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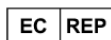
# Silicone Tubing



## Product Information and Instructions for Use



**MEDASIL SURGICAL LIMITED**  
Medasil House, Hunslet Road  
Leeds, LS10 1AU (UK)  
Tel: +44 (0)113 243 3491  
E-Mail: [orders@medasil.com](mailto:orders@medasil.com)  
Website: [www.medasil.com](http://www.medasil.com)



**European Healthcare & Device  
Solutions (Ireland) Ltd**  
Stratton House, Bishops Town  
Road, Cork, Ireland T12 Y9TC  
Tel: +353 (86) 228 0846  
[www.europeandevicesolutions.eu](http://www.europeandevicesolutions.eu)

**UK  
CA  
0120**

**CE  
1639**

SYMBOLS					
	Catalogue Number		Lot Number		Use by date.
	Manufactured By		Manufactured Date		Do Not Use if Packaging is Open or Damaged
	Keep Dry		Latex Free		Phthalate free
	Keep away from Sunlight		Sterilisation by Gamma Irradiation		Medical Device
	Do Not Reuse		Do Not Resterilize		Consult Instructions For Use
	Authorised Representative in the European Community		Non Sterile		Single Sterile Barrier
	Sterile Barrier With inner non sterile Barrier				

### INSTRUCTIONS FOR USE

#### ➤ INTENDED USE:

Medasil Silicone Tubing is intended for routine fluid transfer involving suction/aspiration and drainage or other similar applications. The device is intended for short term use (up to 29 days).

#### ➤ INTENDED PATIENT POPULATION:

Silicone Tubing is intended for use on the general patient population, applied on adults and children.

#### ➤ INTENDED USERS:

Silicone Tubing is intended to be used by the Healthcare Professionals (HCP) only within a Clinical/ healthcare setting.

#### ➤ DEVICE DESCRIPTION:

Silicone Tubing is manufactured from Silicone elastomer which is biocompatible, Latex and Phthalate free. Designed to be durable and is offered in a range of internal and external diameters. The non-wetting surface properties resist encrustation to facilitate suction/aspiration and drainage applications. The Opaque variant of the device contains Barium Sulphate (BaSO<sub>4</sub>) which may aid visibility under X-ray. BaSO<sub>4</sub> is listed as a medicine, classed as a radiopaque contrast agent in the pharmacopoeia. The BaSO<sub>4</sub> in this device does not function as a medicine and no clinical claims are made.

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

Sterile Tubing-Standard cut lengths - 30, 60, 90, 120, 180 & 240 cm.

#### ➤ INDICATIONS FOR USE:

- Removal of fluids through suction/aspiration and drainage.

#### ➤ PERFORMANCE CLAIMS:

- Facilitates suction/aspiration and drainage applications and can be used for routine fluid transfer processes.
- Non-wetting surface properties.
- High tear-resistance, tensile strength, and good memory characteristics.
- Capable of resisting distortion when subjected to flexing or stretching.

#### ➤ SAFETY CLAIMS:

- Biologically Safe

#### ➤ CONTRAINDICATIONS:

- Must not be used for implantation within the body.

#### ➤ WARNINGS AND PRECAUTIONS:

Prior to use, the HCP should consider the following:

- Carefully select the internal and external diameters of tubing to ensure that it meets the needs of each specific application, whilst minimising adverse effects.
- Ensure that the lumen of the tubing does not become blocked or obstructed during use.
- Must not be used if the patient has known allergic reaction towards silicone.
- For devices supplied sterile, the sterility is only guaranteed in a sealed, undamaged, and unopened pouch.
- Must not be used for delivering medicine.
- Must not be used if the packaging has been compromised.
- Must not be used beyond expiry date on the label.
- Must be stored in the original unopened packaging.
- Must be stored away from moisture and direct sunlight.
- Tubing is a single use device.
- In the event of any serious adverse effects, medical attention must be sought immediately.
- Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
- Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.

#### ➤ STERILITY:

The Sterile Silicone Tubing has been terminally sterilized using gamma Radiation. The Non-sterile silicone tubing must be sterilized by the end user through validated methods. **Do not resterilize.**

#### ➤ SINGLE USE:

The device has not been validated for reuse. Anyone reusing a single use device, may be held legally liable for the safe performance of the device.

#### ➤ DISPOSAL OF THE DEVICE:

Biohazardous related waste means related products which were in use and in direct contact with Human Body Fluids and Tissues.

Please note that the proper disposal of products protects the environment. It prevents possible harmful effects on humans and the environment which could be caused by improper handling of the waste.

Disposal of biohazardous waste shall follow local regulations and environmental requirements, taking different contamination levels into account.

Do not dispose biohazardous related waste as unsorted municipal waste.

