

Passivation of the instruments and implants in the domain of the medical technique – Safe and ecological processes



The medical branch is not only confronted with cleaning problems but also with passivation problems.

During the instruments and implants manufacturing process, the requests of cleaning and passivation will be more and more important. The method of the passivation which results from the mode of dive or more recently the mode of cleaning by aspersion. The passivation is possible with the use of citric acid or nitric acid.

Process of passivation:

The free iron is taken away from the surface of the stainless steel and a protective coating enriched in chromium appears. The surface of all the stainless steel surgical instruments can be very effectively protected from the corrosion, by the meadow corresponding cleaning and the passivation. To reach a maximal anticorrosive protection in the medical technique, a careful cleaning and a passivation is absolutely necessary, because surfaces so handled answer all the requirement and the tests, as for examples in the salt-sprayed test and in the others validated methods.

Anticorrosive protection, constant quality and reduction in the bare minimum of risk for the producer

For more restrictive requests to the producer, we try to minimize the risks of pollutions and to eliminate them. As for examples by the observation of the standards ISO IN 13485 (the norm of the quality management in the medical technique) and ISO IN 14971 (the norm of management of risks) who pays a particular attention on the cleaning and the packaging.

The norm A ASTM 380 also added (Instructions for the cleaning and descaling of the parts, the devices and the stainless steel accessories).

Through their traceability, the medical products must be separately labelled so that these can be clearly classified and listed.

The process's problematic character remind mainly in the use of the laser for inscriptions. This process causes a combustion and a change of the surface. Even steels very high quality can by the change on their surface begin to corrode.

The new generation of machine with spray cleaning in not only of use for the final cleaning and for the thermic disinfection but also for the passivation

The idea is that through the technology of the installations, and the independently of the technicians and the state of baths, we can always use the same process. From Monday to Friday.

This is possible and may be applied to very load with new chemicals. According to if we proceed to the passivation with some citric acid or some nitric acid, wasted water must be neutralized in every case.

Amsonic, supplier for personalized solutions

To discover which method is the best adapted for the cleaning of a determined part, the know-how, the machine as well as tests in close relations of the reality are necessary. There are many possibilities of cleaning. The normal way to find the correct method, is to begin cleaning tests in laboratory. Amsonic proposes to customers the possibility of testing all technologies in his laboratory. Consequently a pre cleaning with solvent or on an aqueous basis. Then, the range of cleaning devices by spraying Hamo will allow a professional final cleaning to be able to integrate a white room.

Not only a producer but also a partner

Amsonic doesn't sell devices to the classic sense, but we are as partner for our customers there. Because we know all the technologies, we can advice individually the customers and we don't have to concentrate only on one solution. With the choice of the correct devices and the technological environment, a big part of the concept is executed. Amsonic suggests to the customer accompanying him with the documentation and the qualification of the installation (according to the requests of the medical industry, as for examples the cGmP instructions FDA).

Amsonic Deutschland GmbH
Fabio Cordaro
Neckaraue 25
D-71686 Remseck
Phone +49 7146 28081-0
Fax +49 7146 28081-10
fabio.cordaro@amsonic.com
www.amsonic.com