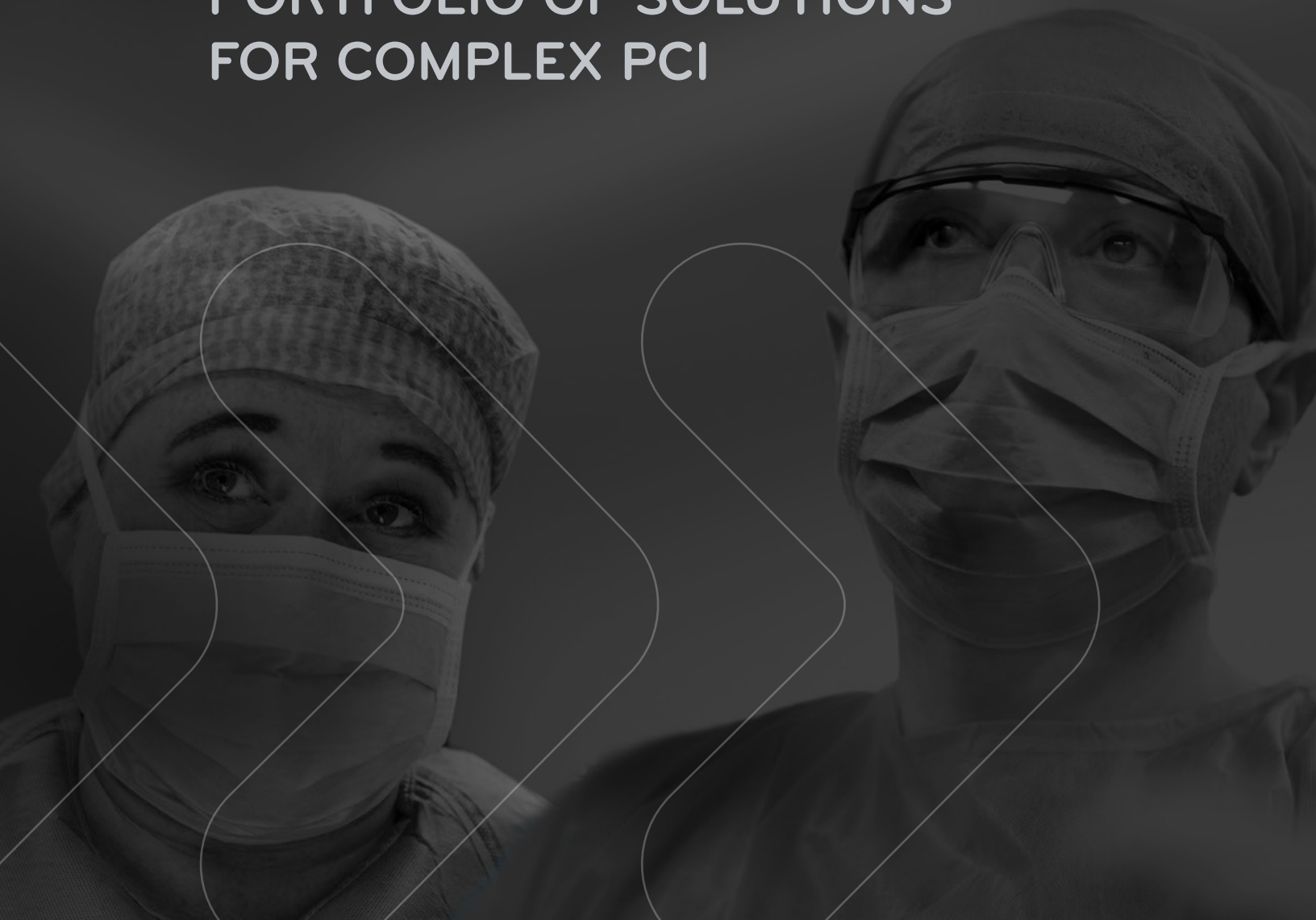
CARDIOVASCULAR SYSTEMS, INC.

