

### Proven ease of injection and accurate dosage control

Single-use, pre-filled syringes (PFS), and autoinjectors are growing in demand as they remain an efficient means of delivering a measured dose of vital medicines or vaccines. The elastomer components used within these devices must conform to critical tolerances and demonstrate specific material characteristics to maintain dose integrity and meet performance requirements. For over 40 years, components molded from **Santoprene® TPV** – a medical-grade thermoplastic vulcanizate from Celanese – have ensured drugs are fully protected and patient needs are fully met.



# **Syringe-specific solution**Enabling ease of injection and accurate dosage control.



# **Drug integrity and patient safety**Delivering improved long-term sealing performance.



#### Product consistency and availability Global/local manufacturing ensures security of supply; USP Class VI, ISO-10993, DMF.

## Syringe and autoinjector applications

- Syringe stopper or plunger tip
- Syringe cap or needle cover
- Stoppers and seals in PFS and non-PFS syringes and autoinjectors

## Reasons to specify Santoprene $^{\!\circ}$ TPV over thermoset rubber-like butyl, SBR and isoprene

- Long term sealing performance for a leak-proof barrier between the drug and the syringe barrel
- Stringent dimensional tolerances
- Achievable desired break-loose and glide forces through material and design
- High-precision molding with high-cavitation tooling and no deflashing steps
- Low propensity for migration of contaminants
- A sustainable alternative with a lower carbon footprint potential



#### Drug integrity and patient safety

Santoprene® TPV delivers improved long-term sealing performance compared with thermoset rubber or other TPEs, securely protecting against external contaminants. Santoprene® TPV can withstand steam, radiation, and EtO sterilization with minimal polymer degradation. Its service temperature range between -60°C and 135 °C allows better compatibility with cold chain storage conditions than other TPEs (styrene block copolymers).

Santoprene® TPV Medical (MED) grades	Color	Hardness A scale (+/-5)	Specific gravity at 23°C	Tensile strength (MPa)	Elongation at break (%)	Modulus at 100% (MPa)	Comp. Set (168h at 23°C)
Santoprene® TPV 181-55MED	black	59	0.98	6.1	440	2.1	19%
Santoprene® TPV 281-55MED	natural	60	0.96	4.9	410	2.0	20%
Santoprene® TPV 8281-35MED	natural	38	0.91	2.6	330	0.9	13%
Santoprene® TPV 8281-45MED	natural	49	0.91	3.6	440	1.3	12%
Santoprene® TPV 8281-55MED	natural	59	0.92	5.2	430	2.0	14%

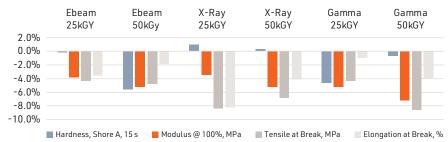
USP Class VI, ISO 10993-4,5,6,10, and 11 Representative grades are tested annually for cytotoxicity and heavy metals Drug Master File maintained with FDA Global supply availability

### Component solutions delivered collaboratively

With a global service offering that encompasses everything from assistance with material selection and medical device design through to tooling recommendations and local processing support, Celanese can help accelerate the development of your medical device applications.

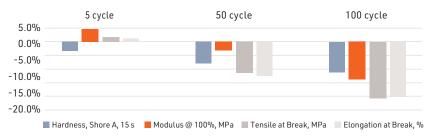


### Santoprene® TPV 181-55MED Resistance to Radiation Property Retention after Exposure, %



Compatible with steam (132C, 6 min/cycle, 100 cycles), gamma, x-ray, and e-beam \*Additional data available upon request

## Santoprene® TPV 8281-55MED Resistance to Steam Sterilization, 132°C, 6 min/cycle



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#### **Contact Information**

Website: healthcare.celanese.com | Customer Service t: +1-800-526-4960 t: +1-859-372-3214

Americas

8040 Dixie Highway, Florence, KY 41042 USA Product Information Service t: +1-800-833-4882 t: +1-859-372-3244

#### Europ

Am Unisys-Park 1, 65843 Sulzbach, Germany Product Information Service t: +[00]-800-86427-531 t: +49-[0]-69-45009-1011

#### Asi

4560 Jinke Road, Zhang Jiang Hi Tech Park Shanghai 201203 PRC Customer Service t: +86-21-3861-9266 f: +86-21-3861-9599