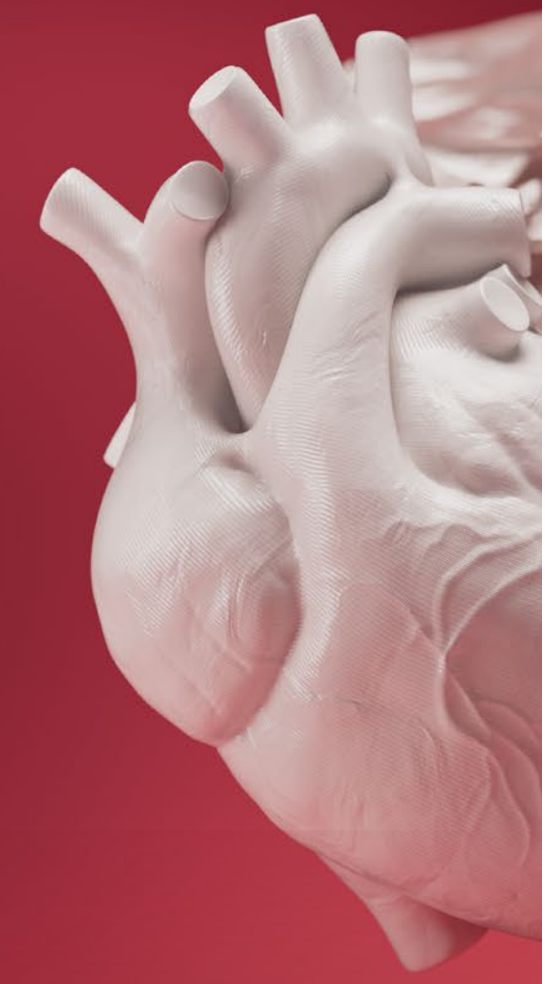

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Medical polyurethanes

Proven hemocompatibility for your vascular applications.

Hemocompatibility is critical for a medical polyurethane in blood-contacting Devices. By providing medical materials to our customers, dsm-firmenich's polyurethanes can minimize adverse reactions such as thrombosis, hemolysis, inflammation response, and/or activation of blood components (platelets and the complement system[1]. dsm-firemenich's medical polyurethanes, specifically Carbosil® 20 80A TSPCU and Biospan® SPU have undergone extensive hemocompatibility testing.

A partnership was started between dsm-firmenich and the University of Tübingen to execute this testing using an in-vitro Chandler loop model. This extensive testing included two different pure polyurethane films. Blood with no material contact was used as an internal control and heparinized PVS was used as a negative control.

These samples were evaluated per ISO 10993-4 for hemocompatibility testing categories such as coagulation, platelet number and activation, hemolysis, leukocyte activation, and complement activation. Each of these evaluations and results are described below.

1. Szycher M. Biostability of Polyurethane Elastomers: A Critical Review. Journal of Biomaterials Applications. 1988;3(2):297-402. doi:10.1177/088532828800300207

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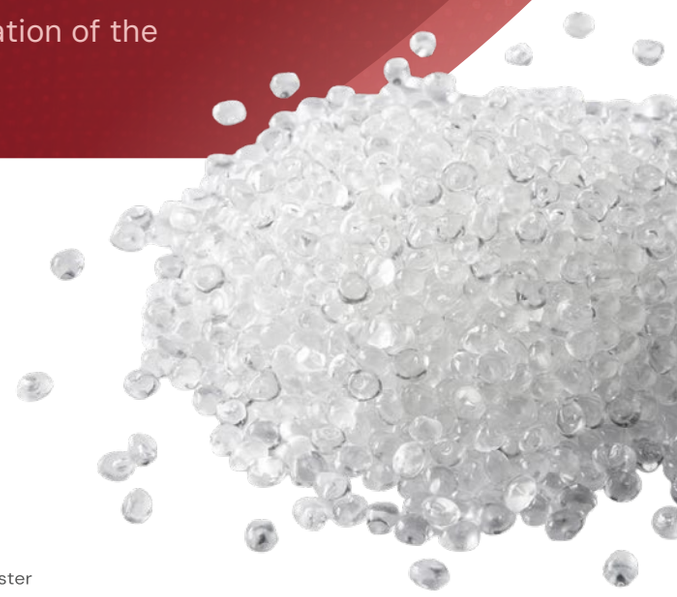
Platelets