# UNIQUE CHALLENGES. INDIVIDUALIZED SOLUTIONS.

## PORTFOLIO OF SOLUTIONS FOR COMPLEX PCI



# DRIVING SUCCESSFUL OUTCOMES FOR HIGH-RISK PCI PATIENTS

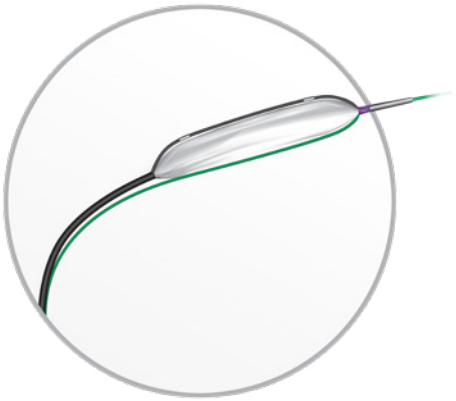
**Every complex case is uniquely challenging. That's why we focus on providing the therapies, tools, and specialized knowledge that enable you to take an individualized approach and optimize long-term durable outcomes.**

| ENSURING MAXIMUM PREPARATION | INDIVIDUALIZED INNOVATION & GUIDANCE | IMPROVING LONG-TERM OUTCOMES |
|---|---|---|
| We bring notable clinical acumen and product expertise to support optimal clinical preparation in advance of treatment. | We invest in novel tools and deliver lesion-level specialized guidance to meet individualized needs in your most challenging cases. | We advance the latest evidence-based solutions to improve clinical outcomes and economic value for the most challenging interventional procedures. |

# TOOLS TO TAKE ON THE COMPLEX

We equip you with a growing portfolio of therapies and tools for complex cases — from an innovative non-compliant scoring balloon, catheters for tracking tortuous anatomy, and ultra-low profile microcatheters for challenging lesions to the proven dual-action efficacy of our orbital atherectomy system.

## SCOREFLEX® NC SCORING PTCA CATHETER*



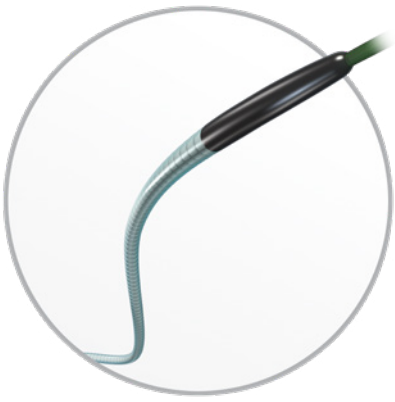
scoreflex® NC
Scoring PTCA Catheter

### FOCUSED-FORCE ANGIOPLASTY

Scoreflex® NC is a focused-force dilatation balloon for non-compliant plaque modification and lesion preparation. It uses a a dual-wire system, which creates a focal stress pattern to facilitate safe and controlled plaque modification at lower resolution pressure.

- **First non-compliant coronary scoring balloon**
- **Highest-rated burst pressure**
- **Low crossing profile**
- **Indicated for ISR**

## TELEPORT® MICROCATHETER*



Teleport®
Microcatheter

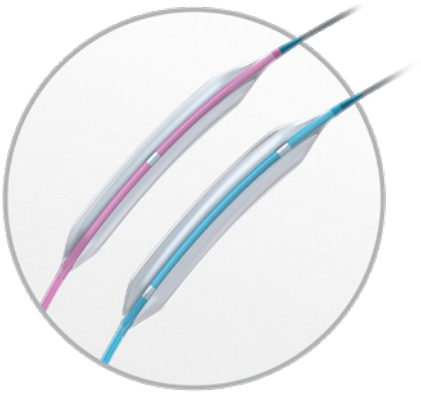
### ULTIMATE CONTROL AND TRACKABILITY

- **Ultra low profile and pushability** for navigation inside challenging lesions and micro channels
- **HYbrid BRAiding + Coil (HYBRACOIL) construction** for guidewire support and crossing
- **DUal-Layer RAdiopaque (DURA) tapered tip** for robustness and visibility
- **Indicated for coronary and peripheral intervention**

***Manufactured by:**

OrbusNeich™
*Pioneers in life-changing technologies*

## SAPPHIRE® II PRO DILATATION CATHETER*



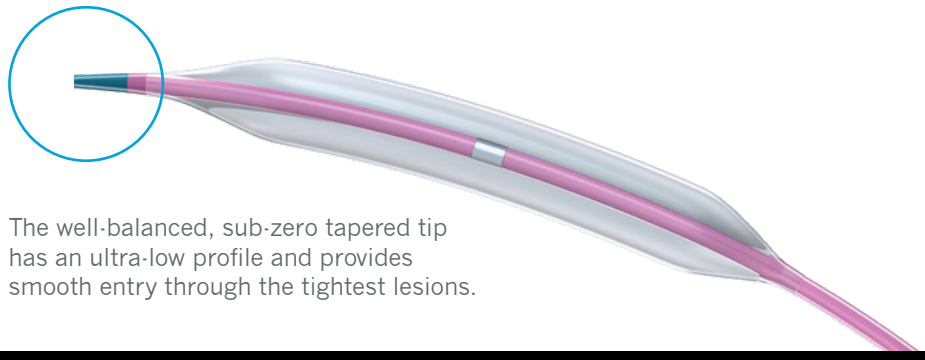
SAPPHIRE® II PRO
Balloon Dilatation Catheter

# CROSS WITH CONFIDENCE

The Sapphire® II PRO is specifically engineered for crossing difficult lesions and tracking tortuous anatomy.

