HYDROPHILIC COATINGS FOR BIOMEDICAL DEVICES:

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Hydrophilic coatings for biomedical application and more specifically medical devices serve numerous purposes and can be found applied to a wide range of surfaces of medical materials (LaPorte, 1997).
This presentation addresses the need for coatings in both *in-* and *ex-vivo* settings for both blood-contacting and non-blood-contacting applications and illustrates the preferred coating chemistry used in each setting.
Application for non-fouling surfaces in diagnostics, lubricious surfaces on cardiovascular devices and both lubricious and antimicrobial hydrophilic surfaces for urological applications are discussed.

These areas of application are conveniently split into *ex* and *in-vivo* blood contact and non-blood contacting, the division reflecting the regulatory requirements in each application area.

Coating application areas will be discussed with reference to DSM's ComfortCoat™ range of hydrophilic and VitroStealth™ non-biofouling coatings.

Blood contact *ex-vivo*
As analytical technology has evolved and microfluidics has emerged as a valuable tool for *in-vitro* diagnostics (IVD), there is an ever increasing demand for hydrophilic surfaces either to simply aid wetting, induce capillary flow or to specifically prevent protein adsorption, or blood clotting.
This becomes especially relevant where an analytical technique exists to determine the presence or extent of a medical condition, whether from a blood, urine or saliva sample, biopsy or other source of analyte but where the signal source is weak and may be lost into or onto the surface of the sampling device, storage container or device it's self. Under such circumstances it is important to generate the right surface properties on the test, sampling or storage device to maintain sample integrity without the risk of interfering with the test procedure (Bowen *et al.*, 2010). DSM's VitroStealth™ non bio-fouling coating has been developed to tackle these problems. By combining fouling resistance with good mechanical durability and low levels of extractables, this system is a good coating choice for many such applications.
The application process used to obtain such non-biofouling surfaces and the coating chemistry used will be explored and elaborated upon..

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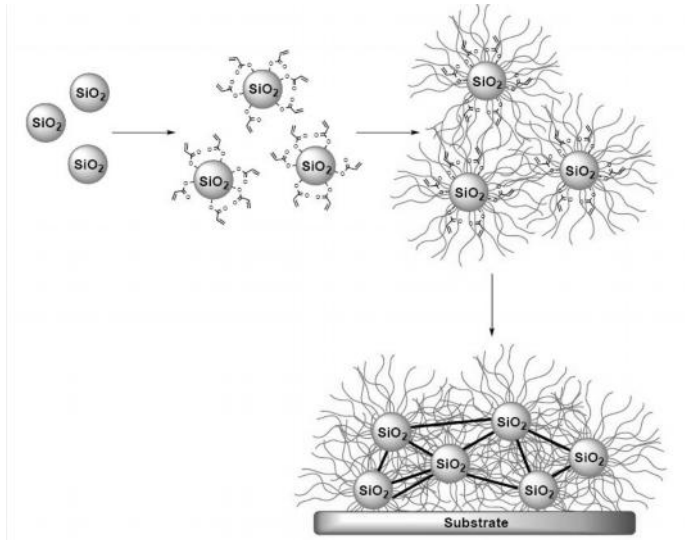

Scheme illustrating the basis of VitroStealth™

Non blood contacting *in-vivo*

The application of hydrophilic coatings to medical devices is a relatively recent field (Montagnino, 2000); this is despite the long history of many devices which would clearly benefit from the added properties imparted by a hydrophilic or lubricating surface. Somewhat surprisingly, for instance, urinary catheterization dates back to the 5th Century BC where the use of bronze tubes was apparently common (Moog *et al.*, 2005). The placement procedure was no doubt rather painful!

The properties required of such coatings and the performance obtained using a UV-cured polyvinylpyrrolidone based coating systems will be outlined and the coating application process illustrated.

Non blood contacting *in-vivo* antimicrobial

As the mode of use changes from intermittent catheterization, wherein the user inserts the catheter to empty their bladder, then removes it and disposes of it, to a device such as a Foley catheter which is usually placed by a practitioner and may remain in the urinary tract for a period of up to 30 days, the risk of infection, in such cases, a catheter acquired urinary tract infection, increases dramatically.

In order to mitigate this risk, antimicrobial agents may be added to a coating. In this instance, the inclusion of silver in a hydrophilic coating will be presented in conjunction with the special case of coating application and adhesion on a silicone rubber substrate.

Blood contacting *in-vivo*

The evolution of minimally invasive procedures over the last century since a German surgical resident, Werner Frossman, first placed a catheter into his own right atrium (and took an x-ray to prove it) has been quite remarkable (Lakhan *et al.*, 2009). This experiment laid down the foundations for Charles Dotter and Melvin Judkins who subsequently introduced transluminal angioplasty and spawned a whole new discipline.

Dotter in fact developed PTFE coated guidewires and such coatings are still widely used on many similar such devices today.

The earliest use of hydrophilic coated devices for such purposes, however, is likely to have been in the mid eighties when the first lubricious hydrophilic guidewires were placed on the market (Kikuchi *et al.*, 1989). In contrast to Urologiocal catheters , devices for “key-hole” surgery which are placed directly in the blood stream must be significantly more durable and of course must be blood compatible. Using the example of guidewires, which are often produced from medical grade stainless steels or nickel titanium alloys, an application process on such wires will be described along with, as for previous categories of coating, the end user performance requirements and preferred chemistries.

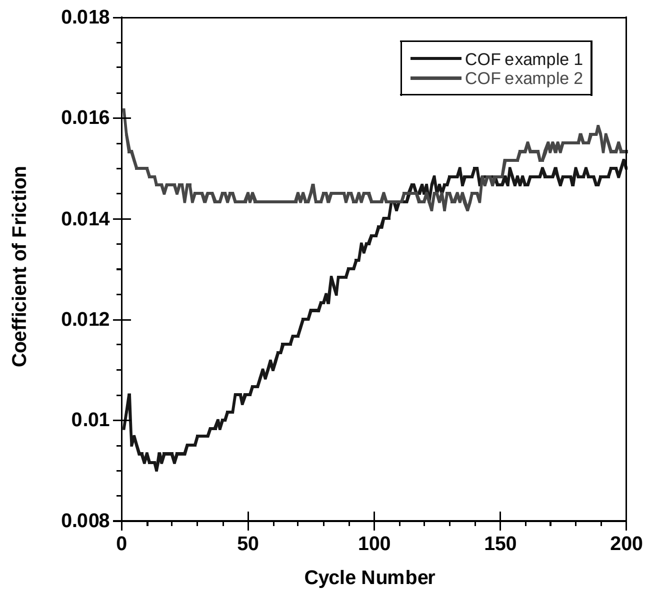

Illustration of a wear profile for two differing lubricious coatings on stainless steel wire

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