ASAHI®
PTCA Guide Wire

SYMBOLS

	Legal manufacturer	REF	Catalogue number
	Do not use if package is damaged	STERILE EO	Sterilized using ethylene oxide
	Do not reuse		Consult instructions for use
	Do not resterilize	Rx ONLY	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician
	Caution, consult Accompanying documents	1mm Mini pre-shape	1mm mini pre-shaped
	Use by	Mini pre-shape	Mini pre-shaped
	Keep dry	Straight	Straight
	Keep away from sunlight	Pre-shape	Pre-shaped
LOT	LOT number	Straight	Straight

AMK-DT409 Ver.2.10/17TS020

ASAHI PTCA Guide Wire
INSTRUCTIONS FOR USE

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

Read these instructions carefully before using this guide wire and observe the Indications for Use, Warnings, Precautions, and How to Use sections in this instructions for Use. Failure to do so may result in complications, including serious injury to the patient or death.

These Instructions for Use apply to the ASAHI PTCA Guide Wires. For details (length of the guide wire, length of radiopaque section, etc.), refer to the product label.

Descriptions

This PTCA/PTA guide wire has a coil-type distal end or a plastic covered-type distal end. The coil is partly or entirely radiopaque to facilitate selection of the blood vessel and confirmation of the position of the guide wire's distal end by fluoroscopy.

The guide wire surface is coated with polytetrafluoroethylene (PTFE) and/or hydrophilic polymer and/or silicone. About 2 cm of the distal end can be shaped. The product with a pre-shaped tip is also available as an option.

ASAHI INTECC detachable extension wire is available to connect with the proximal end of this guide wire with a length of less than 300 cm. A total length after the connection will be 300 to 350 cm.

Indications for Use

ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The ASAHI PTCA Guide Wires **are not to be used in the neurovasculature.**

Warnings

- This guide wire and package is presterilized with ethylene oxide gas (EOG) and is intended for single use only. Do not reuse or resterilize. If reused or resterilized, the performance or quality of this guide wire and package may be compromised and there is a risk of complications, including infection.
- Do not use the guide wire after the expiration date indicated on the label. Discard any guide wire that exceeds the expiration date.
- This guide wire must be used only by a physician who is fully trained in PTCA/PTA treatment.
- The coil section is especially fragile, so do not bend or pull it more than necessary. Otherwise, the guide wire may be damaged.
- Do not use a damaged guide wire. Using a damaged guide wire may result in blood vessel damage and/or inaccurate torque response. Injury to the patient may result.

- Never use metallic needles or metallic sheaths for insertion and withdrawal of this guide wire. Otherwise, the surface of this guide wire may be damaged significantly.
- Do not use this guide wire in combination with catheters (atherectomy catheter, metallic dilator etc.) which metallic parts may contact surface of this guide wire. Otherwise, this guide wire may be damaged or break apart.
- Always advance and withdraw the guide wire slowly.
- Observe movement of this guide wire in the vessels. Before this guide wire is moved or torqued, the tip movement should be examined and monitored under fluoroscopy. Do not move or torque the guide wire without observing corresponding movement of the tip; otherwise, the guide wire may be damaged and/or trauma may occur. In addition, ensure that the distal tip of this guide wire and its location in the vessel are visible during manipulations of the guide wire.
- Never push, auger, withdraw, or torque this guide wire that meets resistance. Torquing or pushing this guide wire against resistance may cause damage and/or tip separation of this guide wire or direct damage to a vessel. Resistance may be felt and/or observed under fluoroscopy by noting any buckling of the guide wire. If the prolapse of the guide wire tip is observed, do not allow the tip to remain in a prolapsed position; otherwise damage to the guide wire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.
- If resistance is felt due to spasm, bending of the guide wire, or due to trap while operating this guide wire in the blood vessel or removing it, do not torque and/or pull the guide wire itself. Stop the procedure. Determine the cause of resistance under fluoroscopy and take appropriate remedial action. If the guide wire is moved excessively, it may break or become damaged, which may cause blood vessel injury or result in fragments being left inside the vessel.
- If resistance is felt between this guide wire and the other interventional devices while operating this guide wire in the blood vessel, avoid applying excessive force. When abnormal resistance is felt, remove the entire system from the patient's body and determine the cause. Otherwise, the guide wire may break or be damaged and may cause injury to the blood vessel or leave fragments inside the vessel.
- This guide wire must be used in an institution where emergency surgical operation can be performed immediately. If an emergency surgical operation is unavailable, in the worst case, life-threatening events may occur.
- When torquing this guide wire inside the blood vessel, do not torque continuously in the same direction. This may cause the guide wire to become damaged or break apart, causing injury to the blood vessel or leaving fragments inside the vessel. When torquing the guide wire, rotate it clockwise and counterclockwise alternately. Do not exceed two rotations (720°) in the same direction.
- Do not push the guide wire more than necessary to advance the tip through the narrowed part of the vessel. (For example, do not push the guide wire when the distal tip of the guide wire is bent by the force of manipulation.) After crossing the targeted area, do not roughly twist, push or pull the guide wire. If the guide wire is moved excessively, it may be damaged or break apart, which may injure the blood vessel or leave fragments inside the vessel.

