



CARDIOVASCULAR SURGERY PRODUCTS

 **KoçMedical**

 **BIÇAKCILAR**
Touching Lives One Device at a Time

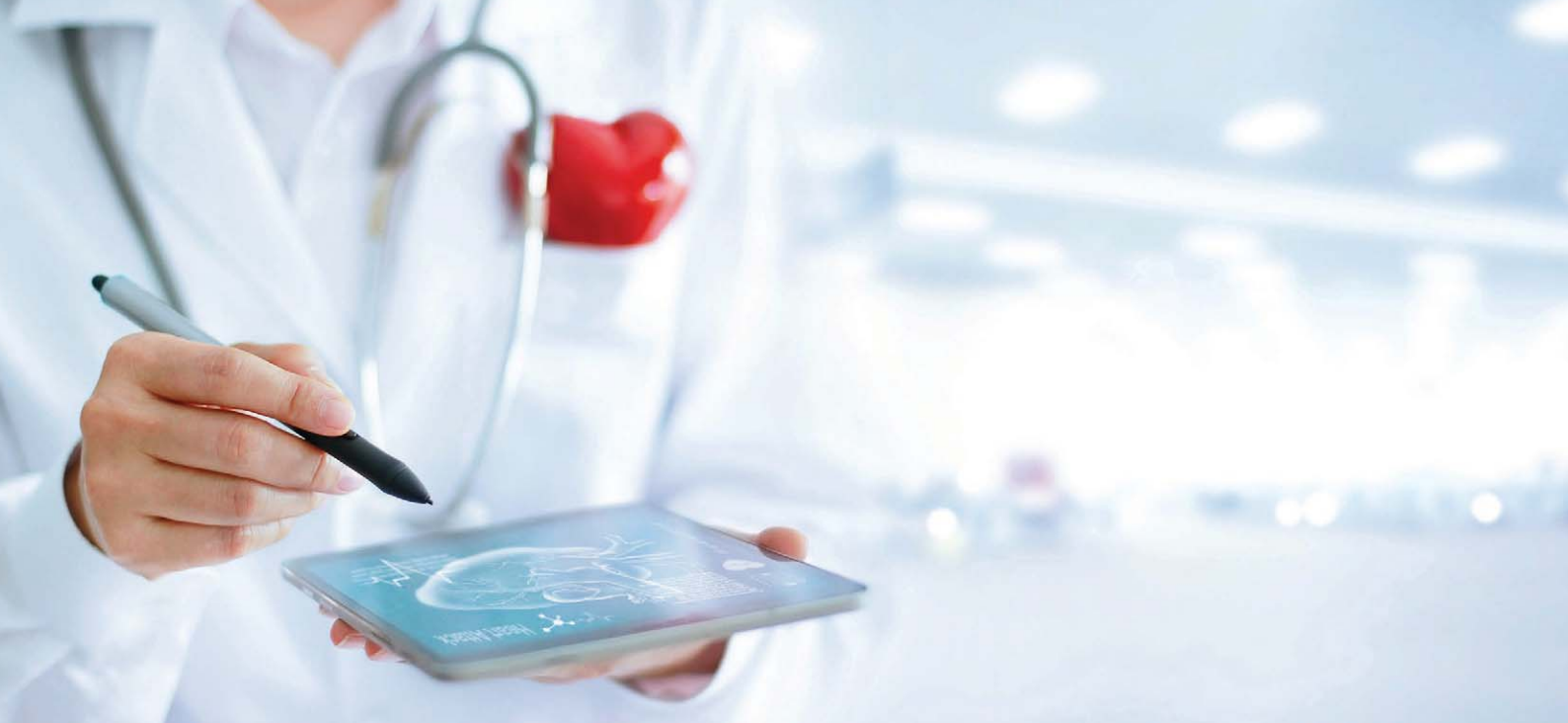
64
YEARS OF
EXPERIENCE

100
EXPORT
COUNTRIES

4
REGIONAL
OFFICES

31.000m²
MANUFACTURING
FACILITIES





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64 YEARS OF EXPERIENCE

“

Bıçakcılar, Turkey's leading disposable medical device and electro-medical device manufacturer, is a part of the Koç Group. The company was founded in 1959. Being an innovative and environmentally friendly company, Bıçakcılar not only offers single-use consumable products both in Turkey and globally but also brings its products used in operating rooms and intensive care units, along with various treatment, cardiovascular surgery, and neurosurgery therapy services, together with its business partners and patients. As Bıçakcılar, in collaboration with our business partners, we manufacture and supply innovative, reliable, and environmentally friendly medical devices, serving our customers. We take care of the benefits our brand provides to both society and the community.



