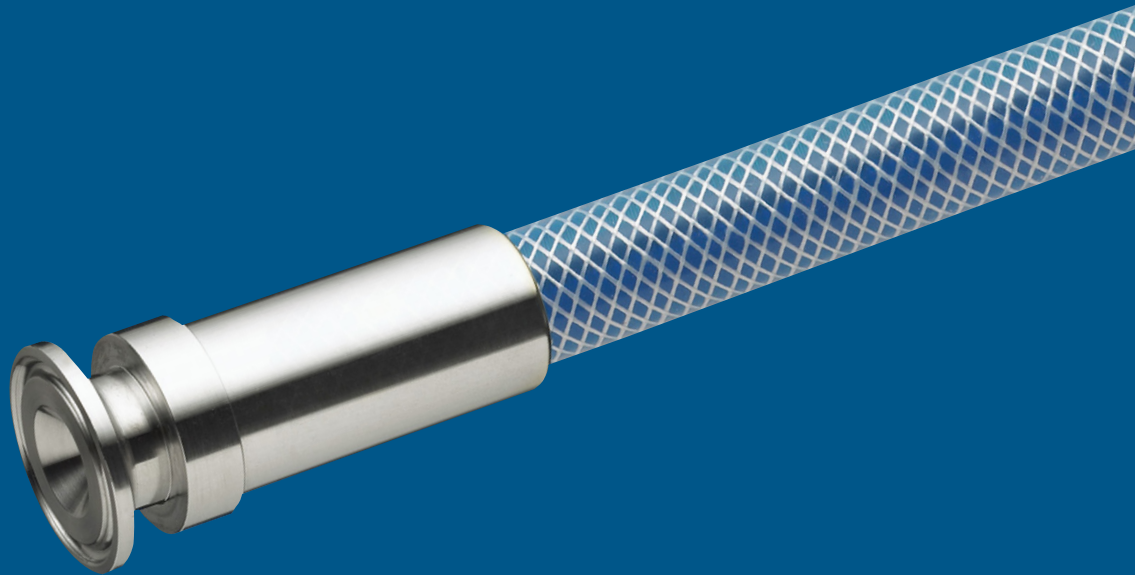


SILICON TUBING

A6093 / AE6093 / AES6093



TECNO PLAST
INDUSTRIE TECHNIK GMBH

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For your assurance:

Please visit <https://www.tecnoplast.de> to be informed
about the technical status of our product range.

Introduction

TECNO PLAST provides three different Silicon qualities in its product portfolio. All three qualities exhibit multiple advantageous properties that considerably exceed those of common natural rubber and plastic-derived material types.

- **TP RED**

peroxide-cured with reinforcement
(see individual brochure)

- **A6092**

platinum-cured, transparent pharma quality
(see individual brochure)

- **A6093/AE6093/AES6093**

platinum-cured, transparent pharma quality

The production of these tubing is performed by extrusion technology. The HTV (HTV = high temperature cross-linked) silicon material is brought into the desired shape with the aid of an extruder and a suitable spray washer.

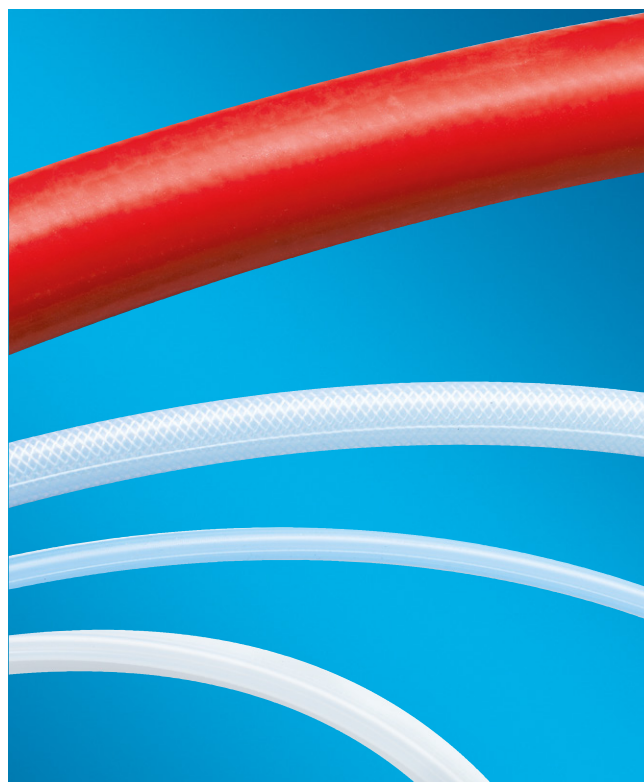
A succeeding post-vulcanization step of at least 4 hours at +200 °C is usually performed in annealing furnaces with a continuous supply of fresh air for the removal of cleavage products. In general, silicon can be cured by two different methods, either using **peroxides** or by an addition reaction = **platinum curing**.

In contrast to peroxide-cured tubing, platinum-cured silicon tubing exhibit a particularly high purity. Peroxide-cured silicon tubing is produced by curing of the silicone starting material with 2,4 dichlorobenzoyl peroxide and succeeding tempering to remove potential catalyst-based cleavage products from the end product. However, despite of appropriate tempering, minimum residual amounts of peroxide-originated cleavage products from the catalyst may remain in the tubing and, thus, may migrate from the tubing.

This problem does not apply to platinum-cured tubing. For this reason, primarily **platinum-cured** tubing has been used in pharmaceutical operations, medicinal techniques as well as in biotechnology.