Per ISO 10993-4 platelet assessments were completed by counting the number of platelets in the blood after exposure to dsm-firmenich's medical polyurethane materials, as well as determination of the β-Thromboglobulin (β -TG) concentration.



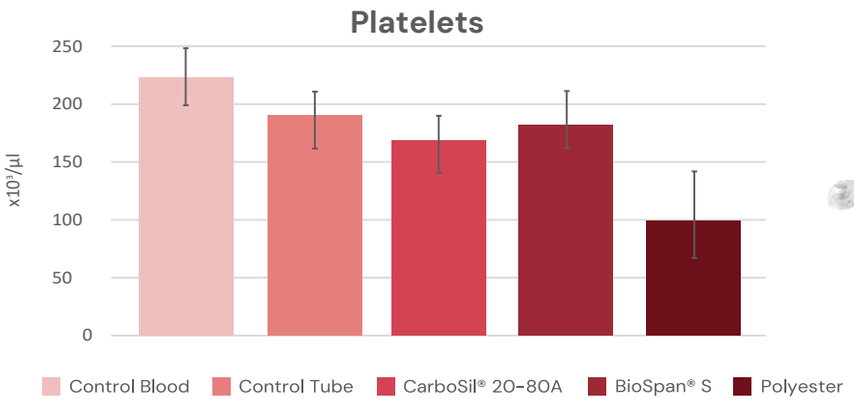


Figure 2: 2a Results of Platelet Cell Counting for Biomedical's medical polyurethanes compared to controls

When blood contacts an artificial surface, this can lead to activation and alteration of the platelets. This alteration could also lead to loss of platelet functionality. The level of alteration of the platelets can be measured via blood cell counting. After exposure, no strong drop was observed for platelet count in any of the Biomedical polyurethane exposed samples when compared to the controls (figure 2a). It is important to note that there is an insignificant drop which is accounted for by platelets sticking to the surface and not destruction.

Platelet activation is a physiological process that occurs when blood vessel walls are damaged and is a pivotal event in hemostasis and thrombosis. When platelets are activated, they release β -thromboglobulin (β-TG), and therefore this protein can be used as a marker of this activation (figure 2b).

All samples exposed to Biomedical's polyurethanes also demonstrated low β -TG compared to the control.

Information for both platelet counts and measurement of β -TG indicate that Biomedica's polyurethanes have low platelet activation.

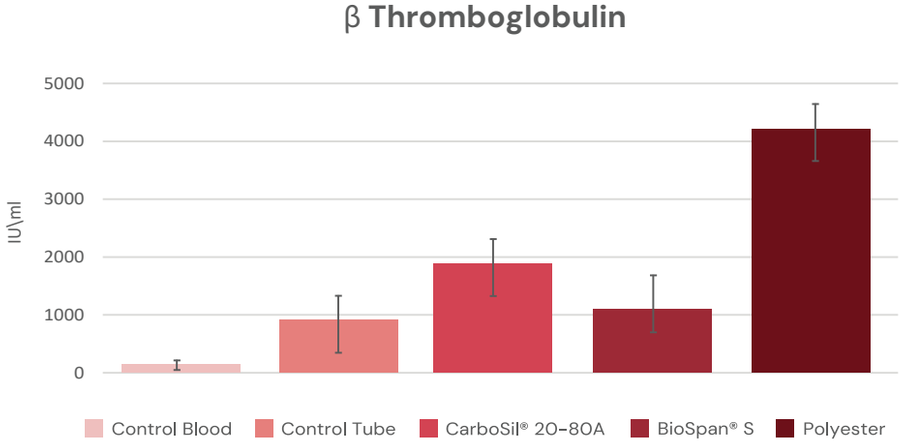


Figure 2: 2b analysis for control samples compared to Biomedical's polyurethane films

Hemolysis

Hemolysis is the process of red blood cells breaking down and releasing their contents into the surrounding fluids. When hemolysis occurs, it can lead to several other complications such as thrombosis, inflammation, organ damage, and kidney disease among others.

