

Solutran Plus®

*Medical PVC for infusional sector:
container for peritoneal dialysis -
haemodialysis - infusional solution*

Solutran Plus® PVC GRANULE

Solutran Plus® is the Meditalia srl brand for granules, tubulars, tube and bags in PVC of a non-toxic medical grade, to be used in the sector of peritoneal dialysis, haemodialysis and infusion solutions.

To better satisfy the most various requests from their customers Meditalia Srl, after decades of specialization in the sector, possess a vast range of formulations of **Solutran Plus®** PVC compounds:

- from granules of a natural colour to those in light blue (crystal colour) in customized shades;
- granules from 83 to 85 Shore A of hardness, to be used both in the extrusion process and in the moulding of the support components in the infusion and haemodialysis sectors;
- granules featuring different gradients of fluidity or lubrication (low, medium or high).

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

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

As many types of non-toxic, biocompatible lay flat tubes, double wound flat film and tubes extrude from the vast range of **Solutran Plus®** compounds.

Solutran Plus® is for the production of bags used in the peritoneal dialysis, haemodialysis and infusional solution.

The medical bags produced using Solutran Plus® maintain good transparency after the steam sterilization process and optimal chemical stability.

We can satisfy any request made by our customers:

Tubulars:

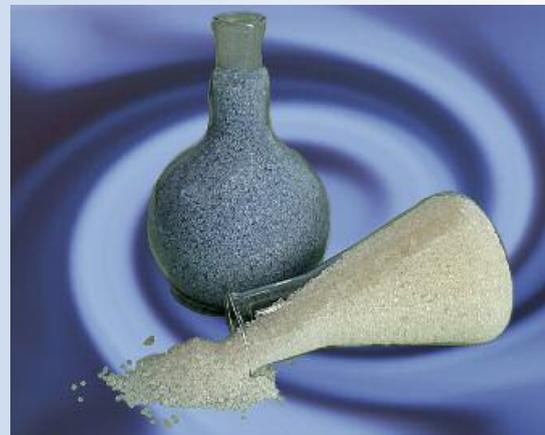
- from 0.30 to 0.40 mm in thickness (single layer)
- from 60 to 420 mm in width

Tubes:

- of any diameter (from epicranial tubes to large tubes for pump set)
- of any hardness (from 60 to 90 Shore A)
- rolling on coils 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.

The extrusion plants for the tube production are fitted with laser detectors for the continuous monitoring of the size parameters.



Solutran Plus®

Technical sheet

Medical grade PVC granule - lay flat tube - double wound flat film - tube - container for infusional solution - haemodialysis - peritoneal dialysis

CHEMICAL SPECIFICATIONS Eur. Ph. Sez. 3.1.1.1

FORMULATION

Poly(vinyl chloride)	> 55%
Di(2-ethylhexyl)phtalate	< 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 83 ShA tubular

TEST	VALUE	UNIT	REFEREN.	
Appearance	Omogeneous granules			
	Omogeneous film			
	Natural colour			
	Crystal colour			
	Contamination free			
	Burned Point free			
Hardness	83	Shore A	ISO 868	
Tensile strenght at break	170	Kg/cm2	ISO R527	
Elongation at break	300	%	ISO R527	
Temperature of stiffening	-9	°C	ISO R458	
Density	1,24	g/cm3	ISO R1183	

BIOLOGICAL REACTIVITY UNI EN ISO 10993

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