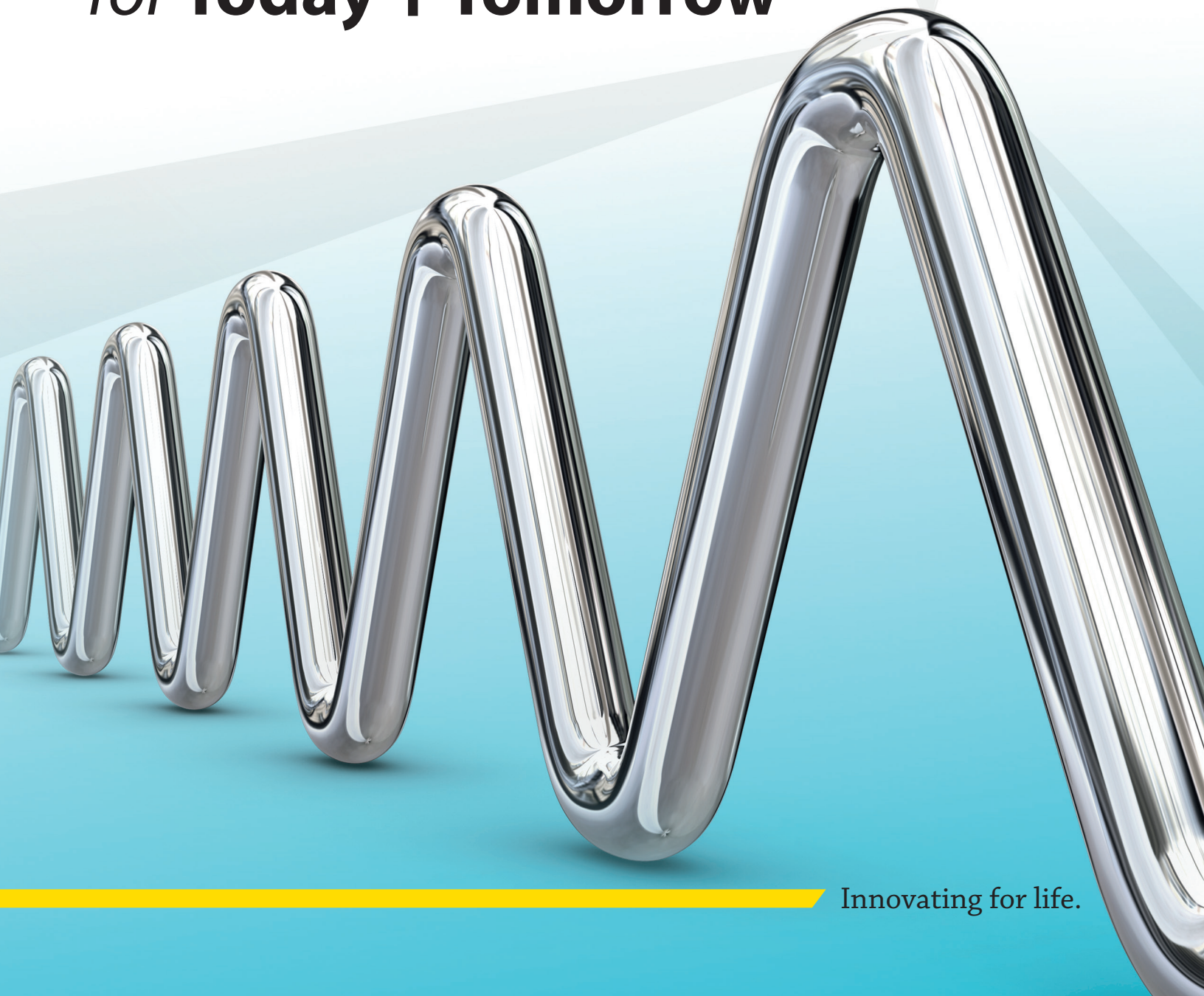
Medtronic

# Resolute Integrity™

ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

# DES Technology *for* Today + Tomorrow



Innovating for life.

