

ZERTIFIKAT / Certificate

DIN EN ISO / EN ISO 13485 : 2016

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

Andocor N.V. Kruisblok 9 2320 Hoogtraten 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.* 3532 8180



Zertifizierungsstelle für Medizinprodukte *Certification body for medical devices*

Gültigkeit / Validity von / from 2023-01-31 bis / until 2023-12-28 Edition 2

Essen, 2023-01-31

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 witout 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 Kennummer 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

Zertifizierungsstelle für Medizinprodukte Certification body for medical devices

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

Essen, 2021-05-25

Langemarckstraße 20 45141 Essen TÜV NORD CERT GmbH

www.tuev-nord-cert.de

medical@tuev-nord.de

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





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 Products of class IIb	Тур Т <i>уре</i>	GMDN
Produkte zum Einmalgebrauch Single use Devices	Hemoconcentrators Set for haemoconcentration	44602 44602
Produkte der Klasse IIa Products of class IIa	Тур Т <i>уре</i>	GMDN
Produkte zum Einmalgebrauch Single use Devices	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 34905 34905 34905 34905 34905 46363 35917 35917

Bericht Nr. / Report No. 3528 2680

Ts

Zertifizierungsstelle für Medizinprodukte Certification body for medical devices Gültigkeit / Validity von / from 2021-05-25 Edition 2

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarcks

Langemarckstraße 20

45141 Essen www.tuev-nord-cert.de

medical@tuev-nord.de

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

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

Bericht Nr. / Report No. 3528 2680

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Zertifizierungsstelle für Medizinprodukte Certification body for medical devices Gültigkeit / Validity von / from 2021-05-25 Edition 2

Essen, 2021-05-25

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

Benannt durch/Designated by Zentralstelle der Länder & für Gesundheitsschutz & bei Arzneimitteln und Medizinprodukten ZLG-BS-236.10.16



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 Products of class Is	Тур Т <i>уре</i>	GMDN
Produkte zum Einmalgebrauch Single use Devices	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.

Bericht Nr. / Report No. 3528 2680

Zertifizierungsstelle für Medizinprodukte Certification body for medical devices Gültigkeit / Validity von / from 2021-05-25 Edition 2

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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	Standard	With vent plug	With vented red cap	Standard	With vent plug	With vented red cap
	20 Fr	A2016	A2016V	-	B2016	B2016V	-
Without connector	22 Fr	A2216	A2216V	-	B2216	B2216V	-
	24 Fr	A2416	A2416V	-	B2416	B2416V	-
	20 Fr	A20161	-	A20161V	B20161	-	B20161V
With connector	22 Fr	A22161	-	A22161V	B22161	-	B22161V
	24 Fr	A24161	-	A24161V	B24161	-	B24161V
	20 Fr	A20162	-	A20162V	B20162	-	B20162V
With luer connector	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.

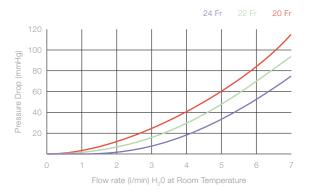
All versions with a vented red cap can be equipped with a vent plug. Upon request the luer connector can be mounted at an angle 180° - facing up.



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

AndoCor 9 29 Fr. TYPE A AndoCor 9 24 Fr. 24 Fr. TYPE B

TYPE A - BODY LENGTH: 30 CM

TYPE B - BODY LENGTH: 21 CM

Description	Size	Standard	With vent plug	With vented red cap	Standard	With vent plug	With vented red cap
	20 Fr	A2013	A2013V	-	B2013	B2013V	-
Without connector	22 Fr	A2213	A2213V	-	B2213	B2213V	-
	24 Fr	A2413	A2413V	-	B2413	B2413V	-
	20 Fr	A20131	-	A20131V	B20131	-	B20131V
With connector	22 Fr	A22131	-	A22131V	B22131	-	B22131V
	24 Fr	A24131	-	A24131V	B24131	-	B24131V
	20 Fr	A20132	-	A20132V	B20132	-	B20132V
With luer connector	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.

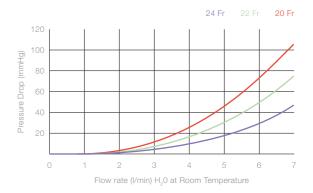


Connection site: 3/8" Qty/box: 20 Pcs

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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.



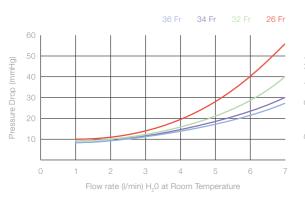
Connection site: 3/8" - 36 Fr: 1/2" Length: 39 cm Qty/box: 20 Pcs

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

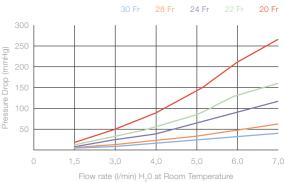
Size	Straight tip	Right angled 90° tip
20 Fr	01V201L8	01V201L9
22 Fr	01V221L8	01V221L9
24 Fr	01V241L8	01V241L9
26 Fr	01V261L8	01V261L9
28 Fr	01V281L8	01V281L9
30 Fr	01V301L8	01V301L9
32 Fr	01V321L8	01V321L9
34 Fr	01V341L8	01V341L9
36 Fr	01V361L8	01V361L9

