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IMPORTANT INFORMATION REGARDING CURRENT EUROPEAN DIRECTIVES AND THE TECHNOLOGY USED IN MISCEA SENSOR FAUCET SYSTEMS

Compliance with the latest European directives and regulations are of the utmost importance to miscea as a manufacturer of quality medical products, because it ensures our products are safe to use. miscea systems are developed in accordance with the latest standards and directives governing medical technology (established by the Robert Koch Institute in Germany) and within the sanitary industry.

We have found that there are some uncertainties or misinterpretations of the regulatory information. Therefore, we would like to take this opportunity to inform you in detail about various key areas of the current standards in technology regarding miscea sensor fittings:

- miscea systems meet the specifications for product documentation regarding the processing of medical devices according to DIN EN ISO 17664
- miscea systems meet the latest technology standards with regards to correct handling procedures where hand hygiene is concerned and is compliant with TRBA 250 and the KRINKO directive
- miscea systems use the latest technology standards in drinking water hygiene for faucets
- miscea systems use the latest technology standards in dispenser hygiene

If you have any questions, please do not hesitate to contact us.

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Specifications for product documentation regarding preparation according to DIN EN ISO 17664

In April of this year, a revised version of the standard DIN EN ISO 17664 was published. This standard regulates the requirements for the information that manufacturers of medical devices must provide, in particular regarding the reprocessing of the medical device (including cleaning and subsequent disinfection / sterilization). It applies to manufacturers of medical devices that are intended for ready-to-use preparation by the user or third parties. (1)

We would like to announce the following:

For the reprocessing of the miscea systems, only manual cleaning is required. For cleaning, we offer in our assortment the SystemCare Set, which contains all the items needed for the preparation. The reprocessing procedure is described in detail in the instructions that accompany each set.

The SystemCare Set is available in the miscea hygienic pouch format and the Euro bottle format under the following article numbers:

- S02056001 - miscea SystemCare Set (Pouch)
- S02057001 - miscea SystemCare Set (Bottle)

According to the Hygiene Guideline of the Commission for Hospital Hygiene and Infection Prevention (KRINKO), there is no evidence or regulation regarding how frequent this procedure should be performed (Recommendation "Hand hygiene in healthcare facilities", 2016, Chapter 7, page 1204). Nevertheless, we recommend carrying out the treatment after every change of a refill product in order to minimize the risk of contamination.

In the operating manual of your miscea product, you can read these preparation requirements in chapter 6.2 in detail. The operating instructions are part of the scope of delivery of every miscea system.

Since the information on reprocessing is already contained in our operating instructions, we do not consider a separate list of reprocessing requirements, as given in the standard as an example (appendix B), to be sensible. Such a setup is not required in the standard.

With today's provision of the reprocessing information in the operating instructions, we therefore meet the requirements set out in the DIN EN ISO 17664 standard.

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Fulfilling the requirements of the latest directives in regards to handling procedures for proper hand hygiene

The 'Technical Rules for Biological Agents' (TRBA) include the latest technology standards, occupational and occupational hygiene, and other valid scientific knowledge for activities involving biological agents. Within the scope of its coverage, the TRBA 250 specifies the requirements of the Biological Agents Ordinance, which in turn was effectively approved by the Federal Government and came into force legally. The aim of the TRBA 250 is to protect staff and patients in the aforementioned areas from the transmission of pathogens with infectious properties. (2)

To protect personnel and patients from pathogens, facilities are required by law to install water fittings for the construction, extension or modernization of existing wash stations, which provide hot and cold water and are operated without hand contact (TRBA 250 point 4.1.1). Commercially available non-contact fittings should therefore not be used, since temperature adjustment is either not possible in principle, or can only be realized with hand contact.

According to the current KRINKO recommendation, sinks used by employees with direct patient contact or in critical areas must be equipped with fittings and dispensers that enable hands-free operation to prevent further spread of pathogens. Following these guidelines, we have developed the miscea CLASSIC system. The activation of water, soap and disinfection and the adjustment of the desired water temperature is completely contactless. Cross-contamination during washing of the hands can therefore be ruled out if used correctly, where as a residual risk exists in conventional fittings and dispensers which are operated by means of the forearm. In addition, the operation with the forearm is complicated, time-consuming and possible only with unnatural movements. The operation of a miscea sensor fittings supports natural movements and designed for efficient flow in work processes.

