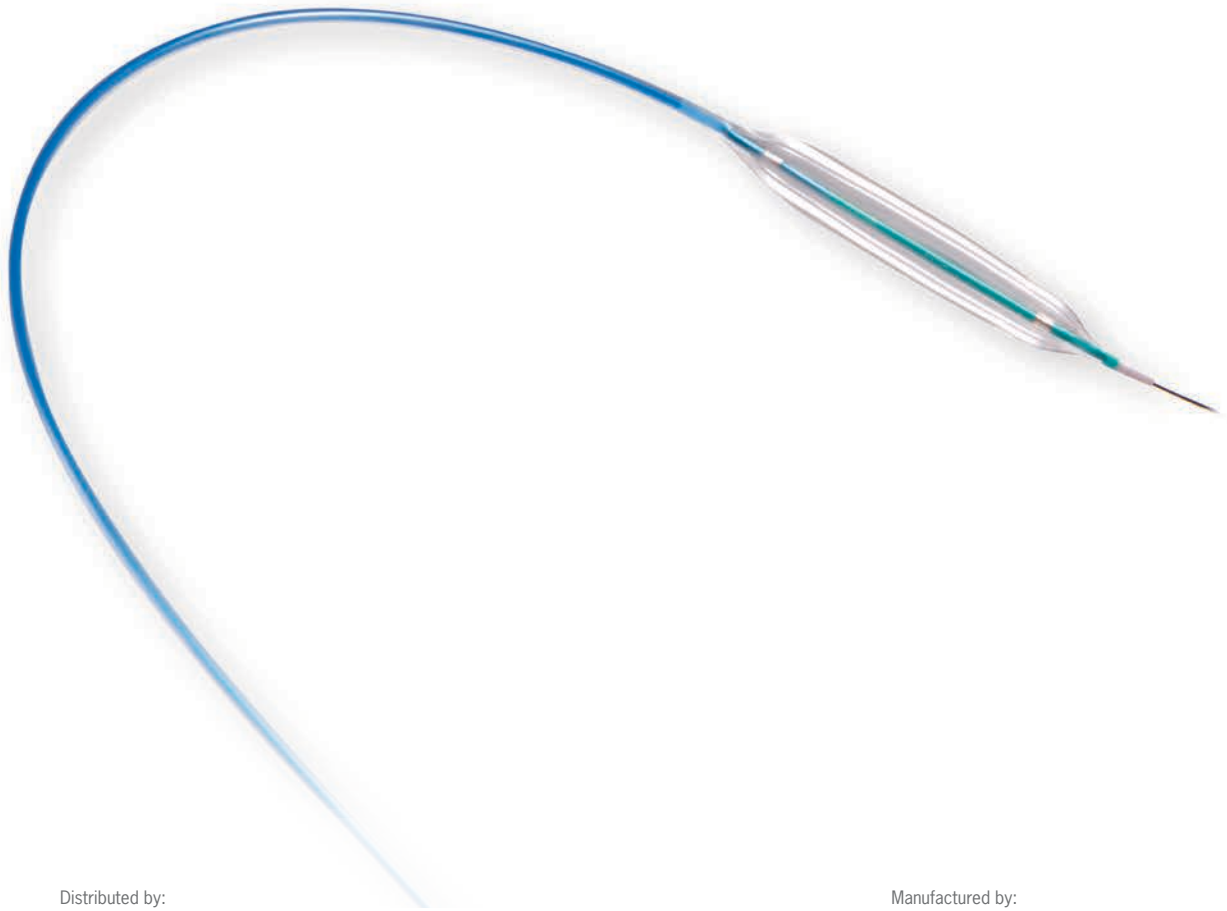
# NC SAPPHIRE®

Coronary Dilatation Catheter

# 24

## *Engineered for true controlled compliance, high pressure tolerance and re-crossability*



Introducing

# 24 atm RBP

Distributed by:

CSI® | CARDIOVASCULAR SYSTEMS, INC.

