Original Article

Influence of sodium bicarbonate pre-treatment on final cleaning performance in a washer-disinfector

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All authors confirm that there is no conflict of interest according to the guidelines of the International Committee of Medical Journal editors (ICMJE).

Abstract

BICARMed® is a pre-treatment method using a pressurized sodium bicarbonate jet. We evaluate here the benefit of BICARMed® to facilitate and improve the quality of the final cleaning and compare it to the pre-treatment by immersion. After use in the operating room, the instruments are randomly divided into 2 arms. Arm A: pre-treatment with detergent-disinfectant (n=539 instruments); Arm B: pre-treatment with BICARMed® (n=555 instruments). At the end of the pre-treatment, the instruments were cleaned in a washer-disinfector (WD) and the residual contamination after cleaning was visually assessed and evaluated by a semi-quantitative colorimetric method. The percentage of soiled instruments after cleaning in the WD was on average higher in arm A (44.7%; n=241) than in arm B (19.8%; n=110) (p-value < 0.001). Contaminated areas and color intensity were also higher in arm A. The effectiveness of the bicarbonate pre-treatment improves the quality of the final cleaning.

Introduction

In France, pre-disinfection by immersion in a detergent-disinfectant solution is recommended as soon as the surgical equipment has been used in the operating room in order to avoid drying of the soils and to protect the personnel and the environment [1, 2]. In many other countries, there is no pre-treatment before the equipment is sent to the sterilization unit. Instead, the material is shipped in its reusable container or in a sealed plastic bag to maintain humidity. In Germany, dry transport is recommended by the DGSV [3]. BICARMed® is a pre-treatment method using a pressurized sodium bicarbonate jet. The sterilization unit has compared this new method to traditional pre-disinfection by immersion. The objectives of this work are to evaluate the effectiveness of BICARMed® to facilitate and improve the quality of the final cleaning and to compare this method to the conventional pre-disinfection by immersion.

Materiel and method

BICARMed® is a pre-treatment equipment using a pressurized sodium bicarbonate jet. After use in the operating room, the soiled instruments are treated manually in a closed enclosure by means of the action of a pressurized sodium bicarbonate jet. The technique allows the removal of dirt and residues from surgical instruments through its emollient action (saponification of fats) and its controlled and adapted granulometry. The bicarbonate used is a white crystalline powder of pharmaceutical quality, packaged in 6 kg cans (Safeklinic®, Solvay). The bicarbonate ($NaHCO_3$) is insoluble in alcohol and incompatible with acids. The major advantage of this compound lies in its innocuousness for humans and the environment as it is rapidly soluble and biodegradable. For this study, the instruments selected were from different surgical disciplines: orthopaedics, gynaecology, vascular surgery, ... After use in the operating room, the surgical instruments were randomly divided into 2 arms. For arm A, the instruments were immersed immediately after surgery in the pre-disinfection liquid (SeptoPredis 0.5%, Dr. Weigert) for at least 15 minutes. The

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- pretreatment
- sodium bicarbonate
- cleaning

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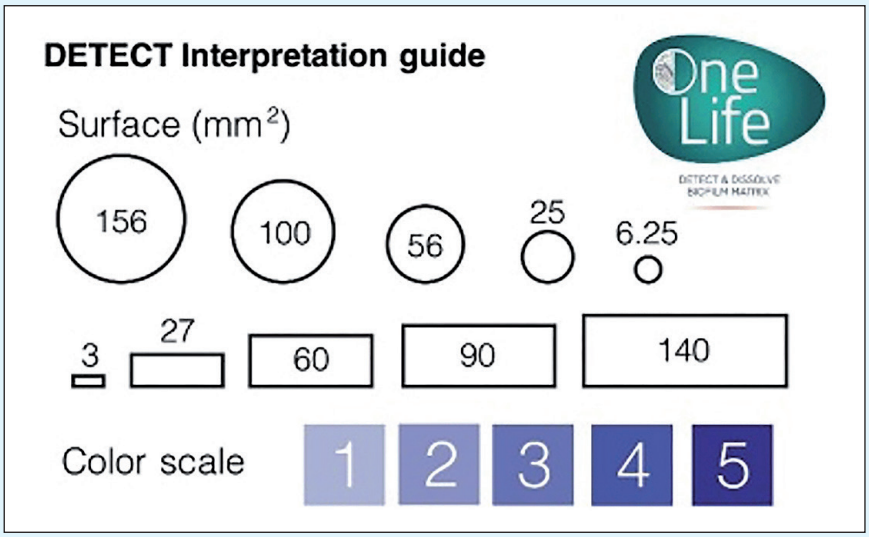

