

EC CERTIFICATE

Number: 2107788CE11

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

ASAHI INTECC CO., LTD. Medical Division

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

For the product category(ies)

Peripheral Guide Wires

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2107788CN
Addendum, initially dated 29 January 2009

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 February 2023
Issued for the first time: 29 January 2009
Reissued: 1 February 2018

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2107788CE11

1/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Peripheral 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):

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
Treasure 12	PAGH18M070	ASAHI Peripheral Guide Wire Treasure 12
	PAGH18M370	ASAHI Peripheral Guide Wire Treasure 12 300cm
Astat0 30	PAGH18M071	ASAHI Peripheral Guide Wire Astat0 30
	PAGH18M371	ASAHI Peripheral Guide Wire Astat0 30 300cm
Regalia XS 1.0	PAGP140000	ASAHI Peripheral Guide Wire Regalia XS 1.0
	PAGP140300	ASAHI Peripheral Guide Wire Regalia XS 1.0 300cm
Astat0 XS 20	PAGH143092	ASAHI Peripheral Guide Wire Astat0 XS 20
	PAGH143392	ASAHI Peripheral Guide Wire Astat0 XS 20 300cm
Treasure Floppy	PAGH18M072	ASAHI Peripheral Guide Wire Treasure Floppy
	PAGH18M372	ASAHI Peripheral Guide Wire Treasure Floppy 300cm

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ADDENDUM

Belonging to certificate: 2107788CE11

2/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Peripheral Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
ASAHI Gladius	PPW14R100S PPW14R200S PPW14R300S PPW18R100S PPW18R200S PPW18R300S PPW14R100P PPW14R200P PPW14R300P PPW18R100P PPW18R200P PPW18R300P	ASAHI Peripheral Guide Wire ASahi Gladius

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ADDENDUM

Belonging to certificate: 2107788CE11

3/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Peripheral Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

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

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
ASAHI Halberd	PHW14R101S	ASAHI Peripheral Guide Wire ASAHI Halberd
	PHW14R201S	
	PHW14R301S	
	PHW18R101S	
	PHW18R201S	
	PHW18R301S	
	PHW14R101P	
	PHW14R201P	
	PHW14R301P	
	PHW18R101P	
	PHW18R201P	
	PHW18R301P	

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



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ADDENDUM

Belonging to certificate: 2107788CE11

4/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Peripheral Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

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

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
ASAHI Gaia PV	PHW18R102S PHW18R202S PHW18R302S PHW18R102P PHW18R202P PHW18R302P	ASAHI Peripheral Guide Wire ASahi Gaia PV
Astato XS 40	PAGHW143094 PAGHW143394	ASAHI Peripheral Guide Wire Astato XS 40

Initial date: 29 January 2009

Revision date: 16 May 2016

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

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) Peripheral Guide Wires
(Model) ASAHI Peripheral Guide Wire (Refer to Table 1 in page 2/4)
(Serial of Lot No.) From 93075-10642 to
.....
Name, type or model, batch or serial number, possibly source and number of items

of Class
IIa
.....
According to annex IX of directive 93/42/EEC

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

2. CE Marking of Conformity Certificate No.
2107788CE11
.....
Issued by
DEKRA Certification B. V. (Notified under No. 0344)
.....

3. Manufacturing Facility
(1) ASahi INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
.....
(2) ASahi INTECC (THAILAND) CO., LTD.
158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi
Amphur Muang, Pathumthani 12000 Thailand
.....
(3) ASahi INTECC HANOI CO., LTD.
THANG LONG Industrial Park Dong Anh District Hanoi Vietnam
.....

