



# NuSil Silicone Biomaterials Regulatory Support

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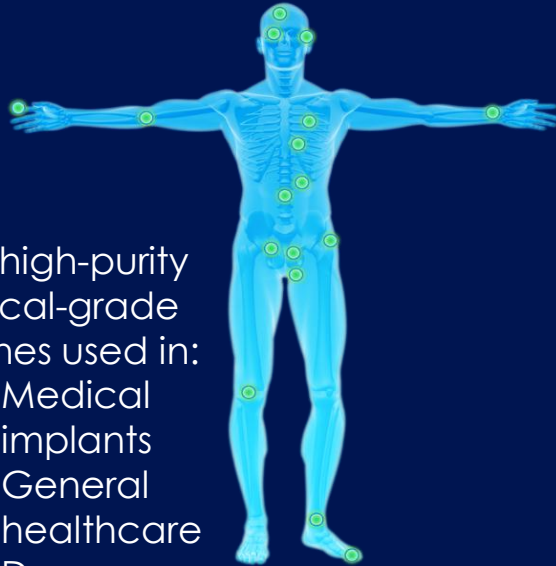
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# NuSil® brand silicones in two primary segments

## Biomaterials

SILICONE TECHNOLOGY ENHANCING THE LIVES OF PATIENTS WORLDWIDE



- Ultra-high-purity medical-grade silicones used in:
  - Medical implants
  - General healthcare
  - Drug delivery applications

**40+**  
**YEARS**

supporting biomaterials, aerospace & defense customers

Supplier to

**9 of 10**

medical device companies

Supplier to

**100%**

of top defense contractors

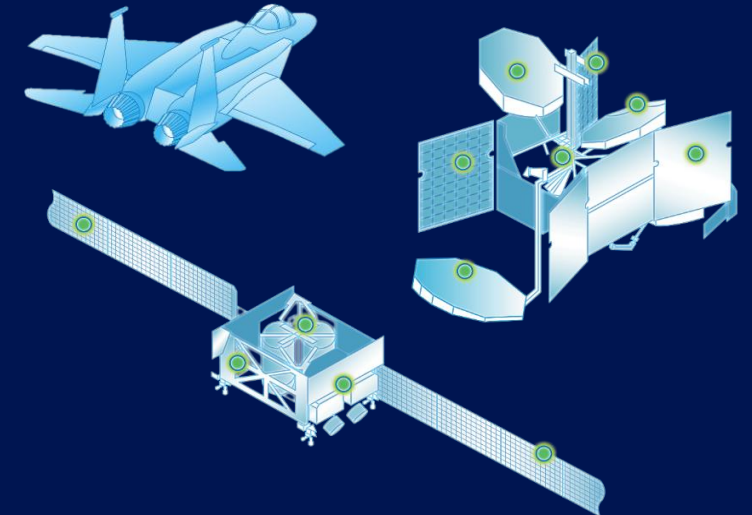
**550+**

innovation projects in pipeline

## Advanced Technologies

HIGHEST LEVELS OF PURITY FOR MISSION-CRITICAL APPLICATIONS

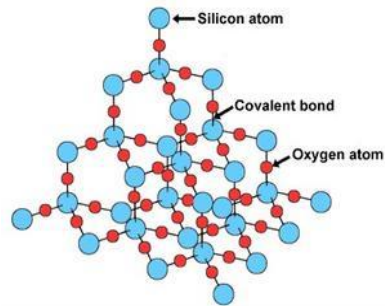
- Antennas
- Cameras
- Sensors
- Solar panels
- General assembly
- Aircraft paints, coatings, fillers and fabricated parts



