

**1-Step Coating
for SILICONE,
HDPE, PU, PVC**



**One-Step Coating
Solvent-Based
For *Difficult Materials***

**Formula
2314-172**

**Highly Lubricious,
Non-Eluting,
Antimicrobial
surface coating
for the reduction
of biofilm adhesion.**

**US FDA
MAF-1786**

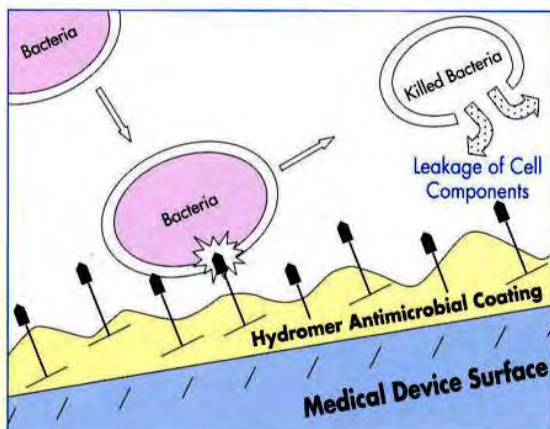
New 2011

How it works:

“A one-two punch”

- Based on proprietary and patent pending polyvinylpyrrolidone-polyurethane interpolymers with non-leaching Tertiary Amine functional groups.
- Highly effective by employing two different strategies: minimizing the ability of bacteria to adhere to the coated surface and destroying the few colony forming units that do adhere.
- Upon exposure to body fluids Hydromer 2314-172 Kills surface contacting bacteria rapidly via the electrostatic interaction between the coatings cationic electrostatic force and the anionic bacterial outer membrane. This results in damaging the bacterium's outer membrane leading to its permeability and demise.
- Since this is not a drug the Hydromer 2314-172 reduces the likelihood of Bacterial mutation, adaptation or resistance.

Surface Bonded Non-leaching Antimicrobial Coating



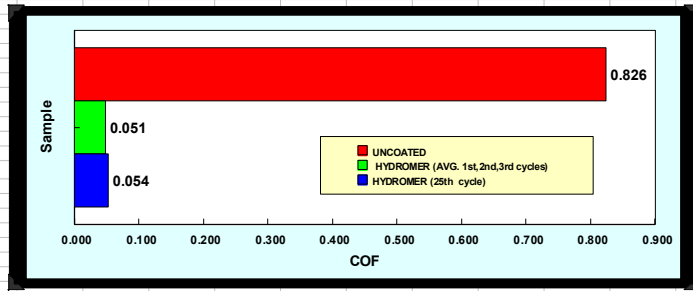
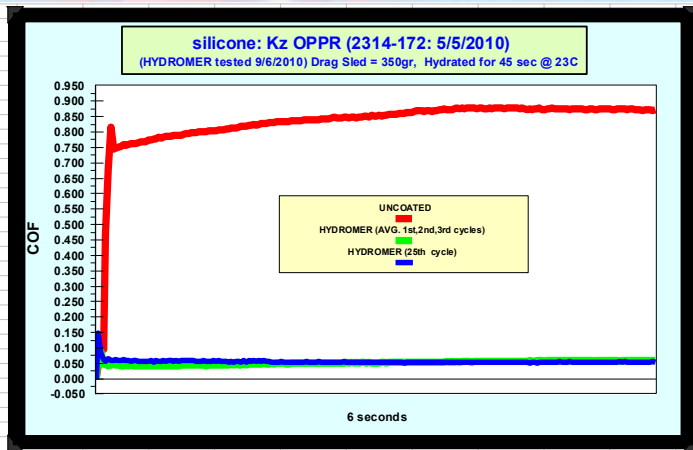
Active ingredients are bonded, not depleted

Hydromer's Antimicrobial Coating is a stable, bacterial wall piercing coating that reduces the potential for bacterial colonization. A non-leaching coating provides protection at the medical device site. In addition, the coating can be designed to be lubricious, and/or allow for drug elution.

