WHITE PAPER

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Bearing and magnetic coupling design for magnetically driven agitators in bioprocess

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ABSTRACT : The most common purpose of agitation in biopharmaceutical processing is liquid/liquid and solid/liquid blend (solutions and suspensions). Agitators are performing their duty while submerged in a fluid phase, and consequently designed for this intended use, considering that running in air would not fit any purpose. This article discusses different bearing designs and materials of construction typically available.

1. INTRODUCTION

Bottom entry magnetically driven agitators feature an impeller that is driven by a magnetic coupling, rather than physically connected to a shaft. This means there is no need to penetrate a process vessel, eliminating mechanical seals and reducing the risk of leaks. By not having a shaft, it is easy to design the process contact surfaces for effective CIP and SIP. The impeller typically runs on a bearing that will support it along all axes while rotating. A magnetic coupling, using only permanent magnets, cannot suspend objects in space without radial or axial support (Earnshaw's theorem). In general, bearings are designed to work with a lubricant. In the case of magnetically driven agitators in bioprocess, the lubricant is the process fluid. This could vary from fluids, such as water for injection (WFI) to final product, as well as CIP detergents and clean steam. The lubricating properties of all these vary greatly.

2. BEARING DESIGN

Most magnetically driven agitators for biopharmaceutical use a journal type bearing. See figure 1. Other designs have been used, such as ball bearing, but are not preferred due to their inherited complex geometry that would negatively impact cleanability. This discussion will focus on journal bearings.

A journal bearing will have a stationary component (male bearing) and a rotating component (female bearing) that is affixed to the impeller. While most designs use the same material for both male and female components, some use dissimilar materials. Unlike mechanical

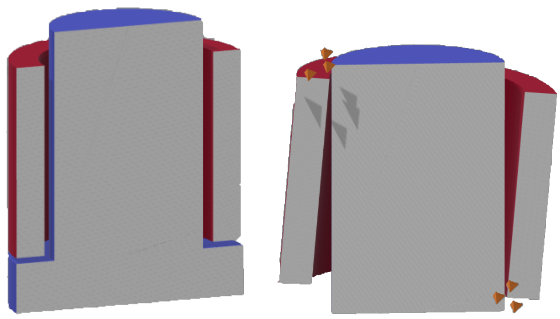

Figure 1 Axially supported journal bearing arrangement versus a non-supported design and consequential particle generation.

seal stationary and rotating seal faces, the male and female components in a journal bearing are not intended to seal and a small gap between them exists so that the components can be lubricated by the process fluid. In biopharmaceutical applications, this gap is also essential to ensure cleanability and drainability. Therefore, bearing exposure to process fluids during formulation and CIP is important to ensure cleanability and avoid dry-running. In mechanical seal's design, the rotating and stationary seal rings could be made of dissimilar materials, where the softer material would wear out faster, but will be held against the opposite face by spring force. With journal bearings, there is no spring that keeps the components together, so if one component wears faster than the other, the gap between them will increase. While a gap is necessary to provide lubrication, a big gap can result in wobbling and instability of the assembly that can cause premature damage.

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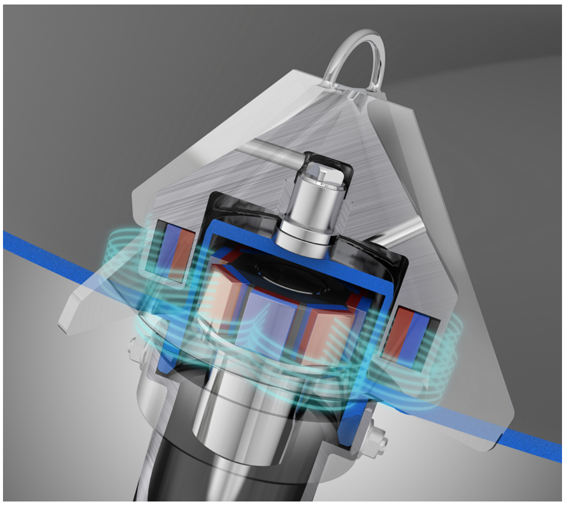
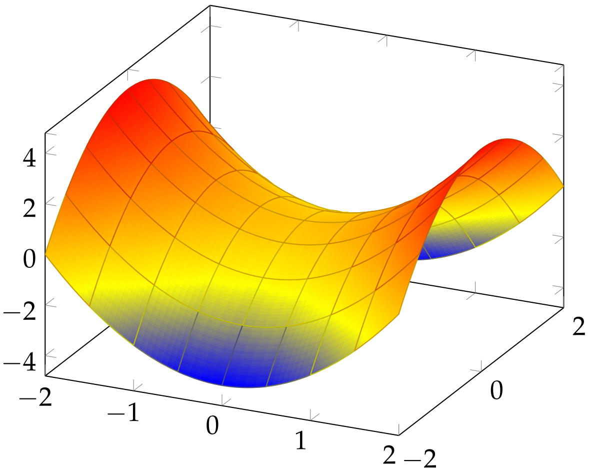