Advantageous properties that clearly cannot be reached by common natural or other plastic-derived material types:

- Excellent hot air resistance up to +200 °C (special ivory quality up to +300 °C)
- A virtually extremely low variation of properties over a wide temperature range
- Excellent resistance to cold up to -60 °C.
- Highly flexible.
- Excellent resistance to aging and weathering (UV, ozone).
- Good resistance to weak acidic and alkaline solutions.
- Odor and taste neutral.
- Toxicologically harmless.
- Free from plasticizers.



- Physiologically inert.
- Can be sterilized (steam, irradiation).

Specific explanation regarding steam sterilization can be found under <https://tecnoplast.de/de/download/silicon-schlaeuche-und-schlauchleitungen/>

In addition, further supporting information regarding the subject silicon is provided there:

- Silicon storage conditions and usage durations.
- Silicon resistance list

In addition to silicon tubing without fabric lining, the standard product range also contains reinforced silicon tubing. Common reinforcements are polyester monofilament (PET), polyester yarn (PET), glass silk or Aramid.

Properties of pressure tubing reinforcements

Reinforcement	Designation Presentation	Textile	Temperature Resistance
PES-MF	Polyester multifilament (PET)	Yarn	Up to 160°C
PES-Mono	Polyester monofilament (PET)	Monofil	Up to 160°C
Glass silk	E-glass	Yarn	Up to 180°C
Aramid	Aramid fiber	Yarn	Up to 180°C

The A6093 Product Family

The A6093 product family comprises different products, the core tubing consists of a platinum-cured extruded silicon:

- **A6093** platinum-cured silicon tubing **without** reinforcement
- **AE6093** platinum-cured silicon tubing **with** reinforcement (fabric)
- **AES6093** platinum-cured silicon tubing **with** reinforcement (fabric) for RE-LINK SI

These especially – intended for pharmaceutical/biotechnological uses – developed products consist of a specific material (60 Shore base material) and are produced according to a special production process that is established upon detailed quality agreements with the manufacturer.

Standards – Regulations

Comprehensive testing have been performed using representative A6093 end product samples. All transparency silicon tubing of A6093 quality are compliant with the following (coloured translucent silicon tubes are excluded):

- European Pharmacopoeia 3.1.9.:
Silicone Elastomer for Closures and Tubing
- USA, FDA 21 CFR 177.2600 (a)-(c),(e):
Rubber articles intended for repeated use
- European Framework Regulation (EC) 1935/2004 and German Foods, Consumer Goods and Foodstuff Code (LFBG) as well as BfR recommendations, XV Silicone
- Biological Reactivity *in vivo*, USP General Chapter <88>, Class VI + 121 °C (Systemic Intravenous, Intracutaneous Irritation, Systemic Intraperitoneal, Intramuscular)
- Biological Reactivity *in vitro*, ISO 10993-5/USP General Chapter <87>: Determination of Cytotoxicity, MEM Elution
- Bacterial Endotoxins (Limulus-Amebocyte-Lysate-Test), USP General Chapter <85>
- Rabbit Pyrogen Test, USP General Chapter <151>
- Bioburden (Quantitative Detection, DIN EN ISO 11737, Part 1)
- Particles, International Pharmacopoeia (WHO) 5.7
- Extractables
Sample preparation corresponds to or exceed ISO 10993-12 recommendations, utilization of specific analytical methods (HS-GC/MS, GC/MS, LC-MS, ICP/MS)

Additional references:

- Ongoing characterization (qualification/validation)
 - Extractables
 - Identification (IR), European Pharmacopoeia 3.1.9., 2.2.24
 - Acidity/Alkalinity, European Pharmacopoeia 3.1.9.
 - Reducing Substances, European Pharmacopoeia 3.1.9.
 - Thermoanalysis (DSC), European Pharmacopoeia 2.2.34/ USP General Chapter <891>
- Elemental Impurities
EMA/CPMP/SWP/4446 – Guideline on the specification limits for residues of metal catalysts or metal reagents, ICH Q3D – Guideline for Elemental Impurities ICP/MS according to European Pharmacopoeia 5.20 / 2.4.20 / 2.2.58 and USP General Chapters <232> / <233> / <730> / <1730>
- Tests according to USP General Chapter <661.1>
Plastic Materials of Construction
 - Biological Reactivity *in vitro* and *in vivo* (see above)
 - Physicochemical tests
 - Compliance with food contact requirements (see above).

Toxicological Assessment

All detected extractable substances have been reviewed by toxicological experts (DGPT/Eurotox Registered Toxicologists (ERT)). They have been assessed to be of no toxicological concern and to do not present a health risk to the patients.

Regulatory Support File

As a special service, we have summarized all results in a very comprehensive “Regulatory Support File of the A6093 Silicon Tubing Product Family”. It is available upon request.

All silicon tubing from TECNO PLAST is also free from animal-derived materials and meet the requirements of the TSE Guideline EMA/410/01 of the European Union.

In conclusion, we can provide you specific customized solutions for all applications.

Standard packaging of A6093 platinum-cured silicon tubing:

- Tubing coil fixture: A6093 silicon tubing
- Non-perforated PR bags (pharma quality – EP 3.1.3)
- Not imprinted or imprinted with white ink (standard) – ink is free from benzophenone!
Laser-engraving is under development.

**All types correspond to
DIN EN 16821**

A6093 Silicon Tubing

Silicon Tubing without Reinforcement (Fabric)

A6093 is an advancement of silicon quality A6092.