Our Manufacturing Facilities

31.000 m²

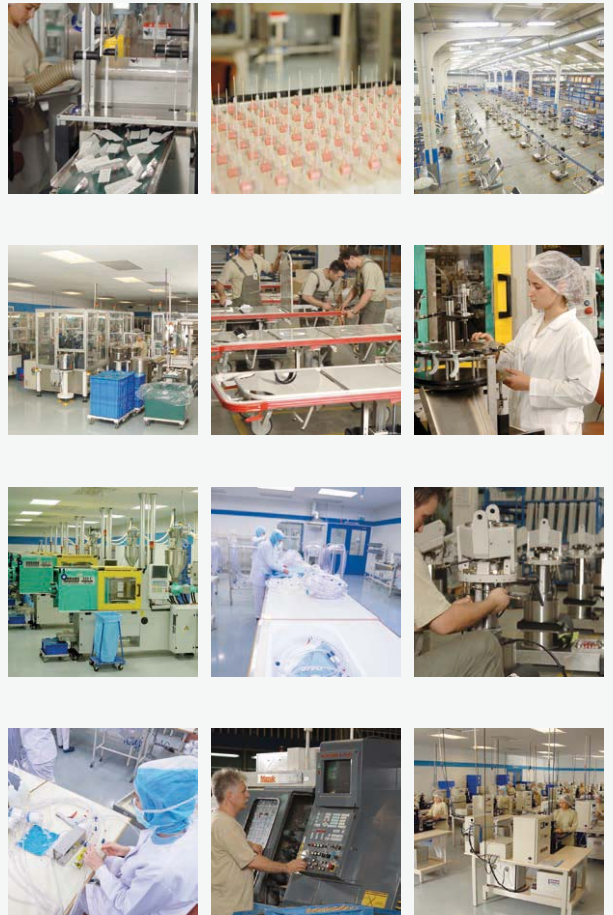
MANUFACTURING FACILITIES

Our manufacturing facilities are located in a closed area of 31,000 m² constructed on a total area of 26,500 m² in Esenyurt, İstanbul. Biçakçılar offers a wide range of sterile/non-sterile disposable medical devices and electro-medical devices.

Disposable medical device manufacturing is performed in clean-rooms with a total area of 4.226 m². Sterilization safety is ensured by bio-burden monitoring in these clean rooms. Ethylene oxide gas is used in sterilization process. Sterilization process is performed in-house with 'state-of-the-art' equipment and has been validated in conformity with ISO 11135. Disposable medical devices are packaged in clean-rooms using fully automatic packaging machines and packaging materials that maintain their sterile condition throughout their shelf life.

Disposable device division includes injection, extrusion, blow molding, assembly, packaging and sterilization departments whereas electro-medical equipment manufacturing division includes metal shop, machining, surface cleaning, dyeing, mechanical and electrical assembly departments. Pre-shipment storage in airconditioned 3.500 m² warehouses operates with around the clock humidity/temperature monitoring.

Raw material warehouses are temperature and humidity controlled areas meeting high industry standards. In-house mould design and production capability add strength and flexibility both in device design and development stages





Global Market Network

With a team of 100 people that work in the headquarters and 4 sales branches, Bıçakçılar owns the largest sales and distribution team in medical field in Turkey. Considering the significance of close relationship with users, it serves on 24/7 schedule with the target of continuous and optimum service. Marketing team follows the developments in the world constantly, supports the required clinical trials, and supplies these to end-users, and thus pioneers the introduction of new products into the Turkish market.

100

 EXPORT COUNTRIES

Bıçakçılar exports its medical devices to more than 100 countries all around the world;



QUALITY ASSURANCE



Quality

Biçakçılar Quality System complies with ISO 9001, EN ISO 13485, ISO 14001, and ISO 27001 has been certified by TÜV NORD, TÜV THÜRINGEN, and KIWA. Biçakçılar products are CE marked. The company operates as a global brand.

Biçakçılar medical disposable devices and electro-medical devices are produced according to GMP. Biocompatible raw materials used in production are in conformity to USP and ISO 10993 Standards. In-house acceptance controls are also performed to meet the stringent demands of our quality system.

When placing medical devices on the market or putting them into service, BIÇAKCILAR ensures that they have been designed and manufactured in compliance with the requirements of 2017/745 MDR.





Quality Policy

Our quality policy in Bıçakcılar Tıbbi Cihazlar A.Ş. is;

- Innovative thinking is our mandate. Our research and development along with focus on competitiveness, we continuously develop ways of being more productive without any negative impact on quality.
- We fulfill all regulatory and normative requirements (e.g Medical Device Directive and ISO EN 13485 Standard).
- We guarantee compliance for our products as per international standards.
- We make sure that each employee in the organization shares the same mission, vision and strategy so that our corporate culture can only enhance our products and solution for our customers.
- The effectiveness of quality management systems is a top priority for our organisation to meet customer and regulatory requirements.
- We provide the resources for improvement of activities by reviewing the effectiveness of the available quality system and the quality targets which are created in line with the quality policy, on a continuous basis.
- We implement our quality system effectively in every phase of our processes to assure complete customer satisfaction.



R&D Activities

“Research, Development and Creative Thinking” are the milestones of the anticipated growth in the future. We have a solid R&D infrastructure that follows the improving and changing world and industry, and develops new product designs to offer the best product in optimum quality and at the best price.

R&D is the most significant element of company's mission and vision, and the primary unit that receives the largest amount of investment in Biçakçılar.

Along with the new product developments in disposable devices and electro-medical equipment, and strengthening and expansion of operations within the company, all activities are incorporated under the “R&D Center” structure, and cooperation with universities and technology transfer offices, as well as government institutes, such as TÜBİTAK are mainstream activities.

Our multidisciplinary R&D team monitors the new trends, market/user requirements and technological developments.

Our priority is to design and develop medical devices that are economically manufacturable with patient safety in mind.

BIÇAKCILAR olarak çağdaş tıp teknolojisine sahip yeni ürünler geliştirmek amacıyla projelerimize hız vererek, yüksek ürün teknolojisi ve ürün kalitesi ile BIÇAKCILAR ismini global bir marka haline getirmeyi hedefliyoruz. Sağlık sektöründe yurt içindeki öncü konumumuzu bir adım daha ileri taşımak ve kendi ürettiğimiz yüksek katma değerli ürünler ile uluslararası piyasalarda ülkemizi temsil eden bir değer olmayı amaçlamaktayız.

BIÇAKCILAR; yıllık ortalama 100-150 fikir/proje önerisi havuzunu değerlendirerek halihazırdaki hastaneler, doktorlar, sağlık görevlileri ve hastalar için güvenilir bir çözüm ortağı olma konumunu devam ettirirken, her alanda ulusal/uluslararası üniversite ve sanayi işbirlikleri sağlayarak, katma değeri yüksek ürünler için global pazarın büyük oyuncularında içinde aranılan bir marka olma yolunda hedeflerini belirlemiştir.