# *AHEAD OF THE CURVE*

**Resolute Integrity DES is a leading product in the Medtronic Interventional Portfolio. Designed for increasingly complex clinical practice, Resolute Integrity DES is built to simplify your everyday challenges. Featuring the groundbreaking Integrity™ platform, Resolute Integrity DES delivers powerful performance.**

### DES Technology for Today + Tomorrow

- Unique Continuous Sinusoid Technology defines current performance and enables future innovations of Core Wire Technology, drug-filled stents and bioabsorbable stents

### Rooted in Real-World Experience to Help Patients with Diabetes

- First FDA-approved DES for the treatment of CAD in patients with diabetes

### Powerful Clinical Evidence to Address Challenging Cases

- More than 7600 patients studied, including a real-world patient population, and 2 million patients treated

## **MEDTRONIC INTERVENTIONAL** *PRODUCT PORTFOLIO*


Export Advance™ Aspiration Catheter


Confida™ Guidewire


CoreValve™ TAVR System


Reveal LINQ™ Insertable Cardiac Monitoring System


ACIST RXI™ Rapid Exchange FFR System


SEEQ™ MCT (Mobile Cardiac Tetometry)


NC Euphora™ Noncompliant Balloon Dilation Catheter


Euphora™ Semicompliant Balloon Dilation Catheter

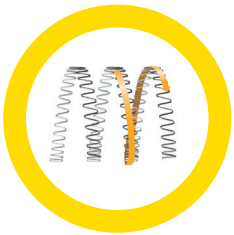

IN. PACT™ Admiral Drug-Coated Balloon

- TCV
- PCI
- CRHF
- APV

# DES Technology
## *for Today + Tomorrow*

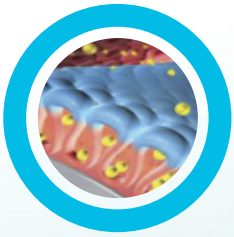
Resolute Integrity™ stent's continuous range of motion permits uniform response along the full stent length—simplifying navigation through challenging anatomies.

**Sinusoid-formed wire**

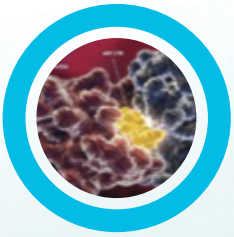


**Helical wrap**

**Laser-fused**

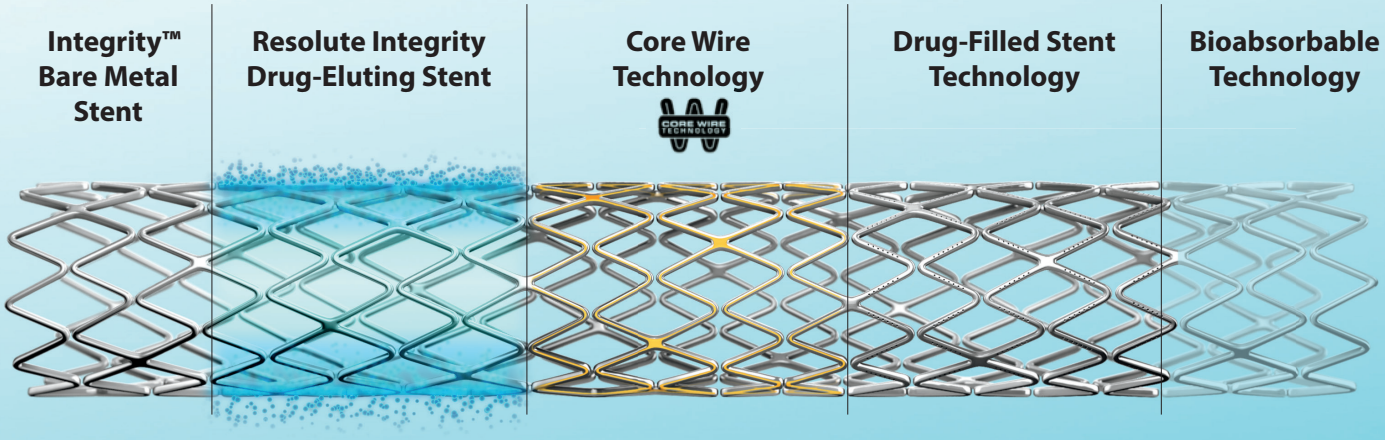


**BioLinx® polymer minimizes inflammation[1]**



**Proven zotarolimus drug**

**MicroTrac™ delivery system**




[1]Preclinical porcine data on file at Medtronic, Inc.

