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Medical products guide

Santoprene® thermoplastic vulcanizate (TPV) medical (MED) product grades meet the requirement of USP Class VI and ISO 10993-1 Biocompatibility. Active U.S. FDA Drug Master Files (DMFs) are held for all Santoprene TPV MED product grades. Ideal for medical device applications, these products can be used in a range of environments, and can be sterilized (steam, ethylene oxide, and gamma radiation) with minimal degradation.

Table 1: Santoprene TPV Medical (MED) grades - Typical values

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)	Sterilization			Process injection extrusion	Bonding substrate	Typical applications
		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	Syringe tips, seals, gaskets
Santoprene TPV 281-55MED	natural	60	0.96	4.9	410	2.0	20%	✓	✓	✓	I, E	Polyolefin	Syringe tips, seals, gaskets
Santoprene TPV 281-64MED	natural	71	0.95	6.1	432	2.7	27%	✓	✓	✓	I, E	Polyolefin	Peristaltic pump tubing
Santoprene TPV 8281-35MED	natural	38	0.91	2.6	330	0.9	13%	✓	✓	✓	I, E	Polyolefin	Syringe tips, seals, gaskets
Santoprene TPV 8281-45MED	natural	49	0.91	3.6	440	1.3	12%	✓	✓	✓	I, E	Polyolefin	Syringe tips, soft touch grips, seals, gaskets
Santoprene TPV 8281-55MED	natural	59	0.92	5.2	430	2.0	14%	✓	✓	✓	I, E	Polyolefin	Syringe tips, soft touch grips, seals, gaskets, wire jacketing
Santoprene TPV 8281-65MED	natural	68	0.92	5.9	480	2.4	19%	✓	✓	✓	I, E	Polyolefin	Soft touch grips, seals, gaskets, wire jacketing, peristaltic tubing
Santoprene TPV 8281-75MED	natural	79	0.92	7.8	510	3.6	24%	✓	✓	✓	I, E	Polyolefin	Caps and closures, bumpers, covers, wire jacketing
Santoprene TPV 8281-90MED	natural	94	0.93	13	650	6.7	36%	✓	✓	✓	I, E	Polyolefin	Caps and closures, bumpers, covers, wire jacketing

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- Excellent long term compression set and stress relaxation for sealing performance
- Lower density (~20%) than thermoset can reduce part weight
- Better stability at higher temperatures and chemical resistance than styrenic TPEs
- Colorable and non-hygroscopic (no pre-drying required) product availability
- High precision molding; eliminates deflashing or trimming
- Over-molding and part consolidation options with 2K injection molding
- Faster cycle times and no mixing or curing versus thermoset rubber
- Potential for in process and end of life recycling

Table 2: Santoprene TPV Medical (MED) grades - Improved performance when compared with other elastomers

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

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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	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Active US FDA Drug Master Files
12719: Santoprene TPV 8281 / 8281 MED grades
17690: Santoprene TPV 181-281 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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Contact us for more information:
santoprene.com
santoprene.answerperson@celanese.com

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