This formulation is **platinum-cured**.

A6093 silicon tubing is provided by default with an excellent abrasion-resistant white ink imprinting according to DIN EN 16821, Type 1 without reinforcement. Customer-requested imprinting can be offered.

Properties

Multiple options regarding internal diameter and wall thickness are provided. A selection of the currently most common dimensions can be reviewed in the table below. Operation pressure and bending radius correspond to DIN EN 16821, Type 1 without reinforcement.

Specifications

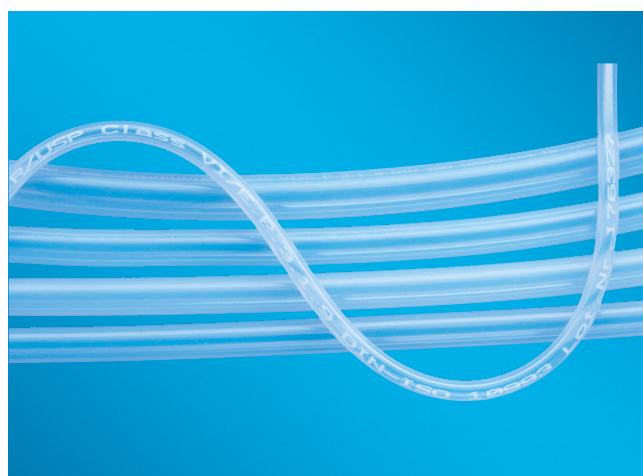
A detailed list of standards and regulations that have been considered are provided on Page 4 of this brochure.

A6093 quality material of Shore A 60 ± 5 is obtained from a special raw material. Other Shore hardness materials can be provided upon request.

All tests have been performed with the **end product**. A summary and discussion of results is described in the Regulatory Support File (RSF) that can be provided upon request.

Temperature Resistance

The transparent tubing without reinforcement of TECNO PLAST quality A6093 can be used in the temperature range of -60 to +180 °C, also up to +200 °C on a short-term basis (depending on the medium).



Selection of the currently most common dimensions

Silicon Quality A6093 without Reinforcement				
Dimensions in mm / inner diameter x wall thickness				
1,6 x 1,6	3,0 x 1,0	3,0 x 1,5	3,0 x 4,0	3,2 x 1,6
3,2 x 2,4	4,0 x 2,0	4,0 x 2,4	4,0 x 3,0	4,8 x 1,6
4,8 x 2,0	4,8 x 2,4	5,0 x 1,5	5,0 x 2,5	5,0 x 3,0
6,0 x 2,0	6,0 x 3,0	6,4 x 1,6	6,4 x 2,4	6,4 x 3,2
7,9 x 2,4	7,9 x 3,2	8,0 x 1,6	8,0 x 2,0	8,0 x 3,0
8,0 x 4,0	8,5 x 3,25	9,5 x 2,4	9,5 x 3,2	9,6 x 3,2
10,0 x 2,5	10,0 x 3,0	10,0 x 4,0	12,0 x 3,2	12,7 x 3,2
15,9 x 3,2	16,0 x 5,0	19,0 x 3,2	20,0 x 5,0	25,4 x 4,8

SILICON TUBING

AE6093 Silicon Tubing

Silicon Tubing with Reinforcements (Fabric)

AE6093 is the designation for an exceptionally highly pure platinum-cured and talcum-free silicon tubing with an inner reinforcement layer (fabric).

AE6093 silicon tubing consist of the core quality A6093 – a special transparent platinum-cured Shore A 60 \pm 5 silicon, a fabric reinforcement layer and a transparent silicon cover layer – also of silicon A6093 quality. Other qualities, shore hardness and colors are available upon request.

Reinforced AE6093 tubing can be autoclaved and sterilized, also by gamma irradiation. Supportive information for steam sterilization can be found at our web page under <https://tecnoplast.de>. In addition, a table providing information regarding chemical resistance is provided there.

Major areas of operations particularly apply to the pharmaceutical industry, medical technology, biotechnology, and cosmetic industry.

A white abrasion-resistant imprinting is standard.

**All types correspond to
DIN EN 16821**

Properties

Multiple options regarding internal diameter and wall thickness are provided. A selection of the currently most common dimensions can be found on page 7. Operating pressure, vacuum resistance and bending radius correspond to DIN EN 16821 Type 2 with a textile reinforcement layer.

Technical data of AE6093 dimension, also including information about stainless steel swage fittings that can be ordered from TECNO PLAST are provided in the adjacent table (Table 1). Divergent dimensions may be provided upon request (Table 2); however, this dimensions are **not** suitable for using TECNO PLAST fitting swage system.

Standards – Regulations

Comprehensive testing have been performed using representative A6093 end product samples. All silicon tubing of A6093 quality are compliant with the following:

- European Pharmacopeia 3.1.9.:
Silicone Elastomer for Closures and Tubing
- USA, FDA 21 CFR 177.2600 (a)-(c),(e):
Rubber articles intended for repeated use
- European Framework Regulation (EC) 1935/2004 and German Foods, Consumer Goods and Foodstuffs Code (LFBG) as well as BfR recommendations, XV Silicone
- Biological Reactivity *in vivo*,
USP General Chapter <88>, Class VI + 121 °C
(Systemic Intravenous, Intracutaneous Irritation, Systemic Intraperitoneal, Intramuscular)
- Biological Reactivity *in vitro*,



ISO 10993-5/USP General Chapter <87>: Determination of Cytotoxicity, MEM Elution

- Bacterial Endotoxins (Limulus-Amebocyte-Lysate-Test), USP General Chapter <85>
- Rabbit Pyrogen Test, USP General Chapter <151>
- Bioburden (Quantitative Detection, DIN EN ISO 11737, Part 1)
- Particles International Pharmacopoeia (WHO), 5.7
- Extractables:
Sample preparation corresponds to or exceed ISO 10993-12 recommendations, utilization of specific analytical methods (HS-GC/MS, GC/MS, LC-MS, ICP/MS)

Additional references can be found on page 4 under Standards – Regulations.

