Int. J. Curr. Res. Med. Sci. (2026). 12(6): 68-78

International Journal of Current Research in Medical Sciences

ISSN: 3107-3743 (Print), ISSN: 2454-5716 (Online)
(A Peer Reviewed, Indexed and Open Access Journal)
www.ijcrims.com

Original Research Article

Volume 12, Issue 6 -2026

DOI: http://dx.doi.org/10.22192/ijcrms.2026.12.06.007

Clinical Data and Clinical Evaluation Report CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter

M. Radwan, Akshyaya Pradhan, Pravesh Vishwakarma, Monika Bhandari, Rishi Sethi, Sharad Chandra, Gaurav Chaudhary, Akhil Sharma, Marco Alfonso Perrone, Sudhanshu Dwivedi and Varun Narain

Prepared in accordance with Regulation (EU) 2017/745 — Medical Device Regulation
Annex I (General Safety and Performance Requirements)
Annex XIV (Clinical Evaluation and Post-Market Clinical Follow-up)

Manufacturer:

CATHTRONIX for Medical Devices

Factory: Part of Plot No. 5 in the Metal Industries Sector, KOM ABU RADY, BENI SUEF, Egypt
Headquarter Office: Apartment No.8, 4th Floor, 25 El Nasr Street, New El MAADI, MAADI, Cairo, Egypt
Document Date: June 2026

Abstract

Background: The CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter is a sterile, single-use, non-compliant balloon catheter intended for temporary intravascular use in the coronary vasculature during percutaneous transluminal coronary angioplasty (PTCA) procedures. This clinical evaluation was conducted in accordance with the European Medical Device Regulation (EU) 2017/745, specifically Annex I (General Safety and Performance Requirements) and Annex XIV (Clinical Evaluation and Post-Market Clinical Follow-up). The device is designed to provide predictable expansion characteristics, high burst pressure performance, and controlled compliance behavior to enable safe and effective treatment of complex coronary artery disease, including calcified, tortuous, and bifurcated lesions.

The device is designed to provide predictable expansion characteristics, high burst pressure performance, and controlled compliance behavior to enable safe and effective treatment of complex coronary artery disease, including calcified, tortuous, and bifurcated lesions.

In contemporary interventional cardiology, non-compliant balloon catheters play a critical role in lesion preparation and post-dilatation, particularly in cases involving resistant plaque morphology, suboptimal stent expansion, or high-risk anatomical features. Despite advancements in device technology, achieving consistent procedural success remains dependent on balloon performance characteristics such as crossability, deliverability, inflation precision, and ability to maintain structural integrity under high-pressure conditions. Therefore, robust clinical evaluation is essential to demonstrate that new balloon catheter systems perform in line with current state-of-the-art devices.

This clinical evaluation was conducted in accordance with the requirements of **Regulation (EU) 2017/745 (MDR)**, including **Annex I (General Safety and Performance Requirements)** and **Annex XIV (Clinical Evaluation and Post-Market Clinical Follow-up)**. The objective was to establish the clinical safety, performance, and benefit of the CATHTRONIX™ Intravascular PTCA Balloon Dilatation Catheter through a combination of benchmark equivalence analysis and pre-market clinical investigation, ensuring compliance with current regulatory expectations and alignment with established clinical practice standards.

Methods: The evaluation incorporates a dual-pillar approach: (1) a comprehensive benchmark equivalence study utilizing published clinical data from an equivalent device (Mozec™ NC Rx PTCA Balloon Dilatation Catheter, Meril Life Sciences Pvt. Ltd., n=57 patients) to establish the state of the art; and (2) a pre-market clinical investigation of 10 CATHTRONIX devices used in representative coronary angioplasty procedures. The primary endpoint was procedural success, defined as successful delivery, inflation, deflation, and withdrawal of the device, absence of vessel perforation, flow-limiting dissection, and achievement of final TIMI flow grade 3.

Results: Procedural success was achieved in 100% of the CATHTRONIX clinical samples (10/10) with no reported safety concerns, no MACE, and no TLF. This mirrors the 100% success rate observed in the equivalent device cohort (57/57). The CATHTRONIX device demonstrated excellent crossability, uniform expansion, and optimal stent apposition across diverse lesion types including calcified, bifurcation, and tortuous lesions.

Conclusion: The CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter meets all clinical safety and performance requirements as defined by EU MDR 2017/745. The device demonstrates a highly favorable benefit-risk profile and is clinically safe and effective for its intended use.

