SUMITOMO RUBBER INDUSTRIES

Medical Rubber Components

Global Network

We provide safe, high-quality medical rubber components that support overall public health.
Our know-how and the advanced polymer and rubber processing technologies that we have developed over many years in the business are embodied in our high-performance products,which must meet the strictest quality requirements.
With our acquisition of a Swiss medical rubber component manufacturer in January of 2015,
we are actively accelerating the global development of our medical supply business.

Company Outline

Company Name :
Sumitomo Rubber Industries, Ltd.
Address : 3-6-9 Wakinohama-cho, Chuo-ku, Kobe, Hyogo 651-0072, Japan
Incorporated : 1917
Group consolidated subsidiaries :
75 companies (32 in Japan)
Consolidated employees : 30,224
Paid-in Capital :
42.7 billion yen (as of the end of 2014)

Head Office

Kakogawa Factory 2010 Began production

Izumiohtsu Factory 2000 Began production

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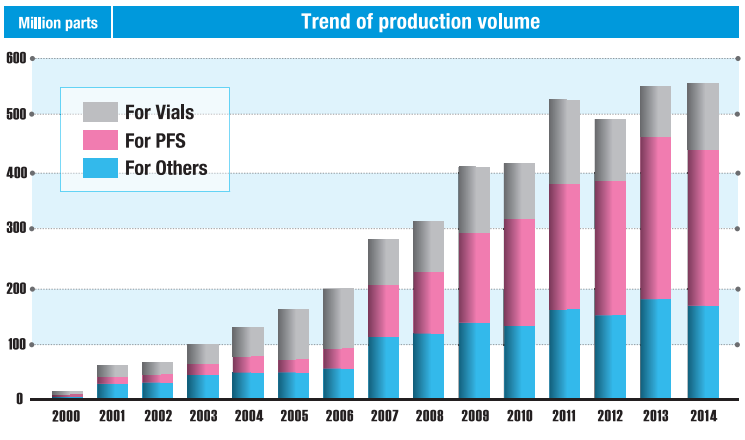
Company Profile

Ever since our founding in October of 1909 as the first modern rubber factory in Japan,
we at Sumitomo Rubber Industries have worked continuously to produce advanced, environmentally friendly
products based on rubber technology to support more comfortable lifestyles for people in a wide range of settings.
For medical rubber products, we supply high-quality and high-performance products in Japan,
and invited Lonstroff AG into our group as the strong partner in Europe in January of 2015.
Now we organize a system to supply the high quality products from Japan and Switzerland to people all over the world.

Our rubber products for medical use are constantly evolving as new values begin to define a new era.

Sumitomo Rubber's medical rubber conponents grew out of a fusion between Sumitomo Rubber Group's own technology and low extractable component technology, as used in our tyre, sports, and industrial divisions. By providing high-quality rubber products for medical use, we aim to make your life healthier and easier.



Trend of production volume

Polymers, rubber-processing technology, and low extractable component technology help define the need for advanced technology.

Sumitomo Rubber has applied its knowhow in the tyre field to the research and development of rubber made, medical products. Using computerized design analysis, we have succeeded in creating more effective, higher-quality products. And with cutting-edge equipment, we have achieved a faster and more accurate production process.

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Product Overview

Outstanding safety and reliability for all kinds of medical products and processes.

■ Stoppers for vial cap

■ Medical rubber parts and parts for infusion bag

●Packing ●Components for IV bottles
●Rubber parts for medical divices

■ Plunger stoppers for PFS

■ Tip caps for PFS

Aiming to be the best in terms of quality control and reliability, the fundamental elements at Sumitomo Rubber are cleanliness and safety.

Using a unique one-way production process, we protect against cross contamination by carrying out each part of the process into a separate work room. And through the introduction of the latest, automatic inspection equipment, we also ensure against mixed up different types and shapes of products. It is thanks to this scrupulous quality control system that we have been able to meet the international standards for acquisition of ISO9001 certification.

■ Production process

Mixing

Sheeting

Forming

1st Inspection

Class C Zone

Punching

Wash

Final Inspection

Packaging

Class C Zone | Class B Zone | Class A Zone

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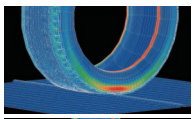
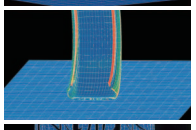
Medical Rubber Components

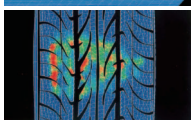
Dynamic Simulation Technology

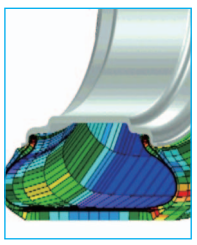
Computer Aided Engineering

Dynamic Simulation for medical rubber parts are based on Sumitomo's "Digital Rolling Simulation (DRS)" technology. DRS is the tyre design technology for predicting tyre movement. It can be applied to the simulation of tip cap and plunger stoppers for PFS(Pre-filled syringes) and vial caps.









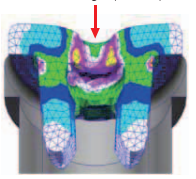
Penetration Force - Dynamic

Design A (Old)

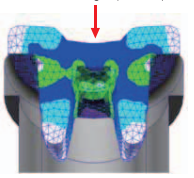
Design B (Current)

Needle Penetration Simulation

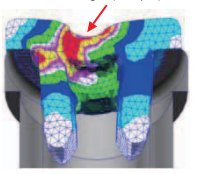
Needle Angle (vertical)



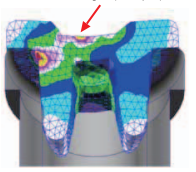
Needle Angle (vertical)



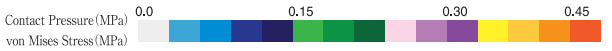
Needle Angle (oblique)



Needle Angle (oblique)

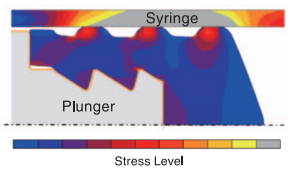


New Design could reduce the Penetration Force by needle with vertical angle and even with oblique angle.