- Use proper technique to ensure and verify that no air enters the interventional device when pulling this guide wire from the interventional device or reinserting it. Otherwise, air embolism could occur.
- Flush the guide wire with heparinized and sterilized saline or other suitable solution while removing and reinserting it to prevent air from entering the interventional device. Perform exchange of this guide wire carefully to prevent air entry and/or trauma. When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and is not against the vessel wall. Failure to do so may result in trauma. Use the radiopaque marker of the interventional device to confirm position.
- Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit the guide wire movement.
- Do not perform stent placement using more than one guide wire or wire operation through stent strut. Otherwise, the stent may be damaged or the guide wire may break or break apart.
- Do not use in areas of vessel that are not or cannot be visualized.
- Do not connect this guide wire with detachable extension wires produced by the manufacturers excluding ASAHI INTECC. Otherwise, the guide wire may be damaged, or the detachable extension wire may be unintentionally detached. Please see the ASAHI EXTENSION® instructions for use.
- Do not manipulate this guide wire while the detachable extension wire is connected. The detachable extension wire should be needed only for the sole purpose of insertion and/or removal of the interventional device used at the same time. Otherwise, the guide wire may be damaged, or the detachable extension wire may be unintentionally detached.
- When connecting/detaching the detachable extension wire to/from this guide wire or inserting/removing combined interventional devices, the guide wire should be tightly secured and careful attention given to the motion of the tip of the guide wire under X-ray fluoroscopy. Otherwise, the blood vessel may be damaged.
- When connecting the detachable extension wire with this guide wire, it should be securely inserted to the boundary line between non PTFE coating and PTFE coating at the proximal end of the guide wire. Otherwise, the detachable extension wire may be unintentionally detached.
- If something abnormal is felt and/or detected on the connection while attaching/detaching the detachable extension wire to/from this guide wire, stop using this guide wire immediately. Otherwise, this guide wire may be damaged, or the detachable extension wire may be unintentionally damaged/detached.
- Before use, make sure that tip flexibility, size and shape of this guide wire is suitable for the intended procedure.
- Do not wipe this guide wire using an organic solution such as alcohol.
- Use this guide wire carefully as the guide wire may penetrate the blood vessel. Otherwise, it may cause adverse events such as blood vessel perforation and coronary artery dissection. The higher torque performance, stiffer distal end, and/or higher advancement force may present a higher risk of perforation or injury than if using a more flexible guide wire. Therefore, use the most

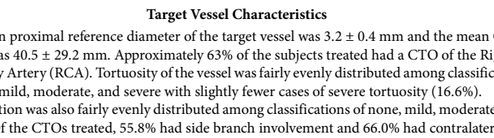
flexible guide wire that will treat the lesion (i.e., the guide wire with the smallest tip load that will treat the lesion), and take due care to minimize the risk of perforation or other damage to blood vessels.

- Use the most suitable guide wire that will treat the lesion. There are patient risks when using any guide wire including those that may result from damage to, or breakage of, the guide wire. If guide wire damage or breakage occurs, it may cause damage to the vessel and injury to the patient, or death. Accordingly, care should be taken that all persons who operate the guide wire are properly trained in their use, that they observe proper technique, and that guide wires are used carefully in accordance with the Instructions for Use.
- When treating coronary CTO stenosis where a stenting length of more than 40 mm is required, and particularly when using a combined antegrade and retrograde approach with these devices, procedure success may be less, and the risk of adverse events, including death, MI and coronary perforations may be increased.