The regular use of conventional wall dispensers ensures contamination on vanity tops, worktops and / or floors. Some of this damage the materials, generate a great deal of cleaning and may even pose an accident risks. The dispensers of a miscea sensor faucet systems are integrated into the fitting and the liquid is dispensed directly over the wash basin. Thus, drops made during hand washing and residues of liquid products are washed away directly at the next water activation.

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Hygienic safety of drinking water quality in sensor fittings

In accordance with the general requirements of the Infection Protection Act (§ 37) and the Drinking Water Ordinance 2001, drinking water must be safe for the health of the consumer, fit for human consumption and pure. Over time, however, biofilm may form on the surfaces of the aqueducts. In this biofilm, germs can grow and endanger the drinking water quality and thus the health of those consuming the water.

Installations where drinking water is concerned, contamination of harmful bacteria is particularly critical in facilities where people with weakened immune systems are present (such as nursing homes, clinics, medical practices). Pathogens such as Pseudomonas aeruginosa can cause serious diseases, e.g. Wound infections, urinary tract infections, eye infections and external ear infections. In the United States, there are approximately 1,400 deaths per year. For Germany, there are currently no statistics available.

If contamination is detected, the fittings are often suspected first. We are surprised that sensor faucets are often assumed to be more susceptible to nucleation compared to hand-operated taps. As a result, the use of manual fittings is recommended in favor of minimizing potable water contamination risks.

However, the current state of scientific knowledge clearly shows that there is no fundamental difference in terms of sensitivity to contamination between sensor and manual fittings.

The 2016 Bédard, Prévost and Déziel literature study provides a very recent, comprehensive and detailed review of the current state of scientific knowledge related to contamination by P. aeruginosa in faucets (22). Well-known studies are compared in content. The study concludes that there are very large differences in the technical characteristics of the valves, which have led to very different test results. The sensitivity to contamination is very much dependent on the technical design of the valve and not fundamentally dependent on its design form (sensor fitting or manual valve). Furthermore, the science now gives clear information on the correct technical design of the valves to minimize the sensitivity to contamination.

We would like to inform you about the latest state of scientific knowledge and the factors influencing the risk of microbial contamination.

Water Flow (flow volume)
Different studies have shown that hydrodynamics, i.e. the rate of water flow in the fitting and the amount of water released, have a major impact on the growth of biofilm (3) (4) (5) (6). Higher flow valves are better flushed, greatly minimizing the growth of biofilm. Many faucets are developed with the intention to save water. This is usually realized by using a special water flow regulator / aerator at the end of the water outlet. Waterflow regulators of this type can reduce the flow rate down to 1.9 L / min. They are used in sensor fittings, but also often used in manual fittings.

In a study by Halabi et al. For example, low flow sensor fittings have been compared to fittings that have a normal flow (6). This study identifies the difference in flow rate as the cause of the increased nucleation: "It was concluded that the local contamination of non-touch fittings is a result of the low amount of water that flows through the outlet, the low water pressure and column of water, which is 'still-standing' (...)'

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A study by Chaberny et al. arrives at the same conclusion:

„Due to the water-saving function of the electronic faucets, there was not enough water to sufficiently flush them to clean them. This resulted in the repeated finding of P. aeruginosa and other nonfermentive gram-negative bacteria during out examinations and hinted at a rapid growth of biofilm due to the construction of the faucets".

In a 2015 Charron et al study, the direct relationship between flow and growth of P. aeruginosa in fittings was explicitly demonstrated. For valves with a flow rate greater than 5 L / min, formation of P. aeruginosa was only detected in 3% of the samples, whereas 16% of the valves were affected by a flow rate of less than 5 L / min. (7)

In principle, aerators with water saving features should be avoided to minimize sensitivity to bacterial growth. The flow rate achieved varies between different faucet models and sanitary fitting manufacturers. Frequently, aerators that greatly reduced the flow rate are used in sensor fittings.

miscea GmbH does not use aerators with water saving functions. Our systems achieve a flow rate of 6 to 7 L / min (at 3 bar line pressure, the flow depends on the applied water pressure).

Use of poor quality materials in uncertified products

The Drinking Water Ordinance states that only products which comply with the recognized engineering standards may be used (8). The Federal Environment Agency (UBA) in Germany has the task of establishing the requirements for materials and materials in contact with drinking water in the form of binding assessment documents.

