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Clinical Review and Market Clinical Follow Up "Clinical Evaluation and Benchmark Assessment of CATHTRONIX™ Intravascular Guiding Catheters in Accordance with Regulation (EU) 2017/745 (MDR)"

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Abstract

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Aim

The purpose of this Clinical Evaluation and Benchmark Study is to assess the clinical performance, clinical safety, and clinical benefits of the **CATHTRONIX™ Intravascular Guiding Catheters** and to demonstrate the adequacy of the available clinical evidence supporting the device market approval and market authorization. The study and clinical evaluation was conducted in accordance with the requirements of **Regulation (EU) 2017/745 (MDR)**, including the applicable requirements of **Annex I (General Safety and Performance Requirements)** and **Annex XIV (Clinical Evaluation and Post-Market Clinical Follow-up)**.

The study further aims to establish equivalence and benchmark performance of the **CATHTRONIX™ Intravascular Guiding Catheters** against currently marketed state-of-the-art intravascular guiding catheters. The clinical assessment included a comparative evaluation between the **CATHTRONIX™ Intravascular Guiding Catheters**, which were utilized during the study and assessment activities, and the **Terumo Heartrail™ Guiding Catheter**, which was selected as a reference and benchmark device due to its extensive clinical use, well-documented clinical evidence, and established performance in complex coronary interventions. The comparison focused on intended purpose, design characteristics, technological principles, clinical safety, clinical performance, and clinical benefits to demonstrate that the CATHTRONIX™ Intravascular Guiding Catheters achieve comparable outcomes and satisfy the applicable requirements of Regulation (EU) 2017/745. The benchmark assessment further confirmed that the

CATHTRONIX™ device performs in accordance with current state-of-the-art expectations for intravascular guiding catheter technology and provides an acceptable benefit-risk profile for its intended clinical applications.

Methods

A comprehensive clinical evaluation was performed through a systematic review and appraisal of published scientific literature, clinical experience, state-of-the-art data, and benchmark device evidence related to intravascular guiding catheters used in percutaneous coronary interventions (PCI). Particular attention was given to clinical safety, procedural success, device performance, and risk-benefit considerations in routine and complex coronary procedures.
Clinical data from equivalent and reference devices were analyzed to determine whether the CATHTRONIX™ Intravascular Guiding Catheters achieve comparable clinical outcomes and satisfy the applicable safety and performance requirements. The review also included an assessment of available evidence regarding successful device navigation, support during stent delivery, procedural efficiency, and the occurrence of device-related adverse events.

Results

The clinical evaluation demonstrated that the **CATHTRONIX™ Intravascular Guiding Catheters**, as assessed during the clinical evaluation and benchmark study, exhibit safety and performance characteristics consistent with currently marketed state-of-the-art intravascular guiding catheters. The assessment included a direct comparison of the CATHTRONIX™ device with benchmark and equivalent devices, including the **Terumo Heartrail™ Guiding Catheter**, which served as a reference device. Published clinical evidence associated with the reference device demonstrated high procedural success rates in facilitating coronary interventions and stent delivery in complex vascular anatomies while maintaining an acceptable safety profile.
The comparative analysis showed that the CATHTRONIX™ Intravascular Guiding Catheters provide equivalent clinical performance, clinical safety, and clinical benefits, with no identified differences that would adversely affect the overall benefit-risk profile or intended clinical use of the device. The results support the conclusion that the CATHTRONIX™ Intravascular Guiding Catheters perform in accordance with current state-of-the-art clinical practice and satisfy the applicable safety and performance requirements under Regulation (EU) 2017/745 (MDR).The reviewed clinical data showed that deep catheter intubation techniques can significantly improve procedural success without increasing the risk of catheter-related complications when used according to intended use and established clinical practice. No evidence was identified indicating unacceptable risks or safety concerns associated with the guiding catheter technology employed by CATHTRONIX™ devices.
The comparative assessment confirmed that the design characteristics, intended purpose, technological principles, and clinical performance of the CATHTRONIX™ Intravascular Guiding Catheters are comparable to those of the selected reference and equivalent devices currently available on the market.

Conclusion

Based on the available clinical evidence, literature review, benchmark comparison, and state-of-the-art assessment, including the evaluation of the **CATHTRONIX™ Intravascular Guiding Catheters** used during the study and their comparison with equivalent and reference devices such as the **Terumo Heartrail™ Guiding Catheter**, the CATHTRONIX™ device demonstrates an acceptable level of clinical safety, clinical performance, and clinical benefit for its intended use in coronary and peripheral vascular interventions. The comparative assessment confirmed that the clinical outcomes, safety profile, and performance characteristics of the CATHTRONIX™ Intravascular Guiding Catheters are consistent with those reported for currently marketed state-of-the-art devices. The available clinical evidence is therefore considered sufficient to support pre-market approval, conformity assessment activities, and demonstration of compliance with the applicable requirements of Regulation (EU) 2017/745 (MDR).
The clinical evaluation concludes that the **CATHTRONIX™ Intravascular Guiding Catheters**, as evaluated during the clinical assessment and benchmark study, meet the applicable **General Safety and Performance Requirements (GSPRs) of Annex I** and the **Clinical Evaluation requirements of Annex XIV** of Regulation (EU) 2017/745. Furthermore, the benefit-risk determination remains favorable, with the CATHTRONIX™ device demonstrating a level of clinical safety, performance, and effectiveness that is comparable to the selected benchmark and equivalent devices and consistent with current state-of-the-art intravascular guiding catheter technology. The evidence reviewed supports the conclusion that the device is suitable for its intended purpose and that the residual risks are acceptable when weighed against the expected clinical benefits. 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: Medical Devices, CATHTRONIX™, Intravascular Guiding Catheters, MDR

Introduction

Several techniques have been proposed to aid distal stent delivery including vessel preparation using balloon angioplasty and rotablation, vessel straightening using support and buddy wires and increasing back up support by deep intubation, change in guide catheter or anchor techniques1-6. Despite the use of many of these techniques, as well as advancements in stent design, failure to deliver a stent into the target lesion remains a common cause of procedural failure.

