

Extrusion
Molding
Assembly



RAUMEDIC®
— Lifeline to Health —

RAUMEDIC ECC

Program for
Extracorporeal Circulation



RAUMEDIC – your development partner and system supplier

RAUMEDIC AG is a worldwide development partner and manufacturer for the medical engineering and pharmaceutical industry. We produce tubing, precision molded parts, and catheters as well as modules and systems. RAUMEDIC processes polymers – thermoplastics and silicone – into high quality medical products.

RAUMEDIC is diversity

RAUMEDIC programs are at home everywhere in medical engineering: in dialysis, gas supply, the catheter and drainage sector, infusion and transfusion, diagnostics, urology, the pharmaceutical industry as well as extracorporeal circulation.



RAUMEDIC is safety

- We take on responsibility with our own formulations: from compound to end product.
- Diverse manufacturing technologies and material alternatives form the basis for RAUMEDIC's variety of products such as RAUMEDIC polyvinyl chloride, silicone, polyurethane, polycarbonate and much more.
- Our printing technologies, coextrusion- or assembly capabilities provide evidence of our flexibility.
- Our research and development department is well prepared for the future.

RAUMEDIC is reliability

RAUMEDIC ECC products have stood the test of time for more than 40 years in many countries.



RAUMEDIC products for extracorporeal circulation

RAUMEDIC offer semi-finished products and system solutions from polymer materials for almost every medical and pharmaceutical use.

For ECC we supply a complete program of semi-finished products – as a one-stop shop

- Blood line PVC noDOP
- Silicone pump tubing
- Polycarbonate connectors
- Silicone U-connectors burr-free on the inner surface available in 3/8 x 3/8 and 1/2 x 3/8
- Accessories such as silicone tubing for hypothermia circulation, multilumen tubing, tubing coils, and funnels
- We are also pleased to offer special developments according to customer specifications



RAUMEDIC means safety: biological qualifications and tests

Safety assurance as a result of GMP-compliant production and careful documentation of all processing parameters

RAUMEDIC manufacturing complies with the requirements for the production and quality assurance of medical products according to the principles of the World Health Organization (= GMP regulations). This means: documented receiving inspections guarantee the quality of the raw materials to be processed. Every single raw material used for the production of ECC tubing is checked by the batch. Special supplier conditions that enable such an elaborate control system are contractually agreed upon with the raw material suppliers.

The material, strictly separated by individual batches of raw materials, is processed into silage batches. Due to this kind of documentation, it will be possible to reconstruct every single process even 7 years later on. On request, we will include with the delivery a certificate for every test carried out and that complies with applicable pharmacopoeia, international standards and FDA requirements.

Safety assurance due to certified manufacturing sites

Production, quality control and documentation of RAUMEDIC products comply with international quality standards (DIN EN ISO 13485).

Safety assurance due to biological toxicology testing

A prerequisite for polymer material formulations to be eligible in the ECC sector is their compliance with biological toxicological requirements.

The following internationally recognized tests are carried out by RAUMEDIC and other institutions:

- Cytotoxicity test in compliance with DIN EN ISO 10993-5
- Implantation test, system toxicity test and intradermal test in compliance with USP class VI
- Pyrogen test in compliance with DAB E. Ph.
- Hemolysis test according to DIN EN ISO 10993-4
- Chemical biological toxicology tests in compliance with DIN EN ISO 3826
- LAL test in compliance with USP and E. Ph.

Manufacturing conditions in the clean room in compliance with ISO 13485

Strictest tests and innovative testing methods guarantee continuous quality. Therefore our products have been awarded with the prestigious "IGT-tested" rating.



RAUMEDIC means safety

IGT is not only a symbol for implant and histopathologically tested plastics. Moreover, IGT stands for a large number of complex chemical, physical and biological rules and regulations.

RAUMEDIC ECC sets new standards in medical engineering.

