

ASAHI

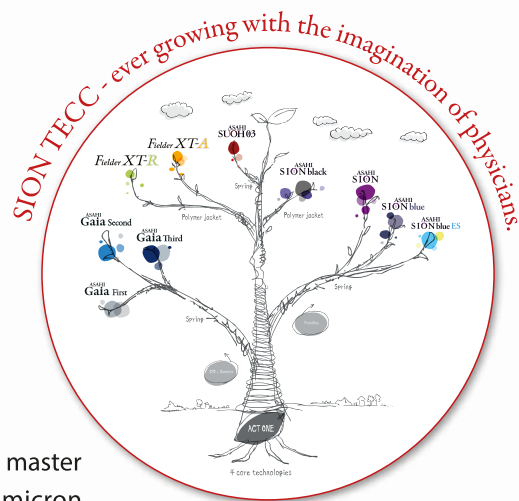
PTCA Guide Wire

ASAHI's unique guide wire technology with Composite Core

SION TECC 
Leading to the NEXT

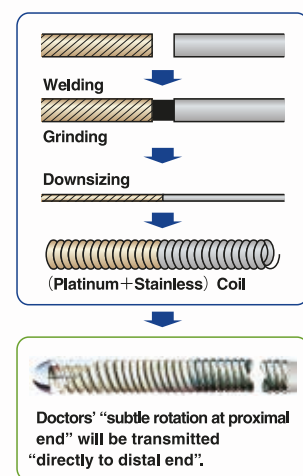
SION TECC 
Leading to the NEXT

Technology that pushes back the boundaries of guide wire manipulation,
enabling movement just as you imagine it.



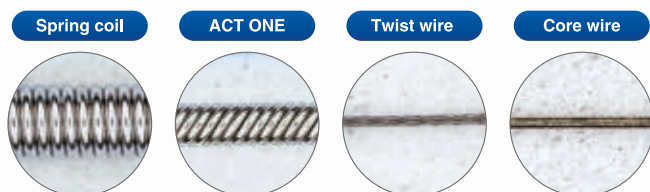
A variety of tip designs to facilitate branch selection or penetration ability. Asahi offers the right wire for any lesion.

Ensures a smooth transition from platinum to stainless steel spring coil. The smooth surface of the coil enables good slide with other interventional devices and maintain torqueability of the wire.



with
ACT ONE

Employs the ASAHl brand rope coil,
which provides torqueability, flexibility and resiliency.



*Twist wire involved only with ASAHI SION, ASAHI SION blue and ASAHI SION black.

A variety of coatings provide either superior lubricity, tactile feedback, or an optimal combination of the two.

- Lubricity**
- Hydrophilic coating with uncoated tip
ULTIMATEbros 3, ASAHI Gaia series, ASAHI Conquest Pro / ASAHI Confianza Pro series
- Full hydrophilic coating (SLIP-COAT®)
ASAHI SION, ASAHI SUOH 03
- Polymer jacket + Hydrophilic coating (SLIP-COAT®)
Felder XT-R, Fielder XT-A, ASAHI SION black
- Higher**

One-piece core wire supports the entire guide wire from the proximal to the distal end. This design transmits the guide wire torque from one end to the other without loss.

Frontline guide wires

ASAHI SION blue



- Tip load 0.5 gf
- Tip radiopacity 3 cm
- SLIP-COAT® coating over the spring coil*



First choice guide wire with proprietary Composite Core construction for greater tip flexibility and support performance. Easily-discernible shaft color for differentiation from other ASAHI wires. *Silicone coating up to 15mm from the tip for safer procedures.

ASAHI SION



- Tip load 0.7 gf
- Tip radiopacity 3 cm
- SLIP-COAT® coating over the spring coil



First choice guide wire with proprietary Composite Core construction for excellent tip durability and torque performance in tight anatomy. Flexible shaft and atraumatic tip for stress-free operation.

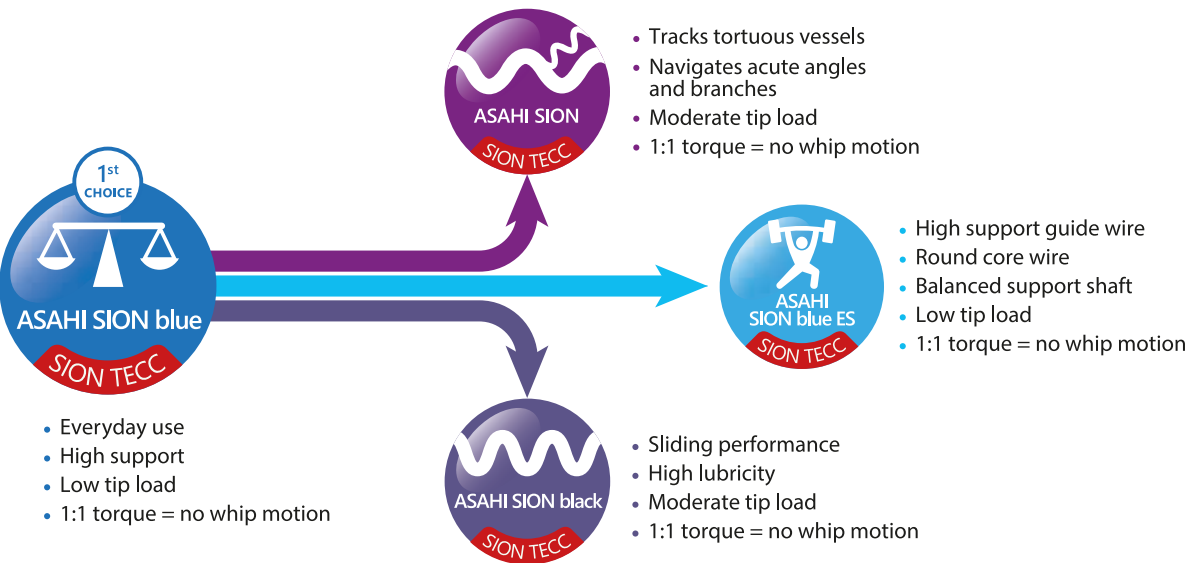
ASAHI SION black



- Tip load 0.8 gf
- Tip radiopacity 3 cm
- Polymer jacket length 20 cm
- SLIP-COAT® coating 40 cm



Frontline guide wire with a polymer jacket designed to retain flexibility while crossing high resistance stenosis and vessels.