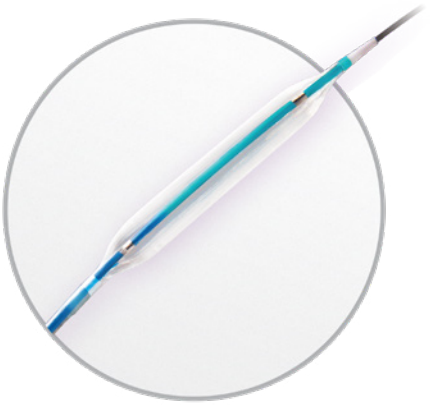
- **Featuring the first and only 1.0 mm balloon with FDA clearance****
- **Excellent pushability**
- **Robust material**
- **Ultimate crossability**

**Sub-zero tip technology for smooth lesion entry**



The well-balanced, sub-zero tapered tip has an ultra-low profile and provides smooth entry through the tightest lesions.

## SAPPHIRE® NC 24 NON-COMPLIANT PTCA CATHETER*



SAPPHIRE® NC 24
Coronary Dilatation Catheter

# CONTROLLED COMPLIANCE

- **Highest RBP on the US market at 24 atm****
- **High-pressure tolerance and recrossability**
- **Controlled balloon compliance** for the most accurate sizing and stent optimization

***Manufactured by:**

OrbusNeich™
*Pioneers in life-changing technologies*

** *at time of publication*

DIAMONDBACK 360®
CORONARY ORBITAL ATHERECTOMY SYSTEM

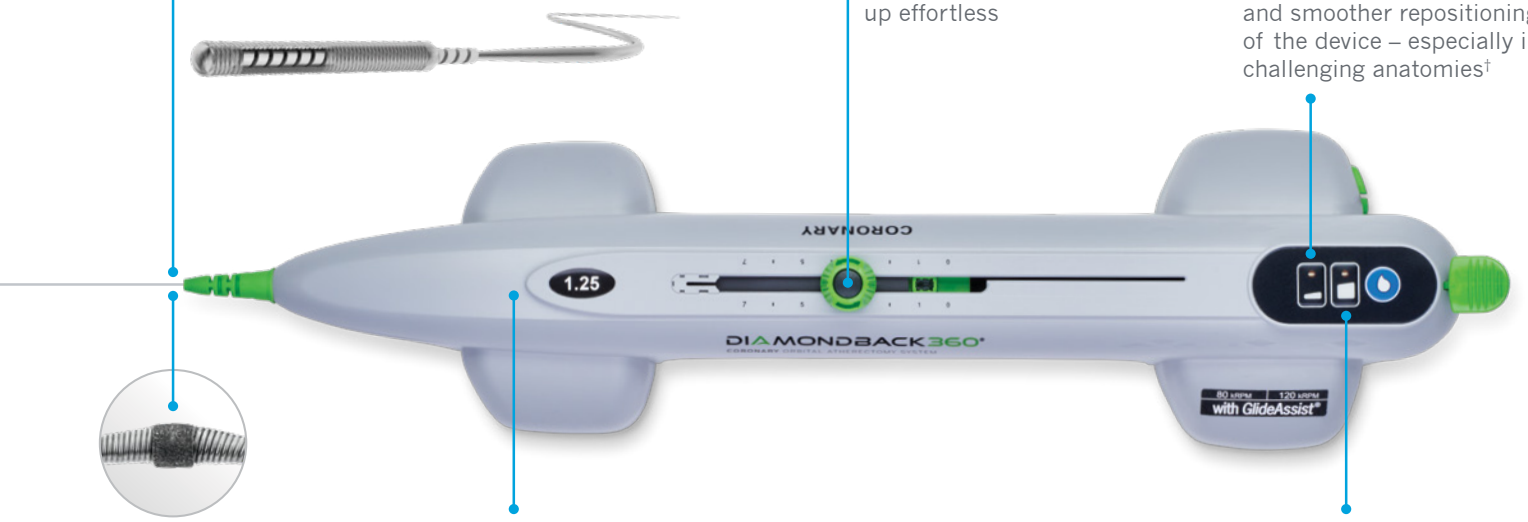
# SEVERE CALCIUM ONE SOLUTION

The Diamondback 360® Orbital Atherectomy System is your single solution for severely calcified coronary artery disease, with proven success in challenging anatomies and lesions.