Hemolysis can be measured via free blood hemoglobin since when hemolysis occurs hemoglobin is released from the cells.

Free plasma hemoglobin was within the normal range for all samples exposed to dsm-firmenich's medical polyurethanes (figure 3).

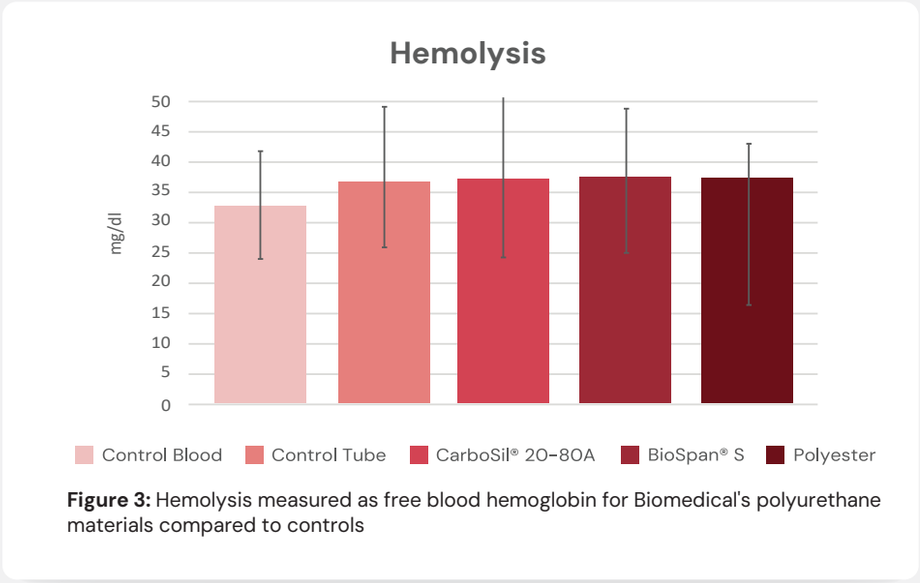


Figure 3: Hemolysis measured as free blood hemoglobin for Biomedical's polyurethane materials compared to controls

Inflammation

PMN elastase is a proteinase that is used by the granulocytes. This enzyme is released when the neutrophils are activated. Neutrophils are the primary defense cells which respond to pathogens and damaged tissue. When tissue is damaged, or hemolysis occurs, PMN elastase can increase as part of the body's inflammatory response. No significant increase in PMN-Elastase was observed in any of the blood samples exposed to Biomedical's polyurethane materials tested (figure 4).