Temperature Resistance

AE6093 silicon tubing with reinforcement can be used in the temperature range of -60 +180 °C. Maximum usage temperatures are also dependent on the reinforcement type.

Properties of Textile Reinforcements (Fabric)

Dependent on the nominal size the following reinforcements (fabrics) can be used by default:

Polyester yarn (up to +160 °C), Polyester monofilaments (up to +160 °C) as well as glass silk yarn (up to +180 °C).

A reinforcement made of Aramid fibers (up to +180 °C) can also be provided. The suitability of the reinforcement is primarily dependent on the temperature and/or movement. Glass silk demonstrates a lower dynamic load capacity than Polyester, whereas the tensile strength of glass silk and Polyester is virtually identical. However, brakeage by movement faster occurs with glass silk than with Polyester, but, on the other hand, is recommended for higher temperature exposure. In total, Aramid fibers demonstrate the best properties; however, a restricted UV resistance at direct sunlight exposure applies.

Solely AE6093 tubing with PES yarn reinforcement can be provided for swaging with TECNO PLAST fitting swage system.

SILICON TUBING

Tubing Connectorization

TECNO PLAST has developed its own fitting program for the utilization with the tubing quality AE6093. Virtually all fittings are provided as a finished end product. If not otherwise desired, TECNO PLAST performs a 100% pressure hold test with tap water by applying the 1.5-fold operation pressure.

Connections are made under consideration of hygienic aspects in order to minimize residues in the fitting areas.

The material consists of stainless steel 1.4404/1.4435, other materials can be provided upon request.

Standard surface finish $R_a < 0.8 \mu\text{m}$, optionally available also as electro-polished finish up to $R_a 0.2 \mu\text{m}$.



1. AE6093 Tubing Quality (for fitted tubing using the TECNO PLAST Swage-Fitting-System, Reinforcement Layer: PES Yarn)

Product	Inner Diameter	External Diameter	Recommended Operation Pressure at 20 °C	Burst Pressure at 20 °C	Minimum Bending Radius
	mm	mm	bar	bar	mm
AE6093-06	6,4	12,8	9	37	25,4
AE6093-10	9,6	16,0	9	37	25,4
AE6093-12	12,7	22,2	7	28	76,2
AE6093-16	15,9	25,2	6.5	27	76,2
AE6093-20	19,0	28,6	6	24	101,6
AE6093-25	25,4	35,7	4	15	152,4

Remark: Starting at a temperature of 20 °C and while increasing the temperature by 35 °C, the burst pressure must be reduced by 10 %. Above-noted values correspond to regularly available tubing coils (bulk stocks). For fitted products please consider potential pressure-reducing properties.

2. AE6093 Quality for Non-fitted Tubing

Explanations for a customer-specific TP-Product-Number

Example: ID 10 x 4.0 mm wall thickness

SI tubing, transparent
PES monofilament fiber
transparent cover layer
Shore A 60 ±5
ID 10.0 x 2.5 mm
Total wall thickness: 4.0 +/- 0.3 mm
Talcum-free, platinum-cured

Material correspond to:
BfR/FDA/USP Class VI
EP 3.1.9/DIN EN ISO 10993-5
50 m packed in PE bag

Our Product Number: 10100400903

Configuration see below 1 01 100400 9 03

1 = Polyester Monofilament (PES Mono)
2 = Glass silk
3 = Polyester yarn
01 = transparent coating
100400 = Dimension 10 x 4 mm
9 = platinum-cured
0 = without imprinting 7 = with imprinting
3 = A6093 corresponds to: Shore A 60 ±5 – platinum-cured – conforms to BfR/FDA/USP Class VI/EP 3.1.9/ DIN EN ISO 10993-5

Limitations: Smallest inner diameter: 0.5 mm, minimum wall thickness 1.5 mm

Largest inner diameter*: 55 mm

* The ratio of wall thickness to inner diameter must suitable!

SILICON TUBING

The Re-usable Mounting System

RE-LINK SI/TO und SI: The Program

In addition to the possibility of connecting AE6093 tubing with press fittings, also re-usable fittings for self-installation by the customer are available.

The re-usable **RE-LINK SI/TO** fitting program has been developed for the connection with silicon tubing without reinforcement. Information regarding suitable tubing coils can be found on page 4

However, the re-usable **RE-LINK SI** program is intended to be used with silicon tubing with a special reinforcement (AES6093, page 12).

The jackets for these programs are composed of stainless steel 1.4301 (standard). These can be found on the opposite page. Other materials, for example 1.4435 BN2 are available upon request.

All suitable tools, jackets and fittings intended to be used with the appropriate mounting apparatus are identified by a symbol.



