NC EMERGE™
PTCA Dilatation Catheter

Select from these topics
- Overview
- Importance of Post-dilatation
- Economic Benefits of Post-dilatation
- Design Overview
- Performance Overview

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority product registrations. Information not intended for use or distribution in France.
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For decades, we have worked together to define the future. By bringing technology and performance together, we continue our commitment to evolving balloon catheter technology.

Experience the enhanced performance of NC Emerge PTCA Dilatation Catheter
Many DES Clinical Trials Require Pre and Post-dilatation to Optimize Stent-Deployment

**STent Optimization (STOP) Study:** The Impact of Routine and Intravascular Ultrasound-Guided High-Pressure Post-dilatation After Drug-Eluting Stent Deployment

**Objectives:** Drug-eluting stent (DES) implantations with low final cross-sectional area (CSA) are associated with adverse clinical outcomes. However, there is no guidance to facilitate optimal stent deployment (SD). The stent optimization (STOP) study was performed to assess DES routine post-dilatation (PD) following implantation with intravascular ultrasound (IVUS) guidance.

- Single-center prospective study (48 patients)
- All DES deployed at 16 atm for 20 seconds and underwent routine non-compliant balloon PD (min 20 atm for 10 seconds)
- IVUS performed after SD (blinded) and PD (unblinded) measured CSA at 4 stent reference points
- Optimal deployment defined as distal and proximal stent CSA ≥ 60% distal and proximal reference CSA; mid and minimum stent CSA ≥ 70% of distal reference CSA. All per-protocol criteria were required to define optimal SD
- Sub-optimally deployed DES underwent further PD with IVUS guidance (IVPD)
Many DES Clinical Trials Require Pre and Post-dilatation to Optimize Stent-Deployment

**CONCLUSION:**

DES deployment may lead to sub-optimal deployment, which can be optimized by routine post-dilatation. IVUS identifies DES implantations that benefit from further PD. Optimizing final DES-CSA may have long-term clinical benefits, although a randomized study is required.
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Difference Between Compliant and Non-compliant Balloons During High-pressure Inflation²

- Semi-compliant balloon demonstrates a “dog-bone” effect at the edge of the cylinder that can damage the vessel wall in vivo
- Incidence of incomplete stent deployment ranges from 20% to 30% of cases
- Adjunctive high-pressure balloon dilation is necessary to improve the minimum stent area and the uniform volumetric stent expansion

Bench test showing the different profile between a non-compliant balloon (A) and a semi-compliant stent delivery balloon (B) during high-pressure (> 14 atm) inflation.

Bench test results may not necessarily be indicative of clinical performance.

References

Bench test showing the different profile between a non-compliant balloon (A) and a semi-compliant stent delivery balloon (B) during high-pressure (> 14 atm) inflation.

Bench test results may not necessarily be indicative of clinical performance.
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Optimizing Stent Deployment Is a Key Element to Obtain Favorable Immediate and Long-term Results

Under angiography, the stent appears fully expanded/apposed
Using IVUS, the stent demonstrates sub-optimal expansion/apposition

- Incomplete apposition may contribute to thrombosis formation and SATs
- Stent under-expansion may increase risk for restenosis
- Post-dilatation reduces target vessel revascularization (TVR)
- Uniform stent apposition facilitates uniform drug absorption into endothelial tissue

Results from case studies are not predictive of results in other cases. Results may vary.

[References]
Post-dilatation has been shown to reduce complications

- Post-dilatation reduces target vessel revascularization (TVR)\(^7\)
- NC Emerge improves compliance by 25% over the market leading NC Quantum Apex™ PTCA Dilatation Catheter*
Select from these topics

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Post-dilatation Can Help Reduce Complications and Costs

Help ensure total stent expansion the first time

- Uniform stent apposition facilitates uniform drug absorption into endothelial tissue$^{3,4,5,6}$
Post-dilatation Can Help Reduce Complications and Costs

Help reduce costs associated with complications; up to $11,100 per patient\(^8\)