Safety assurance due to the production under certified clean room conditions

Prior to extrusion, individual raw materials are retrieved batch-wise by automatic machines within a processing system that is hermetically sealed from the environment. After processing the material is carried to the production lines via feed pipes. The following operations for the manufacturing of "ECC semi-finished products" are carried out in a clean room that complies with ISO 14644-1 class 7 requirements. During this manufacturing process ultra-pure filtered support air and microbiologically monitored coolant guarantee the required level of purity, especially that of the inner lumen of the tubing. Further processing of finished products takes place under special clean conditions. They all meet the high standards of ISO 14644-1 class 6 to ensure low-germ and contamination-free quality.

Safety assurance due to applied research and development

After many years of research and in close collaboration with renowned scientists, formulations could be developed that are tailored specifically to the requirements of ECC technology.

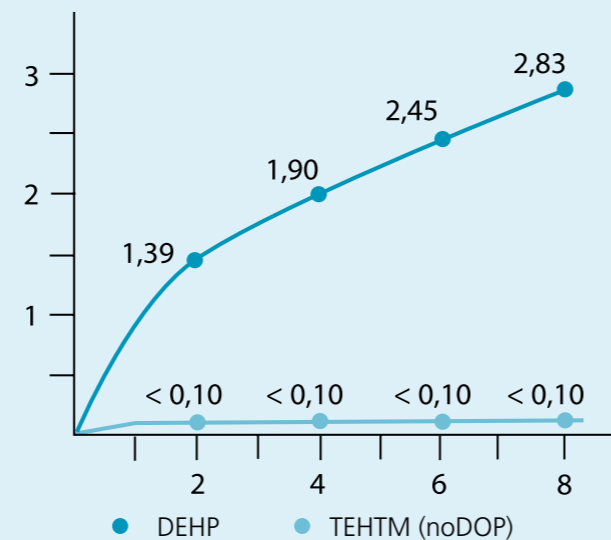
RAUMEDIC ECC tubing guarantees an optimal interaction between temperature, medium and material.

The result: best fit of RAUMEDIC ECC tubing to connectors and distinctive buckling strength.

Safety assurance due to fully developed manufacturing engineering

RAUMEDIC manufacturing guarantees tightest tolerances; their compliance is monitored by state-of-the-art measurement- and control systems. The measurement- and control systems transmit the data to the integrated computer which evaluates them, operates the production line and generates measurement diagrams.

Improved blood compatibility with ECC noDOP



Plasticizer content in blood subject to the blood-tube-contact time in µg/ml

1. Notable characteristics

RAUMEDIC's ECC noDOP line of soft-PVC is manufactured using selected basis PVC types, plasticizers, stabilizers, and process agents. This is the further development of existing soft-PVC qualities for the medical use and does not contain DEHP (Di-2-ethylhexylphthalate) nor DOA (dioctyladipate).

The formulation line is characterized by a special resistance to plasticizer migration.

In order to achieve comparable values, DEHP and noDOP plasticizers are tested with HeLA cells. The result: The toxicity of noDOP plasticizer systems is approximately 1/100 of the toxicity of DEHP:

noDOP: IC50 = 26.00 mg/ml

DEHP: IC50 = 0.27 mg/ml

2. Blood compatibility

For blood-conveying systems there is no doubt that blood compatibility is the essential value for the suitability of a material. With RAUMEDIC ECC noDOP a material has been developed that has a blood compatibility that can only be achieved with polyurethane. The selection of the alternative plasticizer TEHTM is not only a decisive improvement with regards to the migration of plasticizers, but also clearly reduces the damage to the platelets in comparison to traditional plasticized PVC tubing.

3. Chemical resistance

Compared to conventional soft-PVC materials, RAUMEDIC ECC noDOP demonstrates better chemical resistance. The material is not affected by saline solutions, diluted acids and alkaline solutions. Diluted forms of aliphatic hydrocarbons, alcohols and aldehyde do not cause any interferences. The material is resistant to oils and lipid emulsions. The material is dissolved by halogenated hydrocarbons and ketones.