= RE-LINK SI/TO



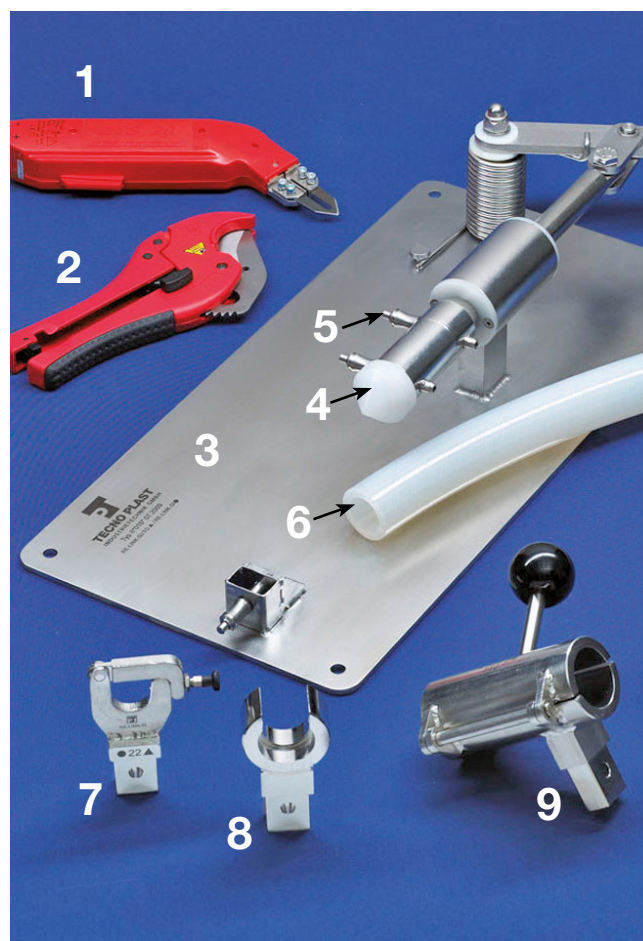
= RE-LINK SI

Assembly and disassembly of both programs is performed on a manual stainless steel assembly/disassembly board.

All assembly and disassembly tools are secured by a locking pin to prevent unintentional removal from the board. The closures of assembly and disassembly tools are also equipped with securing systems.

All spare parts are laser-engraved with the above shown symbols, thus, interchanging is not possible. In addition, these parts and the fittings are identified by homologous digits (description of the spanner flat).

Mounting instructions and a motion picture for both programs can be requested from TECNO PLAST or downloaded (<https://tecnoplast.de>).



Assembly and Disassembly Tools

- 1) Electrical thermos cutter
- 2) Tubing cutting gripper
- 3) Large manual assembly and disassembly apparatus RE-LINK IS and SI/TO
- 4) Universal conus made from PVDF for assembly
- 5) Extension for assemblies of dimensions > DN 20
- 6) Silicon tubing RE-LINK SI
- 7) Disassembly tool for RE-LINK SI and SI/TO
- 8) Assembly tool for RE-LINK SI and SI/TO (dimensions < DN 20) and RE-LINK SI/TO
- 9) Assembly tool for RE-LINK SI (dimensions > DN 20)

SILICON TUBING



RE-LINK SI/TO ▲	
Inner diameter x wall thickness	Jacket Product Number
mm	
6,0 x 2,0	HWV SI/TO 6,0 x 2,0 V1
8,0 x 3,0	HWV SI/TO 8,0 x 3,0 V1
9,6 x 3,2	HWV SI/TO 9,6 x 3,2 V1
10,0 x 4,0	HWV SI/TO 10,0 x 4,0 V1
12,0 x 4,0	HWV SI/TO 12,0 x 4,0 V1
16,0 x 3,0	HWV SI/TO 16,0 x 3,0 V1
18,0 x 3,2	HWV SI/TO 18,0 x 3,2 V1
25,0 x 4,8	HWV SI/TO 25,0 x 4,8 V1



RE-LINK SI ●	
Tubing Nominal Size DIN/ISO	Jacket Product Number
6,0	HWV SI 06 V1
8,0	HWV SI 08 V1
10/8,0	HWV SI 10 V1
12/10	HWV SI 12 V1
16,0	HWV SI 16 V1
20/15	HWV SI 20 V1
25/20	HWV SI 25 V1
32/25	HWV SI 32 V1



SILICON TUBING

RE-LINK SI/TO, A6093 Silicon Tubing

Re-usable Fitting System for Silicon Tubing without Reinforcement (Fabric) Type A6093

TECNO PLAST has developed a new fitting system to significantly enhance the mounting of silicon tubing. It allows a simple, fast and secure usage for assembly and disassembly. An appropriate mounting aid will effectively assist you in assembly and disassembly operations. RE-LINK SI/TO is pending patent application.

This system has been especially developed for the utilization in pharmaceutical and biotechnological operations. The connection is pressure-resistant up to 2 bars, whereas, in accordance with DIN EN 16821 Type 1, a lower operating pressure for silicon tubing bulk stock without reinforcement applies.

Fitted tubing can be autoclaved and may be cleaned easily. Special emphasis has been taken on the construction to consider the “dead spot” concern to the entire system – in particular regarding the hose nozzle area (transition from filling to tubing interior).

In addition to Tri-Clamp connections according to DIN 32676, also all other common sterile connections can be provided upon request, for example, Aseptic Screwed Union or screwed pipe connections according to DIN 11864.

The standard fitting material is 1.4435; however, also other materials such as PVDF, titan or Hastelloy alloying are possible. The product-contacting surface is $RY < 0.8 \mu m$, other electro-polished finishes can be provided upon request. Fittings are identified (batch tracing) and, in accordance with DIN EN 10204 – 3.1, may be confirmed by material quality certificates that also reflects the surface roughness.

