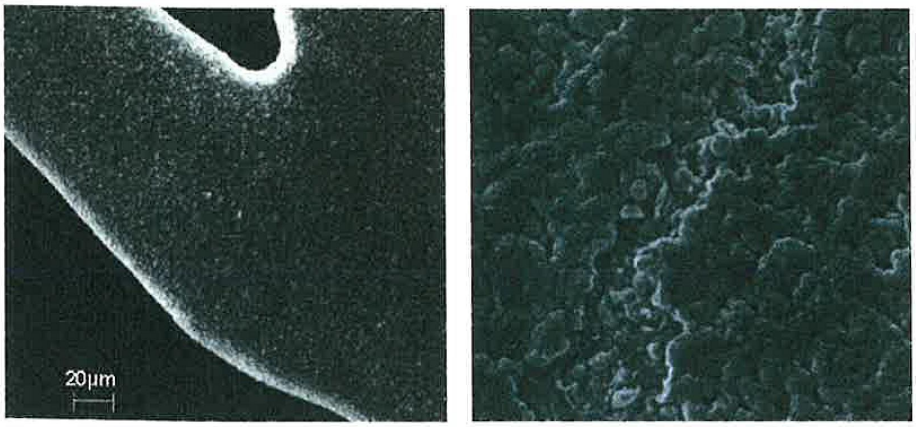


***Figure 17.1:*** *Expanded unmounted Lunar® coronary stent. Insert shows the magnified surface.*

***Figure 17.2:*** *Balloon mounted Lunar® coronary stent.*




*(a)* *(b)*

***Figure 17.3:*** *(a) Electron microscopy of Lunar® stent. (b) Electron microscopy of Lunar stent surface showing the particularly rough surface structure of the iridium oxide coated stent. It is assumed that the iridium oxide coated, rough surface facilitates adhesion and growth of endothelial cells.*

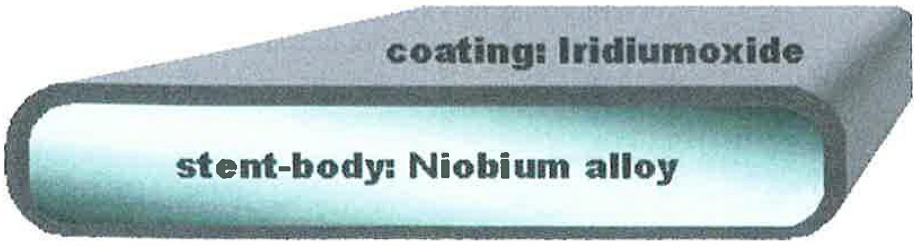



***Figure 17.4:*** *Schematic cross-sectional drawing highlighting the special construction of the Lunar stent. The Niobium core of the stent is covered with the iridium oxide. The Niobium alloy is a heavy-metal-free material, with the same mechanical features as steel. This corrosion-free clinically proven material has self-healing features. The iridium oxide decreases the formation of free oxygen radicals, and thus decreases the inflammatory stimulus after stent implantation.*

| Lunar stent technical specifications | |
|---|---|
| Material composition: | Niobium alloy stent body iridium oxide coated |
| Degree of radiopacity (grade): | Superior |
| Ferromagnetism: | Non-ferromagnetic |
| MRI: | MRI-proof |
| Metallic surface area: | Dependent on expanded diameter (13–19%) |
| Stent design: | Homogeneous, multicellular stent structure, 'Starflex' – design |
| Strut design: | Oval strut cross-section |
| Strut dimensions: | 90 × 85 μm |
| Strut angles: | Dependent on diameter |
| Strut thickness: | 90 μm |
| Crossing profile(s) on the balloons: | 2.5 mm balloon diameter: 0.0382 inch = 0.96 mm<br>4.0 balloon diameter: 0.0471 inch = 1.20 mm |
| Longitudinal flexibility: | Good |
| Percentage shortening (on delivery): | 0% |
| Percentage shortening on expansion: | <3% |
| Expansion range: | 2.5–4.5 mm |
| Degree of recoil (shape memory): | <3% |
| Radial force: | High |
| Currently available diameters: | 2.5–4.0 mm |
| Currently available lengths<br>Mounted/implanted<br>Unmounted: | 8 mm*, 12 mm, 16 mm, 20 mm, 24 mm*, 32 mm |
| Currently available sizes: | Each length for 2.5/3.0/3.5/4.0 mm balloon diameter |
| Recrossability of implanted stent: | Excellent |
| Other non-coronary types available | Peripheral stents<br>Antares Endovascular OTW<br>Antares Renal RX |
| * Planned | |

