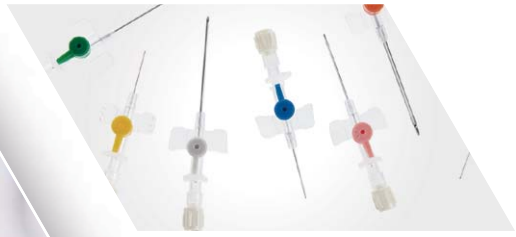
BIÇAKCILAR

Touching Lives One Device at a Time

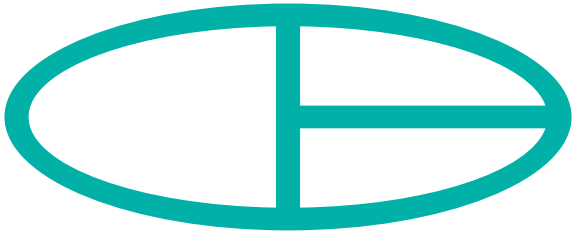
Medical Disposable Solutions

12th Edition



All products and product specifications identified in the product catalogue are based upon the information available to Bıçakcılar at the time of publication. Bıçakcılar reserves the right to discontinue any of these products or to change any such specifications without prior notice.

Patients are at the center of every step we take



61 YEARS OF EXPERIENCE

Bıçakcılar is the leading disposable medical device and electro-medical device manufacturer in Turkey. The company was founded in 1959. Through the years, Bıçakcılar brand has gained wide acceptance and has established a tradition of sustained reliability and customer satisfaction.

As Bıçakcılar employees, together with our business partners, we serve our customers by manufacturing and supplying innovative, reliable and environment friendly medical devices. We diligently value our brand and its benefit to society.

Mission

Our compassion for healthy life is leading us to focus on innovative thinking and new technologies in order to provide medical devices that make living easier, more affordable and effective.

Vision

We believe in a world where everybody is taken care of, comfortable and happy, in sickness and in health.

Group Companies

BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

Operates in manufacturing of disposable medical devices, electro-medical equipment, and distribution of medical devices from leading multinational brands. Manufacturing facilities are in Istanbul Esenyurt, whereas domestic sales and distribution is performed via regional sales branches in İstanbul, Ankara, İzmir, Samsun and Adana. Bıçakcılar Headquarters is in İstanbul.

BIÇAKCILAR
GLOBAL
TIBBİ ÜRÜNLER SANAYİ VE TİCARET A.Ş.

Established in İstanbul, this company conducts the global marketing and sales operations of medical devices. Through its international dealer network, it offers sales and after-sales services in more than 100 countries worldwide.


BIÇAKCILAR
BIÇAKCILAR

31.000 m^2

MANUFACTURING FACILITIES

Our Manufacturing Facilities

Our manufacturing facilities are located in a closed area of 31,000 m^2 constructed on a total area of 26,500 m^2 in Esenyurt, İstanbul. Bıçakcılar offers a wide range of medical products from sterile disposable devices to medical equipment.

The production of disposable medical devices is carried out in a total of 4.226 m^2 clean rooms. Sterilization safety is ensured by keeping the biological load of the products under control in clean rooms. Ethylene oxide gas is used in sterilization process. Sterilization assurance is provided in accordance with ISO 11135 with high technology equipment. Disposable medical products are packed in clean rooms in fully automatic packaging machines by using packaging materials that maintain their sterile condition during 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 manufacturing, surface cleaning, dying, mechanical and electrical assembly departments. Pre-shipment storage processes of our products are also performed in our factories. Finished products are stored in airconditioned 3.500 m^2 warehouses 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.

Sales Network

With a team of 100 people that work in the headquarters and 5 sales branches, Bıçakcılar 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

Global Market Network

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


BIÇAKCILAR

Quality

Bıçakcılar Quality System complies with ISO 9001, EN ISO 13485 and ISO 14001 has been certified by TÜV NORD and TÜV THÜRINGEN. Bıçakcılar products are CE marked. The company globalized as a brand that is relied upon and cared by the world that cares about health.

Bıçakcılar medical equipment and disposable products are produced according to GMP, with latest technologies in modern production facilities established on 26.500 m^2 land with 30.900 m^2 closed area. 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.