4. Physiological characteristics

Materials from the line of RAUMEDIC ECC noDOP are physiologically harmless. The quality of the applied source products is ensured by comprehensive receiving inspections.

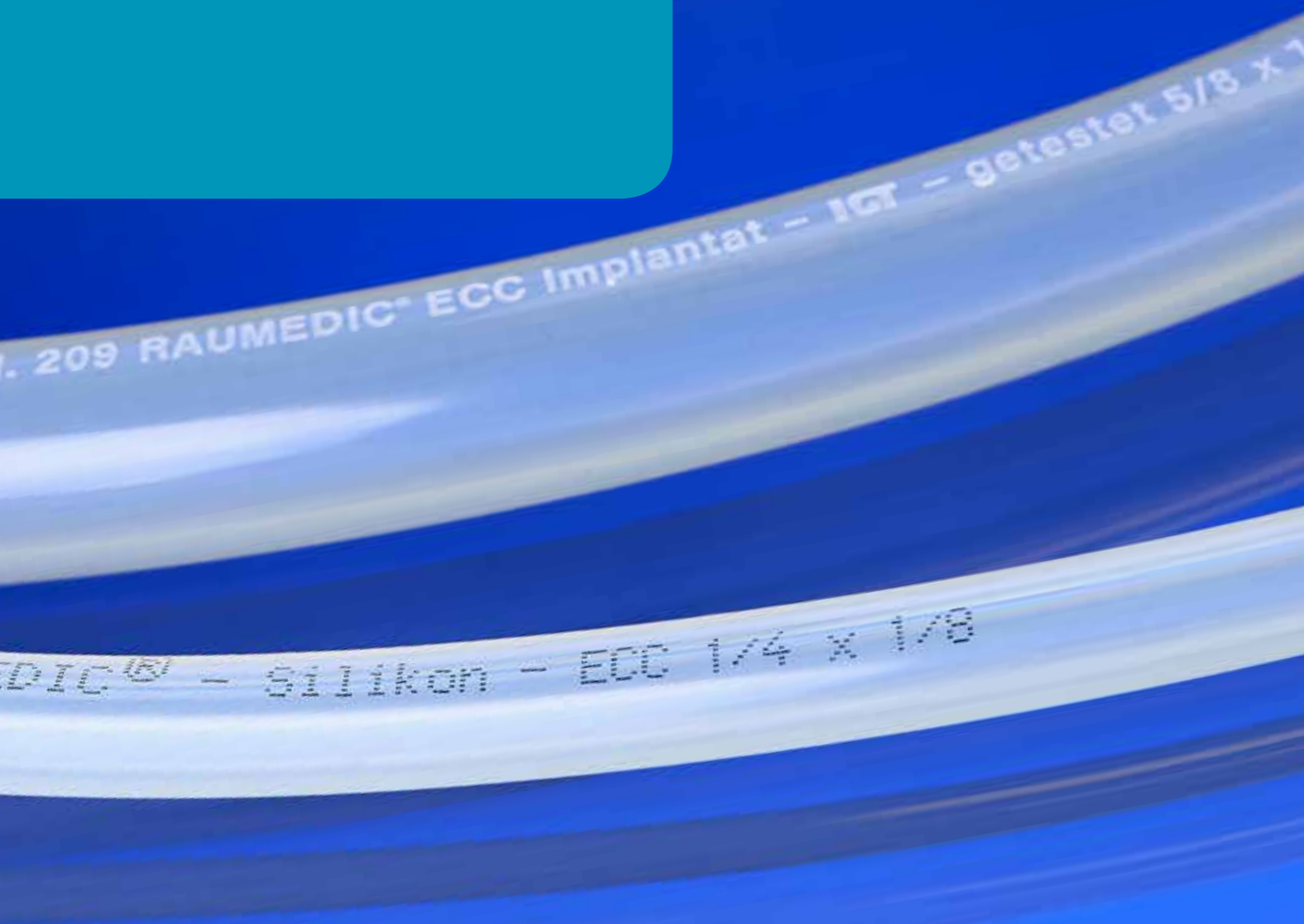
In diverse studies RAUMEDIC ECC noDOP has clearly demonstrated a better blood compatibility on hemocompatibility (e.g. in compliance with DIN EN ISO 10993) than comparable ordinary DOP-containing PVC formulations. Moreover, it fulfills the requirements of the USP class VI (e.g. intradermal tests, implantation tests and acute systematic toxicity tests).

