## Correct Use of Debris-Sanitary flanges in the Pharmaceutical / Food & Beverage industry:

**Debris (or sanitary) flanges were designed to prevent process contamination in the chemical and pharmaceutical sector and have also become an increasingly popular choice as a sealing solution for food producers. However, a widespread lack of awareness about these components and the stringent cleaning processes required to ensure they operate effectively means that, conversely, they can present a high and persistent risk of product contamination. John Smiddy mechanical seal consultant at SMIDDY(IMSC) Ltd explains how this component (intended hero) of the production line can become the villain, and how good practice can eliminate the contamination risk.**

The debris flange is also known as a sanitary flange in the pharmaceutical sector is one of the least understood components by manufacturing industries and its relationship between preventing contamination and causing contamination. (The intended hero can become the villain).

It was developed more than 60 years ago for mechanical seals, fitted to top entry agitators and mixers to help meet the more stringent hygienic standards demanded of the chemical and pharmaceutical industries.

Put simply, the flange captures any debris resulting from the wearing of seal faces, or particulates in the barrier fluid which cross the inboard seal faces, preventing them from entering and contaminating the product.

To function effectively, the debris flange itself must be regularly and thoroughly cleaned.

The biotechnology (biopharmaceutical) sector is an example of best practice. The highest levels of clean in place (CIP) and steam in place (SIP) practices are embedded in its standard procedures and both the mechanical seal and debris flange would typically be cleaned and sanitised hourly, after every batch.

However, from my experience on multiple sites, it would not be an overstatement to say that, in the majority of other industries, debris flanges are inadequately cleaned or, even more commonly, not cleaned at all.

Where cleaning does take place, the difficulty in accessing the debris flange and the methods used to clean it can present risks of their own. For example, carrying out a pressurised steam or air flush to clean out debris can dislodge it over the flange barrier into the process vessel. Even tiny particulates are enough to contaminate the process. Additionally, the use of high-pressure steam or air to clean debris flanges can also cause the seal dynamic O ring to get stuck, or ‘hang-up’, resulting in seal failure.

Far more seriously, when no cleaning is carried out, the mixed product enters and settles in the debris flange, accumulating from batch to batch and causing a very high risk of bacterial growth and contamination.

**Contamination can be costly**

If contamination occurs at the start of the process, maybe the product can be reworked, and production of the batch can progress. But if it occurs during the final stages of the process, the strong likelihood is that the batch will have to be discarded.

For the biotechnological sector, the cost of this product loss can run into hundreds of thousands – perhaps even millions – of euros, which explains why biopharmaceutical companies have strict cleaning procedures in place.

Same for other industries, the cost of a lost product can amount to many thousands of euros. Yet this risk of secondary contamination is present on any manufacturing site which has debris flanges on its mixer seals but does not have the appropriate CIP or SIP procedures in place for regular cleaning.

This scenario should be a nightmare for Quality Assurance (QA) and finance managers alike. Which begs the question: Why is the use of debris flanges without proper CIP procedures in place so prevalent? The answer is quite simple, there is a general lack of awareness that debris flanges may even exist as a component of the mechanical seal that is being used.

This sealing technology dates back so many decades that mixer seals with debris flanges are being purchased repeatedly with no knowledge of its CIP requirements or the potential risks it can present. The debris flange is not visible, so unless you investigate the actual seal drawing, or remove and dismantle the seal, you would be, completely unaware of its existence.