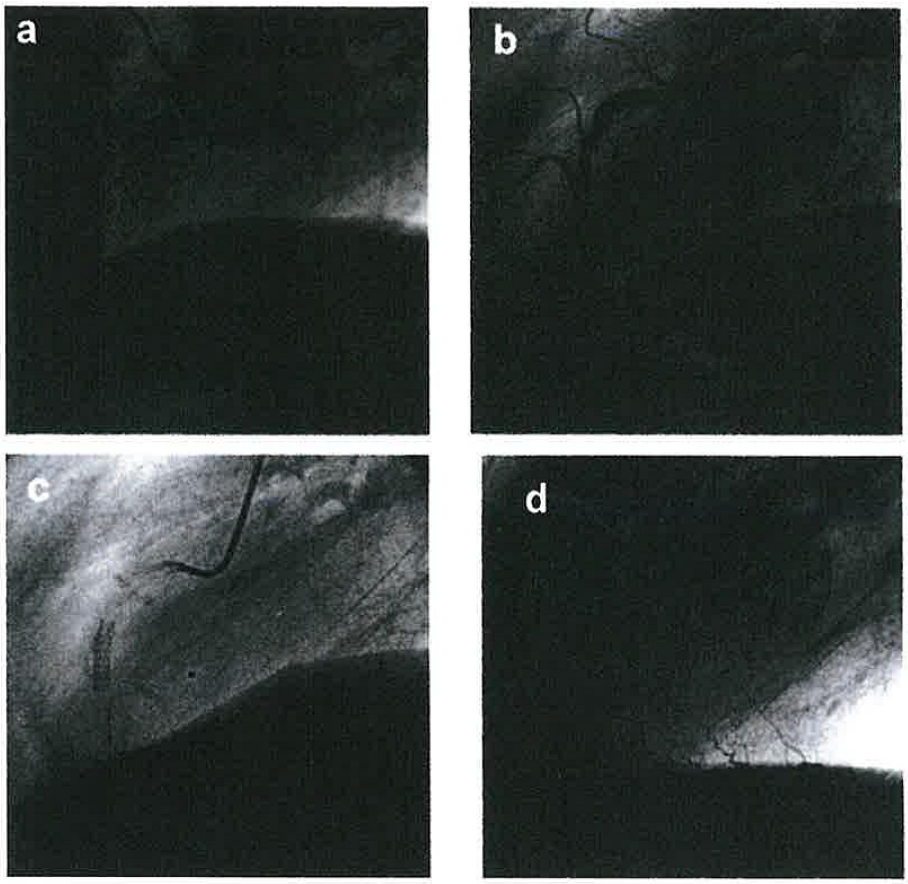



***Figure 17.5:*** *A stenosis in the mid-right coronary artery (a) was treated with the Lunar® coronary stent (b). Fluoroscopy reveals the high radiopacity of the Lunar® stent (c). At 6 months, follow-up angiography shows an excellent late result with minimal restenosis (d).*

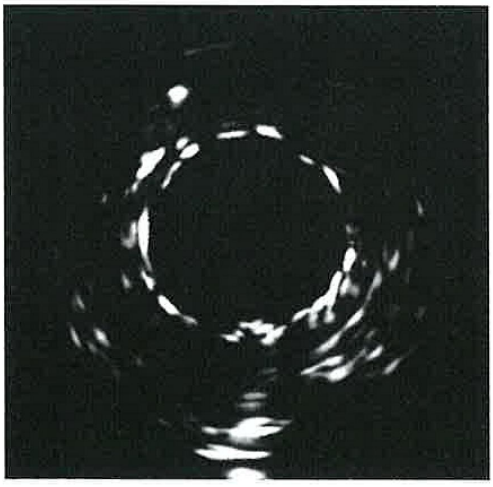


***Figure 17.6:*** *IVUS image of a fully deployed Lunar® stent.*

## Indications for use

- In patients eligible for balloon angioplasty with symptomatic ischemic heart disease characterized by discrete de novo and restenosed coronary artery lesions with reference vessel diameter from 2.5 mm to 4.5 mm.
- In elective implantation and in treatment of acute or threatened closure associated with a coronary intervention, including saphenous vein grafts.

## Why I like this stent

*Conceptual considerations:* The Lunar® Coronary Stent System consists of a Niobium alloy stent body and a layer of homogeneous iridium oxide. The Niobium alloy is a heavy-metal-free material, with the same mechanical features as steel, but with excellent visibility. This corrosion-free clinically proven material has self-healing features.

The Lunar® coronary stent system special coating consists of a layer of ductile gold and a top layer of homogeneous iridium oxide. The gold coating assures fissure-free deployment and is also responsible for the excellent visibility of the stent. The iridium oxide coating is believed to reduce in-stent restenosis by decreasing the inflammatory response to the stent via its antioxidant action. A metallic stent induces a leucocyte reponse as soon as it is deployed. The leucoytes release hydrogen peroxide ($H_2O_2$), which stimulates the proliferation of vascular smooth muscle cells both directly via the activation of NF-κB, or indirectly via the formation of peroxynitrite. Iridium oxide has high catalytic properties, and cleaves $H_2O_2$ into water and oxygen. Therefore, the release and activation of free radicals, which provoke smooth muscle cell growth, is reduced. Experimentally, iridium oxide reduced by 50% free radical formation by stimulated leucocytes adherent to stent struts. Iridium oxide layers form a rough surface. Experimentally, adhesion of endothelial cells to the rough stent surface was markedly increased as compared to a smooth stent surface. In summary, the iridium oxide coating may promote endothelial coverage of the implanted stent while reducing free oxygen radical formation and the inflammatory response, thus reducing smooth muscle cell proliferation and in-stent restenosis. This stent property is maintained over time. The iridium oxide coating is not degraded. Therefore, the Lunar stent is not a drug eluting stent, whose effects are time-dependent.