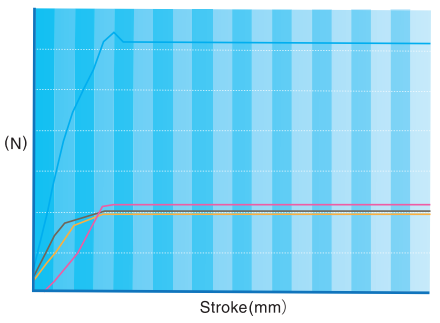


Sliding Resistance - Dynamic

Relation between profile and sliding resistance can be simulated.

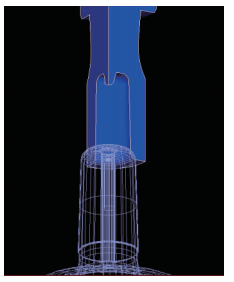


Sliding Force

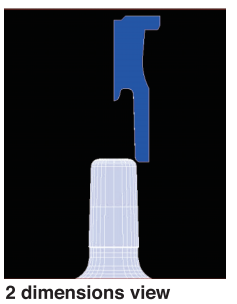


Pull-out Resistance

Cap design and pull-out resistance simulation

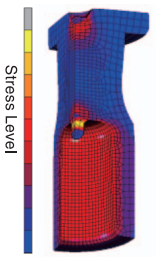


3 dimensions view

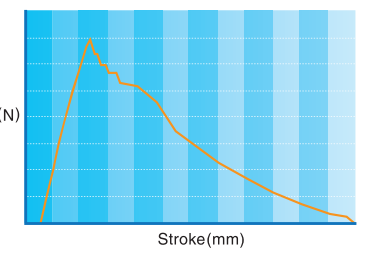


2 dimensions view

Stress Distribution



Pullout Resistance



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Formulation Principle

From the safety point of view, listed substances are not contained in our formulation.

Zinc derivatives	Molecular Sulfur	Secondary Amine
Bisphenol A	Alkyl phenol	2-MBT（2-Mercaptbenzothiazole）
Natural rubber and protein	BSE origin	

Sumitomo's typical formulations

Formulation#	F-100A	P-101A	P-14X	L-200	L-30X
Typical Usage	Lyophilization stopper	Plunger stopper and Tip cap	Tip Cap	Infusion stopper	Vial cap for oily drug
Main Polymer	CIIR	CIIR	CIIR/diene	IR	NBR
	CIIR : Chlorobutyl, IR : Isoprene Rubber, NBR : Nitrile Rubber				
USP/EP/JP	pass	pass	pass**	pass**	pass**
	** : confirmed only JP 7.03				
	note : USP 381 / EP 3.2.9 / JP 7.03				
Hardness	50	50	55	35	60
DMF resistered	Yes	Yes	No	Yes	No
Charactaristics	ULTRA LOW EXTRACTABLE and low hygroscopiy	ULTRA LOW EXTRACTABLE Low Gas&Moisuture Permeability	EOG stealizable	Superior Resealing / Coaring	Oil resistance

All data are typical, not guaranteed.

Physicochemical test data

EP 8.0 3.2.9

Formulation #		F-100A	P-101A
Typical Usage		Lyophilization	Stopper
Items	Specification	Results	
Appearance - Clarity	Not more opelescent than reference II	Pass	Pass
Appearance - Coloraion	Not more intensely coloured than reference solution GY5	Pass	Pass
Acidity or alkalinity	<0,3mL 0,01N NaOH <0,8mL 0,01N HCL	< 0.10mL	< 0.10mL
Absorbance	Not more than 0.2	< 0.01	< 0.01
Reducing substances	< 3.0mL	< 0.5mL	< 0.5mL
Ammonium	≦ 2ppm	Pass	Pass
Extractable Zinc	≦ 5μg/mL	< 1μg/mL	< 1μg/mL
Extractable heavy metals	≦ 2ppm	Pass	Pass
Residue on evaporation	≦ 2mg	< 1.0mg	< 1.0mg
Volatile sulfides	Not more intense that than of the standard	Pass	Pass

All data are typical, not guaranteed.

JP 7.03

Formulation #		F-100A	P-101A	P-14X	L-200	L-30X
Typical Usage	Specification	Lyophilization	Stopper	Cap	Infusion stopper	Vial cap for oily drug
Apperance	Clear and colorless	Pass	Pass	Pass	Pass	Pass
Transmittance 430nm	>99.0 (%)	100	100	99.9	100	99.9
Transmittance 650nm	>99.0 (%)	100	99.9	99.9	100	99.9
PH Acidity or Alkalinity	<±1.0	0.0	0.0	-0.1	+0.1	+0.4
Extractable Zinc	<1.0 (ppm)	N.D.	N.D.	N.D.	N.D.	N.D.
Reducing Substance KMnO4	<2.0 (mL)	0.3	0.2	0.4	1.4	1.8
Absorbance (UV)	<0.20	0.01	0.01	0.01	0.04	0.04

All data are typical, not guaranteed. N.D. = Not Detected