

SurFACTS

in Biomaterials

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Thank You to Our Members!

From President Landon Nash



Welcome to the Winter 2023 edition of the Surfaces in Biomaterials SurFACTS newsletter! It has been a privilege to be a part of this foundation since graduate school, and I'm honored to be this year's President. The emphasis that this foundation puts on cross-pollinating ideas and participation between Academia and Industry has always made it near and dear to me, and I plan to continue fostering these collaborations between Professors, Students, and Medical Device Industry professionals.

The November 2022 Portland BiolInterface Workshop and Symposium was our first in-person event in over 3 years, and it was a pleasure to finally reconnect with old colleagues and the greater biomaterials field. I wanted to take time to thank our past presidents Rob Diller and Angie DiCiccio for helping all of us to stay nimble and successfully navigate multiple years of pandemic-related Foundation hurdles.

Thanks to their leadership, and the insight from the SIBF Board of Directors, the Foundation has emerged from those unprecedented times in a strong position,

and I endeavor to continue growing and strengthening our SIBF community.

The entire SIBF Board looks forward to seeing everyone at the 2023 BiolInterface Workshop and Symposium at the Catamaran Resort in San Diego, Monday 9/25/23 - Wednesday 9/27/23. The program is just starting to take shape, but we are excited to include an Orthopedic session to highlight recent advances in this space. Please reach out to any of the SIBF Board members if you are interested in chairing a session in the biomaterials/surface science fields, being an exhibitor, or sponsoring any component of the 2023 BiolInterface event. You can find more details about these opportunities on our website: www.surfaces.org

On behalf of the Surfaces in Biomaterials Foundation, I wish you and your families a prosperous 2023. Please stay tuned for future SurFACTS newsletters, BiolInterface 2023 updates, and other SIBF events.

Choosing the Right Silicone Adhesive for Your Medical Device

Elkem Silicones USA Corp.

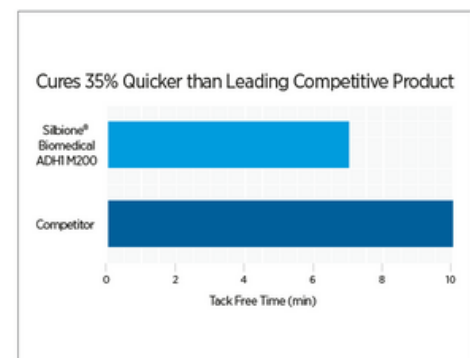
In most medical devices currently produced today the combination of different material substrates makes choosing the correct adhesive a critical step in device design. It is necessary to find the right balance between performance, manufacturability, and total cost. Adhesive chemistry in medical device is diverse, including cyanoacrylates, epoxies, polyurethanes, and solvent welding. While each of these systems has their benefits, many times silicone adhesives are the material of choice due to their excellent biocompatibility, adaptability, and performance. Silicone Adhesives can be used for both assembly of medical devices and sealing critical components.

Silicone adhesives can also be supplied in different forms and choosing the right variation of silicone adhesive is also a critical step. The most common version used today is an RTV-1. These materials are single component and don't require any mixing.

They begin to cure upon exposure to atmospheric moisture. While relatively easy to apply, they can sometimes be slow to cure while offering an adequate bond which can slow down the production process of medical devices. To address some of these concerns Elkem Silicones has worked with our customer base to develop and launch a next generation RTV1 Material referred to as Silbione™ Biomedical ADH1 M200. We have found that tack free time can be cut in half vs. comparable products under ambient conditions (without the addition of humidity) and full cure can be achieved with a 35% improvement on time. Lastly, due to health and environmental concerns, we replaced the traditional tin catalyst traditionally used in mono-component silicone adhesives with an alternate curing mechanism. This new adhesive has shown excellent cohesive bond strength to silicone, polyester, various metals, polyurethanes, and many other traditional and new substrates being used in the industry today.

Silbione™ Biomedical ADH1 M200 profile

Properties	Unit	Value
Appearance		Colorless, clear to translucent
Tack Free Time	Minutes	8
Durometer	Shore A	26
Tensile Strength	Mpa - psi	3.9 - 570
Elongation	%	668
Tear Strength	kN/m - ppi	11 - 64
Specific Gravity		1.06



Choosing the Right Silicone Adhesive for Your Medical ...

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Two-part RTV silicone adhesives have been gaining popularity over the years in the production of next generation medical devices. The product profiles can be adjusted via formulation to a variety of cure times and temperatures. This allows flexibility in terms of device design and can offer a more robust and cost-effective manufacturing process. A mechanical or physical bond between various substrates can sometimes be achieved in seconds or minutes as opposed to hours with some RTV-1 products. Also, these materials do not require exposure to air.