Figure 1: Onelife Detect® Interpretation Guide: Colour Scale and Measured Areas

instruments in arm B were placed in an empty tray for transport outside the operating room and were treated immediately with sodium bicarbonate. After this pre-treatment step, the instruments of arms A and B were cleaned in a qualified washer-disinfector (Belimed® WD 290) using a hyper-concentrated enzymatic detergent for the cleaning phase (Mediclean Advanced® 0.02 %, 5 min., 45 °C , Dr. Weigert). The monitoring and control of the efficiency of each washing cycle was assessed by a washing indicator positioned on the baskets in accordance with the NF EN 15883-5 standard (gke Clean-record®, type MC-CPI).

At the end of each washing cycle in WD, the residual contamination was assessed visually and by a semi-quantitative colorimetric method of protein detection (DETECT2®, OneLife). For this, each basket of clean instruments was immersed in a dye bath for 5 minutes and then rinsed thoroughly with water. Blue dye stains on the instruments indicated residual contamination. The intensity of the staining, from I.1 to I.5, and the surface area in mm² were observed using the interpretation guide (Figure 1). The intensity I1 corresponds to the detection threshold of the method (10 μg/cm²). Each instrument with a stain was identified by its unique identifier (UDI). For each stained instrument, the operator recorded the colorimetric intensity of the blue and the surface area in mm². The execution of the bicarbonate pre-treatment and the estimation of the contamination score after cleaning each instrument were performed by one and the same operator. The statistical tests used in this study were the χ^2 test and the Wilcoxon test. The study protocol is summarized in Figure 2.