Precautions

- If the package is opened or damaged, do not use the guide wire. Do not open the package until just prior to use. Use aseptic technique in handling and using the guide wire and package.
- Contraindications, warnings, precautions, and intended uses of interventional devices are described in the Instructions for Use supplied with the respective interventional devices. Before using an ASAHI PTCA Guide Wire with other interventional devices (Sheath introducer, Shaping device, PTCA guide wire, Extension wire, PTCA guiding catheter, PTCA dilatation catheter, Micro catheter and Stent), read the Instructions for Use of the other devices to ensure the other devices are compatible with the ASAHI PTCA Guide Wire. Ensure you choose the correct ASAHI PTCA Guide Wire and that its use is consistent with the contraindications, warnings, precautions, and Instructions for Use of both the other devices and ASAHI PTCA Guide Wire.
- Guide wires are delicate instruments and should be handled carefully. When taking the guide wire out of the holder tube, do not handle the guide wire roughly or pull it out abruptly.
- For the holder with the distal end protection tube (Figure 1), do not remove or insert the distal end protection tube while the guide wire is housed in the holder.

[Figure.1]



- Inspect the guide wire carefully for bends, kinks, or other damage prior to use and whenever possible during the procedure.
- Take due care when using the guide wire to prevent bending or kinking, and stay within standard practice when using the guide wire.

- When shaping the tip, use the minimum force needed so that the coil is not damaged. Especially the guide wire with plastic covered-type distal end is very delicate against damage. Pay careful attention not to damage the plastic cover when shaping the tip. Check the coil and guide wire for damage after shaping and before using.
- Verify which is the distal end before insertion and be sure to insert the flexible distal end (coiled end or plastic covered end).
- Take due care when shaping the tip of this guide wire. Be sure the guide wire is wet before shaping to avoid damaging the surface coating.
- For the holder with the distal end protection tube (Figure 1), remove the distal end protection tube before housing the guide wire in the holder again.
- Do not modify this guide wire for any reason.
- Take preventive measures against infection after use. Discard this guide wire and package as medical waste.

Malfunction and Adverse effects

Possible malfunction and adverse effects through usage of this guide wire include, but are not limited to the following:

Kink of the guide wire
Abrasion of the guide wire coating
Removal difficulty of guide wire
Failure to cross a lesion
Separation or breakage of the guide wire
Damage to a vessel, including possible vessel perforation
Vessel dissection
Cardiac tamponade due to vessel perforation
Air embolism
Infection
Vessel spasm
thrombus
Hematoma at puncture site
Cardiac perforation

Clinical Summary

A prospective, multi-center, single-arm study of 163 subjects was performed to evaluate the safety and effectiveness of the ASAHI series of Guide Wires and/or Corsair® Microcatheter (study devices) in patients with symptomatic ischemic heart disease attributed to a chronic total occlusion (CTO) in a native coronary artery. The primary objective of the trial was to evaluate placement of any guide wire beyond the CTO in the true vessel lumen in subjects in which at least one of the study devices were used. Procedure success was defined as (1) angiographic visualization of any guide wire crossing the target lesion and (2) absence of in-hospital major adverse cardiac events (MACE), defined as any serious adverse experience that includes cardiac death, target lesion revascularization, or post-procedural myocardial infarction (MI). Secondary endpoints included procedure time; contrast volume; absorbed radiation dose; procedural success

according to crossing technique; and frequency of successful re-canalization, in-hospital MACE, dissections, and perforations.

Key Eligibility Criteria

This study included subjects with clinical signs and/or symptoms considered suggestive of ischemic heart disease (e.g., chest pain or discomfort, heart failure, etc.) or with evidence of myocardial ischemia (e.g., abnormal functional study) attributed to the CTO target vessel, and were suitable for a percutaneous revascularization. CTO characteristics included native coronary stenosis (TIMI 0) per angiography and duration of at least three months by clinical history and/or comparison to earlier testing. Subjects were excluded if they had acute MI within 72 hours, previous coronary intervention in the last 30 days, or stroke and/or TIA within the last 6 months. Only one target lesion was allowed per subject.

Patient Demographics and Medical History

This study included a total of 163 subjects at 12 investigational sites. Basic demographics and medical history are provided in the following table.