The absence of pyrogens has been tested and approved in compliance with DAB and USP.

5. Suited for sterilization by means of gamma rays

RAUMEDIC noDOP formulations enable even the gamma sterilization up to 25 kGy as an alternative to the EO gas sterilization.

ECC silicone pump tubing (SIK)



1. Mechanical physical characteristics

Amongst the notable physical characteristics of RAUMEDIC ECC silicone – (SIK) – are the outstanding values of its resistance to heat and cold, which – due to its special chemical construction of molecules – have a far better ranking than other elastomer plastics.

Extremely resistant Si-O bonds guarantee good strength and elongation values, outstanding recovery properties and only slight, permanent deformation. Therefore, silicone is recommended especially for

the application as pump segments. Due to unfavorable mechanical characteristics of soft-PVC tubing in pumps, we strongly advise the use of RAUMEDIC ECC SIK tubing.

Special qualities of SIK tubing also provide excellent tear and abrasion values. A special emphasis should be given to the high resistance against high-energy radiation.

2. Physiological characteristics

RAUMEDIC ECC SIK is an odorless, tasteless and homogeneous material with very stable molecular bonds. Only such formulations are used for manufacturing that comply with all relevant regulations of the German food law, the FDA regulation paragraph 177.2600 and the European Pharmacopoeia. RAUMEDIC ECC SIK is free of lower molecular plasticizers and anti-oxidants or volatile and extractable components. It is also physiologically harmless and has completely neutral reactions in biological media.

3. Chemical resistance

Like any other silicone, RAUMEDIC ECC SIK is hydrophobic and resistant to chemicals. Under oxidative influences, RAUMEDIC ECC SIK is extremely resistant.

4. Blood compatibility

After having contact with blood, the inner surface of silicone tubing becomes covered with blood components within a very short time. This results in quasi-physiological conditions. This effect can be taken advantage of during the priming operation, when blood proteins (e.g. albumin) are already added to the priming solution. These accumulate on the inner surface of the tube and create optimal conditions for the actual blood contact. These insights are verified by various testing methods.



5. Biocompatibility

With its homogeneous and inert material characteristics RAUMEDIC ECC SIK is highly biocompatible, i.e. it does not contain any components that can lead to interactions in biological media.

Even during long-term contacts (e.g. during some medical pharmaceutical research or with implants), influences on microorganisms and tissues can be excluded.

RAUMEDIC SIK 8363 is cytotoxicologically harmless and is even recommended as reference material for biological toxicological tests in the DIN EN ISO 10993-12.

Thought out to the detail – safe functioning RAUMEDIC ECC connectors

The Luer locks are molded-in but not adhered on all RAUMEDIC ECC connectors. So, the passages become smooth and the mechanical characteristics of the connectors are improved.

The mold seams are located behind the first tube gland ring. This is another detail that optimizes safety during use. Material types and sizes are designed in such a way that damages will not occur even under hard mechanical stress.

RAUMEDIC ECC polycarbonate connectors are of course USP class VI tested.



