

# 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](http://www.tuev-nord-cert.de) [medical@tuev-nord.de](mailto: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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Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



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



# ANLAGE / ANNEX

Anlage 1, Blatt 1 von 3  
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.*

Zertifizierungsstelle für Medizinprodukte  
*Certification body for medical devices*

Essen, 2021-05-25

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



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**ZLG-BS-236.10.16**

# ANLAGE / ANNEX

Anlage 1, Blatt 2 von 3  
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

Bericht Nr. / Report No. 3528 2680

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# ANLAGE / ANNEX

Anlage 1, Blatt 3 von 3  
Annex 1, page 3 of 3

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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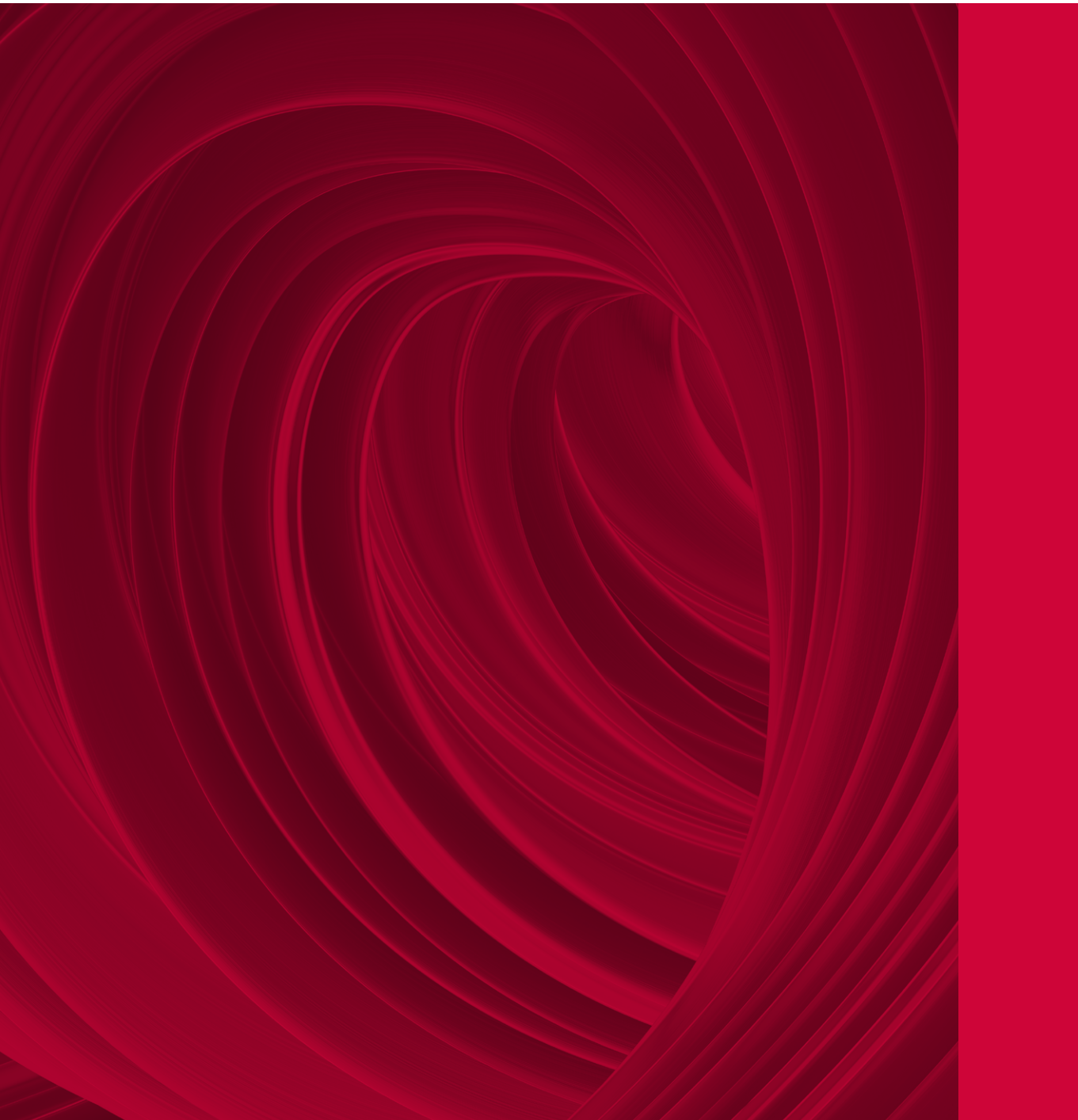