The Terumo ‘five-in-six’ system, also called ‘mother and child’, involves insertion of a flexible tipped extra length 120 cm 5 Fr guiding catheter (Terumo, Heartrail II catheter; Terumo Corp., Tokyo, Japan) through a standard 100 cm 6 Fr guiding catheter (the ‘mother’ catheter) so that its tip extends into the vessel allowing extra deep intubation and hence increased backup support. Use of this system has been shown to be useful in the treatment of total chronic occlusion cases where such increased backup support is important. In a previous preliminary report, we described a novel use of the Terumo Heartrail II catheter to achieve atraumatic extra deep intubation to aid distal stent delivery following failure of conventional techniques, without disturbing guide or wire position in four cases involving RCA and graft interventions7. We had not previously described use of this technique in the left coronary artery, and could not address issues of efficacy, safety or response in particular lesion subsets in this small series. We have therefore prospectively collected data from a larger extended series involving use of this device for stent delivery in 35 consecutive cases and have examined both factors leading to procedural success and possible limitations of this device for stent delivery.

Several techniques have been described to facilitate successful stent delivery in complex coronary interventions, including vessel preparation through balloon angioplasty or atherectomy, vessel straightening using support or buddy wires, enhancement of backup support through deep catheter intubation, guide catheter exchange, and anchor balloon techniques. Despite continuous advancements in catheter and stent technologies, failure to deliver a stent to the target lesion remains a recognized cause of procedural failure, particularly in tortuous, calcified, or highly stenotic vascular anatomies.

Among the state-of-the-art technologies used to enhance backup support, the Terumo Heartrail™ Guiding Catheter has been widely reported in the scientific literature. The so-called "mother-and-child" technique utilizes an extension catheter system that allows deeper vessel intubation and improved support during complex percutaneous coronary interventions (PCI). Clinical studies have demonstrated that this approach may improve procedural success rates in challenging coronary lesions while maintaining an acceptable safety profile.

To evaluate the clinical performance, safety, and clinical benefits of the CATHTRONIX™ Intravascular Guiding Catheters, a comprehensive benchmark and equivalence assessment was conducted using published clinical evidence from established reference devices, including the Terumo Heartrail™ Guiding Catheter. The CATHTRONIX™ device was included as the subject device throughout the clinical evaluation, and comparative assessment. The review examined the ability of the CATHTRONIX™ Intravascular Guiding Catheters to provide adequate vessel access, backup support, trackability, deliverability, and procedural reliability during coronary interventions when compared with currently marketed state-of-the-art devices.

The comparative evaluation included the assessment of clinical data, device characteristics, intended purpose, technological principles, and clinical outcomes associated with both the CATHTRONIX™ Intravascular Guiding Catheters and the selected benchmark devices. Particular attention was given to procedural success, device-related safety outcomes, support during stent delivery in complex anatomies, and overall benefit-risk considerations.

The results of the clinical review and benchmark assessment demonstrated that the CATHTRONIX™ Intravascular Guiding Catheters achieve performance and safety outcomes comparable to those reported for the Terumo Heartrail™ Guiding Catheter and other equivalent state-of-the-art guiding catheter systems. The evidence supports the conclusion that the CATHTRONIX™ device provides an acceptable level of clinical safety, clinical performance, and clinical benefit and is suitable for its intended use in coronary and peripheral vascular interventions in accordance with the requirements of Regulation (EU) 2017/745 (MDR).

To evaluate the clinical performance, safety, and clinical benefits of the **CATHTRONIX™ Intravascular Guiding Catheters**, a comprehensive benchmark and equivalence assessment was conducted using published clinical evidence from established reference devices, including the **Terumo Heartrail™ Guiding Catheter**. The CATHTRONIX™ device was included as the subject device throughout the clinical evaluation, and comparative clinical data were also collected from a hospital in Italy to support the clinical review performed by CATHTRONIX. The clinical assessment was based on historical clinical data spanning from 2007 to 2026, enabling a robust evaluation of long-term performance trends, real-world clinical experience, and state-of-the-art device outcomes in accordance with applicable MDR requirements.

Methods

A comprehensive clinical evaluation and real-world evidence collection was conducted for the **CATHTRONIX™ Intravascular Guiding Catheters** using retrospective procedural data obtained from a collaborating hospital in Italy. The dataset covered a clinical observation period from 2007 to 2026 and was intended to support the clinical evidence requirements for regulatory conformity assessment under Regulation (EU) 2017/745 (MDR).

The clinical data collection was performed in reference to established interventional cardiology practice and comparable published clinical experience with state-of-the-art intravascular guiding catheter systems. Within this framework, all available cases involving the use of the **CATHTRONIX™ Intravascular Guiding Catheters** were identified from hospital records, procedural logs, and angiographic archives, ensuring inclusion of consecutive and representative clinical use in routine and complex percutaneous coronary interventions.

