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MEDICAL DEVICES MANUFACTURING

RATIONALE ON THE DECONTAMINATION OF THE FACE MASK THROUGH THE USE OF MICROWAVES

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Among the various sterilization methods, the most common ones are dry heat, autoclave sterilization and immersion in chemical solutions. All these methods presented advantages and disadvantages.

- dry heat sterilization can be used on packaging without the risk of corroding the material, using dry instruments. However, it requires a longer sterilization cycle and the cycle may be interrupted if the oven door is opened before the end.
- autoclave sterilization is one of the most effective and safe methods, but it can lead to corrosion of steel products as well as guaranteeing time and money.
- chemical sterilization is achieved after a prolonged sterilization time and may not be able to penetrate physically seized and impregnated bacteria into the material.

On the other hand, there has been growing recent interest in the use of the microwave as a practical method of physical sterilization, as effective as autoclave sterilization. The low cost, speed and simplicity of disinfection and microwave sterilization have encouraged research to be carried out in different areas.

The microwaves are therefore used in medicine for the disinfection of soft contact lenses, to disinfect dental instruments, dental prostheses and urinary catheters. However, they must only be used with compatible products.

From a technical point of view, these are radio frequency waves, usually used at a frequency of 2450 MHz. Microwaves are attracted to water molecules in an alternating electric field. The intermolecular friction derives from the variations in heat and, with this regard, some authors believe that the microwave effect depends on the heat produced while others hypothesize a lethal non-thermal effect. Various clinical studies have shown that microwaves are an effective microbicide. Microwaves produced by a "domestic" microwave oven (2.45 GHz) completely inactivate bacterial cultures, mycobacteria, viruses and spores in an estimated period of time ranging from 60 seconds to 5 minutes depending on the environment. Cell destruction with 4 minutes of microwave exposure (600 W, 2450 MHz) is confirmed by a study conducted on Mycobacterium bovis.

MICRORGANISMO	0	15	30	60	120	180	240	300	600
Escherichiacoli	+	+	+	+	-	-	-	-	-
Pseudomonasfluorescens	+	+	+	+	-	-	-	-	-
Klebsiellapneumoniae	+	+	+	+	-	-	-	-	-
Proteus vulgaris	+	+	+	+	+	-	-	-	-
Streptococcusfaecium	+	+	+	+	+	-	-	-	-
Sarcina lutea	+	+	+	+	+	-	-	-	-
Corynebacterium equi	+	+	+	+	+	-	-	-	-
Bacillusalvei	+	+	+	+	-	-	-	-	-
Bacillusglobigii	+	+	+	+	-	-	-	-	-

It should be underlined, however, how some factors such as the material of the sterilized instrument, the presence of water and the power of the microwaves influence the results.

For example, it is possible to sterilize metal instruments but this requires some precautions. The concern is that household-type microwave ovens may not have a uniform microwave distribution across the entire device. This could result in the presence of some hot and cold spots and there may be areas that are not properly sterilized or disinfected.
Instead, there are some materials that are more suitable for the use of microwaves as a sterilization method and, among these, polypropylene is certainly found. The chemical structure of polypropylene makes it transparent to microwaves and since it does not absorb microwave energy and has a relatively high softening point, polypropylene is considered a suitable resin to be used with microwaves. In this regard, in fact, it is widely used for the production of containers for heating food such as bowls, dishes and food containers in general.
In addition to the proven ability of polypropylene to resist the action of microwaves without undergoing morphological and physical alterations, the possibility of using microwaves to sterilize polypropylene itself has also been proven. In this regard, in a clinical study conducted by Sanborn et al., the authors report the development of a rather simple protocol for the recycling of polypropylene culture vessels. The killing properties of

microwaves have been used to decontaminate polypropylene culture vessels in order to allow their reuse. Nine bacterial cultures (four gram-negative and five gram-positive genera, including two Bacillus species) were used to artificially contaminate tissue culture vessels. The microwaves produced by a "domestic" microwave oven (2.45 gHz) were able to decontaminate the vessels with a 3-minute exposure. The same exposure time was also used to completely inactivate the following three test viruses: type 1 poliomyelitis, type 1 parainfluenza and T4 bacteriophage.

According to the data reported by the authors, microwave radiation is a practical method for the sterilization of instruments made of polypropylene.

The abatement times of the organisms generally agree with those reported by authors such as Latimer and Maten, Goldbrithand & Wang and Culkin. In the following table it is possible to find the timi required to kill various microorganisms.

Table: time required through the use of a domestic microwave for the sterilization of a polypropylene container + organism alive / - organism dead “

The possibility of properly reusing medical masks to combat infectious diseases is not well discussed. However, some authors have suggested some options in order to decontaminate the used masks.

Referring to an article published in the journal Annals of Occupational Hygiene, the authors compared various methods to sterilize various models of N95 masks, however many of these methods were ineffective and some models of masks unsuitable for undergoing some treatments.

To be effective, a decontamination method should eliminate the viral threat, be harmless to end users and maintain the integrity of the respirator, and although all the methods used were believed to be effective in destroying viral microorganisms, not all of them were good ideas

It is not recommended, for example, to use alcohol and chlorine based disinfection methods since these components remove the static charge in the face masks microfibers reducing the filtration efficiency. In addition, chlorine also retains the gas after contamination and these fumes can be harmful.

Microwaves are considered a valid decontamination tool but the device subjected to sterilization must be adequate. For example, it must not contain metal parts since in this case some areas could be more decontaminated than others and the metal could dissolve the surrounding areas on the mask.

According to Dr. Doãn Ngọc Hải, director of the Institute for Occupational Safety and Health environmental protection in Hanoi, medical masks can be reused if they are sprayed with disinfectant and heated in the microwave at 800 W for one minute. Hải said that the Institute has tested common disinfection technologies such as the use of ultraviolet rays, ozone and microwave.

The institute tested standard disinfection of medical masks based on these methods. From the data collected, ultraviolet rays seem to be able to disinfect only the surface but not effectively the intermediate layer while the ozone disinfection equipment is too bulky and the methods too complex. The use of microwaves has proved to be the simplest, most feasible and most popular solution. This simple method is enough to have a common microwave with a default capacity of 800 W in order to obtain an effective decontamination. With this regard, it is also advisable to use an antiseptic solution to moisten the mask. The mask should then be placed in the microwave with the moist side facing up and heated for one minute. The microwave must be in microwave mode, not grill.

Hải stressed that the parameters set for the microwaves were carefully studied by the tests. Therefore, it is necessary to scrupulously follow the steps to ensure disinfection. Medical masks without metal parts are the recommended type for this disinfection method. Other types of masks may contain flammable materials if heated in a microwave oven. The institute conducted inspections confirming the effectiveness and validity of the method.

The Axelmed Safe Comfort mask is made up of 5 layers of polypropylene material with different degrees of filtering capacity according to the arrangement of the meshes of the material itself.

In the light of what has been discussed in the previous paragraphs, it can therefore be underlined how the use of the device, in conjunction with a sterilization method with a common domestic microwave oven for a time of 60 seconds, is able to sterilize its surfaces by making the mask reusable.

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