



Specially for use in the food and beverage, pharmaceutical and biotechnology industries, Freudenberg Process Seals has developed a hygienic washer with elastomer sealing ring. The Usit rings are made for static sealing free of dead-spaces between bolts and dome nuts.

The Hygienic Usit provides simple and affordable FDA-compliant sealing for threaded connectors with flanges, while also fulfilling the criteria of Hygienic Design *Metallic flat seal with elastomer sealing ring made of 70 EPDM 291*

Hygienic design-compatible washer



The Hygienic Usit combines metallic flat seal and elastomer ring in one component

When it comes to protecting bolt heads and nuts from being contaminated with products from the food and beverage, pharmaceutical or biotech industries, many plant and machinery manufacturers that supply the process industries use complicated (and often home-made) solutions. This is problematic, as the complete cleanability of these points is the only safeguard for the producers of perishable foods and beverages and high-purity medications. And threaded connectors are generally subject to the risk that contaminating substances can only be removed via disassembly. But today's facilities are predominantly cleaned without disassembly, instead using CIP (Cleaning in Place), WIP (Washing in Place) and SIP (Sterilization in Place) methods.

With this problem in mind, Freudenberg Process Seals has developed a hygienic washer with sealing ring – the Hygienic Usit. The Hygienic Usit is a further evolution of the standard Usit rings often employed in general mechanical engineering applications to simply and affordably protect non-moving machine parts from fluid and gaseous media. The rings consist of a combination of metallic flat seal and elastomeric sealing ring for static sealing. The resilient, trapezoidal sealing ring can be vulcanised on either the inner or outer

diameter of the metal disk to match application-specific requirements. However, their hard-to-clean design makes these sealing elements used in mechanical engineering poorly suited to (and/or not approved for) process engineering applications.

In response, Freudenberg Process Seals has completely reworked the original external sealing design. Together with DIN EN 1665 bolts and dome nuts, the Hygienic Usit forms a very easy-to-clean combination, which has already been tested and approved by the Weihenstephan Research Center for Brewing and Food Quality using the EHEDG (European Hygienic Engineering and Design Group) Cleanability Method.

Consistently hygienic

In traditional threaded connectors, fluids can collect under the bolt head or in the threading. This is by no means EHEDG-compliant and is highly unhygienic. In contrast, the Hygienic Usit ensures the clean sealing of DIN EN 1665 bolt heads with flanges in aseptic isolators, and in areas where they can come into contact with product. This optimal sealing prevents the medium from penetrating under the bolt head, which can lead to the formation of germs and bacteria. The Hygienic Usit's design, which is tailor-made for hexagon bolts with flanges, ensures that the sealing ring is cleanly seated on the flange, precluding the formation of air spaces where microorganisms can accumulate.

70 EPDM 291, a premium compound for the food and beverage and pharmaceutical industries, is used as the elastomer for the sealing ring. In addition to being FDA-approved, it also satisfies the criteria of the European regulation EU (VO) 1935/2004. Needless to say, it is also ADI-free (free of animal-derived ingredients), and as such free of TSE (transmissible spongiform encephalopathy). Its biocompatibility has also been tested and approved for use in pharmaceutical components and facilities in keeping with USP Class VI requirements.

EHEDG-Test and results

The EHEDG has developed a testing method in which microorganisms are allowed to collect in hygienically problematic areas, i.e. in potential air pockets. A subsequent cleanability test identifies those critical points that cannot be adequately reached by the cleaning medium [1]. This same method was used to test the cleanability of the Hygienic Usit's bolt/dome nut combination using a standard size M6 bolt. In the test, the cleanability of the Hygienic Usit was compared with that of a reference pipe with a known, low inner surface roughness ($R_a = 0.7 \mu\text{m}$). However, before this test could be started, the elastomer used had to be tested for antibacterial components, so as to rule out a potential skewing of the test results. As the test found no evidence of antibacterial properties in the EPDM material, we were then ready for the cleanability test.

In order to test their cleanability, components are intentionally soiled with a suspension that contains spores of a thermophile bacterium. These spores not only remain stable at high cleaning temperatures; they are also resistant to the cleaning media. Following the soiling, components are CIP cleaned using a 1.0%-concentration detergent at a temperature of +63 °C for ten minutes, followed by a rinsing with water. The test area is then coated with an agar growth medium, which is allowed to incubate for 18 hours at a temperature of +58 °C. In the last step, the colour of the MSHA agar medium, which changes from violet to yellow [1,2] in response to spore growth, is assessed. In order to ensure that the results are representative, the cleanability test is conducted a total of four times. In our case, none of the four tests showed a yellow discoloration following the incubation of the agar coating covering the Hygienic Usit's bolt and dome nut. The yellow discoloration in the reference pipe was present in an average of 13 % of its inner surface, which is within the tolerance range of 5 to 30 % laid out in EHEDG Guideline 2 and corresponds to an acceptable level of contamination after a standard cleaning cycle. As such, the Hygienic Usit clearly demonstrated better cleanability than the reference pipe.

[1] EHEDG Guideline Nr. 2, Method for Assessing the In-place Cleanability of Food Processing Equipment, 3rd Edition, July 2004, revised June 2007

[2] EHEDG Report 01: Cleanability Test, Hygienic Usit with Bolt, Weihenstephan Research Center for Brewing and Food Quality, TU Munich, from December 5, 2011

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