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.


CERTIFICATE

for the management system
according to ISO 9001:2015

The proof of the conforming application with the regulation was furnished and in accordance with certification procedure it is certified for the company

BIÇAKÇILAR TIBBİ CİHAZLAR
SAN. VE TİC. A.Ş.
Head Office: Osmangazi Mah. Gazi Cad. No: 21
Esenyurt İstanbul Turkey
Branch: Merkez Mahallesi. Akar Caddesi, Itower No:3 Kat:15
Bomonti Şişli İstanbul Turkey
with branch (see enclosure)

Scope
Customs, foreign trade, manufacturing, logistics, management and administrative organization activities of medical devices and related raw materials and semi-finished products and related sales and service delivery

Certificate Registration No.: TIC 15 100 169656
Valid until: 2022-07-24
Valid from: 2019-07-25

Audit Report No.: 3330 2U38 D0

This certification was conducted in accordance with the TIC auditing and certification procedures and is subject to regular surveillance audits.

TÜV Thüringen e.V.
Certification body for systems and personnel

Jena, 2019-07-08


TÜV NORD

ZERTIFIKAT / *Certificate*

DIN EN ISO / EN ISO 13485 : 2016

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

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 Istanbul
Türkiye

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 authorization to affix the CE mark.

Geltungsbereich / *Scope*

Entwicklung, Herstellung, Sterilisation und Vertrieb von medizinischen Einmalartikeln. Entwicklung, Herstellung und Vertrieb von medizinischen Geräten und deren Zubehör.
Design, Manufacturing, Sterilization and Distribution of Disposable Medical Devices. Design, Manufacturing and Distribution of Medical Equipments and all their Accessories.

Reg.-Nr. / *Reg.-No.* 04 221 980886
Bericht Nr. / *Report No.* 3521 8284

Gültigkeit / *Validity*
von / *from* 2018-09-17
bis / *until* 2021-09-16
Edition 6

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

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*


TÜV NORD

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*

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 Istanbul
Türkiye

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

Medizinische Einmalartikel und Absauggeräte
Disposable medical devices and devices for aspiration and vacuum extraction

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 erweitert. 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.* 04 232 980886
Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
bis / *until* 2021-09-16
Edition 7

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

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*


TÜV NORD

CERTIFICATE

Management system as per
ISO 14001 : 2015

In accordance with TÜV NORD CERT procedures, it is hereby certified that

Bıçakcılar Tıbbi Cihazlar San. ve Tic. A.Ş.
Osmangazi Mah., Gazi Cad., No 21, Esenyurt,
TR-34522 Istanbul,
Turkey

applies a management system in line with the above standard for the following scope

Design, manufacturing and distribution of medical equipment and sterile and non sterile disposable medical products