# What is silicone?



**Silicon**

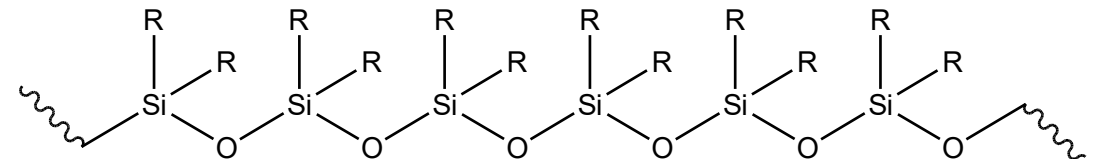


**Silica (silicates, sand)**



**Silicone**

Combines The Best Characteristics  
Of Organic And Inorganic Materials

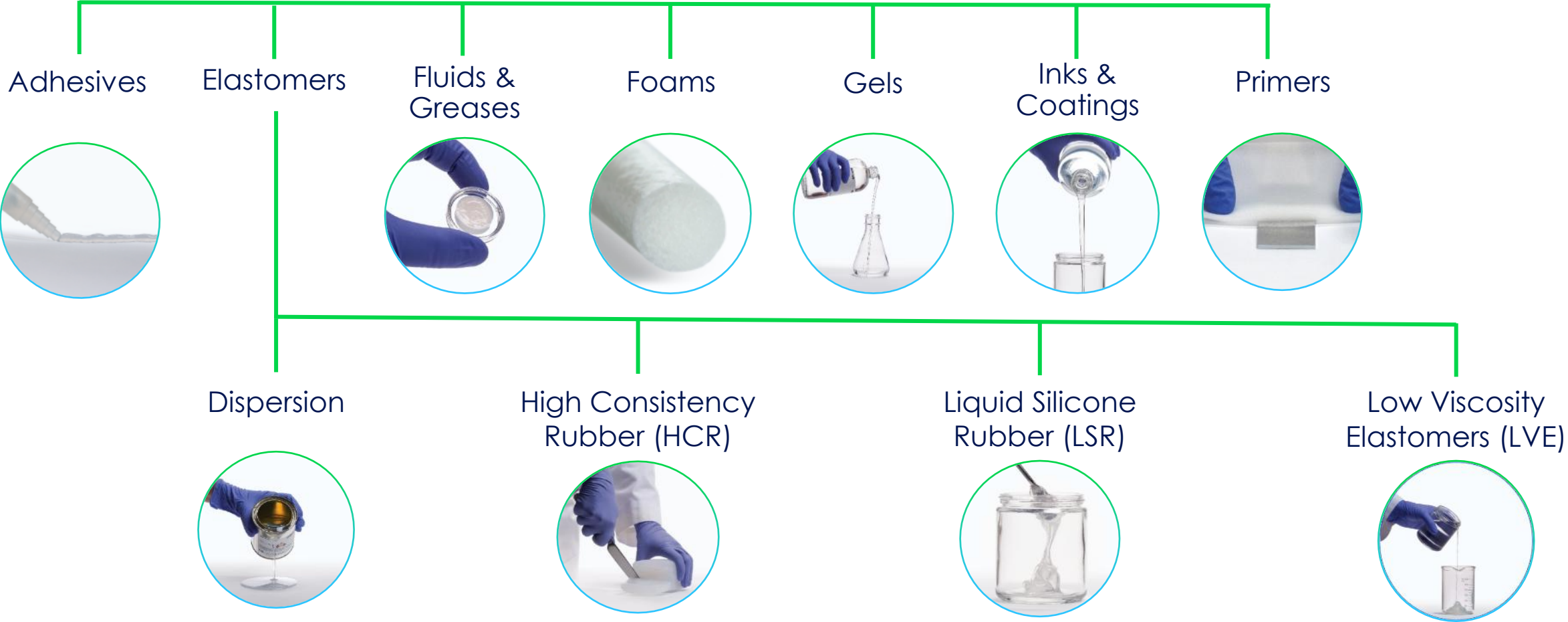


# Key silicone properties

- Biocompatible in a large range of applications
- Chemically stable
- Strong & flexible
- Broad operating temperature range
- Gas permeable
- Low volatility
- Conductive or insulative
- Hydrophobic surface energy
- Other surface mods (lubricious)
- Optically clear to color matching
- Customizable