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VENOUS CANNULA PRESSURE DROP VS FLOW



VENOUS CANNULA PRESSURE DROP VS FLOW



Special configurations

CONNECTION SITE 3/8"

C 190 69 70 69 97 70 110 110 110 130 140 140 1

Size	Straight tip	Right angled 90° tip
36 Fr	01V362L8	01V362L9

NON-REINFORCED

 Size
 Straight tip

 32 Fr
 VC3208

Flex line two stage venous cannulae



PROXIMAL AND DISTAL REINFORCED WITH LIGHTHOUSE TIP



	FLAT BODY		ROUND BODY				
ith luer nnector	With connector	Without connector	With luer connector	With connector	Without connector	Length	Size
2L402FB	01V32L401FB	01V32L40FB	01V32L402	01V32L401	01V32L40	36	32/40
4L462FB	01V34L401FB	01V34L40FB	01V34L402	01V34L401	01V34L40	36	34/40
4L462FB	01V34L461FB	01V34L46FB	01V34L462	01V34L461	01V34L46	40	34/46
6L462FB	01V36L461FB	01V36L46FB	01V36L462	01V36L461	01V36L46	40	36/46
6L512FB	01V36L511FB	01V36L51FB	01V36L512	01V36L511	01V36L51	40	36/51
6	01V36L461FB	01V36L46FB	01V36L462	01V36L461	01V36L46	40	36/46

PRODUCT INFORMATION

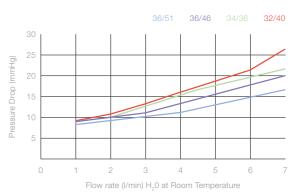
Andocor two stage venous cannulae are intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.



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



Aortic root cannulae





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

PRODUCT INFORMATION

Andocor aortic root cannulae are intended for use during cardioplumonary 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.

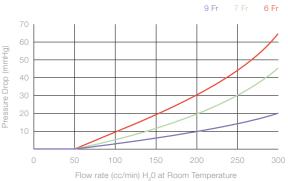


Length: 15 cm Connection size

Connection size vent line: 1/4" Qty/box: 20 Pcs

Easy of use Anti-bleeding valve helps reduce blood loss

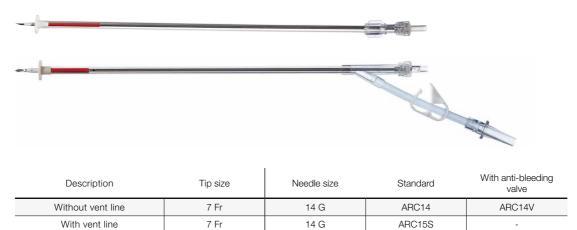
AORTIC ROOT CANNULAE PRESSURE DROP VS FLOW



Tate (coming H₂0 at Nooth Temperature

WITH 2 CLAMPS Description Tip size Needle size Reference 7 Fr With vent line 14 G ARC10 WITH ANTI-BEELDING VALVE AND AL C - C - William -Description Tip size Needle size Reference ARC07V 6 Fr 16 G Without vent line 7 Fr 14 G ARC04V 9 Fr 12 G ARC01V 6 Fr 16 G ARC08V 14 G ARC05V With vent line 7 Fr 9 Fr 12 G ARC02V

MINIMAL INVASIVE TYPE, LENGTH: 28 CM



Retrograde cardioplegia cannulae





Size	Balloon diameter	Reference
14 Fr	18 mm	RCC01

PRODUCT INFORMATION

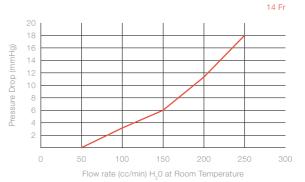
Andocor retrograde cardioplegia cannulae are intended to be connected to the cardioplegia line in order to infuse cardioplegic solution and blood into the patient's coronary sinus during open heart procedures.



Length: 31 cm Qty/box: 20 Pcs



RETROGRADE CARDIOPLEGIA CANNULA PRESSURE DROP VS FLOW



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

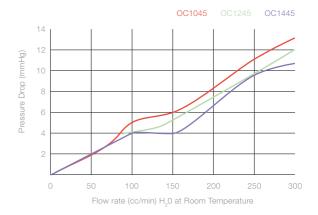
Andocor ostial perfusion cannulae are intended for use in delivery of cardioplegia solution directly to the coronary arteries during cardiopulmonary bypass surgery.