## Tips and tricks for delivery

The low profile of the Lunar stent allows easy delivery through 5 Fr guiding catheter systems. The crimping is adequate. The stent delivery system is suitable for direct stenting, but extremely tortuous vessels and calcification should be avoided.

## Ongoing studies

- Moonlight study: European prospective, multicentre registry of 120 consecutive patients with single or multivessel disease. Follow-up 1 and 6 months. Started March 2001.
- Clinical evaluation of the Lunar coronary stent system at the Swiss Cardiovascular Center, Bern, Switzerland
- Clinical evaluation of the Lunar coronary stent system in Argentina and Brazil, with 40 patients.

# 32. The Spiral Force Stent

*Bolton Medical Inc. Fair Lawn, NJ, USA*

Norman T Kanesaka and Tomás Berrazueta

| | |
|---|---|
| **Definition** | The Spiral Force coronary stent is a tubular stent, which is cut from 316 L stainless steel and electro-polished. It features a unique spiral strut design in which all of the struts are connected with inverted C-joints. This spiral design provides unsurpassed flexibility, while the connection of all struts ensures uniform expansion and a high radial force. The stent offers outstanding radial force and minimum recoil, because the scaffolding design connects all struts together for uniform distribution of support. |

| | |
|---|---|
| **History** | Introduced in 1999 and distributed worldwide since then. The Spiral Force's unique spiral design provides excellent flexibility. |