BIÇAKCILAR bu hedefler doğrultusunda Türkiye'nin yenilikçi, işlevsel ve patent koruması altına alınabilir kendi teknolojilerini geliştiren, global anlamda güvenilir bir marka olma yolunda çalışmalarına hız kesmeden devam etmektedir.



Laboratory

Each stage of manufacturing is under the control of Bıçakcılar Quality Control Laboratory, which employs specialized staff working in line with the GLP rules, and modern equipment. This laboratory is accredited by Turkish Accreditation Institution (TÜRKAK).

Due to changing regulatory environment in healthcare industry both in Turkey and the world, Bıçakcılar Laboratory started to comply with all articles of ISO 17025 Standard in order to offer its know-how to the use of other Medical Device Manufacturers. Chemical Test Laboratory commenced its operation as of January 2005.

Bıçakcılar Quality Control Laboratory has been accredited to perform physical, chemical, bio-burden, sterility, stability, ETO residual, biocompatibility, cosmetic, cleanroom testing. Equipped with state-of-the-art technology and highly trained personnel.



Test
TS EN ISO/IEC 17025
AB-0052-T



Waste Treatment Facilities

In line with the sustainable development principle, Bıçakçılar constantly keeps environmental effects under control in order to leave a clean and healthy world to the next generations. Bıçakçılar is the the first medical device manufacturing company in Turkey that has established an ethylene oxide treatment facility that operates through catalytic oxidation for the sterilization unit air emission.

Thanks to its waste management activities that reduce waste production in its own source, Bıçakçılar stores operational waste in its waste repositories that are specially designed for each waste stream, and disposes collected waste in conformity with regulations.

While maintaining its leader position in the Turkish medical device industry, it is also the primary target of Bıçakçılar to be a leader in the matters of environment and occupational health and safety.





Social Responsibility and Environment

Adopting increased environmental awareness, and protection of environment as main principles, Bıçakcılar Management established an Environmental Management System in order to conform manufacturing and operation to the environmental policy and targets.

Bıçakcılar Occupational Health and Safety- Environment Management System has been designed and documented in conformity with the terms of ISO 14001:2015 and OHSAS Standards. Compliance of Environment Management System with these standards is maintained while its efficiency is constantly enhanced.

Social Associations

that we cooperate with





DEHP-free Production

Unplasticised PVC is hard and brittle at room temperature. A plasticiser, softener, is typically added to increase flexibility of the polymer. Virtually all medical devices made from PVC utilise one plasticizer: DEHP. It has been known for a long time that DEHP can leach out of PVC, resulting in exposure to body tissues and fluids. The amount of DEHP that will leach out depends on temperature, the lipid content of the liquid and the duration of contact with the plastic.

It has been known that according to in vivo and in vitro research studies; DEHP or its metabolites result in adverse effects in the liver, reproductive tract, kidneys, lungs, and heart. DEHP seems to pose a relatively low risk of hepatic cancer in humans. However uncertainties about the relevance of the mechanism of action of DEHP-related carcinogenic effects in humans cannot be ruled out.

As a result of these developments, scientific research that continues today and customer demand, medical device industry started looking for alternatives to DEHP. DEHT has a significant market use experience in place of traditional DEHP. Also, DEHT has similar extraction values to DEHP in oil and hexane, lower in soapy water. Lower volatility than DEHP. The low temperature flexibility of DEHT in PVC is equal to that of DEHP. All relevant studies show that DEHT is not genotoxic, has no effect on irritation and sensitization. It is not absorbed from the GI tract upon oral

exposure where it is rapidly excreted. This contrast to the metabolite profile of the ortho-phthalate DEHP which primarily undergoes hydrolysis to form the mono ester (MEHP) (Scientific Committee Report 2008). The report released in 2015 also concludes the same results.

“At doses where DEHP, BBP and DINP all altered sexual differentiation, DEHT was inactive”

European Commission, 2002

DEHT is not genotoxic (like its isomeric relative DEHP).

As a result of all these, customer demands for the DEHP-free medical devices cannot be ignored. Many manufacturers started to search for alternatives for DEHP as a plasticiser. Referring to the literature search, guidance documents and reports prepared by competitors, it can be easily seen that, DEHT is a well known and common plasticizer, as an alternative to DEHP. There is no evidence, showing any toxic effect in the literature. The literature findings show that the metabolites of DEHT are not toxic and it is not classified as a “phthalate”, so it can be concluded that this raw material does not carry any risk for pediatric and breast-feeding female patients.

Considering the strong market demand for DEHP-free product, we, as Biçakçılar, have changed our product portfolio to DEHP-free constituents.

Extracorporeal Tubing Set

Adult, pediatric and infant tubing sets

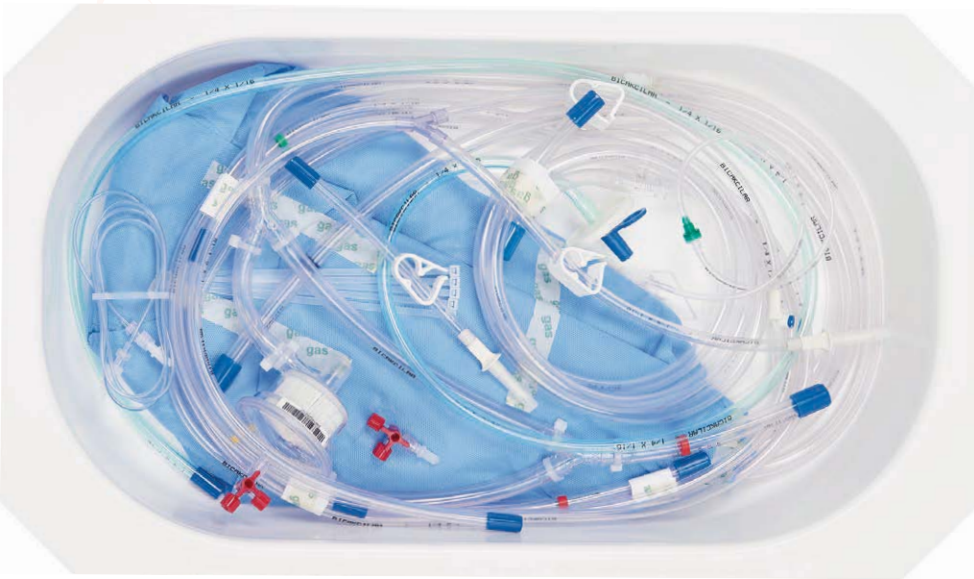
- Custom made to meet individual requirements. Maximum safety with the most economic solution.
- Table set includes; arterial, venous and cardiotomy lines.
- Perfusionist set includes lines for oxygenator, cardiotomy vent and cardiotomy reservoir. These two sets can be dispensed separately or together upon request.
- Supplied with a packaging system that provides maximum safety for sterility and transportation