**VIPERWIRE ADVANCE® NITINOL**
coronary guidewire with flex tip[1]

**ONE-TOUCH START BUTTON**
makes device power up effortless

**GLIDEASSIST®**
Easier tracking and removal and smoother repositioning of the device – especially in challenging anatomies†




**SINGLE 1.25 MM CROWN**
treats vessels 2.5 to 4.0

**ELECTRIC-POWERED HANDLE**
allows two-minute set up and provides efficient torque transfer to the shaft and crown

**TWO CONVENIENT SPEED CONTROLS**
allow for quick speed adjustments within the sterile field

## DUAL ACTION

Uniquely designed to enable simultaneous modification of both intimal and medial calcium for optimal stent delivery, expansion, and apposition in severely calcified lesions.

## VERSATILE

Treat a broad range of challenging cases, including the most severely calcified lesions, with under 2-minute setup and predictable procedure times.

## PROVEN

Extensively studied, with over 145,000 patients treated, demonstrated to perform effectively in the treatment of severely calcified lesions.

† *as compared to use of Diamondback without GlideAssist*

TO SEE ACCESSORIES, SCAN THE QR CODE

# PRODUCT ORDERING INFORMATION

DIAMONDBACK 360®
CORONARY ORBITAL ATHERECTOMY SYSTEM

## DIAMONDBACK 360® ORBITAL ATHERECTOMY SYSTEM

| DIAMONDBACK 360® ORBITAL ATHERECTOMY DEVICE | | | |
|---|---|---|---|
| MODEL NUMBER | CROWN SIZE | SHAFT LENGTH | QUANTITY |
| DBEC-125 | 1.25 mm Classic | 135 cm | 1 each |

| VIPERWIRE ADVANCE® CORONARY GUIDE WIRES | | | |
|---|---|---|---|
| MODEL NUMBER | SIZE | WIRE LENGTH | QUANTITY |
| GWC-12325LG-FLP | .012”/0.014” Tip | 325 cm | 5 per box |
| GWC-12325LG-FT | .012”/0.014” Flex Tip | 325 cm | 5 per box |

| VIPERSLIDE® LUBRICANT | | |
|---|---|---|
| MODEL NUMBER | DESCRIPTION | QUANTITY |
| VPR-SLD2 | 100 mL Package | 10 bags per box |

| OAS PUMP | | |
|---|---|---|
| MODEL NUMBER | DESCRIPTION | QUANTITY |
| SIP-3000 | OAS Pump | 1 each |

SAPPHIRE® NC 24
Coronary Dilatation Catheter

## SAPPHIRE® NC24 NON-COMPLIANT PTCA CATHETER*

| BALLOON DIAMETER (mm) | BALLOON WORKING LENGTH (mm) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 8 | 10 | 12 | 15 | 18 | 22 | 26 |
| 2.00 | 492000812 | 492001012 | 492001212 | 492001512 | 492001812 | 492002212 | 492002612 |
| 2.25 | 492250812 | 492251012 | 492251212 | 492251512 | 492251812 | 492252212 | 492252612 |
| 2.50 | 492500812 | 492501012 | 492501212 | 492501512 | 492501812 | 492502212 | 492502612 |
| 2.75 | 492750812 | 492751012 | 492751212 | 492751512 | 492751812 | 492752212 | 492752612 |
| 3.00 | 493000812 | 493001012 | 493001212 | 493001512 | 493001812 | 493002212 | 493002612 |
| 3.25 | 493250812 | 493251012 | 493251212 | 493251512 | 493251812 | 493252212 | 493252612 |
| 3.50 | 493500812 | 493501012 | 493501212 | 493501512 | 493501812 | 493502212 | 493502612 |
| 3.75 | 493750812 | 493751012 | 493751212 | 493751512 | 493751812 | 493752212 | 493752612 |
| 4.00 | 494000812 | 494001012 | 494001212 | 494001512 | 494001812 | 494002212 | 494002612 |
| 4.50 | 494500812 | 494501012 | 494501212 | 494501512 | 494501812 | 494502212 | 494502612 |
| 5.00 | 495000812 | 495001012 | 495001212 | 495001512 | 495001812 | 495002212 | 495002612 |