Support guide wires

ASAHI SION blue ES



- Tip load 0.5 gf
- Tip radiopacity 3 cm
- SLIP-COAT® coating 40 cm*



An extra support type wire with SION TECC. A wire that stabilizes the guide catheter for stress-free device delivery. *Silicone coating up to 25mm from the tip for safer procedures.

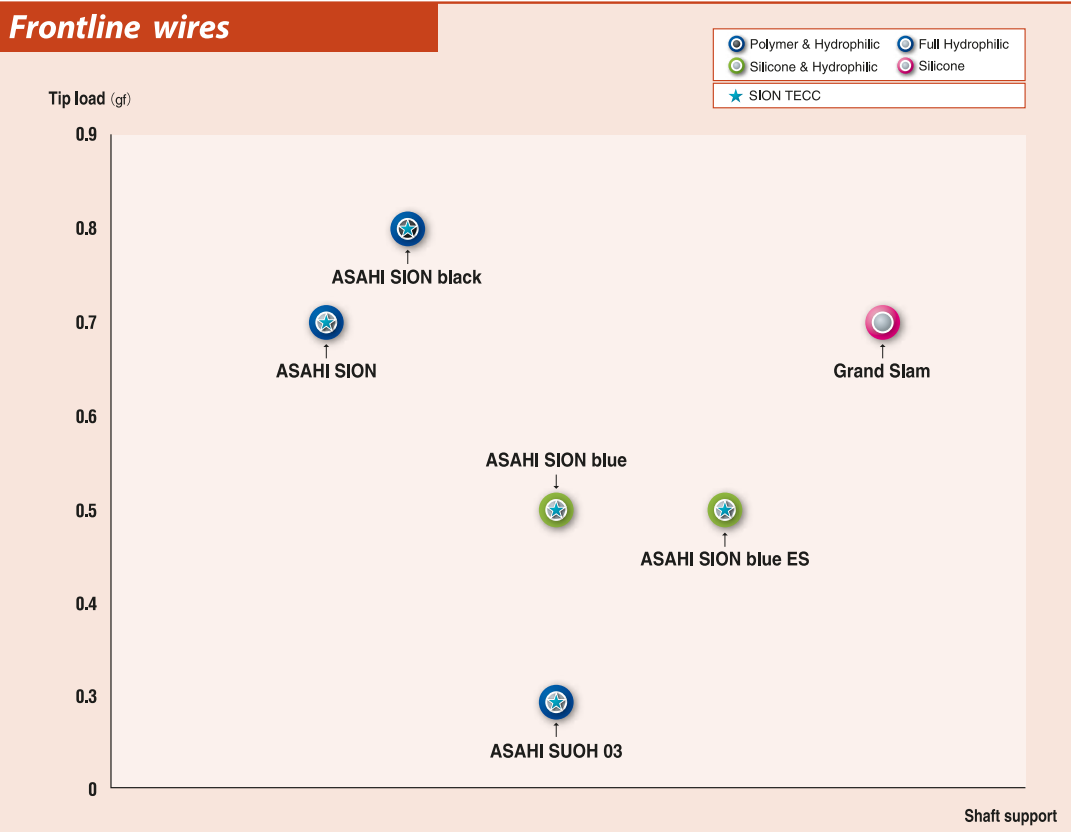
Grand Slam



- Tip load 0.7 gf
- Tip radiopacity 4 cm
- Silicone coating over the spring coil



Stiff wire shaft provides extra support for delivery of interventional devices in extreme cases.



Complex and Chronic occlusion guide wires

Fielder XT-R



- Tip load 0.6 gf
- Tip radiopacity 16 cm
- Polymer jacket length 17 cm
- Tip outer diameter 0.26 mm (0.010 inch)
- SLIP-COAT® coating over the polymer jacket



Guide wire recommended for narrow channel tracking with its low profile, flexible tip, and high lubricity polymer coating.

Fielder XT-A



- Tip load 1.0 gf
- Tip radiopacity 16 cm
- Polymer jacket length 17 cm
- Tip outer diameter 0.26 mm (0.010 inch)
- SLIP-COAT® coating over the polymer jacket



Guide wire with a higher tip load than Fielder XT and XT-R, facilitating entry into the chronic occluded lesion.

ULTIMATEbros 3



- Tip load 3.0 gf
- Tip radiopacity 11 cm
- SLIP-COAT® coating over the spring coil until the middle of the shaft / without tip



Long hydrophilic coating maintains high maneuverability, allowing for improved wire manipulation in heavy stenosed lesions. Fine shaping improves vessel selectivity and reduces the risk of false lumen expansion.

ASAHI Gaia series (First, Second, Third)



- Tip load
ASAHI Gaia First 1.7 gf
ASAHI Gaia Second 3.5 gf
ASAHI Gaia Third 4.5 gf
- Tip radiopacity 15 cm
- Tip outer diameter
ASAHI Gaia First 0.26 mm (0.010 inch)
ASAHI Gaia Second 0.28 mm (0.011 inch)
ASAHI Gaia Third 0.30 mm (0.012 inch)
- SLIP-COAT® coating 40 cm



Guide wire with a high maneuverability in the chronic total occluded lesion, and a tip designed to improve penetrability into the lesion while remaining flexible.

Complex and Chronic occlusion guide wires

ASAHI Conquest Pro series / ASAHI Confianza Pro series

9 / 12



- Tip load 9.0 / 12.0 gf
- Tip radiopacity 20 cm
- SLIP-COAT® coating over the spring coil, excluding the tip
- Tip outer diameter 0.23 mm (0.009 inch)



Tapered guide wire for crossing complex lesion with heavy calcification or tough fibrous tissues.