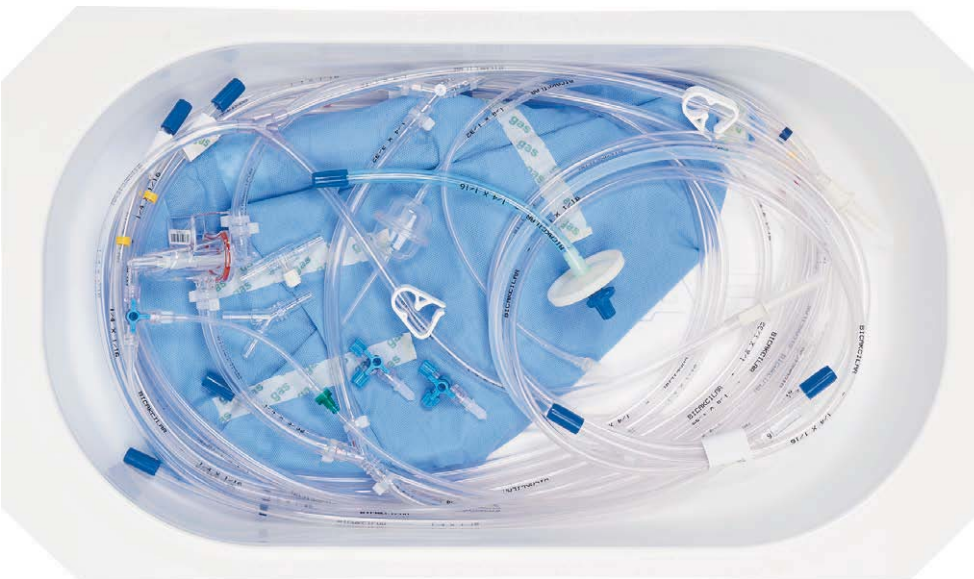
Adult

Ref

300 XXXX 1



Pediatric



Infant

Quick Prime Set

- Allows fast priming of the set
- Custom configuration available upon request



Ref

320 0491 1

Tubing

PVC

- Transparent medical grade PVC
- Kink and pressure resistant
- For extracorporeal circulation and roller pump lines
- Packaged in requested length and sterile or non-sterile in reels



Ref (Sterile)	I.D.	Wall Thickness	O.D.	Length (cm)
305 1175 1	1/4"	1/16"	3/8"	175
305 1200 1	1/4"	1/16"	3/8"	200
306 1175 1	3/8"	1/16"	1/2"	175
306 1200 1	3/8"	1/16"	1/2"	200
306 2175 1	3/8"	3/32"	9/16"	175
306 2200 1	3/8"	3/32"	9/16"	200
307 2175 1	1/2"	3/32"	11/16"	175
307 2200 1	1/2"	3/32"	11/16"	200

Ref (Non-sterile)	I.D.	Wall Thickness	O.D.	Length (m/rulo)
305 1000 3	1/4"	1/16"	3/8"	100
305 2000 3	1/4"	3/32"	7/16"	50
306 1000 3	3/8"	1/16"	1/2"	50
306 2000 3	3/8"	3/32"	9/16"	40
307 2000 3	1/2"	3/32"	11/16"	30

Straight Connector

- Meets all connection requirements of the extracorporeal circulation system
- Unique design and precision moulding techniques allow a smooth transition at tubing and connector junctions reducing blood turbulence
- Produced from crystal clear polycarbonate allowing maximum visibility during de-airing procedures



Ref		Size
	Luer	
750 0111 1	751 0111 1	3/16" x 3/16"
750 0121 1	751 0121 1	3/16" x 1/4"
750 0221 1	751 0221 1	1/4" x 1/4"
750 0321 1	751 0321 1	1/4" x 3/8"
750 0331 1	751 0331 1	3/8" x 3/8"
750 0421 1	751 0421 1	1/4" x 1/2"
750 0431 1	751 0431 1	3/8" x 1/2"
750 0441 1	751 0441 1	1/2" x 1/2"

"Y" Connector

- Meets all connection requirements of the extracorporeal circulation system
- Unique design and precision moulding techniques allow a smooth transition at tubing and connector junctions reducing blood turbulence
- Produced from crystal clear polycarbonate allowing maximum visibility during de-airing procedures



Ref		Size		
	Luer	①	②	③
754 2221 1	755 2221 1	1/4"	1/4"	1/4"
754 3221 1	755 3221 1	3/8"	1/4"	1/4"
754 3321 1	755 3321 1	3/8"	1/4"	3/8"
754 3331 1	755 3331 1	3/8"	3/8"	3/8"
754 4321 1	755 4321 1	1/2"	3/8"	1/4"
754 4331 1	755 4331 1	1/2"	3/8"	3/8"
754 4421 1	755 4421 1	1/2"	1/2"	1/4"
754 4431 1	755 4431 1	1/2"	1/2"	3/8"
754 4441 1	755 4441 1	1/2"	1/2"	1/2"