4. Authorized representative in EU
Emergo Europe
Molenstraat 15, 2513 BH, The Hague, The Netherlands
.....

5. Applied harmonized standards, national standards or other normative documents
Refer to Table 2 in page 3/4-4/4
.....

6. Conformity assessment procedure
Based on Medical Devices Directive 93/42/EEC Annex II.3
.....

7. Signature of Manufacturer
3-100, Akatsuki-cho, Seto, Aichi 489-0071, JAPAN
June 23, 2014
.....
Place, Date

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

Table 1. Model of ASAHI Peripheral Guide Wire

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
Treasure12	PAGH18M070	ASAHI Peripheral Guide Wire Treasure 12
	PAGH18M370	ASAHI Peripheral Guide Wire Treasure 12 300cm
Atrato 30	PAGH18M071	ASAHI Peripheral Guide Wire Atrato 30
	PAGH18M371	ASAHI Peripheral Guide Wire Atrato 30 300cm
Regalia XS 1.0	PAGP140000	ASAHI Peripheral Guide Wire Regalia XS 1.0
	PAGP140300	ASAHI Peripheral Guide Wire Regalia XS 1.0 300cm
Atrato XS 20	PAGH143092	ASAHI Peripheral Guide Wire Atrato XS 20
	PAGH143392	ASAHI Peripheral Guide Wire Atrato XS 20 300cm
Treasure Floppy	PAGH18M072	ASAHI Peripheral Guide Wire Treasure Floppy
	PAGH18M372	ASAHI Peripheral Guide Wire Treasure Floppy 300cm

Table 2. Applied harmonized standards

1. 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 Device Directive (2007)

2. 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 A1:2013	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
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
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: 2013 ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization
EN ISO 10993-11: 2009 ISO 10993-11: 2006	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

Standard Reference	Title
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 ISO11138-1: 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
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
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-
EN ISO 14644-1: 1999 ISO 14644-1: 1999	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness
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
EN ISO 14644-3: 2005 ISO 14644-3: 2005	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14698-1: 2003 ISO 14698-1: 2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
EN ISO 14698-2: 2003 AC: 2006 ISO 14698-2: 2003 Cor1: 2004	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data
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 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



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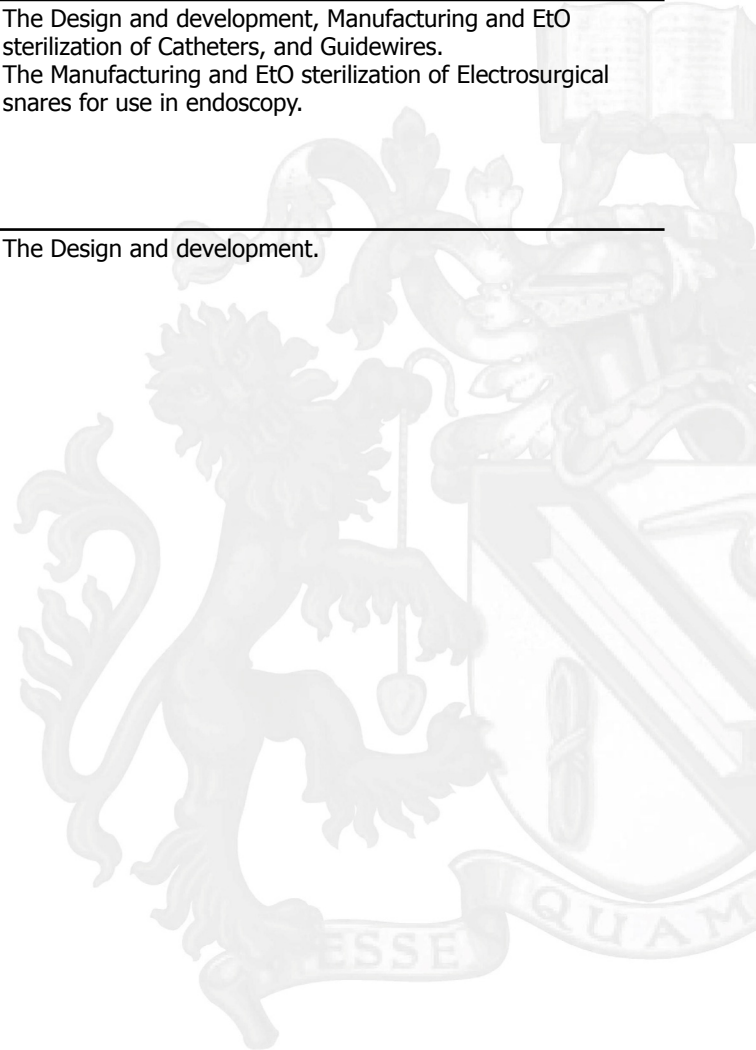
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Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