ASAHI Miracle 12 / ASAHI MIRACLEbros 12

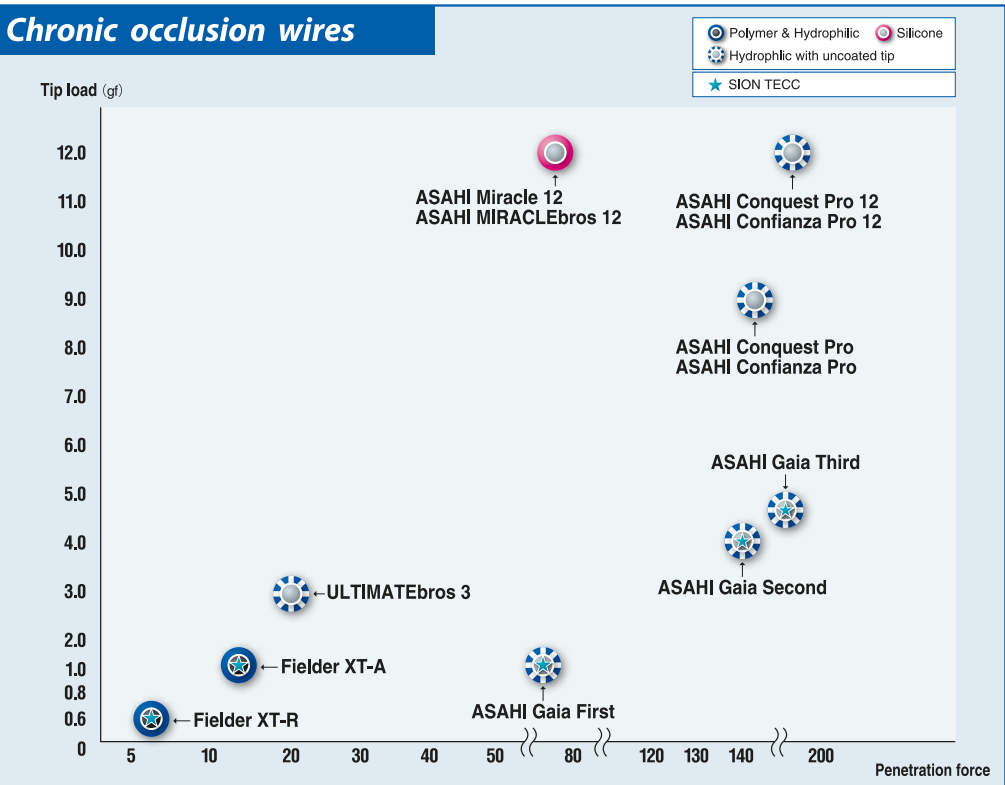


- Tip load 12.0 gf
- Tip radiopacity 11 cm
- Silicone coating over the spring coil



Guide wire with good tactile feed back which maintains torqueability through the occlusion.

Chronic occlusion wires



- Polymer & Hydrophilic
Enhanced lubricity for better crossability of severe stenoses.
- Hydrophilic with uncoated tip
Enhance lubricity for easier wire manipulation in lesions.
- Silicone
Prevent slippage to gain tactile response for lesion morphology.
- SION TECC

Externalization guide wire

ASAHI RG3



- Tip load 3.0 gf
- Tip radiopacity 3 cm
- SLIP-COAT® coating over the spring coil and until the middle of the shaft
- Shaft diameter 0.26 mm (0.010 inch)
- Guide wire length 330 cm



For guide wire externalization only. Optimal wire strength, hydrophilic coating and 0.26 mm (0.010 inch) shaft provide superior inside-catheter pushability. With the inner wall damage possibility reduced in tortuous vessels as well, the risk of complication is minimized.

Retrograde guide wire

ASAHI SUOH 03



- Tip load 0.3 gf
- Tip radiopacity 3 cm
- SLIP-COAT® coating 52 cm

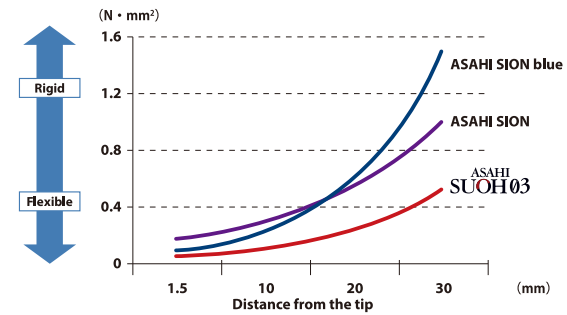


Flexible shaft provides superb trackability and crossability in severe tortuosity. The long radiopaque segment provides good visualization.



Tip flexibility

Radiopaque distal 30 mm is the most flexible among ASAHI guide wires.



Angiogram by tip injection

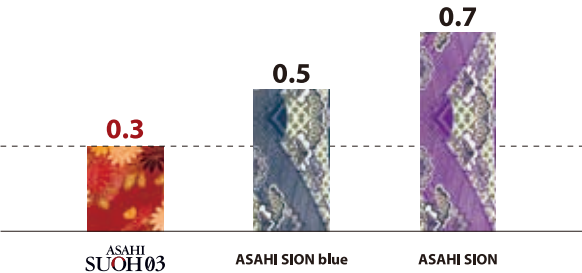


SUOH 03 Wiring



Tip load (gf)