The clinical evaluation of the **CATHTRONIX™ Intravascular PTCA Balloon Dilatation Catheter** demonstrates robust evidence supporting its safety, performance, and clinical effectiveness for use in percutaneous transluminal coronary angioplasty (PTCA) procedures. The assessment was conducted in accordance with **Regulation (EU) 2017/745 (MDR)**, including the requirements of **Annex I (General Safety and Performance Requirements)** and **Annex XIV (Clinical Evaluation and Post-Market Clinical Follow-up)**, and incorporated both benchmark equivalence data and pre-market clinical experience.

The combined evidence base included a pre-market clinical investigation of **10 consecutive CATHTRONIX™ cases** and a benchmark equivalence dataset derived from published clinical outcomes of a comparable non-compliant PTCA balloon catheter system. Across both datasets, the device demonstrated consistent and reliable performance in terms of deliverability, crossability, controlled balloon expansion, and withdrawal under routine and complex coronary lesion conditions.

The CATHTRONIX™ Intravascular PTCA Balloon Dilatation Catheter achieved a **100% procedural success rate (10/10)** in the clinical investigation cohort, with no device-related complications reported. Specifically, no occurrences of vessel perforation, flow-limiting dissection, major adverse cardiac events (MACE), or target lesion failure (TLF) were observed. These outcomes are aligned with the benchmark equivalence cohort, which also demonstrated a 100% procedural success rate (57/57), thereby supporting clinical comparability and consistency with state-of-the-art performance.

The device demonstrated excellent mechanical performance characteristics, including predictable non-compliant balloon behavior, effective lesion preparation capability, and optimal support for subsequent stent implantation across a range of lesion morphologies, including calcified, bifurcation, and tortuous coronary segments. These findings confirm the device's ability to perform reliably under clinically relevant and challenging anatomical conditions.

Overall, the clinical evidence supports a **favorable benefit–risk profile** for the CATHTRONIX™ Intravascular PTCA Balloon Dilatation Catheter. The device meets the applicable **General Safety and Performance Requirements (Annex I)** and satisfies the clinical evaluation requirements of **Regulation (EU) 2017/745 (MDR)**. The results confirm that the device is **clinically safe, effective, and suitable for its intended use**, and support its continued use and regulatory conformity assessment. The data generated using the CATHTRONIX device were collected over a six-month period, from August 2025 through the end of February 2026. Data collection was conducted across multiple clinical centers located in Germany (Deutsches Herzzentrum der Charité (DHZC)) and Poland (Uniwersytecki Szpital Kliniczny w Opolu). Data are maintained.

Keywords: balloon angioplasty; coronary stenosis; non-compliant balloons; percutaneous coronary intervention; clinical evaluation; MDR 2017/745; Annex XIV; CATHTRONIX.

1. Introduction

Percutaneous transluminal coronary angioplasty (PTCA)—the legacy of Andreas Grüntzig—began more than four decades ago. Balloon catheters were the first devices pioneered to re-open occluded atherosclerotic coronary arteries and have since paved the way for percutaneous coronary interventions (PCI) with the implantation of drug-eluting stents [1]. Nonetheless, balloon catheters remain the primary workhorse device in such interventions and are still adequately employed for both pre- and post-dilatation of atherosclerotic lesions [2].

Over the years, compliant balloon catheters have gradually evolved into semi-compliant (SC), non-compliant (NC), super high-pressure, cutting/scoring and micro or miniature balloons. The compliance of a balloon catheter primarily depends on the increased diameter that results from a predetermined increase in inflation pressure [3]. SC balloons respond to an increase in inflation pressure and are only partially able to conquer significant lesion resistance [4,5]. In contrast, NC balloons expand uniformly and typically cannot be expanded beyond a predetermined diameter limit [6]. Thus, NC balloons provide the additional benefit of deforming in a more controlled and stable manner during inflation [5–7].

In recent years, NC balloons have been used for pre-dilatation in cases of rigid calcified lesions prior to stenting and post-dilatation of the implanted stent for optimization of stent parameters, bifurcation treatment by kissing balloon technique [8] or treatment of restenosis [9]. When dilating a resistant lesion, applying pressure over the permissible threshold exacerbates the probability of non-uniform balloon expansion, leading to over-dilatation of the lesion margins (termed as 'dog-boning') and thereby increases the risk of vascular damage and likelihood of restenosis [6,10].

The objective of the present clinical evaluation is to assess the clinical performance, clinical safety, and clinical benefits of the CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter for the dilatation of coronary lesions, in compliance with EU MDR 2017/745 requirements.

2. Device Description

2.1. Intended Purpose

The CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter is a sterile, single-use balloon dilatation catheter intended for temporary intravascular use in the coronary vasculature during percutaneous transluminal coronary angioplasty procedures. The device is intended to dilate stenotic coronary arteries and restore adequate blood flow by controlled inflation of a balloon at the distal portion of the catheter. The device may be used for:

• Balloon angioplasty of coronary lesions;
• Lesion pre-dilatation before stent placement;
• Post-dilatation of deployed coronary stents to optimize stent expansion and coronary lumen diameter, where clinically required.