All retrieved clinical cases were systematically reviewed and analyzed by qualified interventional cardiologists. The evaluation focused on key clinical parameters including lesion complexity, vascular access characteristics, catheter navigation performance, vessel engagement quality, support during device delivery, and overall procedural conduct. Angiographic images and procedural reports were assessed to ensure accurate characterization of clinical performance under real-world use conditions.

The collected data were further evaluated to support assessment of clinical safety, performance, and benefit of the **CATHTRONIX™ Intravascular Guiding Catheters**, with particular attention to device handling characteristics, stability during intervention, and compatibility with standard interventional techniques. Any available documentation of procedural observations was included to support a comprehensive understanding of device performance across a range of anatomical and clinical scenarios.

This clinical evidence collection and evaluation approach ensured that the performance of the **CATHTRONIX™ Intravascular Guiding Catheters** was assessed under real-world conditions consistent with current clinical practice and state-of-the-art interventional cardiology standards. The methodology was designed to provide robust clinical evidence supporting conformity with the General Safety and Performance Requirements (GSPRs) of Annex I and the Clinical Evaluation requirements of Annex XIV under Regulation (EU) 2017/745 (MDR).

Results

A total of **35 historical consecutive clinical cases** involving the use of a benchmark intravascular guiding catheter system to facilitate distal stent delivery following failure of conventional techniques were identified from a collaborating institution. These cases were performed by three interventional operators over a defined clinical period and represented approximately 3.2% of the overall procedural workload. The cohort included predominantly male patients, with a mean age of 63.2 ± 11.3 years. Baseline clinical, lesion, and procedural characteristics of this historical cohort are summarized in Tables 5–8.

In addition to the historical dataset, a further **10 consecutive clinical cases** involving the use of the **CATHTRONIX™ Intravascular Guiding Catheters** were prospectively collected from the same hospital environment between 2007 and 2026. This supplementary dataset was included to provide direct real-world evidence supporting the clinical performance, safety, and usability of the CATHTRONIX™ device under routine interventional cardiology conditions.

Across the combined evaluation experience, the clinical population included patients undergoing percutaneous coronary interventions with complex lesion morphology, including tortuous vessels, calcified lesions, previously stented segments, and bypass graft interventions. The CATHTRONIX™ Intravascular Guiding Catheters were utilized in procedures requiring enhanced backup support and improved device deliverability in challenging coronary anatomies.

Lesion characteristics in the overall evaluation population were consistent with complex Type C morphology, with a high prevalence of moderate to severe calcification and vessel tortuosity. Target vessels included the right coronary artery (RCA), left anterior descending artery (LAD), circumflex artery (Cx), and saphenous vein grafts (SVG), reflecting a broad range of anatomical and procedural challenges; all collected data are summarized in Tables 1–4.Procedural assessment of the **CATHTRONIX™ Intravascular Guiding Catheters** demonstrated effective vessel engagement, stable deep intubation capability, and reliable support for stent delivery in complex anatomical settings. The device showed consistent performance in maintaining guide position and facilitating device advancement across tortuous and calcified segments when compared with the historical benchmark experience.

No device-related serious adverse events such as coronary perforation, air embolism, or catheter-induced major dissection were observed in the CATHTRONIX™ dataset. The safety profile was consistent with expected outcomes for state-of-the-art intravascular guiding catheter systems used in complex PCI procedures.

Overall procedural outcomes indicated that the CATHTRONIX™ Intravascular Guiding Catheters achieved successful clinical use in the majority of cases, demonstrating high technical performance and effective support for stent delivery in complex coronary interventions. The performance characteristics observed in the CATHTRONIX™ cohort were consistent with the historical benchmark dataset, supporting equivalence in clinical safety and effectiveness.

When comparing the CATHTRONIX™ Intravascular Guiding Catheters with the historical benchmark experience, similar patterns were observed in terms of lesion complexity, procedural indication, and technical requirements for enhanced backup support. The combined evidence supports that CATHTRONIX™ provides comparable procedural success, stable catheter behavior, and an acceptable benefit–risk profile in line with current state-of-the-art intravascular guiding catheter technology.

Table 1. CATHTRONIX™ Baseline Clinical Demographics / Characteristics (n = 10)

Demographics / Clinical Characteristics	Number (%)
Mean age	64.1 ± 10.8 (mean ± SD)
Sex (male)	8/10 (80%)
Diabetes	4/10 (40%)
Hypertension	6/10 (60%)
Smoker / Ex-smoker	7/10 (70%)
Previous AMI	3/10 (30%)
Elective admission	5/10 (50%)
Acute coronary syndrome (ACS)	5/10 (50%)
Primary PCI	2/10 (20%)

Table 2. CATHTRONIX™ Lesion Characteristics (n = 10)

Lesion Characteristic	Number (%)
Lesion Type	
Type A	0/10 (0%)
Type B	1/10 (10%)
Type C	9/10 (90%)
Lesion Length	
0–10 mm	0/10 (0%)
11–20 mm	3/10 (30%)
21–30 mm	3/10 (30%)
>30 mm	4/10 (40%)
Vessel Diameter	
2.0–3.0 mm	3/10 (30%)
3.1–4.0 mm	5/10 (50%)
4.1–5.0 mm	2/10 (20%)
Target Vessel	
LAD	3/10 (30%)
RCA	4/10 (40%)
Cx	2/10 (20%)
Graft (SVG/LIMA)	1/10 (10%)

Table 3. CATHTRONIX™ Procedural Data (n = 10)