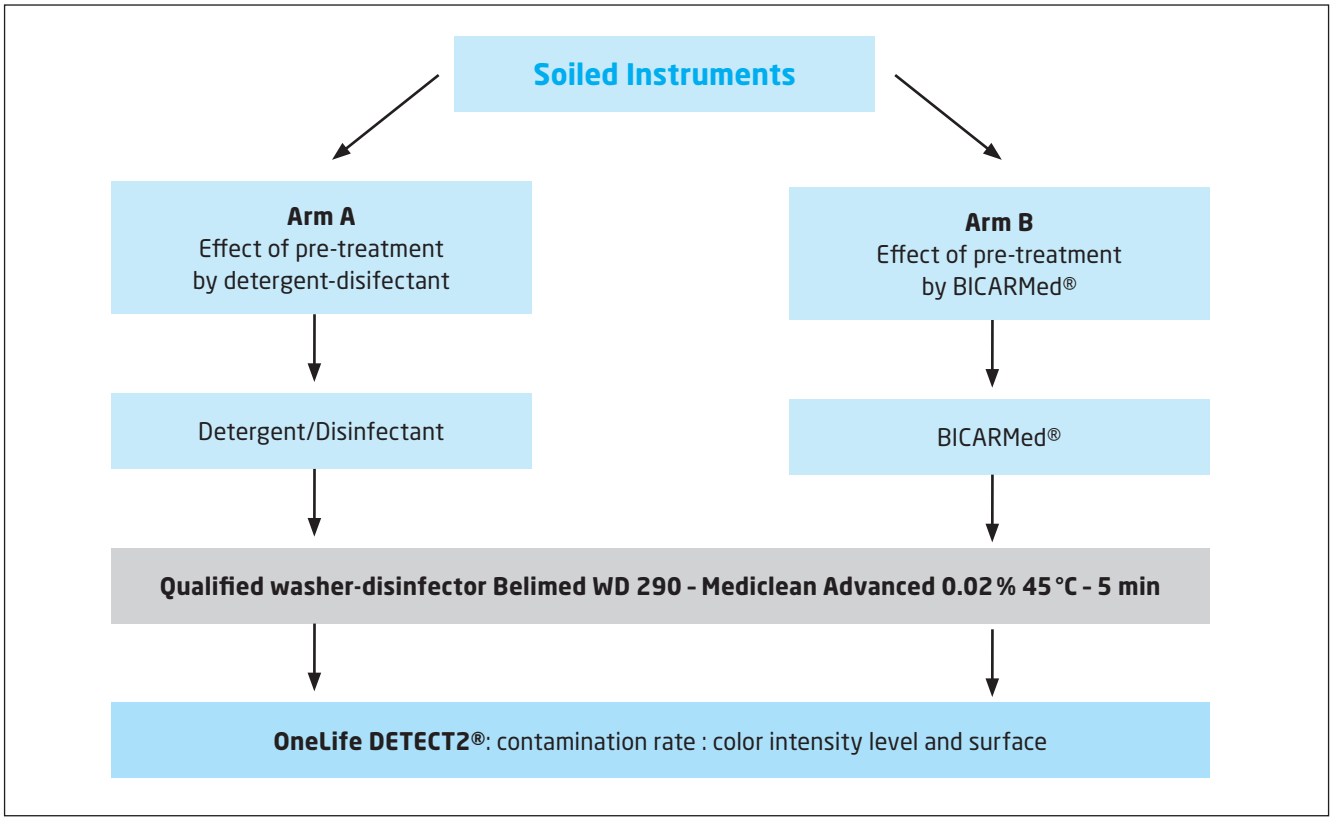

Figure 2: Test protocol

Table 1: Percentage of instruments soiled and average surface area of contamination (mm²) per procedure

Arm	Type Intervention	Number of instruments	Number of soiled instruments	% of soiled instruments	Average contaminated surface area (mm²)
Arm A: conventional pre-treatment (n=539)	Arthroscopic knee lavage	75	24	32	23,7
	C section	37	21	56,8	44
	AV fistula	45	17	37,8	13
	AV fistula	60	31	51,7	11,9
	Peritoneal catheter placement	32	13	40,6	7,4
	Tympanoplasty	27	11	40,7	13,3
	Cervical conisation	41	21	51,2	6,6
	Aortic endoprosthesis	57	26	45,6	23,1
	Thyroidectomy	34	17	50	9,3
	Pacemaker placement	21	6	28,6	23,4
	Shoulder arthroscopy	23	6	26,1	36
	Abortion	23	10	43,5	32
	Tension-free vaginal tape (TVT)	23	16	69,6	37,8
	Amygdalectomy	27	20	74,1	37
	Arthroscopy	14	2	14,3	4,6
Arm B: BICARMed® pre-treatment (n = 555)	Infant hernia	37	2	5,4	3
	Cholecystectomy	30	6	20	3
	Kyphoplasty	12	2	16,7	3
	Total knee replacement	115	17	14,8	
	Total hip replacement	42	15	35,7	17,5
	Thyroidectomy	46	9	19,6	3,4
	Appendectomy	26	6	23,1	10,9
	C section	30	18	60	27,7
	AV fistula	59	15	25,4	12,2
	Knee arthrodesis	19	2	10,5	3
	Toe arthrodesis	42	2	4,8	14
	Shoulder arthroscopy	20	3	15	25
	Removal of material	24	1	4,2	3
	Placement of implantable port	33	5	15,2	9,4
	Carotid surgery	20	7	35	22,6

Results

In this study, 15 procedures were analysed in arm A representing 539 instruments (conventional pre-treatment) and 14 procedures representing 555 instruments were studied in arm B (bicarbonate pre-treatment). The results in Table I show the percentage of soiled instruments and the average surface area of contamination observed per procedure and according to the pre-treatment method applied. Simple visual examination revealed no contamination after washing. Only the colorimetric examination detected residual proteins.

The missing result in arm B concerns a total knee replacement (TKR) and is explained by the fact that the surfaces and intensities were not recorded for all instruments. These are therefore excluded from the averages.

From Table 1, we observe that the percentage of instruments soiled after cleaning varies from 14.3 to 74.1% in arm A and from 4.2 to 60% in arm B. Instruments from thyroidectomy are present in each arm. For this procedure, the proportion of soiled instruments was 50% in the conventional arm versus 19.6% in the experimental arm. The same was true for instruments used during arteriovenous fistula (AVF) with 37.8 to 51.7% of instruments soiled in arm A versus 25.4% in arm B. Shoulder arthroscopy gave the following results: 26.1% of instruments soiled in arm A and 15% in arm B. Only caesarean section did not obey this rule with a higher percentage of soiled instruments in arm B (60%) than in arm A (56.8%). Statistical analysis shows that the percentage of soiled instruments after cleaning in the WD is on average higher in arm A (44.7%; n= 241) than in arm B (19.8%; n= 110) (χ^2 test; p-value < 0.001).