• Incomplete apposition may contribute to thrombosis formation and SATs, and increase risk of restenosis\(^3,4\)
NC EMERGE™
PTCA Dilatation Catheter

NC Emerge is Boston Scientific's Most Advanced PTCA Catheter

Select from these topics
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NC Emerge is Boston Scientific's Most Advanced PTCA Catheter

- Over-the-inner tip design
- Ultra-low lesion entry profile
- Platinum iridium marker bands
- Reduced crossing profile
- Non-compliant balloon material
- Hydrophilic coating
- Reduced shaft profile
- Slope™ outer shaft
- Bi-Segment™ inner shaft design
- Platinum iridium marker bands

Compared to NC Quantum Apex™ by Boston Scientific Corp (n = 15). Bench test results may not necessarily be indicative of clinical performance.
NC EMERGE™
PTCA Dilatation Catheter

NC Emerge is Boston Scientific's Most Advanced PTCA Catheter

Ultra-low lesion entry profile

- 0.017” (0.43 mm) Lesion entry profile
- Improves overall flexibility and performance in tortuous anatomy
- 3% Balloon growth

Compared to NC Quantum Apex™ by Boston Scientific Corp (n = 15). Bench test results may not necessarily be indicative of clinical performance.
NC EMERGE™
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Over-the-inner tip design

- Outer tip material rides over the inner shaft
- Designed to improve overall flexibility and tip performance
- Short tip designed to lessen tip catch occurrence and offer greater control

Compared to NC Quantum Apex™ by Boston Scientific Corp (n = 15). Bench test results may not necessarily be indicative of clinical performance.
NC EMERGE™
PTCA Dilatation Catheter

NC Emerge is Boston Scientific's Most Advanced PTCA Catheter

Non-compliant balloon material

- Designed for less balloon growth and increased rated burst pressure
- Unique blend of balloon materials provides excellent re-wrap

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NC Emerge is Boston Scientific's Most Advanced PTCA Catheter

Platinum iridium marker bands

- Provides optimal radiopacity and excellent visibility

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Bi-Segment™ inner shaft design
- Designed for maximum deliverability
- Both stiff and flexible segments to enhance pushability and trackability

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Reduced shaft profile

- Designed for exceptional simultaneous use performance
- Allows for use of two Monorail™ catheters in a 6 F guide catheter and two Over-the-Wire catheters in an 8 F guide catheter‡

‡ Bench and preclinical testing has shown that one 4.00 x 30 mm (or smaller) and one 3.25 x 20 mm (or smaller) Monorail balloon catheters can be inserted simultaneously into a 6 F (minimum 0.070 in ID) guide catheter. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical trial. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter. Testing completed by Boston Scientific Corp. Data on file.

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Hydrophilic coating

- Reduced frictional force on the catheter shaft

NC Emerge is Boston Scientific's Most Advanced PTCA Catheter

All NC Emerge devices are coated with Boston Scientific's proprietary ZGlide™ hydrophilic coating. The NC Emerge coatings are identical to the coatings of the predicate Emerge balloons.
Slope™ outer shaft

- One piece outer shaft provides a seamless transition
- Designed to optimize pushability

NC Emerge is Boston Scientific's Most Advanced PTCA Catheter

 Compared to NC Quantum Apex™ by Boston Scientific Corp (n = 15). Bench test results may not necessarily be indicative of clinical performance.
NC EMERGE™
PTCA Dilatation Catheter

NC Emerge Offers Improved Performance

**Improved Balloon Performance**
- 25% lower growth*
- Maintain burst pressure
- Reduced balloon overhang**

**Lower Profiles**
- Improved simultaneous use**
- Pre-dilatation balloon profiles in a post-dilatation balloon

**Additional Sizes**
- 5.5 mm and 6.0 mm
- Broadest matrix of sizes

**Improved Deliverability**
- Better mid-balloon profile

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* Compliance Data taken from compliance charts for each reported balloon catheter.

** Testing completed against NC Quantum Apex by Boston Scientific Corp (n = 15). Bench test results may not necessarily be indicative of clinical performance.