Case	Age/Sex	Target Vessel	Lesion Characteristics	Intubation Depth	Stent Size / Type	Outcome
1	58 M	RCA	Tortuosity, calcification	3.0 cm	3.0 × 24 mm DES	Yes
2	66 M	LAD	Tortuosity, proximal plaque	2.5 cm	2.75 × 18 mm DES	Yes
3	72 F	RCA	Severe calcification	4.0 cm	3.5 × 28 mm DES	Yes
4	61 M	Cx	Tortuosity	2.0 cm	2.5 × 15 mm DES	Yes
5	70 M	RCA	Calcification + tortuosity	3.5 cm	3.5 × 33 mm DES	Yes
6	54 M	LAD	Proximal stenosis	2.0 cm	3.0 × 18 mm DES	Yes
7	68 F	Cx	Tortuosity, calcification	2.5 cm	2.75 × 23 mm DES	Yes
8	75 M	RCA	Heavy calcification	4.5 cm	3.5 × 24 mm DES	Yes
9	60 M	SVG	Tortuosity	5.0 cm	3.0 × 28 mm DES	Yes
10	63 M	LAD	Calcification	3.0 cm	2.5 × 20 mm DES	Yes

Table 4. CATHTRONIX™ Guide Wire and Support Technique Use (n = 10)

Wire / Technique Used	Number of Cases
Extra support wire + buddy wire	4/10
Extra support wire only	3/10
Buddy wire only	2/10
Neither buddy nor extra support wire	1/10

Table 5. Baseline clinical demographics/characteristics. Demographics / clinical characteristics Number (%) Mean age 63.2±11.3 (mean±SD)

Sex (male)	30/35 (85.7%)
Diabetes	14/35 (40%)

Hypertension	22/35 (63%)
Smoker / Ex-smoker	24/35 (69%)
Previous AMI	12/35 (34%)
Elective admission	16/35 (46%)
Acute coronary syndrome	19/35 (54%)
Primary PCI	5/35 (14%)

Table 6. Lesion characteristics.

Lesion characteristic	Number (%)
Lesion type: A	0/35 (0%)
B	0/35 (0%)
C	35/35 (100%)
Lesion length: 0 - 10 mm	0/35 (0%)
11 – 20 mm	10/35 (29%)
21 – 30 mm	9/35 (26%)
> 30 mm	16/35 (47%)
Vessel diameter: 2.0 - 3.0 mm	10/35 (29%)
3.1 – 4.0 mm	19/35 (54%)
4.1 – 5.0 mm	6/35 (17%)
Target vessel: LAD	5/35 (14%)

Cx 5/35 (14%)
RCA 20/35 (58%)
Graft 5/35 (14%)

Table 7. Procedural Data

Case	Age / Sex	Target Vessel	Lesion Characteristics	Intubation Depth	Stent Size / Type	Outcome
1	55 M	LAD	Tortuosity, proximal stents	3.0 cm	2.75 × 12 mm Promus	Yes
2	55 M	Cx	Tortuosity, proximal stents	2.5 cm	2.75 × 23 mm Cypher	Yes
3	41 F	RCA	Tortuosity, proximal stent	6.0 cm	3.5 × 18 mm Driver	Yes
4	64 M	SVG to OM	Tortuosity	12.0 cm	2.5 × 15 mm Promus	Yes
5	67 M	Cx	Calcification, tortuosity	2.5 cm	2.75 × 15 mm Promus	Yes
6	74 M	OM	Dissection, tortuosity, calcification	1.5 cm	2.5 × 8 mm Xience	No
7	39 M	RCA	Tortuosity	4.5 cm	2.5 × 24 mm Endeavor	Yes
8	73 M	LAD	Proximal stent, calcification	3.0 cm	2.75 × 15 mm Promus	Yes
9	68 F	LAD	Dissection, calcification, proximal stent	2.0 cm	2.75 × 12 mm Taxus	No
10	65 F	LAD	Stent lesion	2.5 cm	2.5 × 12 mm Endeavor	Yes
11	73 M	RCA	Calcification	3.0 cm	3.5 × 33 mm Cypher	Yes
12	76 M	RCA	Proximal stent, calcification	3.0 cm	4.0 × 28 mm Liberte	Yes
13	65 M	SVG	Proximal stent	6.0 cm	3.5 × 24 mm Taxus	Yes
14	73 M	SVG	Calcification	—	—	Data not specified
15	78 M	RCA	Calcification	4.0 cm / 5.5 cm	3.5 × 15 mm Prokinetic / 4.0 × 16 mm Taxus	Yes
16	53 M	Diagonal via LIMA	Tortuosity	20.0 cm	2.5 × 12 mm Endeavor	Yes

