

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
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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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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





BLOWER/MISTER

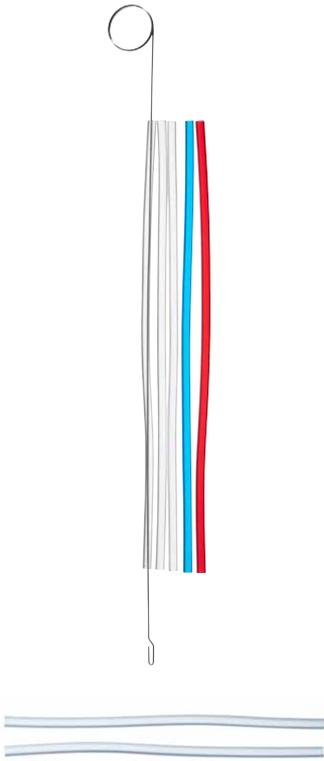
Shaft length	Reference
15 cm	BM001

PRODUCT INFORMATION

The Andocor blower/mister is intended for clearing a wound or surgical site by non-contact means for improved visibility at the site.

- 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

Tourniquet sets



CANNULATION TOURNIQUET SET

Description	Snare	Red tube	Blue tube	Clear tube	Reference
Tube size: 11 Fr Tube length: 17 cm Snare length: 25 cm	1	1	1	3	CT01
	1	1	2	3	CT02
	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.

Q Tubing: flexible PVC
Qty/box: 20 Pcs

	Clear Tube	
Tube size: 21 Fr, Tube length: 20 cm	2	CT10

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.

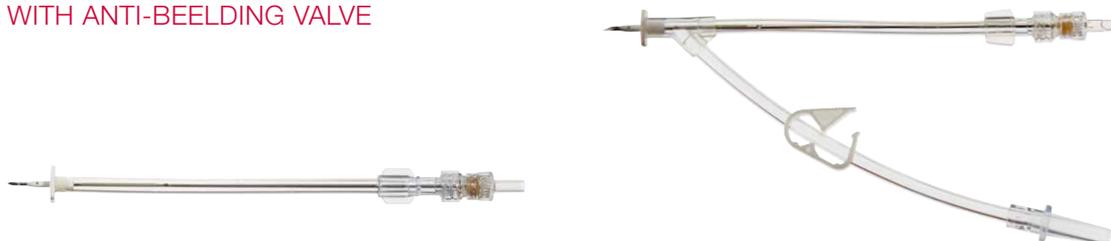
Q PVC tube length: 12 cm
Qty/box: 20 Pcs

WITH 2 CLAMPS



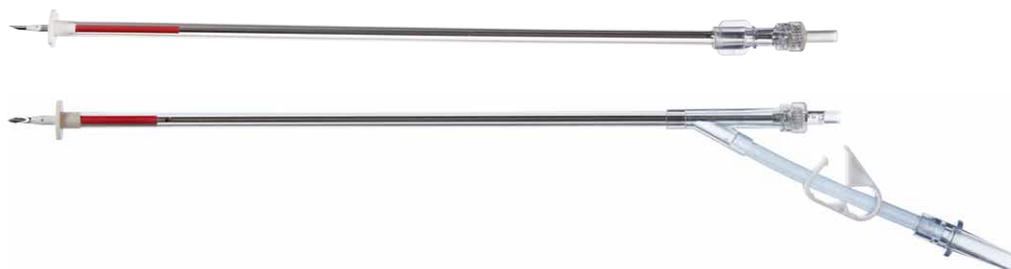
Description	Tip size	Needle size	Reference
With vent line	7 Fr	14 G	ARC10

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	-

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

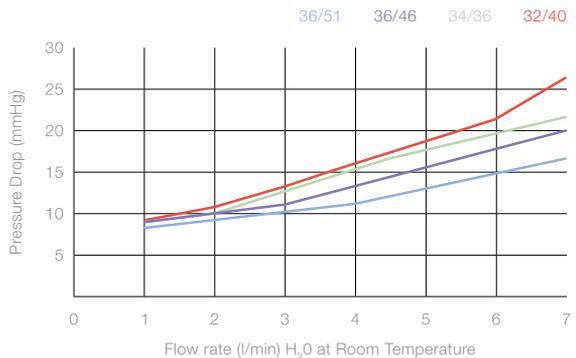
PRODUCT INFORMATION

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



Flex line venous cannulae

REINFORCED WITH LIGHTHOUSE TIP



PRODUCT INFORMATION

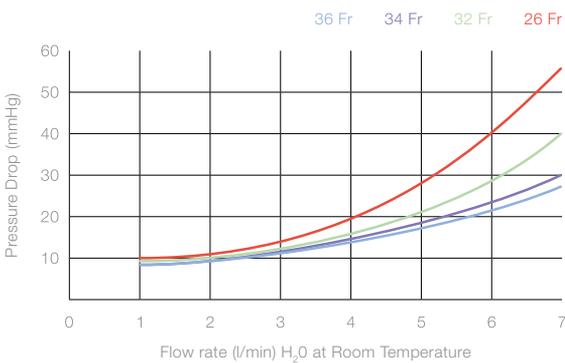
Andocor venous cannulae are intended to drain venous blood from the right atrium and caval veins.

