Celanese
The chemistry inside innovation™

Reliable TPV component solutions for medical and drug delivery devices and packaging

Reasons to specify Santoprene TPV:

Enhanced functionality
- Strong and flexible
- Long-term sealing performance
- Optimized wear and tear
- Protects critical components of device

Resists damage from high temperatures, chemicals and household products

Withstands various sterilization methods

Comfort touch
- Passes the irritation and skin sensitization tests per ISO10993-10
- Designed for comfort touch in skin contact applications

Easy to process/assemble
- Eliminates adhesives, bonding agents
- Eliminates mechanical interlocks

Design flexibility
- Colorability
- Photochromic and thermochromic effects
- Textured surfaces
- 5G connectivity compatibility

Recycling opportunities
- Scrap during manufacture or end of part life

An aging global population, and the increasing prevalence of infectious and chronic diseases is driving demand for trusted material solutions that will help advance medical technologies.

Whether it is peace-of-mind ranging from supply security to regulatory requirements; durability that elevates a patient's experience; or resistance to harsher conditions that extends a product's lifecycle, Santoprene® thermoplastic vulcanizate (TPV) delivers.

For decades, customers have relied on Santoprene TPV to enable innovative solutions that fully comply with standards for a range of medical, healthcare and pharmaceutical industry applications including:

- Medical devices:
  - Wearable and other device grips, seals, and other components
  - Peristaltic pump tubing
  - Electrical cable jacketing and insulation
  - Medical soft-touch grips, seals, gaskets, and diaphragms
- Drug delivery: single-use and pre-filled syringe seals
- Packaging: bumpers, tube gaskets, caps and closures

Medical devices

Santoprene® TPV is the material of choice for medical devices requiring long-term sealing performance, flexibility, or soft-touch for human contact.

Peristaltic pump tubing – Extremely flexible peristaltic pump tubing that is made with Santoprene TPV, resists kinks and retains its shape due to the outstanding flex-fatigue resistance and compression set.

Wearable device grips and seals – Delivery design flexibility and comfort touch, Santoprene TPV helps manufacturers to create wearable devices that offer patients a more comfortable experience. Resistant to household and personal products and easily sterilized and colorable, Santoprene TPV meets the functional needs of components, like grips and seals, used in self-monitoring devices for health checking, therapy delivery, activity trackers, and patient rehabilitation or diagnostics.

Specifically designed for wearables, Santoprene TPV **medical bonding grades** form strong bonds with engineering thermoplastics like PC, ABS, PMMA, for parts integration and for over-molding.

Medical equipment components – Offering strength and flexibility, elastic recovery, excellent chemical and high temperature resistance, and non-hygroscopic properties, Santoprene TPV meets the standards required for a range of device components including grips, strain relief parts, bumpers, caster wheels, seals, liners, and caps.

Electrical cable connectors/jacketing – Used to mold a connector which is then extruded as a wire jacket to bond to the electrical interface, Santoprene TPV helps eliminate openings which can collect moisture and dirt and be a breeding space for bacteria which can cause infection.

Table 1: Typical property comparison of elastomers used in medical applications

Property*	Santoprene TPV	TPS (SEBS)	TPC (COPE)	TPU	Silicone	Butyl (IIR)	EPDM
Density, g/cm^3	0.89 - 0.98	0.90 - 0.98	1.1 - 1.2	~1.1	~1.2	~1.2	~1.2
Hardness, shore	35A - 50D	25A - 80D	85A - 80D	60A - 60D	35A - 90A	55-90A	40A - 90A
Service temp, min/max°C (°F)	-60 / 135 (-76 / 275)	-45 / 110 (-49 / 230)	-65 / 150 (-85 / 302)	-40 / 120 (-40 / 248)	-60 / 150 (-76 / 302)	-40/150 (-40 / 302)	-40 / 135 (-40 / 275)
Compression set	+	Δ	Δ	Δ	+	+	+
Chemical resistance	+	o	+	o	+	o	+
Oil resistance	Δ	x	+	o	+	x	x
Recycling	+	+	+	+	x	x	x
Processing	thermoplastic	thermoplastic	thermoplastic	thermoplastic	thermoset	thermoset	thermoset

*Property values are typical + Excellent o Good Δ Fair x Poor

Drug delivery – syringes

Delivering compatibility and safety, high-performance, and protective properties, Santoprene TPV meets the needs of syringe plunger and pre-filled syringe sealing applications. Mounted on the end of the plunger, Santoprene TPV syringe seals provide a leak-proof seal with the syringe barrel, while optimizing plunger movement for accurate dosage control, ease of injection, and patient comfort. The low compression set and long-term sealing performance of Santoprene TPV helps prevent contamination from outside elements and maintain drug integrity.