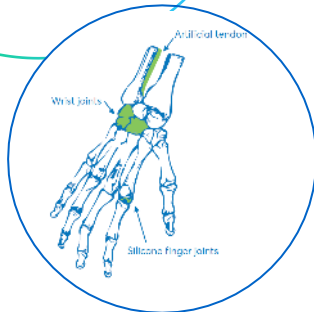


# NuSil silicones in many forms

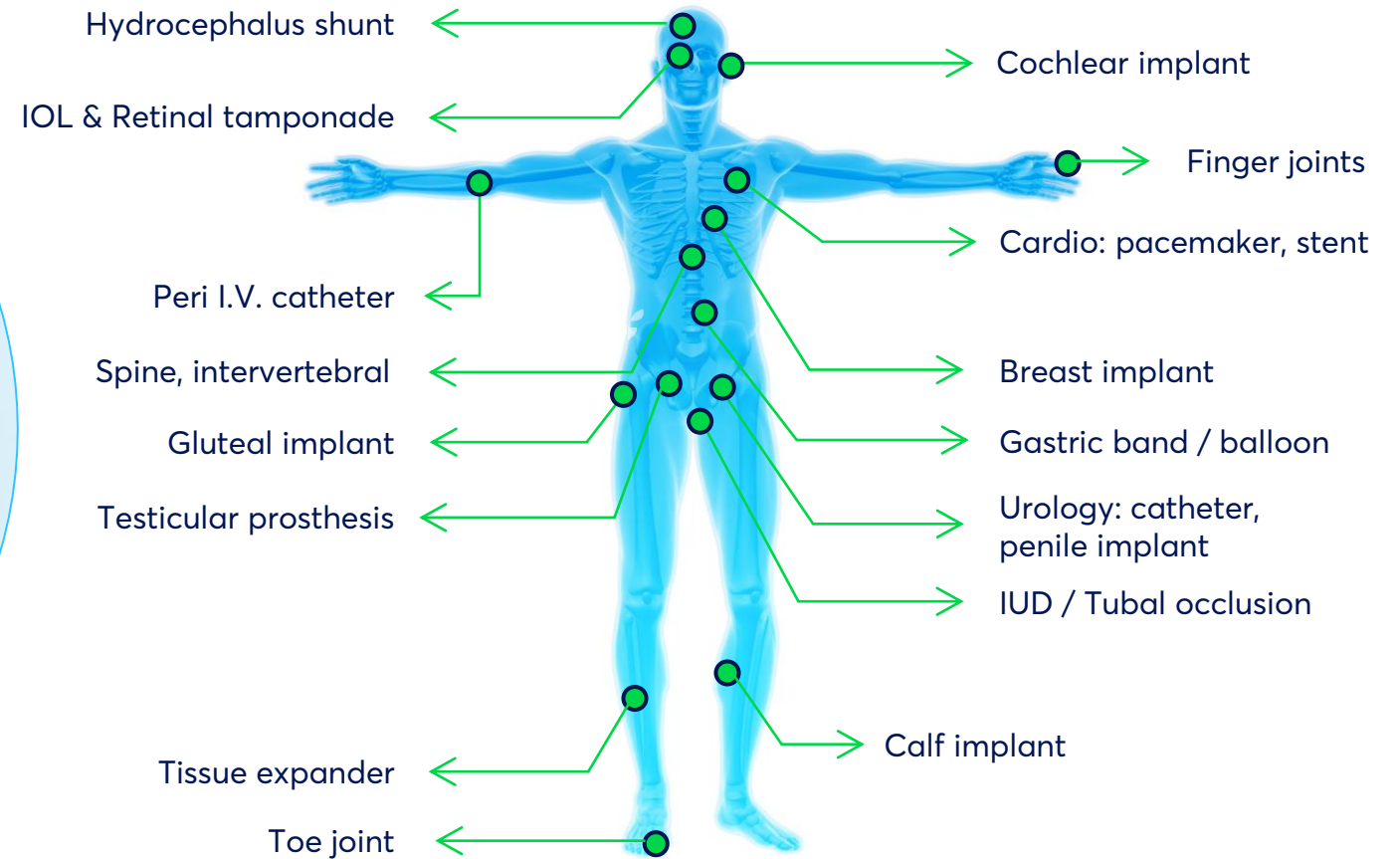
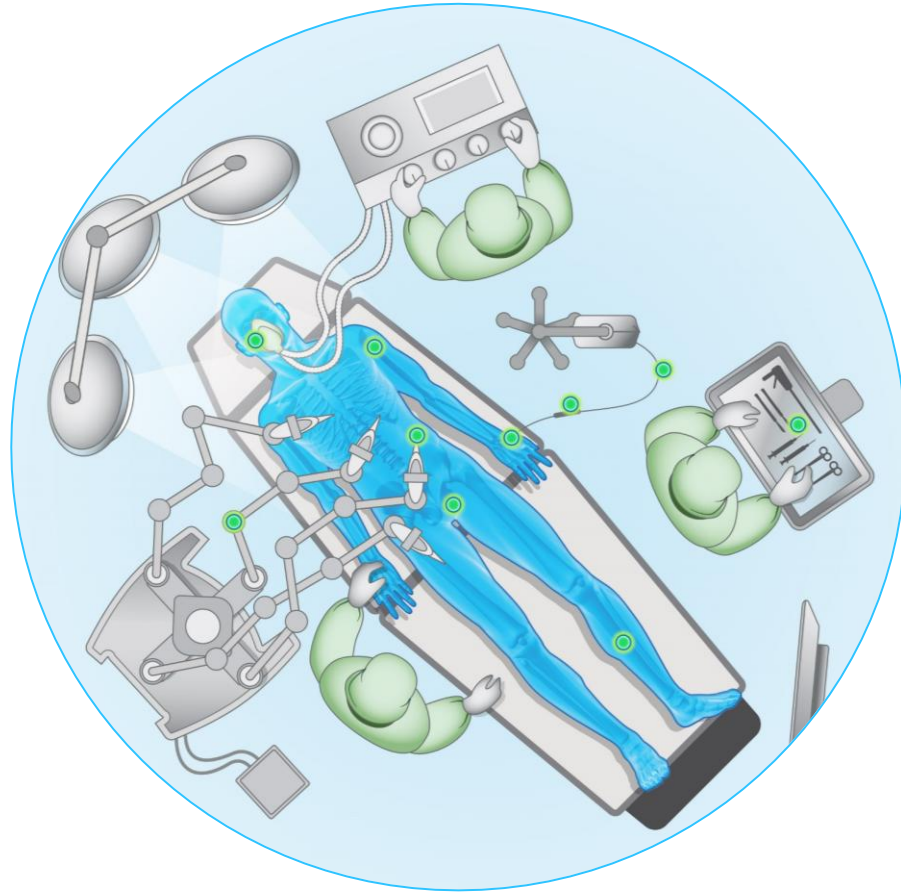