The UBA has published various guidelines, some of which are lists of materials that may be used and test methods for various materials or substances. The following guidelines were published by UBA 2016:

- KTW Guideline: Provides hygienic requirements for plastics and silicones used in contact with drinking water
- Coating Guideline: Contains test instructions with hygienic requirements for organic coating systems
- Elastomer Guideline: Provides requirements for the toxicological evaluation of raw materials needed to make elastomer components for drinking water supply
- De Minimis Guideline: Includes an assessment of substances with a specific technological function and low required quantities relating to the formulation review in accordance with the guidelines of the Federal Environment Agency on the hygienic assessment of organic materials in contact with drinking water.
- Modeling guideline: Mathematical assessment of the migration of individual substances from organic materials into drinking water
- Lubricant Guideline: Contains test specifications with hygienic requirements for sanitary lubricants in contact with drinking water
- Thermoplastic elastomers in contact with drinking water
- Valuation basis for metal materials in contact with drinking water

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The DVGW is the recognized body in Germany for the creation of binding guidelines regarding the latest technology standards and engineering practices. These are developed in cooperation with the UBA. The DVGW carries out product certifications to check whether these standards are followed by the manufacturer.

For sensor fittings, the DVGW test specification 6514 (sanitary fittings with electronic opening and closing function) is available. This basis covers a wide range of tests, with mechanical testing according to EN 15091 (the European standard for sensor fittings) and drinking water hygiene according to KTW, W 270 and compliance with the relevant guidelines of the Federal Environmental Agency (DVGW Cert GmbH, n. D.). A test according to W 270 is only possible for sensor fittings as part of the test according to DVGW test specification 6514. The DVGW seal of approval for sensor fittings is shown in FIG. This seal is considered to be a very easily recognizable feature for industry professionals to identify tested and, above all, approved product quality.

Figure 1 The DVGW mark of conformity for sensor fittings

Various scientific studies have demonstrated that meeting these material requirements results in a significant reduction in contamination sensitivity for e.g. Pseudomonas aeruginosa leads (9) (10).

At miscea only high-quality components which meet the material requirements of the UBA guidelines, are used. This in turn was independently verified by DVGW. The miscea systems are one of the few sensor fitting that have the DVGW certificate of conformity according to EN 15091 and W 270 (11).

Often, uncertified sensor fittings with inferior quality are used and so a higher risk of drinking water contamination may exist!

Design of the flow regulator / aerator

Studies show that flow regulators are an important source of germ growth (12). In the study by Walker JT et al, 494 mechanical components from 30 fittings (partly manual, partly sensor fittings) were tested for contamination with P. aeruginosa. The study revealed that the flow regulators are very sensitive to germ contamination. However, it was also found that the amount of CFUs (Colony Forming Units) varies greatly between different types of flow regulators (13). In simple plastic or metal flow regulators, the number of P. aeruginosa CFUs was significantly lower than with complex flow regulators.

miscea uses only plastic flow regulators. We also recommend regular replacement and cleaning of the flow regulators. For this we developed the miscea "SystemCare" set. This set includes all the components for a complete cleaning of the miscea system. A flow regulator, mounting tool and cleaning cup (to remove any limescale from the water spout) are included in this set.

Water Stagnation

Stagnant water in the water pipeline network is scientifically proven to increase the formation and multiplication of germs, where the duration of stagnation and the water temperatures are key factors. Both the DVGW and the VDI explicitly stipulate in their norms that water stagnation in water pipeline networks should be avoided. A non-usage of more than 72 hours constitutes an interruption of operation according to

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VDI / DVGW 6023. Also, DIN EN 806-5 does not allow any interruption of operation of more than 7 days. Otherwise, either disconnect the lines at the main shut-off valve or renew the water regularly, e.g. by flushing.

Automatic and regular flush cycles can be preset individually for each miscea system with a remote control. Not only the time interval between the flushes, but also the duration can be programmed separately from each other. If a miscea system has not been used over the specified time interval, the self-flushing starts for the defined duration. The flushing process always starts with cold water. During the flushing period, the system independently changes the water temperature and ends the flushing process with warm water after the specified time has elapsed. If the water temperatures entering the system are high enough, even a thermal disinfection can take place in this way. It is therefore ensured that both line sections, cold and hot water, are flushed equally. Manual flushing in conventional fittings is difficult to organize, unreliable, costly and labor intensive.