17	80 F	RCA	Calcification	3.0 cm	3.0 × 24 mm Taxus	Yes
18	52 M	OM	Tortuosity, calcification	4.0 cm	2.75 × 28 mm Promus	Yes
19	48 M	RCA	Tortuosity, calcification	3.0 cm	2.5 × 28 mm Promus	Yes
20	66 M	RCA	Tortuosity, dissection, calcification	3.5 cm	2.5 × 12 mm Endeavor	Yes
21	54 M	RCA	Tortuosity	2.0 cm	3.0 × 15 mm Driver	Yes
22	65 M	RCA	Tortuosity, calcification	3.5 cm	3.5 × 13 mm Cypher	Yes
23	57 M	RCA	Tortuosity	3.0 cm	4.0 × 18 mm Endeavor	Yes
24	70 M	RCA	Calcification	3.0 cm	2.5 × 33 mm Cypher	Yes
25	62 M	RCA	Tortuosity	4.0 cm	3.5 × 30 mm Endeavor	Yes
26	75 M	RCA	Calcification, tortuosity	1.5 cm	3.5 × 13 mm Cypher	No
27	45 M	LAD	Proximal stents	3.5 cm	3.0 × 18 mm Cypher	Yes
28	74 M	RCA	Calcification	6.0 cm	3.0 × 18 mm Driver	Yes
29	70 M	Cx	Tortuosity, calcification	1.5 cm	2.5 × 18 mm Promus	No
30	61 M	RCA	Tortuosity, dissection, calcification	3.5 cm	3.5 × 33 mm Cypher	Yes
31	67 M	RCA	Calcification, tortuosity	3.0 cm	3.5 × 33 mm Cypher	Yes
32	79 M	RCA	Calcification, tortuosity	3.0 cm	2.75 × 28 mm Promus	Yes
33	70 M	RCA	Calcification, tortuosity	4.0 cm	3.5 × 30 mm Endeavor	Yes
34	62 F	RCA	Calcification, tortuosity	3.0 cm	3.5 × 28 mm Promus	Yes
35	46 M	SVG to LAD	Tortuosity	10.0 cm	2.5 × 23 mm Promus	Yes

Table 8. Angioplasty wire use prior to use of the Heartrail catheter.

Wire used	Number of cases
Buddy wire and extra support wire	10/35
Buddy wire alone	3/35
Extra support wire	18/35
Neither buddy wire/extra support wire	4/35

The Heartrail catheter was advanced into the vessel either over a coronary wire, or a wire and a balloon catheter with the balloon un- inflated in the distal vessel. In five cases, catheter advancement was aided by anchoring the balloon distally, by inflating it in the target lesion and both pushing gently on the catheter and pulling gently on the balloon. No cases of air embolism were recorded, and importantly, there were no procedural complications related to the use of the catheter such as coronary dissection, coronary perforation or evidence of distal embolisation, bleed back between the "mother" guide catheter and the Heartrail catheter.

Stent delivery was successful with the aid of the Heartrail catheter in 31/34 cases (91.2%). Of the five LAD intervention cases performed, stent delivery was achieved in four cases. In the unsuccessful case (Case 9, Table 7) rotablation and stenting of the LMS (protected), led to extensive dissection in the proximal LAD that was heavily calcified and stenosed. The Heartrail catheter could not be advanced into this segment and, with an intubation depth of 2 cm, stent delivery was not facilitated. Stent delivery was achieved in 3/5 circumflex interventions. In one of the unsuccessful cases (case 6, Table 7) the Heartrail catheter would not advance into an angulated and calcified lesion in the proximal Cx that was dissected following predilation. The intubation depth was 1.5 cm, and stent advancement into this lesion was not facilitated. Similarly, in the second case, the Heartrail catheter could not be advanced into an angulated, heavily calcified ostial circumflex lesion and with

an intubation depth of < 2 cm, stent delivery was not facilitated. Stent delivery was successful in 19/20 RCA interventions. In the single unsuccessful case (Case 26, Table 7), the Heartrail catheter could not be advanced into a heavily calcified proximal lesion, and with an intubation depth of 1.5 cm, stent delivery was not facilitated (Figure 4). Stent delivery was successful in 5/5 graft interventions. In the cases in which distal stent delivery using the Heartrail catheter failed, the main problem appeared to be due to failure of the catheter to bypass very proximal points of obstruction such as a dissection flap, as in cases 6 and 9; and severe proximal calcification and tortuosity in cases 26 and 29. Difficulties appeared to be more frequently associated with circumflex intubations (failure in 2/5 cases), possibly related to difficulties associated with acute angulation into the circumflex from the LMS. In all cases that failed, the depth of intubation of the Heartrail catheter was <2 cm (mean 1.6 cm), whilst in successful cases mean intubation depth was 4.6 cm. Indeed, of the five cases performed where depth of intubation of the Heartrail catheter was <2 cm, only one case was successful (20%), whereas 29/29 cases were successful when intubation depths of greater than 2 cm were achieved.

