NuSil® Medical Grade Silicones

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Agenda

01
Who we are

02
Our areas of focus

03
Defining Medical Grade Silicones

04
Summary

Our unique heritage provides a strong foundation for future success

Founded in 1904, a global manufacturer of high-purity materials for the production and research needs of customers in the biotechnology, pharmaceutical, medical device, diagnostics, aerospace & defense, and semiconductor industries.

Founded in 1852, a global distributor with an unmatched range of laboratory products and services—millions of SKUs and comprehensive service solutions from custom kitting and manufacturing to bioprocessing are offered.

Founded in 1979, Avantor's® NuSil brand has set the global standard in medical- and space-grade silicones, advancing purity and quality while redefining expectations in customer care.

Strong science and innovation supports advanced industries

BIOPHARMA

Broad portfolio of cGMP materials that meets stringent global regulatory and industry best practice standards

BIOMATERIALS

Market leading medical grade silicones for use in the body, on the body or in contact with the body.

ADVANCED TECHNOLOGIES

Innovative, high-purity materials including both NuSil™ silicones and J.T.Baker® brand chemistry platforms engineered for the most demanding applications.

RESEARCH & DIAGNOSTICS

Avantor® has been helping our customers achieve groundbreaking research that has reshaped the world with J.T.Baker® and BeneSphera™ brands.

Avantor® NuSil™ brand biomaterials

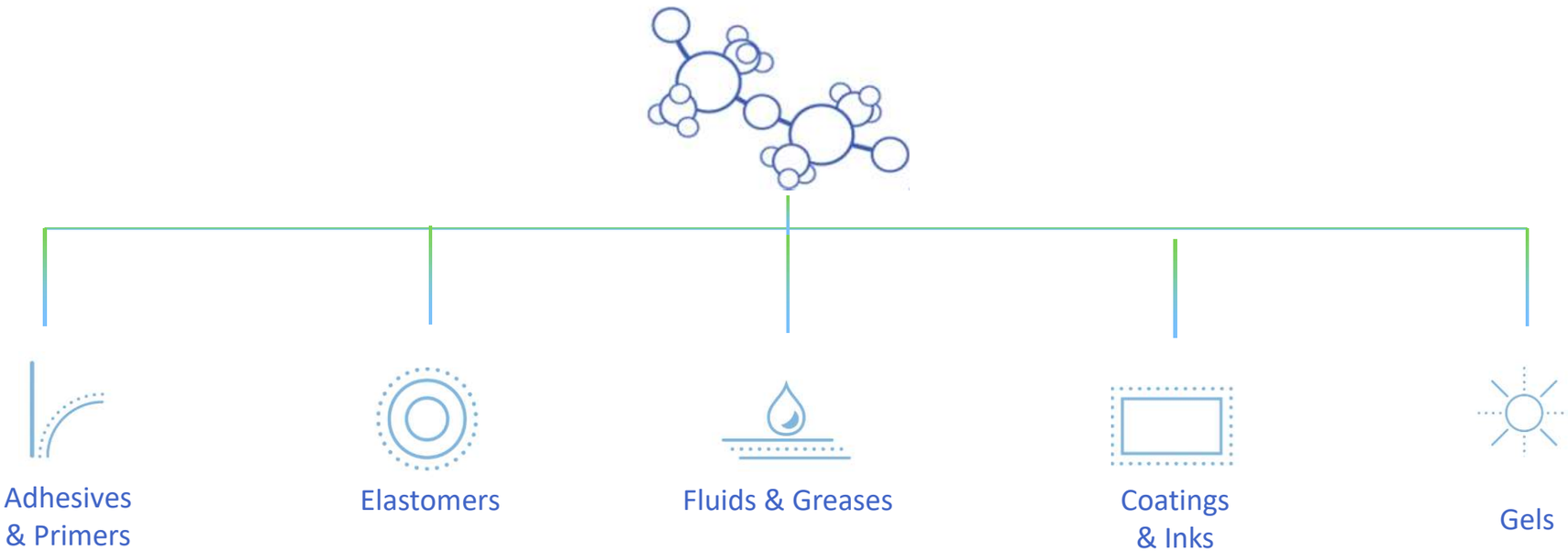
KEY CAPABILITIES

- Leader in medical-grade silicone
- Committed to supplying the medical device industry and long heritage of silicone innovation
- Custom and off-the-shelf silicones for medical devices
- Highly purified to meet industry demands
- Deep regulatory expertise assisting customers to complete regulatory clearance

Silicone is highly biocompatible:
60+ years in medical applications

Silicone market segments

NuSil medical grade silicones in many forms



Innovative solutions

Ultra high strength elastomer

Electrically conductive elastomers

Self-matting LSR

Drug delivery – Treylst

Liquid additive manufacturing (LAM)

In situ

Defining Medical Grade Silicones

3 KEY FACTORS:

1. Intended Use
2. Manufacturing Controls
3. Testing & Regulatory Support

Intended use of medical grade silicone

Class VI Line

- Implantable (≤ 29 days), insertable, external contact, non-contact external
- USP Class VI biological testing