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CATALOGUE 2021

CARDIAC CATHETERS  
AND CANNULAE



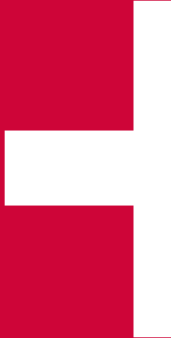




# 1



# Cardiovascular cannulation



## Index

- 4 Arterial cannulae
- 10 Aortic catheters
- 12 Flex line venous cannulae
- 14 Flex line two stage venous  
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

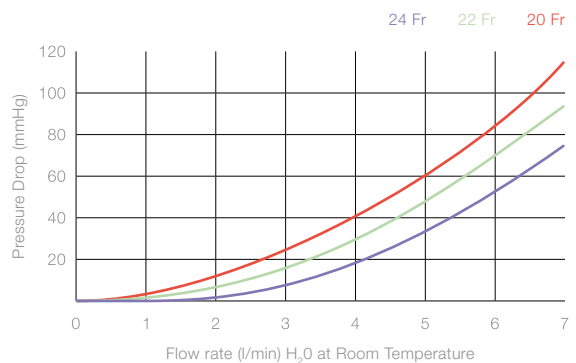
Andocor arterial cannulae are intended for use in perfusion of the ascending aorta during cardiopulmonary bypass.

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







# Flex line venous cannulae

REINFORCED WITH LIGHTHOUSE TIP



## PRODUCT INFORMATION

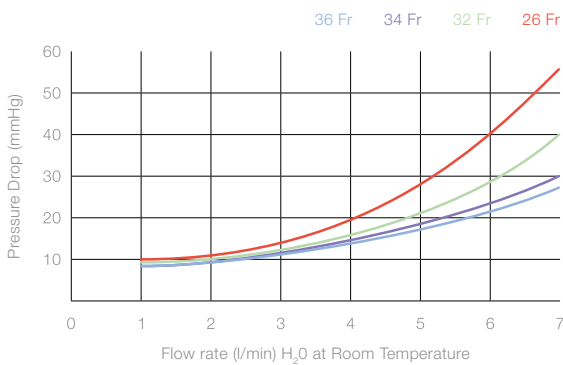
Andocor venous cannulae are intended to drain venous blood from the right atrium and caval veins.

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

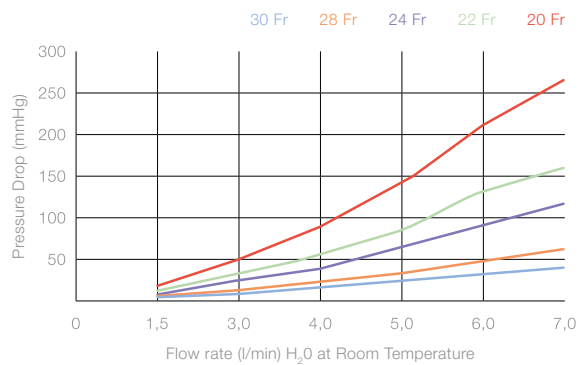
**+** Single piece construction  
Open and flexible lighthouse tip  
Easy positioning  
Insertion depth marker

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





# 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

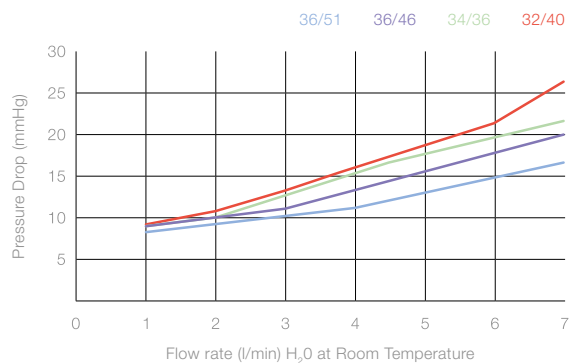
PRODUCT INFORMATION

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

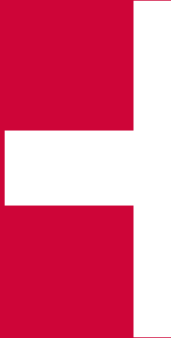
**+** Single piece construction  
Open and flexible lighthouse tip  
Easy positioning  
Insertion depth marker