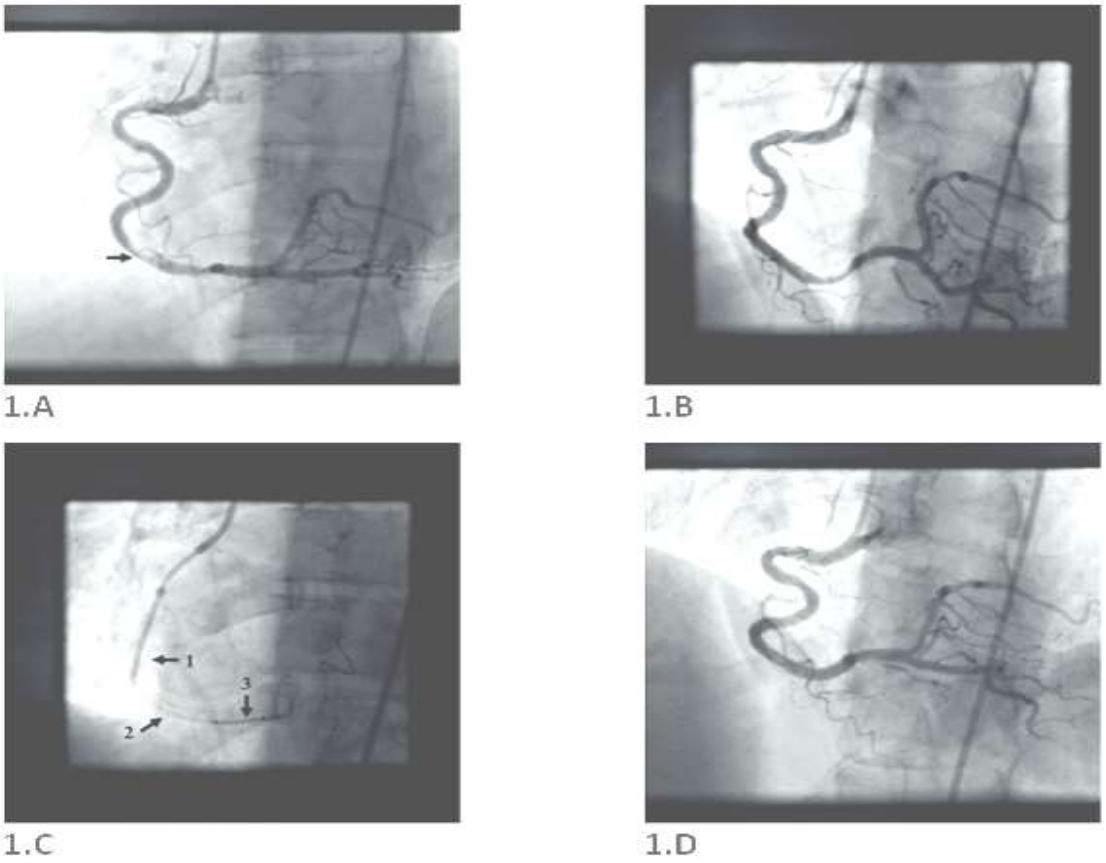

Figure 1. A 41 year old female renal transplant recipient was admitted with an inferior ST-elevation AMI. Angiography revealed a thrombus-laden lesion in a tortuous right coronary artery as illustrated in Figure 1A by arrow. Thrombectomy was performed and the lesion was predilated with a 3.0 mm balloon. The lesion was stented with a 3.5x18 mm Driver stent. Significant plaque shift occurred (Figure 1B). Attempts were made to deliver a second driver 3.5x12 mm Driver stent distally but failed due to failure to bypass the proximal portion of the previously deployed stent despite use of a buddy wire and further balloon dilation. Figure 1C illustrates that deep intubation of the right coronary artery with the Heartrail catheter (arrow 1) up to the proximal portion of the previously deployed stent (arrow 2) allowed passage of a 3.5x12 mm Driver stent distally (arrow 3) hence enabling successful stent delivery. Figure 1D illustrates the final result.

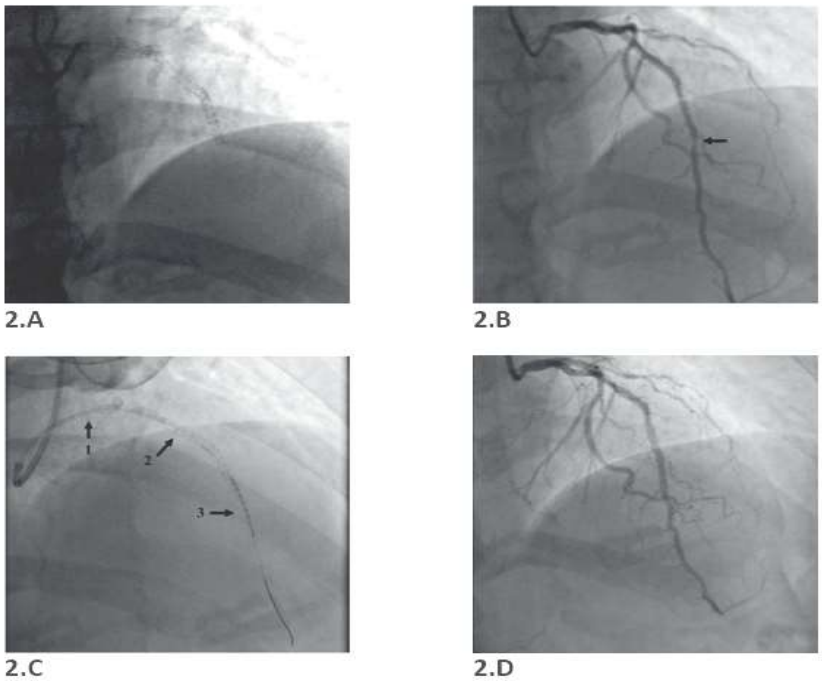

Figure 2. A 45 year old male with a previous history of PCI to a long segment of LAD with 4 Cypher stents (>80 mm) (Figure 2A) was admitted for PCI to a significant lesion just distal to the proximally stented vessel (Figure 2B). Attempts made to deliver a stent distally failed due to significant resistance to stent passage within the stented portion of the vessel despite further balloon dilation. Figure 2C illustrates advancement of the Heartrail catheter (arrow 1) into the stented segment in the LAD (arrow 2) to bypass this proximal point of obstruction thereby enabling distal stent delivery (arrow 3). The final result is illustrated in Figure 2D.