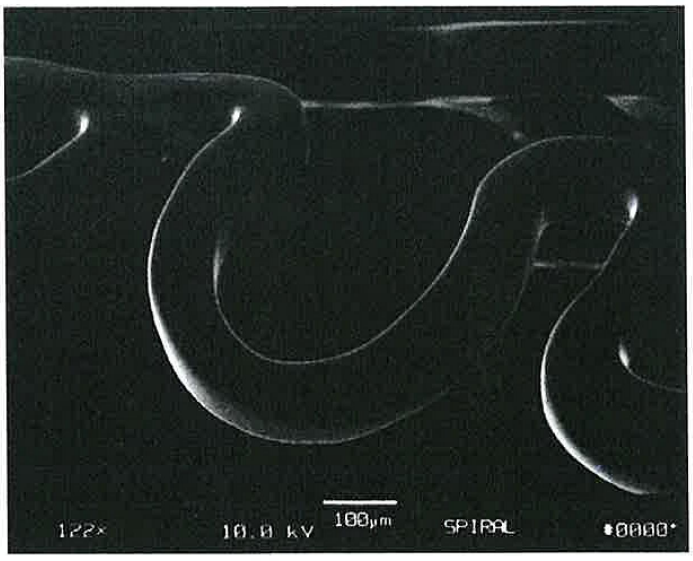



***Figure 32.1:*** *Electron micrograph of Spiral Force Stent.*

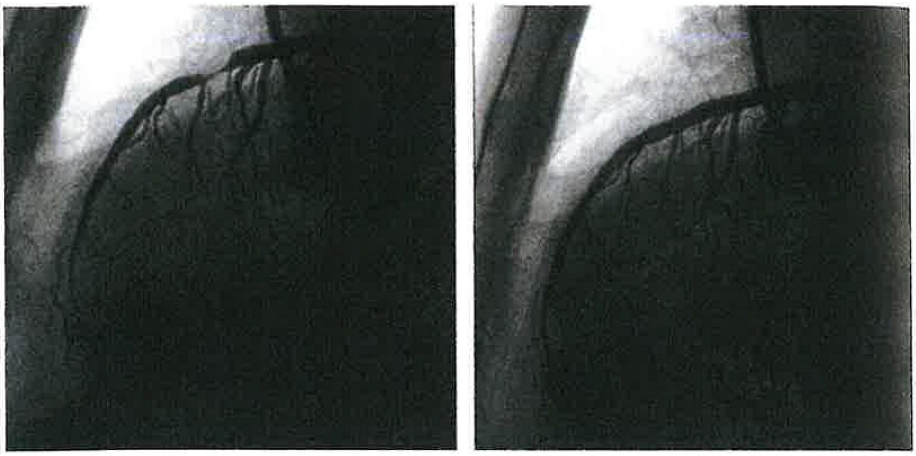


***Figure 32.2:*** *Spiral Force Stent, pre- and post-LAD implantation.*

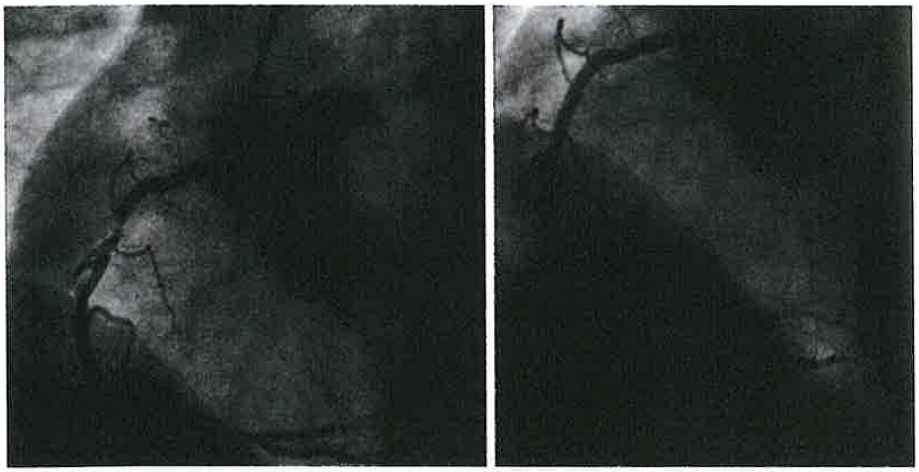


***Figure 32.3:*** *Spiral Force Stent, pre- and post-RCA implantation.*

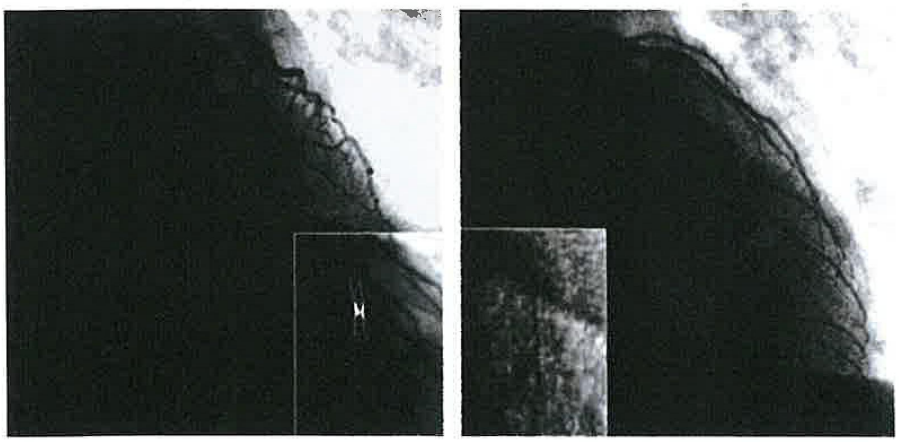


***Figure 32.4:*** *Spiral Force Stent, pre- and post-LAD implantation.*

| Spiral Force stent technical specifications | |
|---|---|
| Material composition: | 316 L stainless steel |
| Degree of radiopacity (grade): | Moderate |
| Ferromagnetism: | Non-Ferromagnetic |
| MRI: | MRI Safe |
| Stent design: | Spiral cut with C-joints |
| Strut design: | Straight struts |
| Strut dimensions: | 0.005 inch × 0.026 inch to 0.005 inch × 0.035 inch |
| Strut angles: | 40°–45° 4 mm internal diameter |
| Strut thickness: | 0.003 inch |
| Wire thickness: | Not applicable |
| Mesh angle: | Not applicable |
| Mesh braid angle: | Not applicable |
| Profile(s): non-expanded (uncrimped): | 0.067 inch |
| expanded: | 2.7 to 4.2 mm |
| on the balloons: | 0.039 inch to 0.042 inch |
| Longitudinal flexibility: | Excellent |
| Percentage shortening on expansion: | 3.8–8.2% depending an expansion |
| Expansion range: | 2.5 mm to 4.25 mm |
| Degree of recoil (shape memory): | 1.2% |
| Radial force: | Very high |
| Currently available diameters: | 2.5, 3.0, 3.5, 4.0 mm |
| Currently available lengths mounted/unmounted: | 9, 13, 17, 21 and 27 |
| Other non-coronary types available: | Femoral, iliac, renal in late 2001 |

## Delivery system

The rapid exchange Runner is the latest generation stent delivery balloon catheter. The Zylite balloon material (semi-compliant) gives: controlled compliance, increased flexibility, optimal refolding and high pressure seating.

The Runner balloon is also designed to be used for standard PTCA procedures, such as routine pre-dilatation angioplasty and post-stent deployment. It is available in all lengths and diameters.

### Tips and tricks for delivery

This is a really simple stent to use due to the adequate radiopacity and flexibility. Due to the low compliance of the balloon and the easy stent expansion at mid-pressures, it is recommended to slightly oversize the stent. It is unusual to observe distal dissections. All sizes of the Spiral Force stent can be easily delivered through all commercially available 6 Fr guiding catheters and through a Medtronic Zuma 5 Fr guiding catheter.