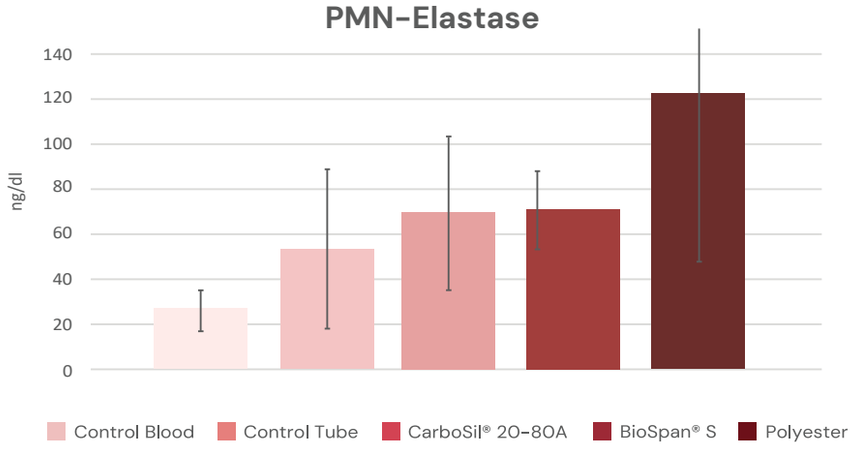


Figure 4: Analysis in PMN Elastase in Blood Samples after exposure to Biomedical's polyurethanes showing no increase in PMN elastase vs. the controls.

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Complement Activation System

The complement system is part of the immune system and helps the body fight off pathogens and/or damaged cells.

Complement activation during blood-material contact takes place as a defense reaction against the supposed pathological invader[2].

When the complement system is activated, it produces SC5b-9, a water-soluble protein complex. SC5b-9, can be measured to determine complement activation.

Levels of the final end product of the complement pathway SC5b-9 reflected a moderate complement activation without any considerable differences between all test groups. (figure 5).

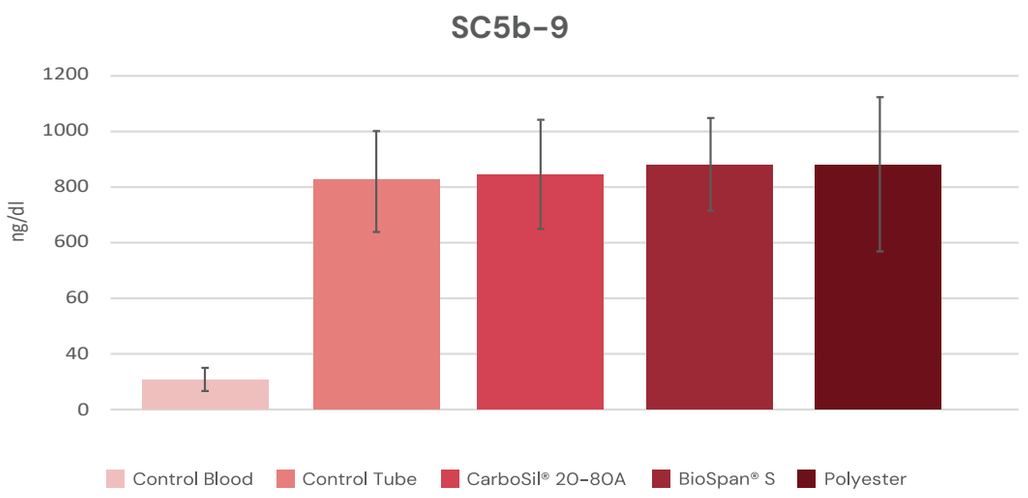
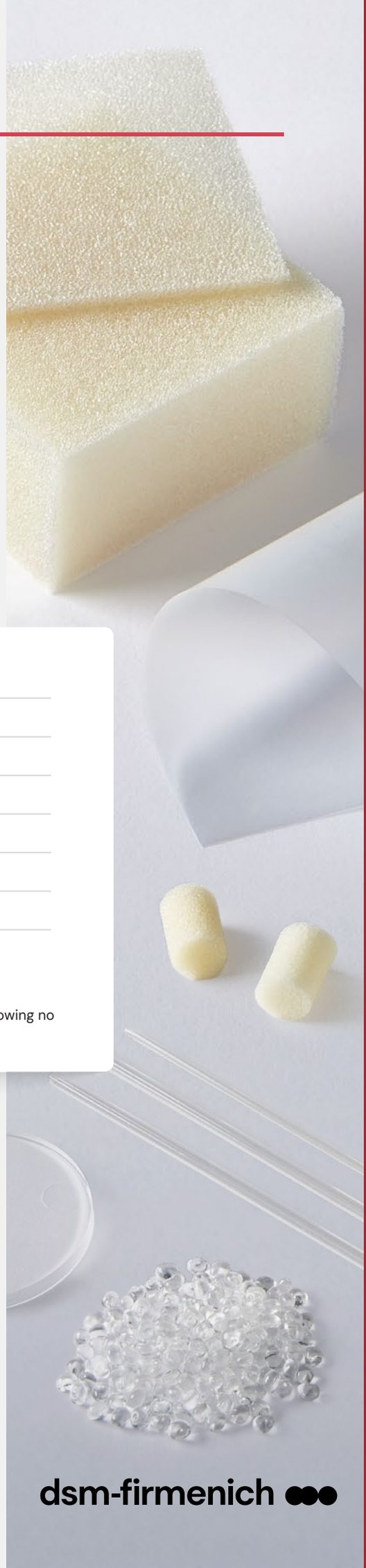