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

Effective Date: 2020-03-25

Latest Revision Date: 2021-05-14

Expiry Date: 2023-03-24

Page: 2 of 2

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

ASAHI

Peripheral Guide Wire

New Guide Wires

ASAHI **Gladius** ASAHI **Halberd**
ASAHI **Gaia PV** ASAHI **Astato XS 40**

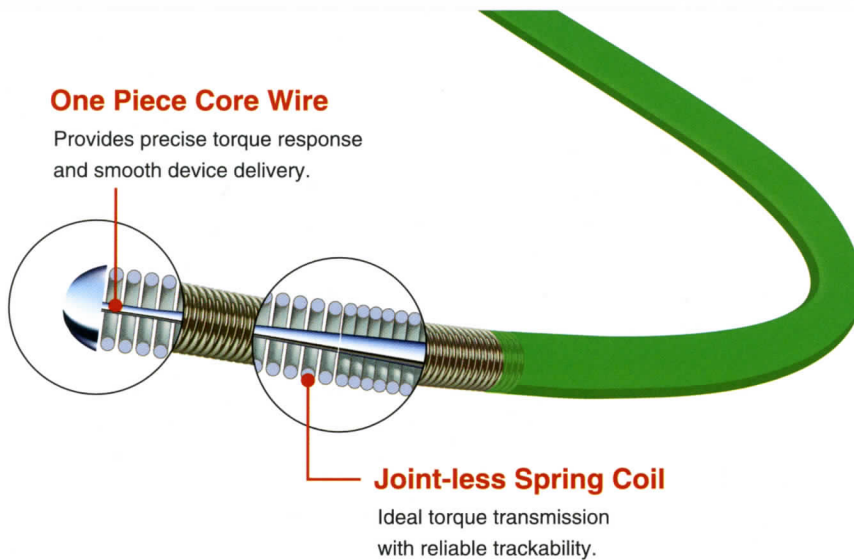
ASAHI's unique guide wire technology with Composite Core

SION TECC 
Leading to the NEXT

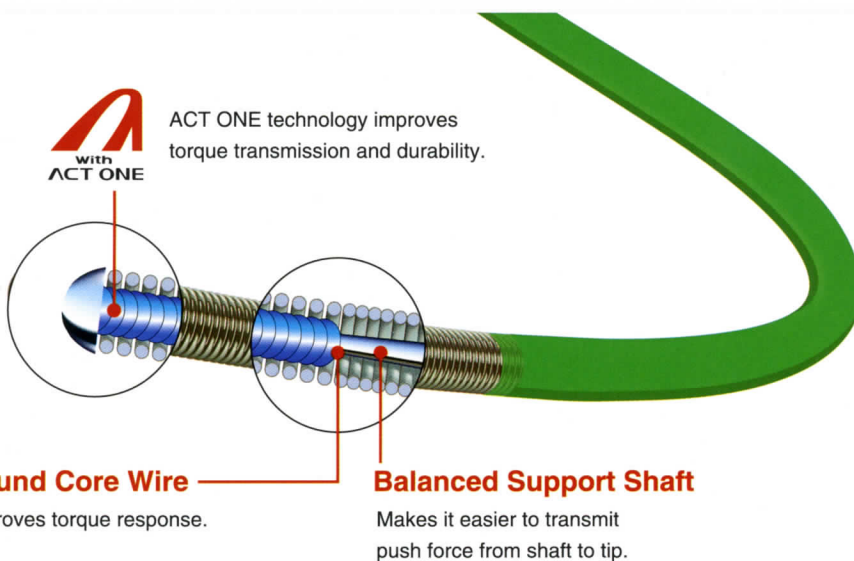
ASAHI

Peripheral Guide Wire

Exceptional guide wires for precise interventions.



**Regalia
Treasure
Astat**



ASAHI's unique guide wire technology with Composite Core
SION TECC 
Leading to the NEXT

ASAHI **Gladius**
ASAHI **Halberd**
ASAHI **Gaia PV**

Frontline

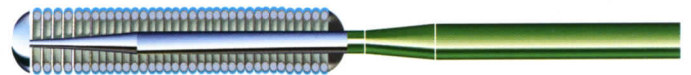
Regalia XS 1.0 0.36mm (0.014inch) Sub-total/Tortuous



- Support ● ● ○ ○ ○
 Torque ● ○ ○ ○ ○
 Penetration ● ○ ○ ○ ○
- Balanced lubricity and trackability for BTK procedures.



Treasure Floppy 0.46mm (0.018inch) Workhorse



- Support ● ● ○ ○ ○
 Torque ● ● ○ ○ ○
 Penetration ● ● ○ ○ ○
- Precise handling with a flexible tip for tortuous anatomy.



Specialty

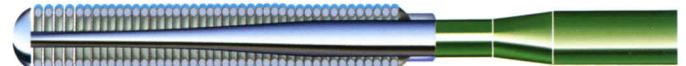
ASAHI Halberd 0.36mm (0.014inch) Complex Lesion



- Support ● ● ● ○ ○
 Torque ● ● ● ● ○
 Penetration ● ● ● ● ●
- Composite core improves torque for navigation, and the micro-cone tip improves penetration.