We will explore Elkem Silicones newest addition into our RTV-2 adhesive family referred to as Silbione™ Biomedical ADH2 M213, available in a standard cure version, FC (fast cure) version and SLC(slow cure version). This material is a 1:1 mix ratio platinum catalyzed poly addition reaction.

	Measurement standard	Silbione™ BIOMEDICAL ADH2 M213 QC	Silbione™ BIOMEDICAL ADH2 M213	Silbione™ BIOMEDICAL ADH2 M213 SLC
Durometer, heat cured (D2240)	ShA	23-33	23-33	23-33
Tensile strength (D412)	psi	> 550	> 550	> 550
Elongation (D412)	%	>150	>150	>150
Tear Strength (D624)	lb/in	>75	>75	>75
Appearance (D2090)	n/a	Colorless, clear to translucent		
Work Life @ RT, part A&B	hrs	>0.5	>2	>19

Table 1: Silbione™ BIOMEDICAL ADH2 M213 specifications.

We evaluated the adhesion of this new material conducting internal peel tests using various substrates, the Elkem Silicones team has been able to achieve cohesive failure results on many thermoplastic polyurethane substrates, metallic substrates, and other silicone polymers without the use of surface treatments or primers.

We have also seen a significant adhesion improvement over equivalent competitive biomedical materials on adhesion to titanium and aluminum.

Choosing the Right Silicone Adhesive for Your Medical ...

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Results

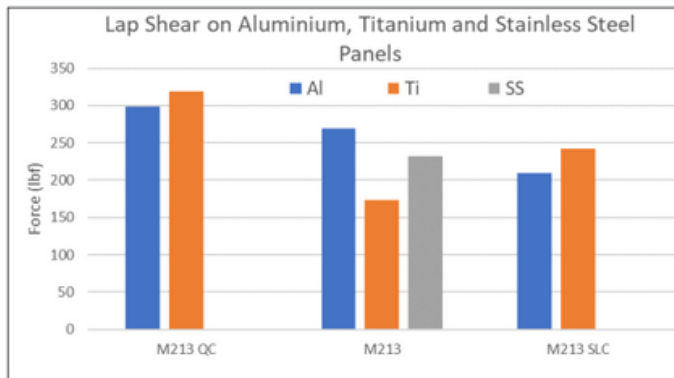


Figure 1: Comparison of lap shear adhesion to various substrates for all cure speeds grades.

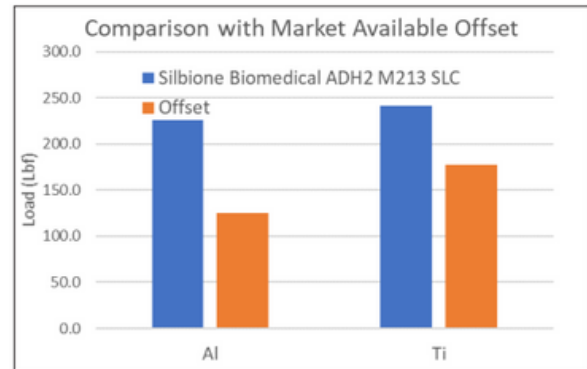


Figure 2: Comparison between of ADH2 to BIOMEDICAL adhesive offset using lap shear adhesion method to Al and Ti.

With more difficult substrates we have several tools available that we can recommend to our customer base to get the desired results, including one or a combination of the following: OpenAir Plasma treatment, surface abrasion and/or the addition of primer.

Cure inhibition with addition cure systems is another aspect to note with these two-part adhesive systems.

Chlorinated solvents, sulfur cure organic rubbers, latex gloves.

These adhesives include a master access file (MAF) present with the FDA and all associated biocompatibility testing and are produced in packaged in ISO certified clean rooms. Attestations and toxicological summaries available by request.

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BioInterface 2022

Portland, Oregon

Thank you to everyone for bringing BioInterface in person again!



BioInterface 2022

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SAVE THE DATE

**33rd Annual
BioInterface 2023
Workshop & Symposium**

**September 25-27, 2023
Catamaran Hotel
San Diego, CA**



Mentorship Program

Surfaces in Biomaterials is hosting a **mentorship program**. The goal is to build a professional relationship between mentor and mentees. Once matched, mentors and mentees can create a timeline to meet virtually. The goal is to meet twice in the first month and then at least once a month for a total of six months.

Please sign up to start your mentorship

SurFACTS in Biomaterials is the official publication of the Foundation and is dedicated to serving industrial engineers, research scientists, and academicians working on the field of biomaterials, biomedical devices, or diagnostic research.

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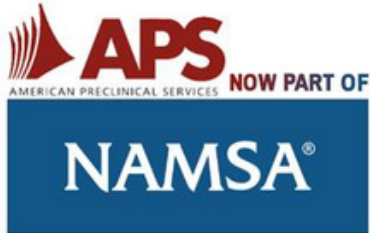
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