

ZERTIFIKAT / Certificate

DIN EN ISO / EN ISO 13485 : 2016

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Andocor N.V.
Kwikaard 104
2980 Zoersel
Belgium

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält.
Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

*has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.
This certificate is not an authorisation to affix the CE mark.*

Geltungsbereich / *Scope*

Design, manufacturing and sales of medical devices for cardiovascular surgery and anaesthesia: sterile cardiovascular cannulation devices, sterile cardioplegia devices, sterile bloodlines for haemoconcentration with or without haemofilter, sterile gas diffusers

Reg.-Nr. / *Reg.-No.* 44 221 200262
Bericht Nr. / *Report No.* 3528 2619

Gültigkeit / *Validity*
von / *from* 2021-05-25
bis / *until* 2023-12-28
Edition 1

M.Y.

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

Die Gültigkeit kann unter <https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank> verifiziert werden.
Validity can be verified at <https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank>.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

EG-Zertifikat / EC-Certificate

gem. 93/42/EWG Anhang II ohne (4) / acc. 93/42/EEC Annex II without (4)

Hiermit wird bescheinigt, dass die Firma / This certifies, that the company

Andocor N.V.

**Kwikaard 104
2980 Zoersel
Belgium**

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Sterile kardiovaskuläre Einweg-Kanülen
Sterile Einweg-Kardioplegie-Produkte
Sterile Einweg-Blutleitungen zur Hämokonzentration mit oder ohne Hämofilter
Sterile Einweg-Gasdiffusoren
Sterile disposable cardiovascular cannulation devices
Sterile disposable cardioplegia devices
Sterile disposable bloodlines for haemoconcentration with or without haemofilter
Sterile disposable gas diffusers

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennnummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / Reg.-No. 44 232 200262
Bericht Nr. / Report No. 3528 2680

Gültigkeit / Validity
von / from 2021-05-25
bis / until 2024-05-26
Edition 2



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / ANNEX

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Annex 1, page 1 of 3

Reg.-Nr. / Reg. No. 44 232 200262

Produkte der Klasse IIb <i>Products of class IIb</i>	Typ <i>Type</i>	GMDN
Produkte zum Einmalgebrauch <i>Single use Devices</i>	Hemoconcentrators Set for haemoconcentration	44602 44602
Produkte der Klasse IIa <i>Products of class IIa</i>	Typ <i>Type</i>	GMDN
Produkte zum Einmalgebrauch <i>Single use Devices</i>	Arterial Cannula, reinforced Arterial Cannula, non-reinforced Aortic Catheter Venous Catheter Flex Line Venous Catheter Two Stage Venous Catheter Flex Line Two Stage Venous Catheter Vent Catheters Pericardial Sump Rigid Sucker	34893 34893 34893 34905 34905 34905 34905 34905 46363 35917 35917

Bericht Nr. / Report No. 3528 2680

Gültigkeit / Validity
von / from 2021-05-25
Edition 2

M. Y. S.

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*



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ANLAGE / ANNEX

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Annex 1, page 2 of 2

Reg.-Nr. / Reg. No. 44 232 200262

Produkte der Klasse IIa <i>Products of class IIa</i>	Typ <i>Type</i>	GMDN
Produkte zum Einmalgebrauch <i>Single use Devices</i>	Intracardiac Suckers	35917
	Yankauer Suction Tubes	35917
	Suction connecting tubes	16779
	Aspiration tubes	16779
	Vessel Cannulae	47798
	Connectors	61661
	Extremity Perfusion Cannulae	/
	Cannulation Tourniquet Set	58830
	Quick Prime Line	47889
	Aortic Root Cannulae	47799
	Retrograde Cardioplegia Cannula	36109
	Cardioplegia Set	58824
	Cardioplegia Needle	47799
	Ostial Perfusion Cannulae	34896
	Gas Diffuser	42977
	Hemoconcentrator Tubing Sets	44602

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ANLAGE / ANNEX

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Reg.-Nr. / Reg. No. 44 232 200262

Produkte der Klasse Is <i>Products of class Is</i>	Typ Type	GMDN
Produkte zum Einmalgebrauch <i>Single use Devices</i>	Vent Plugs Vented Connector Caps Tubing Organizer Pressure Monitoring Line	/ / / 61836

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.