Certificate Registration No. 44 104 080979
Audit Report No. TR 1286

Valid from 2017-10-14
Valid until 2020-10-13
Initial certification 2008

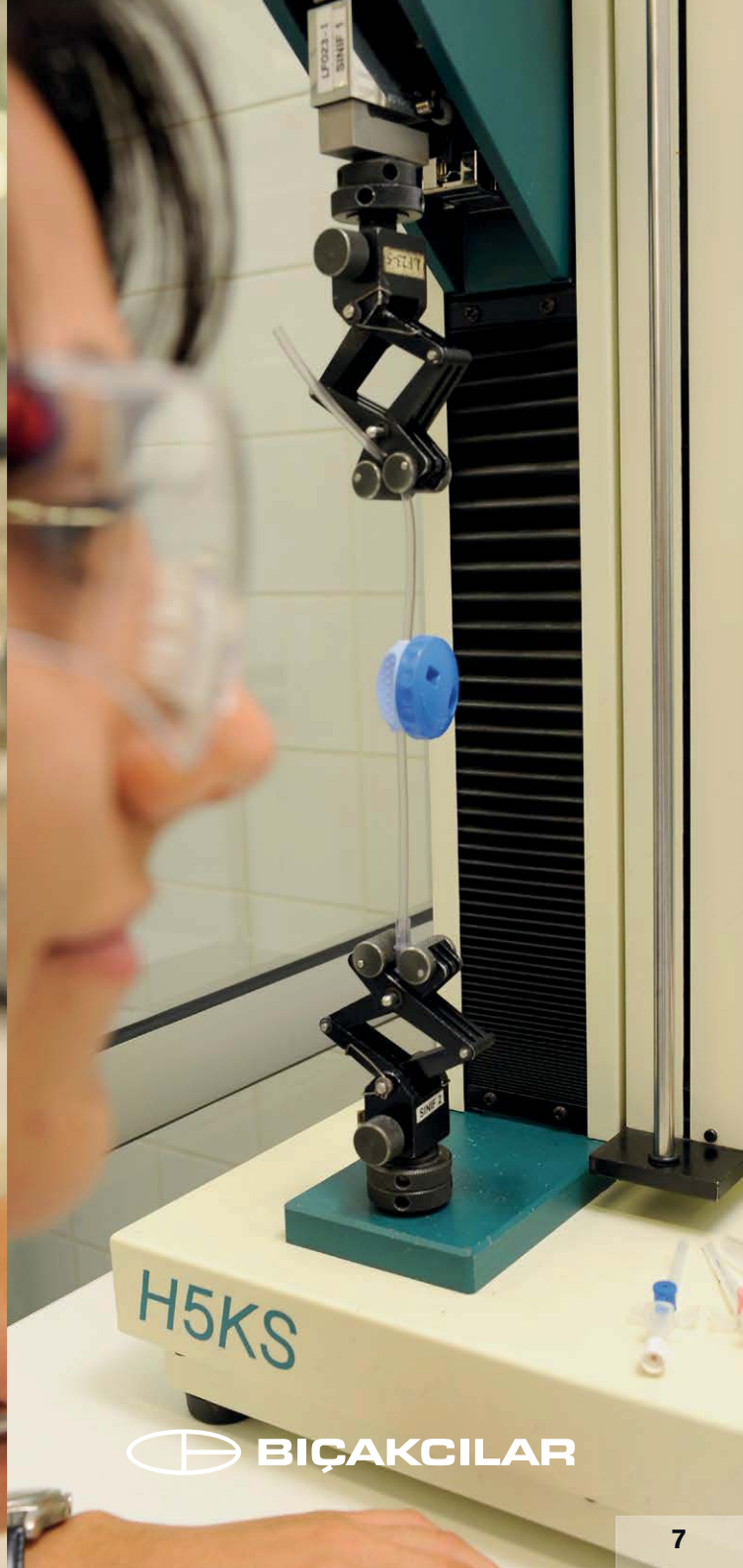
Istanbul, 2017-08-14

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.com


Porosity Tester
Model 6
50-500
300-3000
ml/Min


TH210
000
N/AVE
MAX
ON/OFF


H5KS
BIÇAKCILAR

Turquality®

TURQUALITY® is an ambitious project associated with bringing "Turkey" and "Quality" concepts together.

The project is initiated by the Turkish Government, Ministry of Economy, Turkish Exporters' Assembly (TIM), and Istanbul Textile and Apparel Exporters' Association (ITKIB). The initial legal framework was laid out publicly on January 12th, 2004.

TURQUALITY® is basically an accreditation system, which is designed not only for elevating the beneficiary companies to the level of international benchmarks, but also creating awareness on the internationally accepted values like quality and novelty that are actually carried by these brands.

As a "national brand-building program", TURQUALITY®'s goal is to facilitate and support the success of Turkish brands on international arena.

To achieve these ambitious goals, TURQUALITY® program will broaden its vision to the wider concept of "quality in brand management" and emphasize its support services component with the inclusion of highly customized strategic coaching and consulting.

To support companies in their brand-building efforts, TURQUALITY® helps them to develop essential capabilities, competences, skills and resources necessary to fulfil such a complex commitment through both group and individual activities.

Bıçakcılar brand has been accredited under TURQUALITY® in 2016.