SAPPHIRE® II PRO DILATATION CATHETER*

| BALLOON DIAMETER (mm) | | BALLOON WORKING LENGTH (mm) | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 5 | 8 | 10 | 12 | 15 | 20 | 30 |
| OTW | 1.00 | 501000512 | 501000812 | 501001012 | – | 501001512 | – | – |
| Rx | 1.00 | 210-053-5UU | 210-083-5UU | 210-103-5UU | – | 210-153-5UU | – | – |
| | 1.25 | 212-053-5UU | 212-083-5UU | 212-103-5UU | – | 212-153-5UU | – | – |
| | 1.50 | – | – | 215-103-5UU | 215-123-5UU | 215-153-5UU | 215-203-5UU | – |
| | 1.75 | – | – | 217-103-5UU | – | 217-153-5UU | 217-203-5UU | – |
| | 2.00 | – | – | 220-103-5UU | 220-123-5UU | 220-153-5UU | 220-203-5UU | – |
| | 2.25 | – | – | 222-103-5UU | – | 222-153-5UU | 222-203-5UU | – |
| | 2.50 | – | – | 225-103-5UU | 225-123-5UU | 225-153-5UU | 225-203-5UU | 225-303-5UU |
| | 2.75 | – | – | 227-103-5UU | – | 227-153-5UU | 227-203-5UU | – |
| | 3.00 | – | – | 230-103-5UU | 230-123-5UU | 230-153-5UU | 230-203-5UU | 230-303-5UU |
| | 3.25 | – | – | 232-103-5UU | – | 232-153-5UU | 232-203-5UU | – |
| | 3.50 | – | – | 235-103-5UU | – | 235-153-5UU | 235-203-5UU | 235-303-5UU |
| | 4.00 | – | – | 240-103-5UU | – | 240-153-5UU | 240-203-5UU | – |

SCOREFLEX® NC SCORING PTCA CATHETER*

| BALLOON DIAMETER (mm) | BALLOON WORKING LENGTH (mm) | | |
|---|---|---|---|
| | 10 | 15 | 20 |
| 1.75 | 617-104-1U | 617-154-1U | 617-204-1U |
| 2.00 | 620-104-1U | 620-154-1U | 620-204-1U |
| 2.25 | 622-104-1U | 622-154-1U | 622-204-1U |
| 2.50 | 625-104-1U | 625-154-1U | 625-204-1U |
| 2.75 | 627-104-1U | 627-154-1U | 627-204-1U |
| 3.00 | 630-104-1U | 630-154-1U | 630-204-1U |
| 3.50 | 635-104-1U | 635-154-1U | 635-204-1U |
| 4.00 | 640-104-1U | 640-154-1U | 640-204-1U |

TELEPORT® MICROCATHETER*

| MODEL NUMBER | PROFILE | LENGTH |
|---|---|---|
| 220-13-1000U | 2.0 Fr | 135 cm |
| 220-15-1000U | 2.0 Fr | 150 cm |
| 221-13-1000U | 2.1 Fr | 135 cm |
| 221-15-1000U | 2.1 Fr | 150 cm |

1. CSI data on file: based on cadaver atheroschlerotic lesions, porcine coronary lesions and graphite block test models.

**Indication:** The DIAMONDBACK 360® Coronary Orbital Atherectomy Systems (OAS) are percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions. **Contraindications:** The OAS are contraindicated when the VIPERWIRE® guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS are contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children. **Warnings/Precautions:** Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS were only evaluated in severely calcified lesions, A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25% has not been evaluated. See the Instructions for Use before performing DIAMONDBACK 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information call CSI at 1-877-274-0901 and/or consult CSI's website at **www.csi360.com**. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

**Indication:** The Scoreflex NC Scoring PTCA Catheter is indicated for balloon dilatation of a de novo stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion, in-stent restenosis. **Contraindications:** The use of the Scoreflex NC Scoring PTCA Catheter is contraindicated in the following patient types: Patients with an unprotected left main coronary artery; Patients with coronary artery spasm in the absence of a significant stenosis. **Warnings:** When using this type of device, the following warnings should be observed: To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Applying excessive force to the catheter can result in tip or catheter breakage, catheter kink, or balloon separation. Do not twist the catheter shaft in excess of 180 degrees when the tip is constrained. Balloon pressure should not exceed the rated burst pressure (RBP) indicated on the package. **Precautions:** Never advance the Scoreflex NC Scoring PTCA Catheter without the guidewire extending from the tip. Do not use oil-based contrast medium, organic solvents or alcohols; there is a possibility of catheter leak, damage, or lubrication loss. The balloon deflation time has been established as 15 seconds based on in vitro bench testing results. Do not reinsert the PTCA catheter into the coil dispenser after procedural use. Discard all disposable devices used during this procedure per local requirements for medical device waste disposal. **Caution:** Federal law (USA) restricts this device to the sale by or on the order of a physician.



**Distributed by:**

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