



A Material Difference

# Mediprene<sup>®</sup> 500M

TPE for Medical Applications - Syringe Plunger Series



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# Introduction

We have developed a range of Mediprene thermoplastic elastomers (TPE) for plunger seals in single-use syringes.

The TPE seal, which is mounted on the end of the plunger, needs to provide a leakproof seal with the syringe barrel. As ease of use for the medical practitioner and patient comfort are also key requirements, the seal helps to optimize plunger movement for accurate dosage control and ease of injection. Mediprene TPE materials are PVC, silicone and latex free, making them allergen free and a viable alternative to PVC based compounds.

The right TPE formulation is the key to a safe and successful medical product. When a standard formulation does not meet the needs of a unique application, we will apply our expertise in formulating a custom solution. In this guide we show typical properties for our most common grades, these tables do not list all available properties and materials.

Please use this guide as an introduction to the Mediprene 500M TPE - Syringe Plunger Seal Series and [contact us](#) to discuss your specific requirements.

# Regulatory Compliance

All Mediprene TPE Syringe Plunger Seal Series compounds fulfil a strict raw material selection policy. The raw materials are food contact compliant (FDA 21 CFR and Commission Regulation (EU) No 10/2011) and have a proven level of biocompatibility:

- The styrenic block copolymer has passed USP Class VI
- The paraffinic oil is a medicinal white oil, complying with the European Pharmacopoeia for liquid paraffin and USP for mineral oils
- The polypropylene has passed the USP Class VI tests and meets the requirements in the EP Monograph 3.1.3 Polyolefins
- The components of the black masterbatch have passed USP Class VI or corresponding parts of ISO 10993

Note: Mediprene grades are not to be used in any devices or materials intended for implantation in the human body.

[Further Information on Raw Material Policy + Change Control >](#)

# Special Features

- Excellent sealing and adhesion
- Short cycle times
- PVC, silicone and latex free
- Resistance to many fluids used in the healthcare environment
- Flexibility and elasticity
- 43 to 73 Shore A
- Black and translucent grades
- Production site is ISO 13485 certified
- Following the VDI 2017 guideline on Medical Grade Plastics
- Sterilizable with gamma, ethylene oxide (EtO) and steam

# Coloured Materials

We offer these grades as translucent or black compounds.

The colour masterbatch supplier has been selected with care, ensuring that not only the pigments and carriers are compliant but also that the masterbatches are manufactured under rigorous controls with regard to traceability, consistency and change control, thereby fitting the Mediprene concept at our ISO 13485 certified facilities.

A fully colour compounded TPE gives a perfectly dispersed, consistent colour with a correct and reproducible addition level. Mediprene colour compounds ensure colour reproducibility and deliver a compound ready for use, with no additional steps for the moulder or extrusion company.

# Typical Grades

Grade	Hardness ASTM D2240 (4mm) Shore A	Colour	Density ASTM D792 g/cm <sup>3</sup>	Tensile Strength ASTM D638 MPa	Stress at 100% Strain ASTM D638 MPa	Stress at 300% Strain ASTM D638 MPa	Elongation at Break ASTM D638 %	Tear Strength ASTM D624 N/mm	MFR ASTM D1238 g/10 mm
Mediprene 500434M-05	43	Translucent	0.88	8	1.2	1.8	800	20	1
Mediprene 502434M-05	43	Black	0.88	8	1.2	1.8	800	20	1
Mediprene 500484M-05	48	Translucent	0.88	10	1.2	1.9	800	22	1
Mediprene 502484M-05	48	Black	0.88	10	1.2	1.9	800	22	1
Mediprene 500534M-05	53	Translucent	0.88	10	1.4	2.2	800	18	2
Mediprene 502534M-05	53	Black	0.88	10	1.4	2.2	800	18	2
Mediprene 500584M-05	58	Translucent	0.88	10	1.8	2.7	800	25	5
Mediprene 502584M-05	58	Black	0.88	10	1.8	2.7	800	25	5
Mediprene 500634M-05	63	Translucent	0.88	11	2.0	3.0	800	26	4
Mediprene 502634M-05	63	Black	0.88	11	2.0	3.0	800	26	4
Mediprene 500684M-05	68	Translucent	0.88	11	2.4	3.5	750	30	5
Mediprene 502684M-05	68	Black	0.88	11	2.4	3.5	750	30	5
Mediprene 500734M-05	73	Translucent	0.88	11	2.8	4.0	750	33	7
Mediprene 502734M-05	73	Black	0.88	11	2.8	4.0	750	33	7

# Processing

The material has excellent processing characteristics and can be processed using standard thermoplastic fabricating methods, including injection moulding and extrusion.

## Processing Temperatures

Barrel Temperatures °C

Mould Temperatures °C

## Injection Moulding

180 to 220

20 to 50

## Extrusion

150 to 210

Service Temperature Range -50 to +125°C 43-73 ShA (unstressed material)

Presentation Free flowing pellets that can be processed without predrying, when stored under normal conditions

[Further TPE Processing + Problem Solving Guides >](#)

# More Mediprene TPE Ranges

Click for more information

**Mediprene® 500M**

Standard Series



**Mediprene® 500M**

Transparent Series



**Mediprene® A**

2K

**Mediprene® BM**



**Mediprene®**



**Mediprene® OF**



**Mediprene®**

Solvent Bondable



**Mass Balance**



# ABOUT US



[info@hexpolTPE.com](mailto:info@hexpolTPE.com) | [www.hexpolTPE.com](http://www.hexpolTPE.com)

## 110,000+

### T/P.A. CAPACITY

Across our Sweden, UK, German, China & North America operations. [Our companies](#)

## 55+

### YEARS HISTORY

We've a proud history in flexible polymer compounding & were among the 1st to produce TPEs in Europe. [About us](#)

## 52,822+

### FORMULATIONS

A comprehensive portfolio in TPE, TPS, TPO, TPU, TPV, soft PVC & Biobased technologies. Learn more about [Our products](#)

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