R&D Activities

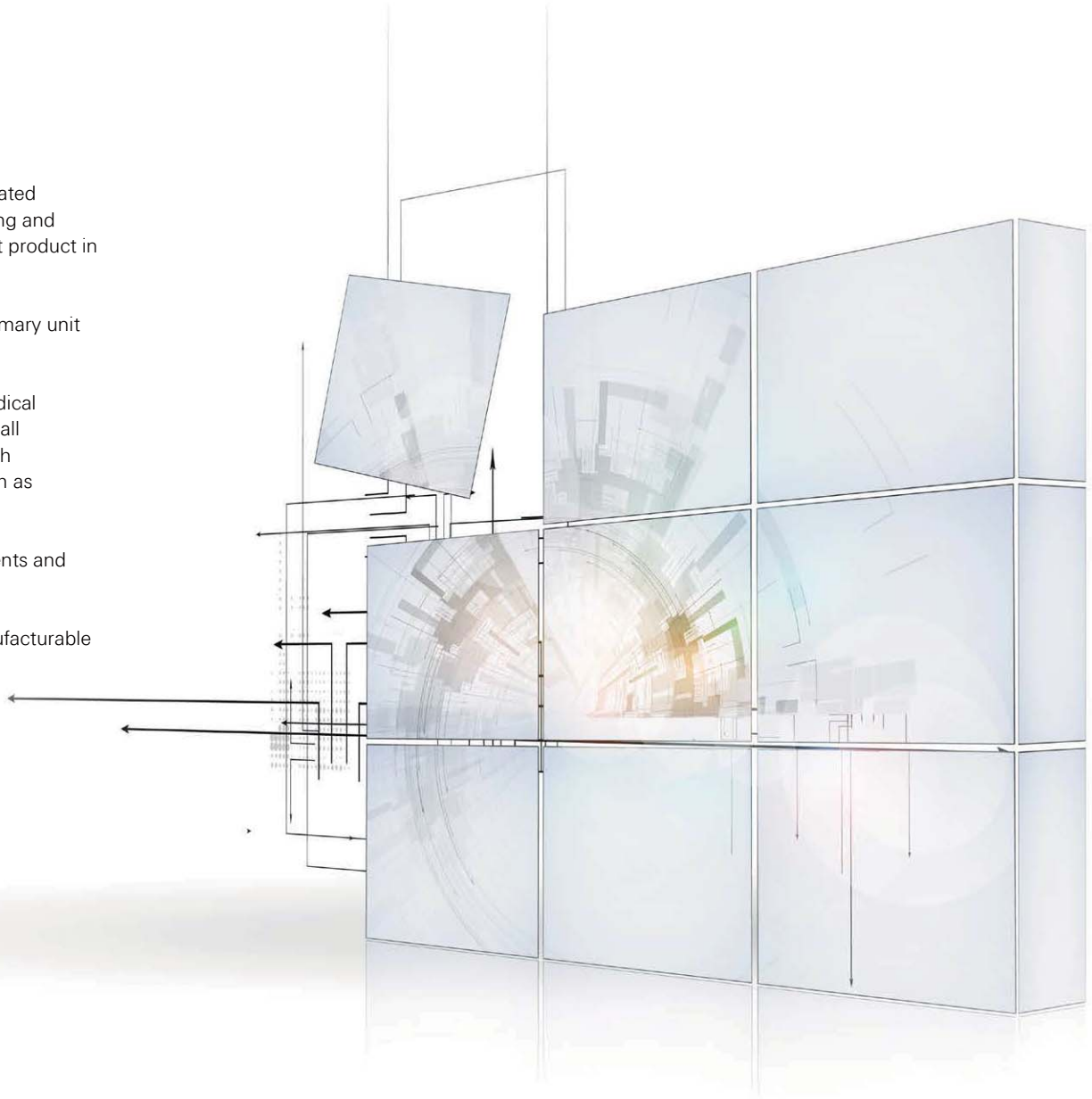
"Research, Development and Creative Thinking" are the milestones of the anticipated growth in the future. We have a solid R&D infrastructure that follows the improving and changing world and industry, and develops new product designs to offer the best product in optimum quality and at the best price.

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 Bıçakcılar.

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

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, and ETO residual testing. Equipped with state-of-the-art technology and highly trained personnel.