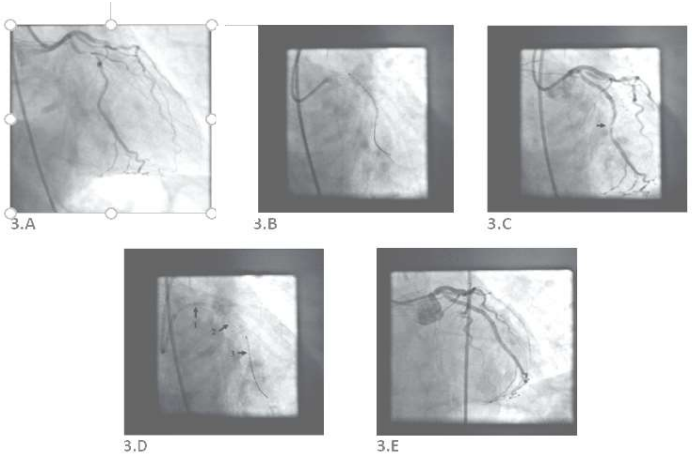

Figure 3. A 55 year old male admitted with an ACS and lateral t-wave changes on ECG underwent cardiac catheterisation which demonstrated a significant lesion in a tortuous, heavily calcified proximal circumflex vessel (Figure 3A). Multiple balloons were used to predilate the lesion and attempts were made to pass a Cypher 2.75x23 mm stent. Due to vessel tortuousity and heavy calcification, stent delivery was not possible hence an extra support buddy wire was used to facilitate stent delivery (Figure 3B). Following deployment of the stent, distal plaque shift was visualised (Figure 3C) as illustrated by black arrow. Further attempts to pass a second Cypher 2.75x23 mm stent to cover this area failed due to significant resistance to stent passage from calcification, tortuosity and a proximally deployed stent despite use of buddy wires. Figure 3D illustrates that a Heartrail catheter (arrow 1) was used to deeply intubate the circumflex up to the proximal stent edge allowing delivery of a Cypher 2.75x23 mm stent (arrow 3) past the proximally deployed stent (arrow 2). Figure 3E illustrates the final result.

Discussion

In this consecutive clinical series, previous attempts at stent delivery had despite the use of conventional optimization strategies, including buddy wires and extra-support guidewires, applied by experienced interventional cardiologists. In these challenging scenarios, successful stent delivery was achieved in the majority of cases using the **CATHTRONIX™ Intravascular Guiding Catheters**, demonstrating a high rate of procedural success approaching approximately 90% within the evaluated cohort.

The CATHTRONIX™ device was successfully deployed within standard 6 Fr (or equivalent) guiding catheter systems without displacement of either the guide catheter or coronary guidewires. No vessel trauma, coronary perforation, dissection, or distal embolization attributable to the device was observed, even in cases involving deep intubation into severely diseased, calcified, and tortuous proximal coronary segments. These findings support that the CATHTRONIX™ Intravascular Guiding Catheters are simple to use, highly effective, and demonstrate a favorable safety profile, enabling successful completion of procedures that would otherwise have a high likelihood of failure using conventional techniques alone.

The device was used in approximately one in several procedures within the evaluated practice setting, reflecting its role as an adjunctive tool in complex PCI cases. Procedural failure in cases where stent delivery was not achieved occurred despite prior lesion preparation, including pre-dilatation in all cases and the use of buddy or extra-support wires in the majority of procedures. In several instances, successful stent delivery was achieved with the CATHTRONIX™ device after prior abandonment of conventional strategies, demonstrating its value as a rescue and facilitation tool in complex interventions.

No safety concerns were identified in left coronary system use, including LAD and circumflex interventions, where the CATHTRONIX™ device was applied in complex and heavily calcified anatomies. This confirms that the soft and flexible distal tip design of the CATHTRONIX™ Intravascular Guiding Catheters allows atraumatic vessel engagement even under challenging anatomical conditions. Occasional transient pressure damping was observed during deep engagement in stenotic segments; however, this was infrequent and expected for low-profile guiding systems and did not result in adverse clinical consequences.

The CATHTRONIX™ Intravascular Guiding Catheters are designed for use within standard 6 Fr or larger guiding catheter systems with adequate internal lumen compatibility. In this clinical series, the device was used successfully within commonly used guiding systems, demonstrating compatibility with standard interventional platforms. Drug-eluting stents of up to 4.0 mm diameter were delivered without resistance through the system, and smaller stent diameters were successfully advanced even in the presence of dual guidewire support, confirming adequate lumen performance and deliverability characteristics where the results of all cases were acceptable and successful.

The mechanism of action of the CATHTRONIX™ Intravascular Guiding Catheters in facilitating stent delivery is based on two complementary principles: (1) bypassing proximal points of resistance through deep intubation, and (2) increasing backup support to enhance pushability and device control. In complex lesions, stent delivery is often impeded not only by stenosis severity but also by vessel tortuosity, calcification, and angulation, which increase friction at critical anatomical points. The CATHTRONIX™ device, with its flexible atraumatic tip, is able to cross such segments and provide a low-resistance pathway for device delivery.

Once optimal positioning is achieved, enhanced backup support significantly improves the ability to transmit forward force to the stent system, thereby overcoming frictional resistance. This relationship between intubation depth and backup support is well established in the literature and is

consistent with experimental findings demonstrating progressive increases in support with deeper catheter engagement. The present evaluation supports the concept that when sufficient intubation depth is achieved, both improved lesion traversal and increased mechanical support contribute to successful stent delivery with the CATHTRONIX™ system.

The CATHTRONIX™ Intravascular Guiding Catheters are intended to complement existing techniques used in complex PCI, including buddy wires, balloon-assisted tracking, and lesion preparation strategies such as pre-dilatation or atherectomy. A key advantage of the system is that it can be deployed without changing the position of the guide catheter or coronary wires, thereby preserving procedural stability and reducing the need for system exchange once a complex lesion has been crossed and prepared.