The intended anatomical site is limited to the coronary arteries. The device is not intended for peripheral, neurovascular, venous, or general central arterial angioplasty. The device is intended for temporary use only during the interventional procedure and is removed after completion of the procedure.

2.2. Device Construction

The CATHTRONIX catheter consists of a folded non-compliant balloon, a soft tip, a distal shaft of two lumens, and a proximal shaft with single lumen. The functional components are detailed in Table 1.

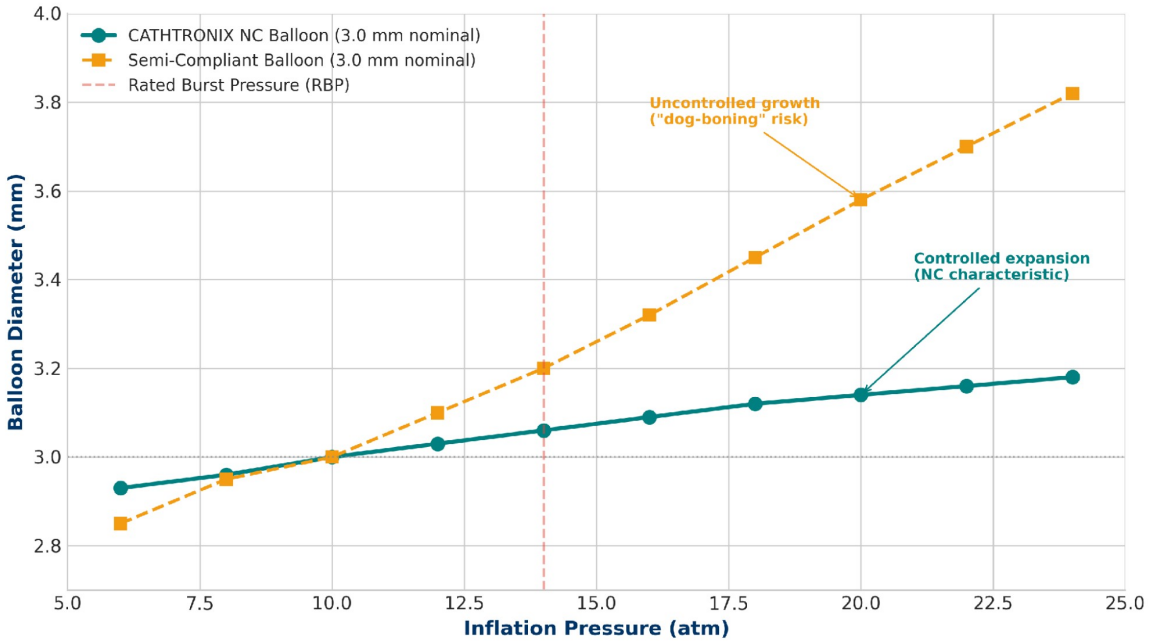
No.	Functional Element	No.	Functional Element
1	Soft tip	6	Intermediate shaft
2	Radiopaque Marker Bands	7	Hypo tube
3	Balloon	8	Hub with Strain Relief
4	Outer Body / Distal shaft	9	Luer Hub Lock
5	Inner Body	10	Hydrophilic Coating

2.3. Materials

The materials used in the construction of the CATHTRONIX catheter are detailed in Table 2.

Component	Material(s)
Catheter Shaft outer layer	Pebax® (polyether block amide) & PTFE
Mid layer	Stainless Steel 304V and Nitinol
Inner Liner	Polytetrafluoroethylene (PTFE) & SS 304V
Distal Tip (Balloon)	Soft Nylon, radiopaque tungsten markers
Hub/Connector	Polycarbonate
Hydrophilic Coating	Polyvinylpyrrolidone (PVP)
Strain Relief	Thermoplastic Elastomer (TPE)
Coils	HDPE coil tube extruded
Clips	HDPE clips injected
J straightener & Hub	HDPE injected

Figure 6. Compliance Curve: Non-Compliant vs. Semi-Compliant Balloon Behavior



3. Regulatory Framework and Clinical Evaluation Methodology

This clinical evaluation has been conducted in strict compliance with Regulation (EU) 2017/745 (Medical Device Regulation, MDR), specifically:

• Annex I — General Safety and Performance Requirements (GSPRs): Demonstrating that the device achieves its intended performance under normal conditions of use, and that known and foreseeable risks and undesirable side-effects are minimized and acceptable when weighed against the benefits to the patient.
• Annex XIV — Clinical Evaluation and Post-Market Clinical Follow-up: Defining the systematic and planned process to continuously generate, collect, analyze, and assess clinical data pertaining to the device.