Tubing Connector

3/8" x 1/4"

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- Conical connector
- Strong and safe connection
- 3/8" x 1/4" connection
- Length: 79 mm



Ref	
236 0005 1	Sterile
236 0005 3	Bulk

Tubing Connector

3/8" x 3/8"



- Conical connector
- Strong and safe connection
- Clear polycarbonate
- 3/8" x 3/8" connection
- Length: 88 mm

Ref	
236 0001 1	Sterile
236 0001 3	Bulk

Conical Connector



- Luer lock proximal end
- Length: 40 mm

Ref	
235 0001 1	Sterile
235 0001 3	Bulk

Cardioplegia Set

- The cardioplegia sets may be design with heat exchanger, aluminum coil or bag
- Adult and pediatric options are available
- For delivery of antegrade/retrograde cardioplegia
- Custom design
- Piercing spike without air vent
- Flexible drip chamber with screen filter
- Clamp
- Male luer lock adapter



Ref	
325 XXXX 1	Adult With Bag
325 XXXX 1	Pediatric With Bag
325 XXXX 1	With Coil
325 XXXX 1	With Heat Exchanger

Cardioplegia Sets



Cardioplegia Set - Adult



Cardioplegia Set - Pediatric



Cardioplegia Set With Coil



Cardioplegia Set With Heat Exchanger

Vent Catheter

- Effective drainage
- Non-traumatic bullet tip
- Flexible, kink-resistant tubing
- Depth markings



Ref		Size	Length
w/o Connector	w/Connector		
330 0391 1	330 0394 1	18 Fr	25 cm
330 0392 1	330 0395 1	18 Fr	40 cm

Ventricular Vent Catheter

PVC

- Effective drainage
- Non-traumatic open tip
- Flexible, kink-resistant tubing
- With straight connector
- Depth markings



Ref	Size	Length	Tip Perforation
330 0360 1	16 Fr	43 cm	2.5 cm

Ventricular Vent Catheter

With Malleable Stylet, PVC

 KoçMedical

 BIÇAKÇILAR

- Effective drainage
- Non-traumatic open tip
- Flexible, kink-resistant tubing
- With straight connector
- Internal, malleable stylet
- Depth markings



Ref	Size	Length	Tip Perforation
330 0356 1	18 Fr	38 cm	3 cm

Ventricular Vent Catheter

PVC

- Effective drainage
- Non-traumatic rounded closed tip
- Flexible, kink-resistant tubing
- With straight connector
- Depth markings



Ref	Size	Length	Tip Perforation
330 0365 1	16 Fr	38 cm	5.5 cm

Ventricular Vent Catheter

With Luer Connector, PVC

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 BIÇAKÇILAR

- Effective drainage
- Non-traumatic rounded closed tip
- Flexible, kink-resistant tubing
- With straight luer connector
- Depth markings

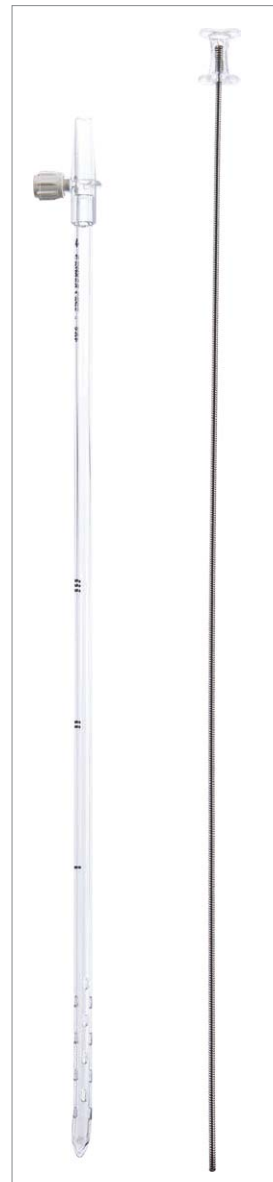


Ref	Size	Length	Tip Perforation
330 0385 1	16 Fr	38 cm	5.5 cm
330 0386 1	18 Fr	38 cm	7 cm
330 0387 1	20 Fr	38 cm	7 cm

Ventricular Vent Catheter

With Malleable Stylet,
With Luer Connector, PVC

- Effective drainage
- Non-traumatic rounded closed tip
- Flexible, kink-resistant tubing
- With straight luer connector
- Removable, malleable stylet
- Depth markings



Ref	Size	Length	Tip Perforation
330 0370 1	10 Fr	32 cm	2 cm
330 0371 1	13 Fr	32 cm	3.5 cm
330 0380 1	16 Fr	38 cm	5.5 cm
330 0381 1	18 Fr	38 cm	7 cm
330 0382 1	20 Fr	38 cm	7 cm

Aortic Root Cannula

Without Vent

- Available without vent line
- Length: 15 cm
- Color coded sizes
- May be used with several unique adapters developed to deliver cardioplegia solution during cardiopulmonary bypass surgery