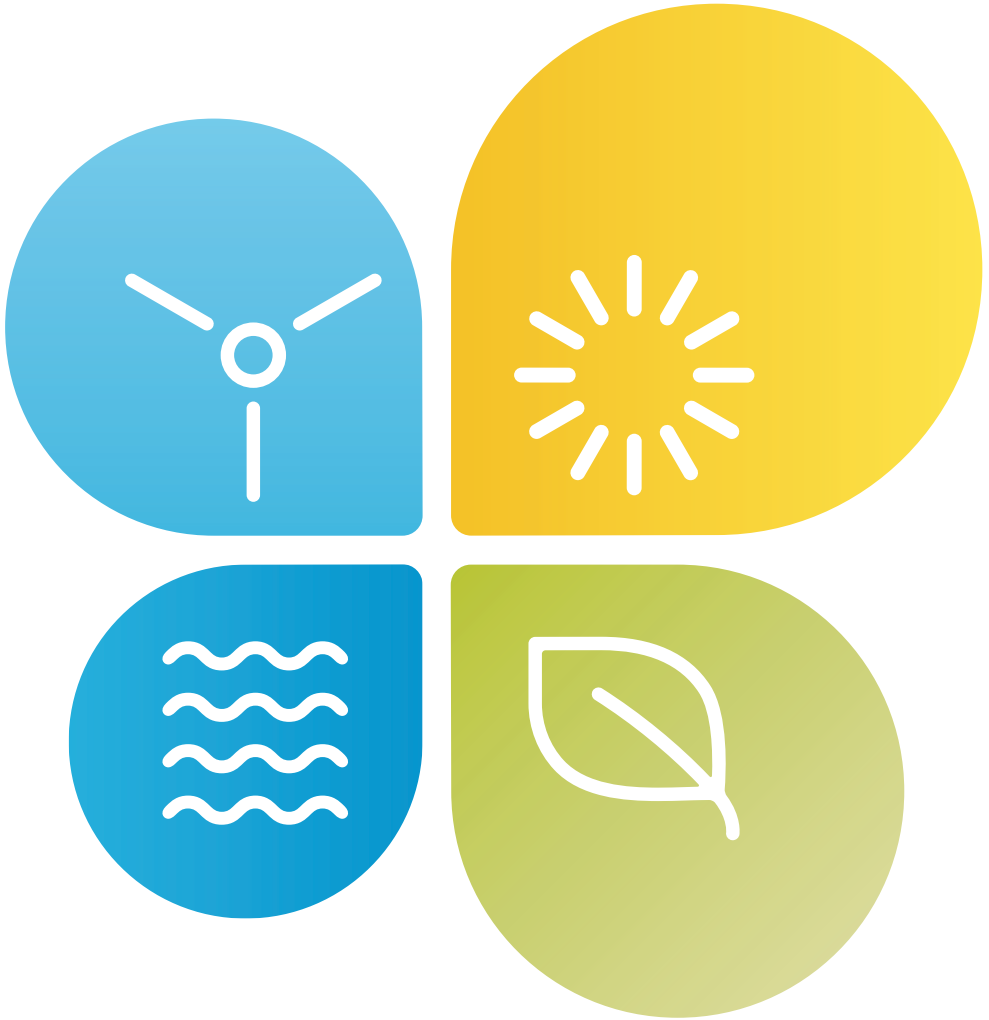
BIÇAKCILAR

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 14001:2009 and OHSAS 18001:2007 Standards. Compliance of Environment Management System with these standards is maintained while its efficiency is constantly enhanced.

ISO 14001
OHSAS 18001



Social Associations

that we cooperate with

ALS MNH DERNEĞİ

TEMA

TOFD

Waste Treatment Facilities

In line with the sustainable development principle, Bıçakcılar constantly keeps environmental effects under control in order to leave a clean and healthy world to the next generations. Bıçakcılar 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, Bıçakcılar stores operational waste in its waste repositories that are specially designed for each waste stream, and disposes collected waste in conformity with regulations.