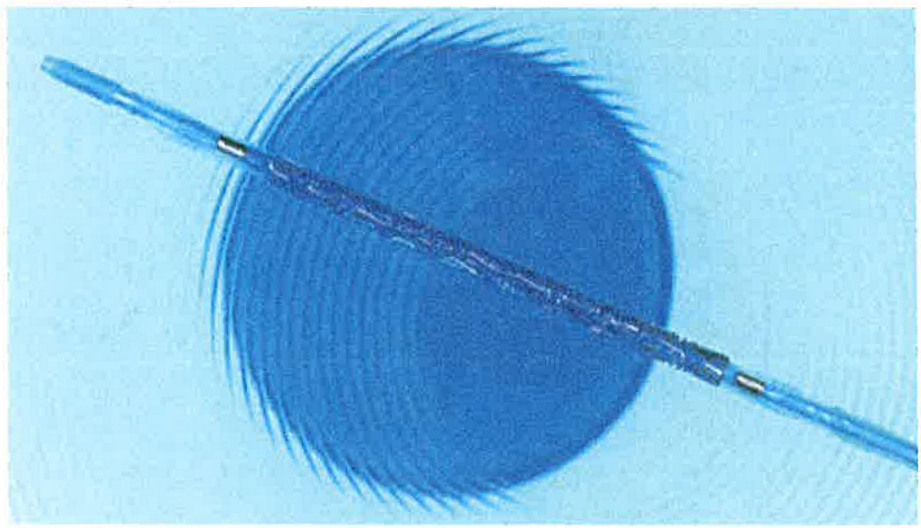


***Figure 32.5:*** *Spiral Force premounted on the Runner delivery system.*

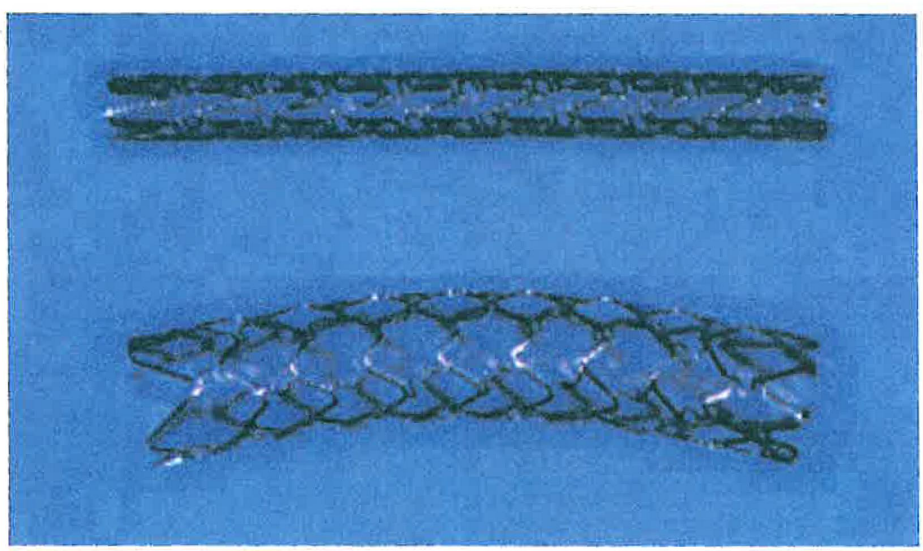


***Figure 32.6:*** *Spiral Force stent.*

## Indications for use

The Spiral Force (SF)™ balloon-expandable stent is indicated for use in de novo native coronary artery lesions with a reference vessel diameter in the range of 2.5–4 mm and a length up to 25 mm. In this population, stenting produces a larger luminal diameter, maintains arterial patency, and reduces the incidence of restenosis at six months as compared with balloon angioplasty. One year and longer follow-up is not well characterized.

## Why I like my stent

There are many specifications for stents, but three major factors – flexibility, radial force and recoil – play the major roles in short and long term performance of the stent. Flexibility can be obtained either by design configuration or skipping connections. Higher radial force can be achieved from using a thicker material or connecting all struts. Reduced recoil rate is a design and material issue. The Spiral Force stent successfully comprises all three factors.

The Spiral Force achieves all three goals with superior engineering without compromising other factors nor resorting to the easier solutions.

## Studies in which stent is involved

1) JAPAN:
   Japanese Spiral Force Study – 100 Patients (Finished)
2) SPAIN + PORTUGAL:
   RESET (Spiral Force Spanish Registry) – 428 Patients (Finished)
3) BELGIUM:
   SPIFO (Spiral Force Patency, Belgium Study) – 75 Patients (Running)
4) FRANCE:
   Spiral Force French Registry – 125 Patients (Running)

# 33. The Tsunami Coronary Stent System

*Terumo Corporation, Japan*

Masakiyo Nobuyoshi

**Description**

- Balloon expandable
- Stainless steel slotted tube stent
- Double-linked diamond cell structure

## Important features of Tsunami

- **Superb deliverability**
  Hydrophilic M coat™ is applied onto the tip and distal shaft of the delivery balloon catheter, decreasing friction when moistened. In addition to the M coat™, the benefits of the ultra-low profile (0.038 inch for 3.0 mm system), the unique double-link connection, the smooth stent surface, and the Tri-fold balloon combine to ensure superb stent delivery, trackability and crossability.
- **Exceptional conformability**
  Terumo's double-link structure — diamond-shaped cells joined by two connectors — results in unequalled stent flexibility. This pliable stent gives exceptional conformability to natural tortuosity of coronary vessels once deployed.
- **Powerful and stable radial force**
  Radial strength and vessel coverage on bends are assured by the stainless steel laser-cut tube design and the double-link cell pattern. When placed in the lesion, the stent firmly retains its shape and position.
- **Minimum injury and maximum security**
  Tsunami's minimal balloon overhang (< 1 mm) lessens injury during dilatation. In addition, the stent edge design reduces flaring risk providing more secure procedure.