■ **Figure 2** Principle of a radial magnet coupling.



■ **Figure 3** Illustration of the stationary points that can be achieved by permanent magnet configurations are mathematically limited to saddle points.

3. MAGNETIC COUPLING DESIGN

Bearing design and magnetic coupling design are strongly related. The bearing design needs to withstand the forces imposed by the weight and rotation of the impeller and by the magnetic field that creates the magnetic coupling. Magnetic couplings can be axial or radial. Radial couplings are preferred by most manufacturers since they do not add additional axial loads to the bearing. Journal bearings are typically able to withstand the forces imposed by a radial coupling. They also provide more space to accommodate more magnets and therefore can provide higher maximum torque ratings. See figure 2.

Axial couplings would add forces acting upon the bearing that would require increased robustness. In those cases, ball or roller bearings may be more adequate to withstand the additional load, but, as discussed, are not considered to be hygienic. This discussion will focus on journal bearings used in combination with radial magnetic couplings.

Magnetic couplings can be of non-floating or floating type. A non-floating coupling is aligned in a way that ensures the female bearing in the impeller is resting on the male bearing, thus providing mechanical support both along the radial, as well as axial axes. A floating coupling is aligned in a way that when engaging the coupling, the impeller slightly lifts up avoiding contact on the axial surfaces of the male and female bearing. While in operation, with a liquid film between the bearings, the designs are roughly equally non-contacting.

3.1. Earnshaw's theorem

From the discovery of magnetism by the ancient Greeks, to today's children playing with magnets, mankind has tried to make objects *float in mid-air* by using the attracting and repelling forces between magnets. For many centuries, and in some cases even today, the prospect of floating objects has triggered many attempts along the lines of *if I could only arrange these magnets in a sufficiently clever geometry, I can make things float.* The internet is full with examples of these attempts.

In 1842 the British mathematician Samuel Earnshaw proved mathematically that permanent magnet configurations cannot lead to magnetic fields with stationary points that are stable in all directions [4], see figure 3. With the exception of a small number of special case, magnetically 'floating' objects are always supported along at least one axis. Real *levitation* by electromagnetic forces is usually achieved by a feedback loop that adjusts (electro)magnetic fields in fractions of seconds depending on the exact position of the object, in practice 'broom-stick-balancing' the object on the saddle-point.

3.2. Implications of Earnshaw's theorem on floating bearing arrangements

As a result of the limitations of positioning objects by magnetic forces (see section 3.1) even the floating bearing arrangement will have contacting surfaces between the male and female bearing, see figure 1. As mentioned before (section 3), with a liquid film between the bearings, this effect might be minimized (to about the same magnitude for both floating as well as non-floating arrangements). Under start-up-conditions or dry-running conditions, this will not hold true.

Moreover, in most applications, the flow pattern is in turbulent regime. Also, the impeller is located offset from the center of the vessel, and therefore the eddies around the impeller are of different magnitudes. As the impeller is pushed side to side by the eddies, the radial surfaces of the journal bearing would become in contact, avoiding the impeller from moving outside of its intended position. This means that the non-contacting bearing now has become a contacting one, with comparable particle-generation and wear to non-floating bearing arrangements.

The lack of support in a floating-bearing arrangement may also allow the impeller to wobble up and down (which is not possible with a non-floating design). This condition may result in damage to the impeller and premature bearing failure, due to increased vibration.

