Medtronic

TECHNICAL BULLETIN

Advantages of Cobalt Alloy for Coronary Stents

The introduction of the Driver Coronary Stent marks the first use of a cobalt-based alloy in a modular stent design. This Technical Bulletin compares the chemical composition of the cobalt alloy to 316L stainless steel and discusses the physical properties of the cobalt alloy that make it ideally suited for current and future stenting applications.

Why did Medtronic choose a cobalt-based alloy for its new Driver Coronary Stent?

Coronary interventionalists have been asking for stents designed with thinner struts. Thin-strut stents tend to have lower profiles than thick-strut stents, making it easier to reach distally. In addition, recent clinical reports[1–3] have suggested that strut thinness may affect restenosis rates—further moving the marketplace toward thinner struts.

Medtronic has reduced strut dimensions for each new generation of modular stents, with the S7 stent representing the ultimate in strut thinness attainable in a 316L stainless steel design. Achieving even thinner struts required challenging the fundamental aspects of modular stent design and replacing 316L stainless steel with a cobalt-based alloy that offers several important advantages.

The alloy, which conforms to ASTM F562, is stronger than stainless steel, making possible thinner struts without decreasing radial strength. Driver struts are an average of 0.0036 in., approximately 20 percent thinner than the S7 struts. Thinner struts, in turn, contribute to a lower profile. The alloy is also denser than 316L stainless steel, such that good radiopacity is maintained despite the thinner strut dimensions.

With enhanced deliverability, superb vessel support and good radiopacity, the Driver design is the foundation for the Medtronic drug-eluting stent program.

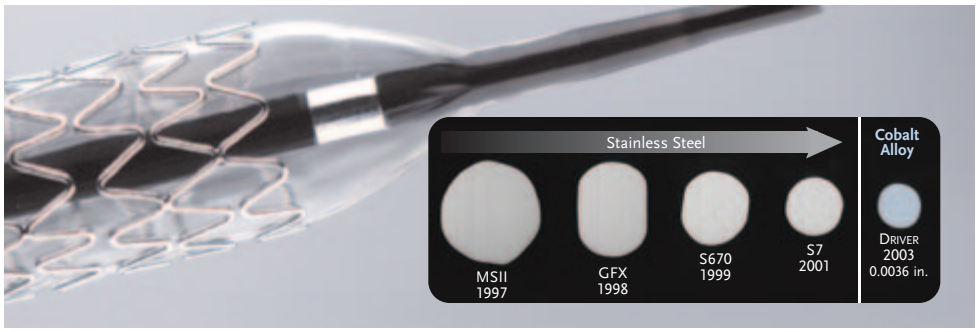

Figure 1. *The Driver struts are approximately 20 percent thinner than the previous generation*

Has the cobalt alloy been used in other implantable devices?

Yes. The family of cobalt alloys has been used since 1937 in medical implants, but its use in stents is a recent advancement. The specific alloy used in Driver has been used in several blood-path implants that have been FDA-approved and CE-marked, including aneurysm clips, a septal occluder and Medtronic pacemaker leads.

The alloy has been chosen for its biocompatibility, strength, non-ferromagnetism, and high resistance to fatigue and corrosion. It conforms to ASTM F562.

How does the cobalt alloy compare to stainless steel?

The composition of the Driver alloy is shown in **Table 1**. The cobalt alloy offers several key advantages over 316L stainless steel:

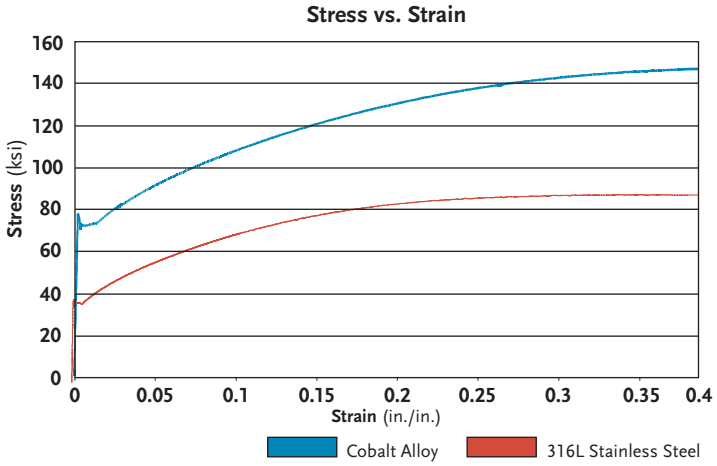

Figure 2. *The horizontal axis represents strain, or deflection, and the vertical axis represents stress, or force*

- **Stronger than stainless steel.** The cobalt alloy has higher strength than stainless steel—allowing thinner struts while maintaining radial strength. **Figure 2** illustrates "stress-strain" curves for both the Driver cobalt alloy and 316L stainless steel. These curves are generated using samples of each material fabricated with the same cross-sectional area.

Table 2. **Density Values**

Material	Pounds per Inch^3
Cobalt alloy	0.304
316L stainless steel	0.287

The cobalt alloy requires more force to deflect to the same degree (*i.e.,* it deflects less with the same force applied). In essence, the cobalt alloy is stronger. **Figure 3** shows the "yield strength" values for the cobalt alloy and 316L stainless steel. The cobalt alloy is about 45 percent stronger than 316L stainless steel. Machine tools designed to cut stainless steel are often made from cobalt alloys.

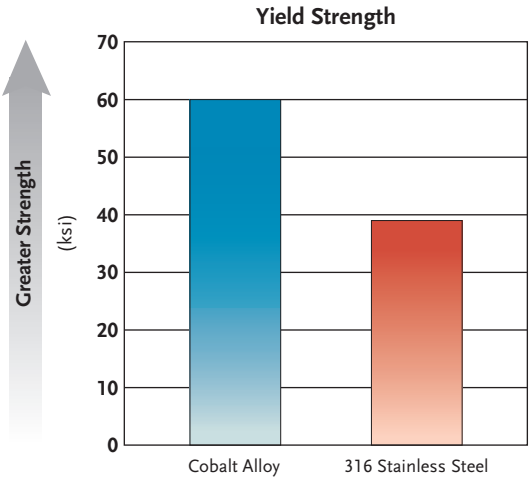

Figure 3. *The alloy used in the Driver stent is approximately 45 percent stronger than 316L stainless steel*

- **Denser than stainless steel.** The cobalt alloy is more dense than 316L stainless steel (see **Table 2**). This higher density makes it possible to design a thin-strut stent with radiopacity as good as or better than a stainless steel stent.
- **More MRI-compatible.** Because the iron content is negligible, the cobalt alloy is non-ferromagnetic. This gives it improved MRI-compatibility compared to 316L stainless steel and other ferromagnetic materials.

Table 1. **Chemical Composition**

Material	Fe	Co	Cr	Ni	Mo	Ti	Mn	Si	C
Cobalt alloy (%) by weight	1.0 max	balance	20	35	10	1.0 max	0.15 max	0.15 max	0.025 max
316L stainless steel (%) by weight	balance	—	18	14	2.9	—	2.0 max	0.75 max	0.03 max

What are the surface properties of this new alloy?

Although the Driver stent is made from an alloy with different composition than 316L stainless steel, manufacturing processes are used to modify the surface, producing a surface composition very similar to the S7 surface. As shown in **Figure 4**, the surfaces of both the Driver and S7 stents are enriched in chromium, creating a chromium-rich oxide layer that acts as a barrier to the release of ions from the bulk material underneath the surface. The chrome-oxide layer on the Driver stent is similar to the chrome-oxide layers found in stainless steel stents, both with nickel content <2%.

In experiments designed to measure the quantity of ions released from stents immersed in a physiological isotonic saline solution at body temperature, the quantities for both the cobalt and stainless steel stents are very low (parts per billion).