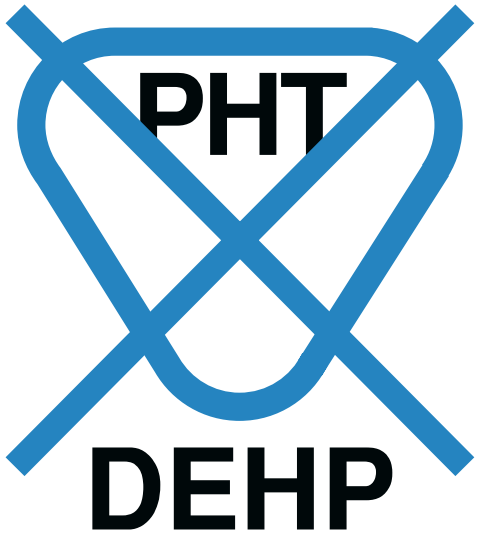
While maintaining its leader position in the Turkish medical device industry, it is also the primary target of Bıçakcılar to be a leader in the matters of environment and occupational health and safety.

For single use only!

Single use medical devices have to comply with 93/42/EEC Directive if hospitals clean, re-package, and re-sterilize these devices with the intention to re-use on other patients, by definition the hospital becomes a medical device manufacturer. Re-processed single use medical devices have to be labeled in conformity with relevant standards and also instructions for use have to be provided. Hospitals neither are medical device manufacturers nor do they carry the responsibilities of manufacturers. Therefore, hospital administration will be held responsible for any disease, injury and/or death of a patient, user, and/or third party resulting directly and/or which may result from re-use of single use medical devices. Furthermore, no hospital has the infrastructure and technologies to process medical devices in a cost-effective manner.

Medical devices labeled as “for single use only”, are not designed to be dismantled for proper cleaning and therefore, it becomes impossible to re-sterilize them; any process to prepare them for re-use may compromise their integrity and/or functionality. The processes used in preparing single use devices for re-use have not been investigated for their effects on patients, users, and/or third parties. For these and many other reasons, do not re-use medical devices that have been labeled “for single use only” and do not re-process them for re-use. Single use medical devices are designed and manufactured for one use only.

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 irritaation and sensitization. It is not absorbed from the GI tract upon oral exposure where it is rapidly excreted. This constrast 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 Commision, 2002

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

As a result of all these, customer demands for the DEHP-free medical devises 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-feding female patients.

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

BIÇAKCILAR

OPERATING ROOM (OR) AND INTENSIVE CARE UNIT (ICU)

Index

INFUSION

BLOOD TRANSFUSION

CARDIOVASCULAR SURGERY

BIÇAKCILAR

B-Leuko
Leukocyte Depletion Filter

B-Leuko leukocyte depletion filter is intended for the leukocyte reduction of red blood cell concentrates and whole blood

Bedside filtration for one or two units of red cells

Bedside and laboratory type options

Bedside filter with air vent options

Clinically proven filter media technology (Non-woven polyester, excellent wettability feature, high biocompatibility)

No requirement for saline solution priming

Transparent polycarbonate housing

High efficiency leukocyte removal (Filtration performance < $2x10^5$)

High red blood cell recovery rate (Erythrocyte recovery rate is greater than 90%)

Low priming volume

Filtration time; approximately 15 minutes for one unit red blood cell concentrate

Latex-free

Air Vented System

Air vent allows recovery of the remaining erythrocytes to be given to the patient.

Filtering material

Non-woven polyester

Excellent wettability feature

High biocompatibility

Filter Design

Bedside is designed to provide

quick priming with upside down position.

Filter Housing

Durable polycarbonate body with superb flow dynamics

Transparent housing facilitates ease of use

Transparent housing for easy monitorization of priming and blood flow

Ref		
EtO Sterile	Gama Sterile	B-Leuko
157 0010 1	157 0010 1G	Bedside, Without Air Vent, With Double Spikes
157 0011 1	157 0011 1G	Bedside, With Air Vent and Double Spikes
157 0012 1	157 0012 1G	Bedside, Without Air Vent, With Single Spike
157 0013 1	157 0013 1G	Bedside, With Air Vent and Single Spike
157 0014 1	157 0014 1G	Bedside, With Air Vent, Single Spike and Prefilter
157 0040 1	157 0040 1G	Laboratory Type
157 0041 1	157 0041 1G	Laboratory Type, With Prefilter