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

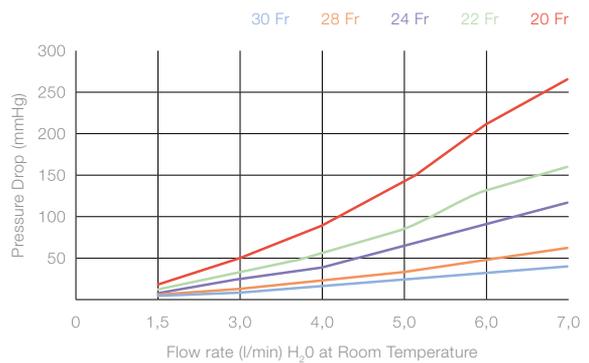
+ Single piece construction
Open and flexible lighthouse tip
Easy positioning
Insertion depth marker

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.

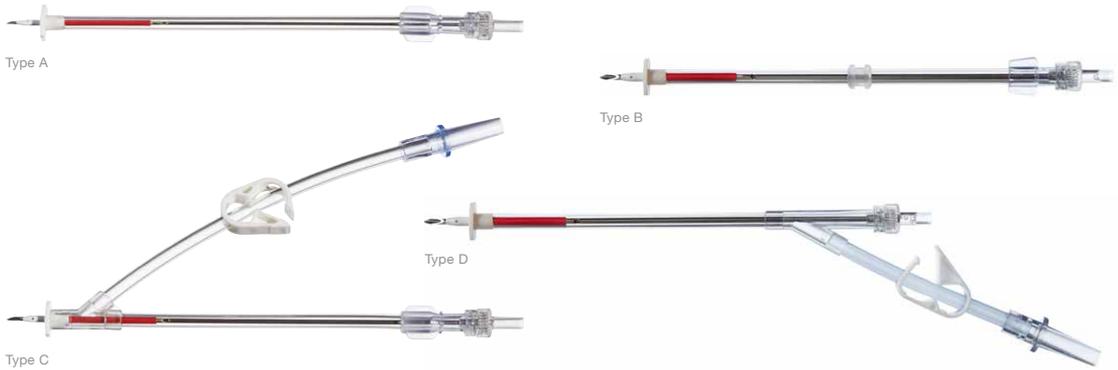


Connection: 1/4"
Qty/box: 20 Pcs



Guidewire stylet
Soft and flexible silicone tubing
Soft tip

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

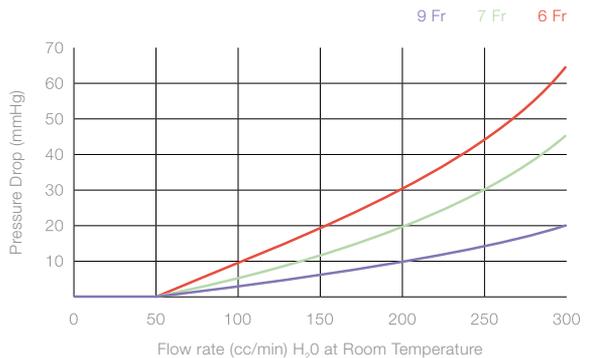
PRODUCT INFORMATION

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



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

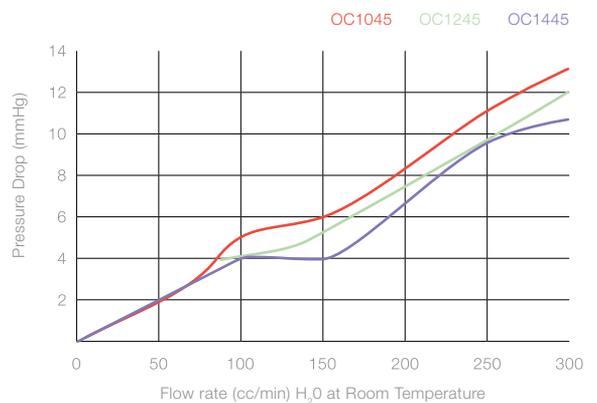
PRODUCT INFORMATION

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



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

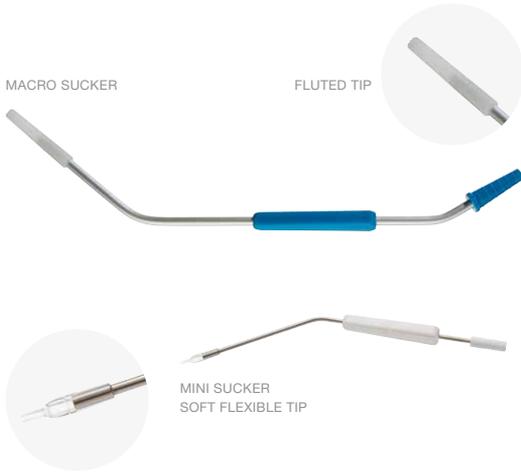


Smooth design
Weighted tip
Stainless steel tip

WIREWOUND TIP

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





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