If we consider the averages of the contaminated surfaces, these evolve from 4.6 to 44 mm² in arm A against 3 to 27.7 mm² in arm B. The use of the non-parametric Wilcoxon test allows us to compare the medians and concludes that there is a significant difference between these 2 arms (Wilcoxon test; p-value < 0.031).

Figure 2 shows the distribution of colorimetric stain intensities for each arm. In arm A, 57.7% of the instruments had an intensity 1 stain compared to 69.9% observed in arm B.

Table 2: Distribution of contaminated surfaces by instrument and by procedure

Arm	Procedure	Number of soiled instruments	Number of soiled instrument with Surface of					
			3 mm² (%)	6,25 mm² (%)	25 mm² (%)	60 mm² (%)	100 mm² (%)	156 mm² (%)
conventional pre-treatment	Arthroscopic knee lavage	24	14 (58,3%)	0	4 (16,7%)	4 (16,7%)	2 (8,3%)	0
	C section	21	4 (19,0%)	0	10 (47,6%)	4 (19,1%)	1 (4,8%)	2 (9,5%)
	AV fistula	17	10 (58,8%)	4 (23,5%)	3 (17,6%)	0	0	0
	AV fistula	31	17 (54,8%)	2 (6,5%)	12 (38,7%)	0	0	0
	Peritoneal catheter placement	13	7 (53,8%)	4 (30,8%)	2 (15,4%)	0	0	0
	Tympanoplasty	11	3 (27,3%)	5 (45,5%)	2 (18,2%)	1 (9,1%)	0	0
	Cervical conisation	21	9 (42,8%)	10 (47,6%)	2 (9,5%)	0	0	0
	Aortic endoprosthesis	26	9 (34,6%)	8 (30,8%)	4 (15,4%)	3 (11,5%)	1 (3,8%)	1 (3,8%)
	Thyroidectomy	17	7 (41,2%)	6 (35,3%)	4 (23,5%)	0	0	0
	Pacemaker placement	6	1 (16,7%)	1 (16,7%)	3 (50%)	1 (16,7%)	0	0
	Shoulder arthroscopy	6	2 (33,3%)	2 (33,3%)	0	0	2 (33,3%)	0
	Abortion	10	3 (30%)	3 (30%)	1 (10%)	2 (20%)	0	1 (10%)
	Tension-free vaginal tape (TVT)	16	2 (12,5%)	4 (25%)	6 (37,5%)	2 (12,5%)	0	2 (12,5%)
	Amygdalectomy	20	2 (10%)	0	8 (40%)	8 (40%)	2 (10%)	0
	Arthroscopy	2	1 (50%)	1 (50%)	0	0	0	0
BICAR-Med® pre-treatment	Infant hernia	2	2 (100%)	0	0	0	0	0
	Cholecystectomy	6	6 (100%)	0	0	0	0	0
	Kyphoplasty	2	2 (100%)	0	0	0	0	0
	Total hip replacement	15	5 (33,3%)	2 (13,3%)	7 (46,7%)	1 (6,7%)	0	0
	Thyroidectomy	9	8 (88,9%)	1 (11,1%)	0	0	0	0
	Appendectomy	6	3 (50%)	1 (16,7%)	2 (33,3%)	0	0	0
	C section	18	4 (22,2%)	1 (5,6%)	8 (44,4%)	5 (27,8%)	0	0
	AV fistula	15	5 (33,3%)	6 (40%)	3 (20%)	1 (6,7%)	0	0
	Knee arthrodesis	2	2 (100%)	0	0	0	0	0
	Toe arthrodesis	2	1 (50%)	0	1 (50%)	0	0	0
	Shoulder arthroscopy	3	0	0	3 (100%)	0	0	0
	Removal of material	1	1 (100%)	0	0	0	0	0
	Placement of implantable port	5	1 (20%)	3 (60%)	1 (20%)	0	0	0
	Carotid surgery	7	3 (42,8%)	2 (28,6%)	1 (14,3%)	1 (14,3%)	0	0