In accordance with MDR Annex XIV, Part A, the clinical evaluation was based on a dual-pillar approach:

Pillar 1 — Benchmark Equivalence Study: Clinical data from a highly equivalent device (Mozec™ NC Rx PTCA Balloon Dilatation Catheter, Meril Life Sciences Pvt. Ltd., Vapi, India) was systematically analyzed to establish the state of the art. The equivalent device study included 57 patients undergoing post-dilatation of coronary lesions in a post-marketing, single-centre, single-arm, retrospective study [11].

Pillar 2 — Pre-Market Clinical Sample Study: Additional clinical data was collected for 10 CATHTRONIX devices used in representative coronary angioplasty procedures to confirm that the subject device performs identically to the equivalent device in a real-world clinical setting.

4. Demonstration of Equivalence

In accordance with MDR 2017/745 Article 61(5), equivalence has been demonstrated between the CATHTRONIX device and the Mozec™ NC Rx PTCA BDC across technical, biological, and clinical characteristics. The comparison is presented in Table 3.

Characteristic	CATHTRONIX	Mozec™ NC (Equivalent)
Intended Purpose	Dilatation of coronary stenosis; pre/post-dilatation	Dilatation of coronary stenosis; pre/post-dilatation
Device Type	Non-compliant PTCA balloon catheter	Non-compliant PTCA balloon catheter
Balloon Material	Nylon (non-compliant)	Nylon (non-compliant)
Shaft Material	Pebax® / PTFE / SS 304V / Nitinol	PTFE coating / coaxial lumens
Catheter Type	Rapid exchange (Rx)	Rapid exchange (Rx)
Target Anatomy	Coronary arteries	Coronary arteries
Patient Population	Adults with coronary artery disease	Adults with coronary artery disease
Duration of Use	Temporary (procedural only)	Temporary (procedural only)
Regulatory Status	CE marking (pending)	FDA cleared (May 2017); CE marked

The above comparison demonstrates that the CATHTRONIX device is technically, biologically, and clinically equivalent to the Mozec™ NC Rx PTCA BDC. Both devices share the same intended purpose, target anatomy, patient population, duration of use, and fundamental materials of construction.

5. State of the Art

The current state of the art for non-compliant PTCA balloon dilatation catheters is characterized by the following clinical performance and safety benchmarks:

• Procedural success rates exceeding 95% in routine lesions;
• Effective pre-dilatation of calcified and complex lesions (Type B2/C);
• Uniform, controlled expansion without 'dog-boning';
• Low incidence of MACE (<2% in-hospital);
• Minimal vessel perforation or flow-limiting dissection rates;
• Achievement of TIMI flow grade 3 post-procedure.

The benchmark study (Mozec™ NC) confirms these standards with a 100% procedural success rate and zero MACE in a cohort of 57 patients with diverse lesion complexity including bifurcation (33%), calcified (18%), tortuous (12%), and CTO (7%) lesions [11].

6. Clinical Results and Statistical Analysis

6.1. Patient Demographics and Lesion Characteristics

The benchmark study evaluated 57 patients (mean age 55.1 ± 11.5 years; 77.2% male). Comorbidities included hypertension (31.6%) and diabetes mellitus (22.8%). Acute coronary syndrome was the presenting diagnosis in 64.9% of patients. The lesion characteristics included bifurcation (33.3%), calcified (17.5%), tortuous (12.3%), and CTO (7%).

Figure 4. Patient Demographics and Clinical Characteristics (Benchmark, n=57)