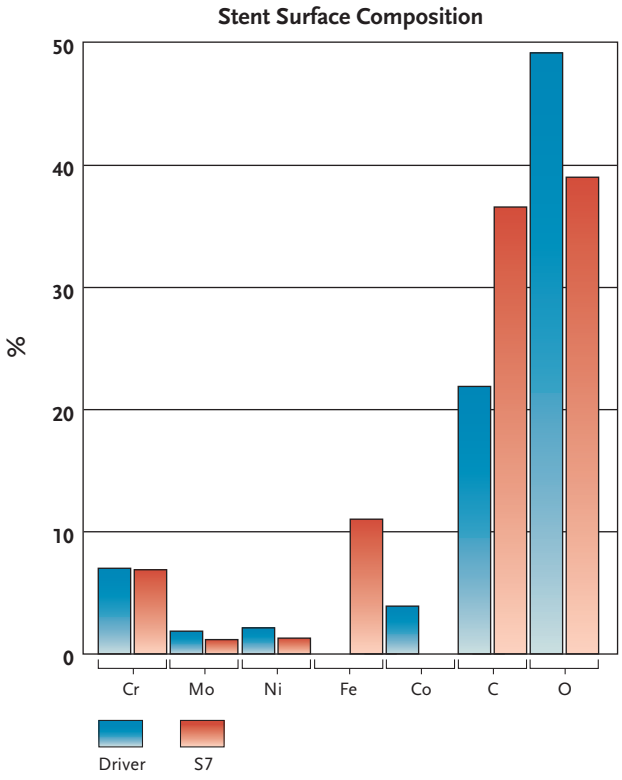

Figure 4. *Although the bulk composition of the cobalt alloy and 316L stainless steel differs, passivation and electropolishing create surfaces that are quite similar*

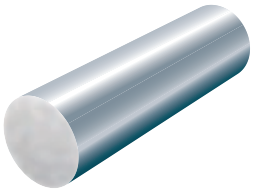

Figure 5. *The chromium-rich surface layer created during passivation and electropolishing processes creates a barrier to ion release*

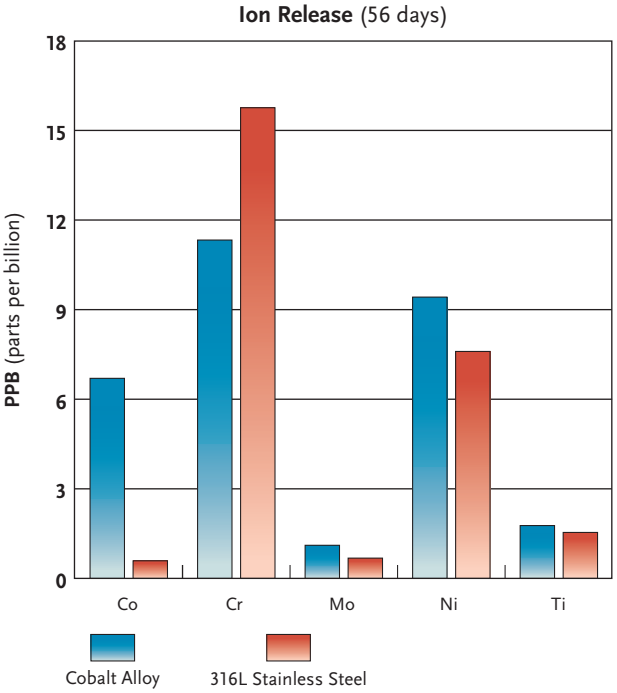

Figure 6. *The cobalt alloy exhibits very low ion release characteristics, similar to 316L stainless steel*

Has the Driver Coronary Stent been evaluated for potential galvanic interaction with 316L stainless steel stents?

Clinical evaluation of this potential risk is not practical, therefore no human clinical data are available. However, the Driver Coronary Stent has been tested in simulated *in vivo* conditions, both in contact with and adjacent to 316L stainless steel stents. Results showed no evidence of galvanic coupling that would indicate accelerated corrosion.[4] The lack of observed galvanic coupling during corrosion testing is to be expected, given the similarity in the surface compositions of the Driver cobalt alloy stent and the S7 316L stainless steel stent (see **Figure 4**).