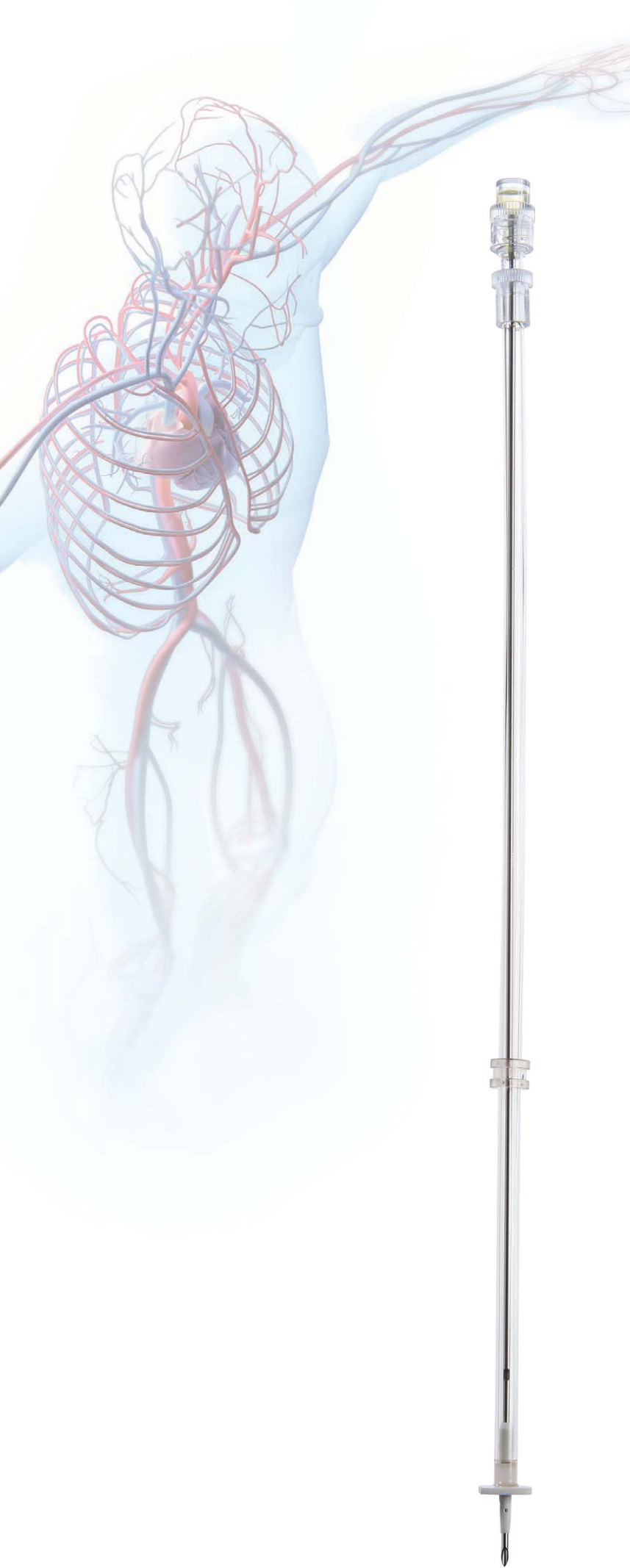
Ref	Size	Color
330 0101 1	12 G	■ Green
330 0102 1	14 G	□ White
330 0103 1	16 G	■ Pink
330 0104 1	18 G	■ Gold

Aortic Root Cannula With Vent

- Available with vent line
- Length: 15 cm
- Color coded sizes
- May be used with several unique adapters developed to deliver cardioplegia solution and to vent the left heart during cardiopulmonary bypass surgery



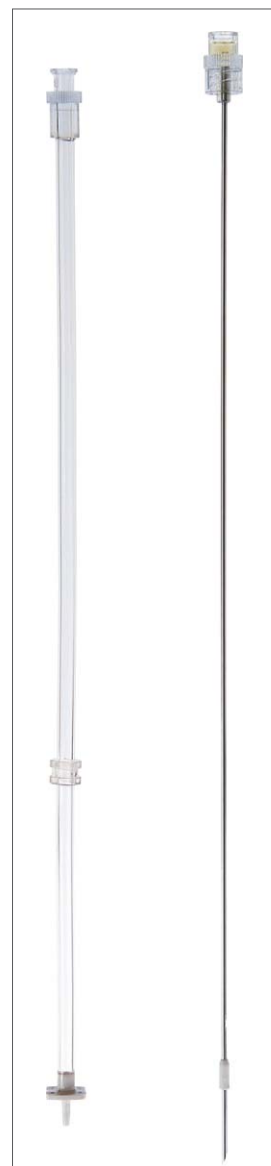
Ref	Size	Color
330 0111 1	12 G	■ Green
330 0112 1	14 G	□ White
330 0113 1	16 G	■ Pink



Aortic Root Cannula

35 cm

- Designed for minimally invasive procedures
- Available without vent line
- Length: 35 cm
- May be used with several unique adapters developed to deliver cardioplegia solution during cardiopulmonary bypass surgery



Ref	Size	Color
330 0122 1	14 G	<input type="checkbox"/> White

Coronary Artery Perfusion Cannula

- Basket tip has a soft flange that occludes the ostium, preventing backflow of cardioplegia
- Large malleable stainless steel shaft with a plastic handle
- Terminates with a distal female luer connector
- Available in either a 45 or 90 degree angle configuration



Ref		Size
45 Degree Tip	90 Degree Tip	
330 0460 1	330 0465 1	10 Fr
330 0461 1	330 0466 1	12 Fr
330 0462 1	330 0467 1	14 Fr