Test for Lubricity on silicone , Dow Corning, RX-50 Medical Grade

2314-172
Before PBS

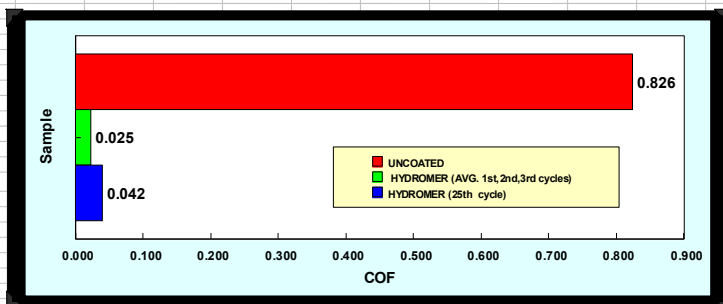
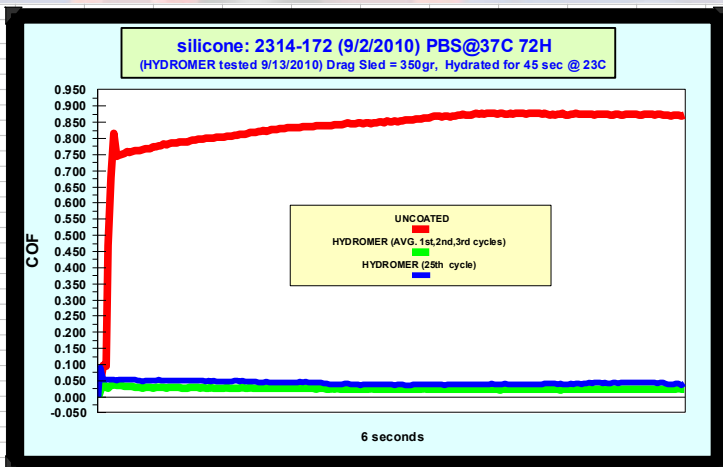
Hydromer Inc. 35 Industrial Parkway Somerville, NJ, 08876 USA & Biosearch Medical Products, Inc. (a subsidiary of Hydromer, Inc.) Tel: 908-722-5000	
COF Values	
UNCOATED	0.826
HYDROMER Coated HYDROMER (AVG. 1st,2nd,3rd cycles)	0.051
HYDROMER Coated HYDROMER (25th cycle)	0.054
Friction Reduction Factor: Uncoated / Avg. of 1,2,3 cycles	
16.287	
Primer: no Top coating: 2316-66	
Friction test: ASTM D1894	
COF= (Pull Force/ Sled Wgt)	
Sled Wgt.= 350 gm = 0.77 lb	
Test method is per Biosearch: STM-92023, Rev. F	



Tested for lubricity after soaking in PBS at 37°C for 72 hours.

2314-172
After PBS

Hydromer Inc. 35 Industrial Parkway Somerville, NJ, 08876 USA & Biosearch Medical Products, Inc. (a subsidiary of Hydromer, Inc.) Tel: 908-722-5000	
COF Values	
UNCOATED	0.826
HYDROMER Coated HYDROMER (AVG. 1st,2nd,3rd cycles)	0.025
HYDROMER Coated HYDROMER (25th cycle)	0.042
Friction Reduction Factor: Uncoated / Avg. of 1,2,3 cycles	
33.497	
Primer: no Top coating: 2316-63	
Friction test: ASTM D1894	
COF= (Pull Force/ Sled Wgt)	
Sled Wgt.= 350 gm = 0.77 lb	
Test method is per Biosearch: STM-92023, Rev. F	



A break-through in the coating of High Density Polyethylene HDPE!

- ❖ No chemical pre-treatment
- ❖ No Corona or Plasma pre-treatment
- ❖ One-step coating process!
- ❖ oven cure@ 160F for 2 hours

Hydromer Inc.
 35 Industrial Parkway
 Somerville, NJ, 08876 USA
 &
 Biosearch Medical Products, Inc.
 (a subsidiary of Hydromer, Inc.)
 Tel: 908-722-5000