Parameter	Result
Age	65.5 ± 10.8
Body Mass Index (BMI)	31.5 ± 5.3
Gender	Male 86.5% (141/163) Female 13.5% (22/163)
Hypertension	90.8% (148/163)
Diabetes (Type I or II)	42.9% (70/163)
Hyperlipidemia	97.5% (159/163)
Smoker	15.6% (25/160)
Prior Stroke	5.5% (9/163)
Prior Transient Ischemic Attack (TIA)	5.5% (9/163)
Prior Myocardial Infarction	41.1% (67/163)
Prior Percutaneous Transluminal Coronary Angioplasty (PTCA)	58.9% (96/163)
Prior Coronary Artery Bypass Graft (CABG)	36.8% (60/163)
Prior Coronary Intervention (Other)	16.7% (27/162)

Target Vessel Characteristics

The mean proximal reference diameter of the target vessel was 3.2 ± 0.4 mm and the mean CTO length was 40.5 ± 29.2 mm. Approximately 63% of the subjects treated had a CTO of the Right Coronary Artery (RCA). Tortuosity of the vessel was fairly evenly distributed among classification of none, mild, moderate, and severe with slightly fewer cases of severe tortuosity (16.6%). Calcification was also fairly evenly distributed among classifications of none, mild, moderate, and severe. Of the CTOs treated, 55.8% had side branch involvement and 66.0% had contralateral collaterals. In regard to TIMI flow, 98.8% of target vessels had a TIMI flow of 0, 0.6% (1 subject) had a TIMI flow of 1, and 0.6% (1 subject) had a TIMI flow of 2 which was reported as a protocol deviation. Japanese Chronic Total Occlusion (J-CTO) scores are provided in the table below.

J-CTO Score

0	1	2	3	4	5
3.1% (5/163)	18.4% (30/163)	25.2% (41/163)	25.2% (41/163)	20.9% (34/163)	7.4% (12/163)

Device Characteristics

Parameter	Result
Study Guide Wire or Catheter Used per Subject[a]	99.4% (162/163)
Crossing Technique per Subject[b]	
Antegrade Only	45.4% (74/163)
Retrograde Only	5.5% (9/163)
Antegrade and Retrograde	49.1% (80/163)

[a] Neither a study microcatheter nor study guide wire was used in the treatment one subject due to clinician error. [b] Antegrade crossing techniques are antegrade, antegrade dissection / re-entry with CrossBoss™/Stingray™, antegrade dissection / re-entry without CrossBoss™/Stingray™ (CrossBoss™ Coronary CTO Crossing Catheter K10275 marketed by Boston Scientific, Stingray™ LP CTO Coronary Re-Entry System K152401 marketed by Boston Scientific). Retrograde crossing techniques are retrograde and retrograde true wire lumen re-entry.

Primary Endpoint Results

The procedure success rate for this study was 73.0% (p=0.0044). The Investigators successfully re-canalized the vessel in 89.0% of procedures. The absence of in-hospital MACE was 81.0%. Study success was defined as meeting the primary endpoint of a successful re-canalization rate and absence of in-hospital MACE above 63.1% with a one-sided lower 95% confidence bound of 67.3%. A summary of primary endpoint procedure success is provided in the table below.

Parameter	Result	Two-Sided 95% CI	Performance Goal	Lower Bound of One-Sided 95% CI[a]	P-value[b]
Procedure Success[c]	73.0% (119/163)	(66.2%, 79.8%)	63.1%	67.3%	0.0044
Successful re-canalization	89.0% (145/163)	---	---	---	---
Absence of in-hospital MACE	81.0% (132/163)	---	---	---	---

Repeating this same data, using the criteria for a clinically relevant MI as recommended in the Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions (SCAI) published in 2013.

Details for the ITT population (using 10xULN) are shown below.

Parameter	Result	Two-Sided 95% CI	Performance Goal	Lower Bound of One-Sided 95% CI[a]	P-value[b]
Procedure Success[c]	84.7% (138/163)	(79.1%, 90.2%)	63.1%	80.0%	<0.0001
Successful re-canalization	89.0% (145/163)	---	---	---	---
Absence of in-hospital MACE	93.9% (153/163)	---	---	---	---

[a] Normal approximation to the binomial. [b] One-sided. [c] Procedure success was defined as angiographic visualization of any guide wire in a position either distal or proximal to the occlusion depending on the route of access (successful re-canalization) and the absence of in-hospital MACE.

Secondary Endpoints Results

Secondary endpoint results that are not already discussed are provided in the table below.