In order to eliminate false use of product tubing, different colored marks can be used, e.g., on tubing exterior, on jackets or fittings.



The following dimensions are available for this system

Inner diameter x wall thickness		This system may be adapted to different dimensions; however, certain ordered quantities have to be considered.
mm		
3,0 x 1,0	9,6 x 3,2	
4,0 x 2,0	10,0 x 2,5	
4,8 x 1,6	10,0 x 4,0	
6,0 x 2,0	12,0 x 3,2	
6,0 x 3,0	12,7 x 3,2	
8,0 x 1,6	16,0 x 3,0	
8,0 x 3,0	19,0 x 3,2	
8,0 x 4,0	25,0 x 4,8	

The RE-LINK SI/TP program has been exclusively developed for assembly / disassembly of silicon tubing of the types A6092 and A6093 and may not be used in combination with other tubing.

The fitting system has been adapted to the special properties of these tubing.

Function and safety features cannot be ensured if a combination with other tubing would apply; liability will be precluded.

Assembly Instructions

All tools for assembly and disassembly are identified by a triangle, thus, providing an explicit allocation to the RE-LINK SI/TO system.

The RE-LINK SI/TO program has been exclusively developed for assembly/disassembly with silicon tubing of the product types A6092 and A6093 and may not be used in combination with other tubing. The fitting system has been adapted to the specific properties of these tubing. Function and safety features cannot be ensured if a combination with other tubing would apply; liability will be precluded.



Push the jacket with juvenescent ending onto the tubing first.



Please note that the tubing must be cut precisely.



Now push the fitting straight into the tubing towards the serrated end.



Then, push the jacket as far as possible onto the fitting and then insert the pre-conditioned tubing into the mounting system.



Pull the tubing ending while simultaneously pushing the universal conus into the tubing by means of lever action.



The jacket must concisely fit to the fitting.

Disassembly Instructions

Insert the appropriate disassembly tool and secure it for disassembly.



Place the tubing end with fitting into the disassembly tool - then lock it.



Pull the tubing while simultaneously twisting the jacket off.



Tear off the tubing from the fitting.



Jacket and fitting now can be re-used.



A supportive video for assembly/disassembly can be found under <https://tecnoplast.de/de/download/silicon-schlaeuche-und-schlauchleitungen/>

SILICON TUBING

RE-LINK SI, AES6093 Silicon Tubing

Re-usable Fitting System for Silicon Tubing with Reinforcement (Fabric) AES6093

The mounting system RE-LINK SI allows the self-dependent assembly and disassembly of silicon tubing bulk stock AES6093. RE-LINK is pending patent application.

The core tubing and cover layer consist of Shore A 60 \pm 5 platinum-cured silicon. Standards and regulations regarding this quality correspond to A6093 (for details please refer to page 5). The silicon tubing bulk stock is equipped with a further developed reinforcement (PES-Mono-Fabric) to provide for the intended specific use.

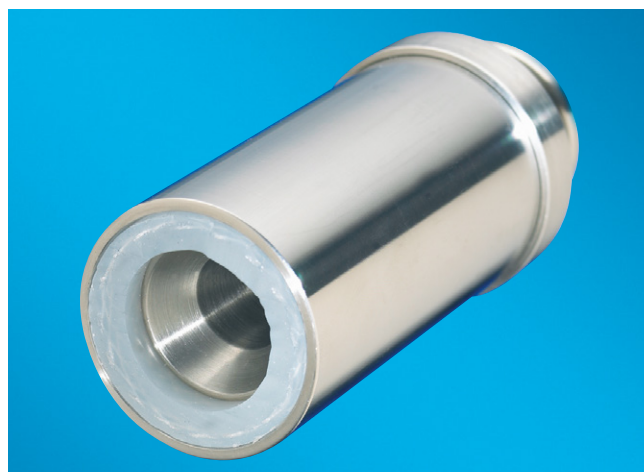
**All types correspond to
DIN EN 16821**

RE-LINK SI offers numerous advantages for you:

- 1.) Self-mounting of silicon tubing within a short operation time.
- 2.) Individual mounting of the desired fitting.
- 3.) Re-use of jacket and fitting, thus, contributing to cost savings.
- 4.) **All** fittings provided by TECNO PLAST can easily be assembled and disassembled.

Connectors themselves can be provided in qualities of all known stainless steel alloys.

Attention: The connection coupling may not be subjected to tension forces when installed in a vertical position. We recommend to contacting TECNO PLAST in advance if exposure of gaseous materials is desired.



The following dimensions are available for this system

DIN/ISO	Recommended operation pressure at 20 °C	Minimum burst pressure at 20 °C*	Vacuum	Bending radius	Ordering number**
	bar	bar	bar	mm	
6	10	40	-0,85	50	AES6093-06
8	10	40	-0,85	60	AES6093-08
10/8	10	40	-0,85	70	AES6093-10
12/10	8	32	-0,80	80	AES6093-12
16	8	32	-0,80	100	AES6093-16
20/15	6	24	-0,80	150	AES6093-20
25/20	4	16	-0,75	185	AES6093-25
32/25	3	12	-0,70	220	AES6093-32

Remark: At temperatures starting at +20 °C and increasing the temperature by each 35°C, the burst pressure must be reduced by 10 %.

The maximum operating temperature represents +160 °C on a short-term. * The safety factor applies to 1:4. The system is not suitable for vibrant pressures.

