

Mediprene® 500M

TPEs for Syringe Plunger Seals



CONTENTS

INTRODUCTION →

REGULATORY COMPLIANCE →

COLOURED COMPOUNDS →

GRADE TABLE →

PROCESSING →

CONTACTS →

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.

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 our Mediprene 500M - syringe plunger seal series and [contact us](#) to discuss your specific requirements.

REGULATORY COMPLIANCE

All Mediprene TPE Syringe Plunger Series compounds fulfil a strict raw material selection policy. The raw materials are food contact compliant (FDA 21CFR 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

COLOURED COMPOUNDS

We offer these grades as translucent or coloured 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 accredited 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

Material	Hardness ASTM D2240 (4mm) Shore A	Colour	Density ASTM D792 g/cm ³	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 190°C/2.16kg ASTM D1238 g/10 min
Mediprene 500434M	43	Translucent	0.88	8	1.2	1.8	800	20	1
Mediprene 502434M	43	Black	0.88	8	1.2	1.8	800	20	1
Mediprene 500484M	48	Translucent	0.88	10	1.2	1.9	800	22	1
Mediprene 502484M	48	Black	0.88	10	1.2	1.9	800	22	1
Mediprene 500534M	53	Translucent	0.88	10	1.4	2.2	800	18	2
Mediprene 502534M	53	Black	0.88	10	1.4	2.2	800	18	2
Mediprene 500584M	58	Translucent	0.88	10	1.8	2.7	800	25	5
Mediprene 502584M	58	Black	0.88	10	1.8	2.7	800	25	5
Mediprene 500634M	63	Translucent	0.88	11	2.0	3.0	800	26	4
Mediprene 502634M	63	Black	0.88	11	2.0	3.0	800	26	4
Mediprene 500684M	68	Translucent	0.88	11	2.4	3.5	750	30	5
Mediprene 502684M	68	Black	0.88	11	2.4	3.5	750	30	5
Mediprene 500734M	73	Translucent	0.88	11	2.8	4.0	750	33	7
Mediprene 502734M	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.

Alongside their material advantages, because of the cost and speed at which they can be manufactured, Mediprene TPEs are being specified as an alternative to thermoset rubber. Fewer process steps, without the need for additional operations such as trimming means less energy is used and production is faster and more cost-efficient. TPEs have a lower specific gravity compared to several alternative materials, you can therefore not only create lighter-weight parts, but can also produce more parts per kilogram of material.

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

Processing Temperatures	Injection Moulding	Extrusion
Barrel Temperatures °C	180 - 220	150 - 210
Mould Temperatures °C	20 - 50	

Further TPE processing, sterilization & problem solving information is available to [download from our website →](#)

WANT TO LEARN MORE?

Email the medical team at
mediprene@hexpolTPE.com

or visit www.mediprene.com

[Other Mediprene Product Series →](#)

[Mediprene 500M : Standard Series](#)

[Mediprene 500M : Transparent Series](#)

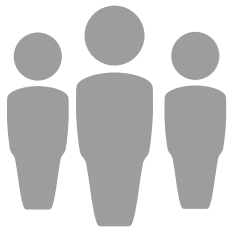
[Mediprene Oil Free Series](#)

[Mediprene Sterilization Guide](#)

[Mediprene 2 Year Supply Guarantee](#)

ABOUT HEXPOL TPE

info@hexpolTPE.com
www.hexpolTPE.com



300+ EMPLOYEES
WORLDWIDE



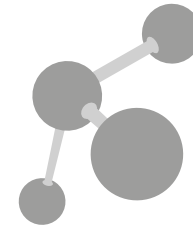
PRODUCTION PLANTS
Sweden, UK, Germany,
China, USA



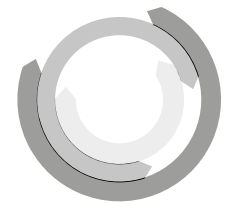
GLOBAL CAPACITY
> 80,000 tonnes p.a.



HEXPOL GROUP
HEADQUARTERS
Malmö, Sweden



34,796+
PROPRIETARY
FORMULATIONS



KEY MARKETS
Consumer,
automotive, medical,
construction,
industrial

All the information about chemical and physical properties consists of values measured in tests on injection moulded test specimens. We provide written and illustrated advice in good faith. This should only be regarded as being advisory and does not absolve the customers from doing their own full-scale tests to determine the suitability of the material for the intended applications. You assume all risk and liability arising from your use of the information and/or use or handling of any product. Figures are indicative and can vary depending on the specific grade selected and the production site. HEXPOL TPE makes no representations, guarantees, or warranties of any kind with respect to the information contained in this document about its accuracy, suitability for particular applications, or the results obtained or obtainable using the information. We retain the right to make changes without prior notice. HEXPOL TPE makes no warranties or guarantees, express or implied, respecting suitability of HEXPOL TPE's products for your process or end-use application. Dryflex® is a registered trademark, property of the HEXPOL TPE group of companies.