VENOUS CANNULA PRESSURE DROP VS FLOW



# 2

# Cardioplegia

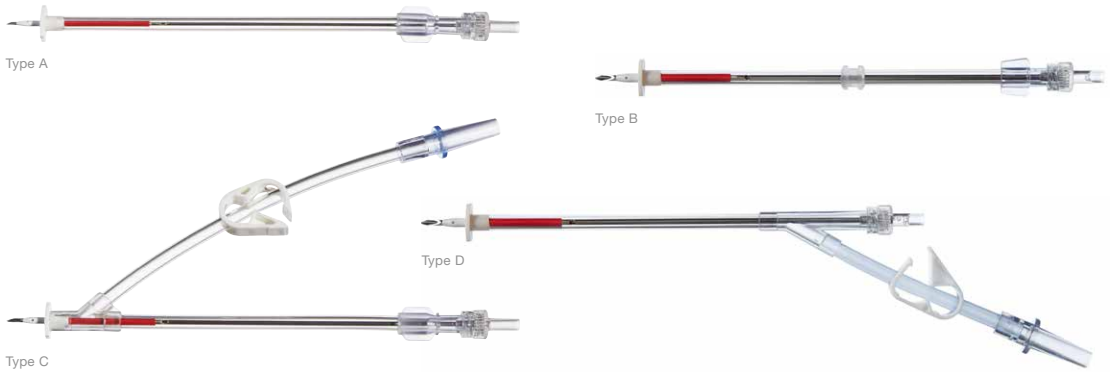


## Index

- 18 Aortic root cannulae
- 20 Retrograde cardioplegia cannulae
- 21 Air aspiration needles
- 22 Ostial perfusion cannulae
- 24 Cardioplegia adapters



# Aortic root cannulae



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

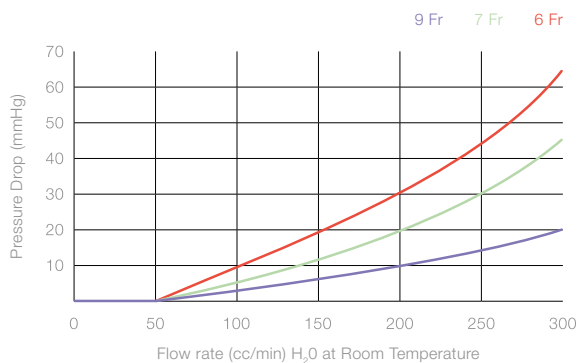
**PRODUCT INFORMATION**

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**

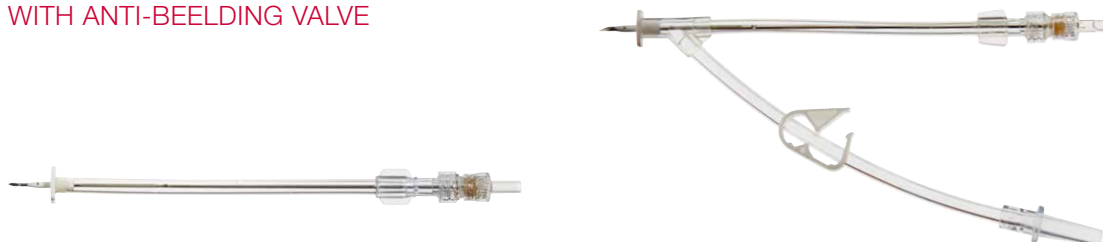


WITH 2 CLAMPS



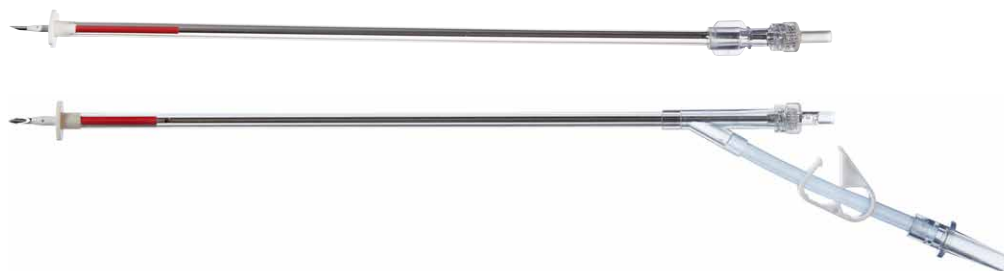
Description	Tip size	Needle size	Reference
With vent line	7 Fr	14 G	ARC10