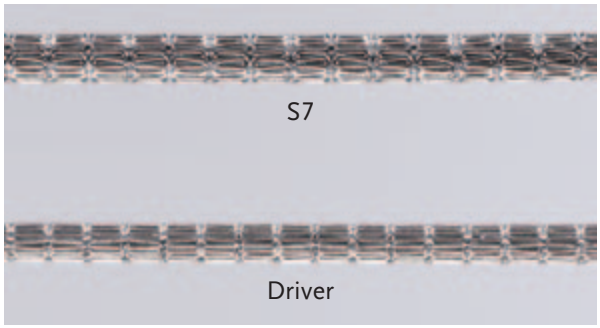

Figure 7. *The Driver Stent System has a lower profile than the S7, making it well suited to direct stenting*

References

[1]Briguori C, Sarais C, Pagnotta P, Liistro F, Montorfano M, Chieffo A, Sgura F, Corvaja N, Albiero R, Stankovic G, Toutoutzas C, Bonizzoni E, Di Mario C, Colombo A. In-stent restenosis in small coronary arteries: impact of strut thickness, *J Amer Coll of Cardiology*, 40:3, 403–409, 2002.

[2]Kastrati A, Mehilli J, Dirschinger J, Dotzer F, Schühlen H, Neumann FJ, Fleckenstein M, Pfafferott C, Seyfarth M, Schömig A. Intracoronary stenting and angiographic results: strut thickness effect on restenosis outcome (ISAR-STEREO Trial), *Circulation*, 103:2816–2821, 2001.

[3]Pache J, Kastrati A, Mehilli J, Schühlen H, Dotzer F, Hausleiter J, Fleckenstein M, Neumann FJ, Sattelberger U, Schmitt C, Müller M, Dirschinger J, Schömig A. Intracoronary stenting and angiographic results: Strut thickness effect on restenosis outcome (ISAR-STEREO-2 Trial), *J Amer Coll of Cardiology,* 41:8, 1283–1288, 2003.

[4]Test data on file at Medtronic Vascular.

Intended Use
The Medtronic Vascular DRIVER Over-the-Wire and Multi-Exchange Coronary Stent Delivery Systems are indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo or restenotic lesions with reference vessel diameters of 3.0 mm to 4.0 mm and ≤30 mm in length using direct stenting or predilatation.

Contraindications
- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

Warnings/Precautions
- Since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events, judicious selection of patients is necessary. Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical to successful stent implantation and follow-up.
- Persons allergic to cobalt, chromium or nickel may suffer an allergic reaction to this implant.
- Only physicians who have received the appropriate training should perform implantation of the stent.
- Stent placement should be performed only at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require redilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different materials in contact with each other may increase the potential for corrosion. The risk of *in vivo* corrosion does not appear to increase based on *in vitro* corrosion tests using a F562 CoCr alloy stent (Medtronic Driver Coronary Stent) in combination with a 316L stainless steel alloy stent (Medtronic S7 Coronary Stent).
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion and may cause acute closure of the vessel requiring additional intervention (*e.g.*, CABG, further dilatation, placement of additional stents or other).
- Outcomes beyond 270 days for this permanent implant are unknown at present.

Adverse Events
Potential adverse events that may be associated with the use of a coronary stent in native coronary arteries (including those listed in the Driver *Instructions for Use*) are listed below in order of severity: death, myocardial infarction, CABG, stent thrombosis, bleeding complications, stroke, vascular complications, stent failures; potential adverse events, *e.g.*, acute myocardial infarction, myocardial ischemia, arrhythmias, dissection, distal emboli, hemorrhage, perforation, restenosis of stented segment, stent embolization, total occlusion of coronary artery.

Please reference appropriate product *Instructions for Use* for a more detailed list of indications, warnings, precautions and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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