# Choosing a silicone

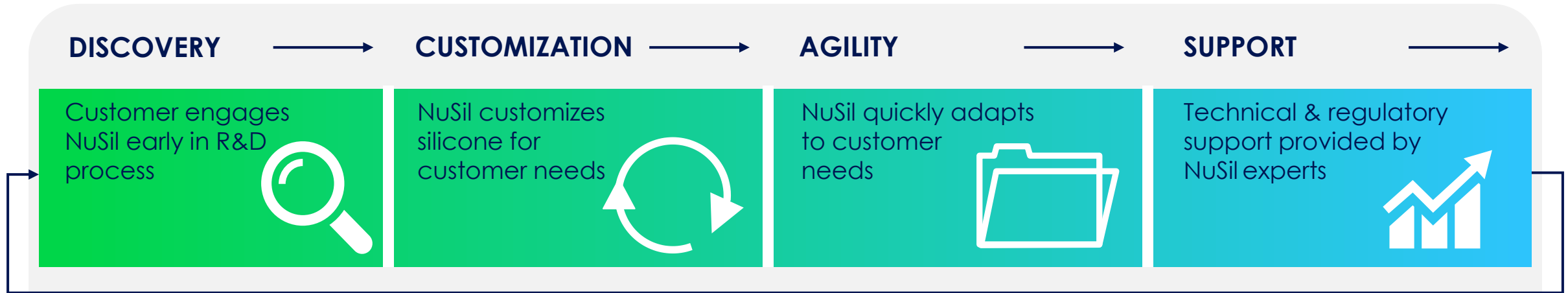
## STEPS IN THE DESIGN PROCESS



# Silicones in the medical industry



# NuSil customizes for application-specific levels of performance



## COLLABORATION TO CREATE LASTING RELATIONSHIPS

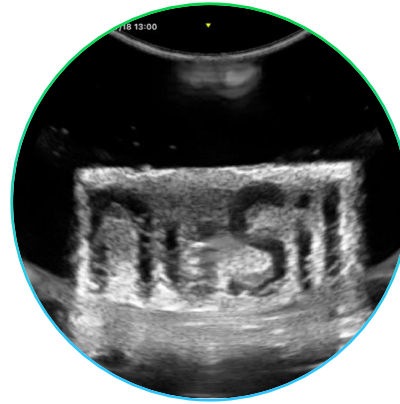
At NuSil, we set science in motion by enabling innovation across the life sciences and technology industries with the highest quality products, services, and solutions to support our customers at every step of their scientific journey.

# Emerging platforms



## PFAS-Free Lubricants

- Fluorine-free biomedical lubricants
- Minimal swell of silicone articles
- Master File support available
- REACH and RoHs compliant
- Customizable viscosity and volatility options



## Echogenic Silicones

- Implantable silicones with modified acoustic properties for visibility under ultrasound
- Improved contrast against soft tissue compared to standard silicone, enhancing visualization for better tracking, placement & performance verifications
- Compatible with existing LSRs, HCRs, and adhesives
- Master File support available



## In-Situ Cure

### *Non-invasive therapies*

- Customized fit for implanted devices
- Easy sterilization with minimal changes
- Minimally invasive procedures with faster recovery
- Tailored silicone formulations for desired performance requirements
- Master File support available

# Regulatory Support – What shapes our approach?

## 3 KEY FACTORS:

- 1 Customer Intended Use
- 2 Material Characterization & Controls
- 3 Testing & Support

# Regulatory Support – Grades to match customer needs



## Class VI Line

- May be considered for implant  $\leq$  29 days, insertable, external contact, non-contact external
- USP Class VI biological testing



## Premium Care Line

- May be considered for implant  $\leq$  29 days, insertable, external contact, non-contact external
- Select ISO 10993 biological testing
- Master File Support