Treasure 12 0.46mm (0.018inch) Complex Lesion



- Support ● ● ○ ○ ○
 Torque ● ● ● ● ○
 Penetration ● ● ○ ○ ○
- Consistent response and tactile feedback for complex lesion navigation.



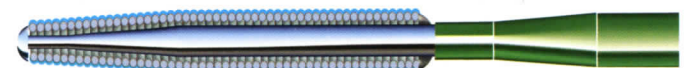
Astato XS 20 0.36mm (0.014inch) Highly Calcified Lesion



- Support ● ● ○ ○ ○
 Torque ● ● ● ● ○
 Penetration ● ● ● ● ●
- Tapered tip provides excellent penetration.



Astato 30 0.46mm (0.018inch) Highly Calcified Lesion



- Support ● ● ● ○ ○
 Torque ● ● ● ● ●
 Penetration ● ● ● ● ●
- Tapered tip provides excellent penetration.



ASAHI Gladius 0.36mm (0.014inch) Workhorse



- Support ● ● ○ ○ ○ Composite core improves tip durability and torque to treat lesions in multiple vessels.
- Torque ● ● ● ○ ○
- Penetration ● ● ○ ○ ○



ASAHI Gladius 0.46mm (0.018inch) Workhorse



- Support ● ● ● ● ● Composite core improves torque response with increased support for device delivery.
- Torque ● ● ● ○ ○
- Penetration ● ● ○ ○ ○



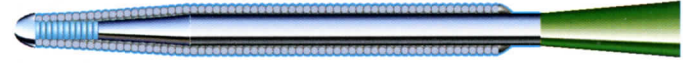
ASAHI Halberd 0.46mm (0.018inch) Complex Lesion



- Support ● ● ● ● ○ Composite core provides precise torque for navigation with more support and micro-cone tip for proximal cap penetration.
- Torque ● ● ● ● ●
- Penetration ● ● ● ● ○



ASAHI Gaia PV 0.46mm (0.018inch) Complex Lesion



- Support ● ● ● ● ○ Composite core with a lower tip load improves navigation and torque. The tapered coil and micro-cone tip makes it easier to advance.
- Torque ● ● ● ● ●
- Penetration ● ● ● ● ○



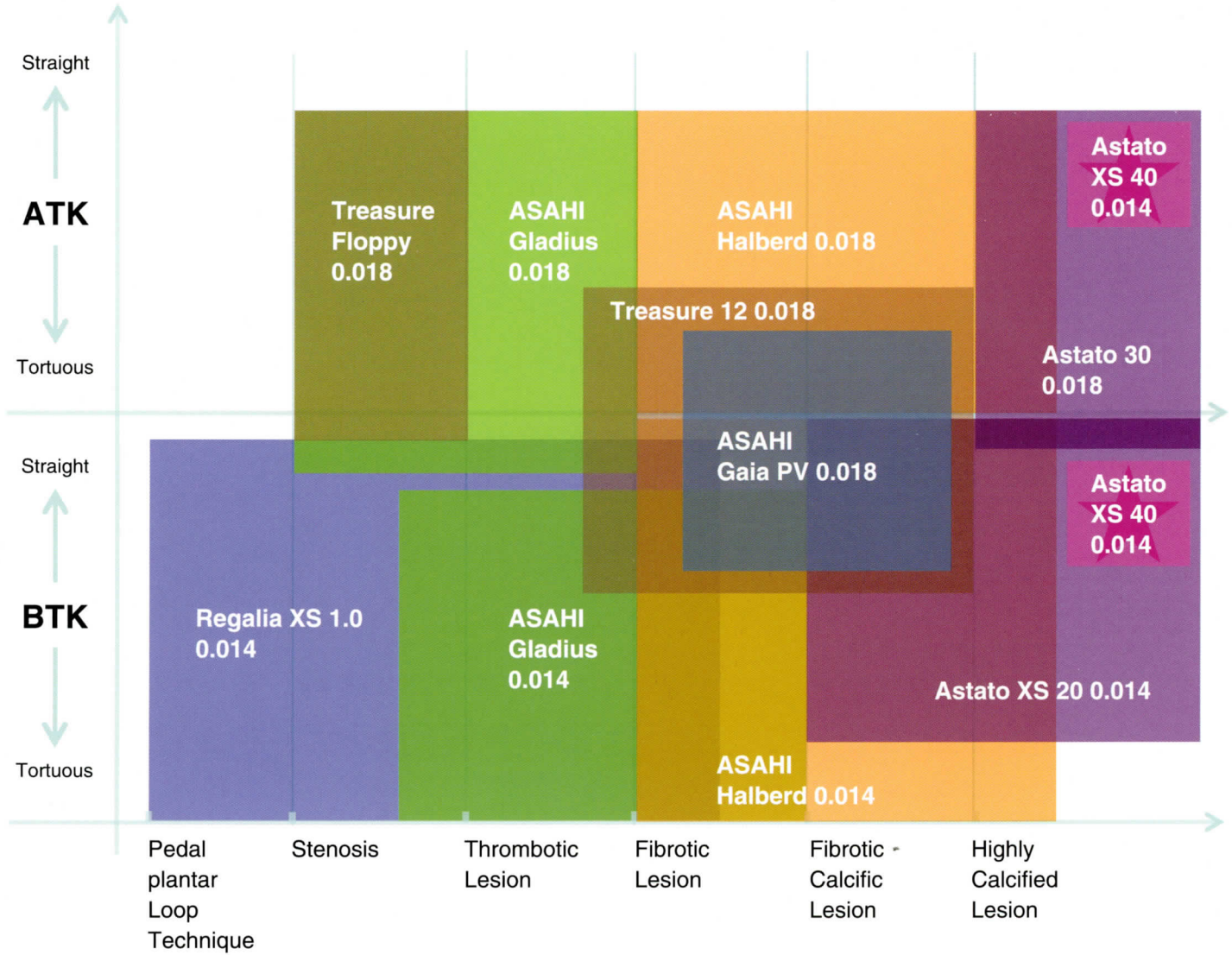
Astato XS 40 0.36mm (0.014inch) Highly Calcified Lesion