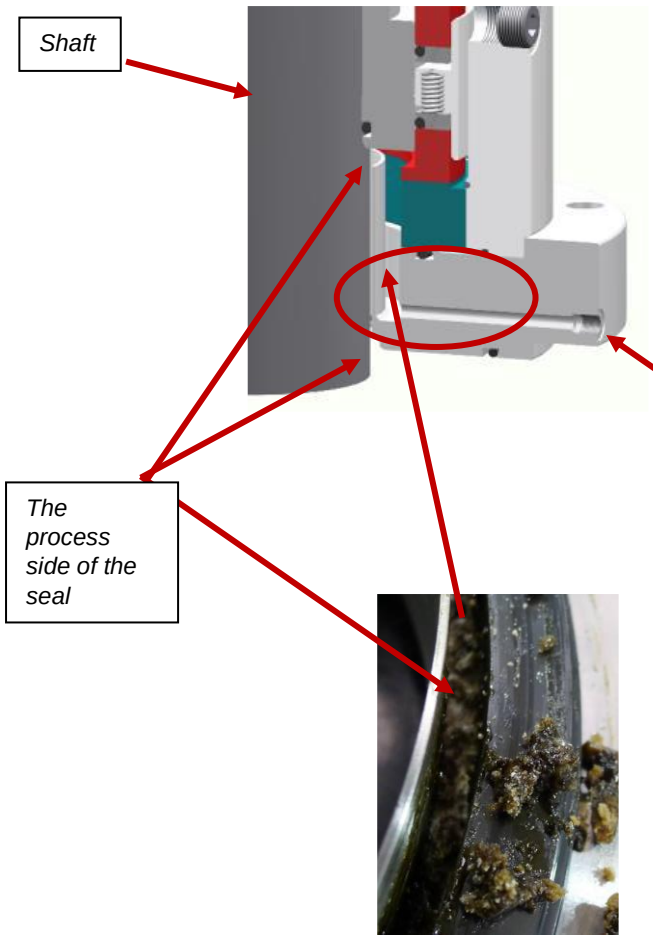
Debris flanges tend to be discovered in two common situations – when there has been a catastrophic seal failure, or when a seal has been removed due to an issue such as leakage and the debris flange, and the accumulation of contaminating product it is carrying is discovered.

Another common occurrence is when a company has discovered contamination of product, for example, black specks in a white powder, but has been unable to identify the source. If the seal is functioning efficiently, our first response is always to check whether the seal has a debris flange - such is the frequency with which they are at the root of a contamination issue, invariably due to lack of awareness leading to neglect.

**Removing the risk of debris flange contamination**

For pharmaceutical and food industries with an otherwise faultless approach to maintaining high standards of hygiene, unidentified debris flanges can be a hidden but lethal enemy. Fortunately, eliminating the risk they present is not a difficult task.

*Fig.1. Seal cross-section with debris flange*



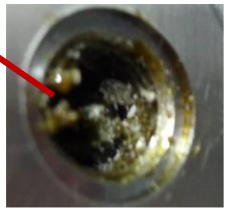



*Fig. 3 Debris flange flush port*



*Fig 2. Uncleaned debris flange*

The first and most obvious action is to ask: Do the mixer seals on our production line incorporate debris flanges? This can be established by referring to the original seal specification and checking whether the stock code indicates that there is a debris flange on the seal, or by removing the seal and checking it visually.

If you establish that your mixer seals do employ debris flanges, it should be considered essential to adopt the best practice evidenced by the biotechnology sector and

implement, as a standard procedure, robust CIP or SIP action between each batch or product cycle.

The other course of action is to consider upgrading to advanced mixer seals which do not include a debris flange in their design. The mixer CIP washes and cleans the

inboard (IB) seal faces after each batch or at the end of every production run, ensuring the seal is clean and the area around the seal flange (process side) is in a sterile state.

Another option that is growing in demand is a design more often seen on dryer seal applications. Again, there is no debris flange. Instead, the seal sleeve is extended, allowing the seal faces to be positioned below the mounting flange.

The CIP spray balls positioned inside the mixing vessel are strategically placed to clean all the areas where the process might otherwise stick and create a contamination risk. This more hygienic design enables better CIP of the IB seal faces, ensuring the vessel remains clean or sterile between batches.

**Cost is not a constraint**

Switching from traditional mixer seals with debris flanges to modern mixer seals without debris flanges is cost-neutral – if not on occasion cheaper.

For example, debris flanges made from HC276 or C22 add a considerable cost to a seal's manufacture. Remove the debris flange and you remove the cost of that expensive material.

Cost neutrality alone should make the modern mixer seal a serious consideration for any manufacturer. However, when you factor in the elimination of the significant contamination risks associated with debris flanges, they really should be the first and only choice for industries that demand high standards of hygiene.

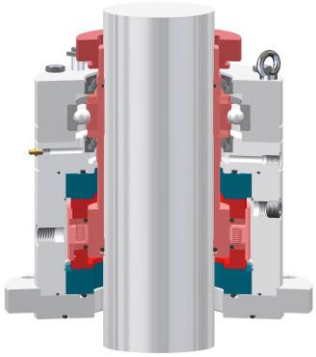


*Fig. 4. Mixer seal without debris flange*

*Fig. 5. Seal design with seal face expose inside the mixing vessel*

***Please contact SMIDDY (IMSC) Ltd to review your mixing applications.***
***We have lots of available options to help with overcoming this potential problem.***
***When the mixer seal is out for repair this is the best time to review and upgrade to a more suitable arrangement***

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