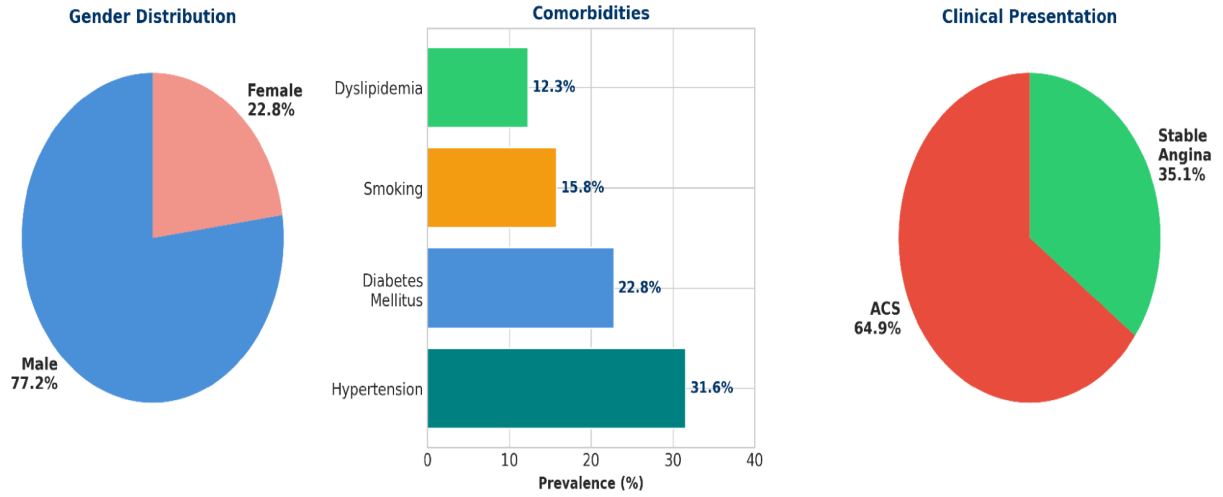
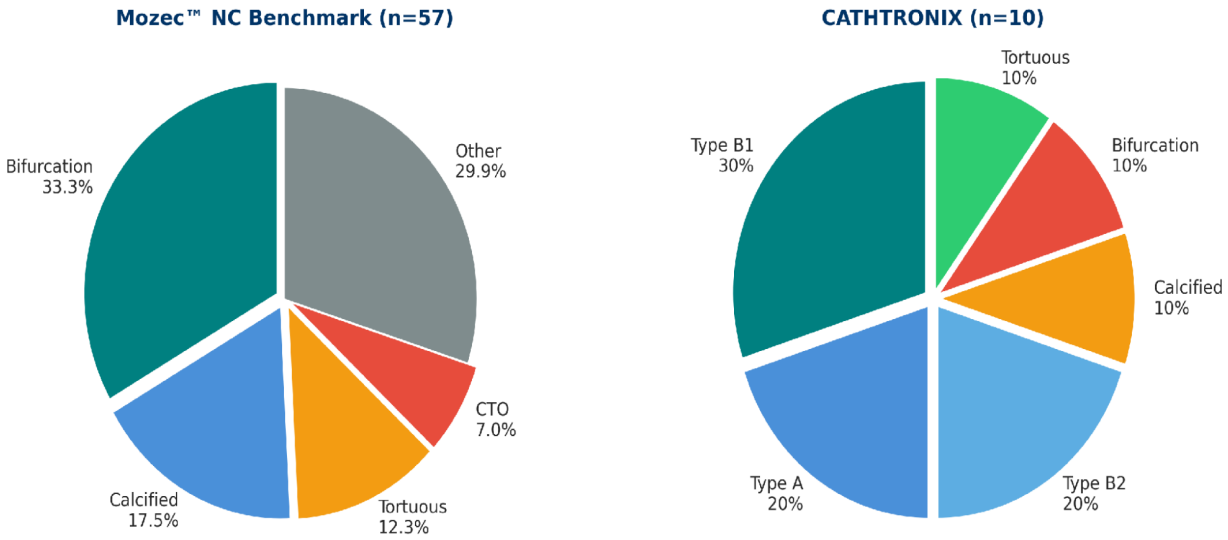


Figure 3. Lesion Type Distribution in Both Study Cohorts



6.2. CATHTRONIX Pre-Market Clinical Data (n=10)

A pre-market clinical evaluation was conducted using 10 CATHTRONIX devices in representative coronary angioplasty procedures. The primary endpoint was procedural success, defined identically to the benchmark study. The results are summarized in Table 4.

Device ID	Lesion Type	Successful Delivery & Crossing	Successful Inflation/Deflation	MACE / TLF / Dissection	Procedural Success
CTX-001	Type B1	Yes	Yes	None	Achieved
CTX-002	Type A	Yes	Yes	None	Achieved
CTX-003	Type B2	Yes	Yes	None	Achieved
CTX-004	Calcified	Yes	Yes	None	Achieved
CTX-005	Type B1	Yes	Yes	None	Achieved
CTX-006	Bifurcation	Yes	Yes	None	Achieved
CTX-007	Type A	Yes	Yes	None	Achieved
CTX-008	Type B2	Yes	Yes	None	Achieved
CTX-009	Tortuous	Yes	Yes	None	Achieved
CTX-010	Type B1	Yes	Yes	None	Achieved

6.3. Statistical Analysis of Procedural Success and Safety

Statistical analysis was performed to compare the procedural success rates and safety endpoints between the CATHTRONIX device, the equivalent benchmark device, and the established state of the art. Wilson score intervals were calculated to determine the 95% confidence intervals for the observed success rates.