** Ordering number for standard material with translucent cover

The fitting system has been exclusively developed for the above-noted TECNO PLAST tubing with reinforcement and may not be combined with other tubing. The fitting system has been adapted to the special properties of these tubing. **Function and safety features cannot be ensured if a combination with other tubing would apply; liability will be precluded! Previously used tubing bulk stock may not be re-used.** The mentioned usage limitations are to be recognized as recommendations only. It is not possible to consider all potential factors along with numerous different usages in one list.

Assembly Instructions

Disassembly Instructions

All tools for assembly and disassembly are identified by a dot, thus, providing an explicit allocation to the RE-LINK SI system.

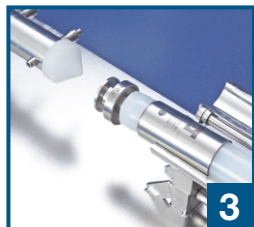
The RE-LINK SI program has been exclusively developed for assembly/disassembly with silicon tubing of the product type AES6093 and may not be used in combination with other tubing. The fitting system has been adapted to the specific properties of these tubing. Function and safety features cannot be ensured if a combination with other tubing would apply; liability will be precluded.



For mounting push the jacket over the precisely cut tubing end. Please note that the phase faces to the tubing end.



Insert the fitting into the tubing – max. up to the mark (red arrow).



Now insert the pre-conditioned tubing into the mounting tool, close and secure it. Use the basic tool for all nominal tubing sizes below DN 20.



Pull at the tubing end



... while simultaneously pushing the universal conus into the tubing by means of lever action.



Finally, check for proper positioning of the jacket in the fitting.

Insert the appropriate disassembly tool and secure it for disassembly.



Place the tubing end with fitting into the U-form - and lock it.



Pull the tubing while simultaneously twisting the jacket off.



Use an electrical thermos cutter to carefully split the tubing up to the fitting end.



Tear off the tubing from the fitting and remove the jacket.



Jacket and fitting now can be re-used.



A supportive video for assembly/disassembly can be found under <https://tecnoplast.de/de/download/silicon-schlaeuche-und-schlauchleitungen/>

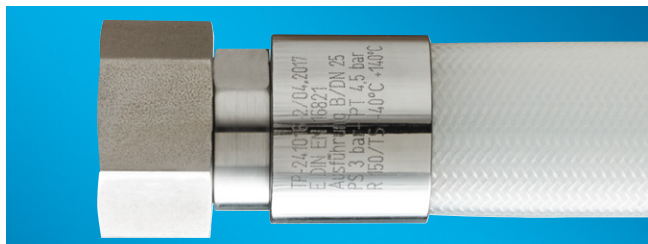
SILICON TUBING

Labeling

Each fitted tubing is provided with an individually labeled crimping jacket or marking ring. The marking contains the name of the manufacturer (TECNO PLAST), the tubing type, the opera-

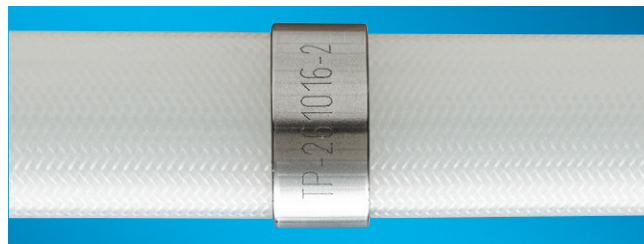
tion and inspection pressure, the permitted temperature, the date of manufacture as well as a specific serial number to allow traceability. An example is presented below.

Crimping Jacket



Basic standard is engraving, laser-engraving possible on request.

Marking Ring



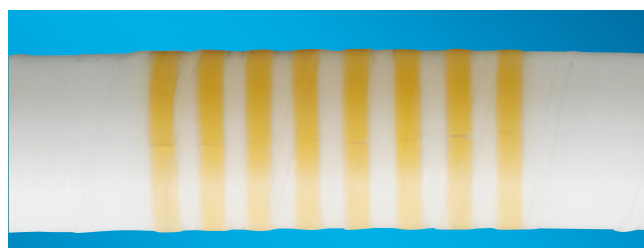
Basic standard is engraving, laser-engraving possible on request.