The softest tip among ASAHI guide wires – 0.3 gf.*

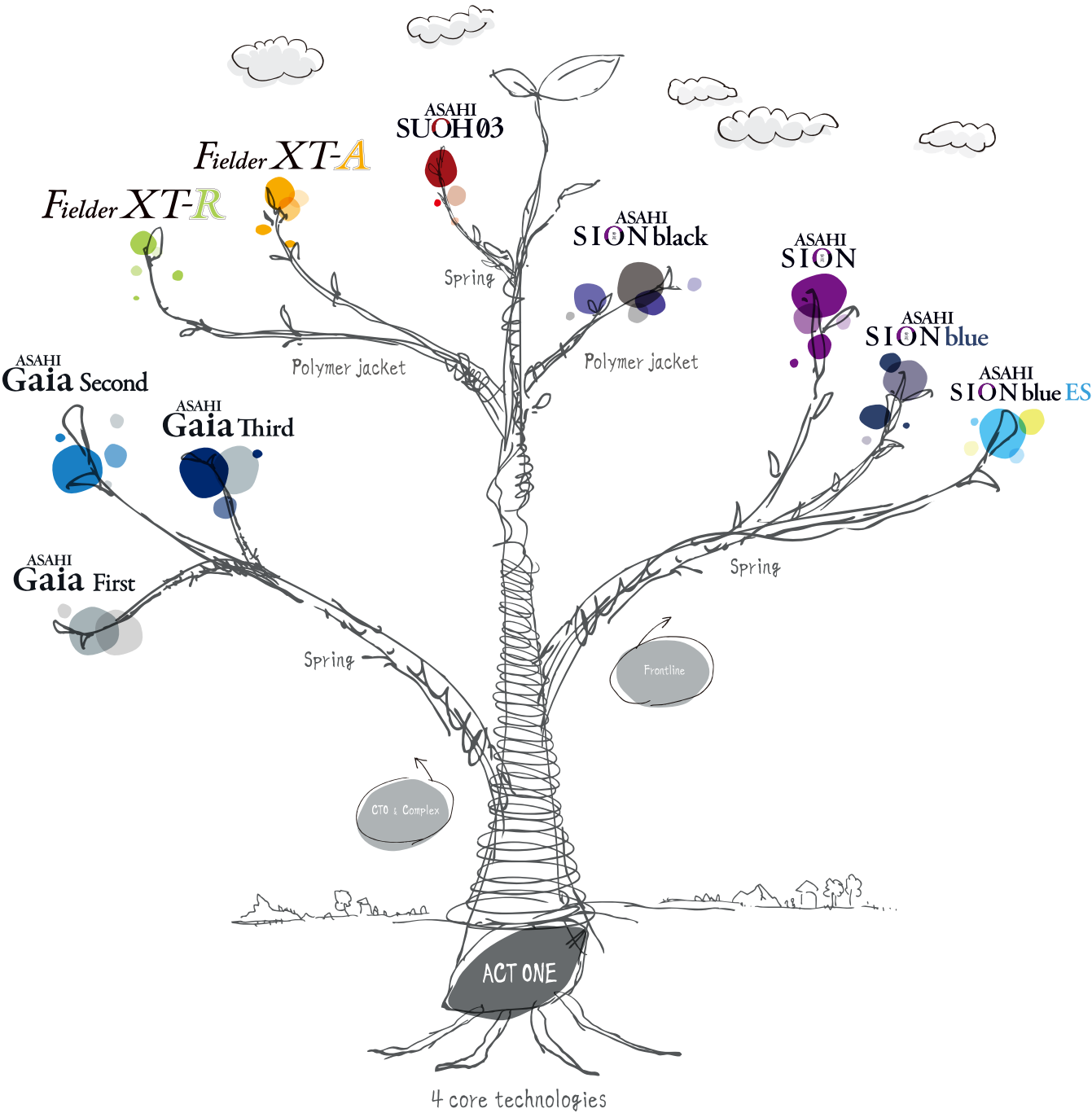


All the data were obtained by company standardized test, which may differ from industry standardized tests.
All the data do not guarantee that all devices have exactly the same performance with the samples used for tests.
*Softest available tip load at 0.3 gf is as of Jan 2017.

ASAHI's unique guide wire technology with Composite Core

SION TECC

Leading to the NEXT



Ordering information

Product	Catalog No.	Diameter (mm (inch))	Radiopaque segment (cm)	Spring coil length (cm)	Length (cm)	Tip shape
ASAHI SION blue SION TECC	AHW14R004S	0.36 (0.014)	3	20	180	Straight
	AHW14R304S				300	Straight
	AHW14R004J				180	J
	AHW14R304J				300	J
ASAHI SION SION TECC	AHW14R001S	0.36 (0.014)	3	28	180	Straight
	AHW14R301S				300	Straight
	AHW14R001J				180	J
	AHW14R301J				300	J
ASAHI SION black SION TECC	APW14R010S	0.36 (0.014)	3	12	190	Straight
	APW14R310S				300	Straight
	APW14R010J				190	J
	APW14R310J				300	J
ASAHI SION blue ES SION TECC	AHW14R017S	0.36 (0.014)	3	8.5	190	Straight
	AHW14R317S				300	Straight
	AHW14R017J				190	J
	AHW14R317J				300	J
Grand Slam	AG141002	0.36 (0.014)	4	4	180	Straight
	AG141302				300	Straight
	AG141002J				180	J
Fielder XT-R SION TECC	APW14R005S	0.26 / 0.36 (0.010 / 0.014)	16	16	190	Straight
	APW14R305S				300	Straight
Fielder XT-A SION TECC	APW14R009S	0.26 / 0.36 (0.010 / 0.014)	16	16	190	Straight
	APW14R309S				300	Straight
ULTIMATEbros 3	AHW14S003S	0.36 (0.014)	11	11	180	Straight
ASAHI Gaia First SION TECC	AHW14R007P	0.26 / 0.36 (0.010 / 0.014)	15	15	190	Pre-shape
	AHW14R307P				300	Pre-shape
ASAHI Gaia Second SION TECC	AHW14R008P	0.28 / 0.36 (0.011 / 0.014)	15	15	190	Pre-shape
	AHW14R308P				300	Pre-shape
ASAHI Gaia Third SION TECC	AHW14R011P	0.30 / 0.36 (0.012 / 0.014)	15	15	190	Pre-shape
	AHW14R311P				300	Pre-shape
ASAHI Conquest Pro / ASAHI Confianza Pro	AGH143090	0.23 / 0.36 (0.009 / 0.014)	20	20	180	Straight
ASAHI Conquest Pro 12 / ASAHI Confianza Pro 12	AGH143091	0.23 / 0.36 (0.009 / 0.014)	20	20	180	Straight
ASAHI Miracle 12 / ASAHI MIRACLEbros 12	AG14M070	0.36 (0.014)	11	11	180	Straight
ASAHI RG3	AHW10S302S	0.26 (0.010)	3	8	330	Straight
ASAHI SUOH 03 SION TECC	AHW14R013P	0.36 (0.014)	3	19	190	Pre-shape
	AHW14R313P				300	Pre-shape
ASAHI EXTENSION 165cm	AG149001	0.36 (0.014)	—	—	165	—



Not all products and shapes are available in all markets. Please check availability with your sales representative.
Coated with SLIP-COAT® coating.

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Manufactured by:

Distributed by:



ASAHI INTECC CO.,LTD.