Parameter	Result
Total Procedure Time[a] (minutes)	118 ± 68.4 (n=162)
Total Study Device Procedure Time[b] (minutes)	73.1 ± 59.2 (n=161)
Total Amount of Contrast (mL)	287.3 ± 141.7 (n=163)
Absorbed Radiation Dose (mGy)	2612.7 ± 1881.3 (n=161)
Procedure Success by Crossing Technique	
Antegrade Only	90.5% (67/74)
Retrograde Only	66.7% (6/9)
Antegrade and Retrograde	57.5% (46/80)
Any MACE	19.0% (31/163)
Cardiac Death	2.5% (4/163)
Myocardial Infarction	16.6% (27/163)
CK-MB >3x ULN	16.6% (27/163)
CK-MB ≥10x ULN	3.7% (6/163)
Target Lesion Revascularization	0.6% (1/163)
Dissections	4.3% (7/163)
Grade A	0
Grade B	5
Grade C	0
Grade D	0
Grade E	1
Grade F	0
Grade unable to be determined	1
Perforations	12.9% (21/163)
Type I	7 (3 Clinically Significant / 4 Not Clinically Significant)
Type II	4 (3 Clinically Significant /1 Not Clinically Significant)
Type III	10 (8 Clinically Significant /2 Not Clinically Significant)

[a] The first successful insertion of the guide catheter at an arteriotomy site was considered the start of the procedure, which was considered complete once the guide catheter was removed from the arteriotomy site. [b] The first successful insertion of a study device (microcatheter or guidewire) into the target artery was considered the start of the study device procedure, which was considered complete once all study devices had been removed.

The demographics, medical history, vessel characteristics and procedural data of the subjects that experienced a safety event are shown in the tables below. Of note is the data on CTO length and stent length in the subjects who died during the study. The overall CTO length for the ITT population was 40.5±29.2mm and for the subjects who died due to CEC adjudicated Cardiac Death, the CTO length was 92.5±19.4mm. Similarly, the stent length implanted in these patients (as determined from the Core Lab analysis) was 63.2±29.6mm for the ITT population and 100.6±28.7mm for the subjects who had an adjudicated cardiac death.

The subjects experiencing a safety event had higher calcification scores, with fewer scores of "none" or "mild" as compared to the overall ITT population. Likewise with the JCTO scores, the subjects experiencing a safety event had higher scores.

Crossing technique is an indicator of complexity of the case. For the overall ITT population, both antegrade and retrograde techniques were used in 49.1% of the subjects. Subjects with the use of the combined antegrade and retrograde techniques had higher rates of safety events.

The incidence of coronary perforation signifies the high-risk nature of CTO PCI as well as the more aggressive design of some of these specialized guidewires. Among 21 angiographically adjudicated perforation events (12.9%), 18 occurred in patients who required a combined antegrade and retrograde procedure, 13 events required intervention and/or resulted in hemodynamic instability, including one case of tamponade. Among 5 cases of procedural-related death (4 of which were adjudicated as cardiac deaths), 3 were related to coronary perforation which were possibly related with study guidewire use. Finally, among all perforation events 3 cases were associated with guidewire crossing failure, and procedural success was achieved in 11 of 21 procedures.