Label



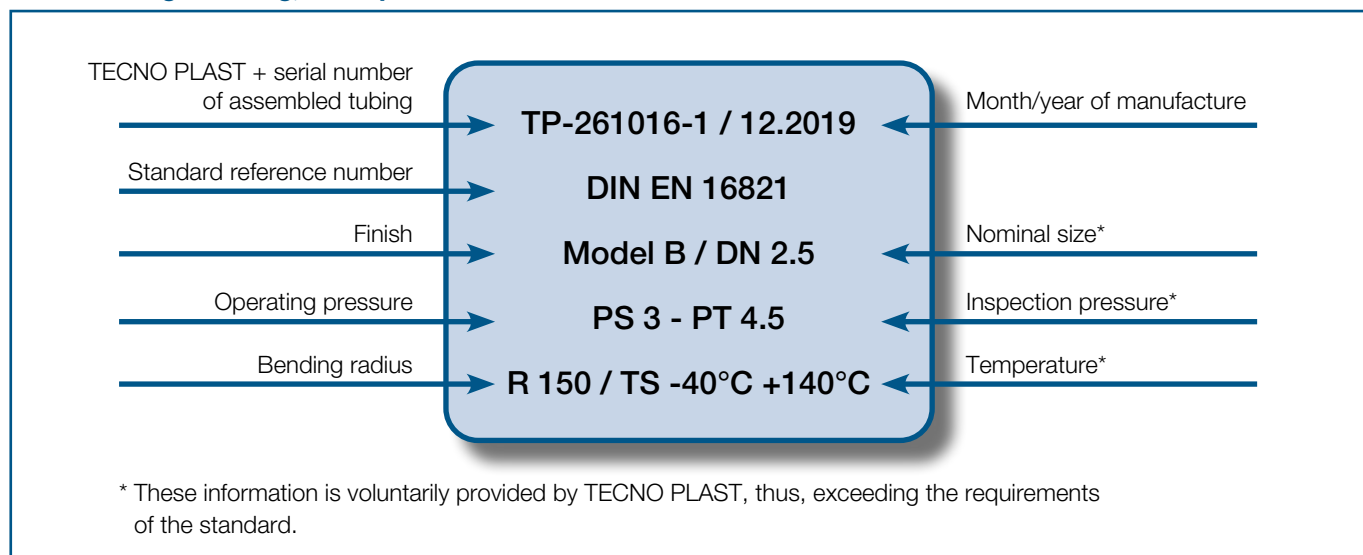
It is possible to add text and up to two additional colored ink ribbons, subsequently followed by vulcanization of an approx. 65 mm wide silicon trip that is applied onto the tubing. The text is limited according to the standardized information: standard reference, characteristic manufacturer's identification, month/year of manufacture, tubing serial number.

EPR-SI with Color Code



Bend protection made of transparent silicon (length between 150 mm to 300 mm) will be applied – starting at the crimping jacket. Up to eight colored ink ribbons can be applied underneath. For example, this supports the visual recognition for the use of the product with a certain medium or provides information regarding the date of manufacture.

Fitted Tubing Labeling, Example



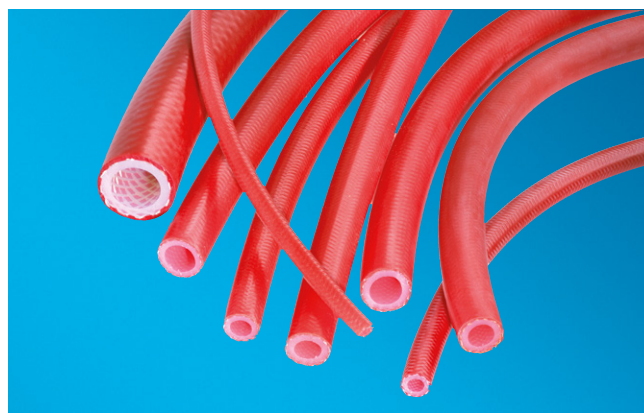
TECNO PLAST Silicon Product Portfolio

TP RED

Silicon Tubing with Reinforcement (Fabric) and Exterior Cover

TP RED is a **peroxide-cured** silicon tubing **with an inner reinforcement** layer and a translucent or colored exterior cover for high-temperature usages. This reinforcement provides a high pressure resistance.

Additional information may be found at our homepage under <https://tecnoplast.de/Silicon-Schlaeuche>.



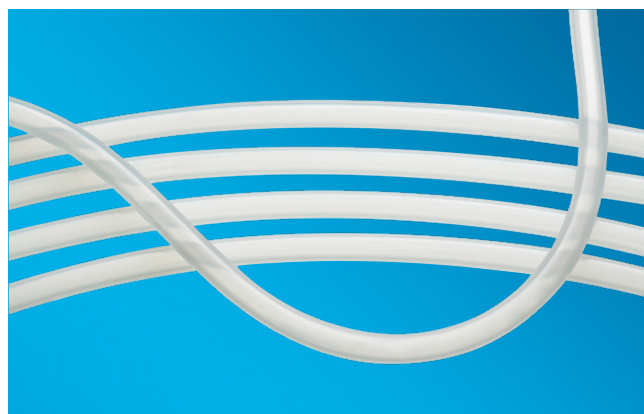
Silicon Tubing A6092

Silicon Tubing without Reinforcement (Fabric)

A6092 is a highly pure platinum-cured talc-free Silicon tubing that corresponds to the high requirements of the pharmaceutical industry.

This tubing quality has been intensively tested (evidence for suitability for meeting the highest requirements of the pharmaceutical industry). Only high-grade compounds are used for the production of this high-pure silicon quality.

Additional information may be found at our homepage under <https://tecnoplast.de/Silicon-Schlaeuche>.



REGULATORY SUPPORT FILE

For Silicon Tubing A6093/AE6093/AES6093

All related information regarding the testing in accordance with the requirements of the European and United States Pharmacopoeia as well as DIN EN ISO standards we have been presented in this Regulatory Support File (RSF). Representative finished A6093 silicon tubing has been subjected to the testing program and thoroughly documented.

In addition, an intensive extractables study was performed comprising several consecutive steps. Special emphasis should be taken to the extraordinary execution of a toxicological risk assessment for all analyzed extractables substances.



You can order the Regulatory Support File (RSF) as printed book version in German and as English document. Further information can be found at our homepage under <https://tecnoplast.de/de/produkte/silicon-schlaeuche-und-schlauchleitungen/a6093-ae6093-aes6093/regulatory-support-file/>

Guidance for Information at our Homepage

You will find useful information in the download section at our homepage representing:

- Silicon storage conditions and operating use times
- Silicon compatibility list
- Silicon steam
- Usage conditions for silicon tubing
- General sales and delivery conditions



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