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TEL:+81-561-48-5551 FAX:+81-561-48-5552
<http://www.asahi-intecc.com>

DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

We declare under our sole responsibility that
the medical device

(Name) NEO'S PTCA Guide Wire
(Series) ASAHI PTCA GUIDE WIRE AG, AGH, and AGP series
(Model) Refer to Table 1
(Serial of Lot No.)
From 8404810031 to
Name, type or model, batch or serial number, possibly source and number of items

of Class

111

According to annex IX of directive 93/42/EEC:

meets all the provisions of the directive 93/42/EEC which apply it.

- | | | |
|----|---|---|
| 2. | EC Design Examination Certificate No. | 2107788DE01 |
| | Issued by | DEKRA Certification B. V. (Notified under No. 0344) |
| 3. | CE Marking of Conformity Certificate No. | 2107788CE01 |
| | Issued by | DEKRA Certification B. V. (Notified under No. 0344) |
| 4. | Manufacturing Facility | <p>(1) ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN</p> <p>(2) ASAHI INTECC (THAILAND) CO., LTD.
158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi
Amphur Muang Pathumthani 12000 Thailand</p> <p>(3) ASAHI INTECC HANOI CO., LTD.
THANG LONG Industrial Park Dong Anh District Hanoi Vietnam</p> |
| 5. | Authorized representative in EU | <p>Emergo Europe
Molenstraat 15, 2513 BH, The Hague, The Netherlands</p> |
| 6. | Applied harmonized standards, national standards or other normative documents | Refer to Table 2 and Table 3 |
| 7. | Conformity assessment procedure | Based on Medical Devices Directive 93/42/EEC Annex II.3 and 4 |
| 8. | Signature of Manufacturer | |

3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

July 12, 2013

Place, Date

Yoshihiko Fukui,
Executive Director
Senior General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1 Model of ASAHI PTCA GUIDE WIRE

Product No.	Product Name	Product No.	Product Name
12780-01 (AG141000)	ASAHI SOFT 180cm	14939-01 (AG141300)	ASAHI SOFT 300cm
12780-02 (AG141000J)	ASAHI SOFT 180cm J	14939-02 (AG141300J)	ASAHI SOFT 300cm J
12781-01 (AG141002)	ASAHI GRAND SLAM 180cm	14940-01 (AG141302)	ASAHI GRAND SLAM 300cm
12781-02 (AG141002J)	ASAHI GRAND SLAM 180cm J	14940-02 (AG141302J)	ASAHI GRAND SLAM 300cm J
12782-01 (AG142000)	ASAHI MEDIUM 180cm	14941-01 (AG142300)	ASAHI MEDIUM 300cm
- (AG142000J)	ASAHI MEDIUM 180cm J	- (AG142300J)	ASAHI MEDIUM 300cm J
12783-01 (AG143000)	ASAHI STANDARD 180cm	14942-01 (AG143300)	ASAHI STANDARD 300cm
- (AG143000J)	ASAHI STANDARD 180cm J	- (AG143300J)	ASAHI STANDARD 300cm J
12785-01 (AG145000)	ASAHI LIGHT 180cm	14944-01 (AG145300)	ASAHI LIGHT 300cm
12785-02 (AG145000J)	ASAHI LIGHT 180cm J	14944-02 (AG145300J)	ASAHI LIGHT 300cm J
12778-01 (AG14M050)	ASAHI MIRACLEbros 3 180cm	14937-01 (AG14M350)	ASAHI MIRACLEbros 3 300cm
- (AG14M050J)	ASAHI MIRACLEbros 3 180cm J	- (AG14M350J)	ASAHI MIRACLEbros 3 300cm J
12777-01 (AG14M045)	ASAHI MIRACLEbros 4.5 180cm	14936-01 (AG14M345)	ASAHI MIRACLEbros 4.5 300cm
- (AG14M045J)	ASAHI MIRACLEbros 4.5 180cm J	- (AG14M345J)	ASAHI MIRACLEbros 4.5 300cm J
12779-01 (AG14M060)	ASAHI MIRACLEbros 6 180cm	14938-01 (AG14M360)	ASAHI MIRACLEbros 6 300cm
- (AG14M060J)	ASAHI MIRACLEbros 6 180cm J	- (AG14M360J)	ASAHI MIRACLEbros 6 300cm J
82903-01 (AG14M070)	ASAHI MIRACLEbros 12 180cm	82903-02 (AG14M370)	ASAHI MIRACLEbros 12 300cm
- (AG14M070J)	ASAHI MIRACLEbros 12 180cm J	- (AG14M370J)	ASAHI MIRACLEbros 12 300cm J
12784-01 (AG143090)	ASAHI CONFIANZA 180cm	14943-01 (AG143390)	ASAHI CONFIANZA 300cm
- (AG143090J)	ASAHI CONFIANZA 180cm J	- (AG143390J)	ASAHI CONFIANZA 300cm J
20629-01 (AGH143090)	ASAHI CONFIANZA PRO 180cm	20629-02 (AGH143390)	ASAHI CONFIANZA PRO 300cm
- (AGH143090J)	ASAHI CONFIANZA PRO 180cm J	- (AGH143390J)	ASAHI CONFIANZA PRO 300cm J
82902-01 (AGH143091)	ASAHI CONFIANZA PRO 12 180cm	82902-02 (AGH143391)	ASAHI CONFIANZA PRO 12 300cm
- (AGH143091J)	ASAHI CONFIANZA PRO 12 180cm J	- (AGH143391J)	ASAHI CONFIANZA PRO 12 300cm J
12776-01 (AGH146000)	ASAHI PROWATER 180cm	14935-01 (AGH146300)	ASAHI PROWATER 300cm
12776-02 (AGH146000J)	ASAHI PROWATER 180cm J	14935-02 (AGH146300J)	ASAHI PROWATER 300cm J
82358-01 (AGH147000)	ASAHI PROWATERflex 180cm	82358-02 (AGH147300)	ASAHI PROWATERflex 300cm
82358-11 (AGH147000J)	ASAHI PROWATERflex 180cm J	82358-12 (AGH147300J)	ASAHI PROWATERflex 300cm J
82359-01 (AGP140000)	ASAHI FIELDER 180cm	82359-02 (AGP140300)	ASAHI FIELDER 300cm
82359-11 (AGP140000J)	ASAHI FIELDER 180cm J	82359-12 (AGP140300J)	ASAHI FIELDER 300cm J