Manufactured by:

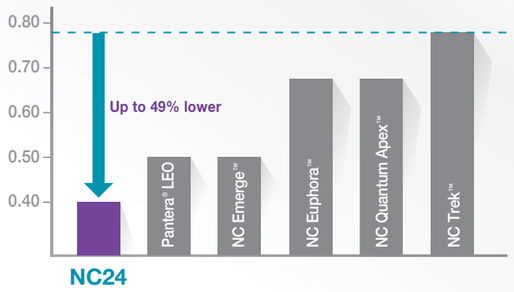
OrbusNeich®

*Pioneers in life-changing technologies*

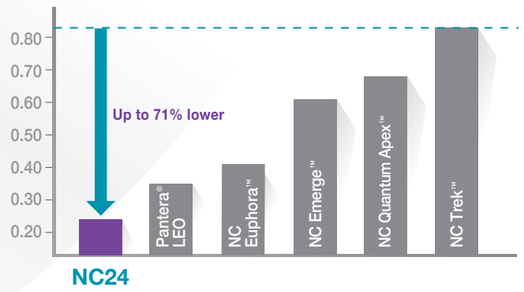
# **Sapphire® NC24** offers a complete balance for **true controlled compliance, high pressure tolerance** and **re-crossability**

**Controlled Balloon Compliance** for most accurate sizing and stent optimization

Lowest % Circumferential Growth* (Nom to RBP)

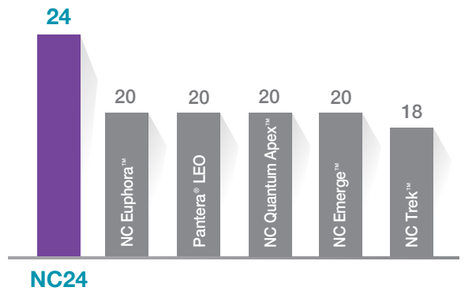



Lowest % Longitudinal Growth* (Nom to RBP)



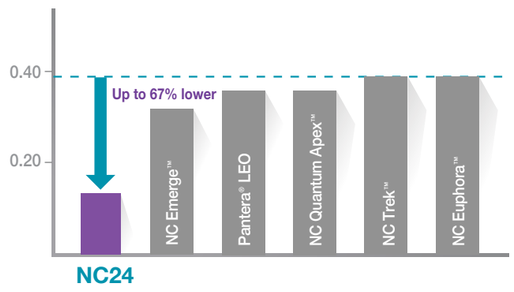

**Highest RBP** on the market at **24 atm**

Rated Burst Pressure* (atm)



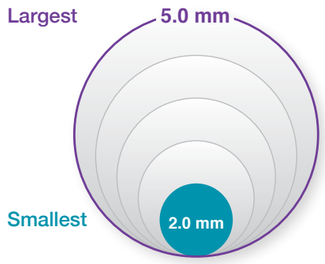

Enhanced balloon design for **minimal dog-bone effect**

Balloon Diameter Variance (BDV) Index*



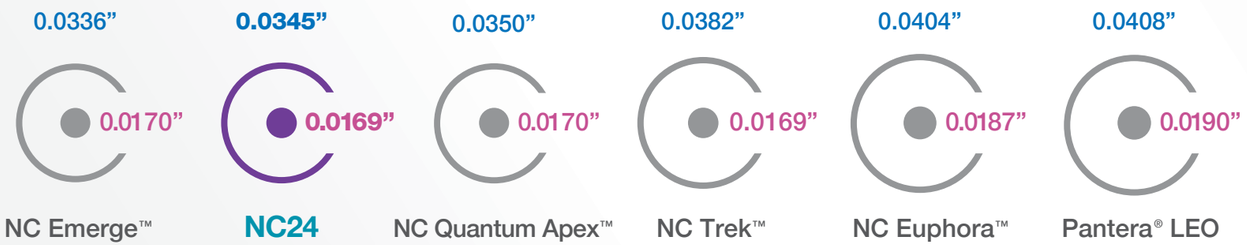

Diameter range of 2.0 to 5.0 mm and new balloon lengths of **22 and 26 mm** for broader range of vessel treatment

Broad range of balloon diameters and working lengths





## The Most Competitive **Crossing** and **Tip Entry** Profile* (Ø 3.0 mm)




*OrbusNeich bench data on file and results are available in the public domain. Bench testing results may not be indicative of clinical performance.