COF Values

UNCOATED
0.415

HYDROMER Coated
HYDROMER (AVG. 1st,2nd,3rd cycles)
0.052

HYDROMER Coated
HYDROMER (25th cycle)
0.064

Friction Reduction Factor:
Uncoated / Avg. of 1,2,3 cycles

8.037

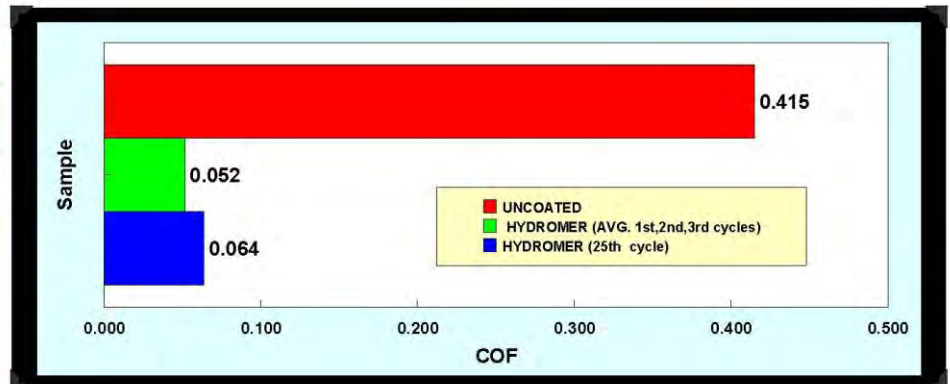
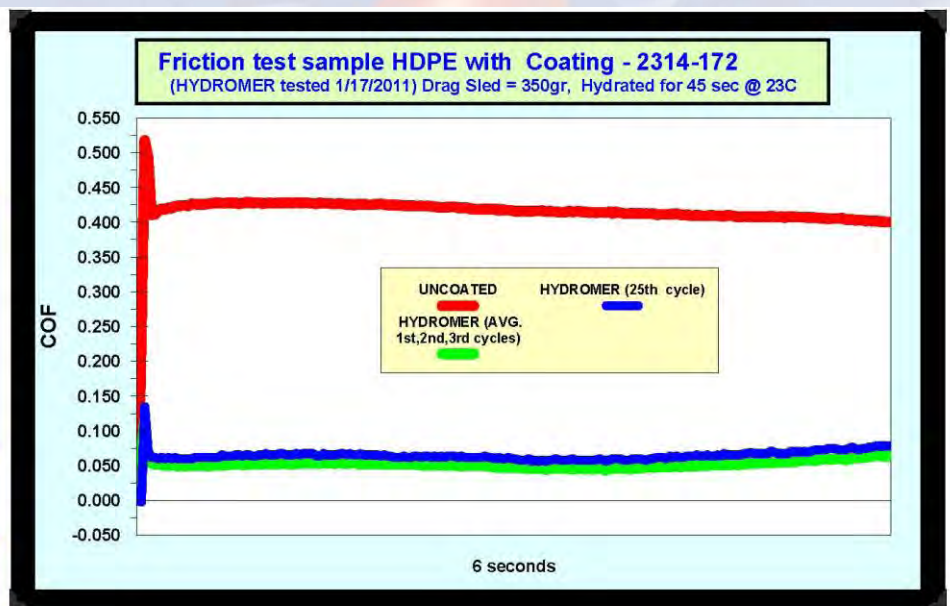
Primer: N/A
 Top coating: 2314-172
 Cure: 160F @ 2 hours

Friction test: ASTM D1894

COF= (Pull Force/ Sled Wgt)

Sled Wgt = 350 gm = 0.77 lb

Test method is per Biosearch:
STM-92023, Rev. F



Test for cytotoxicity of
Hydromer 2314-172 as applied to
Dow Corning, RX-50 Medical Grade Silicone

Uncoated & coated Polyurethane tubes (no pre-wash) were extracted for 24 hours in cell culture medium (MEM) containing 5% FBS.

The extracts are then placed in duplicate 35mm wells with L929 cells at ~10% confluence.

The monolayers were incubated at 37°C in the presence of 5% CO₂. Cells were examined by light microscopy at 72 hours for signs of toxicity.

uncoated, 200x



Grade: 0

2314-172, 200x



Grade: 0

Grade	0	1	2	3	4
cytotoxic	none	slight	mild	moderate	severe

Conclusion: Hydromer 2314-172 is non-cytotoxic

Test Method for Antimicrobial Activity

All tested tubings were washed and soaked in PBS at 37°C for 24 hours before antimicrobial activity test.