| Tsunami technical specifications | |
|---|---|
| Material composition: | 316 L stainless steel |
| Degree of radiopacity: | Moderate |
| Ferromagnetism: | Moderate |
| MRI: | Safe |
| Metallic surface area expanded: | < 18% |
| Stent design: | Several radial diamonds joined by double connector |
| Strut design: | Square |
| Strut thickness: | 0.08 mm |
| Non-expanded profile: | 0.95 mm (0.038 inch) for the 3.0 mm stent system |
| Longitudinal flexibility: | Excellent |
| Percentage shortening: | < 5% |
| Degree of recoil: | < 5% |
| Current available sizes: | 2.5/15, 2.5/20, 2.5/30<br>3.0/10, 3.0/15, 3.0/20, 3.0/30<br>3.5/10, 3.5/15, 3.5/20, 3.5/30<br>4.0/10, 4.0/15, 4.0/20 |
| Other non-coronary types available: | None |

| Tsunami stent delivery system | |
|---|---|
| Mechanism of deployment: | Balloon expandable |
| Minimal internal diameter of guiding catheter: | 0.056 inch, 5 Fr |
| Pre-mounted on delivery catheter | Yes |
| Protective sheath/cover: | No |
| Position of radiopaque markers: | Distal and proximal to stent |
| Recommended deployment pressure: | Nominal at 10 atm (9 atm for 4.0 mm) |
| Further balloon expansion recommended | Discretionary |
| Supply in bare | No |
| Recrossability of deployed stent | Good |
| Sizing diameter | Equal to artery or over-sizing up to 10% |