# **Rooted in Real-World Experience**
## *to Help Patients with Diabetes*

### US DIABETES PATIENTS HAVE:

**2-3x**
increased risk for heart disease[2]

**30%**
of coronary stents implanted in 2011[3]

**60%**
chance of dying from heart disease[2]

***Medtronic is committed to treating these challenging patients and is proud to sponsor the American Diabetes Association's "Make The Link" initiative.***

Diabetes *Simplify the Challenge*

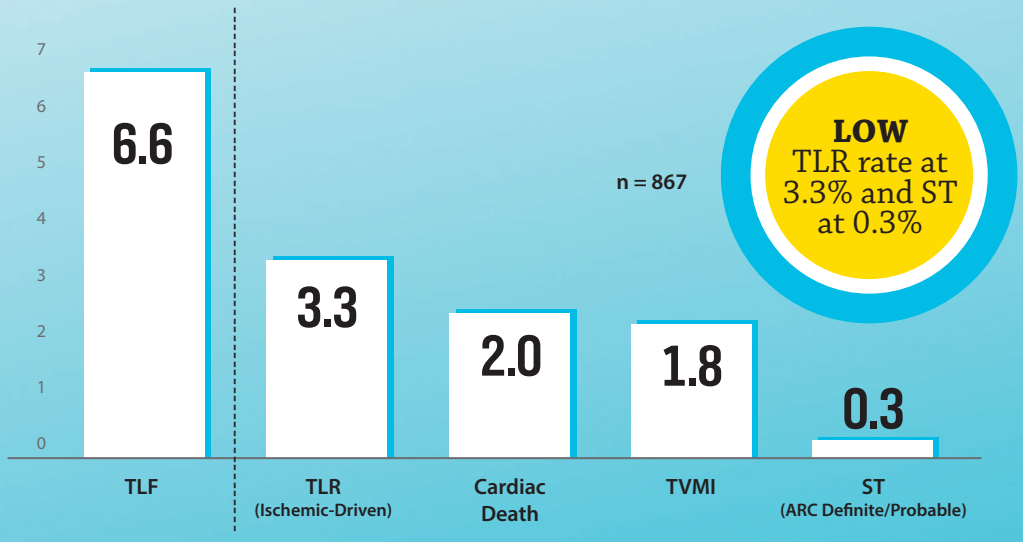
Make The Link! Diabetes Heart Disease and Stroke
American Diabetes Association.

[2]Tan MH. From research to practice: Diabetes and coronary heart disease. *Diabetes Spectrum*;1999(12):80–83.
[3]RESOLUTE Clinical Program Pooled analysis

### FIRST FDA-APPROVED DES FOR THE TREATMENT OF CAD IN PATIENTS WITH DIABETES

- RESOLUTE Pooled analysis showed low event rates in patients with diabetes

RESOLUTE Pooled Analysis—Diabetic Subset at 12 Months




RESOLUTE Pooled analysis was not specifically designed or powered for the endpoints shown above.

# **Powerful Clinical Evidence**
## *to Address Challenging Cases*

Rigorous data from more than 7600 patients studied, including a real-world patient population, support Resolute Integrity stent's safety and efficacy across the clinical spectrum. With no need for platform improvements, Resolute Integrity DES has treated 2 million patients around the world.

### PROCEDURAL SUCCESS

Resolute™ DES and Resolute Integrity DES showed

**ZERO**

**INCIDENTS OF LSD**

in head-to-head prospective clinical trials with Promus Element™ DES[4,5]

### COMPLEX CASES

Low TLR rate at

**3.9%**

**seen in RESOLUTE All Comers**

at 12 months in real-world complex cases[6]

### SAFETY ASSURED

Low stent thrombosis rate at

**0.5%**

**seen in RESOLUTE US at 5 years[7]**

The BioLinx polymer showed

**MINIMAL INFLAMMATION and allows rapid and complete endothelial healing[8]**

RESOLUTE All Comers and RESOLUTE US trials were not specifically designed or powered for the endpoints shown above.

