

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
Santoprene TPV 8181-55B1MED	black	57	1.03	4.6	600	1.5	-	✓	✓	✓	I, E	PC/ABS/COPE	Medical wearables, seals, gaskets, soft touch grips
Santoprene TPV 8281-55B1MED	colorable	57	1.03	4.0	600	1.6	-	✓	✓	✓	I, E	PC/ABS/COPE	Medical wearables, seals, gaskets, soft touch grips

Medical products guide

- 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
- Compatible with PP; Bonding MED grades compatible with PC, ABS, COPE, etc.
- 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	+	○	+	○	+	○	+
Oil resistance	Δ	×	+	○	+	×	×
Recycling	+	+	+	+	×	×	×
Processing	thermoplastic	thermoplastic	thermoplastic	thermoplastic	thermoset	thermoset	thermoset

*Property values are typical + Excellent ○ Good Δ Fair × Poor

Medical products guide

Table 3: Santoprene TPV Medical (MED) grades - Biocompatibility testing

Santoprene TPV Medical (MED) grades	Cytotoxicity		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

Date modified - 01/13/2022

This publication was printed based on Celanese's present state of knowledge, and Celanese undertakes no obligation to update it. Because conditions of product use are outside Celanese's control, Celanese makes no warranties, express or implied, and assumes no liability in connection with any use of this information. Nothing herein is intended as a license to operate under or a recommendation to infringe any patents. Celanese®, registered C-ball design and all other trademarks identified herein with ®, TM, SM, unless otherwise noted, are trademarks of Celanese or its affiliates.

Copyright © 2022 Celanese or its affiliates. All rights reserved.

Contact us for more information:

santoprene.com

santoprene.answerperson@celanese.com

SAN-001-MedicalGuide-EN-SS-0623