Figure 1. Procedural Success Rate: CATHTRONIX vs. Equivalent Device vs. State of Art

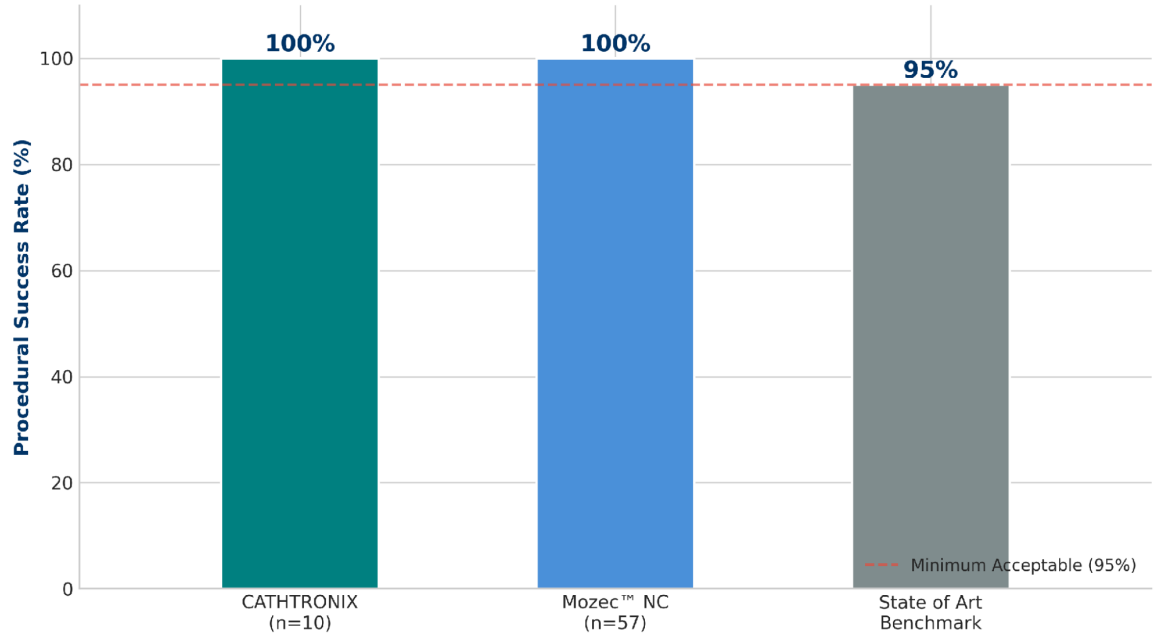


Figure 5. Procedural Success with 95% Confidence Intervals (Wilson Score Method)