[4] Hyo-Soo K. Randomized comparison of PtCr-EES vs. CoCr-ZES in all-comers receiving PCI: The HOST-ASSURE randomized trial, ACC 2013.

[5] von Birgelen C. Highly deliverable third-generation zotarolimus-eluting and everolimus-eluting stents in all-comer patients (DUTCH PEERS): A randomized trial, TCT 2013.

[6] RESOLUTE All Comers: Serruys PW et al. *N Engl J Med.* 2010;363:136-46.

[7] RESOLUTE US: Leon, M B et al. Long-term (five year) clinical evaluation of the Resolute coronary zotarolimus-eluting stent: Final results of the RESOLUTE US Clinical Trial, ACC 2015.

[8] Preclinical porcine data on file at Medtronic, Inc.

# Resolute Integrity DES Product Ordering Information

| Stent Diameter (mm) | Stent Length (mm) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 8 | 12 | 14 | 18 | 22 | 26 | 30 |
| 2.25 | RSINT22508UX/W | RSINT22512UX/W | RSINT22514UX/W | RSINT22518UX/W | RSINT22522UX/W | RSINT22526UX/W | RSINT22530UX/W |
| 2.50 | RSINT25008UX/W | RSINT25012UX/W | RSINT25014UX/W | RSINT25018UX/W | RSINT25022UX/W | RSINT25026UX/W | RSINT25030UX/W |
| 2.75 | RSINT27508UX/W | RSINT27512UX/W | RSINT27514UX/W | RSINT27518UX/W | RSINT27522UX/W | RSINT27526UX/W | RSINT27530UX/W |

| Stent Diameter (mm) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 9 | 12 | 15 | 18 | 22 | 26 | 30 | 34 | 38 |
| 3.00 | RSINT30009UX/W | RSINT30012UX/W | RSINT30015UX/W | RSINT30018UX/W | RSINT30022UX/W | RSINT30026UX/W | RSINT30030UX/W | RSINT30034UX/W | RSINT30038UX/W |
| 3.50 | RSINT35009UX/W | RSINT35012UX/W | RSINT35015UX/W | RSINT35018UX/W | RSINT35022UX/W | RSINT35026UX/W | RSINT35030UX/W | RSINT35034UX/W | RSINT35038UX/W |
| 4.00 | RSINT40009UX/W | RSINT40012UX/W | RSINT40015UX/W | RSINT40018UX/W | RSINT40022UX/W | RSINT40026UX/W | RSINT40030UX/W | RSINT40034UX/W | RSINT40038UX/W |

**Indications for Use:**
The Resolute Integrity Zotarolimus-Eluting Coronary Stent System is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus, with symptomatic ischemic heart disease due to de novo lesions of length ≤35 mm in native coronary arteries with reference vessel diameters of 2.25 mm to 4.20 mm.

**Contraindications**

The Resolute Integrity Zotarolimus-Eluting Coronary Stent System is contraindicated for use in:
- Patients with a known hypersensitivity or allergies to aspirin, heparin, bivalirudin, clopidogrel, prasugrel, ticagrelor, ticlopidine, drugs such as zotarolimus, tacrolimus, sirolimus, everolimus or similar drugs or any other analogue or derivative
- Patients with a known hypersensitivity to the cobalt-based alloy (cobalt, nickel, chromium and molybdenum)
- Patients with a known hypersensitivity to the BioLinx® polymer or its individual components

Coronary artery stenting is contraindicated for use in:
- 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 the stent or stent delivery system

**Warnings**
- Please ensure that the inner package has not been opened or damaged as this would indicate the sterile barrier has been breached.
- The use of this product carries the same risks associated with coronary artery stent implantation procedures, which include subacute and late vessel thrombosis, vascular complications and/or bleeding events.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