	Parameter	ITT Subjects	Subjects who died due to CEC adjudicated Cardiac Death	Subjects w/ in-hospital MACE	Subjects with CEC Adjudicated Dissection	Subjects with CEC Adjudicated Perforation	Subjects w/ MI (5xULN)	Subjects w/ MI (SCAI Definition = 10xULN)
		Mean ± SD (N) (Min, Median, Max) or ##/## (%)	Mean ± SD (N) (Min, Median, Max) or ##/## (%)	Mean ± SD (N) (Min, Median, Max) or ##/## (%)	Mean ± SD (N) (Min, Median, Max) or ##/## (%)	Mean ± SD (N) (Min, Median, Max) or ##/## (%)	Mean ± SD (N) (Min, Median, Max) or ##/## (%)	Mean ± SD (N) (Min, Median, Max) or ##/## (%)
Demographics								
Age at consent (years)		65.5 ± 10.8 (163) (31.0,67.0,88.0)	71.5 ± 3.7 (4) (67.0,71.5,76.0)	67.7 ± 10.7 (31) (40.0,71.0,88.0)	75.7 ± 5.4 (7) (69.0,76.0,85.0)	69.5 ± 8.1 (21) (43.0,71.0,85.0)	67.2 ± 11.3 (27) (40.0,70.0,88.0)	67.7 ± 14.0 (6) (45.0,68.5,88.0)
Gender								
	Male	141/163 (86.5%)	3/4 (75.0%)	28/31 (90.3%)	6/7 (85.7%)	17/21 (81.0%)	25/27 (92.6%)	6/6 (100.0%)
	Female	22/163 (13.5%)	1/4 (25.0%)	3/31 (9.7%)	1/7 (14.3%)	4/21 (19.0%)	2/27 (7.4%)	0/6 (0.0%)
Medical History								
Diabetes								
	None	93/163 (57.1%)	2/4 (50.0%)	17/31 (54.8%)	4/7 (57.1%)	12/21 (57.1%)	15/27 (55.6%)	3/6 (50.0%)
	Type I	2/163 (1.2%)	0/4 (0.0%)	1/31 (3.2%)	0/7 (0.0%)	0/21 (0.0%)	1/27 (3.7%)	0/6 (0.0%)
	Type II	68/163 (41.7%)	2/4 (50.0%)	13/31 (41.9%)	3/7 (42.9%)	9/21 (42.9%)	11/27 (40.7%)	3/6 (50.0%)
	CABG	60/163 (36.8%)	2/4 (50.0%)	16/31 (51.6%)	5/7 (71.4%)	8/21 (38.1%)	14/27 (51.9%)	3/6 (50.0%)
Vessel information								
CTO Length (mm)		40.5 ± 29.2 (163) (5.0,30.0,150.0)	92.5 ± 19.4 (4) (75.0,87.5,120.0)	46.1 ± 33.5 (31) (5.0,35.0,135.0)	46.9 ± 37.6 (7) (5.0,30.0,115.0)	49.0 ± 33.3 (21) (5.0,30.0,120.0)	39.3 ± 29.5 (27) (5.0,30.0,135.0)	25.7 ± 10.7 (6) (10.0,24.5,40.0)
Calcification								
	None	36/163 (22.1%)	0/4 (0.0%)	0/31 (0.0%)	1/7 (14.3%)	2/21 (9.5%)	0/27 (0.0%)	0/6 (0.0%)
	Mild	45/163 (27.6%)	0/4 (0.0%)	5/31 (16.1%)	1/7 (14.3%)	2/21 (9.5%)	5/27 (18.5%)	0/6 (0.0%)
	Moderate	43/163 (26.4%)	0/4 (0.0%)	12/31 (38.7%)	3/7 (42.9%)	8/21 (38.1%)	12/27 (44.4%)	5/6 (83.3%)
	Severe	39/163 (23.9%)	4/4 (100.0%)	14/31 (45.2%)	2/7 (28.6%)	9/21 (42.9%)	10/27 (37.0%)	1/6 (16.7%)
JCTO Score								
	0	5/163 (3.1%)	0/4 (0.0%)	0/31 (0.0%)	0/7 (0.0%)	1/21 (4.8%)	0/27 (0.0%)	0/6 (0.0%)
	1	30/163 (18.4%)	0/4 (0.0%)	1/31 (3.2%)	1/7 (14.3%)	3/21 (14.3%)	1/27 (3.7%)	0/6 (0.0%)
	2	41/163 (25.2%)	0/4 (0.0%)	8/31 (25.8%)	0/7 (0.0%)	4/21 (19.0%)	8/27 (29.6%)	4/6 (66.7%)
	3	41/163 (25.2%)	1/4 (25.0%)	6/31 (19.4%)	5/7 (71.4%)	6/21 (28.6%)	5/27 (18.5%)	0/6 (0.0%)
	4	34/163 (20.9%)	2/4 (50.0%)	12/31 (38.7%)	1/7 (14.3%)	5/21 (23.8%)	10/27 (37.0%)	2/6 (33.3%)
	5	12/163 (7.4%)	1/4 (25.0%)	4/31 (12.9%)	0/7 (0.0%)	2/21 (9.5%)	3/27 (11.1%)	0/6 (0.0%)
Procedural Info								
Stent Length (from core lab analysis)[a]		63.2 ± 29.6 (139) (10.4,59.4,143.3)	100.6 ± 28.7 (4) (73.8,93.9,140.6)	69.0 ± 36.9 (24) (10.6,67.4,140.6)	58.4 ± 33.5 (5) (27.0,56.9,110.2)	77.9 ± 32.2 (18) (12.0,76.8,140.6)	62.7 ± 35.6 (20) (10.6,66.1,120.1)	52.2 ± 37.0 (4) (11.9,50.6,95.7)
Crossing Technique per initial use of device								
	Antegrade only	74/163 (45.4%)	0/4 (0.0%)	5/31 (16.1%)	1/7 (14.3%)	3/21 (14.3%)	5/27 (18.5%)	0/6 (0.0%)
	Retrograde only	9/163 (5.5%)	0/4 (0.0%)	2/31 (6.5%)	1/7 (14.3%)	0/21 (0.0%)	2/27 (7.4%)	2/6 (33.3%)
	Antegrade and Retrograde	80/163 (49.1%)	4/4 (100.0%)	24/31 (77.4%)	5/7 (71.4%)	18/21 (85.7%)	20/27 (74.1%)	4/6 (66.7%)

