# Mediprene® 500M

TPEs for Syringe Plunger Seals





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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.

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 <u>contact us</u> 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 EP for liquid paraffin and USP 24 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<br>ASTM D2240 (4mm)<br>Shore A | Colour      | Density<br>ASTM D792<br>g/cm3 | Tensile Strength<br>ASTM D638<br>MPa | Stress at 100% Strain<br>ASTM D638<br>MPa | Stress at 300% Strain<br>ASTM D638<br>MPa | Elongation at Break<br>ASTM D638<br>% | Tear Strength<br>ASTM D624<br>N/mm | MFR 190°C/2.16kg<br>ASTM D1238<br>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 <u>www.mediprene.com</u>

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







HEXPOL TPE is a global compounding group specialising in Thermoplastic Elastomers (TPE) for key industries such as consumer, medical, packaging, automotive and construction. We have a core belief in being the easiest company to do business with. That's why we invest in our operations, teams and technologies to offer our customers the most reliable, relevant and cost-effective TPE compounds, backed by highly responsive support, technical knowhow and application expertise. Our teams work together, across boundaries, applying the knowledge, experience and talents we have all around the world to meet the needs of our customers.

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. Some of the information arises from laboratory work with small-scale equipment which may not provide a reliable indication of performance or properties obtained or obtainable on larger-scale equipment. 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. Mediprene® is a registered trademark, property of the HEXPOL TPE group of companies.