

Solutran®

*Medical PVC for container
of concentrated solutions*

Solutran® PVC GRANULE

Solutran® is the Meditalia srl brand for granules, tubular, tubes and bags in non-toxic medical PVC to be used for the containing of concentrated solutions adopted in peritoneal dialysis.

We produce under the Solutran® brand:

- from granules of a natural colour to those in light blue in customized shades;
- granules from 60 to 90 Shore A of hardness, to be used in the extrusion of downflow tubes;
- granules from 60 to 90 of Shore A of hardness, to be used in the extrusion of tubulars (other hardness are available).

The Solutran® granules are produced in a completely automated and sealed unit guaranteeing the purity of the finished product, strictly using suitable raw materials certified for medical use.

Solutran® PVC LAY FLAT TUBE, DOUBLE WOUND FLAT FILM AND TUBE

Solutran® is the trade name of the medical lay flat tube, double wound flat film and tube in non-toxic PVC, principally used in the production of medium/high volume bags (3.5 to 5.5 lt), intended for the containing of concentrated solutions for peritoneal dialysis and don't have to undergo a sterilization process.

Meditalia offers a wide range of extruded Solutran®:

Tubulars

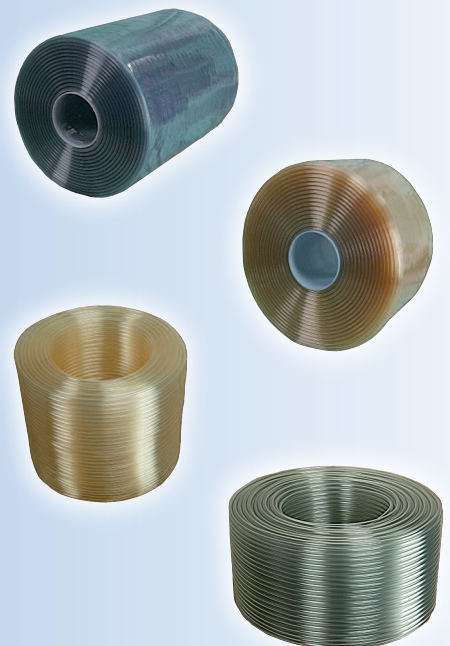
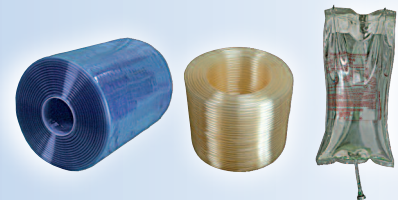
- from 0.30 to 0.40 mm in thickness (single layer)
- from 60 to 420 mm in width

Tubes

- in diameters and hardness requested by customers;
- rolling on coins or in precut pieces.

The extrusion process (class ISO 8 white room) is performed with modern technologies which have been validated to guarantee chemical stability, constant and even coil rolling, absolute constancy in the dimension parameters.

**Solutran® tubular appearance is lucid and transparent;
tubulars and tubes possess excellent chemical stability.**



Medical grade PVC granule - lay flat tube - double wound flat film - tube - container for infusional sector

CHEMICAL SPECIFICATIONS Eur. Ph. Sez. 3.1.1.1

FORMULATION

Poly(vinyl chloride)	> 55%
Di(2-ethylhexyl)phthalate	< 40%
Epoxidised soya oil	< 5%
N,N'-diacylethylenediamines	< 1%
Calcium stearate	< 1%

TEST

LIMIT VALUE

Vinyl chloride	1,0 ppm
Appearance	Clear, colourless
Alkalinity	1,0 ml HCl 0.01 M
Acidity	1,5 ml NaOH 0.01 M
Reducing substances	2,0 ml Na ₂ S ₂ O ₃ 0.01 M
UV absorption	0,25 250-310nm
Residue on evaporation	0,3%
Barium	5,0 ppm
Cadmium	0,6 ppm
Heavy metals	50,0 ppm
Calcium	0,07%
Tin	20,0 ppm
Zinc	0,2%

Small color differences depend only on the color tone of the resin

PHYSICAL PROPERTIES

Typical test results on 85 ShA tubular

TEST	VALUE	UNIT	REFEREN.
Appearance	Omogeneous granules		
	Omogeneous film		
	Natural colour		
	Crystal colour		
	Contamination free		
	Burned Point free		
Hardness	85	Shore A	ISO 868
Tensile strenght at break	175	Kg/cm ²	ISO R527
Elongation at break	290	%	ISO R527
Temperature of stiffening	-7	°C	ISO R458
Density	1,25	g/cm ³	ISO R1183

BIOLOGICAL REACTIVITY UNI EN ISO 10993

TEST	IN CONFORMITY
Irritation	Yes
Cytotoxicity	Yes
Implantation	Yes
Hemolysis	Yes
Systemic toxicity	Yes