Conclusions

The results of this clinical trial demonstrate that the study ASAHI Guidewires, including the ASAHI Gaia® Series, Fielder® XT, MIRACLEbros® Series, ULTIMATEbros® 3, and Confianza® Pro Series, and the Corsair Microcatheter, exceeded the pre-specified safety and effectiveness performance criteria for crossing CTOs and re-canalizing the target vessel in this subject population.

How to Use

1. Inspection prior to use
   a) Before use, inspect carefully and confirm the guide wire and package are undamaged.
   b) Before use, confirm that the guide wire is compatible with the interventional devices to be used.
2. Preparation
   a) Select the most suitable guide wire for the affected area and remove the holder tube containing the guide wire from the sterile pack.
   b) Fill up the holder tube with heparinized and sterilized saline using a syringe to soak the entire device. Take note that heparinized and sterilized saline may spill out of the holder tube at this time. For the holder with the distal end protection tube (Figure 1), a syringe can be connected to the distal end protection tube.
   c) Release the proximal end of the guide wire from the tail clip and slowly push it through the holder.
   d) When the distal end of the guide wire is extended 5 to 6 cm beyond the other end of the holder tube (or the distal end protection tube), if necessary, shape the tip in accordance with standard practice. When shaping the tip, use the minimum force needed so that the coil is not damaged. Especially the guide wire with plastic covered-type distal end is very delicate against damage. Pay careful attention not to damage the plastic cover when shaping the tip. Check the coil and guide wire for damage after shaping and before using.
   e) Gently grasp the guide wire which came out from the distal end of the holder tube (or the distal end protection tube), at the point as close to the holder tube as possible and pull the guide wire out slowly and carefully.
   f) If resistance is felt when removing the guide wire from the holder tube, inject heparinized and sterilized saline into the holder tube again. Continue removing the guide wire after the resistance is not felt anymore. Be sure to inject enough heparinized and sterilized saline to the holder tube because hydrophilic coating may be damaged when removing the coated guide wire forcefully.
   g) Fill the lumen of the interventional device with the heparinized and sterilized saline before inserting the guide wire.
3. Procedures for insertion
   ■ Over-the-wire system
   a) Insert the distal end of the guide wire carefully into the guide wire lumen of the interventional device.
   b) Advance this guide wire carefully until its tip is just proximal to the interventional device tip.

   c) Engage the guiding catheter and insert the interventional device system (with guide wire) into the Y connector.
   d) Advance the interventional device system through the guiding catheter until the tip of the guide wire system is just proximal to the tip of the guiding catheter.
   e) Tighten the hemostatic valve of Y connector to create a seal around the interventional device. Ensure the guide wire movement is still permitted.
   f) Check to make sure the guide wire moves smoothly.
   g) Attach the torque device to the guide wire if necessary.
   h) Advance this guide wire under fluoroscopy to pass through the lesion. Confirm by angiography that the guide wire has passed the narrowed target lesion.
   i) Observe the guide wire movement in the vessels. Before the guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque the guide wire without observing corresponding movement of the tip. Otherwise, trauma may occur.
   j) Do not use in areas of vessel that are not or cannot be visualized.
   k) Advance the interventional device until the lesion is reached while preventing the guide wire from moving. Ensure that guide wire distal tip and its location in the vessel are visible during interventional device manipulations.

   ■ Rapid exchange system
   a) Engage the guiding catheter.
   b) Insert the guide wire introducer into the Y connector of the guiding catheter.
   c) Carefully insert the guide wire tip into the introducer.
   d) Advance the guide wire through the guiding catheter under fluoroscopy until the guide wire tip is just proximal to the tip of the guiding catheter.
   e) Attach the torque device to the guide wire if necessary.
   f) Advance the guide wire under fluoroscopy to pass through the lesion. Confirm by angiography that the guide wire has passed the narrowed target lesion.
   g) Observe this guide wire movement in the vessels. Before the guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque the guide wire without observing corresponding movement of the tip. Otherwise, trauma may occur.
   h) Do not use in areas of vessel that are not or cannot be visualized.
   i) Remove the guide wire torque device and the guide wire introducer.
   j) Track the interventional device over the guide wire while preventing the guide wire from moving, and advance until the lesion is reached. Ensure that the guide wire distal tip and its location in the vessel are visible during interventional device manipulations.
4. Procedures to exchange the guide wire
   ■ Over-the-wire system
   a) Remove this guide wire slowly while monitoring the movement of this guide wire under fluoroscopy.
   b) Insert the next guide wire in accordance with the directions in this "How to Use" section.

