

CASE STUDY



API



Preventing Graphite Contamination in a Post Filtration Process at an API Site

Inspired By Challenge

Graphite contamination found in post filtration process at API site

Background

A major API site in the UK raised an issue after a production batch was rejected by the client's customer due to contamination. It was confirmed that some of the contamination was graphite particles 1-2mm in size. The process was stopped while the cause of the contamination was established. Suspectable sources of contamination were the stem seal and overflow of the graphite body seal onto the metal ring. Although these should be eliminated by initial flushing during commissioning, initial flushing procedures do not always completely remove contaminants, especially particles released over time from degraded porous material.

The API Challenge

The inherent dilemma faced by the API industry begins when defining the piping equipment needed to fulfill the engineering specifications. On the one hand, there is a mandatory requirement for fire safe certified valves when handling flammable media in an Ex-proof zone. This requirement traditionally dictates the use of graphite material for stem and body seals. On the other hand, there is a mandatory requirement that only FDA compliant materials be in contact with the media, along with stringent cleanliness demands for the parts used in API processes.



Contaminant particles from crushed graphite seal

The Solution

Habonim's response to this challenge is the 'G' valve series - a premium line of products based on the HermetiX™ fire safe technology. All soft parts of the valve are made from FDA compliant materials, effectively eliminating possible graphite contamination from the stem seal or from the body seal.

This unique fire safe valve design includes: a zero-contamination HermetiX™ stem seal consisting of a virgin PEEK thrust bearing and anti-abrasion ring; and a stem seal made of TFM material. Both virgin PEEK and TFM are FDA compliant. The double body seal set is comprised of an internal PTFE body seal facing the media, and an external graphite seal to withstand fire.

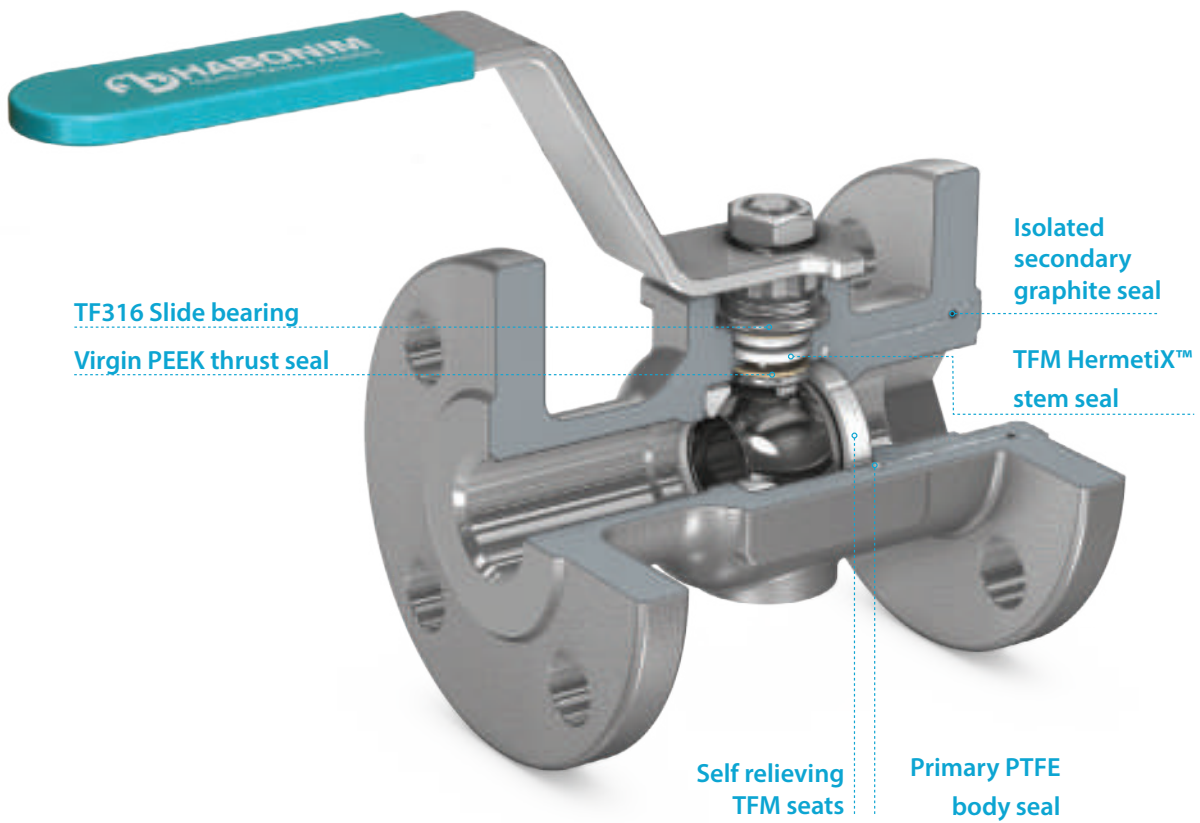
This design effectively isolates the graphite seal in a dry cavity, preventing it from coming into contact with the media. It ensures a high degree of purity for the valuable media, avoiding possible rejection due to batch contamination.

Once the 'G' valve was specified and accepted as a Noble Spec at the corporate level, the complete line was introduced to all the customers' API sites worldwide.

The 'G' valve series solution was introduced and accepted at the corporate level.

A 'Nobel Spec' - a premium valve design complying with multiple site applications and manufactured in a long series with minimum setups. The 'Nobel Spec' reduces the quantity and variety of valves in stock while improving lead time and product quality.

In summary: Efficient production of pharmaceutical ingredients, fewer rejections due to contamination and full compliance with API industrial safety regulations.



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