Suction Wands

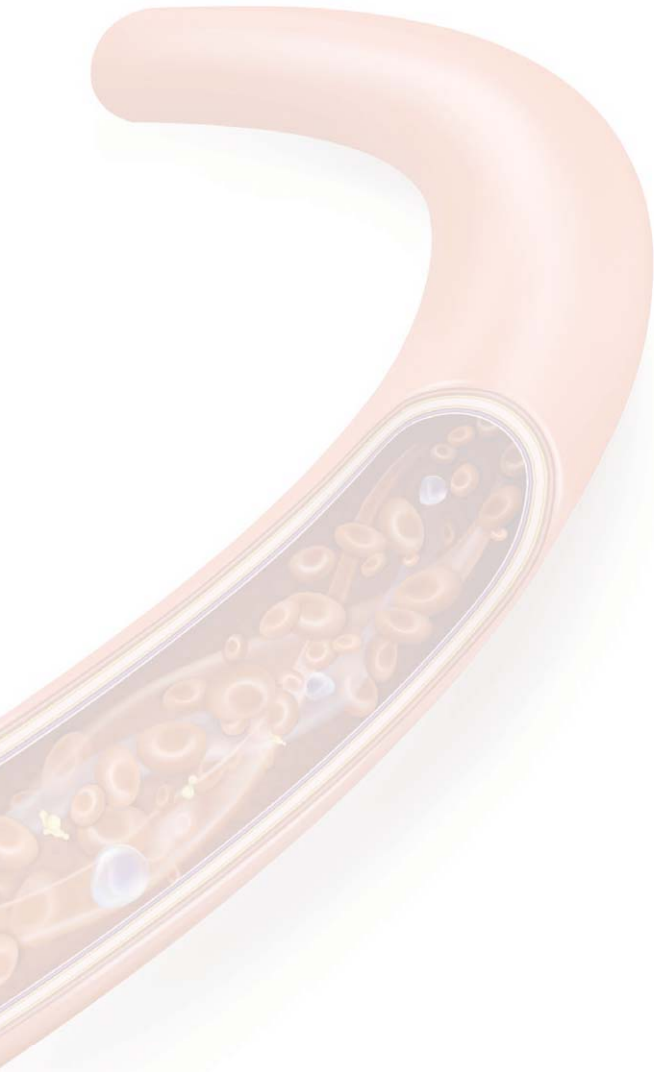
- Standard and low profile options
- Rigid Tip
- Stainless steel design
- Ergonomic plastic handle
- Accepts 6.35 mm (1/4") connection



Ref	
162 0001 1	Standard
162 0002 1	Low Profile

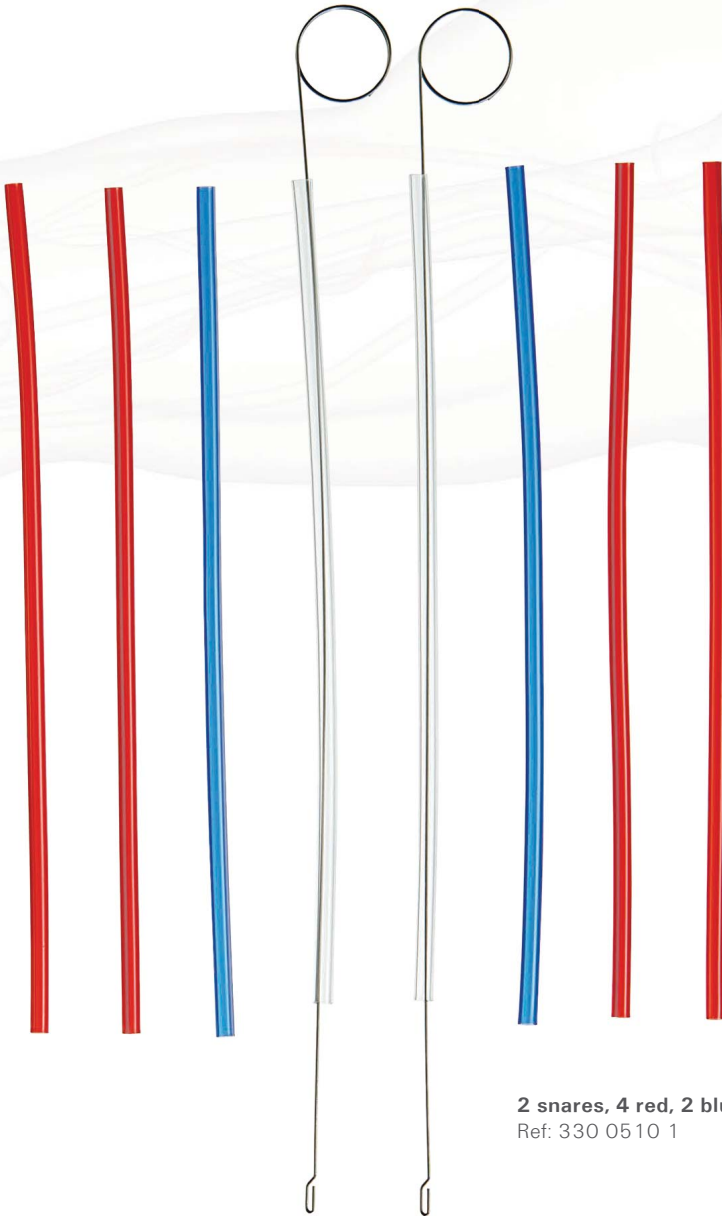
Vascular Tourniquet Set

- Options of 2 tubes, 1 tube, 5 tubes (Length of each tube is 13 cm)
- Integrated plug
- Snare
- Umbilical tape



Ref	Tube Quantity
330 0590 1	2 Tubes
330 0591 1	1 Tube
330 0592 1	5 Tubes

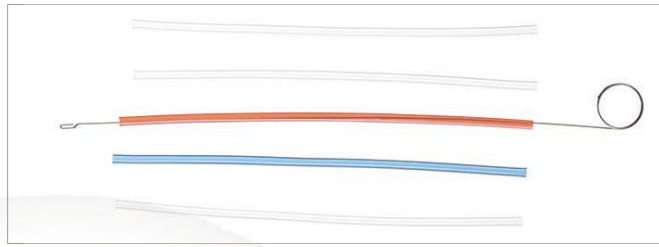
- All tubes with x-ray detectable stripe



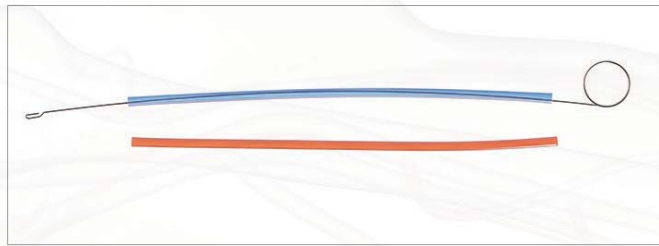
2 snares, 4 red, 2 blue, 2 clear tubes
Ref: 330 0510 1