Table 3: Distribution of soiled instruments by family

Instrument family	Number of soiled instruments
Scissors	**44**
Valve	5
Clamp	12
Hook	1
Cupule	1
Stripper	1
Dissector	6
Retractor	**38**
Tongue depressor	3
Preformed mouth opener blade	2
Mallet	1
Hysterometer	1
Sinus instrument	1
Scalpel handle	9
Dissecting forceps	**53**
Halstead clamp	8
Gripping clamp	5
Syndesmotome Chompret	1
Speculum	1
Cannulated probe	1
Femur lifter	1
Knot pusher	2
Needle holder	**32**
Bengolea Clamp	2
Bourgeois Clamp	4
Birkett's clamp	1
Kocher clamp	**18**
Leriche clamp	**21**
Heart-shaped clamp	7
Gouge clamp	1
Pozzi clamp	2
Pad holder clamp	2
TOTAL	**287**

The proportions of instruments with intensity 1 contamination were significantly different between the two arms (χ^2 test; p-value = 0.040). The proportion of intensity 2 to 5 soils was higher in arm A. Staining of intensity 5 was only found in this arm (caesarean section).

Table II gives the distribution of contaminated surfaces by instrument and by procedure. The surfaces vary from 3 to 156 mm² in arm A and from 3 to 60 mm² in arm B. For 5 out of 14 procedures in arm B, the contaminated instruments have a surface area equivalent to 3 mm². The surface areas were greater for all procedures in arm A.

An analysis by instrument family (Table III) shows that the instruments that remain the most soiled are dissecting forceps (18.5%) followed by scissors (15.3%) and retractors (13.2%). The proximal parts of the instruments are the most soiled (claws and jaws) but also the joints of articulated instruments.

Discussion

In this study, the percentage of soiled instruments observed after cleaning appears to be significant and could call into question the performance of the WD cleaning cycle. These high percentages are related to the size of the sample, the diversity of the surgical procedures observed, and the method used to reveal residual proteins. The large sample size, with more than 500 instruments in each arm, allows for a much more representative observation and analysis of what might be revealed by a small sample size. On the other hand, the diversity of surgical procedures and disciplines included in this study also allows for a clinical response that is closer to reality than a strictly experimental approach based on artificial stains. It can be seen from these results that, contrary to expectations, orthopaedic surgery is not necessarily the surgery with the greatest cleaning difficulties, but that the surgical procedures where the operating instruments are most severely contaminated are gynaecological procedures. This observation has already been noted by Vallée et al. in a previous study [4]. Blood, and in particular heparinized sheep blood, used in experimental studies, is not the ideal marker to reveal residual contamination. Mucus, particularly present in ENT, orodental and gynaecological surgeries, is certainly a more important challenge for our cleaning procedures than blood itself. On the other hand, if no direct visual examination was able to detect the presence of stains after washing, the colorimetric method used, due to its sensitivity and its capacity to mark very small surfaces, around the size of one mm², allowed to highlight stains not detectable by the eye. These small surfaces, much smaller than a cm², allow us to consider that the protein levels detected by this semi-quantitative method are much lower than the acceptable threshold of 3 μg/cm² [5] and that the automated cleaning process used therefore meets the performance requirements. According to our results, statistical analysis of the number of instruments soiled after washing confirms the effectiveness and superiority of pre-treatment with pressurized bicarbonate compared to immersion in a detergent-disinfectant solution. This significant difference between the pre-treatment processes is confirmed by the average contamination areas revealed. Thus, BICARMed®, by its action, allows a significant elimination of soils up to the detection threshold of 3 mm² for nearly 48% of soiled instruments. In the absence of a colorimetric test, these residues could not have been observed by eye, nor detected by an elution method because of their very low residual protein content. The analysis by colorimetric intensity also confirms the importance of the bicarbonate treatment, as nearly 70% of the soiled instruments showed a level 1 intensity corresponding to the detection threshold of the DETECT2® method. Significantly higher intensities were present in arm A.