WITH ANTI-BEELDING VALVE



Description	Tip size	Needle size	Reference
Without vent line	6 Fr	16 G	ARC07V
	7 Fr	14 G	ARC04V
	9 Fr	12 G	ARC01V
With vent line	6 Fr	16 G	ARC08V
	7 Fr	14 G	ARC05V
	9 Fr	12 G	ARC02V

MINIMAL INVASIVE TYPE, LENGTH: 28 CM



Description	Tip size	Needle size	Standard	With anti-bleeding valve
Without vent line	7 Fr	14 G	ARC14	ARC14V
With vent line	7 Fr	14 G	ARC15S	-

# Ostial perfusion cannulae

CORONARY ARTERY OSTIAL CANNULA, BASKET TIP WITH FLANGE



Tip size	45° angled	90° angled
10 Fr	OC1045	OC1090
12 Fr	OC1245	OC1290
14 Fr	OC1445	OC1490

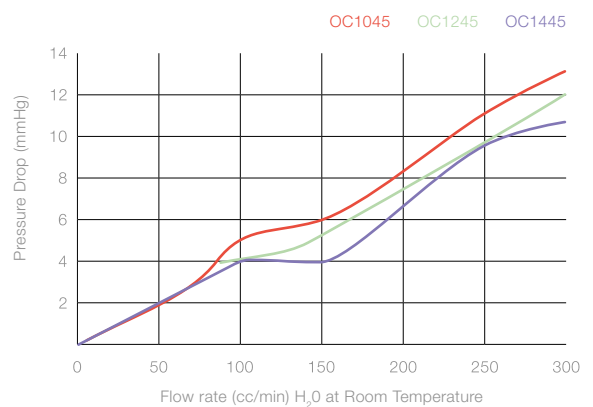
## PRODUCT INFORMATION

Andocor ostial perfusion cannulae are intended for use in delivery of cardioplegia solution directly to the coronary arteries during cardiopulmonary bypass surgery.

**Q** Connection: Female luer lock  
Length: 21 cm  
Qty/box: 20 Pcs

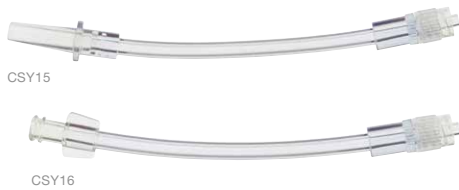
**+** Soft basket tip  
Different configurations  
Stainless steel shaft

## CORONARY ARTERY OSTIAL CANNULA PRESSURE DROP VS FLOW





# Cardioplegia adapters



## STRAIGHT ADAPTERS

Description	Tubing length	Reference
1/4" / male luer connection	10 cm	CSY15
Female / male luer connection	10 cm	CSY16

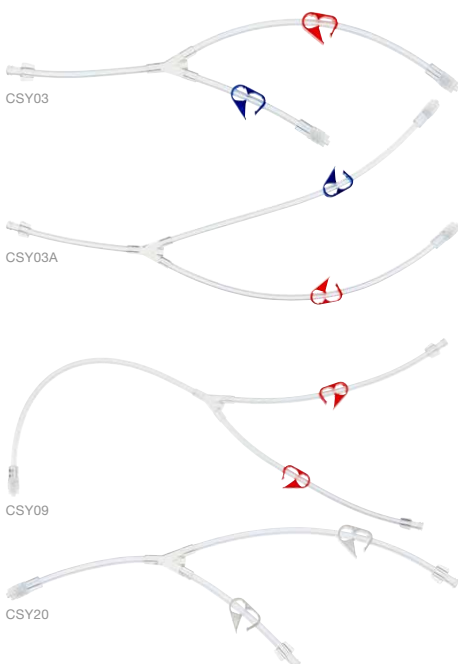


## PERFUSION ADAPTERS

Description	Length	Reference
1/4" to male luer connector	7 cm	CSY17
3/8" to male luer connector	7 cm	CSY18



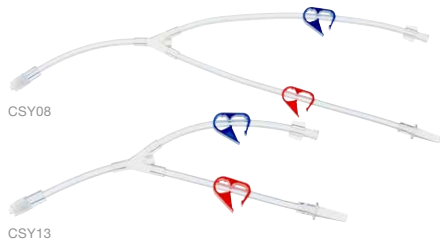
Description	Length	Reference
1/4" to male luer connector with stopcock	10 cm	CSY19



## PERFUSION Y-ADAPTERS

Description	Tubing length	Reference
Female luer lock in combination with 2 male luer lock connectors.	30 cm	CSY03
	35 cm	CSY03A

Description	Tubing length	Reference
Male luer lock in combination with 2 female luer lock connectors.	45 cm	CSY09
	30 cm	CSY20



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.