Note: For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

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CATALOGUE 2021

CARDIAC CATHETERS
AND CANNULAE



Arterial cannulae

REINFORCED, CURVED TIP WITH FLANGE



TYPE A - BODY LENGTH: 30 CM

TYPE B - BODY LENGTH: 21 CM

Description	Size	TYPE A - BODY LENGTH: 30 CM			TYPE B - BODY LENGTH: 21 CM		
		Standard	With vent plug	With vented red cap	Standard	With vent plug	With vented red cap
Without connector	20 Fr	A2016	A2016V	-	B2016	B2016V	-
	22 Fr	A2216	A2216V	-	B2216	B2216V	-
	24 Fr	A2416	A2416V	-	B2416	B2416V	-
With connector	20 Fr	A20161	-	A20161V	B20161	-	B20161V
	22 Fr	A22161	-	A22161V	B22161	-	B22161V
	24 Fr	A24161	-	A24161V	B24161	-	B24161V
With luer connector	20 Fr	A20162	-	A20162V	B20162	-	B20162V
	22 Fr	A22162	-	A22162V	B22162	-	B22162V
	24 Fr	A24162	-	A24162V	B24162	-	B24162V

PRODUCT INFORMATION

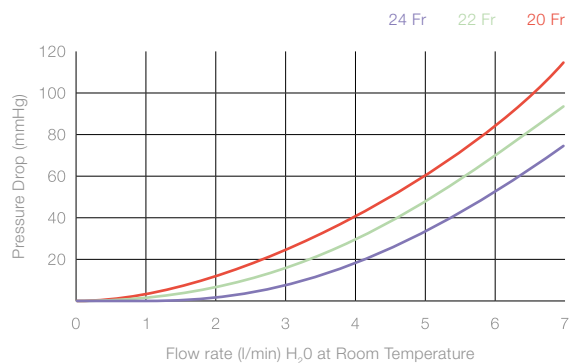
Andocor arterial cannulae are intended for use in perfusion of the ascending aorta during cardiopulmonary bypass.

All versions with a vented red cap can be equipped with a vent plug. Upon request the luer connector can be mounted at an angle 180° - facing up.

Q Connection site: 3/8"
Qty/box: 20 Pcs

+ Kink resistant reinforced tubing
Easy tip orientation thanks to indexing marker
Smooth plastic tip

ARTERIAL CANNULA PRESSURE DROP VS FLOW



Arterial cannulae

REINFORCED, STRAIGHT TIP WITH RING



TYPE A



TYPE B

TYPE A - BODY LENGTH: 30 CM

TYPE B - BODY LENGTH: 21 CM

Description	Size	TYPE A - BODY LENGTH: 30 CM			TYPE B - BODY LENGTH: 21 CM		
		Standard	With vent plug	With vented red cap	Standard	With vent plug	With vented red cap
Without connector	20 Fr	A2013	A2013V	-	B2013	B2013V	-
	22 Fr	A2213	A2213V	-	B2213	B2213V	-
	24 Fr	A2413	A2413V	-	B2413	B2413V	-
With connector	20 Fr	A20131	-	A20131V	B20131	-	B20131V
	22 Fr	A22131	-	A22131V	B22131	-	B22131V
	24 Fr	A24131	-	A24131V	B24131	-	B24131V
With luer connector	20 Fr	A20132	-	A20132V	B20132	-	B20132V
	22 Fr	A22132	-	A22132V	B22132	-	B22132V
	24 Fr	A24132	-	A24132V	B24132	-	B24132V

PRODUCT INFORMATION

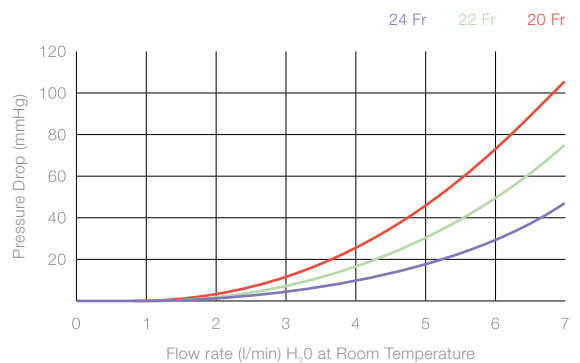
Andocor arterial cannulae are intended for use in perfusion of the ascending aorta during cardiopulmonary bypass.