Y connector without Luer lock

Item number	Dimension (inch)
955113	1/4 x 1/4 x 1/4
955123	1/2 x 1/2 x 1/2
955133	3/8 x 3/8 x 3/8
955143	1/2 x 3/8 x 3/8
961360	3/8 x 3/8 x 1/4

Tube connector with Luer lock

Item number	Dimension (inch)
955183	3/16 x 3/16
955173	1/4 x 1/4
955163	3/8 x 3/8
955153	1/2 x 1/2

Reduction connector with Luer lock

Item number	Dimension (inch)
961370	1/2 x 3/8
961380	3/8 x 1/4
956834	1/4 x 3/16

Tube connector without Luer lock

Item number	Dimension (inch)
955423	3/16 x 3/16
955413	1/4 x 1/4
955403	3/8 x 3/8
955393	1/2 x 1/2

Reduction connector without Luer lock

Item number	Dimension (inch)
955073	3/16 x 1/4
955083	1/4 x 3/8
955093	3/8 x 1/2
955103	1/2 x 5/8

Y connector with Luer lock

Item number	Dimension (inch)
955303	1/2 x 1/2 x 1/2
955313	1/2 x 3/8 x 3/8
955323	3/8 x 3/8 x 3/8
961350	1/4 x 1/4 x 1/4

Most RAUMEDIC ECC connectors are available from stock
(subject to change)

Thought out to the detail – safe functioning ECC tubing range of dimensions

Product range

Dimensions		Dimensions		Blood line RAUMEDIC ECC-noDOP®	Blood line RAUMEDIC ECC MED	pump tubing RAUMEDIC ECC SIK	Blood line with color strips RAUMEDIC ECC-noDOP®
ID	WT	ID	WT				
mm	mm	inch	inch				
2.00	1.00			039565	038004		
3.00	1.00					819380	
3.20	0.80	1/8	1/32	039595	039662	819180	
3.20	1.60	1/8	1/16	039555	039672	819190*	
4.00	0.80			038103	039305		
4.00	1.00			038522	038553		
4.75	1.00			039135			
4.75	1.60	3/16	1/16	038177*	039682	819200*	
4.75	2.40	3/16	3/32			819882	
5.00	1.50					819340	
6.00	2.00					819330	
6.35	1.60	1/4	1/16	039505*	039692	819210*	039019
6.35	2.40	1/4	3/32	039515	039702	819050*	
6.35	3.20	1/4	1/8			818501*	
7.95	1.60	5/16	1/16	038617	039712	819220	
7.95	2.40	5/16	3/32		038645	819890	
8.00	2.00					819320	
9.50	1.60	3/8	1/16	039525	039722	819160*	
9.50	2.40	3/8	3/32	039535*	039732	819060*	039029
9.50	3.20	3/8	1/8			819070*	
10.00	2.50					819310	
12.50	2.80					818481	
12.70	1.60	1/2	1/16	038537	039752	819170	
12.70	2.40	1/2	3/32	039545*	039762	819080*	039039
12.70	3.20	1/2	1/8		038167	819090*	
15.90	2.40	5/8	3/32		039772	819100	
15.90	3.20	5/8	1/8		038285	819110*	

More dimensions available on request.

*Available from stock (subject to change)

Suitable for sterilization process

	RAUMEDIC ECC-noDOP®	RAUMEDIC ECC MED	RAUMEDIC ECC SIK8363	RAUMEDIC Polycarbonate
Steam, 121°C	-	-	+	+
Gas, EO	+	+	+	+
Gamma	+(max 25 kGy)	-	+(max 32 kGy)	-

Progress in heart surgery could only be achieved because specific materials had been developed. RAUMEDIC served as a pioneer in this field from the beginning. RAUMEDIC tubing has been used since the first German heart surgery over 50 years ago. Equipped with special "Laminar Flow equipment", we are in a position to manufacture according to clean room class 6. This way we create the basis necessary for the future use of ECC sets for life support machines.

Please note that the finished and serviceable medical device has to be tested in compliance with ISO 10993-1 for biological evaluation.

Taking into account all of the above warranties, RAUMEDIC reserve the right to make formulation and procedural changes designed to improve a product in the broadest sense.

The information provided does not constitute a specification.



Global service!

What can we do for you?

Thanks to an extensive worldwide sales network our customers and interested parties can be assisted and advised personally and directly on site.



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