Product Family	Length (cm)	Nominal Diameter (inch)	Tip Load (g)	Tip Diameter (inch)	Tip Shape	Coil Length (cm)	Inner coil	Coating Type	Hydrophilic Coating Length (cm)
Fielder XT-R	190 and 300	0.014	0.6	0.010	Straight	16	Y	Hydrophilic/ PTFE	17
Fielder XT	190 and 300	0.014	0.8	0.014	Straight	16	N	Hydrophilic/ PTFE	16
Fielder XT-A	190 and 300	0.014	1	0.010	Straight	16	Y	Hydrophilic/ PTFE	17
Gaia 1st	190 and 300	0.014	1.7	0.010	1mm, 45° bend	15	Y	Hydrophilic/ PTFE	40
MIRACLEbros 3	180 and 300	0.014	3	0.014	Straight	11	N	Hydrophobic / PTFE	--
ULTIMATEbros 3	180 and 300	0.014	3	0.009	Straight	20	N	Hydrophilic/ PTFE	20
Gaia 2nd	190 and 300	0.014	3.5	0.011	1mm, 45° bend	15	Y	Hydrophilic/ PTFE	40
Gaia 3rd	190 and 300	0.014	4.5	0.012	1mm, 45° bend	15	Y	Hydrophilic/ PTFE	40
MIRACLEbros 4.5	180 and 300	0.014	4.5	0.014	Straight	11	N	Hydrophobic / PTFE	--
MIRACLEbros 6	180 and 300	0.014	6	0.014	Straight	11	N	Hydrophobic / PTFE	--
Confianza	180 and 300	0.014	9	0.014	Straight	20	N	Hydrophobic / PTFE	--
Confianza Pro	180 and 300	0.014	9	0.009	Straight	20	N	Hydrophilic/ PTFE	20
MIRACLEbros 12	180 and 300	0.014	12	0.014	Straight	11	N	Hydrophobic / PTFE	--
Confianza Pro 12	180 and 300	0.014	12	0.009	Straight	20	N	Hydrophilic/ PTFE	20

Storage Condition

Do not keep the guide wire and package in a bent and/or heavily-loaded condition. This guide wire and package must be kept out of water. Store in a cool, dark, and dry place.

Expiration date

The expiration date is indicated on the label of the guide wire package.

Contents

5 pieces / box

Special Instructions for hydrophilic coated guide wires:

■ Precautions
Avoid abrasion and peeling of the hydrophilic coating.
Do not withdraw or manipulate the guide wire in a metallic needle or metallic sheath or sharp-edged introducer device, as this may damage the hydrophilic coating.

■ Preparations for use
1) Before pulling the guide wire out of the holder tube, flush it with heparinized and sterilized saline from the holder tube end. If it is difficult to pull the guide wire out of the holder tube, flush it again with heparinized and sterilized saline.
2) After pulling the guide wire out of the holder tube, inspect it to make sure that it is not damaged.
3) If the surface of the guide wire becomes dry, the hydrophilic coating effect can be restored by wetting the surface with heparinized and sterilized saline.
4) Before inserting the guide wire into an interventional device, wet it completely with heparinized and sterilized saline.
5) Be sure to keep this guide wire soaked after it is pulled out of the patient's body.

Special instructions for use when treating CTO

Warning:

When treating coronary CTO stenosis where a stenting length of more than 40 mm is required, and particularly when using a combined antegrade and retrograde approach with these devices, procedure success may be less, and the risk of adverse events, including death, MI and coronary perforations may be increased.

It is recommended to start with the softest wire possible and escalate as needed to attempt to penetrate the CTO. It is common to use lower tip load guidewires as the initial wire in the procedure. Stiffer wires with a higher tip load may be needed for more calcified lesions. There is an increased risk of complications, including perforation, when using wires with stiffer tips, higher tip loads.

Make sure tip is clear visualized under fluoroscopy throughout the procedure.

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