** Compared to NC Quantum Apex. Bench and preclinical testing has shown that one 4.00 x 30 mm (or smaller) and one 3.25 x 20 mm (or smaller) Monorail balloon catheters can be inserted simultaneously into a 6 F (minimum 0.070 in ID) guide catheter. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical trial. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter.
NC Emerge - Balloon Compliance Improvement

<table>
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<tr>
<th>Balloon Catheter</th>
<th>Growth (in/mm)</th>
<th>Growth (%)</th>
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<tr>
<td>NC Emerge</td>
<td>0.09” (2.29 mm)</td>
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<tr>
<td>NC Quantum Apex™</td>
<td>0.12” (3.05 mm)</td>
<td>4.0%</td>
<td>25%</td>
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<tr>
<td>NC Euphora™</td>
<td>0.12” (3.05 mm)</td>
<td>4.0%</td>
<td>25%</td>
</tr>
<tr>
<td>NC Trek™</td>
<td>0.14” (3.56 mm)</td>
<td>4.7%</td>
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<tr>
<td>Quantum Maverick™</td>
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<td>10%</td>
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</table>

†† Compliance data taken from compliance charts for each reported balloon catheter. Data on file.
NC EMERGE™
PTCA Dilatation Catheter

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NC Emerge Offers Improved Profiles for Simultaneous Use

<table>
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<tr>
<th>Monorail™</th>
<th>Balloon Diameter</th>
<th>Balloon Length</th>
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</table>

Any 2 Green Compatible in a 6 F Guide Catheter
Any 1 Green and 1 Red Compatible in a 6 F Guide Catheter
No 2 Red are Compatible for Simultaneous Use

Bench and preclinical testing has shown that one 4.00 x 30 mm (or smaller) and one 3.25 x 20 mm (or smaller) Monorail balloon catheters can be inserted simultaneously into a 6 F (minimum 0.070 in ID) guide catheter. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical trial. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter. Testing completed by Boston Scientific Corp. Data on file.
NC EMERGE™
PTCA Dilatation Catheter

Select from these topics
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Rated Burst Pressure

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</table>

2027 kPa (20 atm) RBP
1824 kPa (18 atm) RBP

Nominal is 12 atm for all sizes

Despite the lower mid-balloon profile we were able to keep the same RBP
See Directions for Use Versus NC Quantum Apex™
**NC EMERGE™**
PTCA Dilatation Catheter

NC Emerge Provides the Largest\(^1\) Matrix on the Latest POBA Platform

<table>
<thead>
<tr>
<th>Balloon Diameter</th>
<th>6 mm</th>
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</tbody>
</table>

Same size offering as NC Quantum Apex™

- New Sizes
- Same as Maverick™ XL on NC Emerge Platform

\(^1\) Versus NC Quantum Apex™
NC EMERGE™
PTCA Dilatation Catheter

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NC Emerge Compliance Chart

<table>
<thead>
<tr>
<th>Pressure</th>
<th>Balloon Size (in mm)</th>
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<tbody>
<tr>
<td>atm</td>
<td>kPa 2.00 2.25 2.50 2.75 3.00 3.25 3.50 3.75 4.00 4.50 5.00 5.50 6.00</td>
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<td>20.0 2027</td>
<td>2.08†† 2.33†† 2.61†† 2.83†† 3.13†† 3.38†† 3.63†† 3.87†† 4.21††</td>
</tr>
</tbody>
</table>

††Rated Burst Pressure and Stent Rated Burst Pressure. DO NOT EXCEED.
See Directions for Use
References


NC Emerge Monorail™ and Over-the-Wire

**CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information contained herein is for distribution outside the U.S., France & Japan only. Illustrations for information purposes—not indicative of actual size or clinical outcome.

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Reduced crossing profile†

- 0.031" (0.787 mm) Crossing profile

†Crossing profile is defined as the maximum diameter found between the proximal end of the balloon and the distal tip of the catheter.

Compared to NC Quantum Apex™ by Boston Scientific Corp (n = 15). Bench test results may not necessarily be indicative of clinical performance.