Product No.	Product Name	Product No.	Product Name
1011895H (AGP140001)	ASAHI FIELDER FC 180cm	1011896H (AGP140301)	ASAHI FIELDER FC 300cm
1011895HJ (AGP140001J)	ASAHI FIELDER FC 180cm J	1011896HJ (AGP140301J)	ASAHI FIELDER FC 300cm J
AGP140002	ASAHI FIELDER XT 190cm	AGP140302	ASAHI FIELDER XT 300cm

Table 2 Applied harmonized standards (QA-Related Standards)

Standard Reference	Title
EN ISO 13485:2012 AC:2012 ISO 13485:2003 Cor1:2009	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EC Directive 93/42/EEC L 169 1993 Amd 1: 1998 Amd 2: 2000 Amd 3: 2002 Amd 4: 2003 Amd 5: 2007	Medical Devices Directive (2007)

Table 3 Applied harmonized standards (Product related standards)

Standard Reference	Title
EN 556-1:2001 AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 1: Requirements for terminally sterilized medical devices
EN 556-2: 2003	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 2: Requirements for aseptically processed medical devices
EN ISO 15223-1: 2012 ISO 15223-1: 2012	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied –Part1: General requirements
EN 1041:2008	Terminology, symbols and information provided with medical devices - Information Supplied by the Manufacturer
EN ISO 10993-1: 2009 AC: 2010 ISO 10993-1: 2009 Cor1: 2010	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-2: 2006 ISO 10993-2: 2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements – Second Edition
EN ISO 10993-4: 2009 ISO 10993-4: 2002 Amd 1: 2006	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood AMENDMENT 1
EN ISO 10993-5: 2009 ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for cytotoxicity: <i>in vitro</i> methods
EN ISO 10993-7: 2008 AC:2009 ISO 10993-7: 2008 Cor1:2009	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10: 2010 ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization

Standard Reference	Title
EN ISO 10993-11: 2009 ISO 10993-11: 2006	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12: 2012 ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 11070: 1999 ISO 11070: 1998	Sterile, single-use intravascular catheter introducers
EN ISO 11135-1:2007 ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1:Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2006 ISO11138-1: 2006	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2: 2009 ISO 11138-2: 2006	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1: 2009 ISO 11607-1: 2006	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems-First edition
EN ISO 11607-2: 2006 ISO 11607-2: 2006	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes-First edition
EN ISO 11737-1: 2006 AC:2009 ISO 11737-1: 2006 Cor 1: 2007	Sterilization of medical devices – Microbiological methods – Part 1: Estimation of population of microorganisms on products Corrigendum 1
EN ISO 11737-2: 2009 ISO 11737-2: 2009	Sterilization of medical devices – Microbiological methods -- Part 2: Tests of sterility performed in the validation of a sterilization process
EN ISO 14155: 2011 AC:2011 ISO 14155: 2011 Cor1:2011	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14161: 2009 ISO 14161: 2009	Sterilization of Health Care Products - Biological Indicators - Guidance for the Selection, Use and Interpretation of Results-First Edition
EN ISO 14644-1: 1999 ISO 14644-1: 1999	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness-First Edition
EN ISO 14644-2: 2000 ISO 14644-2: 2000	Cleanrooms and Associated Controlled Environments - Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1-First Edition
EN ISO 14644-3: 2005 ISO 14644-3: 2005	Cleanrooms and associated controlled environments - Part 3: Test methods-First Edition
EN ISO 14698-1: 2003 ISO 14698-1: 2003	Cleanrooms and associated controlled environments Biocontamination control - Part 1: General principles and methods - First Edition
EN ISO 14698-2: 2003 AC: 2006 ISO 14698-2: 2003 Cor1: 2004	Cleanrooms and associated controlled environments Biocontamination control - Part 1: General principles and methods - First Edition
EN ISO 14971: 2012 ISO 14971: 2007	Medical device – Application of risk management to medical devices
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM
MEDDEV. 2.7.1: 2009	EVALUATION OF CLINICAL DATA: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
MEDDEV. 2.12-2: 2012	POST MARKET CLINICAL FOLLOW-UP STUDIES

CERTIFICATE

Number: 2107788DE01

EC DESIGN-EXAMINATION MEDICAL DEVICES

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

For the product(s) / product category:

PTCA Guide Wires

Documents, that form the basis of this certificate:

Certification Notice 2107788CN, initially dated 1 June 2008

CE Marking of Conformity 2107788CE01

Addendum, initially dated 1 June 2008

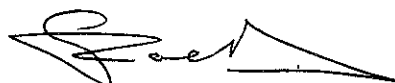
DEKRA hereby certifies that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that the design of the product(s) falling within the product category mentioned above, conforms to the provisions of the Council Directive 93/42/EEC of June 14, 1993, in accordance with Annex II, section 4 of this Directive. The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 12 August 2022

Issued for the first time: 1 June 2008

Reissued: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2107788DE01

1/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

This certificate covers the following product(s):

Series:

PTCA Guide Wire

(ASAHI PTCA GUIDE WIRE and ASAHI PTCA Guide Wire)

- AG series

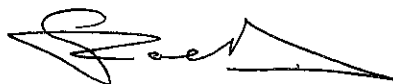
- AGH series

- AGP series

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 2107788DE01

2/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AG Series

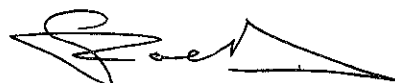
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12780-01 (AG141000)	ASAHI SOFT 180cm	AG141000	Soft
12780-02 (AG141000J)	ASAHI SOFT 180cm J	AG141000J	Soft J
14939-01 (AG141300)	ASAHI SOFT 300cm	AG141300	Soft 300cm
14939-02 (AG141300J)	ASAHI SOFT 300cm J	AG141300J	Soft 300cm J
12781-01 (AG141002)	ASAHI GRAND SLAM 180cm	AG141002	Grand Slam
12781-02 (AG141002J)	ASAHI GRAND SLAM 180cm J	AG141002J	Grand Slam J
14940-01 (AG141302)	ASAHI GRAND SLAM 300cm	AG141302	Grand Slam 300cm
14940-02 (AG141302J)	ASAHI GRAND SLAM 300cm J	AG141302J	Grand Slam 300cm J