**Precautions**
- Only physicians who have received adequate training should perform implantation of the stent.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent stent restenosis or occlusion may require repeat catheter-based treatments (including balloon dilatation) of the arterial segment containing the stent. The long-term outcome following repeat catheter-based treatments of previously implanted stents is not well characterized.
- The risks and benefits of the stent implantation should be assessed for patients with a history of severe reaction to contrast agents.
- Do not expose or wipe the product with organic solvents such as alcohol.
- When drug-eluting stents (DES) are used outside the specified *Indications for Use*, patient outcomes may differ from the results observed in the RESOLUTE pivotal clinical trials.
- Compared to use within the specified *Indications for Use*, the use of DES in patients and lesions outside of the labeled indications, including more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, myocardial infarction (MI) or death.
- Care should be taken to control the position of the guide catheter tip during stent delivery, deployment and balloon withdrawal. Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement into the vessel and subsequent arterial damage.
- Stent thrombosis is a low-frequency event that is frequently associated with MI or death. Data from the RESOLUTE clinical trials have been prospectively evaluated and adjudicated using the definition developed by the Academic Research Consortium (ARC).

The safety and effectiveness of the Resolute Integrity stent have not yet been established in the following patient populations:
- Patients with target lesions which were treated with prior brachytherapy or the use of brachytherapy to treat in-stent restenosis of a Resolute Integrity stent
- Women who are pregnant or lactating
- Men intending to father children
- Pediatric patients
- Patients with coronary artery reference vessel diameters of <2.25 mm or >4.20 mm
- Patients with coronary artery lesions longer than 35 mm or requiring more than one Resolute Integrity stent
- Patients with evidence of an acute MI within 72 hours of intended stent implantation
- Patients with vessel thrombus at the lesion site
- Patients with lesions located in a saphenous vein graft, in the left main coronary artery, ostial lesions or bifurcation lesions
- Patients with diffuse disease or poor flow distal to identified lesions
- Patients with tortuous vessels in the region of the target vessel or proximal to the lesion
- Patients with in-stent restenosis
- Patients with moderate or severe lesion calcification at the target lesion
- Patients with occluded target lesions including chronic total occlusions
- Patients with three-vessel disease
- Patients with a left ventricular ejection fraction of <30%
- Patients with a serum creatinine of >2.5mg/dl
- Patients with longer than 24 months of follow-up

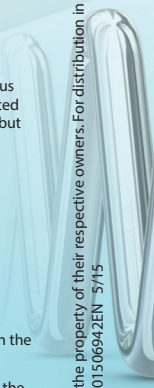
The safety and effectiveness of the Resolute Integrity stent have not been established in the cerebral, carotid or peripheral vasculature.

**Potential Adverse Events**
Other risks associated with using this device are those associated with percutaneous coronary diagnostic (including angiography and IVUS) and treatment procedures. These risks (in alphabetical order) may include but are not limited to:
- Abrupt vessel closure
- Access site pain, hematoma or hemorrhage
- Allergic reaction (to contrast, antiplatelet therapy, stent material, or drug and polymer coating)
- Aneurysm, pseudoaneurysm or arteriovenous fistula (AVF)
- Arrhythmias, including ventricular fibrillation
- Balloon rupture
- Bleeding
- Cardiac tamponade
- Coronary artery occlusion, perforation, rupture or dissection
- Coronary artery spasm
- Death
- Embolism (air, tissue, device or thrombus)
- Emergency surgery: peripheral vascular or coronary bypass
- Failure to deliver the stent
- Hemorrhage requiring transfusion
- Hypotension/hypertension
- Incomplete stent apposition
- Infection or fever
- MI
- Pericarditis
- Peripheral ischemia/peripheral nerve injury
- Renal failure
- Restenosis of the stented artery
- Shock/pulmonary edema
- Stable or unstable angina
- Stent deformation, collapse or fracture
- Stent migration (or embolization)
- Stent misplacement
- Stroke/transient ischemic attack
- Thrombosis (acute, subacute or late)

**Adverse Events Related to Zotarolimus**
Patients' exposure to zotarolimus is directly related to the total amount of stent length implanted. The actual side effects/complications that may be associated with the use of zotarolimus are not fully known. The adverse events that have been associated with the intravenous injection of zotarolimus in humans include but are not limited to:
- Anemia
- Diarrhea
- Dry skin
- Headache
- Hematuria
- Infection
- Injection site reaction
- Pain (abdominal, arthralgia, injection site)
- Rash

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

For further information, please call and/or consult Medtronic at the toll-free numbers or websites listed.



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**www.medtronic.com**
**www.medtronicstents.com**


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