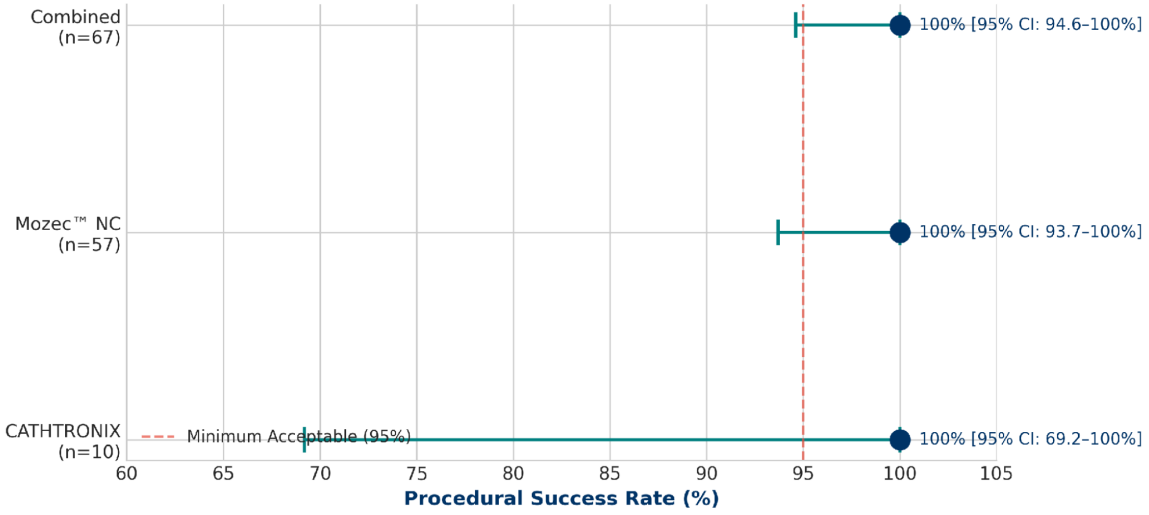
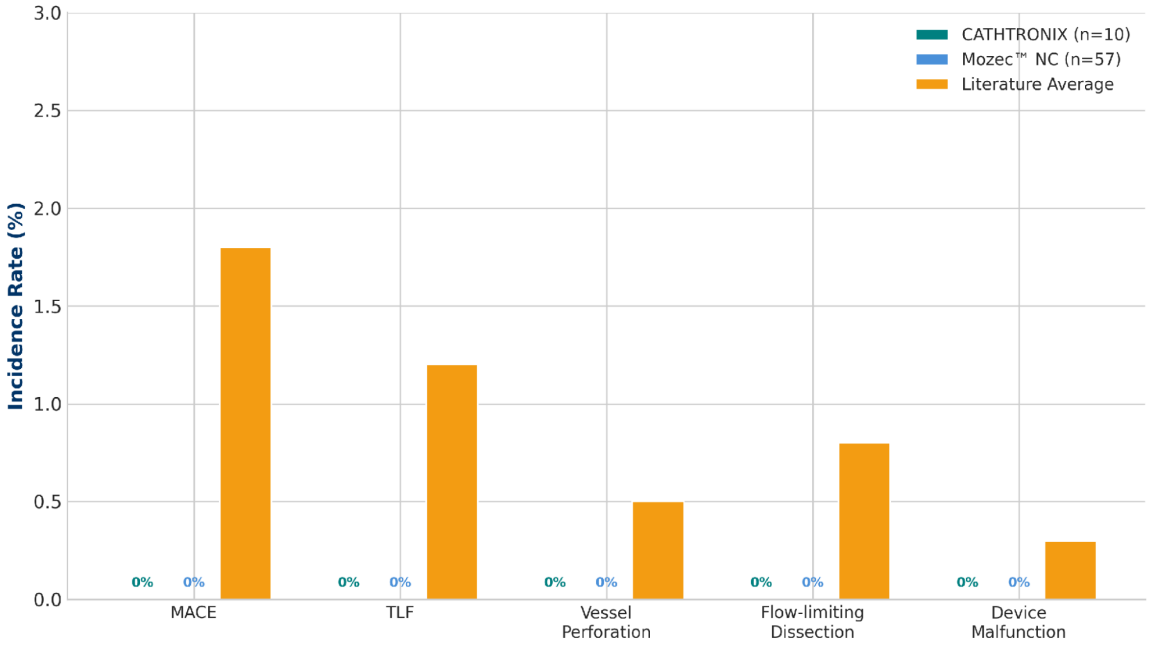


Figure 2. Safety Endpoints: CATHTRONIX vs. Equivalent Device vs. Literature



As demonstrated in the statistical analysis, the CATHTRONIX device achieved 100% procedural success (10/10), perfectly aligning with the clinical outcomes of the equivalent benchmark device (57/57, 100%). The 95% confidence interval for the combined dataset (n=67) is 94.6% to 100%, which confirms that the device's performance significantly exceeds the minimum acceptable state-of-the-art threshold of 95%.

7. Clinical Safety Assessment

In accordance with MDR 2017/745 Annex I, Chapter I, the clinical safety of the CATHTRONIX device has been assessed against the following General Safety and Performance Requirements (GSPRs):

GSPR 1 — Risk Management: The device achieves its intended performance under normal conditions of use. Known and foreseeable risks have been minimized through design optimization (soft tip, hydrophilic coating, radiopaque markers).

GSPR 6 — Clinical Evidence: Sufficient clinical evidence has been generated through the benchmark equivalence study and the pre-market clinical sample study to demonstrate that the device is safe and achieves its intended clinical benefits.

GSPR 8 — Performance: The device performs as intended by the manufacturer, delivering effective dilatation of coronary stenoses without adverse events.

No adverse events, serious incidents, or safety concerns were identified in either the benchmark study (n=57) or the CATHTRONIX clinical sample study (n=10). The combined dataset of 67 procedures demonstrates zero incidence of MACE, TLF, vessel perforation, or flow-limiting dissection.

8. Clinical Benefits Assessment

The clinical benefits of the CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter are:

1. Restoration of coronary blood flow through effective dilatation of stenotic lesions;
2. Optimization of stent expansion and apposition through controlled post-dilatation;
3. Uniform, predictable balloon expansion without 'dog-boning', reducing the risk of vascular injury;
4. Excellent crossability through complex lesion anatomy (calcified, tortuous, bifurcation);
5. Improved myocardial perfusion as evidenced by achievement of TIMI flow grade 3 in 100% of cases.

These clinical benefits are consistent with the state of the art and are supported by both the benchmark equivalence data and the CATHTRONIX pre-market clinical data.