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

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3/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

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Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12782-01 (AG142000)	ASAHI MEDIUM 180cm	AG142000	Intermediate Medium MEDIUM
- (AG142000J)	ASAHI MEDIUM 180cm J	AG142000J	Intermediate J Medium J MEDIUM J
14941-01 (AG142300)	ASAHI MEDIUM 300cm	AG142300	Intermediate 300cm Medium 300cm MEDIUM 300cm
- (AG142300J)	ASAHI MEDIUM 300cm J	AG142300J	Intermediate 300cm J Medium 300cm J MEDIUM 300cm J
12783-01 (AG143000)	ASAHI STANDARD 180cm	AG143000	Standard
- (AG143000J)	ASAHI STANDARD 180cm J	AG143000J	Standard J
14942-01 (AG143300)	ASAHI STANDARD 300cm	AG143300	Standard 300cm
- (AG143300J)	ASAHI STANDARD 300cm J	AG143300J	Standard 300cm J

Initial date: 1 June 2008,

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EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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JAPAN

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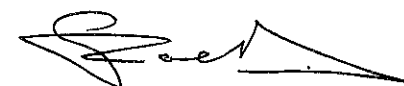
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12785-01 (AG145000)	ASAHI LIGHT 180cm	AG145000	Light
12785-02 (AG145000J)	ASAHI LIGHT 180cm J	AG145000J	Light J
14944-01 (AG145300)	ASAHI LIGHT 300cm	AG145300	Light 300cm
14944-02 (AG145300J)	ASAHI LIGHT 300cm J	AG145300J	Light 300cm J
12778-01 (AG14M050)	ASAHI MIRACLEbros 3 180cm	AG14M050	Miracle 3 Miraclebros 3 MIRACLEbros 3
- (AG14M050J)	ASAHI MIRACLEbros 3 180cm J	AG14M050J	Miracle 3 J Miraclebros 3 J MIRACLEbros 3 J
14937-01 (AG14M350)	ASAHI MIRACLEbros 3 300cm	AG14M350	Miracle 3 300cm Miraclebros 3 300cm MIRACLEbros 3 300cm
- (AG14M350J)	ASAHI MIRACLEbros 3 300cm J	AG14M350J	Miracle 3 300cm J Miraclebros 3 300cm J MIRACLEbros 3 300cm J

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Revision date: 12 August 2017

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EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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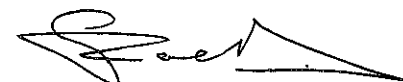
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12777-01 (AG14M045)	ASAHI MIRACLEbros 4,5 180cm	AG14M045	Miracle 4,5 Miraclebros 4,5 MIRACLEbros 4,5 Miracle 4,5 J Miraclebros 4,5 J MIRACLEbros 4,5 J
- (AG14M045J)	ASAHI MIRACLEbros 4,5 180cm J	AG14M045J	Miraclebros 4,5 J MIRACLEbros 4,5 J Miracle 4,5 300cm Miraclebros 4,5 300cm MIRACLEbros 4,5 300cm Miracle 4,5 300cm J Miraclebros 4,5 300cm J MIRACLEbros 4,5 300cm J
14936-01 (AG14M345)	ASAHI MIRACLEbros 4,5 300cm	AG14M345	Miracle 4,5 300cm Miraclebros 4,5 300cm MIRACLEbros 4,5 300cm Miracle 4,5 300cm J Miraclebros 4,5 300cm J MIRACLEbros 4,5 300cm J
- (AG14M345J)	ASAHI MIRACLEbros 4,5 300cm J	AG14M345J	Miraclebros 4,5 300cm J MIRACLEbros 4,5 300cm J Miracle 6 Miraclebros 6 MIRACLEbros 6 Miracle 6 J Miraclebros 6 J MIRACLEbros 6 J
12779-01 (AG14M060)	ASAHI MIRACLEbros 6 180cm	AG14M060	Miracle 6 Miraclebros 6 MIRACLEbros 6 Miracle 6 J Miraclebros 6 J MIRACLEbros 6 J
- (AG14M060J)	ASAHI MIRACLEbros 6 180cm J	AG14M060J	Miracle 6 J Miraclebros 6 J MIRACLEbros 6 J

Initial date: 1 June 2008

Revision date: 12 August 2017

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EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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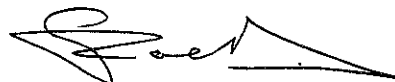
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
14938-01 (AG14M360)	ASAHI MIRACLEbros 6 300cm	AG14M360	Miracle 6 300cm Miraclebros 6 300cm MIRACLEbros 6 300cm Miracle 6 300cm J Miraclebros 6 300cm J MIRACLEbros 6 300cm J
- (AG14M360J)	ASAHI MIRACLEbros 6 300cm J	AG14M360J	Miracle 12 Miraclebros 12 MIRACLEbros 12 Miracle 12 J Miraclebros 12 J MIRACLEbros 12 J
82903-01 (AG14M070)	ASAHI MIRACLEbros 12 180cm	AG14M070	Miracle 12 300cm Miraclebros 12 300cm MIRACLEbros 12 300cm Miracle 12 300cm J Miraclebros 12 300cm J MIRACLEbros 12 300cm J
- (AG14M070J)	ASAHI MIRACLEbros 12 180cm J	AG14M070J	
82903-02 (AG14M370)	ASAHI MIRACLEbros 12 300cm	AG14M370	
- (AG14M370J)	ASAHI MIRACLEbros 12 300cm J	AG14M370J	

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EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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AG Series

Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12784-01 (AG143090)	ASAHI CONFianza 180cm	AG143090	Conquest Confianza CONFianza
- (AG143090J)	ASAHI CONFianza 180cm J	AG143090J	Conquest J Confianza J CONFianza J
14943-01 (AG143390)	ASAHI CONFianza 300cm	AG143390	Conquest 300cm Confianza 300cm CONFianza 300cm
- (AG143390J)	ASAHI CONFianza 300cm J	AG143390J	Conquest 300cm J Confianza 300cm J CONFianza 300cm J

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Revision date: 12 August 2017