The study by W. Michels [3] investigates the influence of the waiting time, including the transport time, on the quality of the final cleaning of instruments in Germany and other countries in the absence of pre-treatment. The author concludes that a maximum drying time of 5 hours should be observed to avoid drying of the soils. In our study, we compare the use of pressurized sodium bicarbonate with a pre-treatment by immersion. Our

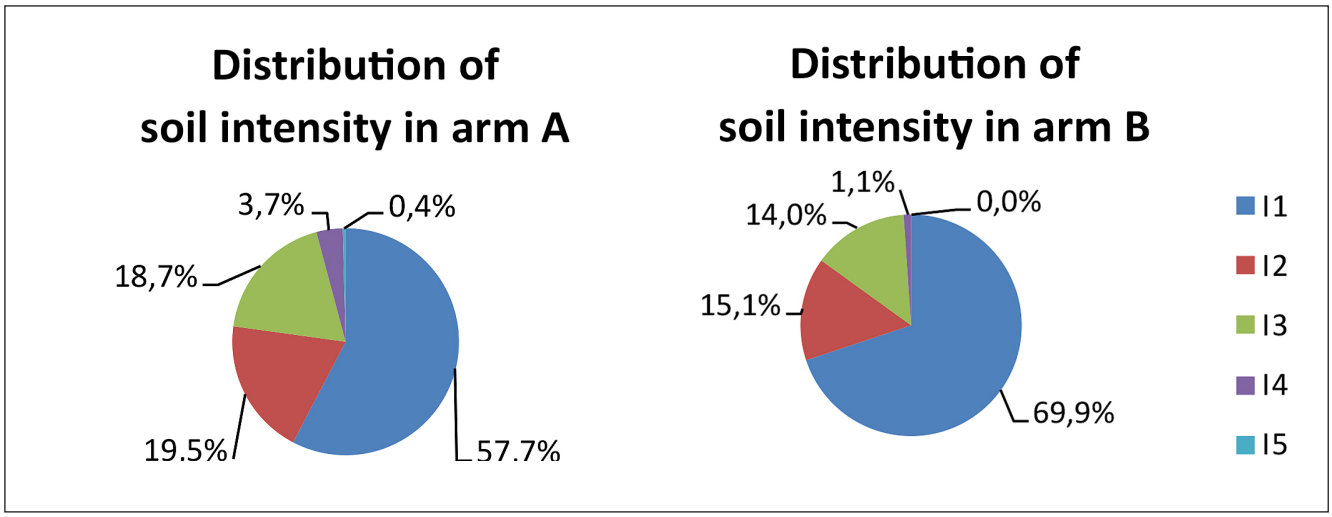

Figure 2: Distribution of soil intensities in each arm

results are in favour of bicarbonate. Therefore, the use of pressurized sodium bicarbonate as a pre-treatment method before the instruments are sent to the sterilization units would probably avoid the drying of the soils in countries that refuse the use of detergent-disinfectant. In these countries where pre-treatment is non-existent, the effectiveness of sodium bicarbonate, its absence of environmental toxicity and its biodegradability should make it possible to achieve the objective of quality assurance of the cleaning process. Nevertheless, in countries where pre-treatment by immersion is practised, a comparative analysis of reprocessing costs may be necessary. The direct human time involved in the use of BICARMed® could be compared with the time required to prepare the containers, empty, clean and rinse them, as well as to record traceability.

Concerning the most soiled instrument families, several elements can explain the classification found. Dissecting forceps are instruments intended for tissue dissection, and the grooves present on the active parts are conducive to tissue adherence and do not promote the accessibility towards detergents during cleaning in a WD. A mechanical action by manual brushing or by a pressurized bicarbonate jet is therefore essential to guarantee the quality of cleaning. It should be noted that retractors, due to their function but also to their repeated use, may have micro-grooves on their surface that facilitate the fixation of stains. Instruments with joints are also difficult to clean because of the delicate access to the junction of the two assembled parts. This classification by family allows us to orient our risk analysis during cleaning and to target the instruments or parts of instruments that are recognized as difficult to clean.

Conclusion

The results of this study demonstrate the effectiveness of pre-treatment with pressurized sodium bicarbonate as compared to pre-treatment by immersion in a detergent-disinfectant solution. This improvement can be observed in the quality of the final cleaning, due to the early handling of instruments at the end of their use in the operating room, avoiding the drying of stains. This new technology can make an indisputable contribution to the quality of the medical device reprocessing process in countries that practice dry transport without prior pre-treatment. The implementation of this practice in the operating room can save the use of detergent-disinfectants and minimize the risk of corrosion attributed to them.

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