4. MATERIALS OF CONSTRUCTION

Materials of construction play the most important role in the ability of a journal bearing to perform satisfactorily

Bearing material[a]	Tungsten Carbide	Silicon Carbide	Dri-amond™
Chemical compatibility	pH range 2-14[b]	Best - inert	Same as silicon carbide
Ease of installation and handling	Best	Harder than tungsten carbide, but more brittle	Somewhat better than silicon carbide
Survivability under dry-running conditions	Good	Poor	Best - lowest coefficient of friction

[a] The use of dissimilar materials in male and female bearings is not recommended.
[b] Exact value depends on particular fluid properties, temperature and exposure time.

Table 1 Comparison of bearing materials.

in an application (with regards to process fluid, temperature, mixer rpm and bearing design). Some of the most common bearing materials are described below (and compared in table 1):

Silicon Carbide: This material is a hard ceramic compound of silicon and carbon. There are two types: reaction bonded, which is considered a multi-phase mixture, or sintered, which is considered a crystalline material. Sintered silicon carbide is commonly used in mag mixer's journal bearings. It is a hard material, with excellent chemical resistance, but it is brittle. This characteristic makes it susceptible to damage during assembly/disassembly and system upsets, such as dry-running or other conditions that would generate excessive vibration.

Tungsten Carbide: This material is a crystalline cemented material produced with a binding metallic matrix. Its chemical compatibility varies depending on the metallic binder that is used. Some alloy and nickel binder tungsten carbides offer the highest corrosion resistance, but its chemical compatibility is not as wide as that of sintered silicon carbide. Straight cobalt-binder tungsten carbide is not recommended in biopharmaceutical applications due to its low corrosion resistance that may cause cobalt to leach out when exposed to low pH fluids. Tungsten carbide is impact resistant, which makes it less prone to damage during assembly and disassembly than silicon carbide. The ductile metal binder also diminishes the brittle characteristics of ceramic carbides, improving toughness and durability. It is considerably more likely to survive system upsets and dry-running conditions.

Zirconium Dioxide: This material is a crystalline, sintered ceramic material. Compared to silicon carbide, it is more impact resistant and less likely to break during assembly/disassembly. It would survive system upsets and dry-running better than silicon carbide. However, it is less wear-resistant and therefore prone to higher particle generation.

Diamond Coated Silicon Carbide: A crystalline diamond film can be deposited on ceramic substrates, such as silicon carbide, by turning natural gas into diamond by means of plasma-assisted carbon deposition techniques[5]. The resulting film creates a bond with the carbon atoms in the silicon carbide structure. The main advantages of this film are related to the properties of diamond, such as high wear resistance, low coefficient of friction that increases dry-running tolerance, high thermal conductivity that results in lower running temperatures, and excellent chemical compatibility. While it may not change the brittle nature of the silicon carbide substrate (it would still be susceptible to damage during assembly and disassembly), it greatly improves survivability during system upsets, such as dry running.

5. BEARING MATERIAL REQUIREMENTS FOR USE IN BIOPROCESS

According to the latest ASME BPE edition [1], per PM-2.1.3 and table PM-2.2.1-1, bearing materials, such as silicon carbide, tungsten carbide, etc., shall comply with the requirements of USP<87> Biological Reactivity Tests, in Vitro [2] or ISO 10993-5 for biocompatibility. Due to the importance of particle generation in biopharmaceutical processes, most manufacturers also test their bearings in accordance to USP<788> Particulate Matter in Injections [3]. The USP defines maximum particle counts of 25/mL for particles $\geq$10 μm and 3/mL for particles $\geq$25 μm.

6. CONCLUSION

Bearings in magnetically driven agitators are lubricated by the process fluid(s). The bearing design, magnetic coupling design and selection of materials of construction greatly affects magnetic coupled mixer performance. Journal bearings and radial couplings are the most common choices for magnetically driven agitators in bioprocess. Non-floating couplings offer more mechanical stability that may prevent premature damage. The material of construction can make the most significant difference in the ability to run dry. Ductile materials, such as tungsten carbide, may not be as prone to fracture during dry-running as ceramic materials, such as silicon carbide. Diamond coatings have shown to greatly improve dry-running capabilities in ceramic materials. Materials shall comply with regulatory requirements, such as USP<87> [2] and USP<788> [3].

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