EFFECTS OF STORAGE CONDITIONS ON REPROCESSED CHEMICAL INDICATORS

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Aim

The colour of the chemical indicators (CI) inside the packages of medical devices can change during the time these packages are kept in storage, despite the storage period being lower than the recommend maximum storage time. This causes a problem when sending the medical devices to the operating room, since nurses may think that the devices were not properly sterilized. The main objective of this study was to evaluate the performance of several CIs under different types of packages and conditions in the storage room of our sterilization service.

Methods

Steam sterilization at 134ºC and 121ºC with holding times of 7 min and 20 min, respectively, were used as sterilization methods. Five different CIs were tested. When presenting the results, the samples were identified by roman numeration, since it was not our goal to compare different manufactures. Four different groups of packages that mimic the most common types of packaging material used in our department were used, and the packages containing the CIs were processed under the pre-determined conditions.

Figure 1. Storage Room. Different types of packaging are stored in the room.

After reprocessing, the packages were stored in the sterile storage room on shelves with different distances from the room's light source.

The colour of the CIs in the packages was recorded once per week during a period of six months. During this period the temperature and relative humidity of the storage room was monitored.

Results

In the course of the experiment several CIs changed their colour depending on the storage conditions. The type of material used in packaging also seems to influence the performance of the chemical indicator. We could observe that CI packaging in two Polypropylene (PP) sheets, did not presented colour variation throughout the experience, no matter the sterilization conditions, nor the proximity to the light source. However, several CIs packaging in: one PP sheet plus laminate paper/film pouch; laminate paper/film pouch; or two layers laminate paper/film presented different colorations over time, depending on light source proximity. In particular, the position of the package on the shelf or the proximity to the light source showed to be important factors.

Chemical Indicator	Time (months)	Color change				Sterilization conditions	Location on the shelf system
		2 Polipropilen sheets	PP + Paper/Film	Laminate Paper/Film	2 Laminate Paper/Film		
Sample I, Type 6	1st	no	no	no	no	134ºC 7 min	Closer to the light source
	2nd	no	no	no	no		
	3rd	no	no	no	no		
	4 th	no	no	1 (in 10)	no		
	5th	no	no	2 (in 10)	2 (in 10)		
	6 th	no	no	2 (in 10)	4 (in 10)		
	1st	n.a.	n.a.	no	no	121ºC 20 min	
	2nd	n.a.	n.a.	1 (in 10)	1 (in 10)		
	3rd	n.a.	n.a.	5 (in 10)	1 (in 10)		
	4 th	n.a.	n.a.	6 (in 10)	4 (in 10)		
	5th	n.a.	n.a.	6 (in 10)	4 (in 10)		
	6 th	n.a.	n.a.	8 (in 10)	4 (in 10)		
	1st	no	no	no	no	134ºC 7 min	More sheltered from the light
	2nd	no	no	no	no		
	3 rd	no	no	no	no		
	4th	no	no	no	no		
	5th	no	no	no	no		
	6th	no	no	no	no		
	1st	n.a.	n.a.	no	no	121ºC	
	2nd	n.a.	n.a.	no	no		
	3 rd	n.a.	n.a.	no	no		

Chemical Indicator	Time (months)	Color change				Sterilization conditions	Location on the shelf system
		2 Polipropilen sheets	PP + Paper/Film	Laminate Paper/Film	2 Laminate Paper/Film		
Sample II, Type 6	1st	no	no	no	no	134ºC 7 min	Closer to the light source
	2nd	no	no	no	5 (in 10)		
	3rd	no	no	3 (in 10)	10 (in 10)		
	4 th	no	no	5 (in 10)	10 (in 10)		
	5th	no	8 (in 10)	7 (in 10)	10 (in 10)		
	6 th	no	10 (in 10)	10 (in 10)	10 (in 10)		
	1st	n.a.	n.a.	no	no	121ºC 20 min	
	2nd	n.a.	n.a.	no	no		
	3rd	n.a.	n.a.	no	no		
	4 th	n.a.	n.a.	no	no		
	5th	n.a.	n.a.	no	no		
	6 th	n.a.	n.a.	no	no		
	1st	no	no	no	no	134ºC 7 min	More sheltered from the light
	2nd	no	no	no	no		
	3 rd	no	2 (in 10)	no	2 (in 10)		
	4th	no	2 (in 10)	no	3 (in 10)		
	5th	no	3 (in 10)	no	3 (in 10)		
	6th	no	3 (in 10)	1 (in 10)	4 (in 10)		

Chemical Indicator	Time (months)	Color change				Sterilization conditions	Location on the shelf system
		2 Polipropilen sheets	PP + Paper/Film	Laminate Paper/Film	2 Laminate Paper/Film		
Sample III, Type 6	1st	no	no	no	no	134ºC 7 min	Closer to the light source
	2nd	no	no	no	no		
	3rd	no	no	no	no		
	4 th	no	no	no	no		
	5th	no	no	no	no		
	6 th	no	no	no	no		
	1st	n.a.	n.a.	no	no	134ºC 7 min	More sheltered from the light source
	2nd	n.a.	n.a.	no	no		
	3 rd	n.a.	n.a.	no	no		
	4th	n.a.	n.a.	no	no		
	5th	n.a.	n.a.	no	no		
	6th	n.a.	n.a.	no	no		

Table 1. Summary of the behavior of the different Chemical Indicators throughout the study. The samples were named: sample I type 6; II type 6 and III type 6, since it was not our goal to compare different manufactures; sample I type 5 and II type 5 showed no change in color during the experiment.

Time (months)	Sample I, 134ºC	Sample I, 121ºC	Sample II, 134ºC	Sample II, 121ºC	Sample III, 134ºC	Sample III, 121ºC
1st	no	no	no	no	no	no
2nd	no	yes	yes	no	no	no
3rd	no	yes	yes	no	no	no
4 th	yes	yes	yes	no	no	no
5th	yes	yes	yes	no	no	no
6 th	yes	yes	yes	no	no	no

Table 2. Comparison of the behavior of the different type 6 Chemical Indicators analyzed. For the sterilizations conditions 134ºC (7'), and the situation "Closer to the light source" we were able to verify that only sample III shows no alteration on color staining. The other samples shows changes from the second month.

Figure 2. The chemical indicators used in this study. Three Type 6 (formally Class 6) and two Type 5 (formally Class 5)

Conclusions

The variations in CIs colour seems to depend on: i) the type of packaging; ii) the proximity to the light source; and iii) the time elapsed since the sterilization of the package.

The results obtained in this study highlight the importance of considering the particular type of packaging as well as the storage conditions of a sterilization service when purchasing CIs. This knowledge will be also important to assign adequate expiration dates to the sterilized items, thus simplifying the work of nurses in the operating room.

References

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