- Support ● ● ○ ○ ○ Tapered tip provides excellent penetration.
- Torque ● ● ● ● ○
- Penetration ★ ★ ★ ★ ★



Wire Selection Chart



Ordering Information

Product	Diameter	Catalog No.	Length	SION TECC	Tip Shape
ASAHI Gladius	0.36mm (0.014inch)	PPW14R100S	200cm	SION TECC	Straight
		PPW14R200S	235cm		
		PPW14R300S	300cm		
	0.36mm (0.014inch)	PPW14R100P	200cm		Pre-shaped
		PPW14R200P	235cm		
		PPW14R300P	300cm		
	0.46mm (0.018inch)	PPW18R100S	200cm		Straight
		PPW18R200S	235cm		
		PPW18R300S	300cm		
ASAHI Halberd	0.36mm (0.014inch)	PHW14R101S	200cm	SION TECC	Straight
		PHW14R201S	235cm		
		PHW14R301S	300cm		
	0.36mm (0.014inch)	PHW14R101P	200cm		Pre-shaped
		PHW14R201P	235cm		
		PHW14R301P	300cm		
	0.46mm (0.018inch)	PHW18R101S	200cm		Straight
		PHW18R201S	235cm		
		PHW18R301S	300cm		
	0.46mm (0.018inch)	PHW18R101P	200cm		Pre-shaped
		PHW18R201P	235cm		
		PHW18R301P	300cm		
ASAHI Gaia PV	0.46mm (0.018inch)	PHW18R102S	200cm	SION TECC	Straight
		PHW18R202S	235cm		
		PHW18R302S	300cm		
	0.46mm (0.018inch)	PHW18R102P	200cm		Pre-shaped
		PHW18R202P	235cm		
		PHW18R302P	300cm		
Regalia XS 1.0	0.36mm (0.014inch)	PAGP140000	180cm	SION TECC	Straight
		PAGP140300	300cm		
Astato XS 20	0.36mm (0.014inch)	PAGH143092	180cm		
		PAGH143392	300cm		
Astato XS 40	0.36mm (0.014inch)	PAGHW143094	200cm		
		PAGHW143394	300cm		
Astato 30	0.46mm (0.018inch)	PAGH18M071	180cm		
		PAGH18M371	300cm		
Treasure Floppy	0.46mm (0.018inch)	PAGH18M072	190cm		
		PAGH18M372	300cm		
Treasure 12	0.46mm (0.018inch)	PAGH18M070	180cm		
		PAGH18M370	300cm		

Indications for Use

This Product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

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

CE 0344

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