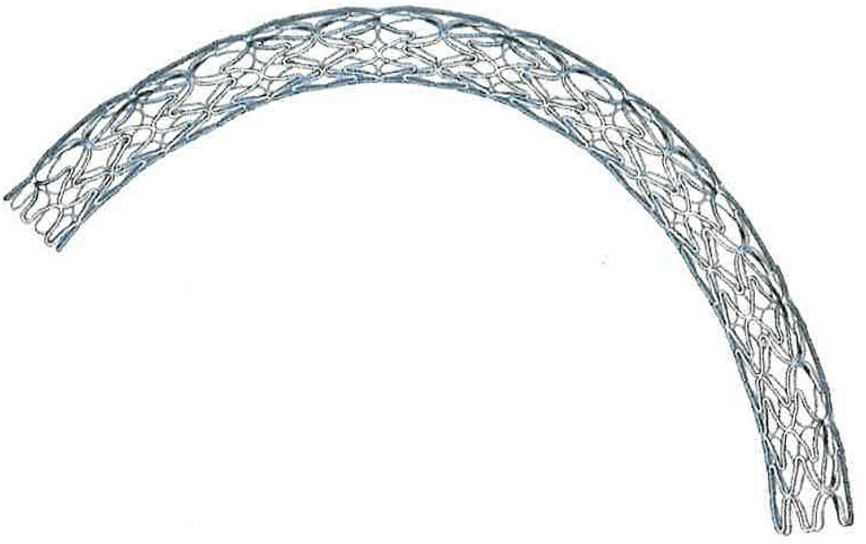


***Figure 33.1:*** *Tsunami – conformability.*

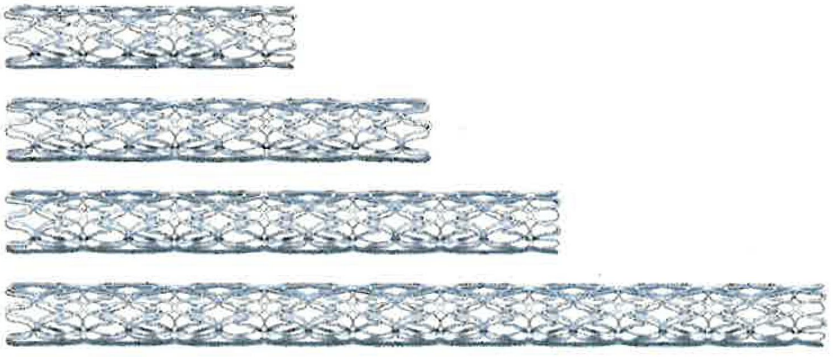


***Figure 33.2:*** *Tsunami product range (10, 15, 20 and 30 mm lengths).*

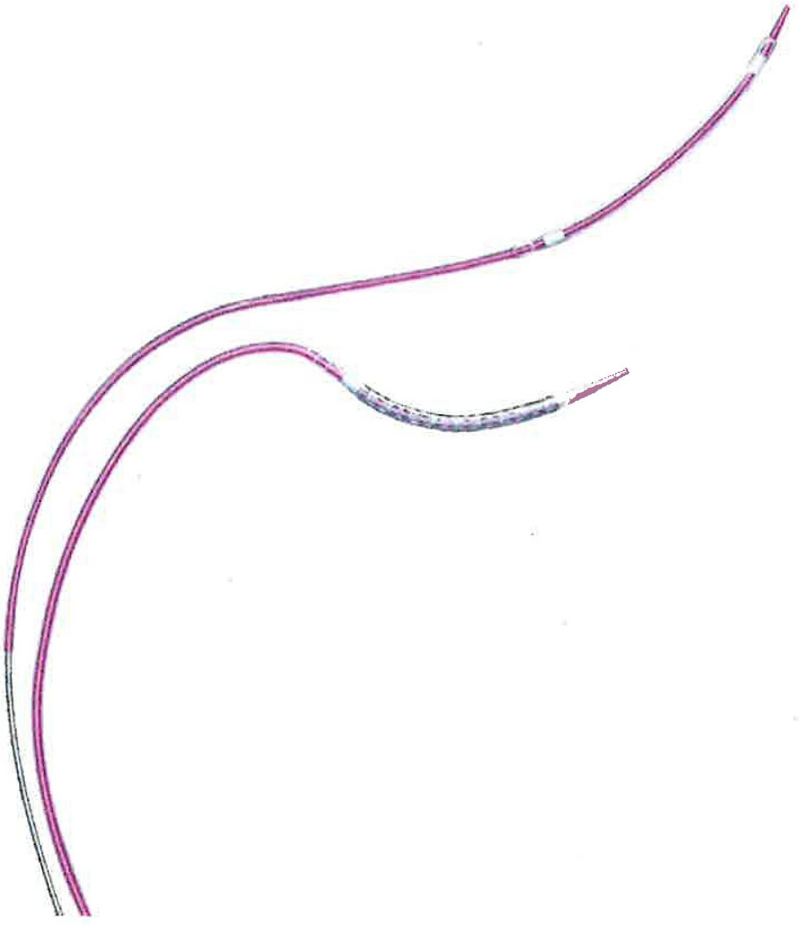


***Figure 33.3:*** *Tsunami delivery system.*

***Figure 33.4:*** *Expanded Tsunami stent system.*

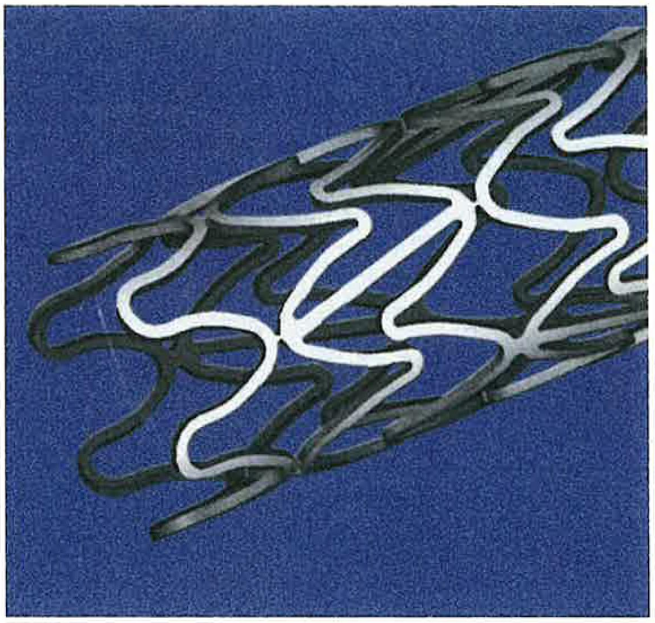


***Figure 33.5:*** *Expanded Tsunami stent.*

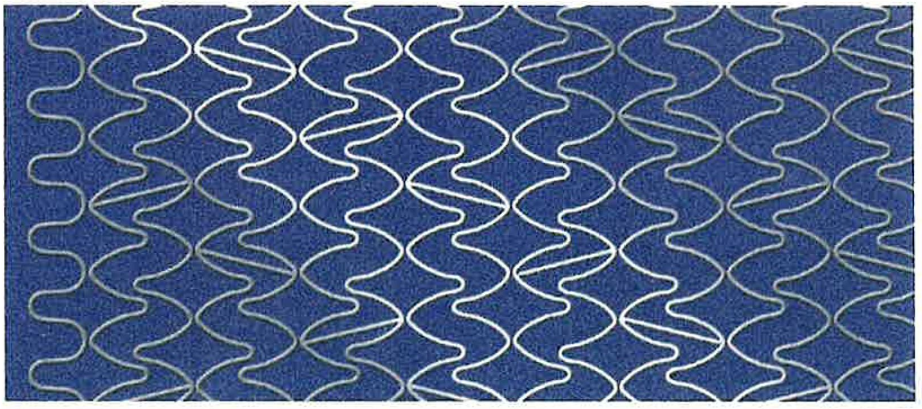


***Figure 33.6:*** *Technical drawing of Tsunami.*

## Indications for use

- Useful in distal and tortuous vessel
- Long lesions
- Acute closure or bail out situations
- Smaller vessels
- Acute myocardial infarction
- De-novo lesions
- Lesions in bends
- Vein graft stenosis
- Sub-optimal PTCA result
- Moderate calcified lesions

## Why I like my stent

- Superior deliverability assured by very low profile (one of the lowest), M coat (Terumo's hydrophilic polymer on tip and shaft), and flexible system (unique double-link connection).
- Good conformability and high radial force for long-term outcome provided by double-linked diamond cells tubular structure.
- Minimum vessel injury realized by minimal balloon overhang.

