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Scientific Explanation on Stability of Silicone Balloon Compared to Isoprene.

■ Isoprene : Organic (hydrocarbon-based)

- **Chemical formula:** C_5H_8
- A hydrocarbon molecule composed only of carbon (C) and hydrogen (H).
- Classified as a typical *organic compound*.
- When polymerized, isoprene becomes polyisoprene (similar to natural rubber), which is used in medical devices as an *organic elastomer*.

■ Silicone : Inorganic backbone (Si–O–Si bond based)

- **Backbone:** Si–O–Si bonds (*siloxane bonds*).
 - This silicon–oxygen backbone gives it *inorganic characteristics*, forming a chain structure distinct from carbon-based compounds.
 - Although side groups such as methyl ($-CH_3$) are attached and can modify properties, silicone is fundamentally an *inorganic polymer*.
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Conclusion

- **Isoprene** = Organic (hydrocarbon-based)
- **Silicone** = Inorganic backbone (Si–O–Si bond based)

Therefore, the reasoning is scientifically valid:

Silicone balloons are inorganic, chemically stable, and superior in drug stability, whereas isoprene balloons are organic and comparatively less stable.

Property	Isoprene Balloon (Organic)	Silicone Balloon (Inorganic)
Chemical Formula / Backbone	C ₅ H ₈ , carbon–carbon hydrocarbon chain with C=C double bonds	Si–O–Si siloxane backbone (inorganic chain)
Classification	Organic compound	Inorganic polymer
Reactivity	Prone to oxidation, UV, ozone, and chemical degradation	Chemically inert, resistant to oxidation and hydrolysis
Drug Stability	Higher risk of adsorption, absorption, or interaction with drugs	Minimal adsorption, maintains drug concentration and potency
Leachables / Extractables	Requires stabilizers and additives (risk of leachables affecting drug quality)	Very low risk; widely recognized for biocompatibility and low extractables
Biocompatibility	Good, but potential concerns due to additives	Excellent, long clinical history in implantable medical devices
Long-term Stability	Can harden, embrittle, or lose elasticity over time	Durable, maintains elasticity and performance over long use

Please refer to below links also.

“Development in Silicone Material for Biomedical Applications”

Summarizes properties of silicone materials in biomedical applications. Highlights biocompatibility, chemical stability, bio-durability, and thermal stability.

([ResearchGate link](#))

“Silicone-based biomaterials for biomedical applications” (M. Zare et al., 2021)



Comprehensive review of silicone biomaterials, emphasizing chemical and physical stability, elasticity, and biocompatibility. ([Wiley Online Library link](#))

In over 30 years of silicone production in elastomeric medical devices, there have never been any reported stability issues or adverse drug reactions associated with silicone balloons.

We hereby confirm the above.

A handwritten signature in black ink, which appears to read "Kiwoon Kim".

S&S MED Co., LTD.

Name: Kiwoon Kim

Title: CEO