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

Soft basket tip Different configurations Stainless steel shaft

CORONARY ARTERTY 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

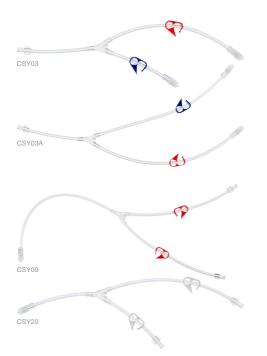


PERFUSION ADAPTERS

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	30 cm	CSY03
with 2 male luer lock connectors.	35 cm	CSY03A

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

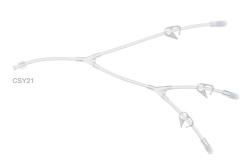


PERFUSION SET WITH VENT LINE

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



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



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

PRODUCT INFORMATION

CSY06

CSY25

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

Paediatric arterial cannulae



REINFORCED WITH 90° METAL TIP



PRODUCT INFORMATION

Andocor paediatric arterial cannulae are intended for perfusion of the ascending aorta during cardiopulmonary bypass surgery up to six hours or less.

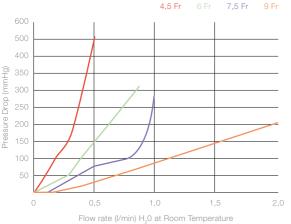
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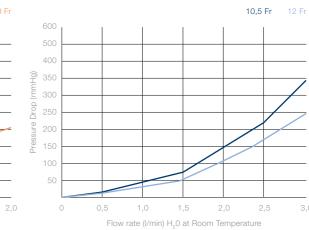
Connection: 3/16" - 1/4" Qty/box: 20 Pcs

Kink resistant wire reinforced PVC tubing Steel tip with thin wall for high flow rates

BODY LENGTH: 23 CM

Size	With vent plug
4,5 Fr	AP04519V
6 Fr	AP06019V
7,5 Fr	AP07519V
9 Fr	AP09019V
10,5 Fr	AP10519V
12 Fr	AP12019V
	4,5 Fr 6 Fr 7,5 Fr 9 Fr 10,5 Fr





METAL TIP ARTERIAL CANNULA PRESSURE DROP VS FLOW

Paediatric venous cannulae



REINFORCED WITH 90° METAL TIP



PRODUCT INFORMATION

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.



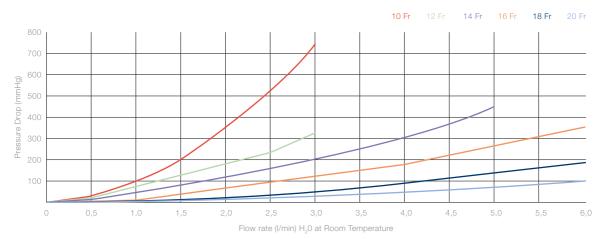
Connection: 10-12 Fr: 3/16" - 1/4" | Other: 1/4" Qty/box: 20 Pcs

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

BODY LENGTH: 35 CM

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METAL TIP VENOUS CANNULA PRESSURE DROP VS FLOW

Silicone vent catheters

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

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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.



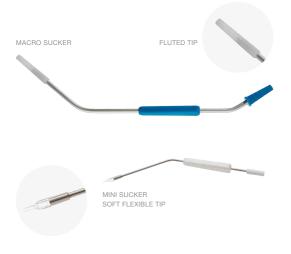
Connection: 1/4" Qty/box: 20 Pcs

Guidewire stylet Soft and flexible silicone tubing Soft tip FLEXIBLE SUCKER

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1 MALLEABLE SUCKER

1



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.



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.



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.



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

Pericardial sumps



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
Туре С	15 Fr	Flexible	2 cm	30 cm	PS40M2
Perforated pool tip	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

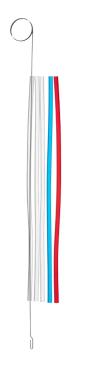
Smooth design Weighted tip Stainless steel tip

WIREWOUND TIP

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



Tourniquet sets



CANNULATION TOURNIQUET SET

Description	Snare	Red tube	Blue tube	Clear tube	Reference
	1	1	1	3	CT01
	1	1	2	3	CT02
Tube size: 11 Fr Tube length: 17 cm Snare length: 25 cm	2	1	2	5	CT03
	1	1	1	-	CT04
	1	2	1	-	CT05
	2	2	2	4	CT06
	2	4	2	2	CT07
	1	5	-	-	CT08
	1	-	-	3	CT09

PRODUCT INFORMATION

Andocor cannulation tourniquet sets are used to secure arterial and venous cannulae during cardiopulmonary bypass.



Tubing: flexible PVC Qty/box: 20 Pcs

Tube size: 21 Fr, Tube length: 20 cm

Clear Tube CT10

2



VASCULAR TOURNIQUET SET

PVC Tube with plug on one end	Plastic snare	Umbilical tapes	Reference
2	2	2	VT01

PRODUCT INFORMATION

The Andocor vascular tourniquet set is an accessory product during cardiopulmonary bypass procedures. It is intended for securing cardiopulmonary bypass cannulae.



PVC tube length: 12 cm Qty/box: 20 Pcs



BLOWER/MISTER

Shaft length	Reference				
15 cm	BM001				
PRODUCT INFORMATION					
The Andocor blower/mister is intended for by non-contact means for improved visib	0 0				
Q Tubing length: 320 cm					



Qty/box: 10 Pcs



Plastic handle and malleable shaft for easy positioning Soft distal tip Roller and clamp to adjust the flow Slip connector for connection to gas source