## Technical Specifications

| | |
|---|---|
| **Proximal Shaft** | 2.1 Fr |
| **Distal Shaft** | 2.36 - 2.7 Fr (Ø2.0 - 5.0 mm) |
| **Catheter Working Length** | 140 cm |
| **Tip Length** | 1.5 mm - 2.5 mm (Ø2.0 - 5.0 mm) |
| **Marker Bands** | 2 (Ø2.0 - 5.0 mm) |
| **Balloon Folds** | 3 (Ø2.0 - 3.0 mm), 5 (Ø3.25 - 5.0 mm) |
| **Coating** | • Hydrophilic (tip to guidewire exit port)<br>• Hydrophobic (guidewire lumen) |
| **Nominal Pressure** | 14 atm |
| **Rated Burst Pressure** | 24 atm (Ø2.0 - 3.5 mm), 22 atm (Ø3.75 - 4.0 mm), 20 atm (Ø4.5 - 5.0 mm) |

# Ordering Information

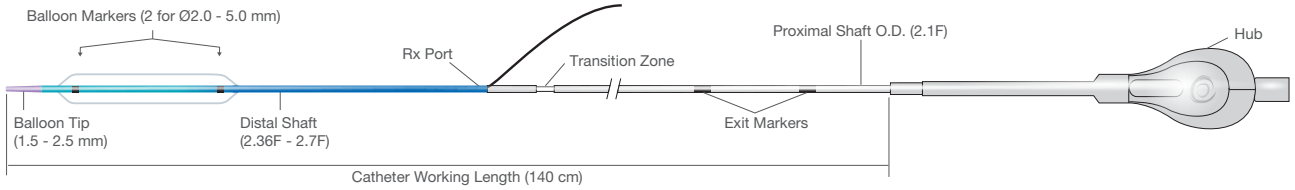
## FDA Cleared Manufacturing Catalogue Numbers

| Balloon Diameter (mm) | Balloon Working Length (mm) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 8 | 10 | 12 | 15 | 18 | 22 | 26 |
| 2.0 | 492000812 | 492001012 | 492001212 | 492001512 | 492001812 | 492002212 | 492002612 |
| 2.25 | 492250812 | 492251012 | 492251212 | 492251512 | 492251812 | 492252212 | 492252612 |
| 2.5 | 492500812 | 492501012 | 492501212 | 492501512 | 492501812 | 492502212 | 492502612 |
| 2.75 | 492750812 | 492751012 | 492751212 | 492751512 | 492751812 | 492752212 | 492752612 |
| 3.0 | 493000812 | 493001012 | 493001212 | 493001512 | 493001812 | 493002212 | 493002612 |
| 3.25 | 493250812 | 493251012 | 493251212 | 493251512 | 493251812 | 493252212 | 493252612 |
| 3.5 | 493500812 | 493501012 | 493501212 | 493501512 | 493501812 | 493502212 | 493502612 |
| 3.75 | 493750812 | 493751012 | 493751212 | 493751512 | 493751812 | 493752212 | 493752612 |
| 4.0 | 494000812 | 494001012 | 494001212 | 494001512 | 494001812 | 494002212 | 494002612 |
| 4.5 | 494500812 | 494501012 | 494501212 | 494501512 | 494501812 | 494502212 | 494502612 |
| 5.0 | 495000812 | 495001012 | 495001212 | 495001512 | 495001812 | 495002212 | 495002612 |