Waste disposed of in biohazard waste accumulation sites must be collected by service provider for final off-site treatment/incineration/disposal through a biowaste vendor in accordance with local regulations and environmental requirements.

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

REF*1	Approx Length (m)	Approx Inner Diameter (mm)	Approx Outer Diameter (mm)	Colour
260-1001-0617	15	0.6	4.00	Translucent
260-1001-1016		1.00	4.20	
260-1001-1504		1.50	2.30	
260-1001-1516			4.70	
260-1001-1811		1.80	4.00	
260-1001-2006		2.00	3.20	
260-1001-2010		2.00	3.90	
260-1001-2018		2.00	5.50	
260-1001-3216		3.20	6.40	
260-1001-4012		4.00		
260-1001-4816			7.90	
260-1001-4820		4.80	8.70	
260-1001-5030		5.00	11.00	
260-1001-6020		6.00	10.00	
260-1001-6416			9.50	
260-1001-6425		6.40	11.30	
260-1001-6432				
260-1001-8024		8.00	12.70	
260-1001-9516				
260-1001-9524		9.50	14.30	
260-1001-9532			15.90	
262-1001-1504-0115		1.50	2.30	Opaque
262-1001-1508-0515			3.00	Red
262-1001-2006-0115		2.0	3.20	Opaque

Table 2: Range of size and colours for sterile tubing.

REF*1	Approx Length (cm)	Approx Inner Diameter (mm)	Approx Outer Diameter (mm)	Colour
261-1101-0617-0003	30	0.60	4.00	Translucent
261-1101-0617-0012	120			
261-1101-1016-0003	30	1.00	4.20	
261-1101-1016-0012	120			
261-1101-1516-0003	30	1.50	4.70	
261-1101-1516-0012	120			
261-1101-2018-0003	30	2.00	5.50	
261-1101-2018-0012	120			
261-1101-3216-0003	30	3.20	6.40	
261-1101-3216-0012	120			
261-1101-4012-0003	30	4.00		
261-1101-4012-0012	120			
261-1101-4816-0003	30	4.80	7.90	
261-1101-4816-0006	60			
261-1101-4816-0009	90			
261-1101-4816-0012	120			
261-1101-4816-0018	180			
261-1101-4816-0024	240			
261-1101-4820-0003	30		8.70	
261-1101-4820-0006	60			
261-1101-4820-0009	90			
261-1101-4820-0012	120			
261-1101-4820-0018	180			
261-1101-4820-0024	240			
261-1101-6416-0003	30	6.40	9.50	
261-1101-6416-0006	60			
261-1101-6416-0009	90			
261-1101-6416-0012	120			
261-1101-6416-0018	180			
261-1101-6416-0024	240			
261-1101-6425-0003	30		11.30	
261-1101-6425-0006	60			
261-1101-6425-0009	90			
261-1101-6425-0012	120			
261-1101-6425-0018	180			
261-1101-6425-0024	240			
261-1101-6432-0003	30	12.70		
261-1101-6432-0012	120			
261-1101-8024-0003	30		8.00	
261-1101-8024-0006	60			
261-1101-8024-0009	90			
261-1101-8024-0012	120			
261-1101-8024-0024	240			
261-1101-9516-0003	30	9.50	12.70	
261-1101-9516-0009	90			
261-1101-9516-0012	120			
261-1101-9516-0024	240			
261-1101-9524-0003	30	9.50	14.30	
261-1101-9524-0012	120			

REF*1	Approx Length (cm)	Approx Inner Diameter (mm)	Approx Outer Diameter (mm)	Colour
261-1101-9532-0003	30	1.50	15.90	Opaque
261-1101-9532-0012	120			
261-1101-9532-0024	240			
261-1101-1504-0103	30	1.98	3.18	Translucent
261-1101-1504-0118	180			
261-1101-2006-0103	30			
261-1101-2006-0118	180			

\*1: Pouch REF: For Individually Packed Devices

**LIABILITY AND WARRANTY:**

Medasil declares that reasonable care has been applied in the design and manufacture of this product. In the event of any damage, please contact Medasil or your supplier. The responsibility of Medasil or your supplier under this warranty is limited to the replacement of product if faulty. On no account may Medasil or your supplier be held responsible for damage, whether direct, indirect and/or incidental resulting from the misuse and/or the manipulation of this device.

**➤ NOTES:**

This device:

- Is not made with natural rubber latex.
- Does not contain any animal or human cells, tissues and/or derivatives thereof, rendered non-viable; cells, tissues and/or derivatives of microbial or recombinant origin; and/or irradiating components, ionizing or non-ionizing.
- Are not intended for use by lay persons.

Any serious incident that has occurred in relation to the Medasil Silicone Tubing must be reported to Medasil and/or the competent authority of the member state in which the user and/or patient is established.