## Ongoing planned trials

- Japan trial, Dr Masakiyo Nobuyoshi, Kokura Memorial Hospital, Japan
- TESTER, Professor Serruys, Thoraxcenter, Rotterdam, The Netherlands

## Review of the current published literature


- Nobuyoshi M, Yokoi H, Mitsudo K, Kadota K, Saito S, Hosokawa J. Early and late outcomes of Coronary Stent System (TRE-963). *J Clin Exp Med* 1998;**75**:209–221.
- Yokoi H, Nakagawa Y, Tamura T, Hamasaki N, Kimura T, Nosaka H, Nobuyoshi M. Preliminary experiences with the Terumo coronary stent [abstract]. *J Am Coll Cardiol* 1998;**31**(suppl):413A.

# 34. THE ZEBRA STENT

*Bolton Medical Inc, Fair Lawn, NJ, USA*

Norman T Kanesaka and Tomás Berrazueta

| | |
|---|---|
| **Definition** | The Zebra coronary stent is a tubular stent, which is laser cut from 316 L stainless steel and electro-polished. It has bigger cells on both ends to give a 'variable metal coverage'. The central part features a spiral strut design in which all of the stents are connected with inverted C joints. |

| | |
|---|---|
| **History** | The Zebra was developed in mid-2000 to incorporate all the superior features of Bolton Medical's Spiral Force stent – flexibility, high radial force and minimum recoil – with reduced metal coverage on the stent ends for better transitions to the non-stented areas. |

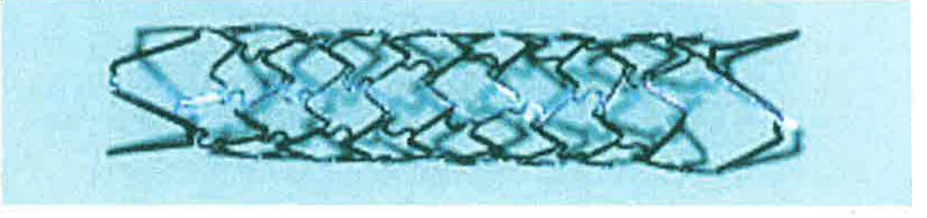


***Figure 34.1:*** *Expanded Zebra stent.*

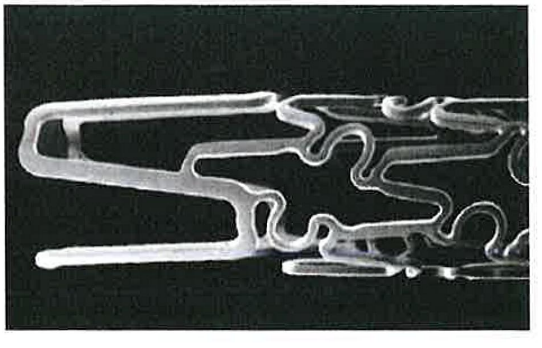


***Figure 34.2:*** *Scanning electron micrograph of the Zebra stent.*

| Zebra stent technical specifications | |
|---|---|
| Material composition: | 316 L stainless steel |
| Degree of radiopacity (grade): | Moderate |
| Ferromagnetism: | Non-ferromagnetic |
| MRI: | MRI safe |
| Metallic surface area expanded: | Approximately 13% at 3.5 mm |
| Stent design: | Spiral cut with C-joints |
| Strut design: | Straight struts |
| Strut dimensions: | 0.005 inch × 0.026 inch to<br>0.007 inch × 0.080 inch |
| Strut angles: | 40° to 55° @ 4 mm internal diameter |
| Strut thickness: | 0.003 inch |
| Wire thickness: | Not Applicable |
| Mesh angle: | Not applicable |
| Mesh braid angle: | Not applicable |
| Profile(s): non-expanded (uncrimped):<br>expanded:<br>on the balloons: | 0.067 inch<br>2.7 mm to 4.2 mm<br>0.039 inch to 0.042 inch |
| Longitudinal flexibility: | Excellent |
| Percentage shortening on expansion: | 2.5–10.8% depending on expansion |
| Expansion range: | 2.5 mm to 4.25 mm |
| Degree of recoil (shape memory): | 1.2% |
| Radial force: | Very high |
| Currently available diameters: | 2.5, 3.0, 3.5, 4.0 mm |
| Currently available lengths<br>mounted/implanted:<br>unmounted: | <br>See tables<br>14 mm, 19 mm |

## Device for delivery

The rapid exchange Runner is the latest generation stent delivery balloon catheter. The Zylite balloon material (semi-compliant) gives: controlled compliance, increased flexibility, optimal refolding and high pressure seating.

The Runner balloon is also designed to be used for standard PTCA procedures, such as routine pre-dilatation angioplasty and post-stent deployment. It is available in all lengths and diameters.

## Indications for use

See Spiral Force chapter.

## Why I like my stent

The Zebra inherits all of the superior, fundamental design patterns of Bolton Medical's Spiral Force in the center of the stent, but the end cells are enlarged for reduced metal coverage. This is a very unique design.

## Studies in which stent is involved

1) ZEBRA BELGIUM STUDY
   7 centres
   150 patients
   Registry
   Will start on June 2001

2) ZEBRA SPAIN STUDY
   5 centres
   200 patients
   Registry
   Will start on June 2001