



Silicone Tubing



Product Information and Instructions for Use

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SYMBOLS			
REF	Catalogue Number	EC REP	Manufacturer By
LOT	Lot Number	MD	Medical Device**
	Use by date (YYMM)		Do Not Use if Packaging is Open or Damaged
	Leak free		Keep Dry
	Pthalate free		Keep away from Sunlight
	Insulations for Use		Do Not Re-sterilise

** Applicable to the Sterile product. Not Applicable to the Non-sterile product type

ENGLISH - INSTRUCTIONS FOR USE

Intended Use:
 Medasil Silicone Tubing is intended for routine fluid transfer involving suction/aspiration and drainage or other similar applications considered suitable by a Healthcare Professional (HCP)

Device Description
 Tubing is manufactured from silicone elastomer which is biocompatible, latex and phthalate free, offered in a range of internal and external diameters. It displays high tear and resistance, tensile strength, and good memory characteristics. It displays high tear-distortion when subjected to compression, flexing, or stretching. The non-wetting surface properties resist encrustation to facilitate suction/aspiration and drainage applications in clinical settings and can be used for routine fluid transfer processes in a laboratory setting.

Non-Sterile Tubing:
 Coils of 15m (50ft), translucent, red and opaque colour.

Sterile Tubing:
 Standard cut lengths - 30, 60, 90, 120, 180 & 240 cm.
 Terminally sterilised using Gamma Radiation.

Indications for Use:
 Indications include, but are not limited to:
 - Removal of fluids through suction/aspiration and drainage.

Contraindications:
 Include, but are not limited to:
 - The Silicone Tubing must not be used for permanent implantation within the body.
 - Intended Patient Population
 The Silicone Tubing is intended for use on the general patient population - applied on adults and children.

Intended Users:
 The Medasil Silicone Tubing is intended to be used by the healthcare professional (HCP).

Warnings and Precautions:
 - Carefully select the internal and external diameters of tubing to ensure that it meets the needs of each specific application, whilst minimising adverse effects.
 - For devices supplied sterile, the sterility is only guaranteed in a sealed, undamaged, and unopened pouch.
 - Must not be used if the patient has known allergic reaction towards silicone.
 - Must not be used for delivering medicine.
 - Must not be used beyond expiry date on the label.
 - Must not be used if the packaging has been compromised.
 - Must be stored in the original unopened packaging.
 - Silicone tubing is a single use device.
 - Additionally, the HCP must ensure that the lumen of the tubing does not become blocked during use by:
 - Accumulation of debris.
 - Pressure on thin walled tubes causing collapse.
 - Sharp bend or kink in tube.

Single Use:
 Medasil Silicone Tubing has not been validated for re-use. Anyone re-using a single use device, may be held legally liable for the safe performance of the device.

Sterility:
 Silicone Tubing is supplied either non-sterile or sterile. The STERILE version has been terminally sterilised using Gamma Radiation. Do not re-sterilise.
 Non-sterile devices must be sterilised by the end user through validated methods.
 Devices must be disposed of in accordance with the local and national regulations.

Table 1: Range of sizes and colours for non-sterile tubing

REF**	Old REF	Non-Sterile Tubing Length (m)	Inner Diameter (mm)	Outer Diameter (mm)	Colour
260-1001-0617	100	15	0.64	3.95	Translucent
260-1001-1016	101	15	1.00	4.20	
260-1001-1504	102	15	1.50	4.70	
260-1001-1516	102	15	1.80	4.80	
260-1001-1811	217	15	1.98	3.18	
260-1001-2006	211	15	1.98	3.93	
260-1001-2010	103	15	2.00	5.50	
260-1001-2018	104	15	2.00	5.50	
260-1001-3116	105	15	3.10	6.40	
260-1001-4012	106	15	4.00	7.90	
260-1001-4816	107	15	4.80	8.70	
260-1001-4820	202	15	5.00	11.00	
260-1001-5020	202	15	6.00	10.00	
260-1001-6020	278	15	6.00	9.50	
260-1001-6416	108	15	6.40	11.30	
260-1001-6435	109	15	6.40	11.30	
260-1001-6432	110	15	8.00	12.70	
260-1001-8024	111	15	8.00	14.30	
260-1001-9516	112	15	9.50	15.90	
260-1001-9524	113	15	9.50	15.90	
260-1001-9532	114	15	9.50	15.90	
260-1001-1504-0115	Z1380	15	1.50	2.30	
260-1001-1508-0515	Z3380	15	1.50	2.99	
260-1001-2006-0115	Z1700	15	1.98	3.18	

*Pouch REF: For Individually Packed Devices

Table 2: Range of sizes and colours for sterile tubing

REF**	Old REF	Sterile Tubing Length (cm)	Inner Diameter (mm)	Outer Diameter (mm)	Colour
261-1101-0617-0003	100	30	0.64	3.95	Translucent
261-1101-0617-0012	101	30	1.00	4.20	
261-1101-1016-0003	102	30	1.50	4.70	
261-1101-1516-0012	102	30	1.80	4.80	
261-1101-2018-0003	103	30	2.00	5.50	
261-1101-2018-0012	104	30	2.00	5.50	
261-1101-3216-0003	104	30	3.20	6.40	
261-1101-3216-0012	104	30	3.20	6.40	
261-1101-4012-0003	105	30	4.00	7.90	
261-1101-4012-0012	105	30	4.00	7.90	
261-1101-4816-0003	106	30	4.80	8.70	
261-1101-4816-0006	106	30	4.80	8.70	
261-1101-4816-0009	106	30	4.80	8.70	
261-1101-4816-0012	106	30	4.80	8.70	
261-1101-4816-0018	106	30	4.80	8.70	
261-1101-4816-0024	106	30	4.80	8.70	