Use of foot or knee activated fittings

Foot and knee operated fittings are usually very similar to sensor faucets from a technical stand point. In both fitting types, the water flow is released via a solenoid valve.

The study by Charron et al (2015) compared manual, sensor and foot-operated fittings. Outbreaks were found to be 14% for manual fittings and 16% for sensor fittings in this study. The result is almost identical. For foot-operated fittings, 29% of the samples were contaminated.

Scientifically, it has been proven that foot-operated fittings can be more sensitive to contamination than sensor or manual fittings.

However, all these influencing factors are decisively responsible for outbreaks and apply equally to every fitting design, irrespective of whether the fitting releases the water through manual operation, foot activation or sensor signal.

Conclusion

According to the latest scientific research, there is a vague picture of the contamination sensitivity of different types of water fittings, with some studies showing that hand-operated faucets are more prone to contamination while other studies suggest that sensor fittings are more sensitive to contamination.

Two studies found that sensor faucets were more sensitive than manual faucets but found that the flow through the sensor faucets was significantly lower than manual faucets (6) (14). However, the fact that a low flow represents an increased risk of contamination has already been proven in separate studies.

More recent studies also show that sensor fittings are fundamentally not more sensitive and show in part better results for sensor fittings compared to manual fittings (7) (15).

Bédard E. et al. (2016) has carried out a detailed review of all previous studies (7). The conclusion of the Bédard study is that previous studies clearly demonstrate technical factors such as flow rate, volume of mixing water in the fitting, design of the aerator, length and material of the connecting hoses or connecting pipes used and materials and parts in contact with water, play a crucial role in the sensitivity for contamination and

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nucleation of the relevant fitting. Recent studies show that inferior products or product properties lead to an increased risk of contamination, which may affect manual as well as sensor fittings equally.

- The statement that sensor fittings are inherently at an increased risk for contamination, is scientifically proven to be incorrect. Scientific studies show very different results, with some studies finding more frequent contamination in sensor fittings, and others finding more frequent contamination in manual or foot-operated fittings.

- The sensitivity of faucets to be contaminated with P. aeruginosa is highly dependent on the mechanical design, selected components, materials used, and the surfaces of these materials which are in contact with water. The sensitivity depends largely on the quality of the product and not dependent on the design (sensor fitting, manual fitting, foot-operated valve).

- Only products which comply with the recognized engineering standards may be used. This means that sensor fittings may only be used with a valid DVGW EN 15091 Certificate of Conformity, since this ensures that the requirements for the materials used are met (DVGW W 270, KTW guideline, requirements for metallic materials, etc.).

- Valves used should have a minimum flow rate of 5 L / min as many studies demonstrate that low flow rates greatly increase the susceptibility to nucleation.

- Stagnation of the water should be avoided. Leading standards of DVGW and VDI must be observed. With the remote control, an automatic stagnation flush can be set for each miscea system.

- Aerators should be periodically checked for formation of P. aeruginosa. We recommend a regular replacement of the aerators, defined in the WSP (Water Safety Plan). Wherever possible, simple aerators made of plastic or metal should be used. For cleaning and replacement of the aerators, miscea offers the System Care set in its range.

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The latest technology in dispenser hygiene

Scientific studies have shown that refilling containers without treatment can lead to an increased risk of contamination (KRINKO guideline, chapter 5.2). To avoid this refilling method, miscea has developed a patented pouch system. These pouches are hermetically sealed, and the liquid products can only be accessed by attaching the pouch to a special connector. This method makes it possible to replace the liquid pouches without creating any mess or contamination of the liquid products.

In euro bottle dispensers, the liquids are not sealed off from the air as the containers are rigid and cannot form around the liquid when it is being delivered. For this reason, air must be pumped into the bottle. The miscea pouch is flexible and takes form around the liquid as soon as the liquid is being dispensed. In the case of the miscea pouch system, the liquid is hermetically sealed so that airborne bacteria cannot enter. These characteristics make this system particularly hygienic.

We source our disinfectant from a German chemical manufacturer as an OEM product. The product miscea Septasol is registered as a biocide and is VAH listed.

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