All versions with a vented red cap can be equipped with a vent plug. Upon request the luer connector can be mounted at an angle 180° - facing up.

Q Connection site: 3/8"
Qty/box: 20 Pcs

+ Kink resistant reinforced tubing
Easy tip orientation thanks to indexing marker
Smooth plastic tip

ARTERIAL CANNULA PRESSURE DROP VS FLOW



Flex line two stage venous cannulae

PROXIMAL AND DISTAL REINFORCED WITH LIGHTHOUSE TIP



ROUND BODY



FLAT BODY



ROUND BODY

FLAT BODY

Size	Length	ROUND BODY			FLAT BODY		
		Without connector	With connector	With luer connector	Without connector	With connector	With luer connector
32/40	36	01V32L40	01V32L401	01V32L402	01V32L40FB	01V32L401FB	01V32L402FB
34/40	36	01V34L40	01V34L401	01V34L402	01V34L40FB	01V34L401FB	01V34L462FB
34/46	40	01V34L46	01V34L461	01V34L462	01V34L46FB	01V34L461FB	01V34L462FB
36/46	40	01V36L46	01V36L461	01V36L462	01V36L46FB	01V36L461FB	01V36L462FB
36/51	40	01V36L51	01V36L511	01V36L512	01V36L51FB	01V36L511FB	01V36L512FB

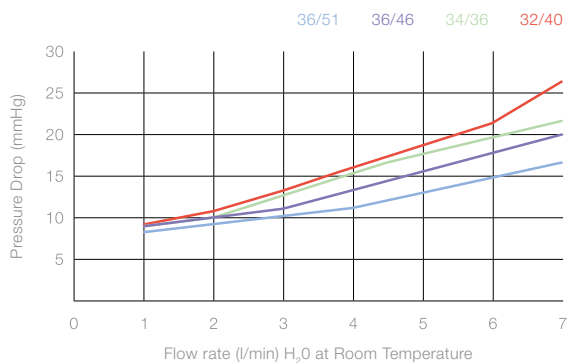
PRODUCT INFORMATION

Andocor two stage venous cannulae are intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.

Q Connection site: 1/2"
Qty/box: 20 Pcs

+ Single piece construction
Open and flexible lighthouse tip
Easy positioning
Insertion depth marker

VENOUS CANNULA PRESSURE DROP VS FLOW



Paediatric venous cannulae

REINFORCED WITH 90° METAL TIP



PRODUCT INFORMATION

BODY LENGTH: 35 CM

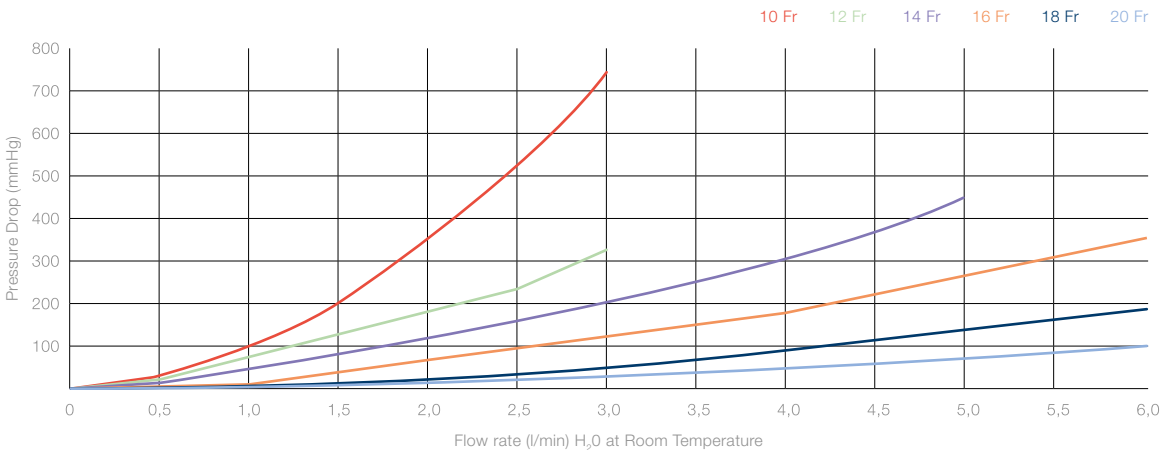
Andocor paediatric venous cannulae are intended for drainage from the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.