Performance Summary*

Erythrocyte Concentration, Gravitational Force**

Additive Solution	RBC Age (days)	Prefiltration (10^9/unit)	Post-filtration (10^5/unit)	Prefiltration Volume (ml)	Post-filtration Volume (ml)	HTC %
SAG-M	10	2,57	0,29	369	338	62,9
	20	1,38	0,28	374	332	66,5

Filtration loss**: 35 ml · RBC recovery**: > 90% · Filtration time**: 20 min

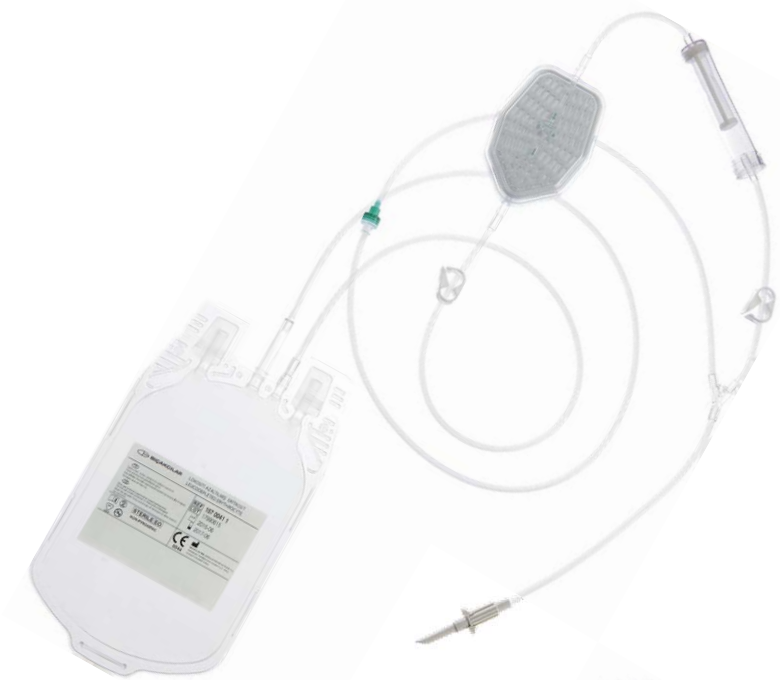
*** Average of unit 1 + unit 2*

1 Unit Whole Blood, Gravitational Force

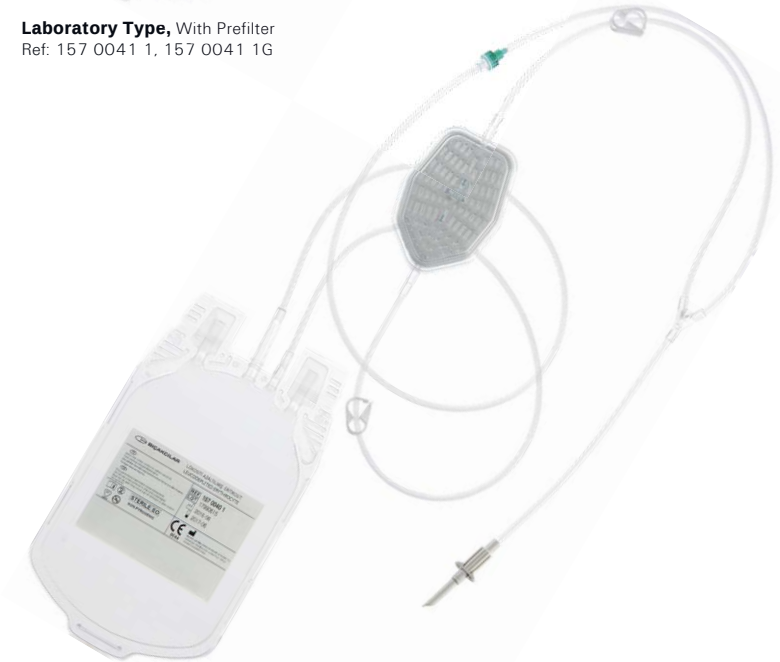
Whole Blood Storage (hours)	Prefiltration (10^9/unit)	Post-filtration (10^5/unit)	Prefiltration Volume (ml)	Post-filtration Volume (ml)	HTC %
2 - 4	4,04	0,54	600	575	42