Packaging – bumpers, tube gaskets, caps, closures

Using Santoprene TPV, manufacturers can create components that contribute to tamper-resistant and child-proof packaging, while lessening the risk of content spoilage. Offering strength, elastic recovery, chemical and high temperature resistance, and colorability properties, Santoprene TPV meets the highest standards required for specimen tube gaskets, bumpers, caps, and closures used in healthcare, medical and pharma packaging.

"In medical and drug delivery devices and packaging, trusted material solutions are required. They need to meet regulatory requirements, deliver design innovation and durability that elevates a patient's experience, while extending a product's lifecycle through resistance to harsh conditions. And supply security is important. Santoprene TPV delivers solutions that fully comply with the standards required for a broad range of applications."

Table 2: Santoprene® TPV medical (MED) grades - Typical values

Santoprene TPV medical (MED) grades	Color	Shore A hardness scale (+/-5)	Specific gravity (at 23°C)	Tensile strength (MPa)	Elongation at break (%)	Modulus at 100% (MPa)	Comp. set (168h at 23°C)	Sterilization			Process injection extrusion	Bonding substrate
		ISO 868	ISO 1183	ISO 37	ISO 37	ISO 37	ISO 815	Steam	Gamma	ETO		
Santoprene TPV 181-55MED	black	59	0.98	6.1	440	2.1	19%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 281-55MED	natural	60	0.96	4.9	410	2.0	20%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 281-64MED	natural	71	0.95	6.1	432	2.7	27%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 8281-35MED	natural	38	0.91	2.6	330	0.9	13%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 8281-45MED	natural	49	0.91	3.6	440	1.3	12%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 8281-55MED	natural	59	0.92	5.2	430	2.0	14%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 8281-65MED	natural	68	0.92	5.9	480	2.4	19%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 8281-75MED	natural	79	0.92	7.8	510	3.6	24%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 8281-90MED	natural	94	0.93	13	650	6.7	36%	✓	✓	✓	I, E	Polyolefin
Santoprene TPV 8181-55B1MED	black	57	1.03	4.6	600	1.5	-	✓	✓	✓	I, E	PC/ABS/ COPE
Santoprene TPV 8281-55B1MED	color-able	57	1.03	4.0	600	1.6	-	✓	✓	✓	I, E	PC/ABS/ COPE

Table 3: Santoprene TPV medical (MED) grades – Biocompatibility testing

Santoprene TPV medical (MED) grades	Cytoxicity	Muscle implantation		Intracutaneous		Maximization sensitization	Systemic toxicity		USP 381 Elastomeric closures for injections - heavy metals	EP Monograph 3.2.9 - extractable heavy metals
	ISO 10993-5	USP VI	ISO 10993-6	USP VI	ISO 10993 -10	ISO 10993-10	USP VI	ISO 10993-11	USP	--
Santoprene TPV 181-55MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 281-55MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 281-64MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 8281-35MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 8281-45MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 8281-55MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 8281-65MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 8281-75MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 8281-90MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 8181-55B1MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Santoprene TPV 8281-55B1MED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Active US FDA Drug Master Files
12719: Santoprene TPV 8281 / 8281 MED grades
17690: Santoprene TPV 181-281 MED grades
34837: Santoprene TPV 8281 / 8181 (B) MED grades

Notes:
ISO 10993 and USP VI testing is done on representative grades
Cytotoxicity and heavy metals testing is done on a yearly basis on representative grades

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Bringing science to life

Through value chain collaboration, Santoprene TPV has been fulfilling the needs of the global medical, healthcare and pharmaceutical industries for decades. With support ranging from material selection and medical device, drug delivery and packaging design assistance to tooling recommendations and local processing support, Celanese can help elevate your medical device, drug delivery and packaging applications to the next level.

Contact us for more information:
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