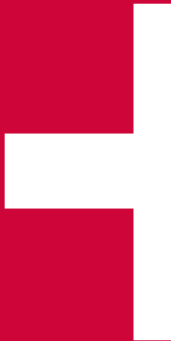
 Qty/box: 20 Pcs

# 4



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# Vent catheters



## Index

- 34 PVC vent catheters
- 37 Silicone vent catheters

# 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

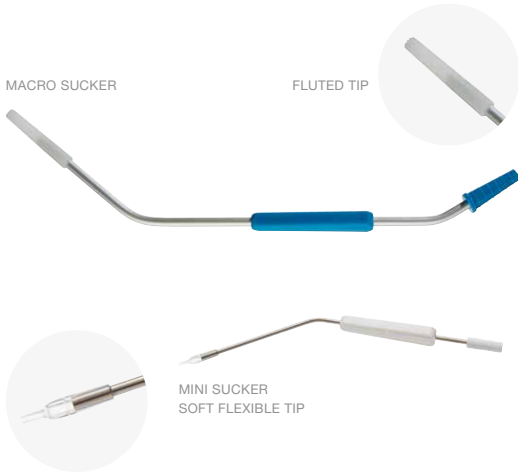
# 5



# Suckers

## Index

- 40 Rigid sucker
- 40 Flexible and malleable suckers
- 40 Yankauer suction tubes
- 41 Pericardial sumps
- 42 Thoracic drains



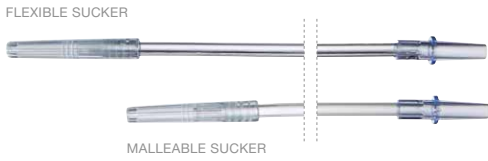
**RIGID SUCKER**

Tip	Length	Reference
Macro sucker	36 cm	RS01
Mini sucker	25 cm	RS02

**PRODUCT INFORMATION**

Andocor suckers are used for the removal of excess fluid from the surgical field.

- Q** Connection: 1/4"  
Qty/box: 20 Pcs
- +** Metal suction tube with plastic handle  
Easy and comfortable directing



**FLEXIBLE AND MALLEABLE SUCKERS**

Tubing	Size	Length	Reference
Flexible	17 Fr	36 cm	FS300
Malleable	17 Fr	25 cm	FS301

**PRODUCT INFORMATION**

Andocor suckers are used for the removal of excess fluid from the surgical field.

- Q** Connection: 1/4"  
Qty/box: 20 Pcs
- +** Provides continuous suction  
Flexible or malleable tubing



**YANKAUER SUCTION TUBES**

Tubing	Length	Open tip 22 Fr	Bulb tip 30 Fr
Vented	25 cm	ST04	ST02
Non-vented	25 cm	ST03	ST01

**PRODUCT INFORMATION**

Andocor yankauer suction tubes are intended to aspirate body waste fluid during surgery.

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

# Pericardial sumps



Type A



Type B



Type C

Description	Size	Tubing	Tip length	Tubing length	Reference
Type A Metal tip	18 Fr	Flexible	2 cm	30 cm	PS40M
	18 Fr	Hard	2 cm	30 cm	PS40MH
	18 Fr	Flexible	2 cm	79 cm	PS40ML
	18 Fr	Hard	2 cm	79 cm	PS40MLH
Type B Perforated pool tip	23 Fr	Flexible	3,5 cm	30 cm	PS40M1
Type C Perforated pool tip	15 Fr	Flexible	2 cm	30 cm	PS40M2
	15 Fr	Hard	2 cm	79 cm	PS40MLH2

## PRODUCT INFORMATION

Andocor suckers are used for the removal of excess fluid from the surgical field.



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



Smooth design  
Weighted tip  
Stainless steel tip

## WIREWOUND TIP

Description	Size	Tubing	Tip length	Tubing length	Reference
Wirewound tip	16 Fr	Flexible	4 cm	30 cm	PS40