# Compliance Chart

| Pressure (atm) | Balloon Diameter (mm) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2.0 | 2.25 | 2.5 | 2.75 | 3.0 | 3.25 | 3.5 | 3.75 | 4.0 | 4.5 | 5.0 |
| 6 | 1.93 | 2.17 | 2.42 | 2.66 | 2.90 | 3.13 | 3.38 | 3.60 | 3.86 | 4.31 | 4.80 |
| 8 | 1.95 | 2.19 | 2.44 | 2.68 | 2.93 | 3.16 | 3.41 | 3.64 | 3.90 | 4.36 | 4.85 |
| 10 | 1.96 | 2.21 | 2.46 | 2.70 | 2.95 | 3.19 | 3.44 | 3.68 | 3.93 | 4.41 | 4.90 |
| 12 | 1.98 | 2.23 | 2.48 | 2.73 | 2.98 | 3.22 | 3.47 | 3.71 | 3.97 | 4.45 | 4.95 |
| 14 NOM* | 2.00 | 2.25 | 2.50 | 2.75 | 3.00 | 3.25 | 3.50 | 3.75 | 4.00 | 4.50 | 5.00 |
| 16 | 2.02 | 2.27 | 2.52 | 2.77 | 3.02 | 3.28 | 3.53 | 3.79 | 4.03 | 4.55 | 5.05 |
| 18 | 2.04 | 2.29 | 2.54 | 2.80 | 3.05 | 3.31 | 3.56 | 3.82 | 4.07 | 4.59 | 5.10 |
| 20 (RBP)** | 2.05 | 2.31 | 2.56 | 2.82 | 3.07 | 3.34 | 3.59 | 3.86 | 4.10 | 4.64 | 5.15 |
| 22 (RBP)** | 2.07 | 2.33 | 2.58 | 2.84 | 3.10 | 3.37 | 3.62 | 3.90 | 4.14 | 4.69 | 5.20 |
| 24 (RBP)** | 2.09 | 2.35 | 2.60 | 2.86 | 3.12 | 3.40 | 3.65 | 3.93 | 4.17 | 4.73 | 5.25 |
| 26 | 2.11 | 2.37 | 2.62 | 2.89 | 3.15 | 3.43 | 3.67 | 3.97 | 4.21 | - | - |
| 28 | 2.12 | 2.39 | 2.64 | 2.91 | 3.17 | 3.46 | 3.70 | - | - | - | - |

* Nominal Pressure. The nominal in vitro device specifications do not take into account any lesion resistance.
** Rated Burst Pressure. Do not exceed RBP




**For more information, please contact your local CSI representative or call customer service at 1-877-274-0901.**

**INDICATIONS:** The Sapphire NC 24 Coronary Dilatation Catheter is indicated for balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction and post-delivery expansion of balloon expandable coronary stents. **CONTRAINDICATIONS:** The use of the Sapphire NC 24 Coronary Dilatation Catheter is contraindicated in patients with an unprotected left main coronary artery and 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. PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk. 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. Balloon pressure should not exceed the Rated Burst Pressure (RBP) indicated on the package. The RBP is based on results of in vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization. PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. This device is designed and intended for single use only. DO NOT reprocess, re-sterilize and/or reuse. Reuse of single-use devices creates a potential risk of patient or user infections. Reuse may lead to impairment of functional performance. Infections and/or limited performance of the device may lead to injury, illness or death of the patient. **PRECAUTIONS:** Do not re-insert the PTCA catheter into the coil dispenser after procedural use. Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is being used. The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty. During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. After the procedure, anticoagulant therapy should be continued for a period of time as determined by the physician. The design and construction of these catheters do not provide the user with distal pressure monitoring capability. Discard all disposable devices used during this procedure per local requirements for medical device waste disposal. Do not use oil-based contrast medium, organic solvents or alcohols; there is a possibility of catheter leak, damage or lubrication loss. Use with caution for procedures involving calcified lesions due to the abrasive nature of these lesions.

**CAUTION:** Federal Law (USA) restricts the sale of these devices to sale by, or on the order of, a physician.



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