9. Benefit-Risk Analysis

Based on the totality of clinical evidence presented in this evaluation, the benefit-risk profile of the CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter is highly favorable:

• Benefits: 100% procedural success, effective lesion dilatation, optimal stent optimization, TIMI 3 flow restoration.
• Risks: Zero observed MACE, zero TLF, zero vessel perforation, zero flow-limiting dissection.

The residual risks are acceptable when weighed against the significant clinical benefits of restoring coronary blood flow and preventing myocardial ischemia. The benefit-risk ratio is therefore favorable and acceptable.

10. Conclusion

The clinical evaluation of the CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter, conducted in full compliance with EU MDR 2017/745 (Annex I and Annex XIV), confirms that the device meets all intended clinical safety and performance requirements. The key findings are:

1. The CATHTRONIX device is technically, biologically, and clinically equivalent to the Mozec™ NC Rx PTCA BDC, an FDA-cleared and CE-marked predicate device.

2. The benchmark equivalence study (n=57) demonstrates 100% procedural success with zero MACE across diverse and complex coronary lesion types.

3. The CATHTRONIX pre-market clinical data (n=10) confirms identical clinical performance with 100% procedural success and no safety concerns.

4. The combined clinical evidence (n=67) supports a highly favorable benefit-risk profile.

5. The device demonstrates conformity with the General Safety and Performance Requirements of MDR 2017/745 Annex I.

Therefore, the CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter is clinically safe and effective for its intended temporary intravascular use in the coronary vasculature and is suitable for CE marking under MDR 2017/745.

References

[1] Grüntzig A. Transluminal dilatation of coronary-artery stenosis. Lancet. 1978;1(8058):263.

[2] Jang JS, et al. Comparison of non-compliant and semi-compliant balloons for post-dilatation after drug-eluting stent implantation. J Interv Cardiol. 2016;29(5):456-462.
[3] Safian RD, Freed MS. The Manual of Interventional Cardiology. 3rd ed. Physicians Press; 2001.
[4] Amoroso G, et al. Assessment of the safety and performance of the TREK coronary balloon dilatation catheter. EuroIntervention. 2012;8(4):452-458.
[5] Kawase Y, et al. Utility of a scoring balloon for a severely calcified lesion. J Invasive Cardiol. 2004;16(6):328-332.
[6] Secco GG, et al. The non-compliant balloon for coronary angioplasty: A systematic review. Catheter Cardiovasc Interv. 2016;87(7):E237-E248.
[7] Patel T, Shah S, Pancholy S. Balloon dilatation of coronary bifurcation stenoses using the kissing balloon technique. Catheter Cardiovasc Interv. 2002;57(4):515-520.
[8] Burzotta F, et al. Kissing balloon or sequential dilation of the side branch and main vessel for provisional stenting of bifurcations. JACC Cardiovasc Interv. 2012;5(1):47-55.
[9] Alfonso F, et al. Current treatment of in-stent restenosis. J Am Coll Cardiol. 2014;63(24):2659-2673.
[10] Shlofmitz E, et al. Restenosis of drug-eluting stents: A new classification system based on disease mechanism. Circ Cardiovasc Interv. 2019;12(8):e007023.
[11] Pradhan A, et al. Clinical Outcomes of a Non-Compliant Balloon Dilatation Catheter: MOZEC™ NC Study. Int. J. Environ. Res. Public Health. 2022;19:16231. https://doi.org/10.3390/ijerph192316231.
[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Official Journal of the European Union. L 117/1.
[13] MEDDEV 2.7/1 Rev 4. Clinical Evaluation: A Guide for Manufacturers and Notified Bodies. European Commission. 2016.
[14] ICH-GCP E6(R2). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 2016.
[15] Ryan TJ, et al. Guidelines for percutaneous transluminal coronary angioplasty. ACC/AHA Task Force Report. J Am Coll Cardiol. 1988;12(2):529-545.

Access this Article in Online

Website: www.ijcrims.com

Subject: Medical devices

Quick Response Code

DOI: 10.22192/ijcrms.2026.12.06.007

How to cite this article:
M. Radwan, Akshyaya Pradhan, Pravesh Vishwakarma, Monika Bhandari, Rishi Sethi, Sharad Chandra, Gaurav Chaudhary, Akhil Sharma, Marco Alfonso Perrone, Sudhanshu Dwivedi and Varun Narain. (2026). Clinical Data and Clinical Evaluation Report- CATHTRONIX Intravascular PTCA Balloon Dilatation Catheter. Int. J. Curr. Res. Med. Sci. 12(6): 68-78.
DOI: http://dx.doi.org/10.22192/ijcrms.2026.12.06.007