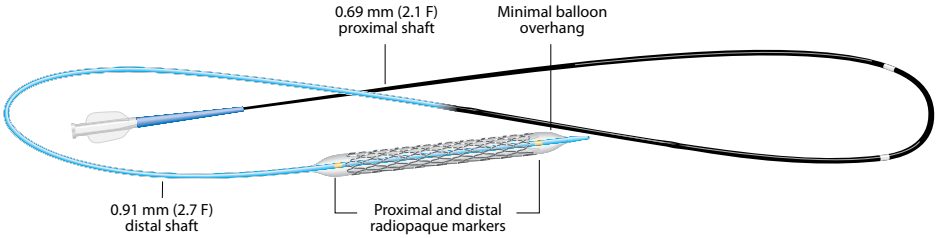
Bare Metal Coronary Stents

Integrity® RX Coronary Stent System



General Characteristics:
Supplied sterile.
Items per box: 1

The Integrity bare metal coronary stent system incorporates continuous sinusoid technology in an advanced, low-profile cobalt alloy stent that is mounted on the extended-pressure, semicompliant RX MicroTrac delivery system.

Integrity RX Ordering Information

Stent Diameter (mm)	Stent Length (mm)								
	8	9	12	14	15	18	22	26	30
2.25	INT22508UX	—	INT22512UX	INT22514UX	—	INT22518UX	INT22522UX	INT22526UX	—
2.50	INT25008UX	—	INT25012UX	INT25014UX	—	INT25018UX	INT25022UX	INT25026UX	—
2.75	INT27508UX	—	INT27512UX	INT27514UX	—	INT27518UX	INT27522UX	INT27526UX	—
3.00	—	INT30009UX	INT30012UX	—	INT30015UX	INT30018UX	INT30022UX	INT30026UX	INT30030UX
3.50	—	INT35009UX	INT35012UX	—	INT35015UX	INT35018UX	INT35022UX	INT35026UX	INT35030UX
4.00	—	INT40009UX	INT40012UX	—	INT40015UX	INT40018UX	INT40022UX	INT40026UX	INT40030UX

Integrity RX Compliance

Pressure (atm)	Stent Diameter Deployed Stent I.D. (mm)					
	2.25†	2.50†	2.75†	3.00†	3.50†	4.00†
6	2.15	2.40	2.65	2.85	3.25	3.70
7	2.20	2.45	2.70	2.90	3.30	3.75
8	2.20	2.50	2.75	2.95	3.40	3.85
9	2.25	2.55	2.80	3.05	3.45	3.90
10	2.30	2.55	2.85	3.10	3.50	4.00
11	2.35	2.60	2.90	3.10	3.55	4.05
12	2.35	2.65	2.90	3.15	3.60	4.10
13	2.40	2.65	2.95	3.20	3.65	4.15
14	2.45	2.70	3.00	3.25	3.65	4.20
15	2.50	2.75	3.05	3.30	3.70	4.25
16	2.50	2.80	3.10	3.30	3.75	4.30
17	2.55	2.80	3.15	3.35	3.80	4.35
18	2.60	2.85	3.20	3.40	3.85	4.40
19	2.65	2.90	3.25	3.45	3.90	4.45
20	2.75	2.95	3.30	3.50	3.90	—

Nominal pressure | Rated burst pressure*

†Do not postdilate the 2.25–2.75-mm stents to greater than 3.50 mm.
Do not postdilate the 3.00–4.00-mm stents to greater than 5.00 mm.

*Rated burst pressure—do not exceed.

Crossing profiles:

2.25–2.75 mm: 0.97–1.04 mm (0.038–0.040 in.)
3.0–4.0 mm: 1.04–1.19 mm (0.041–0.047 in.)

Medtronic

Indications for Use
The Integrity Coronary Stent 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 2.25–4.0 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 or proper placement of a stent or stent delivery system

Warnings/Precautions
The long-term effects of stents and the risks associated with lifelong carrying of these implants are unknown. This lack of knowledge should be considered in making a risk/benefit assessment for the patient prior to implantation.
- The Integrity Coronary Stent Systems are provided sterile, for one procedure only. Do not resterilize. Use by the "Use by" date noted on the package.
- Only physicians who have received appropriate training should perform implantation of the stent. Use of an Integrity Coronary Stent System requires advanced coronary angioplasty technical skills. The instructions will give technical guidance, but do not obviate the need for formal training in the use of the device.
- Patients allergic to cobalt alloy may suffer an allergic reaction to this implant.
- Do not remove the stent from the stent delivery system; the stent cannot be removed and placed on another balloon catheter for deployment.
- Do not try to straighten a kinked shaft or hypotube. Straightening a kinked metal shaft may result in breakage of the shaft. If the device is kinked, it should not be used.
- Significant amounts of air in the balloon may cause uneven expansion of the stent and difficulty in deployment of the stent. Do not pre-inflate balloon prior to stent deployment. Use balloon preparation technique described within this instructional material.
- The Integrity Coronary Stent Systems do not provide for distal dye injections or pressure measurements through the guidewire lumen.
- Expansion of the stent should not be undertaken if the stent is not appropriately positioned in the vessel. If the position of the stent is not optimal, it should not be expanded.
- Incomplete deployment of the stent (i.e., stent not fully expanded) may cause procedural complications resulting in patient injury.
- Advancement of an Integrity Coronary Stent System through a previously stented segment may cause procedural complications resulting in patient injury.
- Placement of the stent has the potential to compromise sidebranch patency.
- Administer appropriate anticoagulant/antiplatelet and coronary artery vasodilator therapy according to current medical guidelines and manufacturer's instructions.
- Caution must be taken when using ancillary equipment, such as intravascular ultrasound catheters, to avoid dislodgement or deformation of the stent.
- 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. Data obtained from *in vitro* corrosion tests using a cobalt alloy stent (Medtronic Integrity Coronary Stent) in combination with a stainless steel alloy stent (Boston Scientific Liberté® Coronary Stent) do not suggest an increased risk of *in vivo* corrosion.
- When using two wires, care should be taken when introducing, torquing and removing one or both guidewires to avoid entanglement. It is recommended that one guidewire be completely withdrawn from the patient before removing any additional equipment.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events. Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical to successful stent implantation and follow-up.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.

Potential Adverse Events
The following complications may be associated with the use of coronary stenting devices or PTCA:
• Acute myocardial infarction • Allergic reaction to contrast medium/stent material/medications • Arrhythmias (including ventricular fibrillation and ventricular tachycardia) • Arteriovenous fistula • Bleeding complications • Cardiac tamponade • Cerebrovascular accident/stroke • Death • Dissection of coronary artery • Drug reactions • Embolization (air, stent, tissue or thrombotic) • Emergency coronary artery bypass graft surgery (CABG) • Endocarditis • Failure to deliver the stent • Stent deformation, collapse or fracture • Hematoma • Hemorrhage requiring transfusion • Injury of the coronary artery • Myocardial ischemia/infarction • Pain and tenderness at the insertion site • Perforation • Peripheral Ischemia • Peripheral nerve injury • Pseudoaneurysm (coronary/femoral/radial) • Pyrogenic reaction • Restenosis of the dilated artery or stented segment • Sepsis/infection • Short-term hemodynamic deterioration (hypotension/hypertension) • Stent thrombosis or occlusion • Total occlusion of coronary artery • Unstable angina • Vascular thrombosis • Vessel dissection/perforation/spasm

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.