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AGH Series

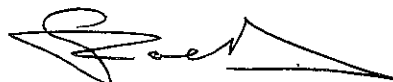
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
20629-01 (AGH143090)	ASAHI CONFIANZA PRO 180cm	AGH143090	Conquest Pro Confianza Pro CONFIANZA PRO
- (AGH143090J)	ASAHI CONFIANZA PRO 180cm J	AGH143090J	Conquest Pro J Confianza Pro J CONFIANZA PRO J
20629-02 (AGH143390)	ASAHI CONFIANZA PRO 300cm	AGH143390	Conquest Pro 300cm Confianza Pro 300cm CONFIANZA PRO 300cm
- (AGH143390J)	ASAHI CONFIANZA PRO 300cm J	AGH143390J	Conquest Pro 300cm J Confianza Pro 300cm J CONFIANZA PRO 300cm J
82902-01 (AGH143091)	ASAHI CONFIANZA PRO 12 180cm	AGH143091	Conquest Pro 12 Confianza Pro 12 CONFIANZA PRO 12
- (AGH143091J)	ASAHI CONFIANZA PRO 12 180cm J	AGH143091J	Conquest Pro 12 J Confianza Pro 12 J CONFIANZA PRO 12 J

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AGH Series

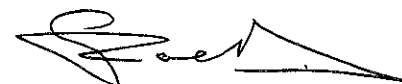
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
82902-02 (AGH143391)	ASAHI CONFIANZA PRO 12 300cm	AGH143391	Conquest Pro 12 300cm Confianza Pro 12 300cm CONFIANZA PRO 12 300cm
- (AGH143391J)	ASAHI CONFIANZA PRO 12 300cm J	AGH143391J	Conquest Pro 12 300cm J Confianza Pro 12 300cm J CONFIANZA PRO 12 300cm J
12776-01 (AGH146000)	ASAHI PROWATER 180cm	AGH146000	Rinato Prowater PROWATER
12776-02 (AGH146000J)	ASAHI PROWATER 180cm J	AGH146000J	Rinato J Prowater J PROWATER J
14935-01 (AGH146300)	ASAHI PROWATER 300cm	AGH146300	Rinato 300cm Prowater 300cm PROWATER 300cm
14935-02 (AGH146300J)	ASAHI PROWATER 300cm J	AGH146300J	Rinato 300cm J Prowater 300cm J PROWATER 300cm J

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EC DESIGN-EXAMINATION MEDICAL DEVICES

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AGH Series

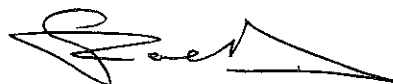
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
82358-01 (AGH147000)	ASAHI PROWATERflex 180cm	AGH147000	Prowaterflex Route PROWATERflex
82358-11 (AGH147000J)	ASAHI PROWATERflex 180cm J	AGH147000J	Prowaterflex J Route J PROWATERflex J
82358-02 (AGH147300)	ASAHI PROWATERflex 300cm	AGH147300	Prowaterflex 300cm Route 300cm PROWATERflex 300cm
82358-12 (AGH147300J)	ASAHI PROWATERflex 300cm J	AGH147300J	Prowaterflex 300cm J Route 300cm J PROWATERflex 300cm J
		AHW14S003S	ULTIMATEbro3
		AHW14S003J	ULTIMATEbro3 J
		AHW14S303S	ULTIMATEbro3 300cm
		AHW14S303J	ULTIMATEbro3 300cm J

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Revision date: 12 August 2017

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11/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AGP Series

Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
82359-01 (AGP140000)	ASAHI FIELDER 180cm	AGP140000	Fielder
82359-11 (AGP140000J)	ASAHI FIELDER 180cm J	AGP140000J	Fielder J
82359-02 (AGP140300)	ASAHI FIELDER 300cm	AGP140300	Fielder 300cm
82359-12 (AGP140300J)	ASAHI FIELDER 300cm J	AGP140300J	Fielder 300cm J
1011895H (AGP140001)	ASAHI FIELDER FC 180cm	AGP140001	Fielder FC
1011895HJ (AGP140001J)	ASAHI FIELDER FC 180cm J	AGP140001J	Fielder FC J
1011896H (AGP140301)	ASAHI FIELDER FC 300cm	AGP140301	Fielder FC 300cm
1011896HJ (AGP140301J)	ASAHI FIELDER FC 300cm J	AGP140301J	Fielder FC 300cm J
AGP140002	ASAHI FIELDER XT 190cm	AGP140002	Fielder XT
AGP140302	ASAHI FIELDER XT 300cm	AGP140302	Fielder XT 300cm

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

ASAHI INTECC (THAILAND) CO.,LTD.
158/1 Moo 5, Bangkadi Industrial Park,
Tiwanon Road, Tambol Bangkadi,
Amphur Muang Pathumthani,
Pathumthani
12000
Thailand

Holds Certificate Number:

MD 718537

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The Design and development, Manufacturing and EtO sterilization of Catheters, and Guidewires.
The Manufacturing and EtO sterilization of Electrosurgical snares for use in endoscopy.
The Design and development, and Manufacturing of metallic wires, metallic wire-ropes and metallic coils for medical devices.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2008-06-01

Latest Revision Date: 2021-05-14

Effective Date: 2020-03-25

Expiry Date: 2023-03-24

Page: 1 of 2



003

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Certificate No: **MD 718537**

Location	Registered Activities
ASAHI INTECC (THAILAND) CO.,LTD. N1 Factory / N2 Factory 142/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand	The Design and development, Manufacturing and EtO sterilization of Catheters, and Guidewires. The Manufacturing and EtO sterilization of Electrosurgical snares for use in endoscopy. The Design and development, and Manufacturing of metallic wires, metallic wire-ropes and metallic coils for medical devices.
ASAHI INTECC (THAILAND) CO.,LTD. 158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand	The Design and development, Manufacturing and EtO sterilization of Catheters, and Guidewires. The Manufacturing and EtO sterilization of Electrosurgical snares for use in endoscopy.
ASAHI INTECC (THAILAND) CO.,LTD. N3 Factory, 149 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand	The Design and development.

Original Registration Date: 2008-06-01

Latest Revision Date: 2021-05-14

Effective Date: 2020-03-25

Expiry Date: 2023-03-24

Page: 2 of 2

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