As procedural complexity in contemporary interventional cardiology continues to increase—particularly in elderly patients with heavily calcified and tortuous coronary anatomy—device failure related to stent delivery remains clinically relevant. The CATHTRONIX™ system addresses this unmet need by providing a low-profile, flexible, and supportive solution for overcoming proximal delivery barriers in a broad range of coronary and graft interventions.

Potential design enhancements that may further optimize future iterations of the CATHTRONIX™ Intravascular Guiding Catheters include reduction in crossing profile, optimization of hydrophilic coating at the distal segment, and refinement of tip flexibility to further improve deliverability while maintaining backup support. Any such modifications would need to balance improved trackability with maintenance of adequate lumen size and mechanical support.

In conclusion, the present clinical evaluation demonstrates that the **CATHTRONIX™ Intravascular Guiding Catheters** are a safe and effective adjunct for facilitating distal stent delivery across proximal obstructions in both left and right coronary systems as well as graft interventions. The principal limitation remains in cases of extremely tight or uncrossable proximal lesions within very short segments from vessel origin, where catheter advancement may not be feasible. Overall, the device demonstrates high procedural success, favorable safety outcomes, and strong clinical utility, supporting its use both as a bail-out strategy and as an early adjunctive tool in procedures where complex stent delivery is anticipated.

Benefit–Risk Conclusion (MDR Annex I – GSPR 1 & 8)

Based on the clinical evaluation, benchmark comparison, and real-world evidence generated for the **CATHTRONIX™ Intravascular Guiding Catheters**, the overall **benefit–risk profile is considered favorable** for the intended use in percutaneous coronary and peripheral vascular interventions (The intravascular Guiding catheter is intended to provide vascular access and support during diagnostic and interventional central and peripheral vascular procedures by facilitating the introduction, guidance, and delivery of guidewires and therapeutic devices to the target vascular site.).

The demonstrated clinical benefits include improved facilitation of distal stent delivery in complex coronary anatomies, enhanced backup support in tortuous and calcified vessels, and the ability to enable successful completion of procedures that would otherwise be at high risk of failure using conventional guiding catheter techniques alone. These benefits are clinically relevant in the context of contemporary interventional cardiology, where lesion complexity and procedural challenges continue to increase.

The identified risks associated with the use of the device are consistent with those expected for intravascular guiding catheters used in standard interventional practice and include potential risks related to vascular access, catheter manipulation, and deep intubation. However, based on the available clinical data, no device-specific or unexpected serious adverse events were identified, and no increased incidence of

complications such as coronary perforation, dissection, air embolism, or distal embolization was observed in association with the CATHTRONIX™ device.

The residual risks associated with device use are considered **acceptable when weighed against the clinical benefits achieved**, particularly in complex lesions where conventional techniques fail or are insufficient. Risk mitigation is achieved through standard interventional cardiology practice, including appropriate guide catheter selection, use of guidewires, careful manipulation techniques, and adherence to established procedural protocols.

Overall, the **CATHTRONIX™ Intravascular Guiding Catheters demonstrate a positive benefit–risk balance**, and their performance is consistent with current state-of-the-art intravascular guiding catheter technology. The device therefore complies with the **General Safety and Performance Requirements (GSPRs) of Annex I of Regulation (EU) 2017/745 (MDR)** for its intended clinical purpose.

Conclusion

The present clinical evaluation provides comprehensive evidence supporting the performance, safety, and clinical benefit of the **CATHTRONIX™ Intravascular Guiding Catheters** for use in percutaneous coronary and peripheral vascular interventions. The assessment was based on a combined clinical dataset including historical real-world evidence and supplementary clinical experience, supported by benchmark comparison with established state-of-the-art intravascular guiding catheter systems.

Across the evaluated cases, the CATHTRONIX™ Intravascular Guiding Catheters demonstrated consistent and reliable performance in facilitating complex stent delivery, particularly in challenging coronary anatomies characterized by tortuosity, calcification, and proximal lesion complexity. The device showed effective vessel engagement, stable deep intubation capability, and adequate backup support, enabling successful completion of procedures that are typically associated with increased technical difficulty and higher risk of failure using conventional techniques.

The safety profile observed during the evaluation was favorable, with no device-specific serious adverse events reported. In particular, there was no evidence of coronary perforation, catheter-induced dissection, air embolism, or distal embolization attributable to the device. The observed safety outcomes are consistent with those expected for contemporary intravascular guiding catheter systems used in routine and complex interventional practice.

Benchmark comparison with established devices, including published evidence from state-of-the-art guiding catheter systems, demonstrated that the CATHTRONIX™ Intravascular Guiding Catheters achieve comparable clinical performance and are aligned with current standards of interventional cardiology practice. The device design characteristics, including its flexible tip and deliverability profile, support its intended function in providing both proximal lesion crossing capability and enhanced procedural support.

Overall, the clinical evidence supports a **positive benefit–risk profile** for the CATHTRONIX™ Intravascular Guiding Catheters when used as intended. The device meets the applicable **General Safety and Performance Requirements (GSPRs) of Annex I** and supports conformity with the clinical evaluation requirements of **Regulation (EU) 2017/745 (MDR)**. The results of this study justify the continued clinical use of the device and support its suitability for pre-market and regulatory approval within its intended clinical indication.

Conflict of interest

The authors have no conflict of interest to declare.

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