Ref

330 XXXX 1



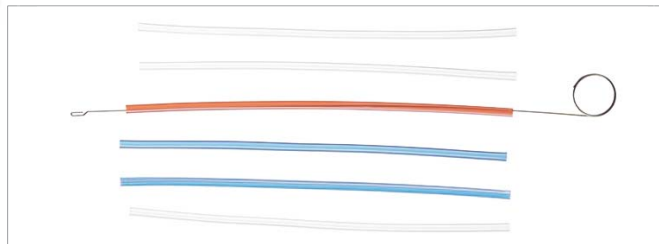
1 snare, 1 red, 1 blue, 3 clear tubes
Ref: 330 0511 1



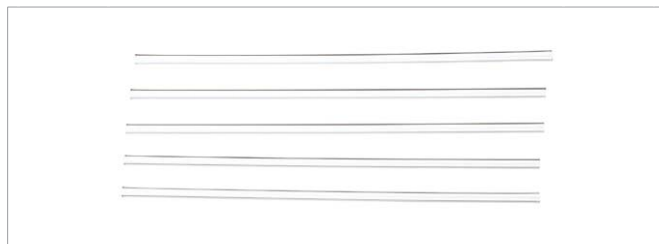
1 snare, 1 red, 1 blue tube
Ref: 330 0518 1



1 snare, 2 red, 1 blue tubes
Ref: 330 0516 1



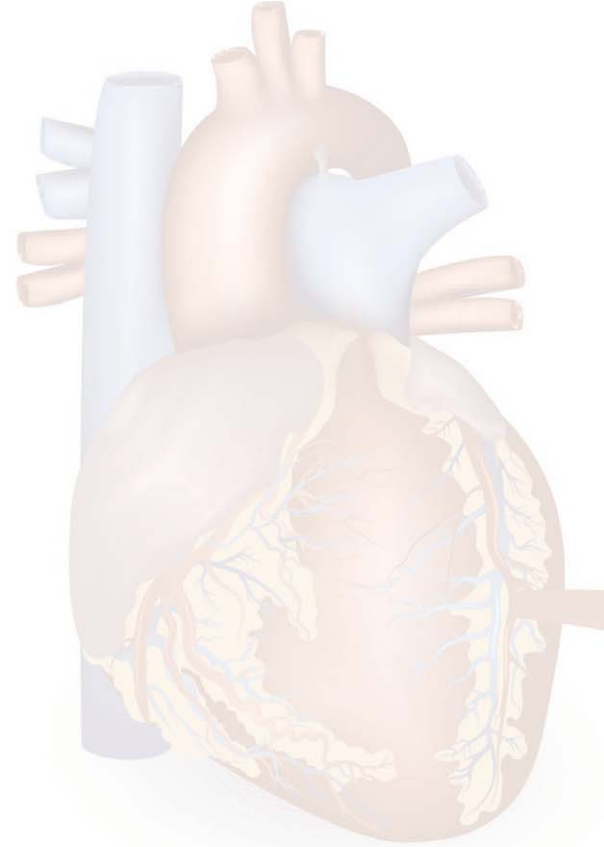
1 snare, 1 red, 2 blue, 3 clear tubes
Ref: 330 0513 1



5 clear tubes
Ref: 330 0610 1

Coronary Artery Retraction Clip

- Used for retracting perivascular tissues during coronary artery bypass surgery
- The sharp, curved prongs engage the tissue layer and provide stability.
- The angulated legs afford room for the anastomosis
- The coating provides non-slip surfaces so that the clip can be gripped with the gloved hand or forceps



Ref	
330 0450 1	3.0 mm
330 0451 1	5.0 mm

Vessel Cannula

- Uni-directional flow valve
- No valve option
- Soft, rounded tip
- Corrugated distal design for secure vessel attachment
- Flexible tubing
- Female luer / Female luer lock connector

Without Valve



Luer Lock, Without Valve



With Valve



Luer Lock, With Valve



Ref	
330 0220 1	Without Valve
330 0221 1	With Valve
330 0230 1	Luer Lock, Without Valve
330 0231 1	Luer Lock, With Valve

Cardioplegia Adapters

- Cardioplegia adapters are designed to be used in conjunction with aortic root and vessel cannula. They are used for delivering the cardioplegia solution to heart during cardiopulmonary bypass surgery.



Venting "Y" Adapter
Ref: 330 0322 1



Cardioplegia Adapter, Duplicate
Ref: 330 0323 1



Perfusion "Y" Adapter
Ref: 330 0321 1

Ref	
330 0322 1	Venting "Y" Adapter
330 0321 1	Perfusion "Y" Adapter
330 0323 1	Kardioplegia Adapter, Duplicate
330 0331 1	Multiple Perfusion Adapter, Triplicate
330 0341 1	Multiple Perfusion Adapter
330 0342 1	Multiple Perfusion Adapter w/Vent Line



Multiple Perfusion Adapter, Triplicate
Ref: 330 0331 1



Multiple Perfusion Adapter
Ref: 330 0341 1



Multiple Perfusion Adapter, w/Vent Line
Ref: 330 0342 1

Surgical Braided Tape

3 x (3 mm x 70 cm)

- Surgical tape with braided uninterrupted filaments
- Width: 3 mm
- Length: 70 cm
- Sterile
- Three pieces in one package



Ref

723 3070 1

Aortic Punch

- Superb cutting feature
- Smooth aortotomy edges
- Easy to use
- Secure grip
- Ergonomic design



Ref	
332 0028 1	2.8 mm
332 0036 1	3.6 mm
332 0040 1	4.0 mm
332 0044 1	4.4 mm
332 0048 1	4.8 mm