Q Connection: 10-12 Fr: 3/16" - 1/4" | Other: 1/4"
Qty/box: 20 Pcs

+ Kink resistant wire reinforced PVC tubing
Steel tip with thin wall for high flow rates
Additional side holes for improved drainage

Description	Size	Reference
90° metal tip	10 Fr	01V101L7
	12 Fr	01V121L7
	14 Fr	01V141L7
	16 Fr	01V161L7
	18 Fr	01V181L7
	20 Fr	01V201L7

METAL TIP VENOUS CANNULA PRESSURE DROP VS FLOW



Flex line venous cannulae

REINFORCED WITH LIGHTHOUSE TIP



PRODUCT INFORMATION

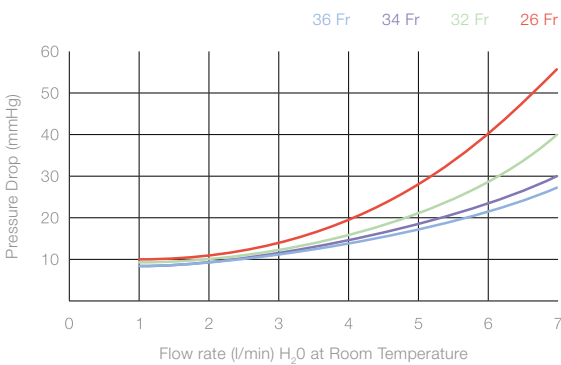
Andocor venous cannulae are intended to drain venous blood from the right atrium and caval veins.

Q Connection site: 3/8" - 36 Fr: 1/2"
Length: 39 cm
Qty/box: 20 Pcs

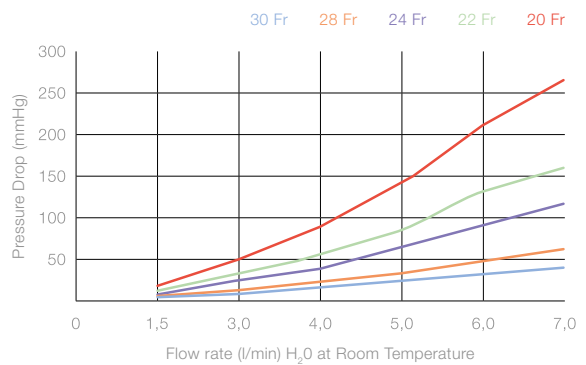
+ Single piece construction
Open and flexible lighthouse tip
Easy positioning
Insertion depth marker

Size	Straight tip	Right angled 90° tip
20 Fr	01V201L8	01V201L9
22 Fr	01V221L8	01V221L9
24 Fr	01V241L8	01V241L9
26 Fr	01V261L8	01V261L9
28 Fr	01V281L8	01V281L9
30 Fr	01V301L8	01V301L9
32 Fr	01V321L8	01V321L9
34 Fr	01V341L8	01V341L9
36 Fr	01V361L8	01V361L9

VENOUS CANNULA PRESSURE DROP VS FLOW



VENOUS CANNULA PRESSURE DROP VS FLOW



Silicone vent catheters



Size	Tip perforation size	Length	Reference
16 Fr	6,5 cm	38 cm	SV16
20 Fr	7,2 cm	39 cm	SV20

PRODUCT INFORMATION

Andocor vent catheters are medical devices to decompress or vent the heart during cardiopulmonary bypass cannulation. Vent catheters are used as a suction catheter to assist in the complete evacuation of blood.



Connection: 1/4"
Qty/box: 20 Pcs



Guidewire stylet
Soft and flexible silicone tubing
Soft tip

PVC vent catheters

ANGLED



TUBING LENGTH: 32 CM

TUBING LENGTH: 34 CM

Description	Size	Tip perforation size 3,8 cm	Tip perforation size 10 cm
		Without stylet	13 Fr
	20 Fr	-	PVBA20

PRODUCT INFORMATION

Andocor vent catheters are medical devices to decompress or vent the heart during cardiopulmonary bypass cannulation. Vent catheters are used as a suction catheter to assist in the complete evacuation of blood.