METHOD:

- **Place tubing (5-6cm length, coated and uncoated control) into a disposable culture tube (16 x 100mm)**
- **Incubate in LB broth containing $\sim 1 \times 10^5$ CFU/ml for 24 hours with moderate shaking @ 37°C (bacteria) or 72 hours @ 25°C for fungal strains**
- **Remove tubing and rinse with PBS**
- **Cut off both ends and place 3 cm section of tubing into 5 ml of LB broth (for bacteria) or Malt Extract Broth (MEB) (for yeast)**
- **Sonicate for 7 minutes followed by vortexing for 1 minute**

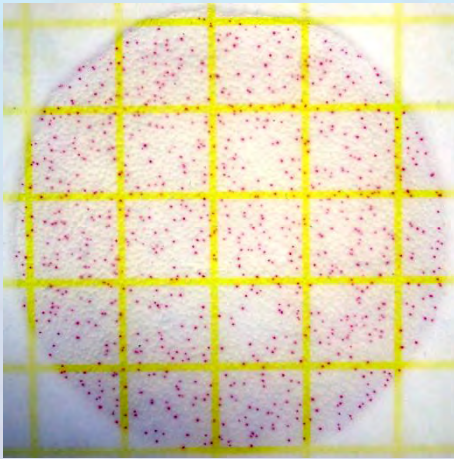
For bacterial

- **Mix 5-8 μ l of this broth and 1.5ml of LB then plate 1ml of this mixture onto 3M petrifilm**
- **Count colonies after incubation at 32°C for 24-48 hours.**

For yeast

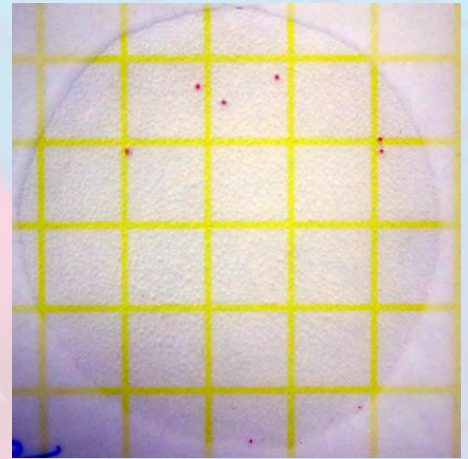
- **Mix 10 μ l of this broth and 70 μ l MEB, then spread onto MEB agar plate**
- **Count colonies after incubation at 25°C for 48-72 hours.**

Test For Antimicrobial Activity Against E. coli (Gram negative)

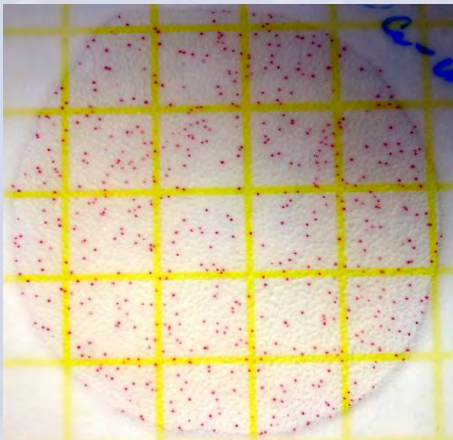


← uncoated: 830 colonies

2314-172: 7 colonies:
< 95% inhibition

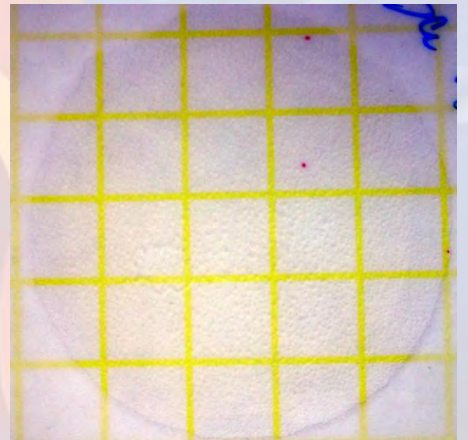


Test For Antimicrobial Activity Against S. aureus (Gram positive)



← uncoated: 520 colonies

2314-172: 2 colonies:
< 95% inhibition

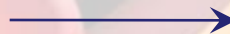


Test For Antimicrobial Activity Against C. albicans (Yeast)



← uncoated: 295 colonies

2314-172: 69 colonies:
< 76% inhibition



Please note that this report contains results from Hydromer's in-house testing departments. It is the responsibility of our clients to seek FDA Approval for this coating system on their devices.

Hydromer is very interested in entering into cost sharing programs to assist in compiling additional product performance data.

**Please contact us
For sample coatings and additional information**

**Martin von Dyck
Executive Vice President Hydromer, Inc.
E-mail: mcdyck@hydromer.com**

**Elena McGuire
Account Manager – Medical Coating Services
E-mail: elena.mcguire@hydromer.com**



**Hydromer, Inc • 35 Industrial Parkway • Branchburg, NJ
08876-3424 USA
Tel: (800) HYDROMER • Fax: (908) 722-5000
www.hydromer.com**