Filtration loss: 25 ml · RBC recovery: > 90% · Filtration time: 6 min

** Post-filtration WBC count was determined by flow cytometry. The blood was stored at 4°C and the filtration was performed at room temperature.*



Laboratory Type, With Prefilter
Ref: 157 0041 1, 157 0041 1G



Laboratory Type
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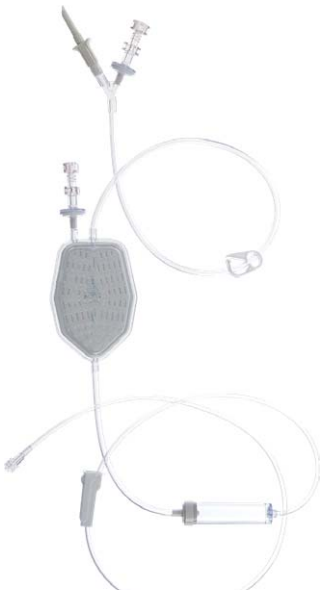
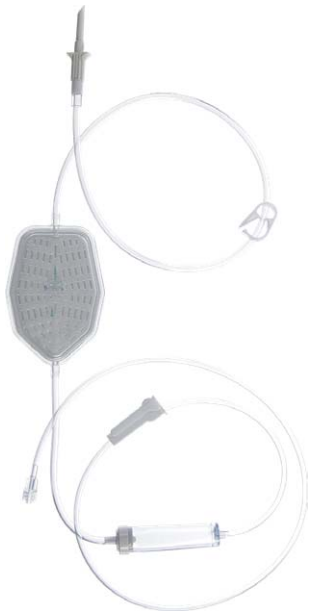


Bedside, With Air Vent and Single Spike
Ref: 157 0013 1, 157 0013 1G



Bedside, Without Air Vent, With Single Spike
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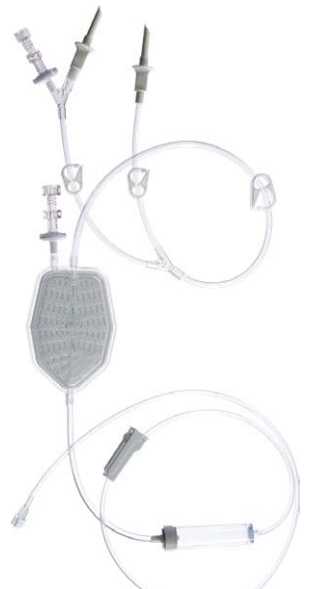
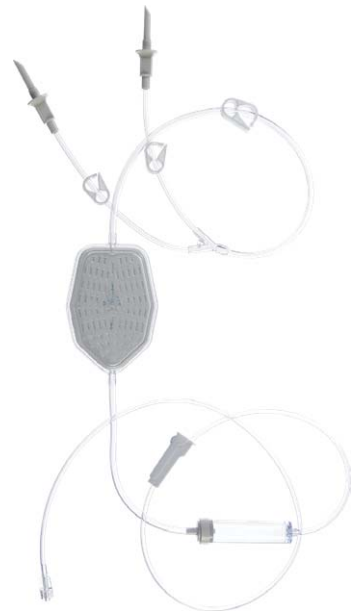


Bedside, With Air Vent and Double Spikes
Ref: 157 0011 1, 157 0011 1G



Bedside, Without Air Vent, With Double Spikes
Ref: 157 0010 1, 157 0010 1G

Bedside, With Air Vent , Single Spike and Prefilter
Ref: 157 0014 1, 157 0014 1G

BIÇAKCILAR

Touching Lives One Device at a Time

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Akar Cad. No:3, Kat:15, Şişli
34381 İstanbul, Turkey
T: +90 (212) 210 85 85
F: +90 (212) 210 85 80
E: export@bicakcilar.com

Factory:
Osmangazi Mah. Gazi Cad.
No:21, Esenyurt
34522 İstanbul, Turkey
T: +90 (212) 689 02 20
F: +90 (212) 689 02 29
E: factory@bicakcilar.com

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LinkedIn
/bıçakcılar-tıbbi-cihazlar

BTK-BIC-021-10

www.bicakcilar.com