Figure 5: Analysis in SC5b-9 in Blood Samples after exposure to Biomedical's polyurethanes showing no considerable differences in SC5b-p concentration among test groups.



2. Cleveland Clinic medical (Ed.). (2024, May 1). Complement system function. Cleveland Clinic. https://my.clevelandclinic.org/health/body/23370-complement-system

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Coagulation

Coagulation is defined as "the action or process of a liquid, especially blood, changing to a solid or semi-solid state"[3].

Coagulation activity can be measured for blood contacting materials by using a Chandler loop model and measuring the thrombin antithrombin-III complex also known as TAT Complex. The TAT complex is a protein complex of thrombin and antithrombin.

Blood material contact initiates intrinsic coagulation factors which then generates thrombin. This thrombin is deactivated by complexing with antithrombin forming the TAT complex. Measurement of this complex is a good marker for the detection of coagulation activity.

Biomedical's polyurethane samples demonstrated low TAT concentrations after blood contact (figure 6) indicating low coagulation activity.

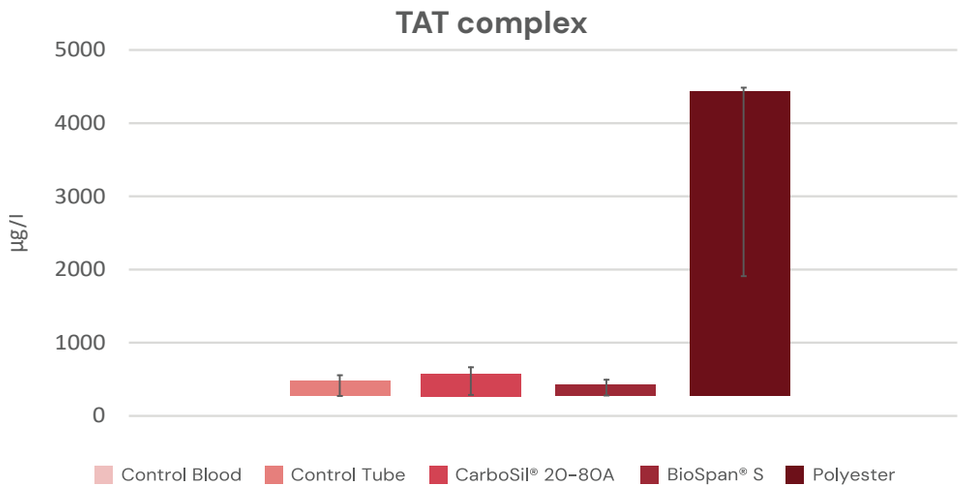

Figure 6: TAT Complex for Biomedical's medical polyurethanes and control samples Carbosil®, TSPCU and Biospan® have demonstrated low TAT complex compared to the positive control indicating low coagulation activity.

3. Favaloro, E. J., Pasalic, L., & Lippi, G. (2022). Getting smart with coagulation. Journal of Thrombosis and Haemostasis, 20(7), 1519–1522. https://doi.org/10.1111/jth.15691

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