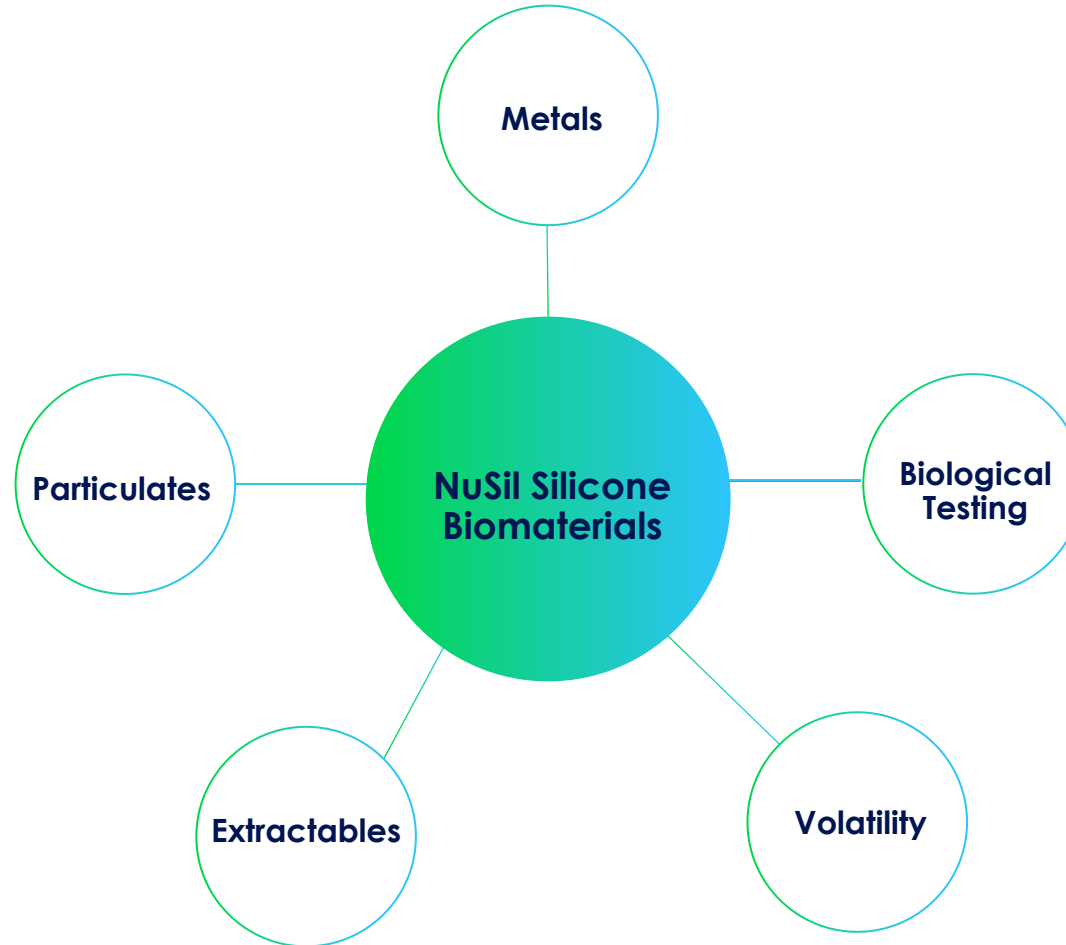
## Implant Line

- May be considered for implant  $>$  29 days, insertable, external contact, non-contact external
- Enhanced ISO 10993 biological testing
- Master File Support

# Understanding NuSil® brand silicone biomaterial grades

	CLASS VI LINE	PREMIUM CARE LINE	IMPLANT LINE
<b>Description</b>	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
<b>Potential Use</b>	Short term implants ( $\leq 29$ days), insertable, external contact, non-contact external	Short term implants ( $\leq 29$ days), insertable, external contact, non-contact external	Long term implants ( $>29$ days)
<b>Quality System &amp; Regulatory Support</b>	Applied across portfolio		
<b>MAF Supported</b>	————	<u>Standard products</u> Yes	<u>Custom products</u> Available upon request
<b>Biological Endpoint Testing</b>	USP Class VI	Select ISO 10993	Enhanced ISO 10993
<b>Cytotoxicity</b>	One time qualification test	Tested per lot	Tested per lot
<b>Trace metals</b>	————	Per NuSil Specification	Per NuSil Specification & ISO 14949 requirements on select products
<b>Customization</b>	Yes	Yes	Yes
<b>Packaging</b>	Controlled Environments	Controlled Environments	Controlled Environments

# Material characterization



# Material controls

## ISO 9001 & AS 9100

Certified QMS ensuring consistent quality

Designed with the user in mind



Stringent starting material requirements



Robust material characterization



Process technology & environmental controls



Packaging process & container design



## Continuous improvement

# Testing and support

## Guided by international standards

- Biological testing aligned with ISO 10993 & USP Class VI standards
- Certified properties informed by:
  - ISO 14949 *Two-part addition-cure silicone elastomers*
  - ISO 14607 *Non-active surgical implants — Mammary implants — Specific requirements*

## Extensive regulatory support that encompasses:

- 750+ Master File (MAF) submissions with FDA
- In-house FDA subject matter experts to support customers during regulatory review cycle
- NuSil's ISO 9001 & AS9100 certified Quality System is well equipped to support FDA regulated customer end-uses with cGMP requirements.

# Thank you



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