Premium Care Line

- Implantable (≤ 29 days), insertable, external contact, non-contact external
- Expanded biological testing

Implant Line

- Silicones may be considered for use in devices implanted for a period of greater than 29 days
- Comprehensive biological testing

Manufacturing medical grade silicones

Testing

Verifying purity & consistency of production

Continuous improvement

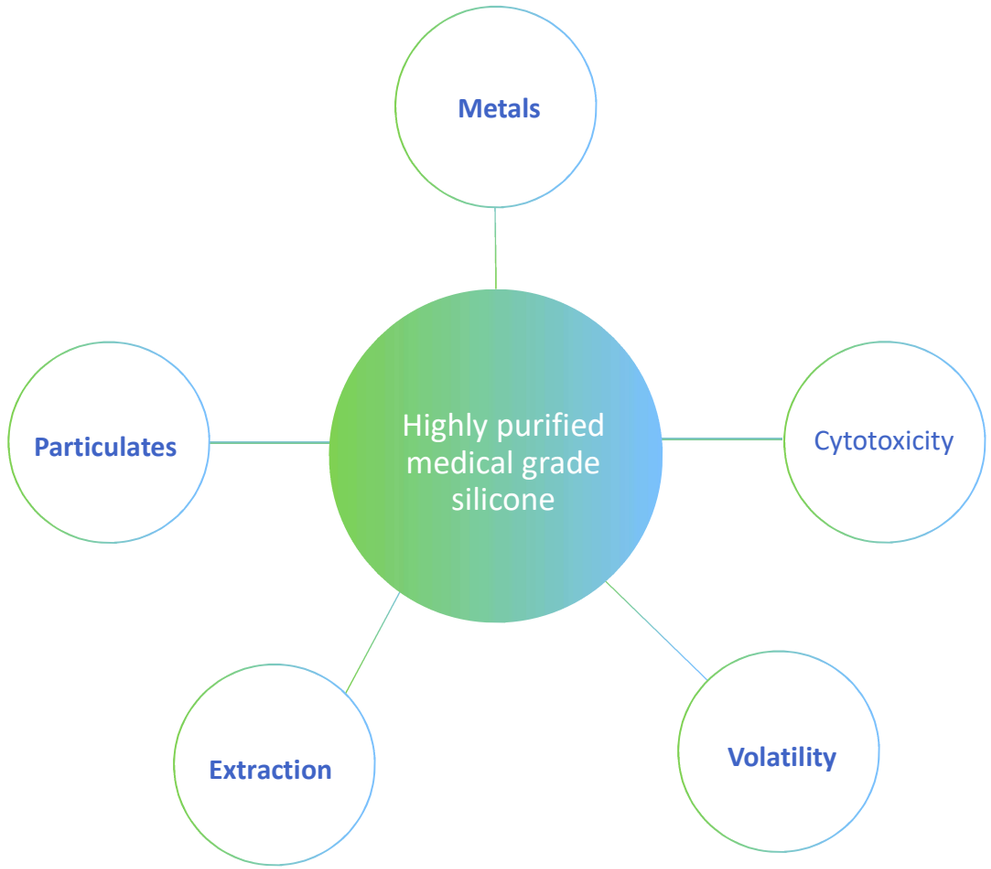
Testing & Regulatory Support

Verifying purity through testing

- Biological testing aligned with ISO 10993 & USP Class VI standards
- Foundation based on:
  - ISO 14949
  - ISO 14607

Extensive regulatory support that encompasses:

- 700+ Master File (MAF) submissions with FDA
- In-house FDA subject matter experts to support customers during regulatory review cycle
- Quality system combines best of ISO 9001, AS 9100 and select cGMP standards



Understanding NuSil medical grade products

	Class VI Line	Premium Care Line		Implant Line	
Description	Standard packaging and class VI testing for high volume applications	For applications that require a higher level of regulatory support, testing and specialized packaging		For implant applications with the highest level of regulatory support and testing	
Use	Implantable (≤ 29 days), insertable, external contact, non-contact external	Implantable (≤ 29 days), insertable, external contact, non-contact external		Implantable (>29 days)	
Quality System & Regulatory Support	Developed for implant line, but applied across portfolio				
MAF Supported	—	**Standard products** Yes	**Custom products** Available upon request	**Standard products** Yes	**Custom products** Available upon request
Biological Testing	USP Class VI	Select ISO 10993		Full ISO 10993	
Cytotoxicity	One time qualification test	Tested per lot		Tested per lot	
Trace metals	—	Per NuSil Specification		Per NuSil Specification & ISO 14949 requirements on select products	
Customization	Yes	Yes		Yes	
Packaging	Controlled Environments	Controlled Environments		Controlled Environments	

Summary

Defining medical grade silicones based on 3 key factors:

1. Intended use
2. Manufacturing Controls
3. Regulatory support & testing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