Q Connection: 1/4"
Qty/box: 20 Pcs

+ Kink resistant reinforced tubing
Insertion dept marker

Aortic root cannulae



Type A



Type B



Type C



Type D

Description	Tip size	Needle size	Reference
Type A Without vent line	6 Fr	16 G	ARC07
	7 Fr	14 G	ARC04
	9 Fr	12 G	ARC01
Type B Without vent line With suture ring	6 Fr	16 G	ARC07R
	7 Fr	14 G	ARC04R
	9 Fr	12 G	ARC01R
Type C With vent line	6 Fr	16 G	ARC08
	7 Fr	14 G	ARC05
	9 Fr	12 G	ARC02
Type D With vent line	6 Fr	16 G	ARC08S
	7 Fr	14 G	ARC05S
	9 Fr	12 G	ARC02S

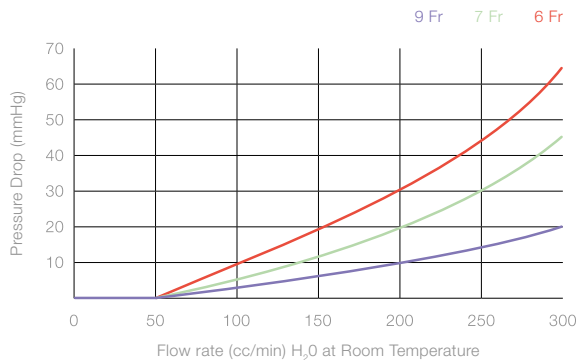
PRODUCT INFORMATION

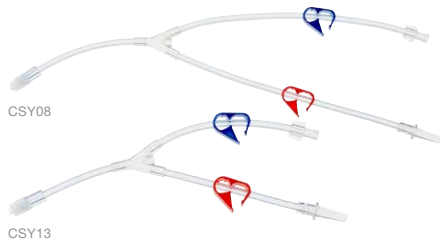
Andocor aortic root cannulae are intended for use during cardiopulmonary bypass for antegrade delivery of cardioplegia solutions and venting of the heart. The cannula may also be used to aspirate air from the aorta at the conclusion of the cardiac procedure.

Q Length: 15 cm
 Connection size vent line: 1/4"
 Qty/box: 20 Pcs

+ Easy of use
 Anti-bleeding valve helps reduce blood loss

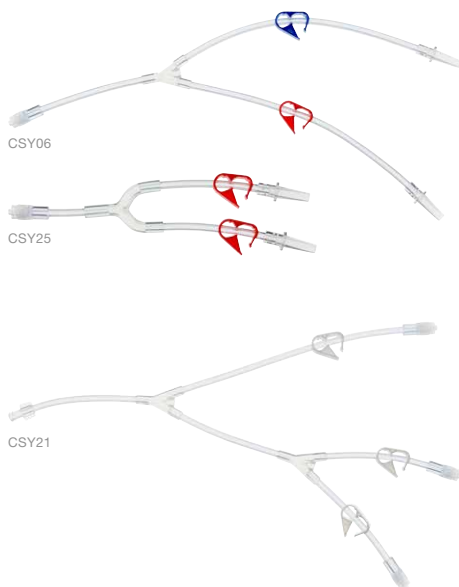
AORTIC ROOT CANNULAE PRESSURE DROP VS FLOW





PERFUSION SET WITH VENT LINE

Description	Tubing length	Reference
Male luer lock in combination with 1 female luer lock and 1 cone connector.	30 cm	CSY08
	18 cm	CSY13



PERFUSION RECIRCULATION ADAPTERS

Description	Tubing length	Reference
Male luer lock in combination with 2 cone connectors.	30 cm	CSY06
	13,5 cm	CSY25

Description	Tubing length	Reference
Female luer lock in combination with 3 male luer lock connectors	30 cm	CSY21

PRODUCT INFORMATION

Andocor cardioplegia adapters connect to the aortic root cannula or vessel cannula and are intended for the delivery of cardioplegia solution or venting the heart during cardiopulmonary bypass surgery.

 Qty/box: 20 Pcs